From: Brad J. Wilkus, Jr. [redacted]
Sent: Monday, January 31, 2022 6:21 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Re: Concerns on Covid Surcharges To the PEBP Board for Public Comment

Dear PEBP Board,

I am an employee at NDOT District 2. I would like to have my letter read for Public Comment to the PEBP Board. I was unaware of the January meeting and would like to have another meeting scheduled to address my concerns.

These surcharges for Covid testing are ridiculous. Why is my spouse being charged for my testing, and why is it $175 for her and only $55 for me? We are on a tight budget already and these fees are going to cause real concern for our household. My wife has a pre-existing condition, and insuring her through private insurance is really really expensive. Our heatlh insurance benefits through the state are already not very good with the extremely high deductibles. This is just making everything worse.

Because of my family's medical history, I have a vaccine exemption from my doctor, and have not heard whether or not my exemption has been accepted from NDOT. My wife has a multitude of allergies from food and medications and her doctor told her NOT to get vaccinated due to the plethora of allergies that she has. My [redacted] (36 years old) had one shot of the Phizer vaccine and suffered a heart attack from blood clotting. Luckily, he survived, had to undergo surgery, but he survived.

My [redacted] are both fully vaccinated, they did not have any complications, but both have recently come down with serious Covid infections. My [redacted] and her family are all vaccinated, and all have recently come down with serious Covid infections. My co-worker, who is fully vaccinated, caught Covid with myself and my other co-worker (both unvaccinated) a couple weeks ago. He was out of work longer than all of us. At this point the vaccine seems to not have any effectiveness against catching or spreading these new Covid variants. So why are the unvaccinated being punished/discriminated against when the vaccinated are just as susceptible to catching and spreading the disease? If the unvaccinated have to test, then everyone should have to test due to the vaccine's failure. Vaccinated people can spread and catch the disease just as easily as the unvaccinated. I also know 20-30 other fully vaccinated people who have caught Covid this January 2022, the VAX DOESEN'T WORK.

Where is the Cares Act money??? The billions Nevada received should be covering these surcharges for employee testing, not going to social programs. Again, the unvaccinated are being singled out and punished for not taking the jabs. Why is the state not allowing the unvaccinated to telecommute? Our director said that they are going forward with weekly testing of unvaxxed because they want to "protect the unvaccinated people because they may

have more server infections of covid." So, shouldn't the unvaccinated be able to work from home as well to limit our exposure to other people, including the vaccinated who could spread the disease? Again, punishment and discrimination towards the unvaxxed...

The State of Nevada is not supposed to discriminate against anyone for any reason, including health status, why is this being ignored? Is the state going to surcharge people for being an alcohol or tobacco user? Is the state going to surcharge people for being overweight? Is the state going to mandate that its employees cannot eat at McDonalds or drink soda and other sugary drinks or get a surcharge? Is the state going to mandate its employees get an hour of rigorous exercise a day or get a surcharge? Are they going to surcharge any of these things since they are SO concerned about our health and wellbeing? Probably not, just Covid vaccines....

The OSHA ruling from the US Supreme Court stated that it is unlawful to mandate vaccines. So why is this still being pursued?
I know this is being pushed from our Governor (don't tell me he's not). He does not have the write to tell us how we should live our lives, and what goes in, and what doesn't go in to our bodies. I feel like I am being punished and discriminated against for being unvaccinated by the State and the Governor. I feel like I am working in hostile environment due to the constant pushing of the vaccines from the NDOT Director and her staff.

During the all Teams chat, I shared my [redacted] stories about their vaccine experiences and my comment was censored and not read to the NDOT employees on the chat. That action alone made me so mad, I almost had to leave for the day. What are they trying to hide, and why is the Director and her staff censoring people? THAT SHOULD NOT HAPPEN WHEN THE STATE IS SUPPOSED TO BE TRANSPARENT ABOUT EVERYTHING!!!

I would like to ask the board that my comment is taken seriously and not brushed under the rug. This issue is very important to myself, my family, and a good majority of NDOT employees that I talk to. Please get rid of this surcharge, its discriminatory and out right wrong. Otherwise, NDOT is going to suffer, and our travelling public will pay the price.

Sincerely,

-Brad Wilkus

From: Parker, Matthew M. [redacted]
Sent: Tuesday, February 1, 2022 9:21 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: PEBP Board Public Comment for Unvaccinated Surcharge

Good morning Wendi,

Would you please be so kind as to add my remarks below to public comment please and thank you.

I am disappointed with the board's latest newsletter. For not only staying the course on the vaccine surcharge, but for also using old data in the myth busting on the second page.

Myth: If you have had COVID already, you don't need to get vaccinated. Fact: It is unclear how long you are protected from the disease after a previous infection. Additionally, new research suggests that COVID-19 vaccines offer better protection than natural immunity.
This is outdated. The CDC published data on January 17th 2022 that as of October 2021, highly vaccinated states like California and New York had more hospitalizations among people who were fully vaccinated than those previously infected with COVID. Among those hospitalized who were fully vaccinated and those previously infected, around 70% percent were fully vaccinated. So, no, the vaccines did not offer better protection, which is precisely why they've had to approve and roll out new boosters. If they were providing better protection than we wouldn't need new boosters to supplement the two-shot protection previously guaranteed to provide protection.*

Myth: The vaccines were manufactured using fetal tissue. Fact: Existing vaccines for diseases such as chickenpox and rubella are produced using cell lines descended from fetuses aborted decades ago. Fetal cells were not used in the development or production of the COVID vaccines.
*This is semantics. Technically "fetal tissue" was not used, but "fetal cell lines" were used.** The use of fetal cell lines, no matter how long ago they originated, is still an ethical concern. So, yes, "fetal cells" were used.*

Myth: The vaccine doesn't work because vaccinated people still get and spread COVID. Fact: While those who are vaccinated can still become infected, the severity is much less. According to the CDC, vaccinated individuals are 8 times less likely to get COVID-19, and 25 times less likely to be hospitalized or die. In PEBP, we have seen several high-cost claims with billed charges over $500k stemming from COVID-19. Unfortunately, most were unvaccinated. These costs ultimately get spread to all members in the form of higher premiums. By getting vaccinated, you are doing your part to reduce costs for the program and to the members covered by PEBP.
This is outdated information and does not reflect the current climate we're in. Again, I point to the CDC's January 17th press release. Let's not also overlook that since 2020 it has been recognized that age and underlying health conditions are the key factors determining hospitalization and death,*** more so than vaccination status.*

And this is one of the biggest flaws with this surcharge policy. Me and my young healthy family have not been a draw on the state's insurance and our monthly payments have been paying for the medical costs of other people in poor health, who ironically, are much more likely to be hospitalized from COVID regardless of vaccination status, statistically speaking, than I am being unvaccinated. Why not surcharge employees with underlying health conditions and comorbidities that are responsible for our high health insurance costs to begin with? The answer is that you cannot legally do that. But you can do this for the

unvaccinated as long as you promise the option of medical and religious exemptions, which we STILL haven't received any direction on, nor a guarantee that they'll even be honored.

To say in one paragraph that our premiums, in general, are being reduced for next year. And then in another paragraph state, in red, that not surcharging the unvaccinated may raise everyone's premiums, seems tailored to further divide the unvaccinated and vaccinated by blaming the unvaccinated for potentially causing a raise in premiums which would otherwise be lowered. This is discrimination that ignores the real causes for COVID hospitalization expenses, and unethical coercion to charge the unvaccinated for weekly testing, which as of the Supreme Court ruling on January 13th, is no longer federally mandated. All of this at the risk of further worsening the state's already problematic recruitment and retention woes.

I, again, strongly urge the board to remove the surcharge for the sake of ethical integrity and doing what is best for the State of Nevada.

**https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm*
***https://www.uclahealth.org/conditions-we-treat/coronavirus/addressing-concerns*
***https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html, https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-who-is-at-risk/art-20483301, and https://www.aljazeera.com/features/2021/5/24/comorbidities-and-covid-a-much-higher-risk-of

From: Kelly Macdonald [redacted]
Sent: Wednesday, March 9, 2022 6:37 PM
To: Wendi Lunz <wlunz@peb.nv.gov>; [redacted]
Subject: Meeting of March 24, 2022 Public Comment

Good Evening,

I would like my statement written below to be added for public comment concerning the PEBP Board meeting on March 24, 2022.

When is this going to stop? You are singling out people and dividing staff in the workplace. You are discriminating and penalizing good employees when everyone knows and has known for months that the vaccinated are carriers of Covid and can still get Covid and transmit to others. So why are they not testing? I know someone who was fully vaccinated and got Covid Pneumonia and that was not a mild case. I know people who are fully vaccinated and have caught Covid more than once and I know people who are not vaccinated and never caught Covid. Why is this? Stop harassing good employees because in the long run the State of Nevada is going to suffer when these employees leave for other jobs because other employers are not mandating testing for their staff or charging them for it. You are taking away the rights of individuals to make their own decision on whether they want to be vaccinated or not. You are also penalizing these employees and their families with this flipping $55.00 surcharge. This needs to stop now and not go any further because the State and its citizens will pay the price later.

Thank you for your time.

Kelly Macdonald

From: Jared Gloistein [redacted]
Sent: Thursday, March 10, 2022 2:45 PM
To: [redacted] Wendi Lunz <wlunz@peb.nv.gov>
Subject: Discriminatory testing

I want my letter response in the pebp board meeting!

If you think we are going to test you are surely mistaken!!!! The emergency declaration is over! Not to mention how unjust it is to healthy fit with no underlying health problems and already had covid individuals!!! Can you say discrimination! Have you ever considered the consequences and repercussions of taking someone's livelihood and how they make a living and their time they have invested into their careers, too just be terminated over discrimination!

Brandy Cox
[redacted]

3/10/22

To: Nevada Public Employees Benefits Board

I am writing this letter today to voice my frustration and anger regarding the unlawful, discriminatory, coercive insurance surcharges and weekly covid tests for those unvaccinated.

This surcharge is outrageous and will cause hardships for many employees. Especially those of us who have medical conditions that we are not comfortable getting the vaccines. And your answer will probably be, get a doctor's note. That is easier said than done. Doctors are to afraid to write exemptions due to the policies in their practices. I was able to get an exemption from my doctor for due to a preexisting condition I have. However, my husband has not been able to get an exemption which is absolutely insane to me. He has had over 30 allergic reactions to antibiotics, he recently had an allergic reaction to an infusion of IVIG (to boost his immune system) and several other allergies. This last reaction caused him to have cerebral edema and be in the hospital for 5 days. Due to his many allergic reactions, he is not comfortable getting the vaccines especially after reading the 9 pages of allergic reactions released just recently.

My husband is disabled and receives a small income from social security and this surcharge will cost us $175.00 per month. Why are we being charged this surcharge for our dependents when they do not get tested weekly? I just had one long term state employee who recently decided to leave state service because this surcharge would cost them over $800.00 per month. Not only are we losing tons of state employees to retirement, but now due to this crazy surcharge.

And how do you justify continuing this course of action of testing unvaccinated and this surcharge with the covid counts plummeting and restrictions being lifted. And with the fact we know everyone can catch it and carry it regardless of vaccination status. Unvaccinated are being discriminated against. If you are going to test employees, you should be testing all employees! In my office 80% of the positive cases were vaccinated individuals.

On January 13, 2022, the U.S. Supreme Court made a ruling, blocking the Biden Administration and OSHA from enforcing covid vaccine mandate and weekly covid tests. As to why, nearly six weeks after this ruling we are now being subjected to these tests. It is a WASTE of money (to say

the least). The weekly covid tests and the unlawful, discriminatory, coercive surcharges should be vacated immediately.

Sincerely,

Brandy Cox

From: Phyllis [redacted]
Sent: Friday, March 11, 2022 6:04 AM
To: Wendi Lunz <wlunz@peb.nv.gov>[redacted]
Subject: Meeting of March 24, 2022 Public Comment

Good Morning,

I would like my statement written below to be added for public comment concerning the PEBP Board meeting on March 24, 2022.

I am in total disagreement with the actions of the PEBP Board regarding testing and the increase in cost of insurance for the unvaccinated. You are discriminating and penalizing State employees when it is known that the vaccinated are carriers of COVID, can still get COVID and transmit to others just as much as unvaccinated. So why are they not testing? I know people who are fully vaccinated and have caught COVID, were hospitalized and died. I also know people who are not vaccinated and never caught COVID. Stop harassing good employees! There are employees leaving for other jobs because other employers are not mandating testing for their staff or charging them for it. You are taking away the rights of individuals to make their own healthcare decision on whether they want to be vaccinated or not. You are also penalizing these employees and their families with the additional surcharge. Why are you not charging extra to those employees that have diabetes, heart problems, drug addictions, or other chronic diseases, they cause more expense to the health insurance than the unvaccinated! I have been employed by the State since 2013, have never been hospitalized, rarely take a sick day, worked through the early days of the pandemic, only use my insurance for dental cleanings, am unvaccinated and don't feel that myself or any of my coworkers should be subject to discrimination. The mandated testing is discriminating and has cause a great deal of stress for all State employees. Stop this now!!

Thank you for your time.

Phyllis Zink

2/16/2022

PEBP Board,

My name is Sarai Berumen, I am currently a PEBP member. I want to share with the board how very unhappy I am with their decision to charge a sur-charge in addition to our health insurance for unvaccinated employees and dependents over the age of 18.

It should be the responsibility of and right for every individual to make medical decisions for themselves and their family. They should not be coerced into injecting something into their body that they do not want or is unnecessary.

The board voted for unvaccinated employees to be charged a surcharge of $55 per month and $175 per dependent over the age of 18. This is intended to absorb the cost of COVID related testing, treatment and hospitalization. You are raising a great sum of money on the backs of hard-working state employees, many whom have had to work through the pandemic without taking time off or the ability to work from home. The same people who showed up to work every day without complaining. The same people who have had to take furloughs to make up budget shortfalls at no fault of their own. These are the people who protect our streets and risking their lives to save yours from criminals, fires, medical emergencies and keeping our roads safe.

Getting vaccinated has not proven to reduced contracting or the spreading of COVID. There are a great number of vaccinated people STILL testing, contracting COVID, and ending up in the hospital. Why are the unvaccinated having to pay the price for everyone? Charging a surcharge to one group of people because they don't consent to your medical treatment is discrimination.

This vaccination is unnecessary because there is over a 99% chance of survival. The survival rate is the same with or without the vaccine. Many people have the same symptoms as the cold or flu. The vaccine has not proven to take away these symptoms and is very much like the flu. You can still get the flu after the vaccine and can still get the symptoms and pass the flu with the vaccine. More people get and die from the flu than COVID and the flu vaccine is not mandatory and nor should it be. Nor should people be coerced into get the flu vaccine.

It is unconstitutional to coerce/force someone to get medical treatment. Are you going to charge people who smoke, drink, do drugs, or overweight a surcharge for those added expenses? These things cause more medical issues and expenses than COVID.

Charging a surcharge to unvaccinated employees is not only discrimination, but it is persecution and is right out of the communist playbook. Both myself and my husband work for the State of Nevada and we cannot afford the surcharge especially with 3 dependents over the age of 18. But is seams as this is what the state wants anyway.

PEBP needs to remove the surcharges being imposed on the hard-working state employees, who keep things moving daily to make everyone else's lives easier. And the State of Nevada needs to quit finding ways to screw over its employees.

Sincerely,

A very disgruntled employee of the State of Nevada

From: Tisha Bernhard [redacted]
Sent: Thursday, March 17, 2022 4:32 PM
To: Wendi Lunz <wlunz@peb.nv.gov>[redacted]
Subject: Insurance Surcharge and Weekly Covid-19 Testing needs to be vacated.

Ms. Lunz,

This letter is intended for the PEBP Board Members and included on record as written public comment for the March 24, 2022 PEBP Board Meeting.

Good afternoon,

I am writing to you regarding the December 2, 2021, PEBP Board Members meeting in which you voted to implement an insurance surcharge on employees and their dependents for those who are unvaccinated and for the weekly surveillance Covid-19 testing for unvaccinated employees.

We, the State of Nevada employees, are one of the lowest paid civil servants in the state. We are still recovering from last year's furloughs, increasing inflation, and the skyrocketing housing and fuel prices. Unlike other businesses in Nevada, our pay is passed through Legislature. Obviously, Covid-19 was not predicted nor was inflation years ago. Unfortunately, it will be some time before the Nevada State Legislature could approve an increase in pay and/or COLA (Cost of Living Amount) for State of Nevada Employees. This does not help us now financially.

Along with most other state employees, we are stressed and struggling to make ends meet. Now the employees and their dependents are being threatened with a financial burden with an insurance surcharge if the employee and dependents don't make a medical decision to submit to the mRNA procedure (aka Covid-19 vaccine). This unlawful, intimidating, discriminating and coercive surcharge and weekly surveillance Covid-19 testing needs to be vacated immediately.

Weekly Surveillance Covid Testing

On November 5, 2021, The U.S. Department of Labor Occupational Safety and Health Administration (OSHA), had implemented a COVID-19 Emergency Temporary Standard (ETS) on Vaccination and Testing to protect unvaccinated employees of large employers with 100 or more employees from workplace exposure to coronavirus. The mandatory vaccination policy was either choose to be fully vaccinated against COVID-19 or provide proof of regular testing for COVID-19 and wear a face covering in lieu of vaccination (29 CFR 1910.501(d)(2)).

- However, on January 13, 2022, the Supreme Court made a ruling that blocked the Biden Administration and OSHA from enforcing covid vaccine mandate and weekly covid testing for businesses. https://www.cnbc.com/2022/01/13/supreme-court-ruling-biden-covid-vaccine-mandates.html
    - Additionally, On January 21, 2022, a Federal District Court Judge in Texas rejected the Biden administrations Vaccine Mandate and blocked it from imposing disciplinary action

on Federal Employees https://executivegov.com/2022/01/texas-judge-rejects-federal-employee-vaccine-mandate/

- On January 25, 2022, OSHA stated effective January 26, 2022, they are withdrawing the vaccination and testing ETS. https://www.osha.gov/coronavirus/ets2

- The Abbott BinaxNOW Covid-19- Ag Card Home Test that was issued to State of Nevada "unvaccinated" employees in February/March 2022, is by prescription only, and has not been FDA cleared or approved. (These statements are listed directly on the covid test kit box). I am not sure what physician prescribed this test to the "unvaccinated" State of Nevada employees.

- To use this Covid test kit, you are required to download the Navica App and create an account prior to your appointment. I am not sure how many people read the disclosure for Navica before hitting accept. However, in BOLD letters, it states **"By using this APP and by acknowledging this privacy notice, we are informing you of these transfers of your personal information to the United States of America, Ukraine, and India and to the access of your personal information, including health-related information, which may be required in exceptional circumstances to respond to any support requests you or related third parties request. These countries may not offer an equivalent level of protection for your personal information when compared with data protection or privacy laws of other countries.**

  - If we don't use this state issued test, we must obtain testing elsewhere at our own cost. This test an improper governmental action which is a waste of money and I am not sure why the State of Nevada is ok with other countries to have our confidential information.

- **Therefore, the weekly surveillance covid testing is no longer mandated by OSHA and should be vacated immediately. For the State of Nevada to keep the weekly surveillance testing is a gross waste of money.**

Insurance Surcharge for unvaccinated employees and unvaccinated dependents

This insurance surcharge is unlawful, discriminatory, intimidating, and coercive. On December 2, 2021, the Public Employees Benefits Program Board (PEBP) held a meeting in which the board members voted to implement a surcharge for unvaccinated employees and unvaccinated dependents effective July 1, 2022. PEBP member(s) stated the insurance surcharge is to "recoup sufficient revenue to offset the expected expenditures of the plan" (for the weekly covid testing costs).

- However, it has been proven that the "Covid vaccines" do NOT prevent transmission of the virus, they are primarily designed to prevent serious illness and death. This was especially seen with the fully vaccinated public who contracted the Covid-19 Omicron variant. https://www.usatoday.com/story/news/factcheck/2022/01/21/fact-check-vaccines-limit-serious-illness-and-death-covid-19/9185671002/

- The Biden Administration and OSHA's mandate vaccine or test emergency temporary standard (ETS) was blocked by the U.S. Supreme Court on January 13, 2022. OSHA announced it had

withdrawn the ETS effective January 26, 2022. Therefore, it is no longer mandated. As such, the weekly surveillance covid testing here in Nevada should be vacated. As the only reason for the insurance surcharge was for the expenditures of the plan to offset the weekly surveillance testing costs.

- According to December 2, 2021, page 47 of the PEBP meeting transcript, F-12-2-21PEBP (state.nv.us), Ms. Rich states "*Health insurance must still be considered affordable under the Affordable Care Act, meaning that the least expensive employee only, and that's important, the employee only premium option must be less than the 9.83 percent of the employee's household income.*"
  - However, on September 7, 2021, as written in SHRM (Society for Human Resource Management), the IRS lowered the 2022 Employer Health Plan Affordability Threshold to 9.61% of pay, (not the 2021 Affordability Threshold of 9.83% as was stated on December 2, 2021). This would be effective July 1, 2022 when the new plan year starts. https://www.shrm.org/resourcesandtools/hrtopics/benefits/pages/irs-2022-employer-health-plan-affordability-threshold.aspx .

- On page 48, Ms. Rich continues, "*While the dependent surcharges must still comply with HIPPA wellness rules they are not subject to the same limitations that employee surcharges are. So employers have a lot more flexibility in dependent surcharges in that amount. PEBP anticipates needing about $175 for surcharge for dependents in order to recoup sufficient revenue to offset the expected expenditures of the plan " pages 53-54, Ms. Rich explains "MS. RICH: So Laura Rich for the record. So quite honestly, I mean, so we're limited in what we can assess in a surcharge. So $55 is what we're limited for the employee. So we have to pick up the rest of the cost through the dependents surcharge. Now this is only addressing the testing cost. We can certainly add in the anticipated COVID hospitalization and treatment on this, but then we're looking at very significantly high numbers for the dependent surcharge, and staff wasn't prepared to really go above that 175." CHAIRWOMAN FREED: "Okay. Okay. Got it. So the surcharge is to cover the testing costs. The cost sharing is to bring PEBP in line with other health plan, tier health plans in Nevada, as well as large public sector health plans in other states and from that end tackle the claims cost side?" MS. RICH: "That is correct."*

- **Therefore, the weekly surveillance covid testing is no longer mandated and as such, the unlawful, discriminatory, intimidating, and coercive surcharges for insurance should be immediately vacated.**

- According to PEBP, if this insurance surcharge is to be implemented, it will affect all employees and dependents 18 years and older that are not "fully vaccinated" against Covid-19. **I personally have a large family of eight (8) that our insurance is covered through PEBP**. This includes my husband and six (6) children. Four (4) of my dependent children are between the ages of 19-21.
  - As a state employee, under this PEBP surcharge, If we are all not vaccinated with the mRNA Covid-19 medical treatment, I would be required to pay an extra $55.00 for myself and $175.00 x 5 dependents amounting to an additional **$930.00/mo (surcharge)**

for my family to stay insured! This is intimidating, discriminatory, and coercive. To mandate the underpaid State of Nevada employees to choose to get the mRNA medical treatment or pay dearly in surcharges or forced to quit their jobs as they can't afford this surcharge is intimidating and coercive.

- The State of Nevada (PEBP) cost of employee + family insurance I currently pay is about $550.77/mo. If the rate stays the same and PEBP requires me to pay a $930.00/mo surcharge, **I will have to pay $1,480.77/mo, or roughly $17,769.24/yr,** for the medical insurance (with the added surcharge).
  This would be a little more than **36% of my gross income**!

- With all the other additional deductions from my pay, **my net pay would be roughly $329/wk**. Individuals on **unemployment receive up to $362/wk. I would have more money being on unemployment!** This would **NOT** meet ACA requirements for affordability in cost of medical coverage. Unfortunately, my husband's job does not offer insurance and the mRNA medical procedure is NOT an option for us. So, I cannot change the insurance to his employer. This is discriminatory and coercive against those who do not to go through with this mRNA medical procedure.

- According to the October 4, 2021, HIPPA nondiscrimination and ACA wellness program requirements, there is an **insurance surcharge cap of 30% that is applied to the cost of coverage for the employee AND dependents enrolled.**
  https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/caghipaaandaca.pdf Also,
  https://www.natlawreview.com/article/impact-aca-employer-shared-responsibility-rules-and-wellness-program-limits-covid-19 , dated January 3, 2022.
  - Therefore, according to this rule, my cost of coverage is roughly $550.77/mo, the cap of 30% of this amount would be roughly $165.23/mo. Therefore, according to this 30% rule, I should NOT incur a TOTAL family surcharge of more than about $165.23/mo.

- **However**, EEOC laws state "**Employers must not require employees to have their family members get vaccinated and must not penalize employees if their family members decide not to get vaccinated**.

  - https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws **K.21. Under GINA, may an employer offer an employee's family member an opportunity to be vaccinated *without* offering the employee an incentive?** *(5/28/21)*
    - "Yes. GINA permits an employer to offer vaccinations to an employee's family members if it takes certain steps to comply with GINA**. Employers must not require employees to have their family members get vaccinated and must not penalize employees if their family members decide not to get vaccinated…**"

  - **As such, the insurance surcharge for the unvaccinated dependents is a violation of EEOC laws and should be vacated immediately.**

- **In a review of Nevada Revised Statutes (NRS), it is blatant unfair discrimination to implement any surcharge for fees charged for health insurance for persons of the same class (Nevada State employees) with the same hazard (covid -19).**

    - **NRS 686A.100 (2)** states "*No person may make or permit any unfair discrimination between persons of the same class and of essentially the same hazard in the amount of premium, policy fees or rates charged for any policy or contract of health insurance or in the benefits payable thereunder, or in any of the terms or conditions of such contract, or in any other manner whatever.*"

        - **NRS 686A.010 Purpose.** The purpose of NRS 686A.010 to 686A.310, inclusive, is to regulate trade practices in the business of insurance in accordance with the intent of Congress as expressed in the Act of Congress approved March 9, 1945, being c. 20, 59 Stat. 33, also designated as 15 U.S.C. §§ 1011 to 1015, inclusive, and Title V of Public Law 106-102, 15 U.S.C. §§ 6801 et seq. (Added to NRS by 1971, 1688; A 2001, 2214; 2019, 1601)

        - **NRS 686A.100 Life insurance, annuities and health insurance: Unfair discrimination prohibited.**
            - 1. No person may make or permit any unfair discrimination between persons of the same class and equal expectation of life in the rates charged for any contract of life insurance or of life annuity or in the dividends or other benefits payable thereon, or in any other of the terms and conditions of such contract.
            - 2. No person may make or permit any unfair discrimination between persons of the same class and of essentially the same hazard in the amount of premium, policy fees or rates charged for any policy or contract of health insurance or in the benefits payable thereunder, or in any of the terms or conditions of such contract, or in any other manner whatever.
            - 3. No person may make or permit any unfair discrimination between persons legally qualified to provide a particular service, in the amount of the fee or charge for that service payable as a benefit under any policy or contract of health insurance. (Added to NRS by 1971, 1690; A 1983, 326)

        - As such, pursuant to NRS 686A.100 (2), the insurance surcharge for those unvaccinated is unlawful and unfair discrimination.

Therefore, the weekly surveillance covid testing that is no longer mandated by OSHA and the insurance surcharge that is unlawful, discriminatory, intimidating, and coercive and both need to be vacated.

Sincerely,

TISHA BERNHARD | Compliance Investigator II
[redacted]

3/18/2022

Dear PEBP Board Members,

My name is Edwin Forges. Since we are switching our PPO Network from Aetna to United Healthcare Choice Plus effective 7/1/2022, I am hoping that the University of Utah Hospitals and Clinics and all their affiliated doctors be added to UHC Choice Plus network. I tried to search this to their website and University of Utah Hospital is showing as an out of network facility.

I am 40 years old diagnosed with [redacted]. I had to be referred to an out of state Hospital and doctors by my NV Neurosurgeon. My Doctor informed me that NV do not have the facilities for the kind of [redacted] I have. I had already 2 [redacted], first was in 2018 and my 2nd was just April of 2021. Our current PPO Network Aetna is currently accepts University of Utah Hospital but come July 1, 2022 it will be changed to UHC Choice Plus. I am scared once this is happened since I have to find another hospital and doctors that can watch my condition since I cannot continue going to University of Utah Hospital at that time.

I am hoping and praying that UHC Choice Plus will add the University of Utah Hospitals and Clinics and its doctors when our networks change by July 1.

Thank you very much,

Edwin Forges

NV State Employee

From: Mindy Maddox [redacted]
Sent: Saturday, March 19, 2022 11:52 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Public comment for PEBP March 24th Meeting

Greetings, Ms. Lunz. Please accept this as written public comment for the March 24, 2022 PEBP Board meeting specific to agenda item #6.

Agenda item #6 appears to be an update on COVID. I'm writing to express my opposition to the PEBP COVID surcharge. I'm hoping the Board members cast the moral and ethical vote to eliminate the surcharge.

I'm recently retired after serving the state for 25 years. The justification for the surcharge doesn't apply to retired employees as we aren't subject to the mandatory testing that is temporary and hopefully being ceased soon.

Additionally, why are we paying up front for medical care that hasn't been administered? Luckily, I have never contracted COVID, therefore, I've never sought medical care for COVID symptoms. Just as with any other medical need, when I seek medical care, PEBP can apply appropriate charges... not before then.

This insurance surcharge for active and retired state employees is unlawful, discriminatory, intimidating, and coercive. Specifically, it's unjust for me to be forced to pay for something that doesn't apply to me.

Retirees are living on a reduced salary and increased medical premiums. To unnecessarily and unfairly add an irrelevant surcharge is abhorrent, inconsiderate, disrespectful, and a slap in the face to all of us who dedicated a large portion of our lives to state service.

I implore the PEBP Board to eliminate the surcharge.

I appreciate your consideration.

Mindy McKay

March 24, 2022

State of Nevada
Public Employees Benefit Committee

Delivered via Email to wlunz@peb.nv.gov

RE: Public Employees' Benefits Program Board Meeting
March 24, 2022

The comments herein are expressly my opinion only and are not representative of my workplace, employer or any associated employee.

The continued implementation of weekly COVID testing and the surcharge being imposed on unvaccinated workers is discriminatory and overreaching government coercion. This requirement is targeting a specific group of people who have chosen not to undergo an irreversible medical procedure, a decision that was upheld by the U.S. Supreme Court on January 13, 2022 for private employers with over 100 employees. This is the Nevada government's (state and local) way of working around this decision by imposing penalties to coerce employees and retirees into complying with this unconstitutional mandate.

In the Interim Retirement and Benefits Committee meeting, it was stated on record that the surcharges for the weekly testing imposed on unvaccinated employees is punitive and a distinct departure from the wellness attitude of PEBP's practice in the past to which Ms. Laura Rich, Executive Officer of the Public Employee's Benefit Program, agreed and stated that the funding for the tests "has to come from somewhere." Why then are diabetics not similarly assessed with additional surcharges related to their exorbitant medical costs and tests? Why is a surcharge not imposed on smokers? The surcharge on unvaccinated employees is just a way for PEBP to force employees and retirees enrolled in PEBP into complying with the Governor's unconstitutional COVID policy.

The U.S. Supreme Court has ruled that the practice of enforcing vaccines or testing on employees is a far overreach and abuse of government power. Why then is the Governor and PEBP continuing to pursue more coercive tactic to force employees into a medical procedure against their will and consent? Why are these weekly tests mandated at all? Evidence continues to mount against the efficacy of vaccinations in preventing COVID infections as well as the reliability of accurate COVID tests. Therefore, why are only unvaccinated employees being targeted and punished with weekly testing and surcharges? This is a disease that has been shown to have a 99.98% survival rate, and there have been increasing cases of vaccinated people continuing to contract and spread COVID.

In addition, natural immunity is not being given consideration when the CDC released a study on January 19, 2022 stating that "persons who survived a previous infection had lower case rates than persons who were vaccinated alone." https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm?s_cid=mm7104e1_w

This is a gross mistreatment of state and local government employees and traps current and retired employees, who have no insurance alternatives, into forced compliance or pay punitive costs. This extreme unfairness is causing widespread mental and emotional anguish, divisiveness, dissension and extremely low morale amongst employees and retirees whether vaccinated or not.

I urge you to stop these tyrannical mandates and discriminating requirements.

Susan Hohn
Carson City, NV 89701

From: CRD64 [redacted]
Sent: Monday, March 21, 2022 11:12 PM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Surcharges and testing

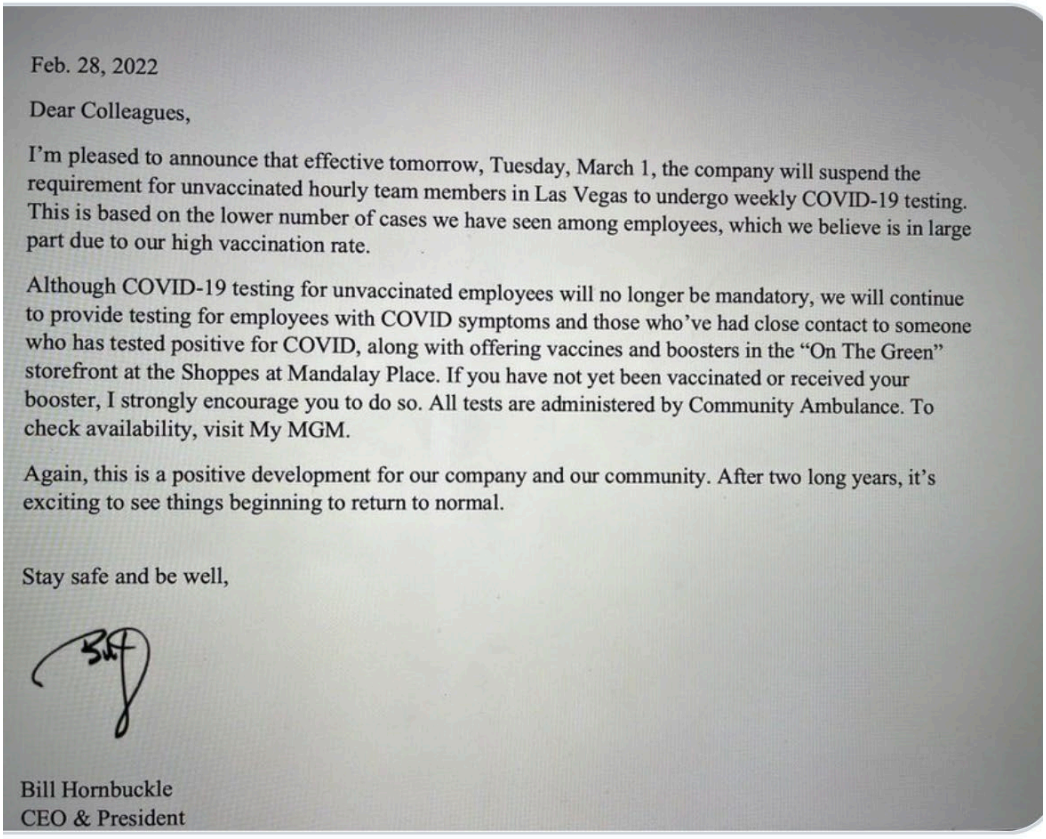
To PEB board on item #6 of the agenda:
Please submit this to public comments.

I am writing you to please withdraw the employee and retiree surcharge. As I stated in the January meeting on public comment, this surcharge is coercion and unlawful. I have looked at Texas Public Employees Benefit program, they are not charging a surcharge. I have also done much research on the effectiveness and consequences of taking an experimental shot. I surly hope all of you have done the same as young healthy athletes and many others have dropped dead or have life long debilitating conditions due to this jab. I have constitutional strong religious beliefs on behalf of not getting this shot that would violate the the rights of my husband and I. I will be asking for information in the near future, and have asked, in emails as to who our attorneys should contact in regards to these surcharges and continued testing of healthy people or suspected transmission. We all now know that 3xs vaccinated are as likely or more likely to contract this virus. Attorneys are gathering their information on this as well. I am hoping that today these questions will be answered so we can begin the process of investigating these questions or have resolution of the violation of our rights.
Thank you for your time and consideration,
23 year employee
Please black out my email
Thank you

Please review attachment of MGM's shot and testing policy and share with the board to adopt the same policy.
Thank you

@VitalVegas

e latest from MGM Resorts. (h/t
neidiology)



Feb. 28, 2022

Dear Colleagues,

I'm pleased to announce that effective tomorrow, Tuesday, March 1, the company will suspend the requirement for unvaccinated hourly team members in Las Vegas to undergo weekly COVID-19 testing. This is based on the lower number of cases we have seen among employees, which we believe is in large part due to our high vaccination rate.

Although COVID-19 testing for unvaccinated employees will no longer be mandatory, we will continue to provide testing for employees with COVID symptoms and those who've had close contact to someone who has tested positive for COVID, along with offering vaccines and boosters in the "On The Green" storefront at the Shoppes at Mandalay Place. If you have not yet been vaccinated or received your booster, I strongly encourage you to do so. All tests are administered by Community Ambulance. To check availability, visit My MGM.

Again, this is a positive development for our company and our community. After two long years, it's exciting to see things beginning to return to normal.

Stay safe and be well,

Bill Hornbuckle
CEO & President

AM · Mar 1, 2022 · Twitter for iPhone

From: Zachary Farinha [redacted]
Sent: Tuesday, March 22, 2022 10:13 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Public Comment for PEBP Board Meeting 03.24.2022

Greetings,

I am writing to respectfully request the PEBP Board eliminate COVID-19 surcharges for unvaccinated state employees.

One can fully support and encourage vaccination and also be opposed to forcing or coercing people to take it against their will, regardless of one's reasoning for not getting vaccinated. We must respect the choices of our fellow citizens and refrain from divisive tactics like mandates and surcharges, which will ultimately do more harm than good.

In this economy, it is already difficult to fill vacant positions - even within state employment - and surcharges like this will likely drive away prospective employees. This will put a hardship on remaining state employees and the constituents they serve. This could result in a financial hardship to the State if it fails to meet Federal standards and is fined by the Federal government due to the overwhelming workload on a diminished workforce. Furthermore, many state employees live paycheck to paycheck, especially in these trying times where the cost of living is drastically increasing. If implemented, these surcharges could double the cost of health insurance for many state employees, if not increase it by much more, and we simply cannot allow that to happen.

At this time, due to COVID-19 being an ever-evolving virus, we do not even know how many vaccines will be needed to maintain effective vaccinated status, or if the vaccines will even be effective against future strains. Everyone's risk profile against COVID is also very different, depending on their particular health histories. Because these vaccines are so new and there are so many unknowns about them and the virus they protect against, imposing a one-size-fits-all policy like surcharges against unvaccinated state employees is nonsensical and unnecessarily reckless.

By all means, continue to persuade those who are hesitant to get vaccinated if it will benefit them. But avoid coercive tactics like surcharges and respect other's freedom of choice.

I therefore implore you to vote to drop the surcharges against unvaccinated state employees.

Thank you for your assistance in this matter. I wish you all well.

PEBP Board:

Without the United States Constitution, we would not have Religious Freedom. As recorded in the United States Constitution, Amendment 1- Freedom of Religion, Press, Expression. Ratified 12/15/1791. "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances," (The Constitution of the United States usconstitution.net -See attachment 1), and affirmed in the Nevada Constitution, Section 1. Inalienable rights. "All men are by Nature free and equal and have certain inalienable rights among which are those of enjoying and defending life and liberty; Acquiring, Possessing and Protecting property and pursuing and obtaining safety and happiness.

The US Constitution protects all US Citizens (***WHICH INCLUDES NEVADA STATE EMPLOYEES***) from tyrants who believe they themselves are little gods by attempting to infringe on our right to protect our own lives from those who would otherwise try to harm us. This includes Governor sisolack, the pebp board, every state director, every HR agency, state supervisor, and any other person who attempts to illegally coerce, threaten, or retaliate against those of us who legally reject the poisonous covid19 injections and covid19 testing. The State of Nevada, and the pebp board has no authority to override the US Constitution as protected by the Almighty Creator Himself.

"All laws which are repugnant to the Constitution are null and void." ~Marbury vs. Madison, 5 US (2 Cranch) 137, 174, 176, (1803)

"When rights secured by the Constitution are involved, there can be no rule making or legislation which would abrogate them." ~Miranda vs. Arizona, 384 US 436 p. 491

"An unconstitutional act is not law; it confers no rights; it imposes no duties; affords no protection; it creates no office; it is in legal contemplation, as inoperative as though it had never been passed." ~Norton vs. Shelby County 118 US 425 p. 442

Although no more needs to be said to prove the atrocity this Board is putting forward to segregate and punish a specific group of Nevadans is illegal and against Human Rights, we insist the following also be included in the record – including every attachment.

Amendment IV of the United States Constitution states, "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

18 USC 241: Conspiracy against rights states, "If two or more persons conspire to injure, oppress, threaten, or intimidate any person in any State, Territory, Commonwealth, Possession, or District in the free exercise or enjoyment of any right or privilege secured to him by the Constitution or laws of the United States, or because of his having so exercised the same; or

If two or more persons go in disguise on the highway, or on the premises of another, with intent to prevent or hinder his free exercise or enjoyment of any right or privilege so secured-

They shall be fined under this title or imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse or an attempt to commit aggravated sexual abuse, or an attempt to kill, they shall be fined under this title or imprisoned for any term of years or for life, or both, or may be sentenced to death."

18 USC 242: Deprivation of rights under color of law states, "Whoever, under color of any law, statute, ordinance, regulation, or custom, willfully subjects any person in any State, Territory, Commonwealth, Possession, or District to the deprivation of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States, or to different punishments, pains, or penalties, on account of such person being an alien, or by reason of his color, or race, than are prescribed for the punishment of citizens, shall be fined under this title or imprisoned not more than one year, or both; and if bodily injury results from the acts committed in violation of this section or if such acts include the use, attempted use, or threatened use of a dangerous weapon, explosives, or fire, shall be fined under this title or

imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse, or an attempt to commit aggravated sexual abuse, or an attempt to kill, shall be fined under this title, or imprisoned for any term of years or for life, or both, or may be sentenced to death."

Furthermore, the Preamble of the Nevada Constitution states, "We the people of the State of Nevada Grateful to Almighty God for our freedom in order to secure its blessings, ensure domestic tranquility, and form a more perfect Government, do establish this Constitution," and goes on to declare:

Section 1. Inalienable rights. All men are by Nature free and equal and have certain inalienable rights among which are those of enjoying and defending life and liberty; Acquiring, Possessing and Protecting property and pursuing and obtaining safety and happiness[.]

Section 18. Unreasonable seizure and search; issuance of warrants.
The right of the people to be secure in their persons, houses, papers and effects against unreasonable seizures and searches shall not be violated; and no warrant shall issue but on probable cause, supported by Oath or Affirmation, particularly describing the place or places to be searched, and the person or persons, and thing or things to be seized.
Amendment IV of the US Constitution, as well as Section 18 of the Nevada Constitution protects the illegal seizure of my DNA. To date, the State or PEBP has not presented me with a warrant to seize my DNA for this illegal testing and I will not give it voluntarily via any means – including home testing. My DNA was perfectly created for me by the Almighty God and is not to be improperly mixed or shared.

In addition to the above, I am not a medical professional and do not have the skill to safely conduct this testing; and I am not going to voluntarily provide my DNA to a state ran testing program that has proven to not have my health, or privacy in mind as demonstrated by the fact no "informed" consent is being offered as required by law.

Emergency Use Authorization

Federal law prohibits the mandate (which is not a law) of Emergency Use of COVID-19 vaccines, tests, and masks. According to the FDA, In Vitro Diagnostics Molecular Diagnostic Tests fall under Emergency Use Authorization (EUA) only. See: In Vitro Diagnostics EUAs - Molecular Diagnostic Tests for SARS-CoV-2 | FDA (Attachment 2) and CDC: CDC Diagnostic Tests for COVID-19 | CDC (Attach 3)

The forced COVID-19 testing, the forced wearing of masks, and the forced vaccines are all in direct violation of the Federal Government's Emergency Use Authorization. The State, PEBP, and its Officers cannot force masks, testing, or vaccines without providing informed consent and my right to refuse without the threat of retaliation and/or coercion.

"Federal law, Title 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) of the Federal Food, Drug, and Cosmetic Act, states the following about products granted emergency authorization usage:

> Individuals to whom the product is administered are informed—
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

Informed Consent

In addition to the Federal EUA law noted above, the Nuremberg Code, which is the foundation of ethical medicine, states no one may be coerced to participate in a medical experiment. Consent of the individuals is "absolutely essential (The Nuremberg Code (cirp.org) (Attach 4)

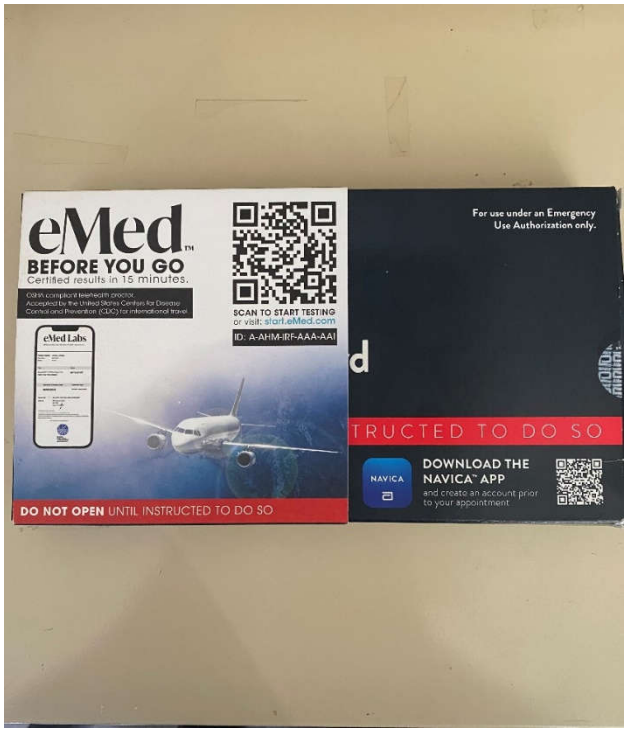
According to the FDA: "To many, the term *informed consent* is mistakenly viewed as the same as getting a research participant's signature on the consent form. FDA believes that obtaining a research participant's verbal or written informed consent is only part of the process. Informed consent involves providing a potential participant with:

- adequate information to allow for an informed decision about participation in the clinical investigation.
- facilitating the potential participant's understanding of the information.
- an appropriate amount of time to ask questions and to discuss with family and friends the research protocol and whether you should participate.
- obtaining the potential participant's voluntary agreement to participate.
- continuing to provide information as the clinical investigation progresses or as the subject or situation requires.

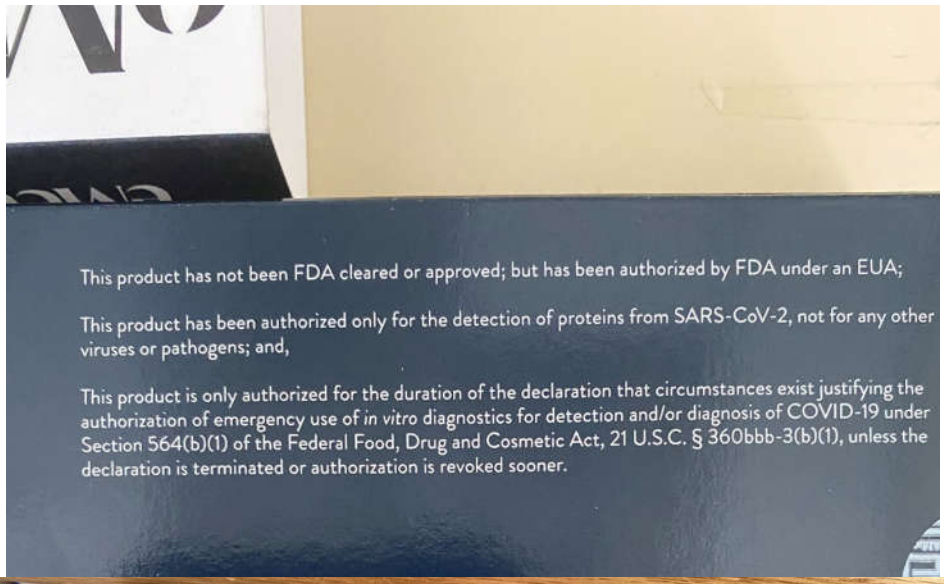
To be effective, the process must provide sufficient opportunity for the participant to consider whether to participate. (21 CFR 50.20.) (Attach 5) FDA considers this to include allowing sufficient time for participants to consider the information and providing time and opportunity for the participant to ask questions and have those questions answered. The investigator (or other study staff who are conducting the informed consent interview) and the participant should exchange information and discuss the contents of the informed consent document. This process must occur under circumstances that minimize the possibility of coercion or undue influence. (21 CFR 50.20.) Informed Consent for Clinical Trials | FDA (Attach 6)

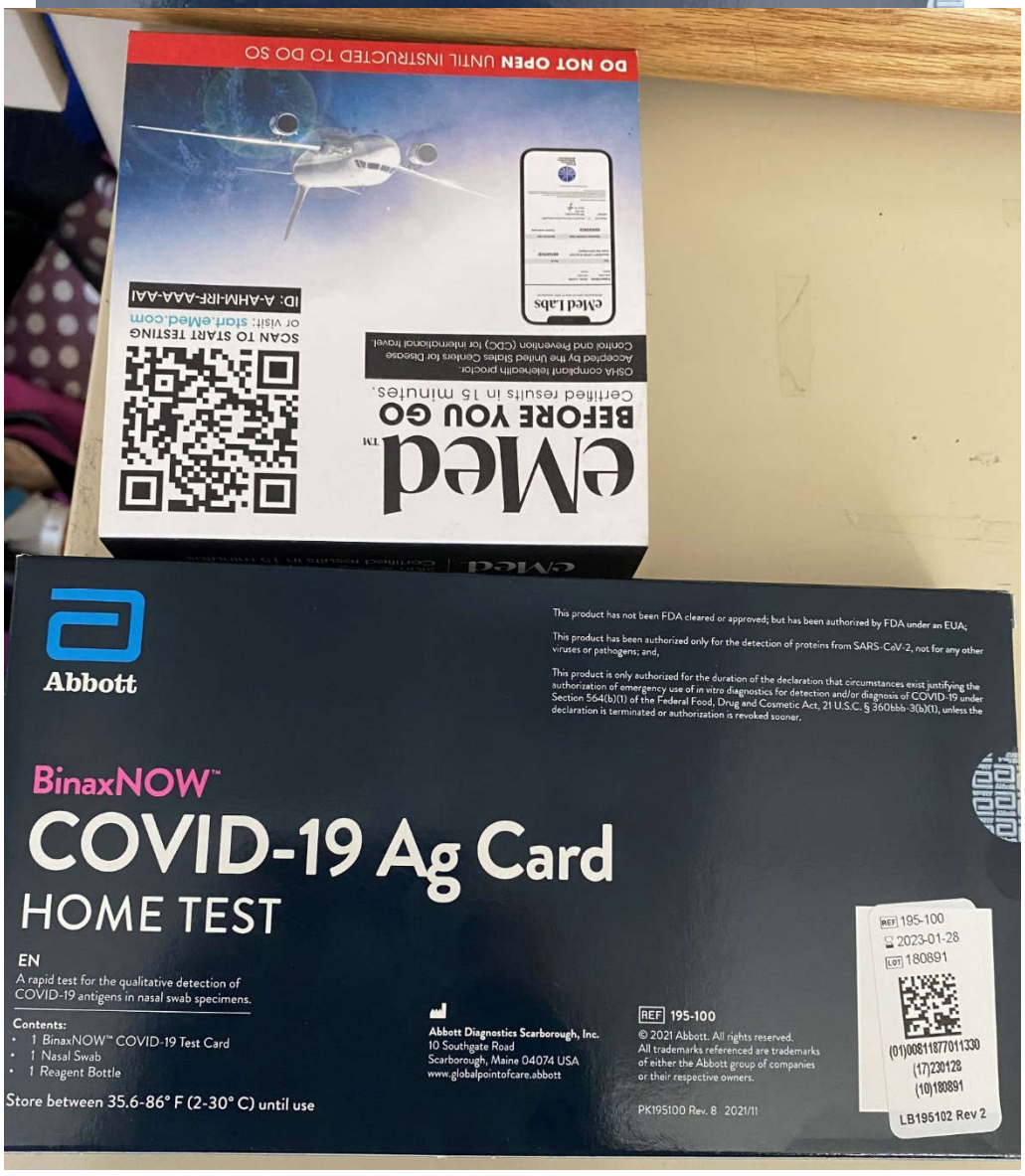
The current "BinaxNOW" test being required by PEBP (and the State) explicitly states that this test is not FDA approved and is only approved under the Emergency Use Authorization – which again, requires my informed consent. There is no ingredient list, no list of side effects, no instructions for use – there is no documentation to inform me of what this product will do to my body, to my DNA, or how it can affect me physically, psychologically, or spiritually.

Photos taken on Monday, February 28, 2022 (please see below):

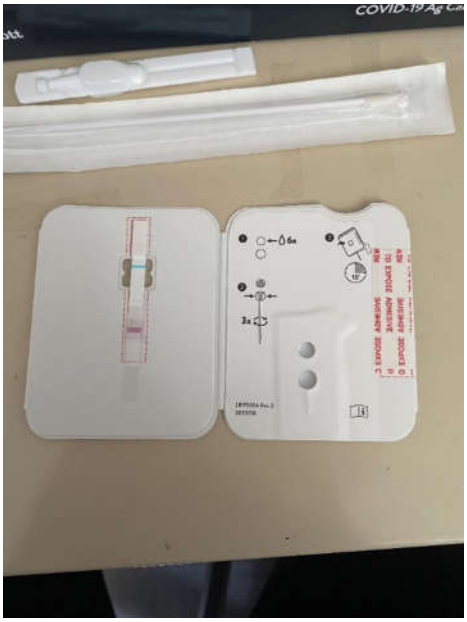





This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.


DO NOT OPEN UNTIL INSTRUCTED TO DO SO
eMed™
BEFORE YOU GO
Certified results in 15 minutes.
OSHA compliant telehealth proctor.
Accepted by the United States Centers for Disease Control and Prevention (CDC) for international travel.
SCAN TO START TESTING
or visit: start.eMed.com
ID: A-AHM-IRF-AAA-AAI
Abbott
This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
BinaxNOW™
COVID-19 Ag Card
HOME TEST
EN
A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.
Contents:
• 1 BinaxNOW™ COVID-19 Test Card
• 1 Nasal Swab
• 1 Reagent Bottle
Store between 35.6-86° F (2-30° C) until use
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.globalpointofcare.abbott
REF 195-100
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All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.
PK195100 Rev. 8 2021/11
REF 195-100
2023-01-28
LOT 180891
(01)00811877011330
(17)230128
(10)180891
LB195102 Rev 2







EUA products are, by definition, experimental, and thus require the right to refuse. Any entity or organization that requires EUA COVID-19 vaccinations, COVID-19 tests or masks are in direct violation of the United States Constitution, the Federal Government EUA, and the Nuremburg Code.

A little bit of research has proven that these tests are poisonous and harmful to the body:

Human toxicity from COVID-19 rapid home test kits (nih.gov) (Attach 7)

Poison Control Center Issues Warning on Toxic Chemical in At-Home COVID-19 Test Kits (resistthemainstream.org) (Attach 8)

CDC | Facts About Sodium Azide (Attach 9)

Virginia Poison Center urges caution, potentially dangerous ingredient in at-home COVID tests | WRIC ABC 8News (Attach 10)

Poison centers around the country sound alarm on chemical in some COVID-19 at-home tests (msn.com) (Attach 11)

The swabs are sterilized with Ethylene Oxide which is labeled "EO" on the swab wrapper. The residue can be cumulative so the more tests one does the more build up one gets.

Ethylene oxide | C2H4O - PubChem (nih.gov) (Attach 12)

Ethylene Oxide - Cancer-Causing Substances - National Cancer Institute (Attach 13)

Investigation into ethylene oxide treatment and residuals on DNA and downstream DNA analysis - PubMed (nih.gov) (Attach 14)

The EPA has concluded that Ethylene Oxide is carcinogenic to humans by the inhalation route of exposure. The acute (short-term) effects of ethylene oxide in humans consist mainly of central nervous system depression and irritation of the eyes and mucous membranes:

ethylene-oxide.pdf (epa.gov) (Attach 15)

Here is an article discussing once approved for EUA tests that have been recalled: FDA Issues Warning on 2 Recalled COVID-19 Tests (theepochtimes.com) (Attach 16)

John Hopkins University confirms: YOU CAN BE VACCINATED WITH APCR TEST, EVEN WITHOUT KNOWING Johns Hopkins University confirms: You can be vaccinated with a PCR test, even without knowing - Dr. Leonard Coldwell (drleonardcoldwell.com) (Attach 17)

Abbott, maker of the state provided BinaxNOW tests, clearly understands this Federal Law and its definitions, and has taken measures to ensure the public understands they are not responsible for any damage their product may cause, as this is a "voluntary" product – only to be used (by voluntary consent), during this Plandemic.

Since the manufacturer of this product cannot be held liable for damages, and because I desire to be fully informed and appraised of ALL facts before considering undergoing this medical procedure, please provide the following information, in accordance with statutory legal requirements outlined both above, and further below:

1. Please advise me of the approved legal status of any COVID-19 testing and if it is experimental?

2. Please provide details and assurances that said testing has been fully, independently, and rigorously tested against control groups and the subsequent outcomes of those tests?

3. Please provide the entire list of contents of the COVID-19 testing I am to receive and if any are toxic to the body, mind, and soul and if my DNA will be harvested, stored, improperly used, or changed in anyway?

4. Please fully advise me of all the adverse reactions associated with this testing since its introduction?

5. Please confirm that the COVID-19 testing you are demanding is NOT experimental and contains no chemicals such as Ethylene Oxide, Graphene Oxide, and with swabs that are 100% non-GMO pure organic cotton?

6. Please confirm that I will not be under any duress from yourselves as my employers/state insurer, in compliance with the Nuremberg Code?

7. Please advise me of the likely risk of illness or infection, should I be unfortunate and contract Covid-19 from these tests, or any other means, and the likelihood of recovery?

8. If I were to experience any adverse reactions is the manufacturer of the COVID-19 test liable? If the manufacturer isn't liable, then will the State of Nevada be responsible & liable as it is their demand that I undergo this testing in order to carry on my employment/reasonably priced insurance premium?

Once I have received the above information in full and I am satisfied that there is NO threat to my health and does not conflict with the Word of the Almighty God, I will be happy to accept your offer to receive the testing, but with certain conditions – namely that:
1. You confirm in writing that I will suffer no harm and that I am not receiving no Biblically unclean ingredients derived in any form.

2. Following acceptance of this, the offer must be signed by a fully qualified doctor who will take full legal and financial responsibility for any injuries occurring to myself, and/or from any interactions by authorized personnel regarding this testing.

3. In the event that I should have to decline the offer of this medical procedure, please confirm that it will not compromise my position or increase my insurance premiums, and that I will not suffer prejudice and discrimination as a result.

I would also advise that my inalienable rights are reserved.

Coercion

NRS 207.190 Coercion.

1. It is unlawful for a person, with the intent to compel another to do or abstain from doing an act which the other person has a right to do or abstain from doing, to:

(a) Use violence or inflict injury upon the other person or any of the other person's family, or upon the other person's property, or threaten such violence or injury;

(b) Deprive the person of any tool, implement or clothing, or hinder the person in the use thereof; or

(c) Attempt to intimidate the person by threats or force.

2. A person who violates the provisions of subsection 1 shall be punished:

(a) Where physical force or the immediate threat of physical force is used, for a category B felony by imprisonment in the state prison for a minimum term of not less than 1 year and a maximum term of not more than 6 years, and may be further punished by a fine of not more than $5,000.

(b) Where no physical force or immediate threat of physical force is used, for a misdemeanor.

[1911 C&P § 475; RL § 6740; NCL § 10424] — (NRS A 1967, 522; 1979, 1455; 1995, 1239)

NRS 613.345 Unlawful employment practices: Requiring or encouraging current or prospective employees and members of labor organizations to submit to genetic test; denying or altering employment or membership in labor organization based on genetic information.

1. It is an unlawful employment practice for an employer, a labor organization or an employment agency:

(a) To ask or encourage a prospective or current employee or member of the labor organization to submit to a genetic test.

(b) To require or administer a genetic test to a person as a condition of employment or membership in the labor organization.

(c) To deny employment or membership in the labor organization based on genetic information.

(d) To alter the terms, conditions or privileges of employment or membership in the labor organization based on genetic information.

(e) To terminate employment or membership in the labor organization based on genetic information.

2. As used in this section:

(a) "Genetic information" means information that is obtained from a genetic test.

(b) "Genetic test" means a test that uses deoxyribonucleic acid extracted from the cells of a person, or a diagnostic test that uses another substance extracted or otherwise obtained from the body of a person, which determines the presence of an abnormality or deficiency that:

(1) Is linked to a physical or mental disorder or impairment; or

(2) Indicates a susceptibility to an illness, a disease, an impairment or another physical or mental disorder.

➥ The term does not include a test to determine the presence of alcohol or a controlled substance in the system of the person tested.

(Added to NRS by 1999, 2874)

According to the State of Nevada Employee Handbook, it appears that the Agency/State is in violation of Improper Governmental Action. Direct quote from the handbook, "The law specifically encourages any State Officer or employee to disclose improper government action to the extent not expressly prohibited by law. It is the intent of the legislature to protect the rights of the State Officer or employee who makes such a disclosure.

"Improper governmental action" means any action taken by a State officer or employee in the performance of his/her official duties, whether or not the action is within the scope of his/her employment, which is:

(a) In violation of any State law or regulation;
(b) An abuse of authority;
(c) Of substantial and specific danger to the public health or safety;
(d) A gross waste of public money.

State officers or employees are prohibited by State law from using their authority or influence to prevent disclosure of improper governmental action by other State officers or employees.

"Official authority or influence" includes taking, directing others to take, recommending, processing, or approving any personnel action such as an appointment, promotion, transfer, assignment, reassignment, reinstatement, restoration reemployment, evaluation or other disciplinary action.

NRS 689B.069 appears to prohibit PEBP from using genetic testing data for this purpose, further indicating this surcharge is being threatened as a means to coerce more employees and retirees to get vaccinated. Additionally, as of this date, PEBP has no ability to access employee/retiree vaccination data unless it is voluntarily submitted.

NRS 689B.069 Insurer prohibited from requiring or using information concerning genetic testing; exceptions. [Effective through December 31, 2019.]

1. Except as otherwise provided in subsection 2, an insurer who provides group health insurance shall not:
(a) Require an insured person or any member of the family of the insured person to take a genetic test;
(b) Require an insured person to disclose whether the insured person or any member of the family of the insured person has taken a genetic test or any genetic information of the insured person or a member of the family of the insured person; or
(c) Determine the rates or any other aspect of the coverage or benefits for health care provided to an insured person based on:
(1) Whether the insured person or any member of the family of the insured person has taken a genetic test; or
(2) Any genetic information of the insured person or any member of the family of the insured person.
2. The provisions of this section do not apply to an insurer who issues a policy of group health insurance that provides coverage for long-term care or disability income.
3. As used in this section:
(a) "Genetic information" means any information that is obtained from a genetic test.
(b) "Genetic test" means a test, including a laboratory test that uses deoxyribonucleic acid extracted from the cells of a person or a diagnostic test, to determine the presence of abnormalities or deficiencies, including carrier status, that:
(1) Are linked to physical or mental disorders or impairments; or
(2) Indicate a susceptibility to illness, disease, impairment or any other disorder, whether physical or mental.
(Added to NRS by 1997, 1460)

NRS 689B.069 Insurer prohibited from requiring or using information concerning genetic testing; exceptions. [Effective January 1, 2020.]

1. Except as otherwise provided in subsection 2, an insurer who provides group health insurance shall not:
(a) Require an insured person or any member of the family of the insured person to take a genetic test;
(b) Require an insured person to disclose whether the insured person or any member of the family of the insured person has taken a genetic test or any genetic information of the insured person or a member of the family of the insured person; or
(c) Determine the rates or any other aspect of the coverage or benefits for health care provided to an insured person based on whether the insured person or any member of the family of the insured person has taken a genetic test.
2. The provisions of this section do not apply to an insurer who issues a policy of group health insurance that provides coverage for long-term care or disability income.
3. As used in this section:
(a) "Genetic information" means any information that is obtained from a genetic test.

(b) "Genetic test" means a test, including a laboratory test that uses deoxyribonucleic acid extracted from the cells of a person or a diagnostic test, to determine the presence of abnormalities or deficiencies, including carrier status, that:

(1) Are linked to physical or mental disorders or impairments; or

(2) Indicate a susceptibility to illness, disease, impairment or any other disorder, whether physical or mental.

(Added to NRS by 1997, 1460; A 2019, 299, effective January 1, 2020)

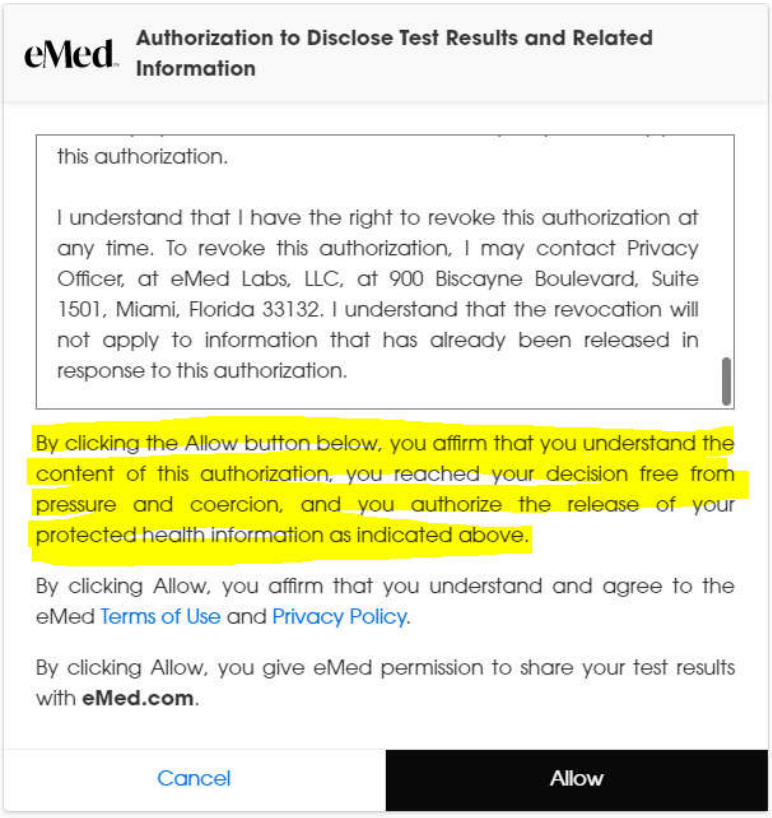
PEBP and its officers, State Directors and their officers and anyone else involved in this atrocity are in violation of state law by requiring unlawful COVID-19 testing that is under EUA and therefore informed consent must be given, and I have the right to refuse under the EUA.

Even the CDC agrees:
Workplace SARS-CoV-2 Testing: Consent Elements and Disclosures | CDC (Attach 18)
SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces | COVID-19 | CDC (Attach 19)

US Supreme Court Facts: US-Supreme-Court-Additional-Facts-2022.1.9-2.pdf (Attach 20)

Disclosing Personal information to a 3rd party provider

eMed, the third-party vendor that state employees are required to use for this forced testing states the following:



eMed clearly recognizes that forced testing is illegal, violates the US Constitution as well as the EUA laws, and requires our consent. **WE DO NOT CONSENT**.

Additional information required by the State/PERS through eMed App:

3. **Grant of Rights to Abbott.** You hereby grant to Abbott a world-wide, perpetual, irrevocable, non-exclusive, sub-licensable, right and license to access, use, disclose, copy, distribute, reproduce, modify, adapt, publish, translate, transform, display, and commercialize the data submitted, input or uploaded by You into the Navica App and all data pertaining to You within the Navica App (collectively, the "**Data**") for the following purposes: (a) to operate the Navica App, including, without limitation, to perform all of its features and functions, which may include, without limitation, data sharing enabled by the Navica App; (b) to further develop and improve the Navica App and other of Abbott's products and services; (c) to monitor the performance of the Navica App; and (d) to aggregate, anonymize, or de-identify the Data and then use, share, and commercialize the aggregated, anonymized, or de-identified output for any business purpose as determined by Abbott in its sole discretion, including, without limitation, to build models, algorithms, learnings or intelligence and develop, manufacture, have manufactured, license, market, and sell, directly or indirectly, products and services.

   You further understand and agree that the Navica App is not intended as a storage repository for Data. Abbott has no responsibility or liability for any loss of Data.

WHERE YOU CHOOSE TO SHARE OR PRINT DATA, INCLUDING, WITHOUT LIMITATION, HEALTH-RELATED INFORMATION, WITH THIRD PARTIES, YOU ACKNOWLEDGE AND AGREE THAT ABBOTT, ITS AFFILIATES, ITS LICENSORS, AND ITS SERVICE PROVIDERS ARE NOT RESPONSIBLE FOR YOUR DECISION TO SHARE OR PRINT DATA, INCLUDING, WITHOUT LIMITATION, HEALTH-RELATED INFORMATION. YOU HEREBY RELEASE ABBOTT, ITS AFFILIATES, ITS LICENSORS, AND ITS SERVICE PROVIDERS FROM ANY AND ALL LIABILITY THAT MAY ARISE FROM SUCH SHARING OR PRINTING.

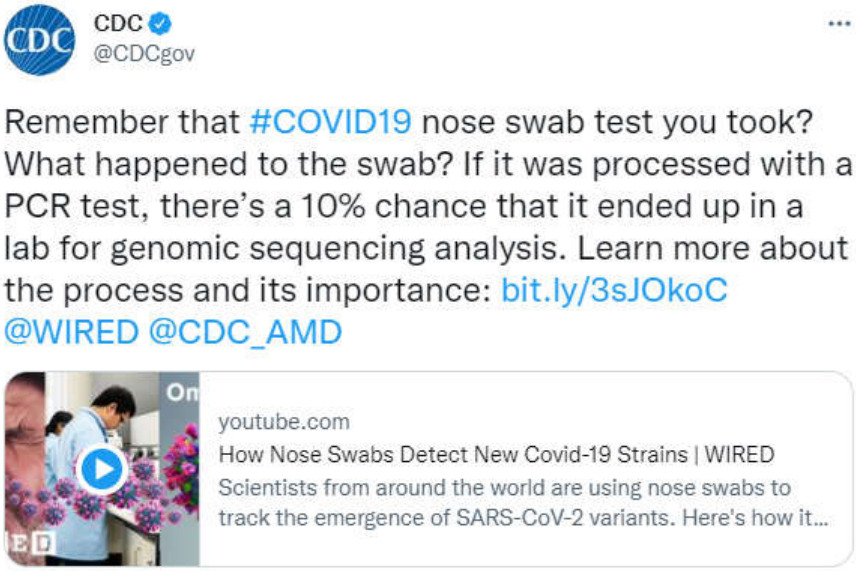
THE NAVICA APP DOES NOT INCLUDE THE PURCHASE OR PROVISION OF OR RIGHT TO USE ANY COVID-19 TEST (INCLUDING, WITHOUT LIMITATION, THE BINAXNOW TEST). WE DO NOT UNDERTAKE ANY OBLIGATIONS AND SHALL HAVE NO LIABILITY UNDER THIS AGREEMENT WITH RESPECT THERETO.

YOU ARE SOLELY RESPONSIBLE AND LIABLE FOR THE DECISIONS YOU MAKE WITH RESPECT TO COVID-19, SAFETY PRECAUTIONS, AND RELIANCE ON THE INFORMATION DISPLAYED THROUGH THE NAVICA APP. ABBOTT, ITS AFFILIATES, AND ITS AND THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, SUCCESSORS, ASSIGNEES AND LICENSORS ARE NOT RESPONSIBLE OR LIABLE FOR YOUR RELIANCE ON THE INFORMATION MADE AVAILABLE THROUGH THE NAVICA APP. THE USE OF THE NAVICA APP AND RELIANCE ON THE INFORMATION AVAILABLE THROUGH OR FROM THE NAVICA APP ARE NOT SUBSTITUTES FOR AND SHOULD BE USED ONLY IN ACCORDANCE WITH APPLICABLE HEALTH GUIDELINES, SUCH AS THOSE PUBLISHED BY THE U.S. CENTER FOR DISEASE CONTROL AND PREVENTION.

BY USING THIS APP AND BY ACKNOWLEDGING THIS PRIVACY NOTICE, WE ARE INFORMING YOU OF THESE TRANSFERS OF YOUR PERSONAL INFORMATION TO THE UNITED STATES OF AMERICA, AND INDIA AND TO THE ACCESS OF YOUR PERSONAL INFORMATION, INCLUDING HEALTH-RELATED INFORMATION, WHICH MAY BE REQUIRED IN EXCEPTIONAL CIRCUMSTANCES TO RESPOND TO ANY SUPPORT REQUESTS YOU OR RELATED THIRD PARTIES REQUEST. THESE COUNTRIES MAY NOT OFFER AN EQUIVALENT LEVEL OF PROTECTION FOR YOUR PERSONAL INFORMATION WHEN COMPARED WITH DATA PROTECTION OR PRIVACY LAWS OF OTHER COUNTRIES.



CDC on Twitter: "Remember that #COVID19 nose swab test you took? What happened to the swab? If it was processed with a PCR test, there's a 10% chance that it ended up in a lab for genomic sequencing analysis. Learn more about the process and its importance: https://t.co/XAHSGANLxu @WIRED @CDC_AMD" / Twitter (see pic below)



Bodily Autonomy

Section I of the Nevada Constitution grants me the unalienable right to enjoy and defend my life, and that is exactly what I am doing- exercising my right to defend my life by not introducing this poison into my body.

According to this Governor and the Attorney General, I cannot choose to save my own life from the destruction the state is attempting to impose on me through illegal testing and coercion to take a series of poisonous injections. However, I can

willingly destroy an innocent life inside the womb, but if I choose not to put poisonous and unclean things in my body, I am threatening someone else's life? Hypocrites!

According to the Attorney General of Nevada, I have the right to protect my own bodily autonomy.

Attorney General Ford Releases Statement on Texas Abortion Law

Sept. 1, 2021

Carson City, NV – Today, Nevada Attorney General Aaron D. Ford issued the following statement on Texas' restrictive abortion law that went into effect early Wednesday.

"Texas has directly attacked the constitutional reproductive rights of its residents, who must be allowed to access safe and legal abortions," said **AG Ford**. "Our office will not sit on the sidelines as these shameful and radical attacks on necessary healthcare continue."

"I want to assure Nevadans that this law will have no effect on their rights. Our state first enacted pro-choice statutes in 1973, and those have been updated and expanded in the decades since. Our office will protect the Constitution, and we will protect the rights and bodily autonomy of our citizens. We are working with several of our colleagues around the country to determine the next best steps."

Natural Immunity is best. It is every individual's right to choose. Bombshell: CDC Admits Natural Immunity Superior to Vaccinated Immunity Alone at Preventing Covid Hospitalizations & Deaths - Becker News (Attach 21)

Israeli vaccine advisor: "We have made mistakes" - The Post (unherd.com) (Attach 22)



Bill Gates: "Sadly the virus itself particularly the variant called Omicron is a type of vaccine, that is it creates both B cell and T cell immunity, and it's done a better job of getting out to the world population than we have with vaccines."

IT IS OUR GOD GIVEN RIGHT TO CHOOSE. This Gene Therapy program was designed to do nothing but destroy the human body. Overwhelming proof of this claim can be found at (not an exhaustive list – not even close to exhaustive):

The McCullough Report - America Out Loud

Home | America's Frontline Doctors (americasfrontlinedoctors.org)

COVID Shot Killing Large Numbers, Warns Top COVID Doc Peter McCullough - The New American

Robert W Malone MD (rwmalonemd.com)

Blog - Naomi Wolf (drnaomiwolf.com)

Discrimination

It is not in dispute that fully "vaccinated" employees still contract and spread COVID-19 with equal and often higher viral loads than those who are not vaccinated (see the CDC website and multiple interviews with the CDC Director as well as Dr. Fauci, and other "officials"), yet they are not subjected to weekly testing ,being threatened with discipline that can result in the loss of livelihood, or having their medical insurance premiums jacked up.

COVID-19 Gene Therapy does not stop the contraction or transmission of the virus.

CDC Director Walensky Admits She Found Out Vaccines were Effective by Watching CNN (thegatewaypundit.com)
(Attach 23)



CDC admits to withholding vaccine data over fears

The CDC has confirmed it is withholding certain vaccine data from the public over fears it would be interpreted as the vaccines aren't effective against the China virus. One America's Pearson ...



And in some cases, are actually enhancing the disease AND causing vicious adverse events:

COVID-19 Vaccines May Be Enhancing Disease: Malone (theepochtimes.com) (Attach 24)

Here is a 38 page document containing 9 pages of adverse events reported by Pfizer contained in the court documents forcing the release of this data: 5.3.6-postmarketing-experience.pdf (phmpt.org) (Attach 25)

COVID-19 takes life of Nashville doctor, family says (wkrn.com)

DOD Caught in MAJOR SCANDAL: US Military Caught in Severe Data Manipulation Following COVID Reveal -- No Way "Revised" Numbers Are Real (thegatewaypundit.com) (Attach 26)

FOIA docs reveal Pfizer shot caused avalanche of miscarriages, stillborn babies - LifeSite (lifesitenews.com) (Attach 27)

Disclose.tv

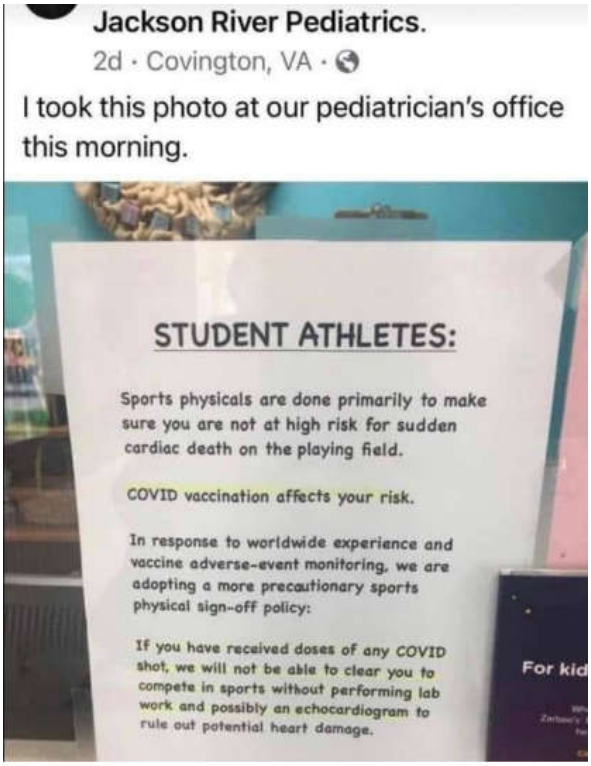
NEW - Board member of large German health insurance company comes forward: Side effects of COVID vaccines much higher than reported by official agencies.

"According to our calculations, we consider 400,000 visits to the doctor by our policyholders because of vaccination complications to be realistic to this day. Extrapolated to the total population, this value would be three million," says BKK board member Andreas Schöfbeck in a report by WELT.

"The numbers that resulted from our analysis are very far away from the publicly announced numbers. It would be unethical not to talk about it."

The new data is an "alarming signal," adds Schöfbeck.

https://www.welt.de/politik/deutschland/plus237106177/Coronavirus-Mehr-Impf-Nebenwirkungen-als-bisher-bekannt.html



PEBP is not punishing those who smoke tobacco or other harmful substances, do not exercise, eat unhealthy, engage in unsafe sexual practices, remain in high stress circumstances, abuse alcohol, abuse pharmaceuticals and other recreational drugs, engage in dangerous outdoor activities, drive their vehicles too fast, exercise too much, do not eat meat, do not eat vegetables, eat too much meat, eat too many vegetables.. the list goes on and on…

PEBP HAS MADE THE UNILATERAL DECISION TO ONLY PUNISH THOSE WHO HAVE LEGALLY DECLINED TO RECEIVE AN EXPERIMENTAL GENE THERAPY (COVID-19" VACCINATION). THIS IS BLANTANT DISCRIMATION AND COERCION.

PEBP, its officers, and anyone other entity or person participating in this coercion and discrimination are in violation of state law by requiring unlawful COVID-19 testing that is under EUA and therefore informed consent must be given and we have the right to decline without retribution. It is also my Constitution right to defend my life and obtain safety – even if it is the State of Nevada, and PEBP that is trying to harm me by forcing poison, and a known carcinogen into my body.

Currently, the state, including PEBP must rely on the voluntary disclosure of personal health information by both active state employees and Retirees to determine who is vaccinated and who is not in order to target and punish the unvaccinated with this unlawful, unethical, and discriminatory surcharge. If PEBP is receiving the vaccination status of its members in any other way, we demand this information be disclosed immediately.

We have, and will continue to PROVE that these illegal mandates, and the acts of the PEBP board to punish those who have made a sound personal medical decision, have participated in willful misconduct, and therefore may not be protected by the PREP Act (please see attachment #28).

Rest assured that if this decision continues moving forward, we will continue to fight it – with more facts, with more data – in Righteousness and in Justice. We are not alone in this fight, and we will not retreat. Thomas Renz, Attorney for Frontline doctors has worked tirelessly for the past two years and has compiled evidentiary findings related to COVID-19 Investigation which has been attached for your convenience (see attachment #29).

It is our desire that PEBP remove themselves from the impending liability that this action will bring onto the State as a whole. And finally, in closing, we leave you with these final two messages:

Created by high school sophomore, Whitney.

If this doesn't explain the last 2 years the... See More



WE DO NOT CONSENT

We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness.--That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed, --That whenever any Form of Government becomes destructive of these ends, it is the Right of the People to alter or to abolish it, and to institute new Government, laying its foundation on such principles and organizing its powers in such form, as to them shall seem most likely to effect their Safety and Happiness.

The Constitution of the United States

Preamble

We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defence, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America.

Article. I. - The Legislative Branch

Section 1 - The Legislature

All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

Section 2 - The House

The House of Representatives shall be composed of Members chosen every second Year by the People of the several States, and the Electors in each State shall have the Qualifications requisite for Electors of the most numerous Branch of the State Legislature.

No Person shall be a Representative who shall not have attained to the Age of twenty five Years, and been seven Years a Citizen of the United States, and who shall not, when elected, be an Inhabitant of that State in which he shall be chosen.

(Representatives and direct Taxes shall be apportioned among the several States which may be included within this Union, according to their respective Numbers, which shall be determined by adding to the whole Number of free Persons, including those bound to Service for a Term of Years, and excluding Indians not taxed, three fifths of all other Persons.) **(The previous sentence in parentheses was modified by the 14th Amendment, section 2.)** The actual Enumeration shall be made within three Years after the first Meeting of the Congress of the United States, and within every subsequent Term of ten Years, in such Manner as they shall by Law direct. The Number of Representatives shall not exceed one for every thirty Thousand, but each State shall have at Least one Representative; and until such enumeration shall be made, the State of New Hampshire shall be entitled to chuse three, Massachusetts eight, Rhode Island and Providence Plantations one, Connecticut five, New York six, New Jersey four, Pennsylvania eight, Delaware one, Maryland six, Virginia ten, North Carolina five, South Carolina five and Georgia three.

When vacancies happen in the Representation from any State, the Executive Authority thereof shall issue Writs of Election to fill such Vacancies.

The House of Representatives shall chuse their Speaker and other Officers; and shall have the sole Power of Impeachment.

Section 3 - The Senate

The Senate of the United States shall be composed of two Senators from each State, *(chosen by the Legislature thereof,)* **(The preceding words in parentheses superseded by 17th Amendment, section 1.)** for six Years; and each Senator shall have one Vote.

Immediately after they shall be assembled in Consequence of the first Election, they shall be divided as equally as may be into three Classes. The Seats of the Senators of the first Class shall be vacated at the Expiration of the second Year, of the second Class at the Expiration of the fourth Year, and of the third Class at the Expiration of the sixth Year, so that one third may be chosen every second Year; *(and if Vacancies happen by Resignation, or otherwise, during the Recess of the Legislature of any State, the Executive thereof may make temporary Appointments until the next Meeting of the Legislature, which shall then fill such Vacancies.)* **(The preceding words in parentheses were superseded by the 17th Amendment, section 2.)**

No person shall be a Senator who shall not have attained to the Age of thirty Years, and been nine Years a Citizen of the United States, and who shall not, when elected, be an Inhabitant of that State for which he shall be chosen.

The Vice President of the United States shall be President of the Senate, but shall have no Vote, unless they be equally divided.

The Senate shall chuse their other Officers, and also a President pro tempore, in the absence of the Vice President, or when he shall exercise the Office of President of the United States.

The Senate shall have the sole Power to try all Impeachments. When sitting for that Purpose, they shall be on Oath or Affirmation. When the President of the United States is tried, the Chief Justice shall preside: And no Person shall be convicted without the Concurrence of two thirds of the Members present.

Judgment in Cases of Impeachment shall not extend further than to removal from Office, and disqualification to hold and enjoy any Office of honor, Trust or Profit under the United States: but the Party convicted shall nevertheless be liable and subject to Indictment, Trial, Judgment and Punishment, according to Law.

Section 4 - Elections, Meetings

The Times, Places and Manner of holding Elections for Senators and Representatives, shall be prescribed in each State by the Legislature thereof; but the Congress may at any time by Law make or alter such Regulations, except as to the Place of Chusing Senators.

The Congress shall assemble at least once in every Year, and such Meeting shall *(be on the first Monday in December,)* **(The preceding words in parentheses were superseded by the 20th Amendment, section 2.)** unless they shall by Law appoint a different Day.

Section 5 - Membership, Rules, Journals, Adjournment

Each House shall be the Judge of the Elections, Returns and Qualifications of its own Members, and a Majority of each shall constitute a Quorum to do Business; but a smaller number may adjourn from day to day, and may be authorized to compel the Attendance of absent Members, in such Manner, and under such Penalties as each House may provide.

Each House may determine the Rules of its Proceedings, punish its Members for disorderly Behavior, and, with the Concurrence of two-thirds, expel a Member.

Each House shall keep a Journal of its Proceedings, and from time to time publish the same, excepting such Parts as may in their Judgment require Secrecy; and the Yeas and Nays of the Members of either House on any question shall, at the Desire of one fifth of those Present, be entered on the Journal.

Neither House, during the Session of Congress, shall, without the Consent of the other, adjourn for more than three days, nor to any other Place than that in which the two Houses shall be sitting.

Section 6 - Compensation

(The Senators and Representatives shall receive a Compensation for their Services, to be ascertained by Law, and paid out of the Treasury of the United States.) **(The preceding words in parentheses were modified by the 27th Amendment.)** They shall in all Cases, except Treason, Felony and Breach of the Peace, be privileged from Arrest during their Attendance at the Session of their respective Houses, and in going to and returning from the same; and for any Speech or Debate in either House, they shall not be questioned in any other Place.

No Senator or Representative shall, during the Time for which he was elected, be appointed to any civil Office under the Authority of the United States which shall have been created, or the Emoluments whereof shall have been increased during such time; and no Person holding any Office under the United States, shall be a Member of either House during his Continuance in Office.

Section 7 - Revenue Bills, Legislative Process, Presidential Veto

All bills for raising Revenue shall originate in the House of Representatives; but the Senate may propose or concur with Amendments as on other Bills.

Every Bill which shall have passed the House of Representatives and the Senate, shall, before it become a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it, with his Objections to that House in which it shall have originated, who shall enter the Objections at large on their Journal, and proceed to reconsider it. If after such Reconsideration two thirds of that House shall agree to pass the Bill, it shall be sent, together with the Objections, to the other House, by which it shall likewise be reconsidered, and if approved by two thirds of that House, it shall become a Law. But in all such Cases the Votes of both Houses shall be determined by Yeas and Nays, and the Names of the Persons voting for and against the Bill shall be entered on the Journal of each House respectively. If any Bill shall not be returned by the President within ten Days (Sundays excepted) after it shall have been presented to him, the Same shall be a Law, in like Manner as if he had signed it, unless the Congress by their Adjournment prevent its Return, in which Case it shall not be a Law.

Every Order, Resolution, or Vote to which the Concurrence of the Senate and House of Representatives may be necessary (except on a question of Adjournment) shall be presented to the President of the United States; and before the Same shall take Effect, shall be approved by him, or being disapproved by him, shall be repassed by two thirds of the Senate and House of Representatives, according to the Rules and Limitations prescribed in the Case of a Bill.

Section 8 - Powers of Congress

The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

To borrow money on the credit of the United States;

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

To establish an uniform Rule of Naturalization, and uniform Laws on the subject of Bankruptcies throughout the United States;

To coin Money, regulate the Value thereof, and of foreign Coin, and fix the Standard of Weights and Measures;

To provide for the Punishment of counterfeiting the Securities and current Coin of the United States;

To establish Post Offices and Post Roads;

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

To constitute Tribunals inferior to the supreme Court;

To define and punish Piracies and Felonies committed on the high Seas, and Offenses against the Law of Nations;

To declare War, grant Letters of Marque and Reprisal, and make Rules concerning Captures on Land and Water;

To raise and support Armies, but no Appropriation of Money to that Use shall be for a longer Term than two Years;

To provide and maintain a Navy;

To make Rules for the Government and Regulation of the land and naval Forces;

To provide for calling forth the Militia to execute the Laws of the Union, suppress Insurrections and repel Invasions;

To provide for organizing, arming, and disciplining the Militia, and for governing such Part of them as may be employed in the Service of the United States, reserving to the States respectively, the Appointment of the Officers, and the Authority of training the Militia according to the discipline prescribed by Congress;

To exercise exclusive Legislation in all Cases whatsoever, over such District (not exceeding ten Miles square) as may, by Cession of particular States, and the acceptance of Congress, become the Seat of the Government of the United States, and to exercise like Authority over all Places purchased by the Consent of the Legislature of the State in which the Same shall be, for the Erection of Forts, Magazines, Arsenals, dock-Yards, and other needful Buildings; And

To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

Section 9 - Limits on Congress

The Migration or Importation of such Persons as any of the States now existing shall think proper to admit, shall not be prohibited by the Congress prior to the Year one thousand eight hundred and eight, but a tax or duty may be imposed on such Importation, not exceeding ten dollars for each Person.

The privilege of the Writ of Habeas Corpus shall not be suspended, unless when in Cases of Rebellion or Invasion the public Safety may require it.

No Bill of Attainder or ex post facto Law shall be passed.

(No capitation, or other direct, Tax shall be laid, unless in Proportion to the Census or Enumeration herein before directed to be taken.) **(Section in parentheses clarified by the 16th Amendment.)**

No Tax or Duty shall be laid on Articles exported from any State.

No Preference shall be given by any Regulation of Commerce or Revenue to the Ports of one State over those of another: nor shall Vessels bound to, or from, one State, be obliged to enter, clear, or pay Duties in another.

No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law; and a regular Statement and Account of the Receipts and Expenditures of all public Money shall be published from time to time.

No Title of Nobility shall be granted by the United States: And no Person holding any Office of Profit or Trust under them, shall, without the Consent of the Congress, accept of any present, Emolument, Office, or Title, of any kind whatever, from any King, Prince or foreign State.

Section 10 - Powers prohibited of States

No State shall enter into any Treaty, Alliance, or Confederation; grant Letters of Marque and Reprisal; coin Money; emit Bills of Credit; make any Thing but gold and silver Coin a Tender in Payment of Debts; pass any Bill of Attainder, ex post facto Law, or Law impairing the Obligation of Contracts, or grant any Title of Nobility.

No State shall, without the Consent of the Congress, lay any Imposts or Duties on Imports or Exports, except what may be absolutely necessary for executing it's inspection Laws: and the net Produce of all Duties and Imposts, laid by any State on Imports or Exports, shall be for the Use of the Treasury of the United States; and all such Laws shall be subject to the Revision and Controul of the Congress.

No State shall, without the Consent of Congress, lay any duty of Tonnage, keep Troops, or Ships of War in time of Peace, enter into any Agreement or Compact with another State, or with a foreign Power, or engage in War, unless actually invaded, or in such imminent Danger as will not admit of delay.

Article. II. - The Executive Branch

Section 1 - The President

The executive Power shall be vested in a President of the United States of America. He shall hold his Office during the Term of four Years, and, together with the Vice-President chosen for the same Term, be elected, as follows:

Each State shall appoint, in such Manner as the Legislature thereof may direct, a Number of Electors, equal to the whole Number of Senators and Representatives to which the State may be entitled in the Congress: but no Senator or Representative, or Person holding an Office of Trust or Profit under the United States, shall be appointed an Elector.

(The Electors shall meet in their respective States, and vote by Ballot for two persons, of whom one at least shall not lie an Inhabitant of the same State with themselves. And they shall make a List of all the Persons voted for, and of the Number of Votes for each; which List they shall sign and certify, and transmit sealed to the Seat of the Government of the United States, directed to the President of the Senate. The President of the Senate shall, in the Presence of the Senate and House of Representatives, open all the Certificates, and the Votes shall then be counted. The Person having the greatest Number of Votes shall be the President, if such Number be a Majority of the whole Number of Electors appointed; and if there be more than one who have such Majority, and have an equal Number of Votes, then the House of Representatives shall immediately chuse by Ballot one of them for President; and if no Person have a Majority, then from the five highest on the List the said House shall in like Manner chuse the President. But in chusing the President, the Votes shall be taken by States, the Representation from each State having one Vote; a quorum for this Purpose shall consist of a Member or Members from two-thirds of the States, and a Majority of all the States shall be necessary to a Choice. In every Case, after the Choice of the President, the Person having the greatest Number of Votes of the Electors shall be the Vice President. But if there should remain two or more who have equal Votes, the Senate shall chuse from them by Ballot the Vice-President.) **(This clause in parentheses was superseded by the 12th Amendment.)**

The Congress may determine the Time of chusing the Electors, and the Day on which they shall give their Votes; which Day shall be the same throughout the United States.

No person except a natural born Citizen, or a Citizen of the United States, at the time of the Adoption of this Constitution, shall be eligible to the Office of President; neither shall any Person be eligible to that Office who shall not have attained to the Age of thirty-five Years, and been fourteen Years a Resident within the United States.

(In Case of the Removal of the President from Office, or of his Death, Resignation, or Inability to discharge the Powers and Duties of the said Office, the same shall devolve on the Vice President, and the Congress may by Law provide for the Case of Removal, Death, Resignation or Inability, both of the President and Vice President, declaring what Officer shall then act as President, and such Officer shall act accordingly, until the Disability be removed, or a President shall be elected.) **(This clause in parentheses has been modified by the 20th and 25th Amendments.)**

The President shall, at stated Times, receive for his Services, a Compensation, which shall neither be increased nor diminished during the Period for which he shall have been elected, and he shall not receive within that Period any other Emolument from the United States, or any of them.

Before he enter on the Execution of his Office, he shall take the following Oath or Affirmation:

"I do solemnly swear (or affirm) that I will faithfully execute the Office of President of the United States, and will to the best of my Ability, preserve, protect and defend the Constitution of the United States."

Section 2 - Civilian Power over Military, Cabinet, Pardon Power, Appointments

The President shall be Commander in Chief of the Army and Navy of the United States, and of the Militia of the several States, when called into the actual Service of the United States; he may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any subject relating to the Duties of their respective Offices, and he shall have Power to Grant Reprieves and Pardons for Offenses against the United States, except in Cases of Impeachment.

He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

The President shall have Power to fill up all Vacancies that may happen during the Recess of the Senate, by granting Commissions which shall expire at the End of their next Session.

Section 3 - State of the Union, Convening Congress

He shall from time to time give to the Congress Information of the State of the Union, and recommend to their Consideration such Measures as he shall judge necessary and expedient; he may, on extraordinary Occasions, convene both Houses, or either of them, and in Case of Disagreement between them, with Respect to the Time of Adjournment, he may adjourn them to such Time as he shall think proper; he shall receive Ambassadors and other public Ministers; he shall take Care that the Laws be faithfully executed, and shall Commission all the Officers of the United States.

Section 4 - Disqualification

The President, Vice President and all civil Officers of the United States, shall be removed from Office on Impeachment for, and Conviction of, Treason, Bribery, or other high Crimes and Misdemeanors.

Article III. - The Judicial Branch

Section 1 - Judicial powers

The judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish. The Judges, both of the supreme and inferior Courts, shall hold their Offices during good Behavior, and shall, at stated Times, receive for their Services a Compensation which shall not be diminished during their Continuance in Office.

Section 2 - Trial by Jury, Original Jurisdiction, Jury Trials

(The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority; to all Cases affecting Ambassadors, other public Ministers and Consuls; to all Cases of admiralty and maritime Jurisdiction; to Controversies to which the United States shall be a Party; to Controversies between two or more States; between a State and Citizens of another State; between Citizens of different States; between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.) **(This section in parentheses is modified by the 11th Amendment.)**

In all Cases affecting Ambassadors, other public Ministers and Consuls, and those in which a State shall be Party, the supreme Court shall have original Jurisdiction. In all the other Cases before mentioned, the supreme Court shall have appellate Jurisdiction, both as to Law and Fact, with such Exceptions, and under such Regulations as the Congress shall make.

The Trial of all Crimes, except in Cases of Impeachment, shall be by Jury; and such Trial shall be held in the State where the said Crimes shall have been committed; but when not committed within any State, the Trial shall be at such Place or Places as the Congress may by Law have directed.

Section 3 - Treason

Treason against the United States, shall consist only in levying War against them, or in adhering to their Enemies, giving them Aid and Comfort. No Person shall be convicted of Treason unless on the Testimony of two Witnesses to the same overt Act, or on Confession in open Court.

The Congress shall have power to declare the Punishment of Treason, but no Attainder of Treason shall work Corruption of Blood, or Forfeiture except during the Life of the Person attainted.

Article. IV. - The States

Section 1 - Each State to Honor all others

Full Faith and Credit shall be given in each State to the public Acts, Records, and judicial Proceedings of every other State. And the Congress may by general Laws prescribe the Manner in which such Acts, Records and Proceedings shall be proved, and the Effect thereof.

Section 2 - State citizens, Extradition

The Citizens of each State shall be entitled to all Privileges and Immunities of Citizens in the several States.

A Person charged in any State with Treason, Felony, or other Crime, who shall flee from Justice, and be found in another State, shall on demand of the executive Authority of the State from which he fled, be delivered up, to be removed to the State having Jurisdiction of the Crime.

(No Person held to Service or Labour in one State, under the Laws thereof, escaping into another, shall, in Consequence of any Law or Regulation therein, be discharged from such Service or Labour, But shall be delivered up on Claim of the Party to whom such Service or Labour may be due.) **(This clause in parentheses is superseded by the 13th Amendment.)**

Section 3 - New States

New States may be admitted by the Congress into this Union; but no new States shall be formed or erected within the Jurisdiction of any other State; nor any State be formed by the Junction of two or more States, or parts of States, without the Consent of the Legislatures of the States concerned as well as of the Congress.

The Congress shall have Power to dispose of and make all needful Rules and Regulations respecting the Territory or other Property belonging to the United States; and nothing in this Constitution shall be so construed as to Prejudice any Claims of the United States, or of any particular State.

Section 4 - Republican government

The United States shall guarantee to every State in this Union a Republican Form of Government, and shall protect each of them against Invasion; and on Application of the Legislature, or of the Executive (when the Legislature cannot be convened) against domestic Violence.

Article. V. - Amendment

The Congress, whenever two thirds of both Houses shall deem it necessary, shall propose Amendments to this Constitution, or, on the Application of the Legislatures of two thirds of the several States, shall call a Convention for proposing Amendments, which, in either Case, shall be valid to all Intents and Purposes, as part of this Constitution, when ratified by the Legislatures of three fourths of the several States, or by Conventions in three fourths thereof, as the one or the other Mode of Ratification may be proposed by the Congress; Provided that no Amendment which may be made prior to the Year One thousand eight hundred and eight shall in any Manner affect the first and fourth Clauses in the Ninth Section of the first Article; and that no State, without its Consent, shall be deprived of its equal Suffrage in the Senate.

Article. VI. - Debts, Supremacy, Oaths

All Debts contracted and Engagements entered into, before the Adoption of this Constitution, shall be as valid against the United States under this Constitution, as under the Confederation.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Senators and Representatives before mentioned, and the Members of the several State Legislatures, and all executive and judicial Officers, both of the United States and of the several States, shall be bound by Oath or Affirmation, to support this Constitution; but no religious Test shall ever be required as a Qualification to any Office or public Trust under the United States.

Article. VII. - Ratification

The Ratification of the Conventions of nine States, shall be sufficient for the Establishment of this Constitution between the States so ratifying the Same.

Done in Convention by the Unanimous Consent of the States present the Seventeenth Day of September in the Year of our Lord one thousand seven hundred and Eighty seven and of the Independence of the United States of America the Twelfth. In Witness whereof We have hereunto subscribed our Names.

Go Washington - President and deputy from Virginia

New Hampshire - John Langdon, Nicholas Gilman

Massachusetts - Nathaniel Gorham, Rufus King

Connecticut - Wm Saml Johnson, Roger Sherman

New York - Alexander Hamilton

New Jersey - Wil Livingston, David Brearley, Wm Paterson, Jona. Dayton

Pensylvania - B Franklin, Thomas Mifflin, Robt Morris, Geo. Clymer, Thos FitzSimons, Jared Ingersoll, James Wilson, Gouv Morris

Delaware - Geo. Read, Gunning Bedford jun, John Dickinson, Richard Bassett, Jaco. Broom

Maryland - James McHenry, Dan of St Tho Jenifer, Danl Carroll

Virginia - John Blair, James Madison Jr.

North Carolina - Wm Blount, Richd Dobbs Spaight, Hu Williamson

South Carolina - J. Rutledge, Charles Cotesworth Pinckney, Charles Pinckney, Pierce Butler

Georgia - William Few, Abr Baldwin

Attest: William Jackson, Secretary

The Amendments

The following are the Amendments to the Constitution. The first ten Amendments collectively are commonly known as the Bill of Rights.

Amendment 1 - Freedom of Religion, Press, Expression. Ratified 12/15/1791.

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Amendment 2 - Right to Bear Arms. Ratified 12/15/1791.

A well regulated Militia, being necessary to the security of a free State, the right of the people to keep and bear Arms, shall not be infringed.

Amendment 3 - Quartering of Soldiers. Ratified 12/15/1791.

No Soldier shall, in time of peace be quartered in any house, without the consent of the Owner, nor in time of war, but in a manner to be prescribed by law.

Amendment 4 - Search and Seizure. Ratified 12/15/1791.

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

Amendment 5 - Trial and Punishment, Compensation for Takings. Ratified 12/15/1791.

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

Amendment 6 - Right to Speedy Trial, Confrontation of Witnesses. Ratified 12/15/1791.

In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses

against him; to have compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defence.

Amendment 7 - Trial by Jury in Civil Cases. Ratified 12/15/1791.

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

Amendment 8 - Cruel and Unusual Punishment. Ratified 12/15/1791.

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

Amendment 9 - Construction of Constitution. Ratified 12/15/1791.

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

Amendment 10 - Powers of the States and People. Ratified 12/15/1791.

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

Amendment 11 - Judicial Limits. Ratified 2/7/1795.

The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

Amendment 12 - Choosing the President, Vice-President. Ratified 6/15/1804.

The Electors shall meet in their respective states, and vote by ballot for President and Vice-President, one of whom, at least, shall not be an inhabitant of the same state with themselves; they shall name in their ballots the person voted for as President, and in distinct ballots the person voted for as Vice-President, and they shall make distinct lists of all persons voted for as President, and of all persons voted for as Vice-President and of the number of votes for each, which lists they shall sign and certify, and transmit sealed to the seat of the government of the United States, directed to the President of the Senate;

The President of the Senate shall, in the presence of the Senate and House of Representatives, open all the certificates and the votes shall then be counted;

The person having the greatest Number of votes for President, shall be the President, if such number be a majority of the whole number of Electors appointed; and if no person have such majority, then from the persons having the highest numbers not exceeding three on the list of those voted for as President, the House of Representatives shall choose immediately, by ballot, the President. But in choosing the President, the votes shall be taken by states, the representation from each state having one vote; a quorum for this purpose shall consist of a member or members from two-thirds of the states, and a majority of all the states shall be necessary to a choice. And if the House of Representatives shall not choose a President whenever the right of choice shall devolve upon them, before the fourth day of March next following, then the Vice-President shall act as President, as in the case of the death or other constitutional disability of the President.

The person having the greatest number of votes as Vice-President, shall be the Vice-President, if such number be a majority of the whole number of Electors appointed, and if no person have a majority, then from the two highest numbers on the list, the Senate shall choose the Vice-President; a quorum for the purpose shall consist of two-thirds of the whole number of Senators, and a majority of the whole number shall be necessary to a choice. But no person constitutionally ineligible to the office of President shall be eligible to that of Vice-President of the United States.

Amendment 13 - Slavery Abolished. Ratified 12/6/1865.

1. Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction.

2. Congress shall have power to enforce this article by appropriate legislation.

Amendment 14 - Citizenship Rights. Ratified 7/9/1868.

1. All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

2. Representatives shall be apportioned among the several States according to their respective numbers, counting the whole number of persons in each State, excluding Indians not taxed. But when the right to vote at any election for the choice of electors for President and Vice-President of the United States, Representatives in Congress, the Executive and Judicial officers of a State, or the members of the Legislature thereof, is denied to any of the male inhabitants of such State, being twenty-one years of age, and citizens of the United States, or in any way abridged, except for participation in rebellion, or other crime, the basis of representation therein shall be reduced in the proportion which the number of such male citizens shall bear to the whole number of male citizens twenty-one years of age in such State.

3. No person shall be a Senator or Representative in Congress, or elector of President and Vice-President, or hold any office, civil or military, under the United States, or under any State, who, having previously taken an oath, as a member of Congress, or as an officer of the United States, or as a member of any State legislature, or as an executive or judicial officer of any State, to support the Constitution of the United States, shall have engaged in insurrection or rebellion against the same, or given aid or comfort to the enemies thereof. But Congress may by a vote of two-thirds of each House, remove such disability.

4. The validity of the public debt of the United States, authorized by law, including debts incurred for payment of pensions and bounties for services in suppressing insurrection or rebellion, shall not be questioned. But neither the United States nor any State shall assume or pay any debt or obligation incurred in aid of insurrection or rebellion against the United States, or any claim for the loss or emancipation of any slave; but all such debts, obligations and claims shall be held illegal and void.

5. The Congress shall have power to enforce, by appropriate legislation, the provisions of this article.

Amendment 15 - Race No Bar to Vote. Ratified 2/3/1870.

1. The right of citizens of the United States to vote shall not be denied or abridged by the United States or by any State on account of race, color, or previous condition of servitude.

2. The Congress shall have power to enforce this article by appropriate legislation.

Amendment 16 - Status of Income Tax Clarified. Ratified 2/3/1913.

The Congress shall have power to lay and collect taxes on incomes, from whatever source derived, without apportionment among the several States, and without regard to any census or enumeration.

Amendment 17 - Senators Elected by Popular Vote. Ratified 4/8/1913.

The Senate of the United States shall be composed of two Senators from each State, elected by the people thereof, for six years; and each Senator shall have one vote. The electors in each State shall have the qualifications requisite for electors of the most numerous branch of the State legislatures.

When vacancies happen in the representation of any State in the Senate, the executive authority of such State shall issue writs of election to fill such vacancies: Provided, That the legislature of any State may empower the executive thereof to make temporary appointments until the people fill the vacancies by election as the legislature may direct.

This amendment shall not be so construed as to affect the election or term of any Senator chosen before it becomes valid as part of the Constitution.

Amendment 18 - Liquor Abolished. Ratified 1/16/1919. Repealed by Amendment 21, 12/5/1933.

1. After one year from the ratification of this article the manufacture, sale, or transportation of intoxicating liquors within, the importation thereof into, or the exportation thereof from the United States and all territory subject to the jurisdiction thereof for beverage purposes is hereby prohibited.

2. The Congress and the several States shall have concurrent power to enforce this article by appropriate legislation.

3. This article shall be inoperative unless it shall have been ratified as an amendment to the Constitution by the legislatures of the several States, as provided in the Constitution, within seven years from the date of the submission hereof to the States by the Congress.

Amendment 19 - Women's Suffrage. Ratified 8/18/1920.

The right of citizens of the United States to vote shall not be denied or abridged by the United States or by any State on account of sex.

Congress shall have power to enforce this article by appropriate legislation.

Amendment 20 - Presidential, Congressional Terms. Ratified 1/23/1933.

1. The terms of the President and Vice President shall end at noon on the 20th day of January, and the terms of Senators and Representatives at noon on the 3d day of January, of the years in which such terms would have ended if this article had not been ratified; and the terms of their successors shall then begin.

2. The Congress shall assemble at least once in every year, and such meeting shall begin at noon on the 3d day of January, unless they shall by law appoint a different day.

3. If, at the time fixed for the beginning of the term of the President, the President elect shall have died, the Vice President elect shall become President. If a President shall not have been chosen before the time fixed for the beginning of his term, or if the President elect shall have failed to qualify, then the Vice President elect shall act as President until a President shall have qualified; and the Congress may by law provide for the case wherein neither a President elect nor a Vice President elect shall have qualified, declaring who shall then act as President, or the manner in which one who is to act shall be selected, and such person shall act accordingly until a President or Vice President shall have qualified.

4. The Congress may by law provide for the case of the death of any of the persons from whom the House of Representatives may choose a President whenever the right of choice shall have devolved upon them, and for the case of the death of any of the persons from whom the Senate may choose a Vice President whenever the right of choice shall have devolved upon them.

5. Sections 1 and 2 shall take effect on the 15th day of October following the ratification of this article.

6. This article shall be inoperative unless it shall have been ratified as an amendment to the Constitution by the legislatures of three-fourths of the several States within seven years from the date of its submission.

Amendment 21 - Amendment 18 Repealed. Ratified 12/5/1933.

1. The eighteenth article of amendment to the Constitution of the United States is hereby repealed.

2. The transportation or importation into any State, Territory, or possession of the United States for delivery or use therein of intoxicating liquors, in violation of the laws thereof, is hereby prohibited.

3. The article shall be inoperative unless it shall have been ratified as an amendment to the Constitution by conventions in the several States, as provided in the Constitution, within seven years from the date of the submission hereof to the States by the Congress.

Amendment 22 - Presidential Term Limits. Ratified 2/27/1951.

1. No person shall be elected to the office of the President more than twice, and no person who has held the office of President, or acted as President, for more than two years of a term to which some other person was elected President shall be elected to the office of the President more than once. But this Article shall not apply to any person holding the office of President, when this Article was proposed by the Congress, and shall not prevent any person who may be holding the office of President, or acting as President, during the term within which this Article becomes operative from holding the office of President or acting as President during the remainder of such term.

2. This article shall be inoperative unless it shall have been ratified as an amendment to the Constitution by the legislatures of three-fourths of the several States within seven years from the date of its submission to the States by the Congress.

Amendment 23 - Presidential Vote for District of Columbia. Ratified 3/29/1961.

1. The District constituting the seat of Government of the United States shall appoint in such manner as the Congress may direct: A number of electors of President and Vice President equal to the whole number of Senators and Representatives in Congress to which the District would be entitled if it were a State, but in no event more than the least populous State; they shall be in addition to those appointed by the States, but they shall be considered, for the purposes of the election of President and Vice President, to be electors appointed by a State; and they shall meet in the District and perform such duties as provided by the twelfth article of amendment.

2. The Congress shall have power to enforce this article by appropriate legislation.

Amendment 24 - Poll Tax Barred. Ratified 1/23/1964.

1. The right of citizens of the United States to vote in any primary or other election for President or Vice President, for electors for President or Vice President, or for Senator or

Representative in Congress, shall not be denied or abridged by the United States or any State by reason of failure to pay any poll tax or other tax.

2. The Congress shall have power to enforce this article by appropriate legislation.

Amendment 25 - Presidential Disability and Succession. Ratified 2/10/1967.

1. In case of the removal of the President from office or of his death or resignation, the Vice President shall become President.

2. Whenever there is a vacancy in the office of the Vice President, the President shall nominate a Vice President who shall take office upon confirmation by a majority vote of both Houses of Congress.

3. Whenever the President transmits to the President pro tempore of the Senate and the Speaker of the House of Representatives his written declaration that he is unable to discharge the powers and duties of his office, and until he transmits to them a written declaration to the contrary, such powers and duties shall be discharged by the Vice President as Acting President.

4. Whenever the Vice President and a majority of either the principal officers of the executive departments or of such other body as Congress may by law provide, transmit to the President pro tempore of the Senate and the Speaker of the House of Representatives their written declaration that the President is unable to discharge the powers and duties of his office, the Vice President shall immediately assume the powers and duties of the office as Acting President.

Thereafter, when the President transmits to the President pro tempore of the Senate and the Speaker of the House of Representatives his written declaration that no inability exists, he shall resume the powers and duties of his office unless the Vice President and a majority of either the principal officers of the executive department or of such other body as Congress may by law provide, transmit within four days to the President pro tempore of the Senate and the Speaker of the House of Representatives their written declaration that the President is unable to discharge the powers and duties of his office. Thereupon Congress shall decide the issue, assembling within forty eight hours for that purpose if not in session. If the Congress, within twenty one days after receipt of the latter written declaration, or, if Congress is not in session, within twenty one days after Congress is required to assemble, determines by two thirds vote of both Houses that the President is unable to discharge the powers and duties of his office, the Vice President shall continue to discharge the same as Acting President; otherwise, the President shall resume the powers and duties of his office.

Amendment 26 - Voting Age Set to 18 Years. Ratified 7/1/1971.

1. The right of citizens of the United States, who are eighteen years of age or older, to vote shall not be denied or abridged by the United States or by any State on account of age.

2. The Congress shall have power to enforce this article by appropriate legislation.

Amendment 27 - Limiting Congressional Pay Increases. Ratified 5/7/1992.

No law, varying the compensation for the services of the Senators and Representatives, shall take effect, until an election of Representatives shall have intervened.

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In Vitro Diagnostics EUAs - Molecular Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostic EUAs: Overview and Templates

- Templates and Other Information (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
- Antigen Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
- IVDs for Management of COVID-19 Patients (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

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- Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2
- Revision Concerning Viral Mutation
- Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2
- Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing
- EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

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Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2

This table includes information about authorized SARS-CoV-2 molecular diagnostic tests. These EUAs have been issued for each individual test with certain conditions of authorization required of the manufacturer and authorized laboratories. Test attributes are listed in the "Attributes" column. For example, tests authorized for the screening of asymptomatic individuals without known exposure are listed with "screening" in the attribute column; pooling, multi-analyte, saliva, home collection, and home testing are similarly listed. Tests available without a prescription include the attribute "DTC" (for direct-to-consumer home collection tests) or "OTC" (for over-the-counter at-

home tests). To see additional authorization documents, such as letters granting EUA amendments or revisions, and a list of other brand names authorized under a specific EUA, select the plus (+) button beside the "Date EUA Issued or Last Updated" for the EUA.

For information on tests that have been revoked see Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#ivd)

Molecular SARS-CoV-2 Diagnostic Tests for COVID-19 that have been granted a De Novo, 510(k) clearance or PMA

- BioFire Respiratory Panel 2.1 (RP2.1) - On March 17, 2021, FDA granted the first marketing authorization using the De Novo review pathway for the BioFire Respiratory Panel 2.1 (RP2.1) (https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf) (PDF - 630 KB). The BioFire RP2.1 is for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. Also see the FDA news release: FDA Permits Marketing of First SARS-CoV-2 Diagnostic Test Using Traditional Premarket Review Process (/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process). With granting of the De Novo for the BioFire RP2.1, the FDA revoked the EUA for this device (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations), which was initially authorized for emergency use in May 2020.

  The BioFire Respiratory Panel 2.1 (RP2.1) was reviewed under the De Novo premarket review pathway (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing criteria, called special controls, that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

Tests with "single target" in the attribute column are:

- designed to detect only one viral target on the SARS-CoV-2 genome;
- more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

Tests with "multiple targets" in the attribute column are:

- designed to detect two or more viral targets, or sections of the SARS-CoV-2 genome;
- more likely to continue to perform well when new variants emerge.

EUAs for standalone specimen collection devices, including home collection kits which do not include an assay in the EUA, will not have a target designation in the attribute column.

Authorized Molecular Diagnostic Tests for SARS-CoV-2 are assigned the QJR product code.

Authorized Home Collection Kits are assigned the QLW product code. Authorized EUAs for Multi-analyte Respiratory Panel Tests are assigned the QLT product code.

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Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/17/2022	Helix OpCo LLC (dba Helix)	Helix SARS-CoV-2 Test (/media/156995/download) 03/17/2022	Real-time RT-PCR, Home Collection, Multiple Targets	H	HCP (/media/156996/download), Patients (/media/156997/download), EUA Summary (/media/156998/download), IFU (Home Collect) (/media/157000/download)
+ 03/15/2022	Bio-Rad Laboratories, Inc	Bio-Rad SARS-CoV-2 ddPCR Test (/media/137576/download) 05/01/2020	RT-droplet PCR, Multiple Targets	H	HCP (/media/137577/download), Patients (/media/137578/download), IFU (/media/137579/download)

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/15/2022	Minute Molecular Diagnostics, Inc.	DASH SARS-CoV-2/S Test (/media/156976/download) 03/15/2022	Real-time RT-PCR, Multiple Targets	H, M, W	HCP (/media/156977/download), Patients (/media/156977/download), IFU (/media/156979/download)
+ 03/10/2022	Premier Medical Laboratory Services	PMLS SARS-CoV-2 Assay (/media/155317/download) 01/07/2022	Real-time RT-PCR, Home Collection, Screening, Multiple Targets	H	HCP (/media/155318/download), Patients (/media/155319/download), EUA Summary (/media/155320/download), IFU (Home Collect) (/media/155322/download)
+ 03/08/2022	Uh-Oh Labs Inc.	UOL COVID-19 Test (/media/156099/download) 02/08/2022	RT-LAMP, Single Target	H, M, W	HCP (/media/156100/download), Patients (/media/156101/download), IFU (/media/156102/download)
+ 03/07/2022	BioFire Defense, LLC	BioFire COVID-19 Test (/media/136356/download) 03/23/2020	RT, Nested multiplex PCR, Pooling, Saliva, Multiple Targets	H, M	HCP (/media/136357/download), Patients (/media/136358/download), IFU (/media/136353/download)
+ 03/04/2022	Thermo Fisher Scientific	TaqPath COVID-19, FluA, FluB Combo Kit (/media/145928/download) 02/10/2021	Real-time RT-PCR, Multi-analyte, Multiple Targets	H	HCP (/media/145929/download), Patients (/media/145930/download), IFU (/media/145931/download)
+ 03/03/2022	Diversified Medical Healthcare	RapidRona Self-Collection Kit (/media/143927/download) 11/23/2020	Home Collection Kit	N/A	EUA Summary (/media/143928/download), IFU (Collection) (/media/143929/download)

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 03/03/2022	Thermo Fisher Scientific Inc.	Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit (/media/147535/download) 04/09/2021	Real-time RT-PCR, Saliva, Multiple Targets	H	HCP (/media/147536/download), Patients (/media/147537/download), IFU (/media/147548/download)
+ 03/01/2022	Cue Health Inc.	Cue COVID-19 Test (/media/138823/download) 06/10/2020	RT, Isothermal amplification, Screening, Single Target	H, M, W	HCP (/media/138824/download), Patients (/media/138825/download), IFU (/media/138826/download)
+ 03/01/2022	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect At-Home Collection Kit (/media/147606/download) 04/09/2021	Home Collection Kit, Saliva, Screening	N/A	EUA Summary (/media/147607/download), IFU-1 (/media/147608/download), IFU-2 (/media/148345/download)
+ 03/01/2022	Thermo Fisher Scientific Inc.	TaqPath COVID-19 RNase P Combo Kit 2.0 (/media/150692/download) 07/08/2021	Real-time RT-PCR, Serial Screening, Home Collection, Multiple Targets	H	HCP (/media/150693/download), Patients (/media/150694/download), IFU (/media/150695/download)
+ 02/23/2022	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect for use with DTC Kits (/media/151845/download) 08/27/2021	Direct to Consumer (DTC), Real-time RT-PCR, Saliva, Home Collection, Screening, Pooling, Single Target	H	HCP (/media/151842/download), Individuals (/media/151844/download), EUA Summary (/media/151841/download)

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/23/2022	Yale School of Public Health, Department of Epidemiology of Microbial Diseases	SalivaDirect DTC Saliva Collection Kit (/media/151840/download) 08/27/2021	Direct to Consumer (DTC), Home Collection Kit, Saliva, Screening	N/A	Individual (/media/151839/download), IFU-1 (/media/151837/download), IFU-2 (/media/151838/download), EUA Summary (/media/151836/download)
+ 02/23/2022	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/media/138151/download) 05/15/2020	Real-time RT-PCR, Home Collection, Multiple Targets	H	HCP (/media/138152/download), Patients (/media/138153/download), EUA Summary (/media/138154/download)
+ 02/23/2022	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel DTC (/media/145981/download) 02/13/2021	Direct to Consumer (DTC), Real-time RT-PCR, Home Collection, Screening, Single Target	H	HCP (/media/145982/download), Individuals (/media/145983/download), EUA Summary (/media/145984/download), IFU (Home Collect) (/media/145985/download)
+ 02/18/2022	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit (/media/137747/download) 05/06/2020	RT-LAMP, CRISPR, Multiple Targets	H	HCP (/media/137745/download), Patients (/media/137748/download), IFU (/media/137746/download)
+ 02/18/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR Complete (/media/143059/download) 10/14/2020	RT, qSTAR amplification, Home Collection, Screening, Pooling, Single Target	H	HCP (/media/143060/download), Patients (/media/143061/download), IFU (/media/143062/download)

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/14/2022	Roche Molecular Systems, Inc. (RMS)	cobas SARS-CoV-2 (/media/136046/download) 03/12/2020	Real-time RT-PCR, Pooling, Screening, Multiple Targets	H, M, H-Pooling	HCP (/media/136047/download), Patients (/media/136048/download), IFU (/media/136049/download)
+ 02/14/2022	Becton, Dickinson and Company (BD)	BD SARS-CoV-2 Reagents for BD MAX System (/media/136813/download) 04/08/2020	Real-time RT-PCR, Screening, Multiple Targets	H, M	HCP (/media/136815/download), Patients (/media/136814/download), IFU (/media/136816/download)
+ 02/14/2022	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit (/media/137781/download) 05/07/2020	Real-time RT-PCR, Multiple Targets	H	HCP (/media/137778/download), Patients (/media/137779/download), IFU (/media/137780/download)
+ 02/14/2022	ChromaCode Inc.	HDPCR SARS-CoV-2 Assay (/media/138787/download) 06/09/2020	Real-time RT-PCR, Multiple Targets	H	HCP (/media/138785/download), Patients (/media/138788/download), IFU (/media/138786/download)
+ 02/14/2022	Roche Molecular Systems, Inc.	cobas SARS-CoV-2 & Influenza A/B (/media/141884/download) 09/03/2020	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	HCP (/media/141885/download), Patients (/media/141886/download), IFU (/media/141887/download)
+ 02/14/2022	Exact Sciences Laboratories	COVID-Flu Multiplex Assay (/media/150558/download) 07/01/2021	Real-time RT-PCR, Multi-analyte, Home Collection, Single Target	H	HCP (/media/150559/download), Patients (/media/150560/download), EUA Summary (/media/150561/download), IFU (Home Collect) (/media/150784/download)

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
+ 02/10/2022	1drop Inc.	1copy COVID-19 qPCR Multi Kit (/media/137934/download) 05/11/2020	Real-time RT-PCR, Multiple Targets	H	HCP (/media/137933/download), Patients (/media/137936/download), IFU (/media/137935/download)

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[1] Authorized settings include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations:

- RT-PCR = reverse transcriptase polymerase chain reaction;
- RT = reverse transcriptase;
- LAMP = loop-mediated isothermal amplification;
- MALDI-TOF = Matrix Assisted Laser Desorption/Ionization - Time of Flight;
- TMA = Transcription Mediated Amplification;
- qSTAR = Selective Temperature Amplification Reaction;
- CRISPR = clustered regularly interspaced short palindromic repeats;

Revision Concerning Viral Mutations

On September 23, 2021, the FDA revised the EUAs of certain molecular, antigen, and serology tests to establish additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2. The revision requires test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance as outlined in the letter. This revision is effective as of September 23, 2021 for all EUAs that are within the scope of the revision. This revision does not apply to EUAs for authorized IL-6 assays or standalone specimen collection devices and does not apply to EUAs that include substantially equivalent viral mutation conditions of authorization.

The FDA has determined that establishing additional conditions is necessary to mitigate the potential risk of false negative results due to either decreased sensitivity or non-reactivity associated with SARS-CoV-2 viral mutations. As set forth in the September 23, 2021 letter, developers of authorized tests that are within the scope of the revision are now required to routinely monitor emerging viral mutations and their potential impact on the performance of the authorized SARS-CoV-2 test(s). If potential impacts are identified, the EUA holder must communicate with the FDA and end users about the potential risk that presence of the mutations may have on test performance. The EUA holder must also update their authorized labeling consistent with the revision letter and submit the labeling to the FDA within 3 months of September 23, 2021. By taking these steps, the FDA and the test developer can quickly act in response to the potential risks identified and, when applicable, share the findings on SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery)

- Viral Mutation Revision Letter - September 23, 2021 (/media/152406/download)

Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2

On April 20, 2021, the FDA issued an amendment allowing certain authorized molecular diagnostic SARS-CoV-2 tests to be distributed and used to pool anterior nasal respiratory specimens from asymptomatic individuals as part of a serial testing program after developers submit a complete notification, including meeting required validation data, as set forth in the letter. Use of tests for these indications is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, except that tests authorized for use in specific named or designated high complexity laboratories can only be used in such laboratories.

This means that tests with EUAs that are amended by this authorization may be used with pooled anterior nasal specimens from individuals without known or suspected COVID-19 when such individuals are tested as part of a testing program that includes testing at regular intervals, at least

once per week. The indications in each appendix (A-H) differ in the number of specimens that can be pooled (up to 3, up to 5, or up to 10) and the type of pooling that can be done (media pooling or swab pooling).

Prior to a test being distributed or used for any new indication, the developer must submit a notification to the FDA with the information required by the amendment, including self-certifying that the applicable validation has been completed. Tests will be added to Exhibit 1 once FDA confirms that the required documentation has been submitted. Please note that being added to Exhibit 1 does not necessarily mean that the FDA has reviewed the underlying validation data submitted or confirmed that the test is appropriately validated.

- Amendment Letter (/media/147737/download)
- Appendix J - Sample Updated Fact Sheet for Health Care Providers (/media/147735/download)
- Appendix K - Sample Updated Fact Sheet for Patients (/media/147736/download)

Exhibit 1 of the Pooling and Serial Testing Amendment

The table below includes information for the authorized RT-PCR molecular diagnostic tests for SARS-CoV-2 amended by this Pooling and Serial Testing Amendment. For authorization documents for each test, see Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2 above.

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Date Added to Exhibit 1	EUA Holder	Test Name	Indication(s)*
01/28/2022	Vela Operations Singapore Pte. Ltd	ViroKey SARS-CoV-2 RT-PCR Test v2.0	Media: Up to 3 (Appendix D)
06/24/2021	Clinical Enterprise, Inc.	Clinical Enterprise SARS-SoV-2-RT-PCR Assay	Swab: Up to 10 (Appendix C)
06/23/2021	Viracor Eurofins Clinical Diagnostics	Viracor SARS-CoV-2 assay	Swab: Up to 10 (Appendix C)
06/22/2021	Biomeme, Inc.	Biomeme SARS-CoV-2 Real-Time RT-PCR Test	Swab: Up to 10 (Appendix C) Media: Up to 5 (Appendix G)

Date Added to Exhibit 1	EUA Holder	Test Name	Indication(s)*
06/15/2021	Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard	CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3)	Swab: Up to 10 (Appendix C)

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* The indications in each appendix (A-H) differ in the number of specimens that can be pooled (up to 3, up to 5, or up to 10) and the type of pooling that can be done (media or swab pooling).

Tests authorized for Swab Pooling are authorized for:

- Qualitative detection of RNA from SARS-CoV-2 in pooled samples containing up to [3, 5, or 10, depending on the applicable appendix] individual human anterior nasal swabs placed in a single vial containing transport media after being collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week as part of a serial testing program.

  This indication is authorized for use in laboratories certified under CLIA to perform high complexity tests except tests authorized for use in specific named or designated laboratories can only be used in such laboratories.

Tests authorized for Media Pooling are authorized for:

- Qualitative detection of RNA from SARS-CoV-2 in pooled samples containing aliquots of transport media from up to [3, 5, or 10, depending on the applicable appendix] individual human anterior nasal swab specimens that were collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from any individual and placed in individual vials containing transport media, including individuals without symptoms or other reasons to suspect COVID-19, when tested as part of a serial testing program including testing at least once per week.

  This indication is authorized for use in laboratories certified under CLIA to perform high complexity tests except tests authorized for use in specific named or designated laboratories can only be used in such laboratories.

Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing

On November 15, 2021, the FDA issued an umbrella EUA for certain RT-PCR molecular-based tests, developed by laboratories, for detection of nucleic acid from SARS-CoV-2 from anterior nasal respiratory specimens for use as part of a serial testing program, that meet certain criteria for eligibility specified in the EUA. Under this EUA, authorized tests can be used with individual or pooled anterior nasal specimens for testing individuals, including individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least once per week. This means that tests authorized by this EUA may be used with individual or pooled anterior nasal respiratory specimens from individuals with or without known or suspected exposure to COVID-19 when such individuals are tested at least once per week, such as testing at regular intervals as part of a testing program implemented by schools, workplaces, or community groups. The indications in each appendix (A-K) differ in the number of specimens that can be pooled (1, up to 3, up to 5, or up to 10), the type of pooling that can be done (media pooling or swab pooling), and whether the test can be used with home collected specimens.

Use of tests authorized by this EUA is limited to use in the single laboratory that developed the authorized test and that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Tests will be added to Exhibit 1 of this EUA following submission of a complete notification to the FDA with the information required by the EUA, including self-certifying that the applicable validation has been completed, and confirmation by the FDA that the required documentation has been submitted. Being added to Exhibit 1 does not necessarily mean that the FDA has reviewed the underlying validation data submitted or confirmed that the test is appropriately validated.

- EUA Letter of Authorization - Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (/media/154111/download)
- Appendix L - Fact Sheet for Health Care Providers (Template) (/media/154112/download)
- Appendix M - Fact Sheet for Patients (Template) (/media/154114/download)
- Appendix N - Test Summary (Template) (/media/154113/download)

Exhibit 1 of the Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing

This exhibit includes information for the RT-PCR molecular diagnostic tests for SARS-CoV-2 authorized by this umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing. All tests authorized by this umbrella EUA are required to have at least two viral targets on the SARS-CoV-2 genome. Tests with multiple targets are more likely to continue to perform well when new variants emerge.

Search:

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Date Added to Exhibit 1	EUA Holder	Test Name	Additional Indication(s)*	Authorization Documents**
02/17/2022	Applied DNA Clinical Labs, LLC.	Linea 2.0 COVID-19 Assay	Media: Up to n=5 (Appendix H)	Test Summary (/media/156757/download), HCP (/media/156751/download), Patients (/media/156752/download)

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* All tests authorized under this Umbrella EUA are authorized for (as described in appendix A):

- Qualitative detection of RNA from SARS-CoV-2 in individual human anterior nasal swab samples collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals, including individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week.

  Each test is authorized for use in the single laboratory that developed the authorized test and that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Additional indications included in appendices (B-K) differ in the number of specimens that can be pooled (up to 3, up to 5, or up to 10), the type of pooling that can be done (media or swab pooling), and the inclusion of use with home collected specimens.

Tests authorized for Swab Pooling (appendices B-D) are authorized for:

- Qualitative detection of RNA from SARS-CoV-2 in individual human anterior nasal swabs or pooled samples containing up to [3, 5, or 10, depending on the applicable appendix] individual human anterior nasal swabs placed in a single vial after being collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals, including individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week.

  This test is authorized for use in the single laboratory that developed the test and that is certified under CLIA and meets requirements to perform high complexity tests.

Tests authorized for Media Pooling (appendices E-I) are authorized for:

- Qualitative detection of RNA from SARS-CoV-2 in individual human anterior nasal swabs or pooled samples containing aliquots of media from up to [3, 5, or 10, depending on the applicable appendix] individual human anterior nasal swab specimens that were collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals, including individuals without symptoms or other reasons to suspect COVID-19 and placed in individual vials when tested at least once per week.

  This test is authorized for use in the single laboratory that developed the test and that is certified under CLIA and meets requirements to perform high complexity tests.

Tests authorized for Home Specimen Collection (appendices J-K) are authorized for the applicable above indications with the following addition regarding specimen collection:

- {or self-collected at home using the following authorized home collection kit(s): [specific named home collection kit(s) with which the test was validated] when used consistent with the home collection kit's authorization for individuals tested at least once per week}

** Authorization Documents include the Test Summary, Fact Sheet for Healthcare Providers (HCP) and Fact Sheet for Patients.

EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests

On March 31, 2020, the FDA issued an umbrella EUA for molecular laboratory developed tests (LDTs) for detection of SARS-CoV-2 that meet certain criteria for eligibility described in the EUA. Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests. Tests authorized under this umbrella EUA were added to Appendix A in the table below.

On November 15, 2021, the FDA reissued this EUA such that only tests that are listed in Appendix A are authorized for use as described in the EUA, and no additional tests will be authorized by this EUA. The reissued EUA also includes updated Conditions of Authorization and Fact Sheets to reflect the most up-to-date information.

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/media/136598/download)
- Fact Sheet for Healthcare Providers (/media/136599/download)
- Fact Sheet for Patients (/media/136600/download)
- See Appendix A table below for a list of tests authorized under this EUA

Appendix A: Authorized Molecular-Based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2

The table below includes information for the high complexity molecular-based laboratory developed SARS-CoV-2 assays authorized by this EUA (/media/136598/download) during the COVID-19 public health emergency.

To see additional authorization documents, such as letters granting EUA amendments or revisions, for a specific test, select the plus (+) button beside the "Date Last Updated" for each test.

All tests in this table are multiple target tests unless noted with an asterisk (*). Multiple target tests are designed to detect two or more viral targets, or sections of the SARS-CoV-2 genome. Tests with an asterisk are single target tests. Single target tests are designed to detect only one viral target on the SARS-CoV-2 genome. Tests with multiple targets are more likely to continue to perform well when new variants emerge. Tests with single targets are more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.

All authorized devices in the table below are assigned the QJR product code.

Search:

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Date Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 02/03/2021	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/media/138933/download) 06/12/2020	EUA Summary (/media/138934/download)
+ 01/29/2021	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/media/138529/download) 06/01/2020	EUA Summary (/media/138528/download)
+ 01/28/2021	AIT Laboratories	SARS-CoV-2 Assay (/media/137373/download) 04/24/2020	EUA Summary (/media/137374/download)
+ 12/28/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/media/137424/download) 04/27/2020	EUA Summary (/media/137423/download)
+ 12/28/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/media/137654/download) 05/03/2020	EUA Summary (/media/137656/download)

Date Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 12/28/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/media/137896/download) 05/07/2020	EUA Summary (/media/137897/download)
+ 09/22/2020	Diatherix Eurofins Laboratory	SARS-CoV-2 PCR Test (/media/137256/download) 04/22/2020	EUA Summary (/media/137255/download)
+ 09/21/2020	Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital	Childrens-Altona-SARS-CoV-2 Assay (/media/136972/download) 04/14/2020	EUA Summary (/media/136971/download)
+ 09/21/2020	Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory	CDI Enhanced COVID-19 Test (/media/137037/download) 04/15/2020	EUA Summary (/media/137036/download)
+ 09/21/2020	CirrusDx Laboratories	CirrusDx SARS-CoV-2 Assay (/media/137035/download) 04/15/2020	EUA Summary (/media/137034/download)
+ 09/14/2020	Columbia University Laboratory of Personalized Genomic Medicine	TRIPLEX CII-SARS-CoV-2 rRT-PCR TEST (/media/137982/download) 05/12/2020	EUA Summary (/media/137983/download)
+ 06/10/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/media/138791/download) 06/10/2020	EUA Summary (/media/138790/download)
+ 06/04/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/media/137545/download) 04/30/2020	EUA Summary (/media/137546/download)
+ 06/04/2020	Yale New Haven Hospital, Clinical Virology Laboratory	SARS-CoV-2 PCR test (/media/136601/download) 03/31/2020	EUA Summary (/media/136602/download)
+ 06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/media/138624/download) * 06/04/2020	EUA Summary (/media/138625/download)
+ 05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/media/138331/download) 05/22/2020	EUA Summary (/media/138332/download)
+ 05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/media/138062/download) 05/13/2020	EUA Summary (/media/138063/download)

Date Last Updated	Laboratory	Letter Granting Inclusion under EUA and Original Issue Date	EUA Summary
+ 04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/media/137371/download) * 04/24/2020	EUA Summary (/media/137372/download)
+ 04/23/2020	Southwest Regional PCR Laboratory LLC. dba MicroGen DX	COVID-19 Key (/media/137369/download) 04/23/2020	EUA Summary (/media/137370/download)
+ 04/13/2020	Integrity Laboratories	SARS-CoV-2 Assay (/media/136941/download) 04/13/2020	EUA Summary (/media/136942/download)
+ 04/10/2020	Orig3n, Inc.	Orig3n 2019 Novel Coronavirus (COVID-19) Test (/media/136874/download) 04/10/2020	EUA Summary (/media/136873/download)
+ 04/10/2020	Specialty Diagnostic (SDI) Laboratories	SDI SARS-CoV-2 Assay (/media/136878/download) * 04/10/2020	EUA Summary (/media/136877/download)
+ 04/02/2020	Diagnostic Molecular Laboratory - Northwestern Medicine	SARS-Cov-2 Assay (/media/136658/download) * 04/02/2020	EUA Summary (/media/136669/download)
+ 04/02/2020	Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia	SARS-CoV-2 RT-PCR test (/media/136657/download) * 04/02/2020	EUA Summary (/media/136656/download)

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[1] The tests listed in this table are all molecular-based tests for COVID-19 and the authorized setting is for use in the identified laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

CDC Diagnostic Tests for COVID-19

Updated Aug. 7, 2021 Print

CDC has developed two laboratory tests that identify SARS-CoV-2, the virus that causes COVID-19. The first test for COVID-19 diagnosis that CDC distributed, released in February 2020, is the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, a test that accurately detects SARS-CoV-2 in respiratory specimens. CDC released a second assay in July 2020, the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, which permits public health laboratories to run three tests in a single reaction well. The Flu SC2 Multiplex is more efficient in its use of test reagents, allows higher throughput, and simultaneously gives accurate results about the presence of SARS-CoV-2, influenza A, and influenza B nucleic acid in a patient specimen. Symptoms for COVID-19 and the Flu can be similar, so testing for all three viruses at the same time will provide public health officials with information they need to help reduce the spread of these viruses in the community while conserving resources that are in short supply.

Please note: CDC will discontinue the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel at the end of 2021. For more details, please see the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel section below.

CDC Influenza SARS-CoV-2 Multiplex Assay

CDC's newest laboratory test, detects two types of influenza viruses (A and B) and SARS-CoV-2 at the same time. This test is called the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay.

A single test that diagnoses current infection with one or more of these viruses allows public health laboratories to continue influenza surveillance while they are also testing for SARS-CoV-2. Information about both viruses will help public health officials control the spread of influenza and COVID-19 in the community and may help health care providers identify co-infections and provide more targeted treatment for influenza and COVID-19. Obtaining this information in a single test, rather than having to run separate SARS-CoV-2 tests and influenza tests, will also allow laboratories to conserve important testing materials that are in short supply and process up to three times as many tests as they can with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and separate influenza diagnostic tests.

The Flu SC2 Multiplex Assay was evaluated in CDC laboratories and three other public health laboratories prior to launch to ensure that the test works as intended. The Flu SC2 Multiplex Assay was designed using data about SARS-CoV-2 genomes that were not available when the first test was designed, which is likely to improve detection of the SARS-CoV-2 virus as compared to the original CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of the Flu SC2 Multiplex Assay on July 2, 2020. The EUA process enables FDA to consider and authorize the use of unapproved but potentially lifesaving medical or diagnostic products during a public health emergency. The U.S Secretary of Health and Human Services declared SARS-CoV-2 to be a U.S. public health emergency on January 31, 2020.

CDC 2019-nCoV RT-PCR Diagnostic Panel





Boxes included in CDC's laboratory test kit for SARS-CoV-2

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On February 3, 2020, CDC submitted an EUA package to expedite FDA-permitted use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel in the United States. FDA issued the EUA the next day and CDC sent the test kits to state and local public health laboratories.

CDC developed and distributed the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel to fill a gap at a time when there were no other FDA-cleared or authorized COVID-19 diagnostics. Since CDC's first test was developed, many commercially available options for SARS-CoV-2 testing have been authorized. Although the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel filled an important unmet need when it was developed and deployed in early 2020, the demand for this test has declined due to the authorization of higher-throughput alternatives and multiplexed assays that detect both SARS-CoV-2 and other common respiratory pathogens simultaneously. For this reason, CDC will discontinue the 2019 nCoV Real-Time RT-PCR Diagnostic Panel after December 31, 2021.

As the test is still performing very well, CDC will continue to make the design of the primers and probes used in the CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel available on the CDC website for others to use in their own research activities or diagnostic assay development. CDC will also continue to offer a blanket right of reference to the CDC EUA for the Diagnostic Panel (EUA200001) to anyone who wishes to reference CDC data in their own FDA regulatory submission. CDC's decision to discontinue the Diagnostic Panel and subsequent withdrawal of the EUA for the Diagnostic Panel will have no impact on those tests that have referenced the CDC EUA data in their EUA submission or on those who plan to do so in the future. The data and submission will remain on file at FDA and available for reference.

CDC is encouraging public health laboratories (PHLs) to adopt the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to enable efficient surveillance for both influenza and SARS-CoV-2, which will save both time and resources for PHLs. Clinical laboratories that had been testing under CDC's EUA using CDC-qualified materials purchased from IDT or BioSearch are encouraged to transition to another FDA-authorized test. If the clinical laboratory conducts influenza diagnostics, CDC encourages the clinical laboratory to consider one of the FDA-authorized tests that can provide results for SARS-CoV-2 and influenza A and B.

Who Can Use These Tests?

CDC tests are provided to U.S. state and local public health laboratories and Department of Defense laboratories that were either previously qualified for being able to perform a similar type of test used to detect influenza or have been recently approved by their state public health laboratory for SARS-CoV-2 testing.

recently approved by their state public health laboratory for SARS-CoV-2 testing.

Additional Resources

- Information for Laboratories
- SARS-CoV-2 Viral Culturing at CDC
- CDC's Diagnostic Test for COVID-19 *Only*
- CDC's Diagnostic Multiplex Assay for Flu and COVID-19
- Testing Data in the US
- Overview of Testing for SARS-CoV-2 (for healthcare providers)
- Testing for COVID-19 (for the public)

Last Updated Aug. 7, 2021

**BRITISH MEDICAL JOURNAL No 7070 Volume 313: Page 1448,
7 December 1996.**

CIRP Introduction

The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide.

This judgment established a new standard of ethical medical behavior for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of *voluntary informed consent* of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.

This code also recognizes that the risk must be weighed against the expected benefit, and that unnecessary pain and suffering must be avoided.

This code recognizes that doctors should avoid actions that injure human patients.

The principles established by this code for medical practice now have been extened into general codes of medical ethics.

The Nuremberg Code (1947)

Permissible Medical Experiments

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person

which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

For more information see Nuremberg Doctor's Trial, *BMJ* 1996;313(7070):1445-75.

Cite as:

- The Nuremberg Code (1947) In: Mitscherlich A, Mielke F. *Doctors of infamy: the story of the Nazi medical crimes*. New York: Schuman, 1949: xxiii-xxv.

(File revised 09 June 2002)

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CFR - Code of Federal Regulations Title 21

The information on this page is current as of Jan 06, 2022.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

[Code of Federal Regulations]
[Title 21, Volume 1]
[CITE: 21CFR50.20]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A - GENERAL

PART 50 -- PROTECTION OF HUMAN SUBJECTS

Subpart B - Informed Consent of Human Subjects

Sec. 50.20 General requirements for informed consent.

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

[46 FR 8951, Jan. 27, 1981, as amended at 64 FR 10942, Mar. 8, 1999]

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Informed Consent for Clinical Trials

en español (/patients/informed-consent-clinical-trials/el-consentimiento-informado-para-participar-en-los-ensayos-clinicos)



On this page you will find information on:

- What is Informed Consent
- Before enrolling in a clinical trial, the following information must be given to each potential research subject
- When Appropriate, one or more of the following elements of information must also be provided in the informed consent document
- A potential research subject must have an opportunity to
- Informed consent may not include language that

To many, the term *informed consent* is mistakenly viewed as the same as getting a research participant's signature on the consent form. FDA believes that obtaining a research participant's verbal or written informed consent is only part of the process. Informed consent involves providing a potential participant with:

- adequate information to allow for an informed decision about participation in the clinical investigation.
- facilitating the potential participant's understanding of the information.
- an appropriate amount of time to ask questions and to discuss with family and friends the research protocol and whether you should participate.
- obtaining the potential participant's voluntary agreement to participate.
- continuing to provide information as the clinical investigation progresses or as the subject or situation requires.

To be effective, the process must provide sufficient opportunity for the participant to consider whether to participate. (21 CFR 50.20 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.20).) FDA considers this to include allowing sufficient time for participants to consider the information and providing time and opportunity for the participant to ask questions and have those questions answered. The investigator (or other study staff who are conducting the informed consent interview) and the participant should exchange information and discuss the contents of the informed consent document. This process must occur under circumstances that minimize the possibility of coercion or undue influence. (21 CFR 50.20.)

What is Informed Consent?

As new medical products are being developed, no one knows for sure how well they will work, or what risks they will find. Clinical trials are used to answer questions such as:

- Are new medical products safe enough to outweigh the risks related to the underlying condition?,
- How should the product be used? (for example, the best dose, frequency, or any special precautions necessary to avoid problems),
- How effective is the medical product at relieving symptoms, treating or curing a condition.

The main purpose of clinical trials is to “study” new medical products in people. It is important for people who are considering participation in a clinical trial to understand their role, as a “subject of research” and not as a patient.

While research subjects may get personal treatment benefit from participating in a clinical trial, they must understand that they:

- may not benefit from the clinical trial,
- may be exposed to unknown risks,
- are entering into a study that may be very different from the standard medical practices that they currently know

To make an informed decision about whether to participate or not in a clinical trial, people need to be informed about:

- what will be done to them,
- how the protocol (plan of research) works,
- what risks or discomforts they may experience,
- participation being a voluntary decision on their part.

This information is provided to potential participants through the informed consent process. Informed consent means that the purpose of the research is explained to them, including what their role would be and how the trial will work.

A central part of the informed consent process is the informed consent document. The Food and Drug Administration (FDA) does not dictate the specific language required for the informed consent document, but does require certain basic elements of consent be included.

Before enrolling in a clinical trial, the following information must be given to each potential research subject:

- A statement explaining that the study involves research.
- An explanation of the purposes of the research.
- The expected length of time for participation.
- A description of all the procedures that will be completed during enrollment on the clinical trial.
- Information about all experimental procedures the will be completed during the clinical trial.
- A description of any predictable risks.
- Any possible discomforts (e.g., injections, frequency of blood test etc.) that could occur as a result of the research.
- Any possible benefits that may be expected from the research.

- Information about any alternative procedures or treatment (if any) that might benefit the research subject.
- A statement describing:
    - the confidentiality of information collected during the clinical trial,
    - how records that identify the subject will be kept
    - the possibility that the FDA may inspect the records.
- For research involving more than minimal risk (/patients/informed-consent-clinical-trials/minimal-risk) information including
- an explanation as to whether any compensation or medical treatments are available if injury occurs,
- what they consist of, or
- where more information may be found.
- questions about the research,
- research subjects' rights,
- injury related to the clinical trial.
- Research subject participation is voluntary,
- Research subjects have the right to refuse treatment and will not losing any benefits for which they are entitled,
- Research subjects may choose to stop participation in the clinical trial at any time without losing benefits for which they are entitled.
- Contact information will be provided for answers to :
- A statement that:

When Appropriate, one or more of the following elements of information must also be provided in the informed consent document:

- A statement that the research treatment or procedure may involve unexpected risks (to the subject, unborn baby, if the subject is or may become pregnant).
- Any reasons why the research subject participation may be ended by the clinical trial investigator (e.g., failing to follow the requirements of the trial or changes in lab values that fall outside of the clinical trial limits).
- Added costs to the research subject that may result from participating in the trial.
- The consequence of leaving a trial before it is completed (e.g. if the research and procedures require a slow and organized end of participation).

- A statement that important findings discovered during the clinical trial will be provided to the research subject.
- The approximate number of research subjects that will be enrolled in the study.

A potential research subject must have an opportunity to:

- read the consent document,
- ask questions about anything they do not understand.

Usually, if one is considering participating in a clinical trial, he or she may take the consent document home to discuss with family, friend or advocate.

An investigator should only get consent from a potential research subject if:

- enough time was given to the research subject to consider whether or not to participate
- the investigator has not persuaded or influenced the potential research subject.

The information must be in language that is understandable to the research subject.

Informed consent may not include language that:

- the research subject is made to ignore or appear to ignore any of the research subject's legal rights,
- releases or appears to release the investigator, the sponsor, the institution, or its agents from their liability for negligence.

Participating in clinical trials is voluntary. You have the right not to participate, or to end your participation in the clinical trial at any time. Read the informed consent document carefully. Ask questions about any information you don't understand or find confusing.

Draft Guidance: Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors (/regulatory-information/search-fda-guidance-documents/informed-consent-information-sheet)

The PMC website is updating on 03/21/2022. Try out this update now on PMC Labs or Learn more.

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Public Health Emergency COVID-19 Initiative

Am J Emerg Med. 2022 Jan 25 PMCID: PMC8786400
doi: 10.1016/j.ajem.2022.01.048 [Epub ahead of print] PMID: 35105473

Human toxicity from COVID-19 rapid home test kits

Kelly Johnson-Arbor, MD,[a,b,*] Nicole Reid, BSN, EdM,[b,c] and Susan Smolinske, PharmD[d,e]

The persistence of the COVID-19 pandemic has necessitated the development and widespread availability of methods to detect the COVID-19 virus in humans. COVID-19 tests, which were initially only available in healthcare facility settings, are now manufactured for home use in the form of rapid diagnostic tests and generally contain a nasal swab, reagent solution, and test device (e.g., card or strip). These kits typically involve application of reagent solution to the test device; in the presence of biological material obtained from the nasal swab, this initiates a chemical reaction that produces the test result.

Multiple COVID-19 rapid antigen home test kids, including those manufactured by Abbott (BinaxNOW™), Beckton, Dickinson and Company (BD Veritor™), Celltrion (Celltrion DiaTrust™), and ACON Laboratories (Flowflex™), contain sodium azide as a component of the reagent solution [[1], [2], [3]]. The reagent in some kits may contain other constituents, including Triton-X, inorganic phosphate, and Pro-Clin 300. The latter ingredients are unlikely to cause human toxicity if small amounts are ingested, but they may cause allergic reactions or local irritation after ocular or dermal exposure. However, sodium azide is well-known for its ability to cause harmful effects in humans, especially after oral exposures and potentially including the ingestion of reagent solution. Additionally, since the reagent solution packaging may include ampules that allow for application of drops of solution to the test device, inadvertent ocular sodium azide exposures can occur if the ampule is mistaken for an eyedropper.

Sodium azide is a water-soluble, tasteless, and odorless chemical that is commonly used as a preservative agent [4]. It is also found as a propellant in some automobile airbags; upon impact, sodium azide ignites and transforms into hydrocarbon gases that cause airbag expansion [5]. Although data concerning acute sodium azide toxicity in humans are limited, the chemical can cause serious adverse events after oral exposure to relatively low doses. In one study, sodium azide was administered at doses of 0.65 and 1.3 mg to healthy and hypertensive individuals (for a 70-kg adult, this corresponds to a dose of 0.01 and 0.02 mg/kg) [6]. Hypotension occurred rapidly, within 45–60 s in some subjects, and lasted for 10–15 min. Despite the fall in blood pressure, reflex tachycardia was not noted, but a detailed description of other adverse events was not provided by the authors. In the same study, one hypertensive subject who received oral doses of 0.3 mg (or 0.004 mg/kg for a 70-kg individual)

experienced a change in blood pressure from 183/104 mmHg pre-treatment to 115/68 mmHg post-treatment. Ingestion of higher doses of sodium azide (>700 mg or 10 mg/kg) by adults is associated with cardiac arrhythmias, metabolic acidosis, and death [[7], [8], [9]].

The reagent fluid in many COVID-19 rapid antigen home test kits contains sodium azide in concentrations of 0.0125–0.0946%, and personal communication with test kit manufacturers revealed that the reagent fluid volume in these kits is small (0.3–0.625 mL) [[1], [2], [3]]. Thus, reagents with sodium azide concentrations less than 0.09–0.095% generally contain extremely low amounts of sodium azide (0.04–0.08 mg), or well below the amount expected to cause transient hypotension in adults. Kits that have reagent fluid with higher sodium azide concentrations (greater than or equal to 0.09%), including the BD Veritor™ and Celltrion DiaTrust™ testing systems, contain approximately 0.3 mg of sodium azide [10,11]. Ingestions of this magnitude may result in hypotension, decreased end-organ perfusion, and syncope. Children may experience serious adverse events after exploratory oral exposures to minimal amounts of the reagent solutions due to their smaller body size and should be monitored closely for hypotension or other sequelae after ingestion of even minute quantities of reagent fluids. Since the onset of hypotension after oral exposure to sodium azide is rapid, prolonged observation is likely unnecessary for individuals who remain asymptomatic after reagent fluid ingestion. The treatment of symptomatic sodium azide intoxication is supportive in nature and includes intravenous fluids and vasoactive medications.

While home COVID-19 tests have remained in short supply throughout most of the current pandemic, the United States government began offering free tests to its residents starting in mid-January 2022. Prior to this distribution of free tests, numerous cases involving oral exposure to COVID-19 home test reagent fluid were reported to United States poison centers. From June 16, 2021 through January 19, 2022, the online webPOISONCONTROL® tool received 153 reports of human exposure to COVID-19 home test kits or reagents. Many of these cases were associated with no adverse effects, suggesting that exposures involving reagent fluid are unlikely to cause significant human toxicity. The expanded access to home tests will likely result in a further increase in human exposures to the reagent fluids. Emergency physicians, pharmacists, and poison center staff should maintain awareness of the potential toxicities associated with ingestion of the reagent fluids and should also be prepared to treat patients who present for care after exposures to the contents of COVID-19 rapid antigen home test kits.

Funding

None.

Prior presentation

None.

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HHS Vulnerability Disclosure

Poison Control Center Issues Warning on Toxic Chemical in At-Home COVID-19 Test Kits

by **RTM Staff** — February 27, 2022



edge

Some at-home rapid COVID-19 tests contain a toxic chemical that may be harmful to both children and adults, according to health officials with the National Capital Poison Center.

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“It is important to know that the extraction vial in many rapid antigen kits includes the chemical sodium azide as a preservative agent,” the Center said in a recent alert. “The BinaxNow, BD Veritor, Flowflex, and Celltrion DiaTrust COVID-19 rapid antigen kits all contain this chemical.”

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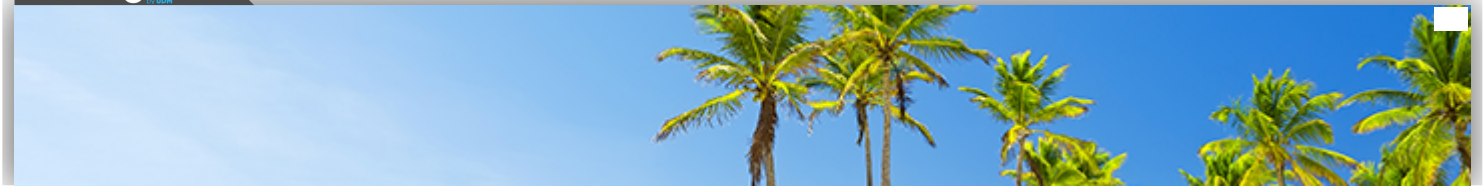
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Sodium azide is a colorless, odorless powder that testers dip cotton swabs into. The chemical is found in herbicides, pest control agents, and airbags for cars.

“Small doses of sodium azide can lower blood pressure, and larger doses may [illegible] serious health effects,” an advisory from Health Canada also said.

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Some hospitals around the United States say they have received a surge in phone calls about exposures to the chemical.

TRENDING TODAY

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“We started getting our first exposures to these test kits around early November,” said Sheila Goertemoeller, pharmacist and clinical toxicologist for the Cincinnati Children’s Hospital Medical Center. “It was, really, all ages.”

“Mostly, I’ve been very worried about our young children,” Goertemoeller said.

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Accidental exposure is occurring among both children and adults, said Dr. Kelly Johnson-Arbor, with the National Capital Poison Center in Washington D.C., according to WNEP.

“People might mistake them for eye drops. Children might drop it onto their skin. Adults will sometimes mistakenly put them into their eyes,” said Johnson-Arbor.

“You don’t want to leave it on the skin because it could potentially cause an allergic reaction or a skin rash. If someone drinks the solution, it’s really important to contact poison control right away,” she added. “The solutions have different ingredients. Some have non-toxic ingredients and others have

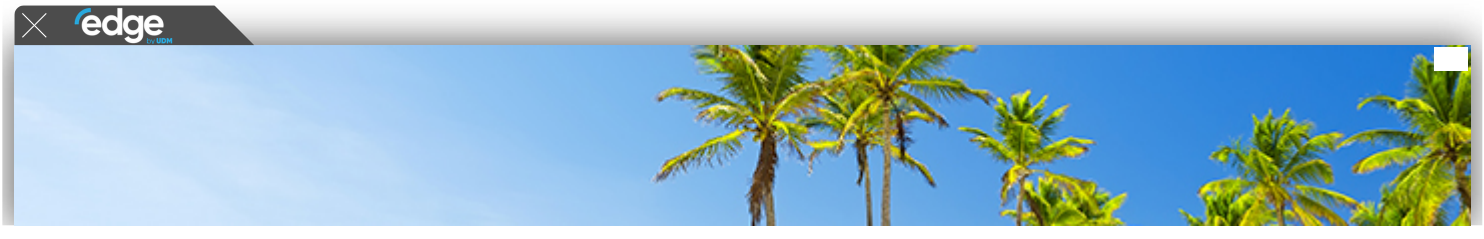
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Officials told WNEP that there is no need to throw away the test kits, but people should be mindful when using them.

This is an excerpt from The Epoch Times.

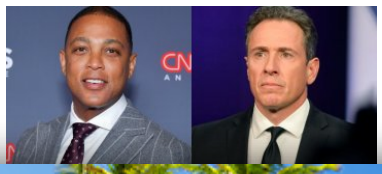
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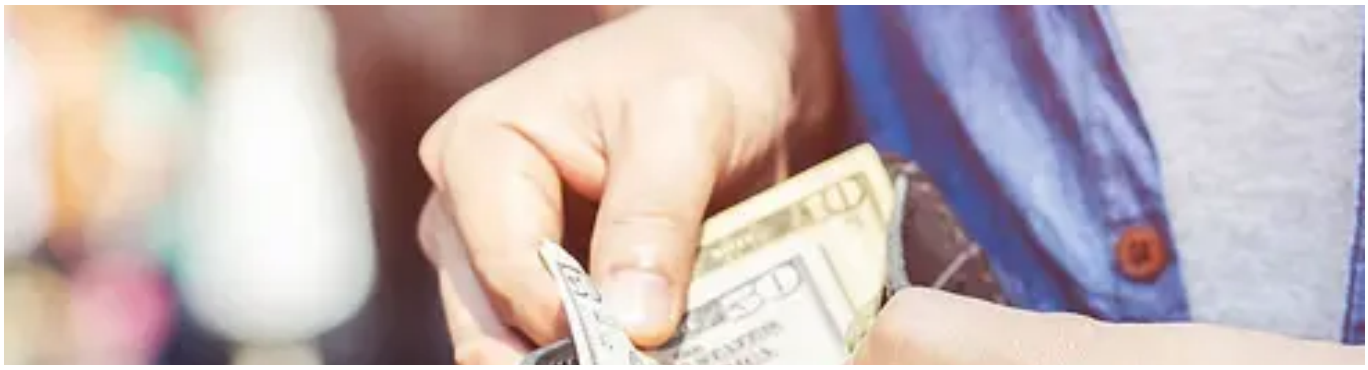


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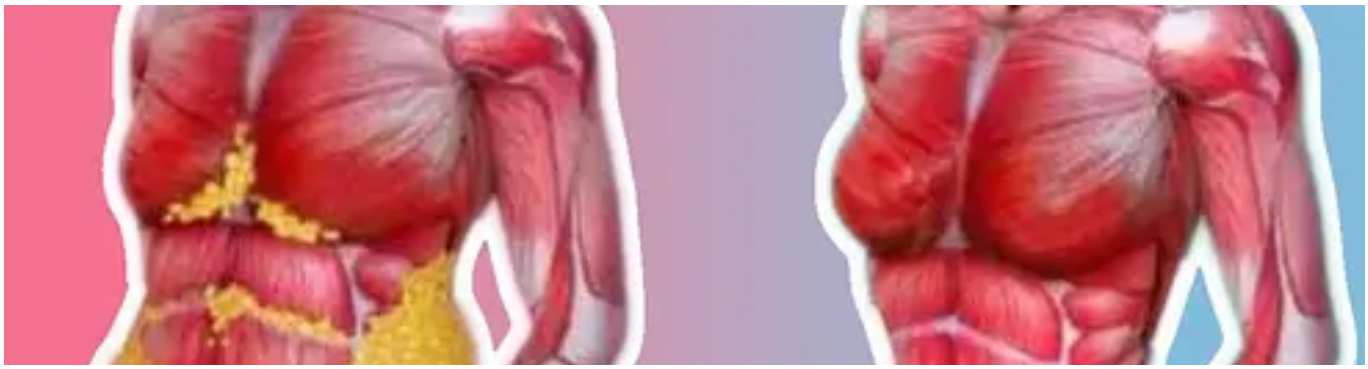
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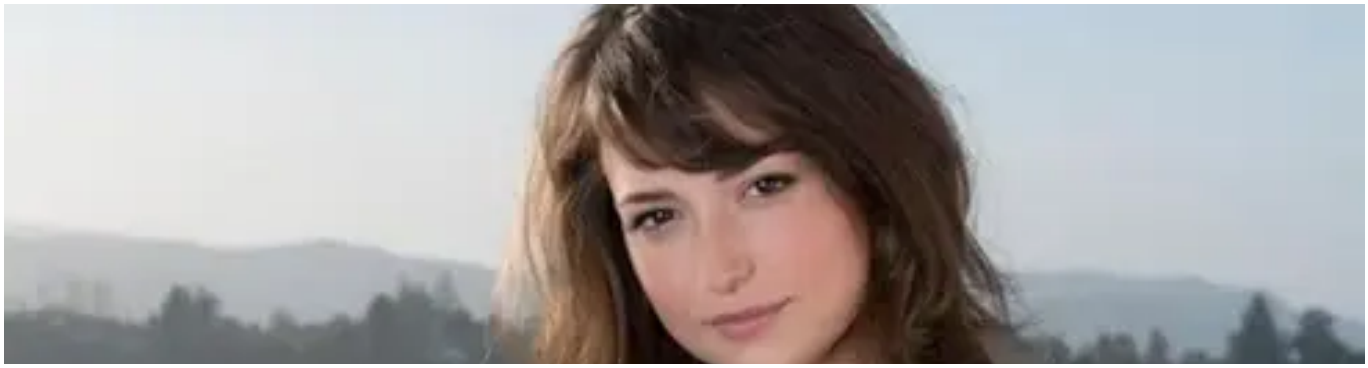
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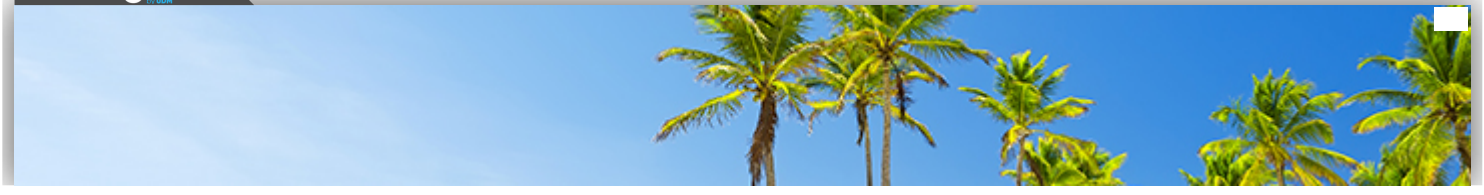


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Facts About Sodium Azide

Related Pages

Facts About Sodium Azide

Case Definition: Sodium Azide

Toxic Syndrome Description: Sodium Azide Poisoning

What sodium azide is

- Sodium azide is a rapidly acting, potentially deadly chemical that exists as an odorless white solid.
- When it is mixed with water or an acid, sodium azide changes rapidly to a toxic gas with a pungent (sharp) odor. It also changes into a toxic gas (hydrazoic acid) when it comes in contact with solid metals (for example, when it is poured into a drain pipe containing lead or copper).
- The odor of the gas may not be sharp enough, however, to give people sufficient warning of the danger.

Where sodium azide is found and how it is used

- Sodium azide is best known as the chemical found in automobile airbags. An electrical charge triggered by automobile impact causes sodium azide to explode and convert to nitrogen gas inside the airbag.
- Sodium azide is used as a chemical preservative in hospitals and laboratories. Accidents have occurred in these settings. In one case, sodium azide was poured into a drain, where it exploded and the toxic gas was inhaled (breathed in).
- Sodium azide is used in agriculture (farming) for pest control.
- Sodium azide is also used in detonators and other explosives.

How you could be exposed to sodium azide

- Following release of sodium azide into water, you could be exposed to sodium azide by drinking the contaminated water.
- Following contamination of food with sodium azide, you could be exposed to sodium azide by eating the contaminated food.
- Following release of sodium azide into the air, you could be exposed by breathing in the dust or the gas that is formed.
- Sodium azide can also enter the body and cause symptoms through skin contact.
- An explosion involving sodium azide may cause burn injury as well as expose people to the toxic gas, hydrozoic acid.

How sodium azide works

- The seriousness of poisoning caused by sodium azide depends on the amount, route, and length of time of exposure, as well as the age and preexisting medical condition of the person exposed.
- Breathing the gas that is formed from sodium azide causes the most harm, but ingesting (swallowing) sodium azide can be toxic as well.
- The gas formed from sodium azide is most dangerous in enclosed places where the gas will be trapped. The toxic gas quickly disperses in open spaces, making it less harmful outdoors.

- The gas formed from sodium azide is less dense (lighter) than air, so it will rise.
- Sodium azide prevents the cells of the body from using oxygen. When this happens, the cells die.
- Sodium azide is more harmful to the heart and the brain than to other organs, because the heart and the brain use a lot of oxygen.

Immediate signs and symptoms of sodium azide exposure

- People exposed to a small amount of sodium azide by breathing it, absorbing it through their skin, or eating foods that contain it may have some or all of the following symptoms within minutes:
  - Clear drainage from the nose (gas or dust exposure)
  - Cough (gas or dust exposure)
  - Dizziness
  - Headache
  - Nausea and vomiting
  - Rapid breathing
  - Rapid heart rate
  - Red eyes (gas or dust exposure)
  - Restlessness
  - Weakness
  - Skin burns and blisters (explosion or direct skin contact)
- Exposure to a large amount of sodium azide by any route may cause these other health effects as well:
  - Convulsions
  - Low blood pressure
  - Loss of consciousness
  - Lung injury
  - Respiratory failure leading to death
  - Slow heart rate
- Showing these signs and symptoms does not necessarily mean that a person has been exposed to sodium azide.

What the long-term health effects may be

Survivors of serious sodium azide poisoning may have heart and brain damage.

How people can protect themselves and what they should do if they are exposed to sodium azide

- First, get fresh air by leaving the area where the sodium azide was released. Moving to an area with fresh air is a good way to reduce the possibility of death from exposure to sodium azide.
  - If the sodium azide release was outside, move away from the area where the sodium azide was released.
  - If the sodium azide release was indoors, get out of the building.
  - If leaving the area that was exposed to sodium azide is not an option, stay as low to the ground as possible, because sodium azide fumes rise.
  - If you are near a release of sodium azide, emergency coordinators may tell you to either evacuate the area or to "shelter in place" inside a building to avoid being exposed to the chemical. For more information on evacuation during a chemical emergency, see "Facts About Evacuation". For more information on sheltering in place during a chemical emergency, see "Facts About Sheltering in Place".
  - If you think you may have been exposed to sodium azide, you should remove your clothing, rapidly wash your entire body with soap and water, and get medical care as quickly as possible.
- **Removing your clothing:**

    - Quickly take off clothing that may have sodium azide on it. Any clothing that has to be pulled over the head should be cut off the body instead of pulled over the head.
    - If you are helping other people remove their clothing, try to avoid touching any contaminated areas, and remove the clothing as quickly as possible.
- Washing yourself:
    - As quickly as possible, wash any sodium azide from your skin with large amounts of soap and water. Washing with soap and water will help protect people from any chemicals on their bodies.
    - If your eyes are burning or your vision is blurred, rinse your eyes with plain water for 10 to 15 minutes. If you wear contacts, remove them and put them with the contaminated clothing. Do not put the contacts back in your eyes (even if they are not disposable contacts). If you wear eyeglasses, wash them with soap and water. You can put your eyeglasses back on after you wash them.
- Disposing of your clothes:
    - After you have washed yourself, place your clothing inside a plastic bag. Avoid touching contaminated areas of the clothing. If you can't avoid touching contaminated areas, or you aren't sure where the contaminated areas are, wear rubber gloves or put the clothing in the bag using tongs, tool handles, sticks, or similar objects. Anything that touches the contaminated clothing should also be placed in the bag. If you wear contacts, put them in the plastic bag, too.
    - Seal the bag, and then seal that bag inside another plastic bag. Disposing of your clothing in this way will help protect you and other people from any chemicals that might be on your clothes.
    - When the local or state health department or emergency personnel arrive, tell them what you did with your clothes. The health department or emergency personnel will arrange for further disposal. Do not handle the plastic bags yourself.
    - For more information about cleaning your body and disposing of your clothes after a chemical release, see "Chemical Agents: Facts About Personal Cleaning and Disposal of Contaminated Clothing".
    - If someone has ingested sodium azide, do not induce vomiting or give fluids to drink. Also, if you are sure the person has ingested sodium azide, do not attempt CPR using mouth to mouth breathing. Performing CPR on someone who has ingested sodium azide could expose you to the chemical.
    - When sodium azide is ingested, it mixes with stomach acid and forms the toxic gas, hydrozoic acid. If a person who has ingested sodium azide is vomiting, isolate and stay away from the stomach contents (vomit) to avoid exposure to the toxic gas.
    - Do not pour substances containing sodium azide (such as food, water, or vomit) in the drain, because the drain can explode and cause serious harm.
- Seek medical attention right away.

How sodium azide poisoning is treated

Sodium azide poisoning is treated with supportive medical care in a hospital setting. No specific antidote exists for sodium azide poisoning. The most important thing is for victims to seek medical treatment as soon as possible.

How you can get more information about sodium azide

You can contact one of the following:

- Regional poison control center: 1-800-222-1222
- Centers for Disease Control and Prevention
    - Public Response Hotline (CDC)
        - 800-CDC-INFO
        - 888-232-6348 (TTY)
    - E-mail inquiries: cdcinfo@cdc.gov
- Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Pocket Guide to Chemical Hazards.

Page last reviewed: April 4, 2018



RICHMOND, Va. (WRIC) – The Virginia Poison Center is on high alert after experts say an ingredient inside the test could be dangerous if used incorrectly.

The center warns the reagent, or liquid inside the vials, is poisonous. While the typical amount of liquid found inside an at-home test is not deadly, it can cause reactions.

“A very uncomfortable feeling,” Fiorella Carhuaz, a public educator at Virginia Poison Center told 8News. “Burning sensation and irritation.”

Virginia Senate approves amendment that may spell end to school mask mandates

She says the center has received a handful of calls for people accidentally misusing the tests.

“Sometimes, it’s left on the counter and a child gets it and they might have a taste for it,” she explained. “We’ve also seen people that can get that confused with eye drops just because the products look very similar.”

The warning comes as the U.S. Postal Service sends out millions of at-home COVID tests straight to people’s doorsteps.

“If you think about it, we’re asking people to conduct mini experiments at home,” Carhuaz said.

“Who doesn’t have one nowadays in the home. The odds are that they are going to use them at some point, but hopefully they won’t have any accidents.”

Related coverage: White House finalizing details to send free COVID tests to Americans soon, report says

If you have a test in your home, you’re encouraged to practice the following safety measures:

- Store out of sight and out of the reach of children
- Do not open the test until needed
- Store away from personal belongings like eye drops
- Never let children test themselves

If you get the reagent in your eyes, you’re encouraged to wash the area for 15 to 30 seconds then call the Poison helpline.

If you or a loved one is exposed, call the Poison hotline number at 1-800-222-1222.

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Poison centers around the country sound alarm on chemical in some COVID-19 at-home tests

Terry DeMio, Cincinnati Enquirer - Feb 28

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CINCINNATI — Be aware: That COVID-19 test kit in [illegible] that may be harmful to your children and you.



The substance is sodium azide, and Cincinnati Children's Hospital Medical Center's Drug and Poison Information Center has seen a surge in calls about exposures to the chemical since more people started self-testing for COVID-19 at home.

Fifty million U.S. households have received some version of the test kits, although it's not clear how many contain sodium azide. The government has sent 200 million of the kits, with about 85% of initial orders filled, officials said at a White House briefing last week.

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"We started getting our first exposures to these test kits around early November," said Sheila Goertemoeller, pharmacist and clinical toxicologist for the center. "It was, really, all ages." The calls to the local center mirror what's been happening nationally. The Upstate New York Poison Center and West Texas Poison Center have warned of similar issues.

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What is sodium azide?

Sodium azide, often used as a preservative, is a liquid reagent in several of the COVID-19 test kits, she said. Poison Control's National Capital Poison Center said the chemical is colorless, tasteless and odorless, and it is mainly used in car airbags and as a pest control agent.

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Kim Kardashian's Sexiest Looks After Kanye West Sp Hottest Post-Divorce Outfits

Kim Kardashian has been embracing some wild styles since splitting from Ka 2021. See the star's sexiest post-breakup looks here.

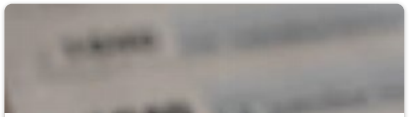
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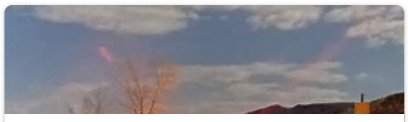
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KRNV Reno

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CNBC

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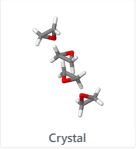
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COVID-19 Information
Public health information (CDC) Research information (NIH) SARS-CoV-2 data (NCBI) Prevention and treatment information (HHS) Español

PubChem

COMPOUND SUMMARY

Ethylene oxide

PubChem CID	6354
Structure	 2D  3D  Crystal Find Similar Structures
Chemical Safety	 Flammable Corrosive Acute Toxic Irritant Health Hazard Laboratory Chemical Safety Summary (LCSS) Datasheet
Molecular Formula	C_2H_4O
Synonyms	Oxirane ETHYLENE OXIDE Epoxyethane 75-21-8 1,2-Epoxyethane More...
Molecular Weight	44.05
Dates	Modify 2022-03-11 Create 2004-09-16

Ethylene Oxide is colorless, odorless, flammable, toxic gaseous cyclic ether with a sweet ether-like smell. Ethylene oxide is used especially in the synthesis of ethylene glycol and as a sterilizing agent for medical supplies and foods, as a fumigant and as an insecticide. Exposure to this substance is highly irritating to the eyes, skin and respiratory tract, induces nausea and vomiting and causes central nervous system depression. Ethylene oxide is mutagenic in humans and chronic exposure is associated with an increased risk of leukemia, stomach cancer, pancreatic cancer and non-Hodgkin lymphoma. (NCI05)

▸ NCI Thesaurus (NCIt)

Ethylene oxide appears as a clear colorless gas with an ethereal odor with a flash point below 0°F. Liquid less dense than water. Vapors heavier than air. May polymerize exothermically if heated or contaminated. If the polymerization takes place inside a container, the container may rupture violently. Vapors very toxic. Vapors irritate the eyes, skin, and respiratory system. Prolonged skin contact may result in delayed burns. Used to make other chemicals, as a fumigant and industrial sterilant.

▸ CAMEO Chemicals

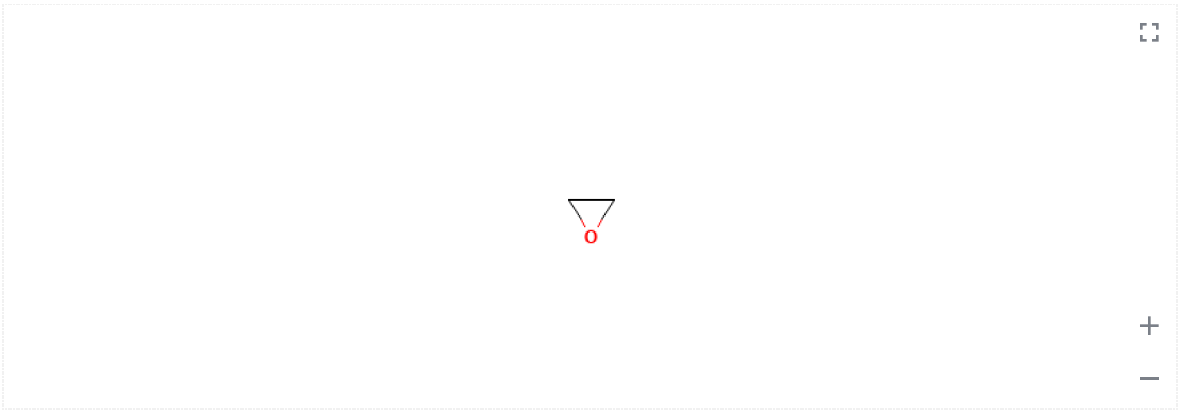
Ethylene oxide is a flammable gas with a somewhat sweet odor. It dissolves easily in water. Ethylene oxide is a man-made chemical that is used primarily to make ethylene glycol (a chemical used to make antifreeze and polyester). A small amount (less than 1%) is used to control insects in some stored agricultural products and a very small amount is used in hospitals to sterilize medical equipment and supplies.

▸ CDC-ATSDR Toxic Substances Portal

1 Structures

1.1 2D Structure

Chemical Structure Depiction



PubChem

1.2 3D Conformer

PubChem

1.3 Crystal Structures

CCDC Number	691554
Crystal Structure Data	DOI:10.5517/ccr6m6r
Crystal Structure Depiction	
Associated Article	DOI:10.1107/S0108768108010197
Associated Article	DOI:10.1021/jo102125n

The Cambridge Structural Database

2 Names and Identifiers

2.1 Computed Descriptors

2.1.1 IUPAC Name

oxirane

Computed by Lexichem TK 2.7.0 (PubChem release 2021.05.07)

PubChem

2.1.2 InChI

InChI=1S/C2H4O/c1-2-3-1/h1-2H2

Computed by InChI 1.0.6 (PubChem release 2021.05.07)

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2.1.3 InChI Key

IAYPIBMASNFSPL-UHFFFAOYSA-N

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2.1.4 Canonical SMILES

C1CO1

Computed by OEChem 2.3.0 (PubChem release 2021.05.07)

PubChem

2.2 Molecular Formula

C2H4O

CAMEO Chemicals; ILO International Chemical Safety Cards (ICSC); Wikipedia; PubChem

2.3 Other Identifiers

2.3.1 CAS

75-21-8

CAMEO Chemicals; CAS Common Chemistry; ChemIDplus; EPA Acute Exposure Guideline Levels (AEGLs); EPA Chemicals under the TSCA; EPA DSSTox; European Chemicals Agency (ECHA); Hazardous Substances Data Bank (H

2.3.2 Deprecated CAS

184288-32-2, 19034-08-3, 37341-05-2, 99932-75-9, 142175-32-4, 436859-78-8

ChemIDplus

2.3.3 European Community (EC) Number

200-849-9

European Chemicals Agency (ECHA)

2.3.4 ICSC Number

0155

ILO International Chemical Safety Cards (ICSC)

2.3.5 RTECS Number

KX2450000

The National Institute for Occupational Safety and Health (NIOSH)

2.3.6 UN Number

1040

CAMEO Chemicals; DOT Emergency Response Guidebook; ILO International Chemical Safety Cards (ICSC); NJDOH RTK Hazardous Substance List; The National Institute for Occupational Safety and Health (NIOSH)

2.3.7 UNII

JJH7GNN18P

FDA/SPL Indexing Data

2.3.8 DSSTox Substance ID

DTXSID0020600

EPA DSSTox

2.3.9 Wikipedia

Ethylene oxide

Wikipedia

2.3.10 NCI Thesaurus Code

C29821

NCI Thesaurus (NCIt)

2.4 Synonyms

2.4.1 MeSH Entry Terms

Ethylene Oxide
Oxide, Ethylene
Oxirane

Medical Subject Headings (MeSH)

2.4.2 Depositor-Supplied Synonyms

Oxirane	Oxidoethane	Qazi-ketcham	JJH7GNN18P	Etilene (ossido di)	epoxy ethane	MFCD00014482
ETHYLENE OXIDE	Oxyfume	oxyde d'ethylene	E.O.	HSDB 170	AI3-26263	Sterilizing gas ethyler
Epoxyethane	Aethylenoxid	FEMA No. 2433	epoxide or oxirane	Ethylene (oxyde d') [French]	Epitope ID:116215	AKOS009031564
75-21-8	1,2-Epoxyaethan	Rcra waste number U115	Oxiraan [Dutch]	Etilene (ossido di) [Italian]	EC 200-849-9	390-EP2272834A1
1,2-Epoxyethane	Merpol	ethyleneoxide	C2H4O	alpha,beta-Oxidoethane	.alpha.,.beta.-Oxidoethane	390-EP2275411A2
Oxacyclopropane	Oxiran	ethylenoxide	Aethylenoxid [German]	Ethylene (oxyde d')	Ethylene oxide, >=99.5%	390-EP2275417A2
Ethene oxide	Oxyfume 12	ETO	Caswell No. 443	EINECS 200-849-9	Ethylene oxide, >=99.9%	390-EP2277622A1
Dimethylene oxide	T-Gas	UNII-JJH7GNN18P	Ethyleenoxide [Dutch]	UN1040	CHEMBL1743219	390-EP2277865A1
Amprolene	Oxirene, Dihydro-	NCI-C50088	Ethox	RCRA waste no. U115	DTXSID0020600	390-EP2281816A1
Anprolene	Ethyleenoxide	ENT-26263	Etylenu tlenek [Polish]	EPA Pesticide Chemical Code 042301	Ethylene oxide (30% or less), propylene oxide mixture	390-EP2284162A2
Anproline	Oxiraan	UN 1040	1,2-Epoxyaethan [German]	monooxirane	Ethylene oxide, purum, >=99.8%	390-EP2284163A2
Dihydrooxirene	Etylenu tlenek	CHEBI:27561	CCRIS 297	ethylene-oxide	c0527	390-EP2289880A1

PubChem

3 Chemical and Physical Properties

3.1 Computed Properties

Property Name	Property Value	Reference
Molecular Weight	44.05	Computed by PubChem 2.1 (PubChem release 2021.05.07)
XLogP3-AA	-0.1	Computed by XLogP3 3.0 (PubChem release 2021.05.07)
Hydrogen Bond Donor Count	0	Computed by Cactvs 3.4.8.18 (PubChem release 2021.05.07)
Hydrogen Bond Acceptor Count	1	Computed by Cactvs 3.4.8.18 (PubChem release 2021.05.07)
Rotatable Bond Count	0	Computed by Cactvs 3.4.8.18 (PubChem release 2021.05.07)
Exact Mass	44.026214747	Computed by PubChem 2.1 (PubChem release 2021.05.07)
Monoisotopic Mass	44.026214747	Computed by PubChem 2.1 (PubChem release 2021.05.07)
Topological Polar Surface Area	12.5 Å²	Computed by Cactvs 3.4.8.18 (PubChem release 2021.05.07)
Heavy Atom Count	3	Computed by PubChem
Formal Charge	0	Computed by PubChem
Complexity	10.3	Computed by Cactvs 3.4.8.18 (PubChem release 2021.05.07)
Isotope Atom Count	0	Computed by PubChem
Defined Atom Stereocenter Count	0	Computed by PubChem
Undefined Atom Stereocenter Count	0	Computed by PubChem
Defined Bond Stereocenter Count	0	Computed by PubChem
Undefined Bond Stereocenter Count	0	Computed by PubChem
Covalently-Bonded Unit Count	1	Computed by PubChem
Compound Is Canonicalized	Yes	Computed by PubChem (release 2021.05.07)

PubChem

3.2 Experimental Properties

3.2.1 Physical Description

Ethylene oxide appears as a clear colorless gas with an ethereal odor with a flash point below 0°F. Liquid less dense than water. Vapors heavier than air. May polymerize exothermically if heated or contaminated. If the polymerization takes place inside a container, the container may rupture violently. Vapors very toxic. Vapors irritate the eyes, skin, and respiratory system. Prolonged skin contact may result in delayed burns. Used to make other chemicals, as a fumigant and industrial sterilant.

CAMEO Chemicals

GasVapor; Liquid

EPA Chemicals under the TSCA

COLOURLESS COMPRESSED LIQUEFIED GAS WITH CHARACTERISTIC ODOUR.

ILO International Chemical Safety Cards (ICSC)

Colorless gas or liquid (below 51°F) with an ether-like odor.

Occupational Safety and Health Administration (OSHA); The National Institute for Occupational Safety and Health (NIOSH)

3.2.2 Color/Form

Colorless ... gas at ordinary room temp and pressure; liquid below 12 °C

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 2006., p. 651

Hazardous Substances Data Bank (HSDB)

Colorless gas or liquid (below 51 degrees F) ...

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005)

Hazardous Substances Data Bank (HSDB)

3.2.3 Odor

Sweet

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

Reminiscent of bruised apples

Reynolds, J.E.F., Prasad, A.B. (eds.) Martindale-The Extra Pharmacopoeia. 28th ed. London: The Pharmaceutical Press, 1982., p. 562

Hazardous Substances Data Bank (HSDB)

... Ether-like odor

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005)

- **Hazardous Substances Data Bank (HSDB)**

3.2.4 Boiling Point

51.3 °F at 760 mm Hg (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

- **CAMEO Chemicals**

10.6 °C

- **EPA DSSTox; Hazardous Substances Data Bank (HSDB)**

11 °C

- **ILO International Chemical Safety Cards (ICSC)**

51°F

- **Occupational Safety and Health Administration (OSHA); The National Institute for Occupational Safety and Health (NIOSH)**

3.2.5 Melting Point

-170.5 °F (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

- **CAMEO Chemicals**

-111.7 °C

- **EPA DSSTox; Hazardous Substances Data Bank (HSDB)**

-111 °C

- **ILO International Chemical Safety Cards (ICSC)**

-171°F

- **Occupational Safety and Health Administration (OSHA); The National Institute for Occupational Safety and Health (NIOSH)**

3.2.6 Flash Point

-0.4 to 0 °F (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

- **CAMEO Chemicals**

-20 °F (-29 °C) (closed cup)

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 325-62

- **Hazardous Substances Data Bank (HSDB)**

-18 °C (open cup)

Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V6 997

- **Hazardous Substances Data Bank (HSDB)**

Flammable gas

- **ILO International Chemical Safety Cards (ICSC)**

-20°F

- **Occupational Safety and Health Administration (OSHA)**

NA (Gas) -20°F (Liquid)

- **The National Institute for Occupational Safety and Health (NIOSH)**

3.2.7 Solubility

Miscible (NTP, 1992)

National Toxicology Program, Institute of Environmental Health Sciences, National Institutes of Health (NTP). 1992. National Toxicology Program Chemical Repository Database. Research Triangle Park, North Carolina.

- **CAMEO Chemicals**

22.70 M

SCHULTZE,HC (1965)

EPA DSSTox

Soluble in benzene, acetone, ethanol, ether

Lide, D.R., G.W.A. Milne (eds.). Handbook of Data on Organic Compounds. Volume I. 3rd ed. CRC Press, Inc. Boca Raton ,FL. 1994., p. V4: 3793

Hazardous Substances Data Bank (HSDB)

Miscible with... carbon tetrachloride.

Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V6: 997

Hazardous Substances Data Bank (HSDB)

Miscible with water

Schultze HC; in Kirk-Othmer Encyclopedia of Chemical Technology. 2nd ed., New York, NY: John Wiley and Sons, V8: 523-8 (1965)

Hazardous Substances Data Bank (HSDB)

Solubility in water: miscible

ILO International Chemical Safety Cards (ICSC)

Miscible

The National Institute for Occupational Safety and Health (NIOSH)

3.2.8 Density

0.8222 at 50 °F (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

0.882 at 10 °C/10 °C

Lide, D.R., G.W.A. Milne (eds.). Handbook of Data on Organic Compounds. Volume I. 3rd ed. CRC Press, Inc. Boca Raton ,FL. 1994., p. V4: 3793

Hazardous Substances Data Bank (HSDB)

Relative density (water = 1): 0.9

ILO International Chemical Safety Cards (ICSC)

0.82 (liquid at 50°F)

Occupational Safety and Health Administration (OSHA)

0.82 (Liquid at 50°F)

The National Institute for Occupational Safety and Health (NIOSH)

1.49(relative gas density)

The National Institute for Occupational Safety and Health (NIOSH)

3.2.9 Vapor Density

1.49 (EPA, 1998) (Relative to Air)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

1.49

Celanese Chemical Co Inc, Product Bulletin Sheet 1978 as cited in Environment Canada; Tech Info for Problem Spills: Ethylene oxide p.3 (1982)

Hazardous Substances Data Bank (HSDB); Occupational Safety and Health Administration (OSHA)

Relative vapor density (air = 1): 1.5

ILO International Chemical Safety Cards (ICSC)

3.2.10 Vapor Pressure

1095 mm Hg at 68 °F (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

1.31e+03 mmHg

EPA DSSTox

1,310 mm Hg at 25 °C (extrapolated)

Daubert, T.E., R.P. Danner. Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, D.C.: Taylor and Francis, 1989.

Hazardous Substances Data Bank (HSDB)

Vapor pressure, kPa at 20 °C: 146

ILO International Chemical Safety Cards (ICSC)

1.46 atm

Occupational Safety and Health Administration (OSHA); The National Institute for Occupational Safety and Health (NIOSH)

3.2.11 LogP

-0.3 (LogP)

HANSCH,C ET AL. (1995)

EPA DSSTox

log Kow = -0.30

Hansch, C., Leo, A., D. Hoekman. Exploring QSAR - Hydrophobic, Electronic, and Steric Constants. Washington, DC: American Chemical Society., 1995., p. 4

Hazardous Substances Data Bank (HSDB)

-0.3

ILO International Chemical Safety Cards (ICSC)

3.2.12 Henrys Law Constant

1.48e-04 atm-m3/mole

EPA DSSTox

Henry's Law constant = 1.48X10-4 atm-cu m/mol at 25 °C

Conway RA et al; Environ Sci Technol 17: 107-112 (1983)

Hazardous Substances Data Bank (HSDB)

3.2.13 Atmospheric OH Rate Constant

7.60e-14 cm3/molecule*sec

ATKINSON,R (1989)

EPA DSSTox

3.2.14 Stability/Shelf Life

HYDROLYZES SLOWLY IN AQ SOLN

Sunshine, I. (ed.). CRC Handbook of Analytical Toxicology. Cleveland: The Chemical Rubber Co., 1969., p. 517

Hazardous Substances Data Bank (HSDB)

STABLE IN WATER

Worthing, C. R. (ed.). Pesticide Manual. 6th ed. Worcestershire, England: British Crop Protection Council, l979., p. 236

Hazardous Substances Data Bank (HSDB)

3.2.15 Autoignition Temperature

804 °F (USCG, 1999)

U.S. Coast Guard. 1999. Chemical Hazard Response Information System (CHRIS) - Hazardous Chemical Data. Commandant Instruction 16465.12C. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

804 °F (429 °C)

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 325-62

Hazardous Substances Data Bank (HSDB)

429 °C

ILO International Chemical Safety Cards (ICSC)

3.2.16 Decomposition

Liquid ethylene oxide is not detonable, but the vapor may be readily initiated into explosive decomposition.

Bretherick, L. Handbook of Reactive Chemical Hazards. 4th ed. Boston, MA: Butterworth-Heinemann Ltd., 1990, p. 272

Hazardous Substances Data Bank (HSDB)

Explosive decomposition may occur.

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 49-76

▸ Hazardous Substances Data Bank (HSDB)

Decompostion products are explosive.

ITII. Toxic and Hazardous Industrial Chemicals Safety Manual. Tokyo, Japan: The International Technical Information Institute, 1988., p. 666

▸ Hazardous Substances Data Bank (HSDB)

3.2.17 Viscosity

9.45X10-3 mPa.s (25 °C, gas) and 0.254 mPa.s (10 °C, liquid)

Matheson Gas Prod; Tech Info for Problem Spills: Ethylene oxide p.4 (1982)

▸ Hazardous Substances Data Bank (HSDB)

3.2.18 Heat of Combustion

1280.9 kJ/mol (liquid); 1306.1 kJ/mol (gas)

Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 75th ed. Boca Raton, FL: CRC Press Inc., 1994-1995., p. 5-76

▸ Hazardous Substances Data Bank (HSDB)

3.2.19 Heat of Vaporization

24.75 kJ/mol at 25 °C

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005), p. 6-109

▸ Hazardous Substances Data Bank (HSDB)

3.2.20 Ionization Potential

10.56 eV

▸ Occupational Safety and Health Administration (OSHA); The National Institute for Occupational Safety and Health (NIOSH)

3.2.21 Polymerization

Precautions designed to prevent explosive polymerization of ethylene oxide are discussed, including rigid exclusion of acids, covalent halides such as **aluminium**, **iron (III)**, and **tin (IV) chloride**, basic materials like alkali hydroxides, **ammonia**, amines, metallic **potassium**, and catalytically active solids such as **aluminium** or iron oxides or rust.

Bretherick, L. Handbook of Reactive Chemical Hazards. 4th ed. Boston, MA: Butterworth-Heinemann Ltd., 1990, p. 274

▸ Hazardous Substances Data Bank (HSDB)

Polymerization is catalyzed by a number of materials, such as acids, alkalis, some carbonates, oxides of **iron** and **aluminum**, and chlorides of **iron**, **tin**, **aluminum**, and **boron**. No **acetylide**-forming metals such as **copper** or **copper** alloys should be in contact with ethylene oxide.

Clayton, G. D. and F. E. Clayton (eds.). Patty's Industrial Hygiene and Toxicology: Volume 2A, 2B, 2C: Toxicology. 3rd ed. New York: John Wiley Sons, 1981-1982., p. 2166

▸ Hazardous Substances Data Bank (HSDB)

Accidental contamination of an ethylene oxide feed tank by **ammonia** caused violently explosive polymerization.

Bretherick, L. Handbook of Reactive Chemical Hazards. 4th ed. Boston, MA: Butterworth-Heinemann Ltd., 1990, p. 273

▸ Hazardous Substances Data Bank (HSDB)

It is relatively stable in aqueous solutions or when diluted with **carbon dioxide** or halocarbons, but it may undergo slow polymerization during storage.

*DHHS/NTP; SUBSTANCE PROFILES REPORT ON CARCINOGENS, ELEVENTH EDITION: Ethylene Oxide CAS No. 75-21-8 p.1. Available from, as of July 23, 2008: **https://ntp.niehs.nih.gov/***

▸ Hazardous Substances Data Bank (HSDB)

3.2.22 Odor Threshold

Recognition: 1.5 mg/cu m= 0.8 ppm, mean detection concn: 700 ppm; absolute perception limit: 260 ppm; 50% recognition: 500 ppm; 100% recognition: 500 ppm

Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 654

▸ Hazardous Substances Data Bank (HSDB)

Low: 520 mg/cu m; High: 1400 mg/cu m

Ruth JH; Am Ind Hyg Assoc J 47: A-142-51 (1986)

▸ Hazardous Substances Data Bank (HSDB)

300 ppm in air

Hayes, W.J., Jr., E.R. Laws, Jr., (eds.). Handbook of Pesticide Toxicology. Volume 2. Classes of Pesticides. New York, NY: Academic Press, Inc., 1991., p. 663

▸ Hazardous Substances Data Bank (HSDB)

3.2.23 Refractive Index

Inex of refraction: 1.3597 at 7 °C/D

Lide, D.R., G.W.A. Milne (eds.). Handbook of Data on Organic Compounds. Volume I. 3rd ed. CRC Press, Inc. Boca Raton ,FL. 1994., p. V4: 3793

Hazardous Substances Data Bank (HSDB)

3.2.24 Kovats Retention Index

Standard non-polar	417, 417, 405.3, 405, 400, 405, 400
Semi-standard non-polar	397, 410
Standard polar	680

NIST Mass Spectrometry Data Center

3.2.25 Other Experimental Properties

Heat of solution in water: 142.57 kJ/kg @ 25 °C

Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed.Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present., p. VA10: 118 (1987)

Hazardous Substances Data Bank (HSDB)

CAN REACT WITH OXIDIZING MATERIALS

Sax, N.I. Dangerous Properties of Industrial Materials. 4th ed. New York: Van Nostrand Reinhold, 1975., p. 741

Hazardous Substances Data Bank (HSDB)

Ratio of specific heats of vapor (gas): 1.212

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

For more Other Experimental Properties (Complete) data for ETHYLENE OXIDE (8 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

3.3 SpringerMaterials Properties

Schoenflies notation	Dispersion	Magnetic susceptibility	Sound absorption
Absorbance	Dissociation energy	Melting temperature	Sound propagation
Atomic environment	Electric dipole moment	Mixing enthalpy	Sound velocity
Boiling point	Energy	Molecular dipole moment	Surface tension
Bond type	Excess enthalpy	Molecular structure	Transition enthalpy
Chemical bond	Fusion temperature	Moment of inertia	Vapor pressure
Chemical diffusion	Heat of solution	Optical coefficient	Vapor-liquid equilibrium
Chemical shift	Heat of sublimation	Phase diagram	Vibrational mode frequency
Density	Hindering potential	Phase equilibrium	Virial coefficient
Diamagnetic susceptibility	Internuclear distance	Phase transition	Viscosity
Dielectric constant	Lineshape	Point group	
Diffusion	Magnetic anisotropy	Refractive index	
Diffusive flux	Magnetic permeability	Rotational excitation cross section	

SpringerMaterials

4 Spectral Information

4.1 1D NMR Spectra

1D NMR Spectra	1D NMR Spectrum 2613 - Ethylene oxide (HMDB0255987)

▸ Human Metabolome Database (HMDB)

1D NMR Spectra	NMRShiftDB Link

▸ NMRShiftDB

4.1.1 13C NMR Spectra

Showing 2 of 3 View More

13C NMR Spectra	13C NMR: 270 (Stothers, Carbon-13 NMR Spectroscopy, Academic Press, New York)

▸ Hazardous Substances Data Bank (HSDB)

Source of Sample	D. R. Paulson, F. Y. Tang, G. F. Moran J. Org. Chem. 40, 184(1975)
Copyright	Copyright © 1980, 1981-2021 John Wiley & Sons, Inc. All Rights Reserved.
Thumbnail	

▸ SpectraBase

4.1.2 17O NMR Spectra

Copyright	Copyright © 2016-2021 W. Robien, Inst. of Org. Chem., Univ. of Vienna. All Rights Reserved.
Thumbnail	

▸ SpectraBase

Copyright	Copyright © 2016-2021 W. Robien, Inst. of Org. Chem., Univ. of Vienna. All Rights Reserved.
Thumbnail	

SpectraBase

4.2 Mass Spectrometry

4.2.1 GC-MS

Showing 2 of 6 View More

MoNA ID	JP001575
MS Category	Experimental
MS Type	GC-MS
MS Level	MS1
Instrument	HITACHI RMU-5B
Instrument Type	EI-B
Ionization Mode	positive
Top 5 Peaks	29 100 44 61.8 15 54.2 14 21.8 43 15.7
SPLASH	splash10-00ou-9000000000-5d524d3951f924d0d702
Thumbnail	
Submitter	University of Tokyo Team, Faculty of Engineering, University of Tokyo

MassBank of North America (MoNA)

NIST Number	18867
Library	Main library
Total Peaks	24
m/z Top Peak	29
m/z 2nd Highest	15
m/z 3rd Highest	44
Thumbnail	

NIST Mass Spectrometry Data Center

4.2.2 EI-MS

EI-MS	EI-MS Spectrum 482 - Ethylene oxide (HMDB0255987)

▸ Human Metabolome Database (HMDB)

4.2.3 Other MS

Other MS	MASS: 61296 (NIST/EPA/MSDC Mass Spectral Database, 1990 version)

▸ Hazardous Substances Data Bank (HSDB)

Accession ID	JP001575
Authors	MASS SPECTROSCOPY SOC. OF JAPAN (MSSJ)
Instrument	HITACHI RMU-5B
Instrument Type	EI-B
MS Level	MS
Ionization Mode	POSITIVE
Ionization	ENERGY 80 eV
Top 5 Peaks	29 999 44 618 15 542 14 218 43 157
SPLASH	splash10-00ou-9000000000-5d524d3951f924d0d702
Thumbnail	
License	CC BY-NC-SA

▸ MassBank Europe

4.3 UV Spectra

MAX ABSORPTION (GAS): 169 NM (LOG E= 3.58); 171 NM (LOG E= 3.57)

Weast, R.C. (ed.). Handbook of Chemistry and Physics. 60th ed. Boca Raton, Florida: CRC Press Inc., 1979., p. C-293

▸ Hazardous Substances Data Bank (HSDB)

UV: HBCP 171

Lide, D.R., G.W.A. Milne (eds.). Handbook of Data on Organic Compounds. Volume I. 3rd ed. CRC Press, Inc. Boca Raton ,FL. 1994., p. V4: 3793

▸ Hazardous Substances Data Bank (HSDB)

4.4 IR Spectra

IR Spectra	IR: 1109 (Sadtler Research Laboratories Prism Collection)

▸ Hazardous Substances Data Bank (HSDB)

4.4.1 Vapor Phase IR Spectra

Instrument Name	DIGILAB FTS-14
Technique	Vapor Phase
Copyright	Copyright © 1980, 1981-2021 John Wiley & Sons, Inc. All Rights Reserved.
Thumbnail	

SpectraBase

Technique	Vapor Phase
Source of Spectrum	Sigma-Aldrich Co. LLC.
Source of Sample	Aldrich
Catalog Number	387614
Copyright	Copyright © 2018-2021 Sigma-Aldrich Co. LLC. - Database Compilation Copyright © 2018-2021 John Wiley & Sons, Inc. All Rights Reserved.
Thumbnail	

SpectraBase

4.5 Raman Spectra

Raman Spectra	Raman: 191 (American Petroleum Insitute spectral collection)

Hazardous Substances Data Bank (HSDB)

4.6 Other Spectra

LIQ IS LIGHTER THAN WATER, VAPOR IS HEAVIER THAN AIR

Fire Protection Guide to Hazardous Materials. 12 ed. Quincy, MA: National Fire Protection Association, 1997., p. 49-68

Hazardous Substances Data Bank (HSDB)

5 Related Records

5.1 Related Compounds with Annotation

PubChem

5.2 Related Compounds

Same Connectivity	14 Records
Same Parent, Connectivity	94 Records
Same Parent, Exact	80 Records
Mixtures, Components, and Neutralized Forms	3,585 Records
Similar Compounds	56 Records
Similar Conformers	236 Records

PubChem

5.3 Substances

5.3.1 Related Substances

All	5,501 Records
Same	182 Records
Mixture	5,319 Records

PubChem

5.3.2 Substances by Category

PubChem

5.4 Entrez Crosslinks

PubMed	1,647 Records
Taxonomy	4 Records
OMIM	7 Records
Gene	14 Records

PubChem

- NCBI

- PubChem

7 Drug and Medication Information

7.1 Clinical Trials

7.1.1 ClinicalTrials.gov

- ClinicalTrials.gov

8 Food Additives and Ingredients

8.1 Food Additive Classes

JECFA Functional Classes

Food Additives -> PRESERVATIVE;

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

8.2 FDA Substances Added to Food

Substance	ETHYLENE OXIDE--NLFG
Used for (Technical Effect)	FUMIGANT
Document Number (21 CFR)	172.710 172.808 175.105 176.180 176.210 177.2470 178.3520

FDA Center for Food Safety and Applied Nutrition (CFSAN)

8.3 FDA Indirect Additives used in Food Contact Substances

Indirect Additives	ETHYLENE OXIDE--NLFG
Title 21 of the U.S. Code of Federal Regulations (21 CFR)	172.710 172.808 175.105 176.180 176.210 177.2470 178.3520

FDA Center for Food Safety and Applied Nutrition (CFSAN)

8.4 Evaluations of the Joint FAO/WHO Expert Committee on Food Additives - JECFA

Chemical Name	ETHYLENE OXIDE
Evaluation Year	1958

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

9 Agrochemical Information

9.1 EU Pesticides Data

Active Substance	ethylene oxide
Status	Not approved [Reg. (EC) No 1107/2009]

EU Pesticides Database

10 Pharmacology and Biochemistry

10.1 MeSH Pharmacological Classification

Disinfectants

Substances used on inanimate objects that destroy harmful microorganisms or inhibit their activity. Disinfectants are classed as complete, destroying SPORES as well as vegetative forms of microorganisms, or incomplete, destroying only vegetative forms of the organisms. They are distinguished from ANTISEPTICS, which are local anti-infective agents used on humans and other animals. (From Hawley's Condensed Chemical Dictionary, 11th ed) (See **all compounds classified as Disinfectants**.)

▸ Medical Subject Headings (MeSH)

10.2 Absorption, Distribution and Excretion

The study reported here examined the dosimetry of ethylene oxide (EO) in male B6C3F1 mice by direct determination of blood EO concentrations. Steady-state blood EO concentrations were measured during a single 4-hr nose-only inhalation exposure (0, 50, 100, 200, 300, or 400 ppm EO). In addition, **glutathione** (**GSH**) concentrations were measured in liver, lung, kidney, and testis to assess the role of the **GSH** depletion in the saturable metabolism previously observed in mice. Blood EO concentrations were found to increase linearly with exposure concentration up to 200 ppm. Markedly sublinear blood dosimetry was observed at exposure concentrations exceeding 200 ppm. An EO exposure concentration-dependent reduction in tissue **GSH** levels was observed, with both liver and lung **GSH** levels significantly depressed at EO exposure concentrations of 100 ppm or greater. /The/ results also indicate that depletion of **GSH** is likely responsible for nonlinear dosimetry of EO in mice and that **GSH** depletion corresponds with reports of dose-rate effects in mice exposed to EO.

PMID:9473528

Brown CD et al; Toxicol Appl Pharmacol 148 (2): 215-21 (1998)

▸ Hazardous Substances Data Bank (HSDB)

... The objectives of this study were to examine the relationship between cigarette smoking and hemoglobin adducts derived from ... EO and to investigate whether null genotypes for **glutathione** transferase (GSTM1 and GSTT1) alter the internal dose of these agents. The hemoglobin adduct ... **N-(2-hydroxyethyl)valine** (HEVal), which is formed from EO, and GST genotypes were determined in blood samples obtained from 16 nonsmokers and 32 smokers (one to two packs/day). Smoking information was obtained by questionnaire, and plasma **cotinine** levels were determined by immunoassay. **Glutathione** transferase null genotypes (GSTM1 and GSTT1) were determined by PCR. ... HEVal levels increased with increased cigarette smoking dose (both self-reported and **cotinine**-based). ... HEVal levels were also correlated. ... GSTM1 null genotypes had no significant impact on HEVal. However, HEVal levels were significantly elevated in GSTT1-null individuals when normalized to smoking status or **cotinine** levels. ... The lack of a functional GSTT1 is estimated to increase the internal dose of EO derived from cigarette smoke by 50-70%.

PMID:10919741

Fennell TR et al; Cancer Epidemiol Biomarkers Prev 9 (7): 705-12 (2000)

▸ Hazardous Substances Data Bank (HSDB)

AFTER EXPOSURE OF MICE TO MIXT OF 1,2-(3)H-ETHYLENE OXIDE VAPOR IN AIR FOR 75 MIN, 90-95% OF RADIOACTIVITY WAS ELIMINATED IN 24 HR. HIGHEST CONCN OF RESIDUAL RADIOACTIVITY WERE FOUND IN PROTEIN FRACTIONS OF SPLEEN; SMALLER AMT OCCURRED IN LIVER, KIDNEY, LUNG & TESTIS.

*IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: **https://monographs.iarc.fr/ENG/Classification/index.php**, p. V11 162 (1976)*

▸ Hazardous Substances Data Bank (HSDB)

Iv injection of (14)C-labeled ethylene oxide indicated that (14)C concn in the testicle, epididymis and other organs were higher than those in the blood when measured 20 min to 4 hr after exposure. Radioactivity was still present in the epididymis 24 hr after exposure had ended.

Appelgren LE et al; Europ Soc Toxicol 18: 315 (1977)

▸ Hazardous Substances Data Bank (HSDB)

For more Absorption, Distribution and Excretion (Complete) data for ETHYLENE OXIDE (11 total), please visit the **HSDB record page**.

▸ Hazardous Substances Data Bank (HSDB)

10.3 Metabolism/Metabolites

Ethylene oxide reacts with **glutathione** to form **cysteine** derivatives, forms **ethylene glycol** by epoxide hydrolase with subsequent metabolism of the glycol, and reacts with **chloride** to form **2-chloroethanol**. The relative importance of these pathways is undefined. **Ethylene glycol glutathione** conjugates are metabolites of ethylene oxide. ...

Dart, R.C. (ed). Medical Toxicology. Third Edition, Lippincott Williams & Wilkins. Philadelphia, PA. 2004., p. 1244

▸ Hazardous Substances Data Bank (HSDB)

In adult male Sprague-Dawley rats, male Swiss CD-1 mice, and male rabbits, 20 or 60 mg/kg ethylene oxide as a solution in distilled **water** was injected into the caudal vein in rats and mice or in the marginal vein in rabbits. Some animals were exposed to 200 ppm ethylene oxide in inhalation chambers. The animals were housed in metabolism cages, and urine samples were collected at 0-6 hr and 6-24 hr. The urine samples were analyzed for **2-hydroxyethylmercapturic acid**, **N-acetyl-S-carboxy-methyl-L cysteine**, **S-(2-hydroxyethyl)-L-cysteine**, **S-carboxymethyl-L-cysteine**, and **ethylene glycol**. Species-related differences in the metabolic disposition of ethylene oxide were observed. Excretion product patterns did not differ significantly between injected doses. Rats (n= 5) eliminated 37% of ethylene oxide as **2-hydroxyethylmercapturic acid** (31%) and **ethylene glycol** (6%); mice (n= 10) converted 19.3% of the ethylene oxide to **2-hydroxyethylmercapturic acid** (8.3%), **S-2-hydroxyethyl-L-cysteine** (5.8%), **S-carboxymethyl-L-cysteine** (1.9%), and **ethylene glycol** (3.3%). The rabbits (n= 3) excreted only 2% of the ethylene oxide, primarily as **ethylene glycol**. In rats, larger amounts of **2-hydroxyethylmercapturic acid** were excreted in the 6-24 hr period, and larger amounts of **ethylene glycol** were excreted in the 0-6 hr period. In mice, equal amounts of 3-hydroxyethylmercapturic acid were excreted in the two collection periods and larger amounts of **ethylene glycol** were excreted in the 6-24 hr period. No urine was voided by the rabbits in the 0-6 hr period. No qualitative differences in urinary metabolite excretion of ethylene oxide were observed relative to the method of exposure.

PMID:3692004

Tardif R et al; Fundam Appl Toxicol 9 (3): 448-53 (1987)

▸ Hazardous Substances Data Bank (HSDB)

In the presence of **water** and **chloride**, ethylene oxide is hydrolyzed to **2-chloroethanol** and **ethylene glycol**. The glycol is further metabolized to **oxalate**, **formic acid** and CO2.

*European Chemicals Bureau; IUCLID Dataset, Ethylene Oxide (CAS # 75-21-8) p. 155 (2000 CD-ROM edition). Available from, as of July 9, 2008: **https://esis.jrc.ec.europa.eu/***

▸ Hazardous Substances Data Bank (HSDB)

Within 24 hours following iv treatment 35% of the administered doses ranging from 1 to 10 mg/kg to the rat were excreted as **2-hydroxyethyl-mercapturic acid** (2-**HEMA**) in the urine. After inhalation exposure to different ethylene oxide concentrations, the 2-**HEMA** levels determined in 24 hr-urine were linearly related to ethylene oxide exposure levels.

European Chemicals Bureau; IUCLID Dataset, Ethylene Oxide (CAS # 75-21-8) p. 155 (2000 CD-ROM edition). Available from, as of July 9, 2008: ***https://esis.jrc.ec.europa.eu/***

Hazardous Substances Data Bank (HSDB)

In animals and humans, there are two routes of ethylene oxide catabolism, both of which are considered to be detoxification pathways. The first involves hydrolysis to **ethylene glycol**, with subsequent conversion to **oxalic acid**, **formic acid**, and **carbon dioxide**. The second involves conjugation with **glutathione**, with subsequent metabolic steps yielding **S-(2-hydroxyethyl)cysteine** (S-(2-carboxymethyl)cysteine) and N-acetylated derivatives (ie, **N-acetyl-S-(2-hydroxyethyl)cysteine** (and **N-acetyl-S-(2-carboxymethyl)cysteine**)) ... . The route involving conjugation with **glutathione** appears to predominate in rats and mice; in larger species (rabbits, dogs), the conversion of ethylene oxide is primarily via hydrolysis through **ethylene glycol** ... . Ethylene oxide may also be formed from the metabolism of **ethylene** ... . A physiologically based pharmacokinetic (PBPK) model for the dosimetry of inhaled ethylene oxide was first developed for rats and included binding of ethylene oxide to hemoglobin and DNA in addition to tissue distribution, metabolic pathways (ie, hydrolysis by epoxide hydrolase and conjugation by **glutathione**-S-transferase), and depletion of hepatic and extra-hepatic **glutathione** ... . The model was then refined and extended to mice and humans ... . Simulations indicate that in mice, rats, and humans, about 80%, 60%, and 20%, respectively, would be metabolized via **glutathione** conjugation ... . This is consistent with observed levels of theta-class **glutathione** S-transferase (GSTT1) enzyme activity in the order mice > rats > humans. In rats and mice, GSTT1 activity was highest in the liver, followed by the kidney and testes. Rat brain and rat and mouse lung contained small amounts of activity compared with other tissues (enzyme activity in mouse brain was not examined). Ethylene oxide is a substrate for the human GSTT1 enzyme ... .

International Programme on Chemical Safety; Concise International Chemical Assessment Document Number 54: ETHYLENE OXIDE (2003). Available from, as of July 22, 2008: ***https://www.inchem.org/pages/cicads.html***

Hazardous Substances Data Bank (HSDB)

10.4 Biological Half-Life

Labeled ethylene oxide is primarily excreted in urine and a half-life of approximately 10 min was estimated for the first-order clearance of ethylene oxide in rodents.

USEPA/OPPTS; Revised Ethylene Oxide HED Risk Assessment for Reregistration Eligibility Document (RED) p.9 EPA-HQ-OPP-2005-0203-0100 (May 2007). Available from, as of July 21, 2008: ***https://www.regulations.gov/search/Regs/home.html#home***

Hazardous Substances Data Bank (HSDB)

The elimination half life is estimated at 40 to 55 minutes in humans.

Dart, R.C. (ed). Medical Toxicology. Third Edition, Lippincott Williams & Wilkins. Philadelphia, PA. 2004., p. 1244

Hazardous Substances Data Bank (HSDB)

10.5 Mechanism of Action

Ethylene oxide is an electrophilic agent that alkylates nucleophilic groups in biological macromolecules .... Since ethylene oxide is formed during the metabolism of **ethylene**, a natural body constituent, endogenous as well as exogenous sources of ethylene and ethylene oxide contribute to background alkylation of proteins such as hemoglobin and albumin, as well as DNA ... . **N-(2-Hydroxyethyl)valine** (HEVal) and hydroxyethylhistidine (HEHis) adducts have been frequently monitored in tissues of workers exposed to ethylene oxide in occupational settings ... . Background levels of HEVal in non-smokers ranged from 9 to 188 pmol/g globin ... Studies of smokers exposed to ethylene oxide in cigarette smoke ... and occupationally exposed workers ... have revealed higher levels of hemoglobin HEVal adducts among individuals with a GSTT1 null genotype (ie, homozygous deletion of GSTT1 gene) than among those with a GSTT1 positive genotype (ie, having at least one copy of the GSTT1 gene). ...

International Programme on Chemical Safety; Concise International Chemical Assessment Document Number 54: ETHYLENE OXIDE (2003). Available from, as of July 22, 2008: ***https://www.inchem.org/pages/cicads.html***

Hazardous Substances Data Bank (HSDB)

Ethylene oxide binding to DNA results primarily in the formation of **7-(2-hydroxyethyl)guanine** (7-HEGua) ... . In DNA extracted from the lymphocytes of unexposed individuals, mean background levels of 7-HEGua ranged from 2 to 8.5 pmol/mg DNA ... Human tissue contains 10- to 15-fold higher levels of endogenous 7-HEGua than rodent tissue. ... In mice, half-lives for the removal of 7-HEGua in DNA from a variety of tissues (brain, lung, spleen, liver, and testes) were 1.5- to 3.9-fold lower than in rats ... . In both rats and mice, substantive depletion of **glutathione** pools has been observed following single exposure to high levels (ie, > 550 mg/cu m) of ethylene oxide ... although it should be noted that increases in tumour incidence have been observed at lower concentrations. ...

International Programme on Chemical Safety; Concise International Chemical Assessment Document Number 54: ETHYLENE OXIDE (2003). Available from, as of July 22, 2008: ***https://www.inchem.org/pages/cicads.html***

Hazardous Substances Data Bank (HSDB)

The /physiologically based pharmacokinetic (PBPK)/ models for rats, mice, and humans are qualitatively similar in their elements and provide for interspecies comparisons of internal ethylene oxide dose. The models are consistent with the conclusion that ethylene oxide is acting as a direct-acting alkylating agent in humans and rodents. Quantitative differences in response in biomarkers of exposure and effect are accounted for by differences in basic physiology between rodents and humans, rather than by factors suggesting a different mode of action.

International Programme on Chemical Safety; Concise International Chemical Assessment Document Number 54: ETHYLENE OXIDE (2003). Available from, as of July 22, 2008: ***https://www.inchem.org/pages/cicads.html***

Hazardous Substances Data Bank (HSDB)

Evidence for a common mechanism of carcinogenesis in humans and experimental animals comes from studies that have demonstrated similar genetic damage in cells of exposed animals and workers. The DNA damaging activity of ethylene oxide provides its effectiveness as a sterilant, and it is this same property that accounts for its carcinogenic risk to humans.

DHHS/NTP; SUBSTANCE PROFILES REPORT ON CARCINOGENS, ELEVENTH EDITION: Ethylene Oxide CAS No. 75-21-8 p.1. Available from, as of July 23, 2008: ***https://ntp.niehs.nih.gov/***

Hazardous Substances Data Bank (HSDB)

10.6 Biochemical Reactions

PubChem

11 Use and Manufacturing

11.1 Uses

Ethylene oxide is used mainly as a chemical intermediate in the manufacture of **ethylene glycol** (antifreeze), textiles, detergents, **polyurethane** foam, solvents, medicine, adhesives, and other products.

Relatively small amounts of ethylene oxide are used as a fumigant, as a sterilant for food (spices) and cosmetics, and in hospital sterilization of surgical equipment and plastic devices that cannot be sterilized by steam.

- EPA Air Toxics

EPA CPDat Chemical and Product Categories

*The Chemical and Products Database, a resource for exposure-relevant data on chemicals in consumer products, Scientific Data, volume 5, Article number: 180125 (2018), **DOI:10.1038/sdata.2018.125***

- EPA Chemical and Products Database (CPDat)

/In the/ manufacture of **ethylene glycol** and higher glycols, surfactants, **acrylonitrile**, ethanolamines; petroleum demulsifier; fumigant; rocket propellant; industrial sterilant (e.g., medical plastic tubing); fungicide.

Lewis, R.J. Sr.; Hawley's Condensed Chemical Dictionary 15th Edition. John Wiley & Sons, Inc. New York, NY 2007., p. 531

- Hazardous Substances Data Bank (HSDB)

For Ethylene oxide (USEPA/OPP Pesticide Code: 042301) ACTIVE products with label matches. /SRP: Registered for use in the U.S. but approved pesticide uses may change periodically and so federal, state and local authorities must be consulted for currently approved uses./

*National Pesticide Information Retrieval System's USEPA/OPP Chemical Ingredients Database on Ethylene Oxide (75-21-8). Available from, as of July 1, 2008: **https://npirspublic.ceris.purdue.edu/ppis/***

- Hazardous Substances Data Bank (HSDB)

ETO is an antimicrobial and conventional chemical. It is a biocide, Pesticide: fungicide, fumigant, herbicide, insecticide, rodenticide used to control the following pests: American foulbrood disease (Bacillus larvae), animal pathogenic bacteria, animal pathogenic fungi, bacteria, bacterial spores, Candida albicans, European foulbrood disease (Streptoccus pluton), Herpes simplex virus, Hew (FDA/BVM), unspecified microorganisms, Mycobacterium spp., Nosema apis, Pseudomonas spp., Rhinoviruses, storage microorganisms, stored product insects, wax moth. ... ETO is used to sterilize medical or laboratory equipment, pharmaceuticals, and aseptic packaging ... or to reduce microbial load on musical instruments, cosmetics, whole and ground spices or other seasoning materials ... and artifacts, archival material or library objects. In North Carolina, ETO is also used to fumigate beehive equipment (eg, woodenware boxes and frames) and wax or plastic combs that are contaminated with the bacteria Paenibacillus larvae, the cause of American Foulbrood Disease.

*USEPA/Office of Pesticide Programs; Reregistration Eligibility Decision Document - Ethylene Oxide p.14 EPA 738-R-08-003 (March 2008). Available from, as of July 21, 2008: **https://www.epa.gov/pesticides/reregistration/status.htm***

- Hazardous Substances Data Bank (HSDB)

ETO is used to sterilize new and reusable medical equipment (eg, surgical instruments, hypodermic needles/syringes, surgical prosthetic parts, hemodialysis machines, heart and lung machines, dental instruments, veterinary instruments, heat labile material, moisture labile material, oral and inhalation equipment, diagnostic instruments, thermometers, surgical dressings, first aid equipment). Approximately 7.4 million pounds are used annually for sterilization of medical and laboratory items/equipment. ... Despite the fact that there are several methods that are available to sterilize medical devices, no currently available sterilization treatment can replace ETO for some uses, including certain heat-sensitive and irradiation-sensitive materials and some instruments and devices that require sterilization on-site in hospitals.

*USEPA/Office of Pesticide Programs; Reregistration Eligibility Decision Document - Ethylene Oxide p.26 EPA 738-R-08-003 (March 2008). Available from, as of July 21, 2008: **https://www.epa.gov/pesticides/reregistration/status.htm***

- Hazardous Substances Data Bank (HSDB)

For more Uses (Complete) data for ETHYLENE OXIDE (20 total), please visit the **HSDB record page**.

- Hazardous Substances Data Bank (HSDB)

11.1.1 Use Classification

Hazardous Air Pollutants (HAPs)

- EPA Air Toxics

Food Additives -> PRESERVATIVE; -> JECFA Functional Classes

- Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Fire Hazards -> Carcinogens, Mutagens, Teratogens, Flammable - 4th degree, Reactive - 3rd degree

- NJDOH RTK Hazardous Substance List

11.1.2 Industry Uses

Finishing agents
Intermediates
Surface active agents

https://www.epa.gov/chemical-data-reporting

EPA Chemicals under the TSCA

11.1.3 Consumer Uses

Adhesives and sealants
Agricultural products (non-pesticidal)
Anti-freeze and de-icing products
Arts, crafts, and hobby materials
Building/construction materials not covered elsewhere
Cleaning and furnishing care products
Foam seating and bedding products
Fuels and related products
Golf and Sports Turf
Internal Feedstock
Laundry and dishwashing products
Paper products
Toys, playground, and sporting equipment

https://www.epa.gov/chemical-data-reporting

EPA Chemicals under the TSCA

11.1.4 Household Products

Household & Commercial/Institutional Products

Information on 57 consumer products that contain Ethylene oxide in the following categories is provided:

- Auto Products
- Commercial / Institutional
- Home Maintenance
- Inside the Home
- Pet Care

Consumer Product Information Database (CPID)

11.2 Methods of Manufacturing

(1) Oxidation of **ethylene** in air or **oxygen** with **silver** catalyst; (2) action of an alkali on **ethylene chlorohydrin**.

Lewis, R.J. Sr.; Hawley's Condensed Chemical Dictionary 15th Edition. John Wiley & Sons, Inc. New York, NY 2007., p. 531

Hazardous Substances Data Bank (HSDB)

Prepared from **ethylene chlorohydrin** and **potassium hydroxide** ... manufactured by catalytic oxidation of **ethylene**.

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 2006., p. 651

Hazardous Substances Data Bank (HSDB)

Direct oxidation ... utilizes the catalytic oxidation of **ethylene** with **oxygen** over a **silver**-based catalyst ... .

Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V9 924

Hazardous Substances Data Bank (HSDB)

The process involves the reaction of **ethylene** with **hypochlorous acid** followed by dehydrochlorination of the resulting chlorohydrin with lime .... . /Chlorohydrin process/

Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V9 923

Hazardous Substances Data Bank (HSDB)

Ethylene oxide was first produced in the United States in 1921. Until 1937, ethylene oxide was produced by the chlorohydrin process, in which **ethylene** was treated with **hypochlorous acid** to produce **ethylene chlorohydrin**. **Calcium hydroxide** or **sodium hydroxide** was used to convert **ethylene chlorohydrin** to ethylene oxide. Currently in the United States, essentially all production of ethylene oxide uses the direct vapor phase oxidation process. This process oxidizes **ethylene** with air or **oxygen** in the presence of a **silver** catalyst to produce ethylene oxide.

DHHS/NTP; SUBSTANCE PROFILES REPORT ON CARCINOGENS, ELEVENTH EDITION: Ethylene Oxide CAS No. 75-21-8 p.2. Available from, as of July 23, 2008: https://ntp.niehs.nih.gov/

Hazardous Substances Data Bank (HSDB)

11.3 Impurities

Ethylene oxide is available commercially in the United States as a high-purity chemical that contains a maximum of 0.03% **water**, 0.003% aldehydes as **acetaldehyde**, and 0.002% acidity as **acetic acid**.

DHHS/NTP; SUBSTANCE PROFILES REPORT ON CARCINOGENS, ELEVENTH EDITION: Ethylene Oxide CAS No. 75-21-8 p.1. Available from, as of July 23, 2008: https://ntp.niehs.nih.gov/

Hazardous Substances Data Bank (HSDB)

11.4 Formulations/Preparations

ETO is formulated and marketed as a gas or a pressurized liquid. The end use formulations are all gas mixtures of ETO and inert gases (eg, carbon dioxide) in varying concentrations.

USEPA/Office of Pesticide Programs; Reregistration Eligibility Decision Document - Ethylene Oxide p.14 EPA 738-R-08-003 (March 2008). Available from, as of July 21, 2008: https://www.epa.gov/pesticides/reregistration/status.htm

Hazardous Substances Data Bank (HSDB)

/ETHYLENE OXIDE/ IS MIXED WITH EITHER CARBON DIOXIDE OR FLUOROCARBON 12 ... TO ELIMINATE FLAMMABILITY ... . CARBOXIDE IS NONFLAMMABLE MIXTURE OF 10% BY WT ETHYLENE OXIDE IN CARBON DIOXIDE ... STERILANT 12 IS NONFLAMMABLE MIXT OF 12% BY WT ... IN FLUOROCARBON 12 ... .

Farm Chemicals Handbook 1981. Willoughby, Ohio: Meister, 1981., p. C-141

Hazardous Substances Data Bank (HSDB)

Grades or purity: commercial: 100% must contain no acetylene.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

GRADES: TECHNICAL; PURE (99.7%).

Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987., p. 490

Hazardous Substances Data Bank (HSDB)

For more Formulations/Preparations (Complete) data for ETHYLENE OXIDE (35 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

11.5 Consumption Patterns

CHEM INT FOR ETHYLENE GLYCOL, 60.5%; CHEM INT FOR NONIONIC SURFACTANTS (ACYCLIC), 7.1%; CHEM INT FOR NONIONIC SURFACTANTS (CYCLIC), 4.6%; CHEM INT FOR GLYCOL ETHERS, 7.2%; CHEM INT FOR ETHANOLAMINES, 7.1%; CHEM INT FOR DIETHYLENE GLYCOL, 5.1%; CHEM INT FOR TRIETHYLENE GLYCOL, 2.1%; CHEM INT FOR POLYETHYLENE GLYCOL, 1.6%; OTHER, 4.7% (1981)

SRI

Hazardous Substances Data Bank (HSDB)

Monoethylene glycol, 59%; higher glycols, 15%; ethoxylates, 10%; ethanolamines, 6%; glycol ethers, 5%; miscellaneous, 5% (1984)

CHEMICAL PRODUCTS SYNOPSIS: Ethylene Oxide, 1985

Hazardous Substances Data Bank (HSDB)

CHEMICAL PROFILE: Ethylene oxide. End-use Pattern for Ethylene Oxide in 1987

Table: End-use Pattern for Ethylene Oxide in 1987

End-use	Percent
Ethylene glycol	59
Nonionic surfactants	14
Ethanolamines	8
Glycol ethers	6
Diethylene glycol	6
Triethylene glycol	2
Miscellaneous, including polyethylene glycol, urethane polyols and exports	5

Anonymous; Chemical Marketing Reporter, 231 (10): 54 (1987); 9 March 1987

Hazardous Substances Data Bank (HSDB)

CHEMICAL PROFILE: Ethylene oxide. US Demand: 1986: 5.7 billion pounds; 1987: 5.8 billion pounds; 1991: 6.4 billion pounds /projected/

Anonymous; Chemical Marketing Reporter, 231 (10): 54 (1987); 9 March 1987

Hazardous Substances Data Bank (HSDB)

For more Consumption Patterns (Complete) data for ETHYLENE OXIDE (18 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

11.6 U.S. Production

Aggregated Product Volume (EPA CDR 2016)

5,000,000,000 - 10,000,000,000 lb

https://www.epa.gov/chemical-data-reporting

EPA Chemicals under the TSCA

(1977) 2.03X10+12 G

SRI

Hazardous Substances Data Bank (HSDB)

(1982) 2.26X10+12 G

SRI

Hazardous Substances Data Bank (HSDB)

(1986) 2.49X10+12 g /Estimated/

CHEMICAL PRODUCTS SYNOPSIS: Ethylene Oxide, 1985

Hazardous Substances Data Bank (HSDB)

(1985) 2.58X10+12 g

Chem Eng News 64 (40): 13 (1986)

Hazardous Substances Data Bank (HSDB)

For more U.S. Production (Complete) data for ETHYLENE OXIDE (20 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

11.7 U.S. Imports

(1977) 1.15X10+10 G

SRI

Hazardous Substances Data Bank (HSDB)

(1982) 4.30X10+9 G

SRI

Hazardous Substances Data Bank (HSDB)

(1985) 1.03X10+10 g

BUREAU OF THE CENSUS. U.S. IMPORTS FOR CONSUMPTION AND GENERAL IMPORTS 1985 p. 1-583

Hazardous Substances Data Bank (HSDB)

CHEMICAL PROFILE: Ethylene Oxide. US Imports: 1994: 32 million pounds

Anonymous; Chemical Marketing Reporter, 249 (10): 37 (1996); 4 March 1996

Hazardous Substances Data Bank (HSDB)

For more U.S. Imports (Complete) data for ETHYLENE OXIDE (8 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

11.8 U.S. Exports

(1978) 3.46X10+10 G

SRI

Hazardous Substances Data Bank (HSDB)

(1983) 6.27X10+9 G

SRI

Hazardous Substances Data Bank (HSDB)

(1985) 2.82X10+10 g

BUREAU OF THE CENSUS. U.S. EXPORTS, SCHEDULE E, 1985 p.2-76

Hazardous Substances Data Bank (HSDB)

CHEMICAL PROFILE: Ethylene Oxide. US Exports: 1994: 27 million pounds

Anonymous; Chemical Marketing Reporter, 249 (10): 37 (1996); 4 March 1996

Hazardous Substances Data Bank (HSDB)

For more U.S. Exports (Complete) data for ETHYLENE OXIDE (8 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

11.9 General Manufacturing Information

Industry Processing Sectors

All other basic organic chemical manufacturing
Asphalt paving, roofing, and coating materials manufacturing
Construction
Miscellaneous manufacturing
Oil and gas drilling, extraction, and support activities
Paint and coating manufacturing
Paper manufacturing
Pesticide, fertilizer, and other agricultural chemical manufacturing
Petrochemical manufacturing

Plastic material and resin manufacturing

EPA Chemicals under the TSCA

EPA TSCA Commercial Activity Status

Oxirane: ACTIVE

https://www.epa.gov/tsca-inventory

EPA Chemicals under the TSCA

The WHO Recommended Classification of Pesticides by Hazard /does not classify gaseous or volatile fumigants, including Ethylene oxide/. According to the PIC /Prior Informed Consent/ Convention, export of /Ethylene oxide/ can only take place with the prior informed consent of the importing Party. ...

*WHO (2005) The WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2004, International Programme on Chemical Safety, p.39 (further information can be found at: **https://www.pic.int/**).*

Hazardous Substances Data Bank (HSDB)

A variety of new process concepts for ethylene oxide-**ethylene glycol** are being developed based on such raw materials as synthesis gas and **ethanol**.

CHEMICAL PRODUCTS SYNOPSIS: Ethylene Oxide, 1985

Hazardous Substances Data Bank (HSDB)

The compatibility of **polycarbonate** with ethylene oxide was studied. The **polycarbonate** devices can be safely exposed to 3 ethylene oxide cycles. Polycarbonates are compatible with **ethanol** at 73-158 °F.

Miller-Mizia R; Med Device Diagn 8 (11): 36-7 (1986)

Hazardous Substances Data Bank (HSDB)

The chlorohydrin process is not economically competitive, and was quickly replaced by the direct oxidation process as the dominant technology. At the present time, all ethylene oxide production in the world is achieved by the direct oxidation process.

Kirk-Othmer Encyclopedia of Chemical Technology. 4th ed. Volumes 1: New York, NY. John Wiley and Sons, 1991-Present., p. V9 923

Hazardous Substances Data Bank (HSDB)

11.10 Sampling Procedures

NIOSH Method 3702. Analyte: Ethylene oxide. Sampler: Ambient air or bag sample. Flow Rate: Greater or equal to 0.07 l/min; spot samples possible. Shipment: Calibration and carrier gas shipment must comply with hazardous materials shipment regulations. Sample Stability: Bag samples stable 24 hrs @ 25 °C.

U.S. Department of Health and Human Services, Public Health Service. Centers for Disease Control, National Institute for Occupational Safety and Health. NIOSH Manual of Analytical Methods, 3rd ed. Volumes 1 and 2 with 1985 supplement, and revisions. Washington, DC: U.S. Government Printing Office, February 1984., p. 3702-1

Hazardous Substances Data Bank (HSDB)

NIOSH Method 1614. Analyte: Ethylene oxide. Matrix: Air. Sampler: Solid sorbent tube (**hydrogen bromide**-coated petroleum **charcoal**, 100 mg/50 mg) Flow Rate: 0.05 to 0.15 l/min: Sample Size: 24 liters. Shipment: Routine. Sample Stability: 90% recovery after 17 days @ 25 °C in the dark.

U.S. Department of Health and Human Services, Public Health Service. Centers for Disease Control, National Institute for Occupational Safety and Health. NIOSH Manual of Analytical Methods, 3rd ed. Volumes 1 and 2 with 1985 supplement, and revisions. Washington, DC: U.S. Government Printing Office, February 1984., p. 1614-1

Hazardous Substances Data Bank (HSDB)

Analyte: Ethylene oxide. Procedure: Trapping on solid adsorber. Sample flow: 0.05 to 1.15 l/min. Sample Size: 11 (at 5 ppm) to 24 liters.

Royal Society of Chemistry. Measurement Techniques for Carcinogenic Agents in Workplace Air. Publ. No. EUR 11897, Commission of the European Communities/Scientific and Technical Communication Unit, Luxembourg. Great Britian: St. Edmundsbury Press Ltd, 1989., p. 21

Hazardous Substances Data Bank (HSDB)

The method uses a **hydrobromic acid**-coated **charcoal** tube to collect ethylene oxide as its **2-bromoethanol** reaction product. Similar high recoveries were obtained for 4 hr samples collected at a sampling rate of 0.1 l/min from test atmospheres in the concentration range of 0.1 to 16 ppm ethylene oxide at high humidity (80%) and ambient temperature (22 deg to 25 °C). Samples collected under these same conditions and stored for a minimum of 2 weeks resulted in average recoveries that ranged from 84% to 101%. Average recoveries of 97% were obtained for 2 ppm air samples collected at low humidity with no storage; however, storage of these samples at 22 °C to 25 °C resulted in an approximated loss of 5% per week.

Cummins KJ et al: Am Ind Hyg Assoc J 48 (6): 563-73 (1987)

Hazardous Substances Data Bank (HSDB)

12 Identification

12.1 Analytic Laboratory Methods

NIOSH Method 3702. Analyte: Ethylene oxide. Procedure: Gas chromatography (portable) with photoionization detector. For ethylene oxide this method has an estimated detection limit of 2.5 pg/injection @ .001 ppm/ml injection. The precision/RSD is less than 0.07 @ 0.05 to 0.02 ppm. Applicability: The working range is 0.001 to 1000 ppm in relatively non-complex atmospheres (eg, sterilization facilities). Interferences: Freon 12, **carbon dioxide** and alcohols do not interfere.

U.S. Department of Health and Human Services, Public Health Service. Centers for Disease Control, National Institute for Occupational Safety and Health. NIOSH Manual of Analytical Methods, 3rd ed. Volumes 1 and 2 with 1985 supplement, and revisions. Washington, DC: U.S. Government Printing Office, February 1984., p. 3702-1

Hazardous Substances Data Bank (HSDB)

NIOSH Method 1614. Analyte: Ethylene oxide. Matrix: Air. Procedure: Gas chromatography electron capture detector. For ethylene oxide this method has an estimated detection limit of 1 ug **ethanol**/sample. The precision/RSD is 0.028 @ 18 to 71 ug **ethanol**/sample. Applicability: The working range is 0.05 to 4.6 ppm (0.08 to 8.3 mg/cu m) for a 24 liter air sample. Interferences: **2-Bromoethanol**, if present in the sample, interferes.

U.S. Department of Health and Human Services, Public Health Service. Centers for Disease Control, National Institute for Occupational Safety and Health. NIOSH Manual of Analytical Methods, 3rd ed. Volumes 1 and 2 with 1985 supplement, and revisions. Washington, DC: U.S. Government Printing Office, February 1984., p. 1614-1

Hazardous Substances Data Bank (HSDB)

Analyte: Ethylene oxide. Procedure: Gas chromatography/Electron capture detector. Carrier gas flow: 25 ml/min. Sample size: 1 ml. The working range is 0.04 to 0.98 ppm (24 liter sample). Overall precision: 0.13 and detection limit of 1 ug/sample. Interference: **2-Bromoethanol**.

Royal Society of Chemistry. Measurement Techniques for Carcinogenic Agents in Workplace Air. Publ. No. EUR 11897, Commission of the European Communities/Scientific and Technical Communication Unit, Luxembourg. Great Britian: St. Edmundsbury Press Ltd, 1989., p. 21

Hazardous Substances Data Bank (HSDB)

Ethylene oxide can be determined by spectrophotometry and by colorimetry or volumetrically. Gas chromatography of air samples and residues from fumigated materials has been used for foodstuffs, pharmaceuticals and surgical equipment. It can also be found in cigarette smoke by gas chromatography or mass spectrometry ... and also in mixtures of lower olefin oxides and aldehydes. Limits of detection by spectrophotometry and gas chromatography were generally of the order of 1 mg/kg.

*IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: **https://monographs.iarc.fr/ENG/Classification/index.php**, p. V11 160 (1976)*

Hazardous Substances Data Bank (HSDB)

For more Analytic Laboratory Methods (Complete) data for ETHYLENE OXIDE (12 total), please visit the **HSDB record page**.

Hazardous Substances Data Bank (HSDB)

12.2 Clinical Laboratory Methods

Medical devices that are sterilized with ethylene oxide (EtO) retain small quantities of EtO residuals, which ... The goal of this round-robin study is to investigate the capability of a novel solid-phase microextraction-gas chromatographic (SPME-GC) method for trace-level EtO residuals analysis: three independent laboratories conducted a guided experiment using this SPME-GC method, in assessing method performance, ruggedness and the feasibility of SPME fibers. These were satisfactory across the independent laboratories, at the 0.05-5.00 ppm EtO range. This method was then successfully applied to analyze EtO residuals in several sterilized/aerated medical devices of various polymeric composition, reliably detecting and quantifying the trace levels of EtO residuals present (approximately 0.05 ppm EtO). SPME is a feasible alternative for quantifying trace-level EtO residuals in sterilized medical devices, thereby lowering the limit of quantification (LOQ) by as much as two to three orders of magnitude over the current GC methodology of direct liquid injection.

PMID:17853387
Harper T et al; Biomed Chromatogr 22 (2): 136-48 (2008)

Hazardous Substances Data Bank (HSDB)

A gas chromatography-electron impact ionization-mass spectrometric (GC-EI-MS) assay was developed for the determination of ethylene oxide-hemoglobin adduct (N-2-hydroxyethylvaline, HEVal). HEVal and deuterated HEVal (d(4)-HEVal) were synthesized for identification and quality control. Globin samples were separated from red blood cells (RBCs) by acidic **isopropanol** and extracted with **ethyl acetate**. HEVal adduct in globin was transformed to HEVal-**pentafluorophenylthiohydantoin** derivative by modified Edman-degradation method, which was extracted from globin with **diethylether**. d(4)-HEVal was used as an internal reference standard. The dried extract was derivatized with **N-methyl-N-(tert-butyldimethylsilyl) trifluoroacetamide** (MTBDMSTFA)-NH(4)I (1000:4, w/w) containing 0.4 mg of dithioerthritol. The TBDMS derivative of HEVal had very good chromatographic property and offered sensitive response of GC-EI-MS. The recovery of HEVal was about 81.6% and the coefficient of variation was 5.0% at the concentration of 311 pmol/g. Low limit of detection (LOD) of the assay was 1.8 pmol/g in 0.1g hemoglobin. The experiments have demonstrated to detect background level of HEVal adduct in human blood. HEVal adduct in globin was detected between 12 and 6573 pmol/g.

PMID:16828349
Ahn HS, Shin HS; J Chromatogr B Analyt Technol Biomed Life Sci 843 (2): 202-8 (2006)

Hazardous Substances Data Bank (HSDB)

... Methods were developed using capillary gas chromatography. Gas chromatography with mass spectrometry for determining **S-methylcysteine**, N(r)(2-hydroxyethyl)histidine and N(r)(2-hydroxypropyl)histidine in hemoglobin, allowing the monitoring of in vivo exposure of laboratory animals and humans to methylating agents, ethylene oxide and **propylene oxide**, respectively. ... An alternative method of dose monitoring of some methylating agents by the measurement of the urinary N-7-methylated guanine derived from alkylated DNA break-down products was also investigated.

PMID:3619640
Bailey E et al; Arch Toxicol 60 (1-3): 187-91 (1987)

Hazardous Substances Data Bank (HSDB)

12.3 OSHA Chemical Sampling

GC-ECD - **OSHA 1010v.2 (fully validated)**

Occupational Safety and Health Administration (OSHA)

12.4 NIOSH Analytical Methods

ORGANIC AND INORGANIC GASES BY EXTRACTIVE FTIR SPECTROMETRY 3800

- NIOSH Manual of Analytical Methods

ETHYLENE OXIDE 1614

- NIOSH Manual of Analytical Methods

ETHYLENE OXIDE by Portable GC 3702

- NIOSH Manual of Analytical Methods

13 Safety and Hazards

13.1 Hazards Identification

13.1.1 GHS Classification

Showing 1 of 6 View More

Pictogram(s)	 Flammable, Corrosive, Acute Toxic, Irritant, Health Hazard
Signal	Danger
GHS Hazard Statements	H220: Extremely flammable gas [**Danger** Flammable gases] H301: Toxic if swallowed [**Danger** Acute toxicity, oral] H314: Causes severe skin burns and eye damage [**Danger** Skin corrosion/irritation] H318: Causes serious eye damage [**Danger** Serious eye damage/eye irritation] H331: Toxic if inhaled [**Danger** Acute toxicity, inhalation] H335: May cause respiratory irritation [**Warning** Specific target organ toxicity, single exposure; Respiratory tract irritation] H336: May cause drowsiness or dizziness [**Warning** Specific target organ toxicity, single exposure; Narcotic effects] H340: May cause genetic defects [**Danger** Germ cell mutagenicity] H350: May cause cancer [**Danger** Carcinogenicity] H360Fd: May damage fertility; Suspected of damaging the unborn child [**Danger** Reproductive toxicity] H372: Causes damage to organs through prolonged or repeated exposure [**Danger** Specific target organ toxicity, repeated exposure]
Precautionary Statement Codes	P201, P202, P210, P260, P261, P264, P270, P271, P280, P281, P301+P310, P301+P330+P331, P303+P361+P353, P304+P340, P305+P351+P338, P308+P313, P310, P311, P312, P314, P321, P330, P363, P377, P381, P403, P403+P233, P405, and P501 (The corresponding statement to each P-code can be found at the GHS Classification page.)

▸ EU REGULATION (EC) No 1272/2008

13.1.2 Hazard Classes and Categories

Showing 2 of 6 View More

Flam. Gas 1

Press. Gas

Carc. 1B

Muta. 1B

Repr. 1B

Acute Tox. 3

Acute Tox. 3

STOT SE 3

STOT SE 3

STOT RE 1

Skin Corr. 1

Eye Dam. 1

▸ EU REGULATION (EC) No 1272/2008

Skin Irrit. 2 (53.41%)

Skin Sens. 1B (53.41%)

Eye Dam. 1 (53.41%)

Aquatic Chronic 2 (46.59%)

Aquatic Chronic 3 (53.41%)

▸ European Chemicals Agency (ECHA)

13.1.3 NFPA Hazard Classification

Showing 1 of 2 View More

NFPA 704 Diamond	 3-4-3
NFPA Health Rating	3 - Materials that, under emergency conditions, can cause serious or permanent injury.
NFPA Fire Rating	4 - Materials that rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and burn readily.
NFPA Instability Rating	3 - Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction but that require a strong initiating source or must be heated under confinement before initiation.

Hazardous Substances Data Bank (HSDB)

13.1.4 Substance of Very High Concern (SVHC)

OSHA Highly Hazardous Chemicals, Toxics and Reactives

Chemical: Ethylene Oxide
Threshold: 5000 [lb]
Note: Ethylene Oxide in quantities at or above 5000lb presents a potential for a catastrophic event as a toxic or reactive highly hazardous chemical.

Occupational Safety and Health Administration (OSHA)

13.1.5 Health Hazards

It can cause death. Lowest inhalation concentration causing toxic effects is 12500 ppm/10 seconds. It is a strong skin irritant. Neurological disorders and even death have been reported. (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

13.1.6 Fire Hazards

Severe explosion hazard when exposed to heat or flame. Irritating vapors are generated when heated. Vapor is heavier than air and may travel considerable distance to a source of ignition and flash back. Vapor forms explosive mixtures with air over a wide range. Liquid is not detonable but the vapor may be readily initiated into explosive decomposition. Avoid metal fittings containing **copper**, **silver**, **mercury** or **magnesium**; **ammonia**, oxidizing agents; acids, organic bases; amines; certain salts; alcohols; mercaptans, **ferric chloride**; **magnesium perchlorate**; **m-nitroaniline**; **trimethylamine**, **potassium**, tin chlorides; alkanethiols; **bromoethane**; **aluminum chloride**; **aluminum oxide**; iron chlorides; and iron oxides. Avoid air, heat, acids and bases, metal or metal **chloride** catalysts. Hazardous polymerization may occur. Avoid acids; covalent halides such as chlorides of **aluminum**, **iron (III)**, tin (IV); basic materials like alkali hydrides, **ammonia**, amines, and **potassium**; catalytically active solids such as **aluminum** or iron oxides or rust, chlorides of **boron**, **aluminum**, **tin**, and **iron**; some carbonates; and metals such as **copper** and **copper** alloys (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

Extremely flammable. Gas/air mixtures are explosive. Risk of fire and explosion as a result of decomposition when heated.

ILO International Chemical Safety Cards (ICSC)

Carcinogens, Mutagens, Teratogens, Flammable - 4th degree, Reactive - 3rd degree

NJDOH RTK Hazardous Substance List

13.1.7 Hazards Summary

Ethylene oxide is a flammable gas with a somewhat sweet odor. It dissolves easily in **water**. Ethylene oxide is a man-made chemical that is used primarily to make **ethylene glycol** (a chemical used to make antifreeze and polyester). A small amount (less than 1%) is used to control insects in some stored agricultural products and a very small amount is used in hospitals to sterilize medical equipment and supplies.

CDC-ATSDR Toxic Substances Portal

The major use of ethylene oxide is as a chemical intermediate in the manufacture of **ethylene glycol**. Ethylene oxide is also used as a sterilizing agent for medical equipment and a fumigating agent for spices. The acute (short-term) effects of ethylene oxide in humans consist mainly of central nervous system depression and irritation of the eyes and mucous membranes. Chronic (long-term) exposure to ethylene oxide in humans can cause irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There also is some evidence linking ethylene oxide exposure to reproductive effects. EPA has concluded that ethylene oxide is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to ethylene oxide increases the risk of lymphoid cancer and, for females, breast cancer.

EPA Air Toxics

13.1.8 Fire Potential

Flammable gas.

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 49-76

Hazardous Substances Data Bank (HSDB)

13.1.9 Skin, Eye, and Respiratory Irritations

Ethylene oxide is irritating to the eyes, respiratory tract, and skin.

Rom, W.N. (ed.). Environmental and Occupational Medicine. 2nd ed. Boston, MA: Little, Brown and Company, 1992., p. 1034

Hazardous Substances Data Bank (HSDB)

Exposure to high concentrations of ethylene oxide vapor or eye splashes of concentrated solutions can cause eye irritation, inflammation of the eye membrane and corneal injury. Exposure to ethylene oxide has also been linked to the development of cataracts.

*ATSDR; Medical Management for Ethylene Oxide CAS 75-21-8; UN 1040. 19 pp. Available from, as of July 21, 2008: **https://www.atsdr.cdc.gov/MHMI/mmg137.html***

Hazardous Substances Data Bank (HSDB)

Aqueous solutions of ethylene oxide or solutions formed when the anhydrous cmpd comes in contact with moist skin are irritating and may lead to a severe dermatitis with blisters, blebs and burns. It is also absorbed by leather and rubber and may produce burns or irritation. Allergic eczematous dermatitis has also been reported. Exposure to the vapor in high concn leads to irritation of the eyes. Severe eye damage may result if the liquid is splashed in the eyes. Large amounts of ethylene oxide evaporating from the skin may cause frostbite.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 1985. 2nd ed. Park Ridge, NJ: Noyes Data Corporation, 1985., p. 433

Hazardous Substances Data Bank (HSDB)

Irritating to skin, eyes, and respiratory system.

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 49-76

Hazardous Substances Data Bank (HSDB)

The vapors are irritating to the eyes, skin, and respiratory system. /Ethylene oxide or ethylene oxide with nitrogen/

Association of American Railroads; Bureau of Explosives. Emergency Handling of Hazardous Materials in Surface Transportation. Association of American Railroads, Pueblo, CO. 2005, p. 410

Hazardous Substances Data Bank (HSDB)

13.1.10 EPA Hazardous Waste Number

U115; A toxic waste when a discarded commercial chemical product or manufacturing chemical intermediate or an off-specification commercial chemical product or a manufacturing chemical intermediate.

Hazardous Substances Data Bank (HSDB)

13.2 Safety and Hazard Properties

13.2.1 Acute Exposure Guideline Levels (AEGLs)

13.2.1 AEGLs Table

AEGLs	10 min	30 min	60 min	4 hr	8 hr
AEGL 1: Notable discomfort, irritation, or certain asymptomatic non-sensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure (Unit: ppm)	NR	NR	NR	NR	NR
AEGL 2: Irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape (Unit: ppm)	80	80	45	14	7.9
AEGL 3: Life-threatening health effects or death (Unit: ppm)	360	360	200	63	35

EPA Acute Exposure Guideline Levels (AEGLs)

13.2.2 AEGLs Notes

NR=Not recommended

AEGLs Status: Final

EPA Acute Exposure Guideline Levels (AEGLs)

13.2.2 Flammable Limits

Lower flammable limit: 3.0% by volume; Upper flammable limit: 100% by volume

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 325-62

Hazardous Substances Data Bank (HSDB)

Flammability

Flammable Gas

The National Institute for Occupational Safety and Health (NIOSH)

13.2.3 Lower Explosive Limit (LEL)

3 % (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

3.0%

Occupational Safety and Health Administration (OSHA); The National Institute for Occupational Safety and Health (NIOSH)

13.2.4 Upper Explosive Limit (UEL)

100 % (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

CAMEO Chemicals

100%

Occupational Safety and Health Administration (OSHA)

13.2.5 Critical Temperature & Pressure

Critical temperature = 469.15 K; Critical pressure = 7.1941X10+6 Pa

Daubert, T.E., R.P. Danner. Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, D.C.: Taylor and Francis, 1989.

Hazardous Substances Data Bank (HSDB)

13.2.6 Physical Dangers

The gas is heavier than air and may travel along the ground; distant ignition possible.

ILO International Chemical Safety Cards (ICSC)

13.2.7 Explosive Limits and Potential

LOWER EXPLOSIVE LIMIT: 3.0%, UPPER EXPLOSIVE LIMIT: 100%. EXPLOSION HAZARD: SEVERE, WHEN EXPOSED TO FLAME.

Sax, N.I. Dangerous Properties of Industrial Materials. 6th ed. New York, NY: Van Nostrand Reinhold, 1984., p. 1347

Hazardous Substances Data Bank (HSDB)

GAS IS EXPLOSIVE IN CONCN ABOVE 3% & MUST BE MIXED WITH CARBON DIOXIDE OR FLUOROCARBONS.

Gilman, A.G., L.S.Goodman, and A. Gilman. (eds.). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 7th ed. New York: Macmillan Publishing Co., Inc., 1985., p. 972

Hazardous Substances Data Bank (HSDB)

Flammable gas. Volatile flammable liquid below room temperature. Explosive decomposition may occur in vapor or liquid phase. Vapor forms explosive mixtures with air over a wide range. Vapors are heavier than air and may travel to a source of ignition and flash back. Closed containers may rupture violently when heated.

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 49-76

Hazardous Substances Data Bank (HSDB)

Ethylene oxide is highly reactive and potentially explosive when heated or in the presence of alkali metal hydroxides and highly active catalytic surfaces. ... Vapors may be flammable or explosive if there is inadequate heat dissipation.

*DHHS/NTP; SUBSTANCE PROFILES REPORT ON CARCINOGENS, ELEVENTH EDITION: Ethylene Oxide CAS No. 75-21-8 p.1. Available from, as of July 23, 2008: **https://ntp.niehs.nih.gov/***

Hazardous Substances Data Bank (HSDB)

Explosive limits , vol% in air: 3-100

ILO International Chemical Safety Cards (ICSC)

13.2.8 OSHA Standards

Permissible exposure limits -(1) 8-hour time weighted average (TWA). The employer shall ensure that no employee is exposed to an airborne concentration of ethylene oxide in excess of one (1) part ethylene oxide per million parts of air (1 ppm) as an 8-hour time-weighted average (8-hour TWA). (2) Excursion limit. The employer shall ensure that no employee is exposed to an airborne concentration of ethylene oxide in excess of 5 parts of ethylene oxide per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.

*29 CFR 1910.1047(c) (USDOL); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 2, 2008: **https://www.ecfr.gov***

Hazardous Substances Data Bank (HSDB)

13.2.9 NIOSH Recommendations

Recommended Exposure Limit: 10 Hr Time-Weighted Avg: <0.1 ppm (<0.18 mg/cu m).

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005)

Hazardous Substances Data Bank (HSDB)

Recommended Exposure Limit: 10 min/day ceiling value: 5 ppm (9 mg/cu m).

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005)

Hazardous Substances Data Bank (HSDB)

NIOSH considers ethylene oxide to be a potential occupational carcinogen.

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005)

Hazardous Substances Data Bank (HSDB)

13.3 First Aid Measures

13.3.1 First Aid

Warning: Ethylene oxide is corrosive to moist tissues. Caution is advised. Signs and Symptoms of Acute Ethylene Oxide Exposure: Signs and symptoms of acute exposure to ethylene oxide may be severe, and include dyspnea (shortness of breath), cough, pulmonary edema, pneumonia, and respiratory failure. Lethargy, headache, dizziness, twitching, convulsions, paralysis, and coma may be observed. Cardiac arrhythmias and cardiovascular collapse may also occur. Gastrointestinal effects of acute exposure may include nausea, vomiting, and abdominal pain. Ethylene oxide may severely irritate or burn mucous membranes and moist skin. Eye contact may result in conjunctivitis (red, inflamed eyes) and erosion of the cornea. Emergency Life-Support Procedures: Acute exposure to ethylene oxide may require decontamination and life support for the victims. Emergency personnel should wear protective clothing appropriate to the type and degree of contamination. Air-purifying or supplied-air respiratory equipment should also be worn, as necessary. Rescue vehicles should carry supplies such as plastic sheeting and disposable plastic bags to assist in preventing spread of contamination. Inhalation Exposure: 1. Move victims to fresh air. Emergency personnel should avoid self-exposure to ethylene oxide. 2. Evaluate vital signs including pulse and respiratory rate, and note any trauma. If no pulse is detected, provide CPR. If not breathing, provide artificial respiration. If breathing is labored, administer oxygen or other respiratory support. 3. Obtain authorization and/or further instructions from the local hospital for administration of an antidote or performance of other invasive procedures. 4. Transport to a health care facility. Dermal/Eye Exposure: 1. Remove

victims from exposure. Emergency personnel should avoid self- exposure to ethylene oxide. 2. Evaluate vital signs including pulse and respiratory rate, and note any trauma. If no pulse is detected, provide CPR. If not breathing, provide artificial respiration. If breathing is labored, administer oxygen or other respiratory support. 3. Remove contaminated clothing as soon as possible. 4. If eye exposure has occurred, eyes must be IMMEDIATELY flushed with lukewarm water for AT LEAST 15 minutes. 5. If liquid is spilled on the skin, allow ethylene oxide to vaporize before washing THOROUGHLY with soap and water. 6. Obtain authorization and/or further instructions from the local hospital for administration of an antidote or performance of other invasive procedures. 7. Transport to a health care facility. Ingestion Exposure: 1. Evaluate vital signs including pulse and respiratory rate, and note any trauma. If no pulse is detected, provide CPR. If not breathing, provide artificial respiration. If breathing is labored, administer oxygen or other respiratory support. 2. Obtain authorization and/or further instructions from the local hospital for administration of an antidote or performance of other invasive procedures. 3. Give the victims water or milk: children up 1 year old, 125 mL (4 oz or 1/2 cup); children 1 to 12 years old 200 mL (6 oz or 3/4 cup); adults, 250 mL (8 oz or 1 cup). Water or milk should be given only if victims are conscious and alert. 4. Activated charcoal may be administered if victims are conscious and alert. Use 15 to 30 g (1/2 to 1 oz) for children, 50 to 100 g (1-3/4 to 3-1/2 oz) for adults, with 125 to 250 mL (1/2 to 1 cup) of water. 5. Ethylene oxide generally acts as its own cathartic; however, if deemed necessary, excretion may be promoted by administering a saline cathartic or sorbitol to conscious and alert victims. Children require 15 to 30 g (1/2 to 1 oz) of cathartic; 50 to 100 g (1-3/4 to 3-1/2 oz) is recommended for adults. 6. Transport to a health care facility. (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

▸ CAMEO Chemicals

(See procedures)

Eye: Irrigate immediately - If this chemical contacts the eyes, immediately wash (irrigate) the eyes with large amounts of water, occasionally lifting the lower and upper lids. Get medical attention immediately.

Skin: Water flush immediately - If this chemical contacts the skin, immediately flush the contaminated skin with water. If this chemical penetrates the clothing, immediately remove the clothing and flush the skin with water. Get medical attention promptly.

Breathing: Respiratory support

Swallow: Medical attention immediately (liquid)

▸ The National Institute for Occupational Safety and Health (NIOSH)

13.3.2 Inhalation First Aid

Fresh air, rest. Refer for medical attention.

▸ ILO International Chemical Safety Cards (ICSC)

13.3.3 Skin First Aid

Remove contaminated clothes. ON FROSTBITE: rinse with plenty of water, do NOT remove clothes. Rinse skin with plenty of water or shower. Refer for medical attention .

▸ ILO International Chemical Safety Cards (ICSC)

13.3.4 Eye First Aid

First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then refer for medical attention.

▸ ILO International Chemical Safety Cards (ICSC)

13.4 Fire Fighting

Move container from fire area if you can do so without risk. Stay away from ends of tanks. Fight fire from maximum distance. For massive fire in cargo area, use unmanned hose holder or monitor nozzles; if this is impossible, withdraw from area and let fire burn. Withdraw immediately in case of rising sound from venting safety device or any discoloration of tank due to fire. Isolate for 1 mile in all directions if tank car or truck is involved in fire. Keep unnecessary people away; isolate hazard area and deny entry. Stay upwind; keep out of low areas. Wear positive pressure breathing apparatus and full protective clothing. Evacuate area endangered by gas. Extinguish with alcohol foam, carbon dioxide, dry chemical or water spray, fog, or foam. Let burn unless leak can be stopped immediately. (EPA, 1998)

U.S. Environmental Protection Agency. 1998. Extremely Hazardous Substances (EHS) Chemical Profiles and Emergency First Aid Guides. Washington, D.C.: U.S. Government Printing Office.

▸ CAMEO Chemicals

Shut off supply; if not possible and no risk to surroundings, let the fire burn itself out. In other cases extinguish with powder, alcohol-resistant foam, water spray, carbon dioxide. In case of fire: keep cylinder cool by spraying with water. Combat fire from a sheltered position.

▸ ILO International Chemical Safety Cards (ICSC)

13.4.1 Fire Fighting Procedures

GAS: Poisonous gases are produced in fire. Do not estinguish the fire unless the flow of gas can be stopped and any remaining gas is out of the line. Specially trained personnel may use fog lines to cool exposures and let the fire burn itself out. Vapors are heavier than air and will collect in low areas. Vapors may travel long distances to ignition sources and flashback. Vapors in confined area may explode in fire. Storage containers and parts of containers may rocket great distances, in many directions. If materials or contaminated runoff enters waterways, notify downstream users of potentially contaminated waters. Notify local health and fire officials and pollution control agencies. From a secure, explosion-proof location, use water spray to cool exposed containers. If cooling streams are ineffective (venting sound increases in volume and pitch, tank discolors, or shows any signs of deforming), withdraw immediately to a secure position. If employees are expected to fight fires, they must be trained and equipped. LIQUID: Poisonous gases are produced in fire. Use dry chemical, carbon dioxide, or foam extinguishers. Although soluble in water, solutions will continue to burn until diluted to approximately 22 volumes of water to one volume of ethylene oxide. Vapors are heavier than air and will collect in low areas. Vapors may travel long distances to ignition sources and flashback. Vapors in confined area may explode in fire. Storage containers and parts of containers may rocket great distances, in many directions. If materials or contaminated runoff enters waterways, notify downstream users of potentially contaminated waters. Notify local health and fire officials and pollution control agencies. From a secure, explosion-proof location, use water spray to cool exposed containers. If cooling streams are ineffective (venting sound increases in volume and pitch, tank discolors, or shows any signs of deforming), withdraw immediately to a secure position. If employees are expected to fight fires, they must be trained and equipped.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1101

▸ Hazardous Substances Data Bank (HSDB)

Fire extinguishing agents: water.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

Stop flow of gas if possible. Combat fires from behind barrier, with unmanned hose holder or monitor nozzle. Flood discharge area with water. Cool exposed containers and protect men effecting shut off with water.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

Carbon dioxide and dry-chemical extinguishers are useful against small fire.

ITII. Toxic and Hazardous Industrial Chemicals Safety Manual. Tokyo, Japan: The International Technical Information Institute, 1988., p. 238

Hazardous Substances Data Bank (HSDB)

For more Fire Fighting Procedures (Complete) data for ETHYLENE OXIDE (8 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

13.4.2 Firefighting Hazards

Vapor is heavier than air and may travel considerable distance to a source of ignition and flash back.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

13.5 Accidental Release Measures

13.5.1 Isolation and Evacuation

Excerpt from ERG Guide 119P [Gases - Toxic - Flammable]: As an immediate precautionary measure, isolate spill or leak area for at least 100 meters (330 feet) in all directions. SPILL: See ERG Tables 1 and 3 - Initial Isolation and Protective Action Distances on the UN/NA 1040 datasheet. FIRE: If tank, rail car or tank truck is involved in a fire, ISOLATE for 1600 meters (1 mile) in all directions; also, consider initial evacuation for 1600 meters (1 mile) in all directions. (ERG, 2016)

*U.S. Department of Transportation, Transport Canada, and Secretariat of Communications and Transport of Mexico, with collaboration from Argentina's Centro de Información Química para Emergencias. 2016 Emergency Response Guidebook. **https://www.phmsa.dot.gov/hazmat/outreach-training/erg** (accessed April 26, 2016).*

CAMEO Chemicals

13.5.2 Spillage Disposal

Evacuate danger area! Consult an expert! Personal protection: gas-tight chemical protection suit including self-contained breathing apparatus. Ventilation. Do NOT wash away into sewer. NEVER direct water jet on liquid. Remove gas with fine water spray.

ILO International Chemical Safety Cards (ICSC)

13.5.3 Cleanup Methods

GAS: Evacuate and restrict persons not wearing protective equipment from area of spill or leak until cleanup is complete. Remove all ignition sources. Establish forced ventilation to keep levels below explosive limit. Stop the flow of gas if it can be done safely. If source of leak us a cylinder and the leak cannot be stopped in place, remove leaking cylinder to a safe place in the open air, and repair leak or allow cylinder to empty. Keep this chemical out of a confined space, such as a sewer, because of the possibility of an explosion, unless the sewer is designed to prevent the build-up of explosive concentrations. LIQUID: For small spills flush area with flooding amounts of water. For large spills, dike spill for later disposal. Absorb liquids in vermiculite, dry sand, earth, or a similar non-organic materials and deposit in sealed containers. May also be covered with weak reducing agents; resulting sludge neutralized and flushed to sewer. Collect powdered material in the most convenient and safe manner and deposit in sealed containers. Ventilate area of spill or leak after clean-up is complete. It may be necessary to contain and dispose of this chemical as a hazardous waste. If material or contaminated runoff enters waterways, notify downstream users of potentially contaminated waters. Contact your Department of Environmental Protection or your regional office of the federal EPA for specific recommendations. If employees are required to clean-up spills, they must be properly trained and equipped.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1101

Hazardous Substances Data Bank (HSDB)

Shut off ignition sources and call fire dept. Stop /flow/ if possible. Stay upwind and use water spray to "knock down" vapor. Isolate and remove discharged material. Notify local health and pollution control agencies.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

PRECAUTIONS FOR "CARCINOGENS": A high-efficiency particulate arrestor (HEPA) or charcoal filters can be used to minimize amt of carcinogen in exhausted air ventilated safety cabinets, lab hoods, glove boxes or animal rooms ... Filter housing that is designed so that used filters can be transferred into plastic bag without contaminating maintenance staff is avail commercially. Filters should be placed in plastic bags immediately after removal ... The plastic bag should be sealed immediately ... The sealed bag should be labelled properly ... Waste liquids ... should be placed or collected in proper containers for disposal. The lid should be secured & the bottles properly labelled. Once filled, bottles should be placed in plastic bag, so that outer surface ... is not contaminated ... The plastic bag should also be sealed & labelled. ... Broken glassware ... should be decontaminated by solvent extraction, by chemical destruction, or in specially designed incinerators. /Chemical Carcinogens/

Montesano, R., H. Bartsch, E.Boyland, G. Della Porta, L. Fishbein, R. A. Griesemer, A.B. Swan, L. Tomatis, and W. Davis (eds.). Handling Chemical Carcinogens in the Laboratory: Problems of Safety. IARC Scientific Publications No. 33. Lyon, France: International Agency for Research on Cancer, 1979., p. 15

Hazardous Substances Data Bank (HSDB)

Eliminate all ignition sources. Releases may require isolation or evacuation. Approach release from upwind. Stop or control the leak, if this can be done without undue risk. Use water spray to cool and disperse vapors, protect personnel, and dilute spills to form nonflammable mixtures. Water solutions no longer flammable in open areas when diluted as 1 part in 22 parts water. In enclosed areas such as sewers, dilution to 1 part in 100 parts water may be required to eliminate flash potential. Control runoff and isolate discharged material for proper disposal.

Fire Protection Guide to Hazardous Materials. 13 ed. Quincy, MA: National Fire Protection Association, 2002., p. 49-76

Hazardous Substances Data Bank (HSDB)

13.5.4 Disposal Methods

[40 CFR 240-280, 300-306, 702-799 (7/1/2006)] Generators of waste (equal to or greater than 100 kg/mo) containing this contaminant, EPA hazardous waste number U115, must conform with USEPA regulations in storage, transportation, treatment and disposal of waste.

▸ Hazardous Substances Data Bank (HSDB)

Concentrated waste containing no peroxides-discharge liquid at a controlled rate near a pilot flame. Concentrated waste containing peroxides-perforation of a container of the waste from a safe distance followed by open burning.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1102

▸ Hazardous Substances Data Bank (HSDB)

A good candidate for rotary kiln incineration at a temperature range of 820 to 1,600 °C and residence times of seconds for liquids and gases, and hours for solids. A good candidate for fluidized bed incineration at a temperature range of 450 to 980 °C and residence times of seconds for liquids and gases, and longer for solids.

USEPA; Engineering Handbook for Hazardous Waste Incineration p.3-13 (1981) EPA 68-03-3025

▸ Hazardous Substances Data Bank (HSDB)

Evaporation & open burning: A) Place on ground in an open area. Evaporate or burn by igniting from a safe distance. B) Dissolve in **benzene**, petroleum ether or higher alcohol such as **butanol**. Dispose by burning the soln. Recommendable method: Incineration. Peer review: Ethylene oxide boils @ 11 °C, therefore burning in an incinerator can cause difficulties unless a gas feed can be arranged. It is soluble in **water** or alcohol and these soln can be burned. (Peer-review conclusions of an IRPTC expert consultation (May 1985))

United Nations. Treatment and Disposal Methods for Waste Chemicals (IRPTC File). Data Profile Series No. 5. Geneva, Switzerland: United Nations Environmental Programme, Dec. 1985., p. 180

▸ Hazardous Substances Data Bank (HSDB)

For more Disposal Methods (Complete) data for ETHYLENE OXIDE (9 total), please visit the **HSDB record page**.

▸ Hazardous Substances Data Bank (HSDB)

13.5.5 Preventive Measures

SRP: The scientific literature for the use of contact lenses in industry is conflicting. The benefit or detrimental effects of wearing contact lenses depend not only upon the substance, but also on factors including the form of the substance, characteristics and duration of the exposure, the uses of other eye protection equipment, and the hygiene of the lenses. However, there may be individual substances whose irritating or corrosive properties are such that the wearing of contact lenses would be harmful to the eye. In those specific cases, contact lenses should not be worn. In any event, the usual eye protection equipment should be worn even when contact lenses are in place.

▸ Hazardous Substances Data Bank (HSDB)

Wear protective gloves and clothing to prevent any reasonable probability of skin contact. Safety equipment suppliers/manufacturers can provide recommendations on the most protective glove/clothing material for your operation. All protective clothing (suits, gloves, footwear, headgear) should be clean, available each day, and put on before work. Contact lenses should not be worn when working with this chemical. Wear gas and splash-proof chemical goggles and face shield unless full facepiece respiratory protection is worn. Employees should wash immediately with soap when skin is wet or contaminated. Provide emergency showers and eyewash.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1100

▸ Hazardous Substances Data Bank (HSDB)

SRP: Contaminated protective clothing should be segregated in such a manner so that there is no direct personal contact by personnel who handle, dispose, or clean the clothing. Quality assurance to ascertain the completeness of the cleaning procedures should be implemented before the decontaminated protective clothing is returned for reuse by the workers. Contaminated clothing should not be taken home at end of shift, but should remain at employee's place of work for cleaning.

▸ Hazardous Substances Data Bank (HSDB)

Prevent overfeeding of OECD Make sure that all interlocks and other safeguards are in place before sterilization begins. Periodically wash or vent sterilized products that sit idle in a sterilizer or aeration room to prevent EtO buildup. Monitor EtO concentrations in the sterilizer before the back vents are activated to avoid venting high EtO concentrations to the oxidizing emission control device (OECD). Vent confined spaces such as the sterilizer and the aeration room to the outisde after a power loss. Do not purge EtO lines to an OECD. Perform regular preventive maintenance. Obtain management approval before changing the process or safety interlocks.

*NIOSH; NIOSH Publication No. 2007-164: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities (Revised Edition) 40 pp. (August 2007). Available from, as of July 21, 2008: **https://www.cdc.gov/niosh/docs/2007-164/pdfs/2007-164.pdf***

▸ Hazardous Substances Data Bank (HSDB)

For more Preventive Measures (Complete) data for ETHYLENE OXIDE (34 total), please visit the **HSDB record page**.

▸ Hazardous Substances Data Bank (HSDB)

13.6 Handling and Storage

13.6.1 Nonfire Spill Response

Excerpt from ERG Guide 119P [Gases - Toxic - Flammable]: ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). All equipment used when handling the product must be grounded. Fully encapsulating, vapor-protective clothing should be worn for spills and leaks with no fire. Do not touch or walk through spilled material. Stop leak if you can do it without risk. Do not direct **water** at spill or source of leak. Use **water** spray to reduce vapors or divert vapor cloud drift. Avoid allowing **water** runoff to contact spilled material. FOR CHLOROSILANES, use AFFF alcohol-resistant medium-expansion foam to reduce vapors. If possible, turn leaking containers so that gas escapes rather than liquid. Prevent entry into waterways, sewers, basements or confined areas. Isolate area until gas has dispersed. (ERG, 2016)

*U.S. Department of Transportation, Transport Canada, and Secretariat of Communications and Transport of Mexico, with collaboration from Argentina's Centro de Información Química para Emergencias. 2016 Emergency Response Guidebook. **https://www.phmsa.dot.gov/hazmat/outreach-training/erg** (accessed April 26, 2016).*

▸ CAMEO Chemicals

13.6.2 Safe Storage

Fireproof. Cool.

- ILO International Chemical Safety Cards (ICSC)

13.6.3 Storage Conditions

Prior to working with this chemical you should be trained on its proper handling and storage. Before entering a confined space where this chemical may be present, check to make sure that an explosive concentration does not exist. It must be stored to avoid contact with even small amounts of acids (such as nitric or sulfuric acids); alkalis (such as sodium bydroxide or potassium hydroxide); cataylic anhydrous chlorides of iron, aluminum or tin; iron or aluminum oxide; or metallic potassium hydroxide); catalytic anhydrous chlorides of iron, aluminum or tin; iron or aluminum oxide; or metallic potassium hydroxide, since it may react by itself, liberating much heat and causing a possible explosion. Ethylene oxide should not contact oxidizers (such as perchlorates, peroxides, permanganates, chlorates, and nitrates) since an explosion could occur. Store in tightly closed containers in a cool, well-ventilated area away from heat, sparks, or sunlight. Sources of ignition such as smoking and open flames are prohibited where ethlyene oxide is handled, used, or stored. Metal containers involving the transfer of 5 gallons or more of ethylene oxide should br grounded and bonded. Drums must be equipped with self-closing valves, pressure vacuum bungs, and flame arresters. Use only non-sparking tools and equipment, especially when opening and closing containers of ethylene oxide . Wherever ethylene oxide is used, handled, manufactured, or stored, use explosion-proof electrical equipment and fittings.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1101

- Hazardous Substances Data Bank (HSDB)

Store EtO in tightly closed cylinders or tanks in a cool, shaded, well-ventilated, explosion-proof area.

NIOSH; NIOSH Publication No. 2007-164: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities (Revised Edition) 40 pp. (August 2007). Available from, as of July 21, 2008: https://www.cdc.gov/niosh/docs/2007-164/pdfs/2007-164.pdf

- Hazardous Substances Data Bank (HSDB)

Temperature: ambient

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

- Hazardous Substances Data Bank (HSDB)

Protect containers against physical damage, check for leakage intermittently. Store in distant outdoor tank or container protected from direct sunlight, lined with insulating material, equipped with an adequate refrigeration and water system. Indoor storage should be restricted to small quantities. Place material in a combustible liquid cabinet which is fireproof in conformity with regulations.

ITII. Toxic and Hazardous Industrial Chemicals Safety Manual. Tokyo, Japan: The International Technical Information Institute, 1988., p. 237

- Hazardous Substances Data Bank (HSDB)

For more Storage Conditions (Complete) data for ETHYLENE OXIDE (7 total), please visit the HSDB record page.

- Hazardous Substances Data Bank (HSDB)

13.7 Exposure Control and Personal Protection

13.7.1 Recommended Exposure Limit (REL)

REL-TWA (Time Weighted Average)

<0.1 ppm (<0.18 mg/m^3)

- Occupational Safety and Health Administration (OSHA)

REL-C (Ceiling)

5 ppm (9 mg/m^3)[10 minutes]

- Occupational Safety and Health Administration (OSHA)

Ca TWA <0.1 ppm (0.18 mg/m^3) C 5 ppm (9 mg/m^3) [10-min/day] See Appendix A

- The National Institute for Occupational Safety and Health (NIOSH)

13.7.2 Permissible Exposure Limit (PEL)

PEL-TWA (8-Hour Time Weighted Average)

1 ppm [0.5 ppm Action Level]

- Occupational Safety and Health Administration (OSHA)

PEL-C (Ceiling)

5 ppm [15 minute excursion limit]

- Occupational Safety and Health Administration (OSHA)

CAPEL-TWA (California PEL - Time Weighted Average)

1 ppm (2 mg/m^3)

- Occupational Safety and Health Administration (OSHA)

CAPEL-STEL (California PEL - Short Term Exposure Limit)

5 ppm

- Occupational Safety and Health Administration (OSHA)

[1910.1047] TWA 1 ppm 5 ppm [15-minute Excursion]

- The National Institute for Occupational Safety and Health (NIOSH)

13.7.3 Immediately Dangerous to Life or Health (IDLH)

800 ppm ; A potential occupational carcinogen. (NIOSH, 2016)

*National Institute of Occupational Safety and Health. NIOSH Pocket Guide to Chemical Hazards (full website version). **https://www.cdc.gov/niosh/npg** (accessed August 2016).*

- CAMEO Chemicals

NIOSH considers ethylene oxide to be a potential occupational carcinogen.

NIOSH. NIOSH Pocket Guide to Chemical Hazards & Other Databases CD-ROM. Department of Health & Human Services, Centers for Disease Prevention & Control. National Institute for Occupational Safety & Health. DHHS (NIOSH) Publication No. 2005-151 (2005)

- Hazardous Substances Data Bank (HSDB)

800 ppm

- Occupational Safety and Health Administration (OSHA)

Ca [800 ppm]

See: 75218

- The National Institute for Occupational Safety and Health (NIOSH)

13.7.4 Threshold Limit Values (TLV)

8 hr Time Weighted Avg (TWA): 1 ppm.

American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, OH, 2008, p. 30

- Hazardous Substances Data Bank (HSDB)

Excursion Limit Recommendation: Excursions in worker exposure levels may exceed three times the TLV-TWA for no more than a total of 30 min during a work day, and under no circumstances should they exceed five times the TLV-TWA, provided that the TLV-TWA is not exceeded.

American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, OH, 2008, p. 5

- Hazardous Substances Data Bank (HSDB)

A2; Suspected human carcinogen.

American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, OH, 2008, p. 30

- Hazardous Substances Data Bank (HSDB)

1 ppm as TWA; (skin); A2 (suspected human carcinogen); BEI issued.

- ILO International Chemical Safety Cards (ICSC)

skin absorption (H); carcinogen category: 2; germ cell mutagen group: 2

- ILO International Chemical Safety Cards (ICSC)

TLV-TWA (Time Weighted Average)

1 ppm [1990]

- Occupational Safety and Health Administration (OSHA)

13.7.5 Other Standards Regulations and Guidelines

Germany: 5 ppm; USSR: 0.5 ppm.

American Conference of Governmental Industrial Hygienists. Documentation of the Threshold Limit Values and Biological Exposure Indices. 5th ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists, 1986., p. 257

- Hazardous Substances Data Bank (HSDB)

Emergency Response Planning Guidelines (ERPG): ERPG(1) Not appropriate; ERPG(2) 50 ppm (without serious, adverse effects) for up to 1 hr exposure; ERPG(3) 500 ppm (not life threatening) up to 1 hr exposure.

American Industrial Hygiene Association. The AIHA 1999 Emergency Response Planning Guidelines and Workplace Environmental Exposure Level Guides Handbook. American Industrial Hygiene Association. Fairfax, VA 1999., p. 25

- Hazardous Substances Data Bank (HSDB)

13.7.6 Inhalation Risk

A harmful concentration of this gas in the air will be reached very quickly on loss of containment.

- ILO International Chemical Safety Cards (ICSC)

13.7.7 Effects of Short Term Exposure

The vapour is irritating to the eyes, skin and respiratory tract. Water solutions may cause skin blisters. Rapid evaporation of the liquid may cause frostbite.

ILO International Chemical Safety Cards (ICSC)

13.7.8 Effects of Long Term Exposure

Repeated or prolonged contact may cause skin sensitization. Repeated or prolonged inhalation may cause asthma. The substance may have effects on the nervous system. This substance is carcinogenic to humans. May cause heritable genetic damage to human germ cells.

ILO International Chemical Safety Cards (ICSC)

13.7.9 Allowable Tolerances

Tolerances are established for residues of the antimicrobial agent and insecticide ethylene oxide, when used as a postharvest fumigant in or on the following food commodities:

Commodity	Parts per million
Coconut, copra	50
Spices, whole	50
Walnut, black	50

*40 CFR 180.151(a)(1) (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: **https://www.ecfr.gov***

Hazardous Substances Data Bank (HSDB)

Ethylene oxide may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices and other processed natural seasoning materials, except mixtures to which salt has been added, in accordance with the following prescribed conditions: (i) Ethylene oxide, either alone or admixed with **carbon dioxide** or **dichlorodifluoromethane**, shall be used in amounts not to exceed that required to accomplish the intended technical effects. If used with **dichlorodifluoromethane**, the **dichlorodifluoromethane** shall conform with the requirements prescribed by 21 CFR 173.355 of this chapter. (ii) To assure safe use of the fumigant, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label or labeling. (iii) Residues of ethylene oxide in ground spices from both postharvest application to whole spices and application to the ground spices shall not exceed the established tolerance of 50 parts per million for residues in whole spices in paragraph (a)(1) of this section.

*40 CFR 180.151(a)(2) (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: **https://www.ecfr.gov***

Hazardous Substances Data Bank (HSDB)

13.7.10 Personal Protective Equipment (PPE)

Skin: If chemical is in liquid form, wear appropriate personal protective clothing to prevent skin contact. Eyes: If chemical is in liquid form, wear appropriate eye protection to prevent eye contact. Wash skin: If the chemical is in liquid form, the worker should immediately wash the skin when it becomes contaminated. Remove: Work clothing that becomes wet should be immediately removed due to its flammability hazard(i.e. for liquids with flash point Change: No recommendation is made specifying the need for the worker to change clothing after the work shift. Provide: Facilities for quickly drenching the body should be provided (when chemical is in liquid form) within the immediate work area for emergency use where there is a possibility of exposure. [Note: It is intended that these facilities provide a sufficient quantity or flow of **water** to quickly remove the substance from any body areas likely to be exposed. The actual determination of what constitutes an adequate quick drench facility depends on the specific circumstances. In certain instances, a deluge shower should be readily available, whereas in others, the availability of **water** from a sink or hose could be considered adequate.] (NIOSH, 2016)

*National Institute of Occupational Safety and Health. NIOSH Pocket Guide to Chemical Hazards (full website version). **https://www.cdc.gov/niosh/npg** (accessed August 2016).*

CAMEO Chemicals

NIOSH: 5 ppm: GMFS+ (any air-purifying, full-facepiece respirator (gas mask) with a chin-style, front- or back-mounted canister providing protection against the compound of concern); or SCBAF (any self-contained breathing apparatus with a full facepiece); or SAF (any supplied-air respirator with a full facepiece). Emergency or planned entry into unknown concentrations or IDLH conditions: SCBAF:PD,PP (any self-breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode); or SAF:PD, PP: ASCBA (any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure-demand or other positive pressure mode). Escape: GMFS+ {any air-purifying, full facepiece respirator (gas mask) with a chin-style, front- or back- mounted canister providing protection against the compound of concern); or SCBAE (any appropriate escape-type, self-contained breathing apparatus). (+ End of service life indicator (ESLI) required).

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1101

Hazardous Substances Data Bank (HSDB)

AIR-SUPPLIED MASK; GOGGLES OR FACE SHIELD; RUBBER SHOES & COVERALLS.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

Hazardous Substances Data Bank (HSDB)

Wear **neoprene** gloves, safety glasses, plastic protective clothing and self-contained breathing apparatus.

ITII. Toxic and Hazardous Industrial Chemicals Safety Manual. Tokyo, Japan: The International Technical Information Institute, 1988., p. 237

Hazardous Substances Data Bank (HSDB)

PRECAUTIONS FOR "CARCINOGENS": ... Dispensers of liq detergent /should be available./ ... Safety pipettes should be used for all pipetting. ... In animal laboratory, personnel should ... wear protective suits (preferably disposable, one-piece & close-fitting at ankles & wrists), gloves, hair covering & overshoes. ... In chemical laboratory, gloves & gowns should always be worn ... however, gloves should not be assumed to provide full protection. Carefully fitted masks or respirators may be necessary when working with particulates or gases, & disposable plastic aprons might provide addnl protection. ... gowns ... /should be/ of distinctive color, this is a reminder that they are not to be worn outside the laboratory. /Chemical Carcinogens/

Montesano, R., H. Bartsch, E.Boyland, G. Della Porta, L. Fishbein, R. A. Griesemer, A.B. Swan, L. Tomatis, and W. Davis (eds.). Handling Chemical Carcinogens in the Laboratory: Problems of Safety. IARC Scientific Publications No. 33. Lyon, France: International Agency for Research on Cancer, 1979., p. 8

Hazardous Substances Data Bank (HSDB)

For more Personal Protective Equipment (PPE) (Complete) data for ETHYLENE OXIDE (13 total), please visit the **HSDB record page**.

Hazardous Substances Data Bank (HSDB)

(**See protection codes**)

Skin: Prevent skin contact (liquid)

Eyes: Prevent eye contact (liquid)

Wash skin: When contaminated (liquid)

Remove: When wet (flammable)

Change: No recommendation

Provide: Quick drench (liquid)

▸ The National Institute for Occupational Safety and Health (NIOSH)

13.7.11 Respirator Recommendations

(See Appendix E)

NIOSH

Up to 5 ppm:

(APF = 50) Any air-purifying, full-facepiece respirator (gas mask) with a chin-style, front- or back-mounted canister providing protection against the compound of concern†

(APF = 50) Any self-contained breathing apparatus with a full facepiece

(APF = 50) Any supplied-air respirator with a full facepiece

Emergency or planned entry into unknown concentrations or IDLH conditions:

(APF = 10,000) Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode

(APF = 10,000) Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained positive-pressure breathing apparatus

Escape:

(APF = 50) Any air-purifying, full-facepiece respirator (gas mask) with a chin-style, front- or back-mounted canister providing protection against the compound of concern†

Any appropriate escape-type, self-contained breathing apparatus

Important additional information about respirator selection

▸ The National Institute for Occupational Safety and Health (NIOSH)

13.7.12 Fire Prevention

NO open flames, NO sparks and NO smoking. Closed system, ventilation, explosion-proof electrical equipment and lighting. Use non-sparking handtools.

▸ ILO International Chemical Safety Cards (ICSC)

13.7.13 Exposure Prevention

AVOID ALL CONTACT! IN ALL CASES CONSULT A DOCTOR!

▸ ILO International Chemical Safety Cards (ICSC)

13.7.14 Inhalation Prevention

Use closed system or ventilation.

▸ ILO International Chemical Safety Cards (ICSC)

13.7.15 Skin Prevention

Protective gloves. Cold-insulating gloves. Protective clothing.

▸ ILO International Chemical Safety Cards (ICSC)

13.7.16 Eye Prevention

Wear eye protection in combination with breathing protection.

▸ ILO International Chemical Safety Cards (ICSC)

13.7.17 Ingestion Prevention

Do not eat, drink, or smoke during work. Wash hands before eating.

▸ ILO International Chemical Safety Cards (ICSC)

13.8 Stability and Reactivity

13.8.1 Air and Water Reactions

Highly flammable. Flammable over a wide vapor-air concentration range. Must be diluted on the order of 24 to 1 with water to lose flammability. Soluble in water.

▸ CAMEO Chemicals

13.8.2 Reactive Group

Epoxides

Polymerizable Compounds

▸ CAMEO Chemicals

13.8.3 Reactivity Alerts

Highly Flammable

Explosive

Polymerizable

▸ CAMEO Chemicals

13.8.4 Reactivity Profile

Colorless gas at room temperature (b.p. 11° C), confirmed carcinogen. Highly flammable, severe explosion hazard when exposed to flame. The autoignition temperature may be as low as 140° C in presence of rust. Rapid compression of the vapor with air causes explosion. Ethylene oxide vapor may be initiated into explosive decomposition in absence of air [Hess, L. G., et al., Ind. Eng. Chem., 1950, 42, p. 1251]. Metal fittings containing **magnesium**, **copper** or **silver** should be avoided, since traces of **acetylene** in ethylene oxide may produce metal acetylides capable of detonating the vapor [MCA SD-38, 1971]. Violent polymerization occurs on contact with strong bases (alkali hydroxides, **ammonia**) or acids, amines, metallic **potassium**, oxides (**aluminum oxide**, iron oxide, rust), covalent halides (**aluminum chloride**, **ferric chloride**, **tin(IV) chloride**) [Gupta, A. K., J. Soc. Chem. Ind., 1949, 68, p. 179]. Violent reaction with **m-nitroaniline**, **magnesium perchlorate**, mercaptans, thiols, **triethylamine** [Bretherick, 5th ed., 1995, p. 316]. Ethylene oxide and SO2 can react violently in **pyridine** solution with pressurization if ethylene oxide is in excess (Nolan, 1983, Case History 51).

▸ CAMEO Chemicals

13.8.5 Hazardous Reactivities and Incompatibilities

Forms explosive mixture with air. Dangerously reactive; may rearrange chemically and/or polymerize violently with evolution of heat, when in contact with highly active catalytic surfaces such as anhydrous chlorides or **iron**, **tin** and **aluminum**, pure oxides of **iron** and **aluminum**, and alkali metal hydroxides. Even small amounts of strong acids, alkalis, oxidizers can cause a reaction. Avoid contact with **copper**. Protect container from physical damage, sun and heat. Attacks some plastics, rubber or coatings.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1099

▸ Hazardous Substances Data Bank (HSDB)

Metal fittings containing **copper**, **silver**, **mercury**, or **magnesium** should not be used in ethylene oxide service, since traces of **acetylene** could produce explosive acetylides capable of detonating ethylene oxide vapor.

Bretherick, L. Handbook of Reactive Chemical Hazards. 4th ed. Boston, MA: Butterworth-Heinemann Ltd., 1990, p. 272

▸ Hazardous Substances Data Bank (HSDB)

INCOMPATIBILITIES: BECAUSE OF HIGH CHEMICAL REACTIVITY ... IT REACTS WITH MANY PHARMACEUTICAL SUBSTANCES & WITH VITAMINS, AMINO ACIDS, & OTHER FOOD CONSTITUENTS. ...

Osol, A. (ed.). Remington's Pharmaceutical Sciences. 16th ed. Easton, Pennsylvania: Mack Publishing Co., 1980., p. 1101

▸ Hazardous Substances Data Bank (HSDB)

Accidental contamination of a large ethylene oxide feed-cylinder by reaction liquor containing **trimethylamine** caused the cylinder to explode 18 hr later. Contamination was possible because of a faulty pressure gauge and suck-back of froth above the liquid level.

Bretherick, L. Handbook of Reactive Chemical Hazards. 4th ed. Boston, MA: Butterworth-Heinemann Ltd., 1990, p. 276

▸ Hazardous Substances Data Bank (HSDB)

For more Hazardous Reactivities and Incompatibilities (Complete) data for ETHYLENE OXIDE (16 total), please visit the **HSDB record page**.

▸ Hazardous Substances Data Bank (HSDB)

13.9 Transport Information

13.9.1 DOT Emergency Guidelines

If ... THERE IS NO FIRE, go directly to the Table of Initial Isolation and Protective Action Distances /(see table below)/ ... to obtain initial isolation and protective action distances. IF THERE IS A FIRE, or IF A FIRE IS INVOLVED, go directly to the appropriate guide /(see guide(s) below)/ and use the evacuation information shown under PUBLIC SAFETY.

Table: Table of Isolation and Protective Action Distances for Ethylene oxide

Small Spills (from a small package or small leak from a large package)		
First ISOLATE in all Directions 30 meters (100 feet)	Then PROTECT persons Downwind during DAY: 0.1 kilometers (0.1 miles)	Then PROTECT persons Downwind during NIGHT: 0.2 kilometers (0.1 miles)
Large Spills (From a large package or from many small packages)		
First ISOLATE in all Directions 90 meters (300 feet)	Then PROTECT persons Downwind during DAY: 0.8 kilometers (0.5 miles)	Then PROTECT persons Downwind during NIGHT: 2.4 kilometers (1.5 miles)

U.S. Department of Transportation. 2004 Emergency Response Guidebook. A Guide book for First Responders During the Initial Phase of a Dangerous Goods/Hazardous Materials Incident. Washington, D.C. 2004302

▸ Hazardous Substances Data Bank (HSDB)

/GUIDE 119P: GASES - TOXIC - FLAMMABLE/ Health: TOXIC; may be fatal if inhaled or absorbed through skin. Contact with gas or liquefied gas may cause burns, severe injury and/or frostbite. Fire will produce irritating, corrosive and/or toxic gases. Runoff from fire control may cause pollution.

U.S. Department of Transportation. 2004 Emergency Response Guidebook. A Guide book for First Responders During the Initial Phase of a Dangerous Goods/Hazardous Materials Incident. Washington, D.C. 2004

▸ Hazardous Substances Data Bank (HSDB)

/GUIDE 119P: GASES - TOXIC - FLAMMABLE/ Fire or Explosion: Flammable; may be ignited by heat, sparks or flames. May form explosive mixtures with air. Those substances designated with a "P" may polymerize explosively when heated or involved in a fire. Vapors from liquefied gas are initially heavier than air and spread along ground. Vapors may travel to source of ignition and flash back. Some of these materials may react violently with **water**. Cylinders exposed to fire may vent and release toxic and flammable gas through pressure relief devices. Containers may explode when heated. Ruptured cylinders may rocket. Runoff may create fire or explosion hazard.

U.S. Department of Transportation. 2004 Emergency Response Guidebook. A Guide book for First Responders During the Initial Phase of a Dangerous Goods/Hazardous Materials Incident. Washington, D.C. 2004

- Hazardous Substances Data Bank (HSDB)

/GUIDE 119P: GASES - TOXIC - FLAMMABLE/ Public Safety: CALL Emergency Response Telephone Number ... . As an immediate precautionary measure, isolate spill or leak area for at least 100 meters (330 feet) in all directions. Keep unauthorized personnel away. Stay upwind. Many gases are heavier than air and will spread along ground and collect in low or confined areas (sewers, basements, tanks). Keep out of low areas. Ventilate closed spaces before entering.

U.S. Department of Transportation. 2004 Emergency Response Guidebook. A Guide book for First Responders During the Initial Phase of a Dangerous Goods/Hazardous Materials Incident. Washington, D.C. 2004

- Hazardous Substances Data Bank (HSDB)

For more DOT Emergency Guidelines (Complete) data for ETHYLENE OXIDE (9 total), please visit the **HSDB record page**.

- Hazardous Substances Data Bank (HSDB)

13.9.2 DOT ID and Guide

1040 119P

- DOT Emergency Response Guidebook

1040 119 P

- The National Institute for Occupational Safety and Health (NIOSH)

13.9.3 Shipping Name/ Number DOT/UN/NA/IMO

UN 1040; Ethylene oxide

- Hazardous Substances Data Bank (HSDB)

IMO 2.3; Ethylene oxide

- Hazardous Substances Data Bank (HSDB)

13.9.4 Standard Transportation Number

49 201 08; Ethylene oxide

- Hazardous Substances Data Bank (HSDB)

13.9.5 Shipment Methods and Regulations

No person may /transport,/ offer or accept a hazardous material for transportation in commerce unless that person is registered in conformance ... and the hazardous material is properly classed, described, packaged, marked, labeled, and in condition for shipment as required or authorized by ... /the hazardous materials regulations (49 CFR 171-177)./

49 CFR 171.2 (7/1/96)

- Hazardous Substances Data Bank (HSDB)

The International Air Transport Association (IATA) Dangerous Goods Regulations are published by the IATA Dangerous Goods Board pursuant to IATA Resolutions 618 and 619 and constitute a manual of industry carrier regulations to be followed by all IATA Member airlines when transporting hazardous materials.

International Air Transport Association. Dangerous Goods Regulations. 47th Edition. Montreal, Quebec Canada. 2006., p. 188

- Hazardous Substances Data Bank (HSDB)

The International Maritime Dangerous Goods Code lays down basic principles for transporting hazardous chemicals. Detailed recommendations for individual substances and a number of recommendations for good practice are included in the classes dealing with such substances. A general index of technical names has also been compiled. This index should always be consulted when attempting to locate the appropriate procedures to be used when shipping any substance or article.

International Maritime Organization. International Maritime Dangerous Goods Code. London, UK. 2004., p. 43

- Hazardous Substances Data Bank (HSDB)

13.9.6 DOT Label

Poison Gas Flammable Gas

- CAMEO Chemicals

13.9.7 EC Classification

Symbol: F+, T; R: 45-46-12-23-36/37/38; S: 53-45; Note: E

- ILO International Chemical Safety Cards (ICSC)

13.9.8 UN Classification

UN Hazard Class: 2.3; UN Subsidiary Risks: 2.1

- ILO International Chemical Safety Cards (ICSC)

13.10 Regulatory Information

13.10.1 Atmospheric Standards

This action promulgates standards of performance for equipment leaks of Volatile Organic Compounds (VOC) in the Synthetic Organic Chemical Manufacturing Industry (SOCMI). The intended effect of these standards is to require all newly constructed, modified, and reconstructed SOCMI process units to use the best demonstrated system of continuous emission reduction for equipment leaks of VOC, considering costs, non air quality health and environmental impact and energy requirements. Ethylene oxide is produced, as an intermediate or a final product, by process units covered under this subpart.

40 CFR 60.489 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: ***https://www.ecfr.gov***

- Hazardous Substances Data Bank (HSDB)

Listed as a hazardous air pollutant (HAP) generally known or suspected to cause serious health problems. The Clean Air Act, as amended in 1990, directs EPA to set standards requiring major sources to sharply reduce routine emissions of toxic pollutants. EPA is required to establish and phase in specific performance based standards for all air emission sources that emit one or more of the listed pollutants. Ethylene oxide is included on this list.

Clean Air Act as amended in 1990, Sect. 112 (b) (1) Public Law 101-549 Nov. 15, 1990

- Hazardous Substances Data Bank (HSDB)

13.10.2 State Drinking Water Guidelines

(FL) FLORIDA 10 ug/L

USEPA/Office of Water; Federal-State Toxicology and Risk Analysis Committee (FSTRAC). Summary of State and Federal Drinking Water Standards and Guidelines (11/93) To Present

- Hazardous Substances Data Bank (HSDB)

13.10.3 CERCLA Reportable Quantities

Persons in charge of vessels or facilities are required to notify the National Response Center (NRC) immediately, when there is a release of this designated hazardous substance, in an amount equal to or greater than its reportable quantity of 10 lb or 4.54 kg. The toll free number of the NRC is (800) 424-8802. The rule for determining when notification is required is stated in 40 CFR 302.4 (section IV. D.3.b).

40 CFR 302.4 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of April 16, 2008: ***https://www.ecfr.gov***

- Hazardous Substances Data Bank (HSDB)

Releases of CERCLA hazardous substances are subject to the release reporting requirement of CERCLA section 103, codified at 40 CFR part 302, in addition to the requirements of 40 CFR part 355. Ethylene oxide is an extremely hazardous substance (EHS) subject to reporting requirements when stored in amounts in excess of its threshold planning quantity (TPQ) of 1,000 lbs.

40 CFR 355 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: ***https://www.ecfr.gov***

- Hazardous Substances Data Bank (HSDB)

13.10.4 TSCA Requirements

Pursuant to section 8(d) of **TSCA**, EPA promulgated a model Health and Safety Data Reporting Rule. The section 8(d) model rule requires manufacturers, importers, and processors of listed chemical substances and mixtures to submit to EPA copies and lists of unpublished health and safety studies. **Oxirane** is included on this list. Effective date: 10/4/82; Sunset date: 10/4/92.

40 CFR 716.120 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: ***https://www.ecfr.gov***

- Hazardous Substances Data Bank (HSDB)

13.10.5 RCRA Requirements

U115; As stipulated in 40 CFR 261.33, when ethylene oxide, as a commercial chemical product or manufacturing chemical intermediate or an off-specification commercial chemical product or a manufacturing chemical intermediate, becomes a waste, it must be managed according to Federal and/or State hazardous waste regulations. Also defined as a hazardous waste is any residue, contaminated soil, **water**, or other debris resulting from the cleanup of a spill, into **water** or on dry land, of this waste. Generators of small quantities of this waste may qualify for partial exclusion from hazardous waste regulations (40 CFR 261.5).

40 CFR 261.33 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: ***https://www.ecfr.gov***

- Hazardous Substances Data Bank (HSDB)

13.10.6 FIFRA Requirements

Tolerances are established for residues of the antimicrobial agent and insecticide ethylene oxide, when used as a postharvest fumigant in or on the following food commodities:

Commodity
Coconut, copra
Spices, whole
Walnut, black

40 CFR 180.151(a)(1) (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: ***https://www.ecfr.gov***

- Hazardous Substances Data Bank (HSDB)

Ethylene oxide may be safely used as a fumigant for the control of microorganisms and insect infestation in ground spices and other processed natural seasoning materials, except mixtures to which salt has been added, in accordance with the following prescribed conditions: (i) Ethylene oxide, either alone or admixed with **carbon dioxide** or **dichlorodifluoromethane**, shall be used in amounts

not to exceed that required to accomplish the intended technical effects. If used with **dichlorodifluoromethane**, the **dichlorodifluoromethane** shall conform with the requirements prescribed by 21 CFR 173.355 of this chapter. (ii) To assure safe use of the fumigant, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency and it shall be used in accordance with such label or labeling. (iii) Residues of ethylene oxide in ground spices from both postharvest application to whole spices and application to the ground spices shall not exceed the established tolerance of 50 parts per million for residues in whole spices in paragraph (a)(1) of this section.

40 CFR 180.151(a)(2) (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of June 26, 2008: ***https://www.ecfr.gov***

▸ **Hazardous Substances Data Bank (HSDB)**

As the federal pesticide law FIFRA directs, EPA is conducting a comprehensive review of older pesticides to consider their health and environmental effects and make decisions about their future use. Under this pesticide reregistration program, EPA examines health and safety data for pesticide active ingredients initially registered before November 1, 1984, and determines whether they are eligible for reregistration. In addition, all pesticides must meet the new safety standard of the Food Quality Protection Act of 1996. Ethylene oxide is found on List A, which contains most food use pesticides and consists of the 194 chemical cases (or 350 individual active ingredients) for which EPA issued registration standards prior to FIFRA, as amended in 1988. Case No: 2275; Pesticide type: insecticide, fungicide, rodenticide, antimicrobial; Case Status:In Pre-Special Review. The pesticide is in or has completed the reregistration process and, meanwhile, is also the subject of an in-depth Special Review.; Active ingredient (AI): Ethylene oxide; Data Call-in (DCI) Date(s): 05/24/91; AI Status: The producers of the pesticide has made commitments to conduct the studies and pay the fees required for reregistration, and are meeting those commitments in a timely manner.

United States Environmental Protection Agency/ Prevention, Pesticides and Toxic Substances; Status of Pesticides in Registration, Reregistration, and Special Review. (1998) EPA 738-R-98-002, p. 182

▸ **Hazardous Substances Data Bank (HSDB)**

13.11 Other Safety Information

13.11.1 Toxic Combustion Products

Incomplete combustion releases **carbon monoxide** ... .

DHHS/NTP; SUBSTANCE PROFILES REPORT ON CARCINOGENS, ELEVENTH EDITION: Ethylene Oxide CAS No. 75-21-8 p.1. Available from, as of July 23, 2008: ***https://ntp.niehs.nih.gov/***

▸ **Hazardous Substances Data Bank (HSDB)**

Irritating vapors generated when heated.

U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5.

▸ **Hazardous Substances Data Bank (HSDB)**

13.11.2 History and Incidents

Workers may be at risk of death or serious injury from explosions if safe operating procedures are not established and followed in large-scale industrial processes that use ethylene oxide gas (EtO) for sterilizing medical devices and other products ... . In these processes, products are placed in bulk in a closed, semitrailer-sized chamber, and EtO is injected into the chamber. Once sterilization is completed, EtO is vented at a controlled rate through closed ductwork to an emissions control device. There, to meet environmental emissions limits, the EtO is either burned off or converted to **water** and **carbon dioxide** through heat and catalytic conversion. If EtO is inadvertently "overfed" into the emissions control device at rates or concentrations higher than the device safely can handle, concentrations of the gas may reach flammable levels. If that occurs, heat sources in the emissions control device may trigger an explosion. ... "If ignited from overfeeding in industrial sterilization processes, EtO can explode with enough force to lift a 50,000 pound sterilization chamber three feet off its foundation, and blow out steel ductwork," noted NIOSH Director Linda Rosenstock, M.D., M.P.H. "It is important to treat it with care." Between 1994 and 1998, EtO was associated with 10 explosions at industrial sterilization facilities and also at EtO repackaging plants where EtO is transferred from large drums to small tubes or canisters for later use in small sterilization units at hospitals. In one such explosion, a worker was killed and 59 others were injured.

NIOSH; NIOSH Notes Safeguards to Prevent Explosion Risk in Industrial Ethylene Oxide Sterilization Processes (May 11, 2000) Available from, as of July 21, 2008: ***https://www.cdc.gov/niosh/updates/ethyster.html***

▸ **Hazardous Substances Data Bank (HSDB)**

On August 19, 2004, an explosion at /a contract medical sterilization services/ ... ethylene oxide (EO) sterilization facility in Ontario, California, injured four workers and caused extensive damage to the 66,000 square-foot facility. Flying glass from the control room windows was responsible for all of the injuries, and both the facility structure and equipment sustained severe damage. The ... plant and neighboring facilities were evacuated, and plant operations were disrupted for 9 months. ... /The/ EO facility in Ontario performs services for manufacturers of a variety of medical products such as disposable syringes, urinary tract catheters, and cardiovascular stints and valves. The U.S. Chemical Safety and Hazard Investigation Board (CSB) determined that maintenance personnel overrode safety devices and EO flowed through the ventilation system from a sterilizer to an open-flame catalytic oxidizer (oxidizer) where it ignited. The flame traveled back to the sterilizer chamber through the ventilation system ducting and ignited a large volume of EO in the chamber. The investigation identified the following root causes: Engineering controls installed at the facility did not prevent an explosive concentration of ethylene oxide (EO) from reaching the oxidizer. Employees did not understand the hazards associated with the process. This CSB report makes recommendations to Sterigenics International, Inc., the National Fire Protection Association (NFPA), the National Institute for Occupational Safety and Health (NIOSH), and others.

U.S. Chemical Safety and Hazard Investigation Board; Investigation Report No. 2004-11-I-CA Sterigenics (4 Employees Injured) 59 p. (August 19, 2004) Available from, as of July 22, 2008: ***https://www.csb.gov/completed_investigations/docs/CSBSterigenicsFinalReport.pdf***

▸ **Hazardous Substances Data Bank (HSDB)**

A Chessie System freight train derailed in a wooded, rural area near Woodland Park, Michigan in February 1978. Four tank cars were damaged, spilling approx 300,000 lb of **vinylidene chloride**, 330,000 lb of **phenol**, and 125,000 lb of ethylene oxide. Most of the **phenol**, which had solidified on the surface, was removed by a cleanup contractor although residual **phenol** remained in the soil. The ethylene oxide vaporized, posing no groundwater contamination problems. The **vinylidene chloride** percolated through the sandy soils into the groundwater about 50 ft below the ground surface. **Vinylidene chloride** concentrations as high as 300 mg/L were found in monitoring wells near the derailment site. The groundwater cleanup program was completed over a three yr period. ...

Posthuma AR et al; 1983 Nat Conf Environ Engin p.775-82 (1983)

▸ **Hazardous Substances Data Bank (HSDB)**

13.11.3 Special Reports

NIOSH; NIOSH Publication No. 2007-164: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities (Revised Edition) 40 pp. (August 2007). This Alert informs owners, managers, supervisors, engineers, safety professionals, and workers about the explosions, injuries, and deaths that may occur at industrial industrial ethylene oxide (EtO) sterilization facilities and repackaging plants. Steps are recommended for preventing these explosions. This supersedes NIOSH Publication 2000-119.

▸ **Hazardous Substances Data Bank (HSDB)**

USEPA/Office of Pesticide Programs; Reregistration Eligibility Decision Document - Ethylene Oxide EPA 738-R-08-003 (March 2008). This document provides a thorough review of the scientific data underlying ethylene oxide's registration and fulfills the EPA's requirement to determine whether pesticides containing the active ingredient **pebulate** are eligible for reregistration before calling in data on products.

▸ **Hazardous Substances Data Bank (HSDB)**

ATSDR; Medical Management for Ethylene Oxide CAS 75-21-8; UN 1040. 19 pp. Provides background information on the toxicity and sources of exposure to ethylene oxide as well as medical managements for patients exposed in an emergency situation and their follow-up care.

- Hazardous Substances Data Bank (HSDB)

European Chemicals Bureau; IUCLID Dataset, Ethylene Oxide (CAS # 75-21-8) p. 71 (2000 CD-ROM edition) contains information on use, toxicology, and environmental effects of this chemical as supplied to the European Union by industry.

- Hazardous Substances Data Bank (HSDB)

For more Special Reports (Complete) data for ETHYLENE OXIDE (11 total), please visit the **HSDB record page**.

- Hazardous Substances Data Bank (HSDB)

14 Toxicity

14.1 Toxicological Information

CDC-ATSDR Toxicological Profile

- CDC-ATSDR Toxic Substances Portal

14.1.1 Toxicity Summary

IDENTIFICATION: Ethylene oxide is a colorless, high reactive gas at room temperature and pressure. It used in the manufacture of ethylene glycol and surfactants. It used in the manufacture of surfactants. Ethylene oxide is also used as a sterilant for health care materials and other heat-sensitive products. HUMAN EXPOSURE: Ethylene oxide is rapidly taken up via the lungs, distributed, and metabolized to ethylene glycol and to glutathione conjugates. Ethylene oxide can be absorbed though the skin from the gas phase or from aqueous solutions and is uniformly distributed throughout the body. Ethylene oxide is an alkylating agent and forms protein and DNA adducts. Hemoglobin adducts have been used for biomonitoring. Based on studies primarily in occupationally exposed populations, ethylene oxide is an ocular, respiratory, and dermal irritant and a sensitizing agent. Neurological effects (primarily sensorimotor polyneuropathy) have been observed in workers exposed to relatively high concentrations. The route of likely greatest exposure and focus of the human health is inhalation from air. There is some evidence of an association between exposure to ethylene oxide and the development of haematological cancers in epidemiological studies of occupationally exposed populations, limitations of the data preclude definitive conclusions. There is consistent evidence that ethylene oxide has induced clastogenic changes in exposed workers. ANIMAL/PLANT STUDIES: The acute inhalation toxicity of ethylene oxide in rodents and dogs is low. In inhalation studies, ethylene oxide has induced a wide range of tumours (e.g., leukaemia, lymohoma, brain, lung). Ethylene oxide induces gene mutations at all phylogenetic levels tested in vitro and in vivo. It also induces germ cell mutations and clastogenic effects in experimental animals. In experimental animals, ethylene oxide is fetotoxic in the presence and absence of maternal toxicity at concentrations higher than those associated with cancer and other non-cancer (i.e., neurological) effects; it is teratogenic only at very high concentrations (above about 1600 mg/m3). Evidence from epidemiological studies of reproductive effects (primarily spontaneous abortions) of ethylene oxide in humans is limited. In experimental animals, among non-neoplastic effects, reproductive effects occur at lowest concentration (>90 mg/m3). These include reductions in litter size, increased post-implantation losses, alterations in sperm morphology, and changes in sperm count and motility. Available data on the non-neoplastic effects of repeated exposure to ethylene oxide in studies are limited, with past focus being primarily on the carcinogenicity of the compound. Reported effects in studies in animals were restricted primarily to those on the hematological and nervous systems.

*International Programme on Chemical Safety; Poisons Information Monograph: Ethylene Oxide (PIM) (1999) Available from, as of May 16, 2008: **https://www.inchem.org/pages/pims.html***

- Hazardous Substances Data Bank (HSDB)

14.1.2 NIOSH Toxicity Data

- The National Institute for Occupational Safety and Health (NIOSH)

14.1.3 Evidence for Carcinogenicity

A2; Suspected human carcinogen.

American Conference of Governmental Industrial Hygienists TLVs and BEIs. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, OH, 2008, p. 30

- Hazardous Substances Data Bank (HSDB)

Evaluation: There is limited evidence in humans for the carcinogenicity of ethylene oxide. There is sufficient evidence in experimental animals for the carcinogenicity of ethylene oxide. In making the overall evaluation, the Working Group took into consideration the following supporting evidence. Ethylene oxide is a directly acting alkylating agent that: (1) induces a sensitive, persistent dose-related increase in the frequency of chromosomal aberrations and sister chromatid exchange in peripheral lymphocytes and micronuclei in bone marrow cells of exposed workers; (2) has been associated with malignancies of the lymphatic and hematopoietic system in both humans and experimental animals; (3) induces a dose related increase in the frequency of hemoglobin adducts in exposed humans and dose related increases in the numbers of adducts in DNA and hemoglobin in exposed rodents; (4) induces gene mutations and heritable translocations in germ cells of exposed rodents; and (5) is a powerful mutagen and clastogen at all phylogenetic levels. Overall evaluation: Ethylene oxide is carcinogenic to humans (Group 1).

*IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: **https://monographs.iarc.fr/ENG/Classification/index.php**, p. 60 139 (1994)*

- Hazardous Substances Data Bank (HSDB)

Ethylene Oxide: known to be a human carcinogen.

*DHHS/National Toxicology Program; Eleventh Report on Carcinogens: Ethylene Oxide (75-21-8) (January 2005). Available from, as of July 31, 2009: **https://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s085ethy.pdf***

- Hazardous Substances Data Bank (HSDB)

IARC-1, NIOSH-Ca, NTP-K, OSHA-Ca, TLV-A2

- Occupational Safety and Health Administration (OSHA)

14.1.4 Carcinogen Classification

IARC Carcinogenic Agent	Ethylene oxide
IARC Carcinogenic Classes	Group 1: Carcinogenic to humans
IARC Monographs	Volume Sup 7: Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, 1987; 440 pages; ISBN 92-832-1411-0 (out of print) Volume 60: (1994) Some Industrial Chemicals Volume 97: (2008) 1,3-Butadiene, Ethylene Oxide and Vinyl Halides (Vinyl Fluoride, Vinyl Chloride and Vinyl Bromide) Volume 100F: (2012) Chemical Agents and Related Occupations

▸ International Agency for Research on Cancer (IARC)

14.1.5 Health Effects

Health Effect Code(s)

HE1 - Cancer---Currently regulated by OSHA as carcinogen

HE5 - Reproductive Hazards---Teratogenesis or other reproductive impairment

HE7 - Nervous System Disturbances---Nervous system effects other than narcosis

HE15 - Irritation-Eyes, Nose, Throat, Skin---Moderate

▸ Occupational Safety and Health Administration (OSHA)

14.1.6 Exposure Routes

The substance can be absorbed into the body by inhalation and through the skin.

▸ ILO International Chemical Safety Cards (ICSC)

inhalation, ingestion, (liquid), skin and/or eye contact

▸ The National Institute for Occupational Safety and Health (NIOSH)

14.1.7 Symptoms

irritation eyes, skin, nose, throat; peculiar taste; headache; nausea, vomiting, diarrhea; dyspnea (breathing difficulty), cyanosis, pulmonary edema; drowsiness, lassitude (weakness, exhaustion), incoordination; EKG abnormal; eye, skin burns (liquid or high vapor concentration); liquid: frostbite; reproductive effects; ; In Animals: convulsions; liver, kidney damage [potential occupational carcinogen]

▸ The National Institute for Occupational Safety and Health (NIOSH)

14.1.8 Inhalation Symptoms

Cough. Drowsiness. Headache. Nausea. Sore throat. Vomiting. Weakness.

▸ ILO International Chemical Safety Cards (ICSC)

14.1.9 Skin Symptoms

MAY BE ABSORBED! Frostbite. Redness. Pain.

▸ ILO International Chemical Safety Cards (ICSC)

14.1.10 Eye Symptoms

Redness. Pain. Blurred vision.

▸ ILO International Chemical Safety Cards (ICSC)

14.1.11 Target Organs

Dermal (Skin), Developmental (effects during periods when organs are developing) , Neurological (Nervous System), Ocular (Eyes), Renal (Urinary System or Kidneys)

▸ CDC-ATSDR Toxic Substances Portal

Eyes, skin, respiratory system, liver, central nervous system, blood, kidneys, reproductive system

▸ The National Institute for Occupational Safety and Health (NIOSH)

14.1.12 Cancer Sites

[peritoneal cancer, leukemia]

▸ The National Institute for Occupational Safety and Health (NIOSH)

14.1.13 Acute Effects

ChemIDplus

14.1.14 Interactions

Cell transformation in vitro of C3H/10T1/2 cells, using gamma-radiation and ethylene oxide, in both the absence and presence of the cancer promoter, 12-O-tetradecanoylphorbol-13- acetate, was studied. 12-O-tetradecanoylphorbol-13-acetate promotes transformation of C3H/10T1/2 cells to the same extent. In the dose ranges studied the average enhancement of the transformation frequency was 2.4 and 2.5 for ethylene oxide and gamma-radiation, respectively. The rad-equivalence of ethylene oxide in the presence of 12-O-tetradecanoylphorbol-13-acetate was calculated to be 75 + or - 52 rad/mMh (95% confidence interval) which is consistent with the value 78 + or - 14 rad/mMh (95% confidence interval) obtained without 12-O-teradecanoylphorbol-13-acetate treatment.

PMID:2237937

Kolman A et al; Toxicol Lett 53 (3): 307-13 (1990)

Hazardous Substances Data Bank (HSDB)

14.1.15 Antidote and Emergency Treatment

Establish and maintain vital functions. ... Administer warm humidified oxygen and bronchodilators, if needed. Treat cardiac dysrhythmias and control convulsions with standard treatments. Monitor for several hours after exposure. Significant exposure usually causes effects that indicate hospital admission.

Dart, R.C. (ed). Medical Toxicology. Third Edition, Lippincott Williams & Wilkins. Philadelphia, PA. 2004., p. 1245

Hazardous Substances Data Bank (HSDB)

Immediate first aid: Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand-valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR as necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention. /Ethylene oxide and related compounds/

Currance, P.L. Clements, B., Bronstein, A.C. (Eds).; Emergency Care For Hazardous Materials Exposure. 3Rd edition, Elsevier Mosby, St. Louis, MO 2005, p. 280

Hazardous Substances Data Bank (HSDB)

Basic treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary edema and treat if necessary ... . Anticipate seizures and treat if necessary ... . For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport ... . Do not use emetics. For ingestion, rinse mouth and administer 5 ml/kg up to 200 ml of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool. Administer activated charcoal ... . Cover skin burns with sterile dressings after decontamination ... . Treat frostbite with rapid rewarming techniques ... . /Ethylene oxide and related compounds/

Currance, P.L. Clements, B., Bronstein, A.C. (Eds).; Emergency Care For Hazardous Materials Exposure. 3Rd edition, Elsevier Mosby, St. Louis, MO 2005, p. 280-1

Hazardous Substances Data Bank (HSDB)

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary edema, or is in severe respiratory distress. Positive-pressure ventilation techniques with a bag-valve-mask device may be beneficial. Consider drug therapy for pulmonary edema ... . Monitor cardiac rhythm and treat arrhythmias if necessary. Start IV administration of D5W /SRP: "To keep open", minimal flow rate/. Use 0.9% saline (NS) or lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Watch for signs of fluid overload ... . Treat seizures with diazepam or lorazepam ... . Use proparacaine hydrochloride to assist eye irrigation ... . /Ethylene oxide and related compounds/

Currance, P.L. Clements, B., Bronstein, A.C. (Eds).; Emergency Care For Hazardous Materials Exposure. 3Rd edition, Elsevier Mosby, St. Louis, MO 2005, p. 281

Hazardous Substances Data Bank (HSDB)

For more Antidote and Emergency Treatment (Complete) data for ETHYLENE OXIDE (7 total), please visit the HSDB record page.

Hazardous Substances Data Bank (HSDB)

14.1.16 Medical Surveillance

For those with frequent or potentially high exposure (half the TLV or greater), the following are recommended before beginning work and at regular times after that: Lung function tests. If symptoms develop or overexposure is suspected, the following may be useful: Consider chest x-ray after acute overexposure. Evaluation by a qualified allergist, including careful exposure history and special testing, may help disagnose skin allergy. Liver and kidney function tests.

Sittig, M. Handbook of Toxic and Hazardous Chemicals and Carcinogens, 2002. 4th ed.Vol 1 A-H Norwich, NY: Noyes Publications, 2002., p. 1100

Hazardous Substances Data Bank (HSDB)

Biological monitoring of ethylene oxide exposure by analysis of alveolar air and blood was studied in 10 workers employed in a hospital sterilizer unit. Environmental air, alveolar air, and venous blood were sampled during and at the end of an 8 hr workshift. The mean environmental concentration of ethylene oxide was 5.4 mg/cu m air and the mean alveolar ethylene oxide concentration was 1.2 mg/cu m alveolar air. Regression analysis showed that blood ethylene oxide concentrations were higher than environmental ethylene oxide concentrations by a mean ratio of 3 and higher than alveolar ethylene oxide concentrations by a mean ratio of 12.

PMID:3744564

Brugnone F et al; Int Arch Occup Environ Health 58: 105-12 (1986)

Hazardous Substances Data Bank (HSDB)

PRECAUTIONS FOR "CARCINOGENS": Whenever medical surveillance is indicated, in particular when exposure to a carcinogen has occurred, ad hoc decisions should be taken concerning ... /cytogenetic and/or other/ tests that might become useful or mandatory. /Chemical Carcinogens/

Montesano, R., H. Bartsch, E.Boyland, G. Della Porta, L. Fishbein, R. A. Griesemer, A.B. Swan, L. Tomatis, and W. Davis (eds.). Handling Chemical Carcinogens in the Laboratory: Problems of Safety. IARC Scientific Publications No. 33. Lyon, France: International Agency for Research on Cancer, 1979., p. 23

Hazardous Substances Data Bank (HSDB)

The 1984 OSHA standard for ethylene oxide (EtO) mandates medical surveillance under various circumstances. When performed medical surveillance for EtO must include a complete blood count (CBC) with differential leukocyte count. This requirement is based on reports of EtO associated absolute lymphocytosis and other hematologic effects. This paper describes experiences in providing EtO medical surveillance for a 300 bed hospital over a 6 year period. An apparent relative lymphocytosis which persisted over 3-4 years in sterilization workers with documented TWA personal EtO exposures averaging 0.07 ppm /was observed/. In addition three workers had a history of acutely toxic overexposure to EtO as a result of a sterilizer malfunction. These workers became symptomatic following the high accidental overexposure but did not show absolute lymphocytosis or altered patterns in the relative lymphocytosis. Finally a cross-sectional comparison of the CBC data from the EtO exposed workers to data from non-EtO exposed hospital workers showed no significant differences ruling out an association of the relative lymphocytosis with EtO exposure. These observations led us to review the basis for the inclusion of the CBC in routine EtO medical surveillance. /Such/ experience, review of the literature on EtO associated lymphocytosis and anemia, and review of the literature on the use of the CBC with differential as screening test suggest that the leukocyte differential may not be useful in routine medical surveillance for EtO exposure.

PMID:8213846

LaMontagne AD et al; Am J Ind Med; 24 (2): 191-206 (1993)

Hazardous Substances Data Bank (HSDB)

For more Medical Surveillance (Complete) data for ETHYLENE OXIDE (7 total), please visit the **HSDB record page**.

Hazardous Substances Data Bank (HSDB)

14.1.17 Human Toxicity Excerpts

/SIGNS AND SYMPTOMS/ Ethylene oxide is a highly reactive alkylating agent that reacts with many constituents of tissue resulting in cellular and tissue dysfunction and destruction. Evidence for human exposure to this chemical is the presence of ethylene oxide adducts of DNA and hemoglobin. Direct contact with liquid ethylene oxide or solutions of ethylene oxide produces immediate local irritation of skin and mucous membranes. Inhalation of high concentrations of ethylene oxide can cause CNS depression or pulmonary edema. The onset of symptoms may be delayed for up to 72 hours.

*ATSDR; Medical Management for Ethylene Oxide CAS 75-21-8; UN 1040. 19 pp. Available from, as of July 21, 2008: **https://www.atsdr.cdc.gov/MHMI/mmg137.html***

Hazardous Substances Data Bank (HSDB)

/SIGNS AND SYMPTOMS/ Initially, ethylene oxide affects the nose and throat. Concentrations as low as 200 ppm produce rapid onset of nose and throat irritation. Higher concentrations may cause inflammation of the lining in the trachea and bronchi, narrowing of the bronchi, and partial lung collapse. Accumulation of fluid in the lungs may evolve up to 72 hours after exposure. Severe respiratory distress may lead to cardiovascular collapse.

*ATSDR; Medical Management for Ethylene Oxide CAS 75-21-8; UN 1040. 19 pp. Available from, as of July 21, 2008: **https://www.atsdr.cdc.gov/MHMI/mmg137.html***

Hazardous Substances Data Bank (HSDB)

/SIGNS AND SYMPTOMS/ Ethylene oxide is a CNS depressant. High-dose exposures can result in diverse neurologic manifestations including seizures, loss of consciousness, and coma. Onset of neurologic signs and symptoms may be delayed 6 hours or more after exposure. Respiratory paralysis and delayed peripheral nerve damage have been reported after massive exposure.

*ATSDR; Medical Management for Ethylene Oxide CAS 75-21-8; UN 1040. 19 pp. Available from, as of July 21, 2008: **https://www.atsdr.cdc.gov/MHMI/mmg137.html***

Hazardous Substances Data Bank (HSDB)

/SIGNS AND SYMPTOMS/ Exposure to low vapor concentrations of ethylene oxide can result in nausea and vomiting, which is often delayed.

*ATSDR; Medical Management for Ethylene Oxide CAS 75-21-8; UN 1040. 19 pp. Available from, as of July 21, 2008: **https://www.atsdr.cdc.gov/MHMI/mmg137.html***

Hazardous Substances Data Bank (HSDB)

For more Human Toxicity Excerpts (Complete) data for ETHYLENE OXIDE (81 total), please visit the **HSDB record page**.

Hazardous Substances Data Bank (HSDB)

14.1.18 Non-Human Toxicity Excerpts

/LABORATORY ANIMALS: Acute Exposure/ Exposure of animals to high concn of the gas has caused lacrimation in cats, and inflammation of the conjunctiva and clouding of the cornea in dogs, cats, rabbits, and especially guinea pigs.

Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 419

Hazardous Substances Data Bank (HSDB)

/LABORATORY ANIMALS: Acute Exposure/ When ethylene oxide/saline solutions of varied concentrations (0.1% to > 20%) were applied repeatedly over a 6-hour period to the eyes of rabbits, a dose-dependent increase in congestion, swelling, discharge, iritis, and corneal cloudiness was observed. These effects were an indication of the irritating effect of ethylene oxide on mucous membranes and corneal epithelium. The 0.1% ethylene oxide concentration was the maximum, nondamaging concentration of this chemical for the 6 hour exposure period.

American Conference of Governmental Industrial Hygienists. Documentation of the TLV's and BEI's with Other World Wide Occupational Exposure Values. CD-ROM Cincinnati, OH 45240-1634 2007.

Hazardous Substances Data Bank (HSDB)

/LABORATORY ANIMALS: Acute Exposure/ Infusion of ethylene oxide into the aorta of rats caused a significant decrease (approximately 30%) in kidney glomerular filtration rates, resulting in kidney dysfunction.

American Conference of Governmental Industrial Hygienists. Documentation of the TLV's and BEI's with Other World Wide Occupational Exposure Values. CD-ROM Cincinnati, OH 45240-1634 2007.

Hazardous Substances Data Bank (HSDB)

/LABORATORY ANIMALS: Acute Exposure/ When freshly prepared aqueous solutions (2 to 5%) were injected intravenously into dogs, the LD50 was found to be about 125 mg/kg. A dose of 30 mg/kg or more usually caused vomiting and defecation for about 2 hr, followed by weakness and flaccidity, usually apparent in the hind limbs first. Doses up to 100 mg/kg in dogs under barbiturate

anesthesia caused no apparent changes in blood pressure or cardiac rate. Respiration is adequate until terminal stages, when it becomes labored and cyanosis develops. Tonic extensor spasm may precede respiratory cessation. Since the heart usually beats after all reflexes disappear, death is believed due to respiratory failure .

Clayton, G. D. and F. E. Clayton (eds.). Patty's Industrial Hygiene and Toxicology: Volume 2A, 2B, 2C: Toxicology. 3rd ed. New York: John Wiley Sons, 1981-1982., p. 2172

▸ Hazardous Substances Data Bank (HSDB)

For more Non-Human Toxicity Excerpts (Complete) data for ETHYLENE OXIDE (85 total), please visit the HSDB record page.

▸ Hazardous Substances Data Bank (HSDB)

14.1.19 Human Toxicity Values

No effect level: 5-10 ppm, during 10 yr; severe toxic effects: 60 min 250 ppm= 450 mg/cu m; symptoms of illness: 100 ppm= 180 mg/cu m; unsatisfactory >10 ppm= 18 mg/cu m

Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 654-655

▸ Hazardous Substances Data Bank (HSDB)

14.1.20 Non-Human Toxicity Values

LD50 Rat (male) oral 330 mg/kg /From table/

*USEPA/OPPTS; Revised Ethylene Oxide HED Risk Assessment for Reregistration Eligibility Document (RED) p.11 EPA-HQ-OPP-2005-0203-0100 (May 2007). Available from, as of July 21, 2008: **https://www.regulations.gov/search/Regs/home.html#home***

▸ Hazardous Substances Data Bank (HSDB)

LD50 Rat oral 72 mg/kg bw

*European Chemicals Bureau; IUCLID Dataset, Ethylene Oxide (CAS # 75-21-8) p. 41 (2000 CD-ROM edition). Available from, as of July 9, 2008: **https://esis.jrc.ec.europa.eu/***

▸ Hazardous Substances Data Bank (HSDB)

LD50 Mouse male oral 280 mg/kg bw

*European Chemicals Bureau; IUCLID Dataset, Ethylene Oxide (CAS # 75-21-8) p. 42 (2000 CD-ROM edition). Available from, as of July 9, 2008: **https://esis.jrc.ec.europa.eu/***

▸ Hazardous Substances Data Bank (HSDB)

LD50 Mouse female oral 365 mg/kg bw

*European Chemicals Bureau; IUCLID Dataset, Ethylene Oxide (CAS # 75-21-8) p. 43 (2000 CD-ROM edition). Available from, as of July 9, 2008: **https://esis.jrc.ec.europa.eu/***

▸ Hazardous Substances Data Bank (HSDB)

For more Non-Human Toxicity Values (Complete) data for ETHYLENE OXIDE (19 total), please visit the HSDB record page.

▸ Hazardous Substances Data Bank (HSDB)

14.1.21 Ecotoxicity Values

LC50; Species: Artemia sp. (Brine shrimp); Conditions: saltwater, static; Concentration: 350000 ug/L for 24 hr /formulated product/

Conway RA et al; Environ Sci & Technol 17 (2): 107-12 (1983) Available from, as of June 23, 2008

▸ Hazardous Substances Data Bank (HSDB)

LC50; Species: Artemia sp. (Brine shrimp); Conditions: saltwater, static; Concentration: 490000 ug/L for 48 hr /formulated product/

Conway RA et al; Environ Sci & Technol 17 (2): 107-12 (1983) Available from, as of June 23, 2008

▸ Hazardous Substances Data Bank (HSDB)

LC50; Species: Daphnia magna (Water flea); Conditions: freshwater, static; Concentration: 260000 ug/L for 24 hr /formulated product/

Conway RA et al; Environ Sci & Technol 17 (2): 107-12 (1983) Available from, as of June 23, 2008

▸ Hazardous Substances Data Bank (HSDB)

LC50; Species: Daphnia magna (Water flea); Conditions: freshwater, static; Concentration: 137000 ug/L for 48 hr (95% confidence interval: 83000-179000 ug/L) /formulated product/

Conway RA et al; Environ Sci & Technol 17 (2): 107-12 (1983) Available from, as of June 23, 2008

▸ Hazardous Substances Data Bank (HSDB)

For more Ecotoxicity Values (Complete) data for ETHYLENE OXIDE (10 total), please visit the HSDB record page.

▸ Hazardous Substances Data Bank (HSDB)

14.1.22 Ongoing Test Status

The following link will take the user to the National Toxicology Program (NTP) Test Agent Search Results page, which tabulates all of the "Standard Toxicology & Carcinogenesis Studies", "Developmental Studies", and "Genetic Toxicity Studies" performed with this chemical. Clicking on the "Testing Status" link will take the user to the status (i.e., in review, in progress, in preparation, on test, completed, etc.) and results of all the studies that the NTP has done on this chemical.[Available from: http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm?fuseaction=ntpsearch.searchresults&searchterm=75-21-8]

▸ Hazardous Substances Data Bank (HSDB)

14.1.23 National Toxicology Program Studies

... Toxicology and carcinogenesis studies of ethylene oxide (greater than 99% pure) were conducted by exposing groups of 50 B6C3F1 mice of each sex to air containing 0, 50, or 100 ppm ethylene oxide, 6 hours per day, 5 days per week for 102 wk. ... Conclusions: Under the conditions of these 2 yr inhalation studies, there was clear evidence of carcinogenic activity for B6C3F1 mice as indicated by dose related incr incidences of benign or malignant neoplasms of the lung and benign neoplasms of the harderian gland in both male and female B6C3F1 mice following exposure to ethylene oxide vapors at 50 and 100 ppm. In female mice, ethylene oxide caused additional malignant neoplasms of the uterus, mammary gland, and hematopoietic system (lymphoma).

Toxicology & Carcinogenesis Studies of Ethylene Oxide in B6C3F1 Mice (Inhalation Studies). Technical Report Series No. 326 (1987) NIH Publication No. 88-2582 U.S. Department of Health and Human Services, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709

Hazardous Substances Data Bank (HSDB)

Ethylene oxide (ETO) ... was evaluated for toxic and teratogenic effects in artificially inseminated New Zealand white (NZW) rabbits which were matched for body weight across treatment groups on gestational day (gd) 0. Ethylene oxide in 5% **dextrose** was administered daily in a volume of 1 ml/kg of body weight on gestational day 6 through 14 at dosages of 0, 9, 18 or 36 mg/kg/day, iv, or on gestational day 6 through 9 at dosages of 0, 18 or 36 mg/kg/day, iv. ... Administration of ethylene oxide (0, 9, 18 or 36 mg/kg/day, iv) on gestational days 6-14 resulted in mortality rates of 0% (0/27), 8.3% (2/24), 4.2% (1/24) and 22.2% (6/27), for the control through high-dose groups, respectively. Measures of maternal body weight (gestational days 14 and 30), maternal weight gain (i.e., weight gain during gestation, weight gain during treatment and absolute weight gain) and gravid uterine weight were each decreased in a dose-related manner. Examination of uterine contents on gestational day 30 revealed significant dose-related increases in the percentage of resorptions, nonlive and affected fetuses per litter. Average live litter size was decreased in a dose-related manner, as was the percentage of males per litter. No evidence of a treatment-related teratogenic effect observed, even at dosages which produced maternal and fetal toxicity. Maternal toxicity related to ethylene oxide (0, 18 or 36 mg/kg/day, iv) administered on gestational days 6-9 was limited to localized inflammation at the injection site for 1/23 confirmed-pregnant females in the high-dose group. Maternal weight gain during treatment and during gestation were reduced in a dose-related manner, but absolute maternal weight gain was not affected. At sacrifice on gestational day 30, examination of the uterine contents failed to reveal any evidence of a fetotoxic or teratogenic effect. In conclusion, no evidence for a teratogenic effect of ethylene oxide was observed when the compound was administered intravenously to NZW rabbits on gestational days 6-14 or gestational days 6-9 of gestation.

*Department of Health & Human Services/National Institute of Environmental Health Sciences, National Toxicology Program; Teratologic Evaluation of Ethylene oxide (CAS No. 75-21-8) in New Zealand White Rabbits, NTP Study No. TER82078 (April 18, 1983) Available from, as of August 16, 2002: **https://ntp.niehs.nih.gov/index.cfm?objectid=0847FF31-90CC-C685-88B4D7EAC975BD44***

Hazardous Substances Data Bank (HSDB)

14.1.24 TSCA Test Submissions

Chronic toxicity was evaluated in rats from the Army Chemical Center's Chemical Corps Medical Laboratories colony (20 animals) exposed to 100 ppm ethylene oxide via inhalation for 6 hrs/day for 6 months. The exposed animals showed no toxic signs. No significant effects were observed in weight gain, rectal temperature, EKG's, blood **calcium** and **urea**, or **bilirubin**. Mortalities for exposed and control rats were 3 out of 20 and 3 out of 20, respectively.

Army Chemical Center; The Chronic Toxicity of Inhaled Ethylene Oxide. (1955), EPA Document No. 878211697, Fiche No. 205856

Hazardous Substances Data Bank (HSDB)

Chronic toxicity was evaluated in mice from the Army Chemical Center's Chemical Corps Medical Laboratories colony (30 animals) exposed to 100 ppm ethylene oxide via inhalation for 6 hrs/day for 6 months. The exposed animals showed no toxic signs. No significant effects were observed in weight gain, rectal temperature, EKG's, blood **calcium** and **urea**, or **bilirubin**. Mortalities for exposed and control mice were 8 out of 30 and 4 out of 30, respectively.

Army Chemical Center; The Chronic Toxicity of Inhaled Ethylene Oxide. (1955), EPA Document No. 878211697, Fiche No. 205856

Hazardous Substances Data Bank (HSDB)

In a one-generation teratology study, pregnant female Fischer 344 rats (21-22/group) were exposed to ethylene oxide by inhalation at nominal concentrations of 0, 10, 33 or 100 ppm for 6 hrs on gestation days (GD) 6-15. The only treatment-related effect noted was a significant decrease in male and female fetal body weight relative to fetuses in control groups. No significant differences between treated and control animals were observed in the following: maternal and fetal survival, number of implantation and resorption sites, number of preimplantation losses, crown-to-rump length, the results of examination of all the fetuses for gross external abnormalities and half of each litter for visceral abnormalities and the other half for skeletal abnormalities.

Carnegie-Mellon University; Ethylene Oxide Teratology Study. (1979), EPA Document No. 878213864, Fiche No. OTS0206333

Hazardous Substances Data Bank (HSDB)

Chronic toxicity and oncogenicity were evaluated in groups of male and female Fischer 344 rats (120/sex/group) exposed to ethylene oxide via inhalation at 0, 10, 33 and 100 ppm for 6 hrs/day, 5 days/week for approximately 2 yrs. There was a statistically significant difference between treated animals and controls in the following: mortality (increased for both sexes at 100 ppm), body weight (decreased in males at 100 ppm and females at 100 and 33 ppm), mononuclear cell leukemia (increased in all treated female groups), peritoneal mesothelioma (increased in males at 100 and 33 ppm), cumulative percentage of pituitary adenoma (increased in females at 100 ppm), number of neoplasms/neoplasm bearing rats (increased for all treated rats, especially females), and number of rats with malignant neoplasms (increased in females at 100 and 33 ppm). There were no statistically significant differences in the following: chromosomal aberrations, ophthalmic lesions, urinalysis, hematology, serum clinical chemistry, or histopathology of the testes in males.

Bushy Run Research Center; Ethylene Oxide Two-Year Inhalation Study on Rats, Final Report. (1981), EPA Document No. 878212152, Fiche No. 206028

Hazardous Substances Data Bank (HSDB)

For more **TSCA** Test Submissions (Complete) data for ETHYLENE OXIDE (7 total), please visit the **HSDB record page**.

Hazardous Substances Data Bank (HSDB)

14.1.25 Populations at Special Risk

Inherited genetic traits co-determine the susceptibility of an individual to a toxic chemical. ... The human polymorphic GST catalyzing conjugation of halomethanes, dihalomethanes, ethylene oxide and a number of other industrial compounds could be characterized as a class theta enzyme (GSTT1) by means of molecular biology. "Conjugator" and "non-conjugator" phenotypes are coincident with the presence and absence of the GSTT1 gene. There are wide variations in the frequencies of GSTT1 deletion (GSTT1*0/0) among different ethnicities. Human phenotyping is facilitated by the GST activity towards **methyl bromide** or ethylene oxide in erythrocytes which is representative of the metabolic GSTT1 competence of the entire organism. ...

PMID:12872524

Thier R et al; Int J Hyg Environ Health 206 (3): 149-71 (2003)

Hazardous Substances Data Bank (HSDB)

14.2 Ecological Information

14.2.1 US EPA Regional Screening Levels for Chemical Contaminants

Resident Soil (mg/kg)	2.00e-03
Industrial Soil (mg/kg)	2.50e-02
Resident Air (ug/m3)	3.40e-04

Industrial Air (ug/m3)	4.10e-03
Tapwater (ug/L)	6.70e-04
Risk-based SSL (mg/kg)	1.4e-07
Oral Slope Factor (mg/kg-day)-1	3.10e-01
Inhalation Unit Risk (ug/m3)-1	3.00e-03
Chronic Inhalation Reference Concentration (mg/m3)	3.00e-02
Volatile	Volatile
Mutagen	Mutagen
Fraction of Contaminant Absorbed in Gastrointestinal Tract	1
Soil Saturation Concentration (mg/kg)	1.21e+05

EPA Regional Screening Levels for Chemical Contaminants at Superfund Sites

14.2.2 US EPA Regional Removal Management Levels for Chemical Contaminants

Resident Soil (mg/kg)	2.00e-01
Industrial Soil (mg/kg)	2.50e+00
Resident Air (ug/m3)	3.40e-02
Industrial Air (ug/m3)	4.10e-01
Tapwater (ug/L)	6.70e-02
Oral Slope Factor (mg/kg-day)-1	3.10e-01
Inhalation Unit Risk (ug/m3)-1	3.00e-03
Chronic Inhalation Reference Concentration (mg/m3)	3.00e-02
Volatile	Volatile
Mutagen	Mutagen
Fraction of Contaminant Absorbed in Gastrointestinal Tract	1
Soil Saturation Concentration (mg/kg)	1.21e+05

EPA Regional Screening Levels for Chemical Contaminants at Superfund Sites

14.2.3 ICSC Environmental Data

The substance is harmful to aquatic organisms.

ILO International Chemical Safety Cards (ICSC)

14.2.4 Environmental Fate/Exposure Summary

Ethylene oxide's production and use as a chemical intermediate and medical and foodstuff sterilizing agent may result in its release to the environment through various waste streams. Its use as an agricultural fumigant will result in its direct release to the environment. If released to air, a vapor pressure of 1,310 mm Hg at 25 °C indicates ethylene oxide will exist solely as a gas in the atmosphere. Gas-phase ethylene oxide will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 57 days. Ethylene oxide does not contain chromophores that absorb at wavelengths >290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight. If released to soil, ethylene oxide is expected to have very high mobility based upon a Koc of 2.2. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 1.48X10-4 atm-cu m/mole. Since ethylene oxide hydrolyzes to **ethylene glycol** which is readily biodegraded, the importance of biodegradation of ethylene oxide in aquatic environments is not able to be accurately assessed. If released into **water**, ethylene oxide is not expected to adsorb to suspended solids and sediment based upon the Koc. Volatilization from **water** surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 6 hours and 4 days, respectively. An estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low. Hydrolysis half-lives of 12-14 days for pH's between 5-7 in fresh **water** and 9-11 days in salt **water** indicate that hydrolysis may be an important environmental fate process. Occupational exposure to ethylene oxide may occur through inhalation and dermal contact with this compound at workplaces where ethylene oxide is produced or used. (SRC)

Hazardous Substances Data Bank (HSDB)

14.2.5 Artificial Pollution Sources

Ethylene oxide's production and use as a chemical intermediate and medical and foodstuff sterilizing agent(1) may result in its release to the environment through various waste streams(SRC). Its use as an agricultural fumigant(2) will result in its direct release to the environment(SRC).

(1) Van Agteren MH et al; Handbook on biodegradation and biological treatment of hazardous organic compounds. Norwell, MA: Kluwer Acad Publ p. 39-45 (1998) (2) O'Neil MJ, ed; The Merck Index. 14th ed Whitehouse Station, NJ: Merck and Co., Inc., p. 651 (2006)

Hazardous Substances Data Bank (HSDB)

14.2.6 Environmental Fate

TERRESTRIAL FATE: Based on a classification scheme(1), a Koc value of 2.2(2), indicates that ethylene oxide is expected to have very high mobility in soil(SRC). Volatilization of ethylene oxide from moist soil surfaces is expected to be an important fate process(SRC) given a Henry's Law constant of 1.48X10-4 atm-cu m/mole(3). Ethylene oxide is expected to volatilize from dry soil surfaces(SRC) based upon a vapor pressure of 1.31X10+3 mm Hg(4). Since ethylene oxide hydrolyzes to **ethylene glycol** which is readily biodegraded, the importance of biodegradation of ethylene oxide in the environment is not able to be accurately assessed(3).

(1) Swann RL et al; Res Rev 85: 17-28 (1983) (2) Chu W, Chan KH; Sci Total Environ 248: 1-10 (2000) (3) Conway RA et al; Environ Sci Technol 17: 107-112 (1983) (4) Daubert TE, Danner RP; Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, DC: Taylor and Francis (1985)

▸ **Hazardous Substances Data Bank (HSDB)**

AQUATIC FATE: Based on a classification scheme(1), a Koc value of 2.2(2), indicates that ethylene oxide is not expected to adsorb to suspended solids and sediment(SRC). Volatilization from **water** surfaces is expected(3) based upon a Henry's Law constant of 1.48X10-4 atm-cu m/mole(4). Using this Henry's Law constant and an estimation method(3), volatilization half-lives for a model river and model lake are 6 hours and 4 days, respectively(SRC). According to a classification scheme(5), an estimated BCF of 3(SRC), from its log Kow of -0.30(6) and a regression-derived equation(7), suggests the potential for bioconcentration in aquatic organisms is low(SRC). Since ethylene oxide hydrolyzes to **ethylene glycol** which is readily biodegraded, the importance of biodegradation of ethylene oxide in the environment is not able to be accurately assessed(4).

(1) Swann RL et al; Res Rev 85: 17-28 (1983) (2) Chu W, Chan KH; Sci Total Environ 248: 1-10 (2000) (3) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 15-1 to 15-29 (1990) (4) Conway RA et al; Environ Sci Technol 17: 107-112 (1983) (5) Franke C et al; Chemosphere 29: 1501-14 (1994) (6) Hansch C et al; Exploring QSAR. Hydrophobic, Electronic, and Steric Constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC: Amer Chem Soc p. 4 (1995) (7) Meylan WM et al; Environ Toxicol Chem 18: 664-72 (1999)

▸ **Hazardous Substances Data Bank (HSDB)**

ATMOSPHERIC FATE: According to a model of gas/particle partitioning of semivolatile organic compounds in the atmosphere(1), ethylene oxide, which has a vapor pressure of 1.13X10+3 mm Hg at 25 °C(2), is expected to exist solely as a gas in the ambient atmosphere. Gas-phase ethylene oxide is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals(SRC); the half-life for this reaction in air is estimated to be 57 days(SRC), calculated from its rate constant of 7.6X10-14 cu cm/molecule-sec at 25 °C(3). Ethylene oxide does not contain chromophores that absorb at wavelengths >290 nm(4) and therefore is not expected to be susceptible to direct photolysis by sunlight(SRC). In a smog chamber experiment, 20% of the ethylene oxide degraded in 5.3 hr(5).

(1) Bidleman TF; Environ Sci Technol 22: 361-367 (1988) (2) Daubert TE, Danner RP; Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, DC: Taylor and Francis (1985) (3) Atkinson R; J Chem Phys Ref Data Monograph 1 (1989) (4) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 8-12 (1990) (5) Joshi SB et al; Atmos Environ 16: 1301-10 (1979)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.7 Environmental Biodegradation

AEROBIC: In a dilution bottle test, ethylene oxide 3-5% degradation was observed after 5 days and 52% degradation was observed after 20 days(1,2). In a river die-away test, half-life measurements for ethylene oxide in sterile and natural river **water** were not appreciably different, owing to the hydrolytic degradation of ethylene oxide being more rapid than biodegradation in aqueous media(4). Since ethylene oxide hydrolyzes to **ethylene glycol** which is readily biodegraded, the importance of biodegradation of ethylene oxide in aquatic environments is not able to be accurately assessed(2). Ethylene oxide biodegradation rate constants measured at a full-scale wastewater treatment plant were 0.38 and 0.59 ug/min-g biomass(3).

*(1) Bridie AL et al; Water Res 13:627-30 (1979) (2) Conway RA et al; Environ Sci Technol 17: 107-12 (1983) (3) Green D, Eklund B; Field assessment of the fate of volatile organics in aerated wastewater systems. pp. 478-86 in USEPA/9-87-015. (1987) (4) ATSDR; Toxicological Profile for Ethylene Oxide. Atlanta, GA: Agency for Toxic Substances and Disease Registry, US Public Health Service. Dec, 1990. Available at **https://www.atsdr.cdc.gov/toxprofiles/tp137.html#bookmark07** as of July 10, 2008.*

▸ **Hazardous Substances Data Bank (HSDB)**

AEROBIC: Several bacteria were observed to transform **ethene** to ethylene oxide but cannot degrade the latter(1). Mycobacterium E20 and M. E44 acclimated to **ethene** converted ethylene oxide into **acetyl-coenzyme A** by an uncharacterized enzyme complex(1).

(1) Van Agteren MH et al; Handbook on biodegradation and biological treatment of hazardous organic compounds. Norwell, MA: Kluwer Acad Publ, p. 39-45 (1998)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.8 Environmental Abiotic Degradation

The rate constant for the vapor-phase reaction of ethylene oxide with photochemically-produced hydroxyl radicals is 7.6X10-14 cu cm/molecule-sec at 25 °C(1). This corresponds to an atmospheric half-life of about 57 days at an atmospheric concentration of 5X10+5 hydroxyl radicals per cu cm(1). A base-catalyzed second-order hydrolysis rate constant of 1.7X10-2 L/mole-sec(SRC) was estimated using a structure estimation method(2); this corresponds to a half-life of 13 years at pH 7(2). Ethylene oxide hydrolyzes slowly in fresh and salt **water** to give **ethylene glycol** and **ethylene chlorohydrin**(3). The half-life for this reaction is 12-14 days for pH's between 5-7 in fresh **water**(3-5) and 9-11 days in salt **water**(3). The ratio of chlorohydrin to glycol formed was found to be 0.11 and 0.23 in 1% and 3% **sodium chloride** solutions respectively(3). The hydrolysis rate is increased considerably in acidic or basic solutions(4). Ethylene oxide does not contain chromophores that absorb at wavelengths >290 nm(6) and therefore is not expected to be susceptible to direct photolysis by sunlight(SRC). Earlier smog chamber experiments with both natural and artificial illumination are consistent with a slowly degrading compound(8). In one smog chamber experiment, 20% of the ethylene oxide degraded in 5.3 hr(7).

(1) Atkinson R; J Chem Ref Data, Monograph 1 (1989) (2) Mill T et al; Environmental Fate and Exposure Studies Development of a PC-SAR for Hydrolysis: Esters, Alkyl Halides and Epoxides. EPA Contract No. 68-02-4254. Menlo Park, CA: SRI International (1987) (3) Conway RA et al; Environ Sci Technol 17:107-12 (1983) (4) Bogyo DA et al; Investigation of selected environmental contaminants: Epoxides. USEPA-560/11-80-005 p 69-96 (1980) (5) Mabey W, Mill T; J Phys Chem Ref Data 7:383-415 (1978) (6) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 8-12 (1990) (7) Joshi SB et al; Atmos Environ 16: 1301-10 (1979) (8) Cupitt LT; Atmospheric persistence of Eight Air Toxics. USEPA-600/S3-87/004 (1987)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.9 Environmental Bioconcentration

An estimated BCF of 3 was calculated in fish for ethylene oxide(SRC), using a log Kow of -0.30(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

(1) Hansch C et al; Exploring QSAR. Hydrophobic, Electronic, and Steric Constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC: Amer Chem Soc p. 4 (1995) (2) Meylan WM et al; Environ Toxicol Chem 18: 664-72 (1999) (3) Franke C et al; Chemosphere 29: 1501-14 (1994)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.10 Soil Adsorption/Mobility

Koc of ethylene oxide was reported to be 2.20(1). According to a classification scheme(2), this estimated Koc value suggests that ethylene oxide is expected to have very high mobility in soil(SRC).

(1) Chu W, Chan KH; Sci Total Environ 248: 1-10 (2000) (2) Swann RL et al; Res Rev 85: 17-28 (1983)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.11 Volatilization from Water/Soil

The Henry's Law constant for ethylene oxide is 1.48X10-4 atm-cu m/mole(1). This Henry's Law constant indicates that ethylene oxide is expected to volatilize from **water** surfaces(2). Based on this Henry's Law constant, the volatilization half-life from a model river (1 m deep, flowing 1 m/sec, wind velocity of 3 m/sec)(2) is estimated as 6 hours(SRC). The volatilization half-life from a model lake (1 m deep, flowing 0.05 m/sec, wind velocity of 0.5 m/sec)(2) is estimated as 4 days(SRC). Ethylene oxide is expected to volatilize from dry soil surfaces(SRC) based upon a vapor pressure of 1.31X10+3 mm Hg(3). Although no data on the volatilization of ethylene oxide from soil could be found, a study of the dissipation of ethylene oxide from fumigated commodities gave half-life values of 4 hr to 17.5 days(4).

(1) Conway RA et al; Environ Sci Technol 17:107-112 (1983) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 15-1 to 15-29 (1990) (3) Daubert TE, Danner RP; Physical and Thermodynamic Properties of Pure Chemicals Data Compilation. Washington, DC: Taylor and Francis (1985) (4) Bogyo DA et al; Investigations of Selected Potential Environmental Contaminants: Epoxides. USEPA-560/11-80-005 p. 70-90 (1980)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.12 Effluent Concentrations

Ethylene oxide was detected, not quantified in an effluent sample in Brandenburg, KY in Feb 1974, from an unspecified chemical production facility(1,2). It is estimated that in ethylene oxide production, between 0.25 and 47.5 kg of ethylene oxide is emitted to the air for each kg produced(3).

(1) Shackelford WM, Keith LH; Frequency of Organic Compounds Identified in Water. USEPA-600/4-76-062 p 129 (1976) (2) Bogyo DA et al; Investigation of Selected Potential Environmental Contaminants: Epoxides. USEPA-560/11-80-005 p 17 (1980) (3) Carpenter CE et al; Toxic Subst J 10: 323-71 (1990)

▸ **Hazardous Substances Data Bank (HSDB)**

Ethylene oxide may be present in vent gas and fugitive emissions from its production and use as a chemical intermediate in the manufacture of **ethylene glycol**, ethoxylates, glycol ethers and ethanolamines(1). It may also be present in aqueous effluent associated with its production and use as a chemical intermediate and as fugitive emissions from its use as a fumigant and sterilant of food, cosmetics and hospital supplies(1,3-4) in auto and diesel exhaust/combustion product of hydrocarbon fuels(1,2), and tobacco smoke(1). While its use as a fumigant and sterilant constitute only 2%, emissions from these uses are proportionately higher than other applications and result in greater exposure(3,4).

(1) Bogyo DA et al; Investigations of Selected Potential Environmental Contaminants. Epoxides USEPA-560/11-80-005 p. 60-9 (1980) (2) Graedel TE; Chemical Compounds in the Atmosphere Academic Press, NY p. 272 (1978) (3) Chemical & Engineering News p. 12 (1983) (4) Cawse JN et al; in Kirk-Othmer Encycl Chem Tech 3rd ed. NY,NY: Wiley-Interscience 9: 432-71 (1980)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.13 Atmospheric Concentrations

URBAN/SUBURBAN: Ethylene oxide was targeted but not detected at 25 sites throughout Minnesota tested over an 8 year span from 1991-1998(1).

PMID:11017885

*Full text: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2556921***

(1) Pratt GC et al; Environ Health Perspect 108: 815-25 (2000)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.14 Food Survey Values

According to a 1970-76 FDA Monitoring Program, ethylene oxide was detected, not quantified in 1 out of 2,372 samples of eggs in 1975(1).

(1) Duggan RE et al; Pesticide residue levels in foods in the US from July 1 to June 30, 1976. Food and Drug Admin. page 10-18 (1983)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.15 Fish/Seafood Concentrations

According to a 1970-1976 FDA Food Monitoring Program, ethylene oxide was detected, not quantified in 1 out of 3,262 samples of fish (1975) and not found in 443 samples of shellfish for this period(1).

(1) Duggan RE et al; Pesticide Residue Levels in Foods in the US from July 1 to June 30, 1976. Food and Drug Administration p 10-18 (1983)

▸ **Hazardous Substances Data Bank (HSDB)**

14.2.16 Probable Routes of Human Exposure

NIOSH (NOES Survey 1981-1983) has statistically estimated that 270,683 workers (120.086 of these were female) were potentially exposed to ethylene oxide in the US(1). The NOES Survey does not include farm workers. Occupational exposure to ethylene oxide may occur through inhalation and dermal contact with this compound at workplaces where ethylene oxide is produced or used(SRC).

*(1) NIOSH; NOES. National Occupational Exposure Survey conducted from 1981-1983. Estimated numbers of employees potentially exposed to specific agents by 2-digit standard industrial classification (SIC). Available at **https://www.cdc.gov/noes/** as of Jul 10, 2008.*

▸ **Hazardous Substances Data Bank (HSDB)**

OSHA estimates that approximately 80,000 and 144,000 workers were directly and indirectly exposed to ethylene oxide in ethylene oxide production, chemical synthesis by ethoxylation, health care facilities (sterilization), medical products (sterilization) and miscellaneous manufacturers (e.g., spice sterilization)(1). The number of workers exposed directly (indirectly) in the various industries were: production and synthesis 3676; sterilization - health care facilities 62,370 (25,000); sterilization - medical products manufacture 14,000 (116,900); sterilization - spice manufacturers 160(1). Typical exposures were usually high during short periods in which sterilizer doors are opened, typically 5-10 ppm for 20 minutes(1). Some typical survey results are: Medical products manufactures 0.1.1-2.0 ppm 8 hr TWA; Hospital sterilizer chamber operators 2.5 ppm TWA; 121 use sites in Southern California <5 ppm (TWA) in 114/121 sites; 2 hospitals 3-6 ppm and <5 ppm resp; survey of 27 hospitals TWA exposures less than or equal to 1, <4 and >10 ppm in 9/27, 16/27 and 5/27, respectively(1). Union Carbide production plant in Texas City 5-33 ppm and 7.25 and 10.25 ppm avg in 2 control rooms and 0-56 ppm, 11.6 ppm avg throughout plant(2). In-depth survey of 2 Union Carbide production facilities in West Virginia: 2 of 48 and 4 of 41 samples positive, TWA exposure of positive samples 1.5-82 ppm(4,5). Production and maintenance workers in the 1960's avg exposure levels: 0.6-60 ppm(3).

(1) OSHA; Occupational Exposure to Ethylene Oxide; Proposed Rule. 48 FR 17283-17319 4,21 (1983) (2) Joyner RE; Arch Environ Health 8:700-10 (1964) (3) Hogstedt C et al; Brit J Ind Med 36:276-80 (1979) (4) Oser JL; In-depth Industrial Hygiene Report of Ethylene Oxide Exposure at Union Carbide Corp., WV NIOSH IWS-67.17B 47 p (1978) (5) Oser JL; In-depth Industrial Hygiene Report of Ethylene Oxide Exposure at Union Carbide Corp., South Charleston, WV NIOSH IWS-67.10 25 p (1979)

▸ **Hazardous Substances Data Bank (HSDB)**

Ethylene oxide concentrations in a Rochester, MN hospital were highest (50 ppm) in an area where the ethylene oxide tanks were located, followed by the area directly in front and approximately 12 feet away from a sterilization door (40 ppm), and thirdly were areas where ethylene oxide-sterilized items were opened (30-40 ppm)(1). Levels generally did not exceed the 4 to 10 ppm in areas where employees assembled and sterilized materials during approximately 45 minutes after completion of the sterilization procedure. Concentrations of 1 to 10 ppm generally dissipated within 15 minutes in the area of an aeration cabinet and supervisor's office. Levels in the surgical suite ranged from 5 to 15 ppm upon opening the sterilization door but dissipated to 0 ppm within 10 minutes(1). Personal breathing zone measurements in the central processing department of an Indianapolis, IN hospital indicated that staff were exposed to low concentrations of ethylene oxide(2).

(1) Nevenheim A; Test measure ethylene oxide risk to hospital's central supply staff. Hospitals, J.A.H.A. March 16, pp. 147-50 (1979) (2) Cook CK, Zimmer A; Health Hazard Evaluation Report. St. Vincent Hospital, Indianapolis, IN. HETA 92-273-2312. NTIS PB94-118 338 (1994)

Hazardous Substances Data Bank (HSDB)

A 1989 survey of 1,448 Danish work environments identified 150 potential ethylene oxide exposure events in manufacture of basic metals, 2,000 in manufacture of fabricated metal products, 170 in electrical machinery and apparatus, 330 in manufacture of transport equipment, and 15 potential **ethylene** exposure exposure events to painters and carpenters(1). Also identified were 3,300 potential exposure events in construction, 940 in wholesale trade, 1,700 in manufacture of textiles and leather, 280 in manufacture of wood and furniture, 450 in manufacture of chemicals, 40 in manufacture of non-metallic mineral products, 170 in manufacture of precision and optical instruments, 760 in manufacture of plastic and boat building and repair, 21,000 in personal services, cleaning and hair dressing, 1,100 in agriculture, hunting, and forestry, and 11,000 **ethylene** pxide exposure events in health services and pharmacies(1).

PMID:7670620
Full text: ***https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1128264***
(1) Brandorff NP et al; Occup Environ Med 52: 454-63 (1995)

Hazardous Substances Data Bank (HSDB)

15 Associated Disorders and Diseases

- Comparative Toxicogenomics Database (CTD)

16 Literature

16.1 NLM Curated PubMed Citations

PubChem

16.2 Springer Nature References

Springer Nature

16.3 Thieme References

Thieme Chemistry

16.4 Wiley References

- Wiley

16.5 Depositor Provided PubMed Citations

- PubChem

16.6 Metabolite References

- Human Metabolome Database (HMDB)

16.7 Chemical Co-Occurrences in Literature

- PubChem

16.8 Chemical-Gene Co-Occurrences in Literature

PubChem

16.9 Chemical-Disease Co-Occurrences in Literature

PubChem

17 Patents

17.1 Depositor-Supplied Patent Identifiers

PubChem

Link to all deposited patent identifiers

PubChem

17.2 WIPO PATENTSCOPE

Patents are available for this chemical structure:

https://patentscope.wipo.int/search/en/result.jsf?inchikey=IAYPIBMASNFSPL-UHFFFAOYSA-N

PATENTSCOPE (WIPO)

18 Biomolecular Interactions and Pathways

18.1 Chemical-Gene Interactions

18.1.1 CTD Chemical-Gene Interactions

- Comparative Toxicogenomics Database (CTD)

18.2 Pathways

- PubChem

19 Biological Test Results

19.1 BioAssay Results

PubChem

20 Taxonomy

The LOTUS Initiative for Open Natural Products Research: frozen dataset union wikidata (with metadata) | **DOI:10.5281/zenodo.5794106**

- **LOTUS - the natural products occurrence database**

21 Classification

21.1 Ontologies

21.1.1 MeSH Tree

- Medical Subject Headings (MeSH)

21.1.2 NCI Thesaurus Tree

- NCI Thesaurus (NCIt)

21.1.3 ChEBI Ontology

- ChEBI

21.1.4 KEGG: Drug

KEGG

21.1.5 KEGG: Risk Category of Japanese OTC Drugs

KEGG

21.1.6 KEGG: OTC drugs

KEGG

21.1.7 KEGG: Animal Drugs

KEGG

21.1.8 ChemIDplus

ChemIDplus

21.1.9 CAMEO Chemicals

CAMEO Chemicals

21.1.10 ChEMBL Target Tree

ChEMBL

21.1.11 UN GHS Classification

- UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

21.1.12 EPA CPDat Classification

- EPA Chemical and Products Database (CPDat)

21.1.13 NORMAN Suspect List Exchange Classification

- NORMAN Suspect List Exchange

21.1.14 EPA DSSTox Classification

- EPA DSSTox

21.1.15 International Agency for Research on Cancer (IARC) Classification

- International Agency for Research on Cancer (IARC)

21.1.16 Consumer Product Information Database Classification

- Consumer Product Information Database (CPID)

21.1.17 LOTUS Tree

- LOTUS - the natural products occurrence database

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   https://comptox.epa.gov/dashboard/DTXSID0020600

   CompTox Chemicals Dashboard Chemical Lists
   https://comptox.epa.gov/dashboard/chemical-lists/

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   Oxirane
   https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/7739

   Ethylene oxide
   https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/26125

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    Ethylene Oxide
    https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.119AppA

11. ## Wikipedia

ethylene oxide
https://en.wikipedia.org/wiki/Ethylene_oxide

12. ## DOT Emergency Response Guidebook

ethylene oxide
https://www.phmsa.dot.gov/hazmat/erg/emergency-response-guidebook-erg

13. ## NJDOH RTK Hazardous Substance List

ethylene oxide
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16. ## ChEBI

Oxirane
http://www.ebi.ac.uk/chebi/searchId.do?chebiId=CHEBI:27561

ChEBI Ontology
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Ethylene oxide
https://www.whatsinproducts.com/chemicals/view/1/1454/000075-21-8

Consumer Products Category Classification
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https://comptox.epa.gov/dashboard/DTXSID0020600#exposure

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25. ## EPA Regional Screening Levels for Chemical Contaminants at Superfund Sites

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Ethylene Oxide
https://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search?tool=rml

26. ## EU Pesticides Database

Ethylene oxide
https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=99

27. ## EU REGULATION (EC) No 1272/2008

ethylene oxide;oxirane
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20211001

28. ## Hazardous Chemical Information System (HCIS), Safe Work Australia

ethylene oxide
http://hcis.safeworkaustralia.gov.au/HazardousChemical/Details?chemicalID=1993

29. ## NITE-CMC

Ethylene oxide - FY2006
https://www.nite.go.jp/chem/english/ghs/06-imcg-0012e.html

Ethylene oxide - FY2011
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32. ## SpectraBase

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40. ## Springer Nature

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Animal drugs in Japan
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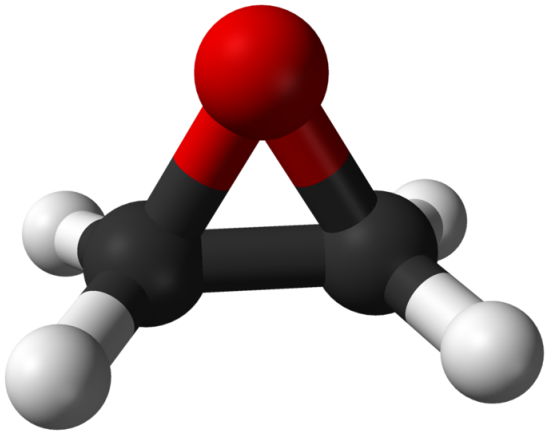
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Ethylene Oxide

What is ethylene oxide?

At room temperature, ethylene oxide is a flammable colorless gas with a sweet odor. It is used primarily to produce other chemicals, including antifreeze. In smaller amounts, ethylene oxide is used as a pesticide and a sterilizing agent. The ability of ethylene oxide to damage DNA makes it an effective sterilizing agent but also accounts for its cancer-causing activity.



A model of the ethylene oxide molecule.

How are people exposed to ethylene oxide?

The primary routes of human exposure to ethylene oxide are inhalation and ingestion, which may occur through occupational, consumer, or environmental exposure. Because ethylene oxide is highly explosive and reactive, the equipment used for its processing generally consists of tightly closed and highly automated systems, which decreases the risk of occupational exposure.

Despite these precautions, workers and people who live near industrial facilities that produce or use ethylene oxide may be exposed to ethylene oxide through uncontrolled industrial emissions. The general population may also be exposed through tobacco smoke and the use of products that have been sterilized with ethylene oxide, such as medical products, cosmetics, and beekeeping equipment.

Which cancers are associated with exposure to ethylene oxide?

Lymphoma and leukemia are the cancers most frequently reported to be associated with occupational exposure to ethylene oxide. Stomach and breast cancers may also be associated with ethylene oxide exposure.

How can exposures be reduced?

The U.S. Occupational Safety and Health Administration has information about limiting occupational exposure to ethylene oxide.

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Sci Justice. 2017 Jan;57(1):13-20. doi: 10.1016/j.scijus.2016.09.001. Epub 2016 Sep 13.

Investigation into ethylene oxide treatment and residuals on DNA and downstream DNA analysis

L Wilson-Wilde [1], D Yakovchyts [2], S Neville [3], P Maynard [2], P Gunn [2]

Affiliations

PMID: 28063580 DOI: 10.1016/j.scijus.2016.09.001

Abstract

Recent years have seen a significant increase in the sensitivity of DNA testing, enabling the determination of DNA profiles from low levels of cellular material. However, the increased sensitivity is in many ways a double-edged sword as background contaminating DNA generated during the manufacture of consumables and sampling devices is now being detected and may compromise the interpretation of the DNA profile results. This study initially demonstrated the effectiveness of ethylene oxide (EO) as a post-production treatment to eliminate DNA on swabs, used as a sampling device for the recovery of cellular material. Subsequently, the potential adverse effects of any residual EO remaining on the swabs on the downstream DNA analysis on both rayon and cotton swabs were investigated and the levels of remaining EO measured. Two main variables were tested: the amount of time elapsed since EO treatment of the swabs prior to use, and the time elapsed between cellular material collection and DNA analysis. Residual levels of EO were found to be below quantitation levels and therefore also international standards. The results indicated that while there was a negligible effect of EO treatment on DNA recovered from rayon swabs, there was however an adverse effect on the DNA profiles recovered from cotton swabs. The adverse effect was negatively correlated with time since EO treatment and positively correlated with time to DNA analysis.

Keywords: DNA analysis; Decontamination; Ethylene oxide; Forensic Science; ISO 18385; Manufacturer contamination.

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Ethylene Oxide

75-21-8

Hazard Summary

The major use of ethylene oxide is as a chemical intermediate in the manufacture of ethylene glycol. Ethylene oxide is also used as a sterilizing agent for medical equipment and a fumigating agent for spices. The acute (short-term) effects of ethylene oxide in humans consist mainly of central nervous system depression and irritation of the eyes and mucous membranes. Chronic (long-term) exposure to ethylene oxide in humans can cause irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There also is some evidence linking ethylene oxide exposure to reproductive effects. EPA has concluded that ethylene oxide is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to ethylene oxide increases the risk of lymphoid cancer and, for females, breast cancer.

Please Note: The main sources of information for this fact sheet are, for cancer, the U.S. Environmental Protection Agency's (EPA's) Integrated Risk Information System and, for other information, the Agency for Toxic Substances and Disease Registry's (ATSDR's) Toxicological Profile for Ethylene Oxide (1,2).

Uses

- Ethylene oxide is used mainly as a chemical intermediate in the manufacture of ethylene glycol (antifreeze), textiles, detergents, polyurethane foam, solvents, medicine, adhesives, and other products. (1,2)
- Relatively small amounts of ethylene oxide are used as a fumigant, as a sterilant for food (spices) and cosmetics, and in hospital sterilization of surgical equipment and plastic devices that cannot be sterilized by steam. (1,2)

Sources and Potential Exposure

- Sources of ethylene oxide emissions to the air include uncontrolled emissions or venting with other gases in industrial settings. (2)
- Other sources of ethylene oxide air emissions include its use as a sterilizer of medical equipment and its release from commodity-fumigated materials. (2)
- The general population may be exposed to ethylene oxide through breathing contaminated air or from smoking tobacco or being near someone who is smoking. Certain occupational groups (e.g., workers in ethylene oxide manufacturing or processing plants, sterilization technicians, and workers involved in fumigation) may be exposed in the workplace. (2)

Assessing Personal Exposure

- Tests are available to determine personal exposure to ethylene oxide, such as the determination of ethylene oxide in the blood or the amount breathed out of the lungs. (2)

Health Hazard Information

Acute Effects:

- Acute inhalation exposure of workers to high levels of ethylene oxide has resulted in nausea, vomiting, neurological disorders, bronchitis, pulmonary edema, and emphysema. (2)
- Dermal or ocular contact with solutions of ethylene oxide has caused irritation of the skin and eyes in humans. (2)
- Tests involving acute exposure of animals have shown ethylene oxide to have high acute toxicity from inhalation exposures. (2)

Chronic Effects (Noncancer):

- Major effects observed in workers exposed to ethylene oxide at low levels for several years are irritation of the eyes, skin, and respiratory passages and effects to the nervous system (e.g., headache, nausea, memory loss, numbness). (2)
- EPA has not established a Reference Dose (RfD) or a Reference Concentration (RfC) for ethylene oxide.
- The California Environmental Protection Agency (CalEPA) has established a chronic inhalation reference exposure level of 0.03 milligrams per cubic meter (mg/m^3) (18 parts per billion [ppb]) for ethylene oxide based on nervous system effects in mice. The CalEPA reference exposure level is a concentration at or below which adverse health effects are not likely to occur. It is not a direct estimator of risk, but rather a reference point to gauge the potential effects. At lifetime exposures increasingly greater than the reference exposure level, the potential for adverse health effects increases. (3)
- ATSDR has established an intermediate inhalation minimal risk level (MRL) of 0.2 mg/m^3 (0.09 parts per million [ppm]) based on an exposure below that associated with renal effects in mice. The MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. The exposure period for an intermediate MRL is from two weeks to a year. (2)

Reproductive/Developmental Effects:

- Some evidence exists indicating that inhalation exposure to ethylene oxide can cause an increased rate of miscarriages in female workers. (2)
- Various reproductive effects have been noted in inhalation exposure studies of animals, including decreased number of implantation sites, decreased testicular weights and sperm concentration, and testicular degeneration. (2)

Cancer Risk:

- Human occupational studies have shown elevated cases of lymphoid cancer and, also breast cancer in female workers. (1)
- Ethylene oxide has been shown to cause lymphoid cancer and tumors of the brain, lung, connective tissue, uterus, and mammary gland in animals exposed to ethylene oxide by inhalation. (1)
- EPA has concluded that ethylene oxide is carcinogenic to humans by the inhalation route of exposure. (1)
- EPA additionally concludes that the weight of evidence supports a mutagenic mode of action for ethylene oxide toxicity. (1)
- EPA uses mathematical models, based on human and animal studies, to estimate the probability of a person developing cancer from breathing air containing a specified concentration of a chemical. EPA has calculated an inhalation unit cancer risk estimate of 3×10^{-3} per $\mu g/m^3$ (6×10^{-3} per ppb) for ethylene oxide for both cancer types combined (lymphoid cancer and, in females, breast cancer). Taking into account the mode of action conclusion, EPA estimates that if an individual were to continuously breathe air containing ethylene oxide at an average of 2×10^{-4} $\mu g/m^3$ (1×10^{-4} ppb) over his or her entire lifetime, that person theoretically would have no more than a one-in-a-million increased chance of developing cancer as a direct result of breathing air containing this chemical. Similarly, EPA estimates that a lifetime of continuously breathing air containing 2×10^{-3} $\mu g/m^3$ (1×10^{-3} ppb) ethylene oxide would result in not greater than one-in-a-hundred thousand

increased chance of developing cancer, and for air containing 2×10^{-2} µg/m³ (1×10^{-2} ppb) ethylene oxide would result in not greater than a one-in-ten thousand increased chance of developing cancer. For a detailed discussion of confidence in the potency estimates, see EPA's Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide. (1)

Physical Properties

- The chemical formula for ethylene oxide is C_2H_4O, and the molecular weight is 44.1 g/mol. (2)
- The vapor pressure for ethylene oxide is 1,095 mm Hg at 20°C, and it has an octanol/water partition coefficient (log Kow) of -0.22. (2)
- Ethylene oxide has a solubility in water of 1×10^6 mg/L at 20°C and is soluble in alcohol, ether, acetone, and benzene. (2)
- Ethylene oxide has an odor threshold of 787 mg/m³. (2)
- Ethylene oxide has an estimated half-life in air ranging from 69 to 149 days, while its half-life in water ranges from 12 to 14 days in sterile, deionized, and natural river water. (2)

Conversion Factors:

To convert concentrations in air (at 25°C) from ppm to mg/m³:

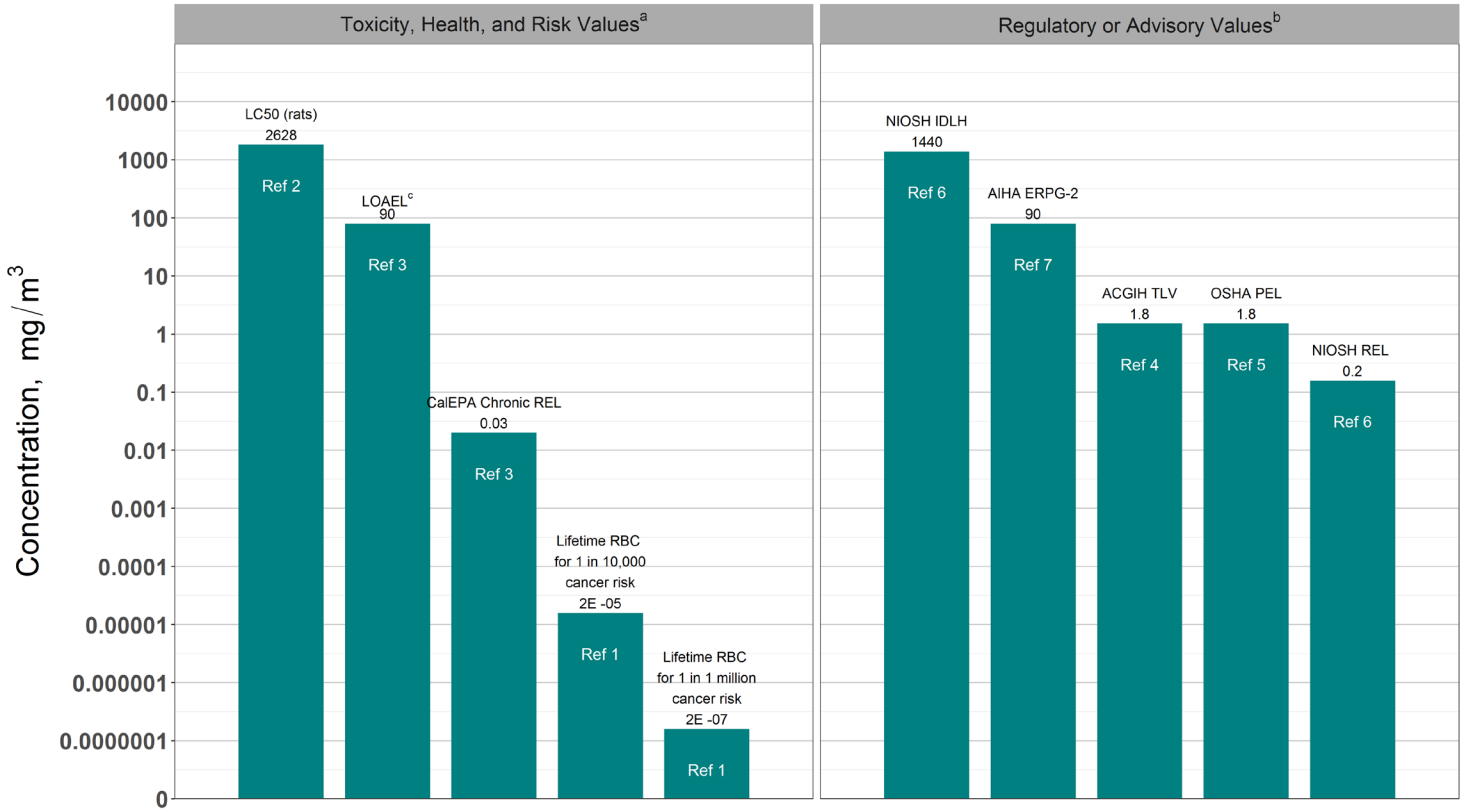
mg/m³ = (ppm) × (molecular weight of the compound) / (24.45).

For ethylene oxide: 1 ppm = 1.8 mg/m³

To convert concentrations in air from µg/m³ to mg/m³:

mg/m³ = (µg/m³) × (1 mg/1,000 µg)

Health Data from Inhalation Exposure



ACGIH TLV — American Conference of Governmental and Industrial Hygienists' threshold limit value expressed as a time-weighted average; the concentration of a substance to which most workers can be exposed without adverse effects.
AIHA ERPG — American Industrial Hygiene Association's emergency response planning guidelines. ERPG-1 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed up to one hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined objectionable odor; ERPG-2 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed up to one hour without experiencing or developing irreversible or other serious health effects that could impair their abilities to take protective action.
CalEPA Chronic REL — California EPA Office of Environmental and Human Health Assessment (OEHHA) chronic reference exposure level is the concentration at or below which no adverse health effect is anticipated for a lifetime exposure.
LC_{50} (Lethal Concentration$_{50}$) — A calculated concentration of a chemical in air to which exposure for a specific length of time is expected to cause death in 50% of a defined experimental animal population.
LOAEL (Lowest Observed Adverse Effect Level) — The lowest dose or concentration at which there was an observed toxic or adverse effect of a target organism distinguished from a normal or untreated organism of the same species.
NIOSH IDLH Value — National Institute of Occupational Safety and Health's immediately dangerous to life or health air concentration value; NIOSH IDLH value is a recommended exposure limit to ensure that a worker can escape from an exposure condition that is likely to cause death or immediate or delayed permanent health effects or prevent escape from the environment.
NIOSH REL — NIOSH's recommended exposure limit; the recommended exposure limit for an 8- or 10-hour time-weighted average exposure and/or ceiling.
OSHA PEL — Occupational Safety and Health Administration's permissible exposure limit expressed as a time-weighted average; the concentration of a substance to which most workers can be exposed without adverse effect averaged over a normal 8-hour workday or a 40-hour workweek.
RBC (Cancer risk-based concentration) — A calculated concentration of a chemical in air to which continuous exposure over a lifetime is estimated to be associated with a risk of contracting cancer not greater than the specified probability (e.g., 1 in a million). The RBCs for ethylene oxide in the above graph are calculated using age-dependent adjustment factors (ADAFs).

[a]Toxicity, Health, and Risk numbers are toxicological values from animal testing or risk assessment values developed by EPA.
[b]Regulatory numbers are values that have been incorporated in Government regulations, while advisory numbers are nonregulatory values provided by the Government or other groups as advice. OSHA numbers are regulatory, whereas NIOSH, ACGIH, and AIHA numbers are advisory.
[c]The LOAEL is from the critical study used as the basis for the CalEPA chronic REL.

Summary updated December 2018.

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THE EPOCH TIMES



A medic collects a swab sample from an Israeli border guard at a COVID-19 drive-through testing site in a file photo. (Ahmad Gharabli/AFP via Getty Images)

PREMIUM **AMERICA**

FDA Issues Warning on 2 Recalled COVID-19 Tests

By Jack Phillips | February 2, 2022 Updated: February 2, 2022

A A Print

The U.S. Food and Drug Administration (FDA) issued a warning about two COVID-19 tests made by Empowered Diagnostics because the tests aren't approved by the FDA, even though the tests' labels indicate that they are.

Empowered Diagnostics makes the CovClear COVID-19 Rapid Antigen and ImmunoPass COVID-19 Neutralizing Antibody Rapid tests.

Both tests have been recalled by Empowered Diagnostics, the FDA said in an announcement in late January. The recall is listed as a Class 1 recall, which the FDA's website describes as the most serious type.

"The U.S. Food and Drug Administration (FDA) is warning people to stop using the Empowered Diagnostics CovClear COVID-19 Rapid Antigen Test and ImmunoPass COVID-19 Neutralizing Antibody Rapid Test," the agency's statement said. "These tests were distributed with labeling indicating they are authorized by the FDA, but neither test has been authorized, cleared, or approved by the FDA for distribution or use in the United States."

The FDA further said that individuals should not use either test due to the "potentially higher risk of false results when using unauthorized tests."

People who used either test should talk to their health care provider if they have concerns about their test results, said the FDA.

"If the antigen test was given less than two weeks ago, consider retesting your patients using an FDA authorized SARS-CoV-2 diagnostic test if you suspect an inaccurate result," the federal drug regulator said.

SARS-CoV-2 is another name for the CCP (Chinese Communist Party) virus, which causes COVID-19.

"False-positive results could lead test users to take fewer precautions to protect themselves from a future SARS-CoV-2 infection if the test result is interpreted to mean that they have had a previous SARS-CoV-2 infection," according to the agency.

The CovClear COVID-19 Rapid Antigen Test nasal swab technology, while the ImmunoPass COVID-19 Neutralizing Antibody Rapid Test uses a fingerstick blood sample to determine whether one has COVID-19, the agency said.

The FDA also confirmed that it is working with Empowered Diagnostics to resolve issues around the recall and "will continue to keep the public informed of significant new information."

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Johns Hopkins University confirms: You can be vaccinated with a PCR test, even without knowing

Apr 13, 2021 | Health Freedom | 0 comments



A theragripper is about the size of a speck of dust. This swab contains dozens of the tiny devices.

In January 2019, the WHO defined the growing number of vaccination critics as one of the top ten threats to global health, and since the unprecedented Corona vaccination fiasco, the number of vaccination refusers has truly multiplied.

Meanwhile, resistance is forming even within the orthodox medical establishment. But the masterminds of the WHO continue to insist on an unrealistic vaccination coverage rate of at least 70 percent.

In this article, Jan Walter describes, with extensive source citations, which techniques are possible to still vaccinate the population, when people are becoming increasingly critical of vaccinations. This is only fueled by the continuing pressure for mass "vaccination" against a non-lethal disease for 99.8% of people, with a new type of "vaccine" that is actually gene therapy by means of mRNA. It seems like science fiction and is chilling, but the metohodes and techniques are available. There question is how far do we let it get?

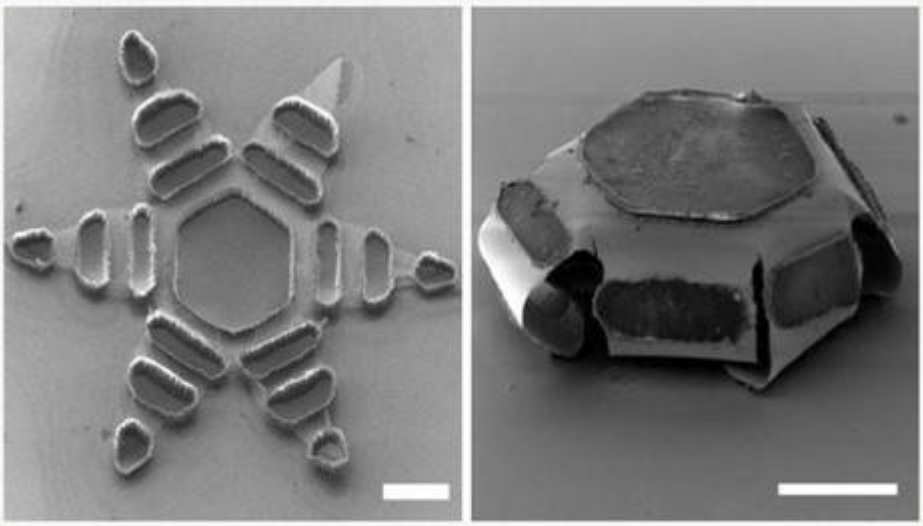
Vaccinations increasingly scrutinized and the chilling alternative

In January 2019, *WHO* [1] defined the growing number of vaccine critics as one of the ten greatest threats to global health, and since the unprecedented corona vaccination *fiasco* [2], the number of vaccine refusers has really multiplied. Meanwhile, resistance is emerging even within the conventional medical community. But the masterminds at WHO continue to insist on an unrealistic vaccination rate of at least 70 percent.

Now several experts and former mainstream journalists like John O'Sullivan are warning that the massive PCR testing campaign could be a WHO vaccination program in disguise. (see *Principia Scientific*) [3] O'Sullivan is referring to a new technology developed at Johns Hopkins University that is supposed to make it possible to carry out covert vaccinations through a PCR test. (See *Johns Hopkins Universitiy*) [4]

Inspired by a parasitic worm that digs its sharp teeth into the intestines of its host, Johns Hopkins researchers have developed tiny, star-shaped micro-devices that attach to the intestinal mucosa and can deliver drugs into the body.

These tiny devices, known as "Theragrippers," are made of metal and a thin film that changes shape. They are covered with heat-sensitive kerosene wax and each no larger than a dust particle. (See Figure 1)



When an open theragripper, left, is exposed to internal body temperatures, it closes on the instestinal wall. In the gripper's center is a space for a small dose of a drug.

When the kerosene coating on the Theragripper reaches body temperature, the devices close autonomously and clamp onto the wall of the colon. Because of the sealing action, the tiny, six-pointed devices burrow into the mucosa and attach to the colon, where they are held and gradually release their drug load to the body. Eventually, the Theragripper lose their grip on the tissue and are removed from the colon through normal gastrointestinal muscle function.

Note: According to Johns Hopkins University, Theragrippers are actually administered with a cotton swab. (see Figure 2)



Figure 2: Theragrippers on a cotton swab

The Johns Hopkins University research team published positive results from an animal study as a cover article in Science Advances on October 28, 2020 [5], confirming that the new technology works flawlessly:

Here we report that GI parasite-inspired active mechanochemical therapeutic grabs, or theragrippers, can survive 24 hours in the gastrointestinal tract of live animals by autonomously adhering to mucosal tissue. We also observe a remarkable six-fold increase in elimination half-life when using ripper-mediated delivery of the model analgesic ketorolac tromethamine. These results provide excellent evidence that shape-shifting and self-locking microdevices improve the effectiveness of long-term drug delivery.

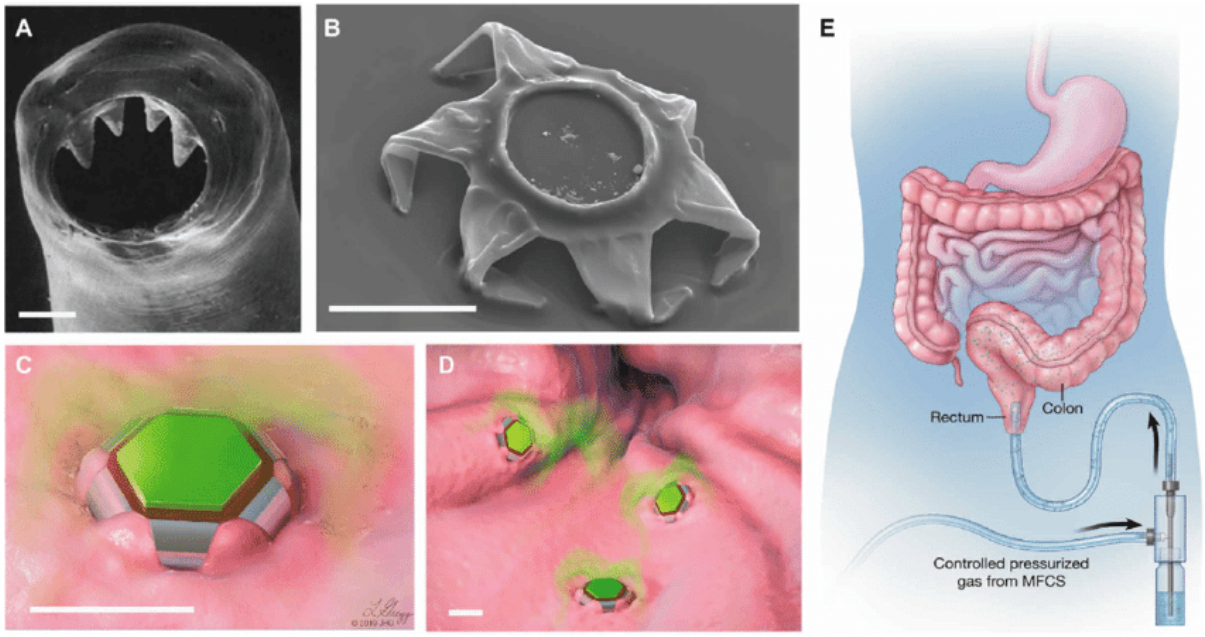


Fig.3: Shape-shifting Theragripper as self-locking drug delivery devices

Coincidentally, the PCR test in China is now also performed anally because the reliability of the results is said to be better and of course this practice is immediately supported in the Western mainstream media. (See *Business Insider*) [6]

Note: If you can't imagine the government administering toxins to you against your will and without your consent, think of all the horrific experiments on humans that were admitted afterwards and which, according to *Wikipedia*, [7] have continued well into modern times. In 2007, the CDC [8] even admitted that between 1955 and 1963, 10-30 million citizens were infected with the carcinogen SV40 via polio vaccination.

The Vaccination that is Not a Vaccination, but Gene Therapy

In a revealing *video conference* [9] with Dr. Judy Mikovits, Robert Kennedy Jr. and Dr. David Martin, it is explained that the mRNA vaccine, by the legal definition, is not a vaccine at all. It is falsely called a vaccine to hide the fact that the purported vaccine is, in fact, a gene therapy. Experienced physician and epidemiologist, Dr. Wolfgang Wodarg, stated in a censored *interview* with Rubikon, "Actually, this 'promising' vaccine should be PROHIBITED for the vast majority of people because it is genetic engineering!" Mary Holland, Vice President and Chief Advocate of the Children's Health Defense Organization, warns, "New vaccine technologies will likely lead to new types of vaccine harms. Since there has never been an approved mRNA vaccine, we really don't know what such damage will look like. Because vaccines have been developed so quickly and clinical trials are so short, the long-term damage is completely unknown."

What is particularly chilling is that the vast majority do not even know what the mRNA vaccine is doing in their bodies. They simply allow themselves to be blindly vaccinated, and this despite the fact that more and more independent and even orthodox medical experts are warning against it. (See doctors from around the world *warn against* mRNA vaccination) [10] In this context, it should not be forgotten that the American company modeRNA Therapeutics was founded in 2010 not as a vaccine manufacturer, but as a GenTech company. The example of the many Monsanto scandals makes it crystal clear that genetic engineering does not serve to protect species, but rather to gain power. The hidden agenda is to genetically modify species in order to patent or own them. Former U.S. Secretary of State Henry Kissinger once said, "Whoever controls the seed controls the world." (See Press Portal) [11]

What's next? Are they going to patent our bodies after they genetically engineer us with the mRNA vaccine?

Dr. Carrie Madej, [12] a specialist in internal medicine with over 19 years of experience, states that the COVID-19 vaccine could actually be a Trojan horse to patent humans because it alters our DNA. According to an Article published in the British science journal Phys.org in January 2020 [13], it is confirmed that modified RNA has a direct impact on our DNA. The following passage is particularly alarming: "Several research groups are now working together to investigate what effect this may have on the DNA molecule. We already know that R-loop regions are associated with DNA sequences that contain active genes, and that this can lead to chromosome breaks and the loss of genetic information." Also alarming is the fact that leading vaccine manufacturers such as Pfizer are warning their subjects not to reproduce after vaccination (see Pfizer, p. 132) [14 PDF] By doing so, the pharmaceutical company is confirming that the mRNA vaccine can have negative effects on human reproduction and is being vaccinated in spite of it!

Conclusion: Anyone who knows a little history knows that **genetic experimentation** and **human experimentation** are nothing new. Although modern **eugenics** has its origins in the 19th century, the ideas, measures and justifications of state and social interventions and influences on reproduction have been known since ancient times. They can already be found in Plato's "Politeia," which, however, is limited to state selection and education. In the Renaissance, corresponding lines of thought can be found in the social utopian writings "Utopia" by Thomas Morus, "Nova Atlantis" by Francis Bacon and "La città del Sole" by Tommaso Campanella. But because common sense instinctively resists such interventions, the establishment has always endeavored to disguise its true intentions with misleading labels. The Nazis, for example, disguised eugenics as "hereditary health science" or "hereditary care" to make it attractive to the masses, and today the same sick agenda is sold to us with a new "vaccine" to save us from a supposed "pandemic".

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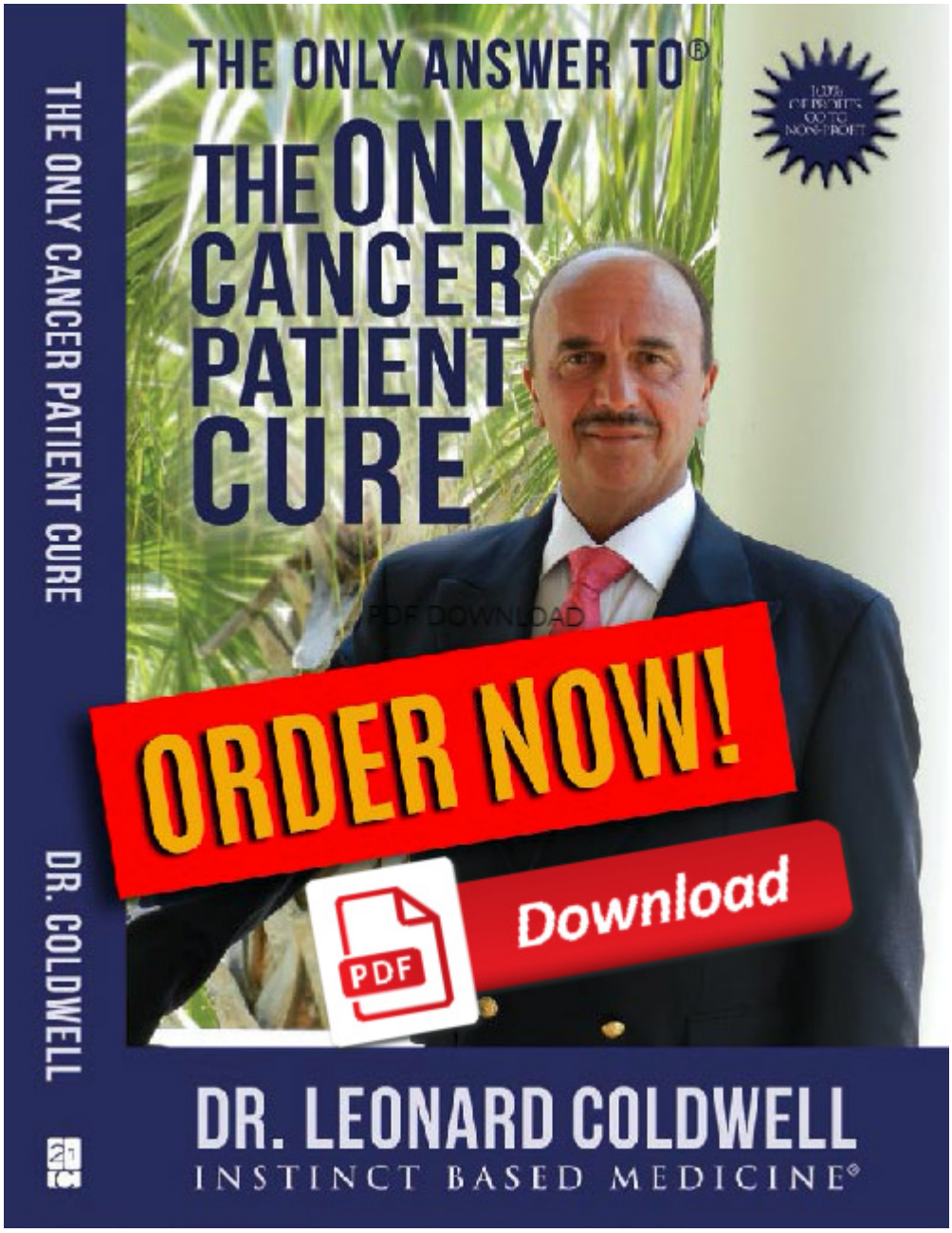
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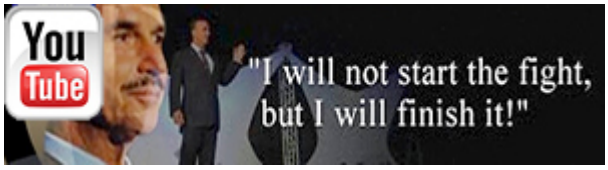


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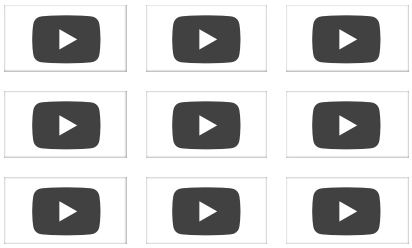
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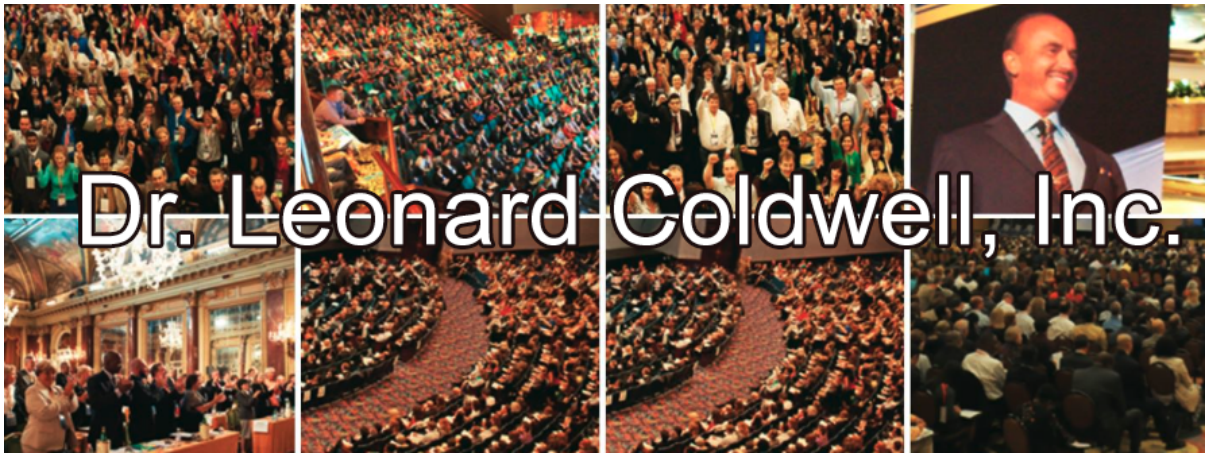
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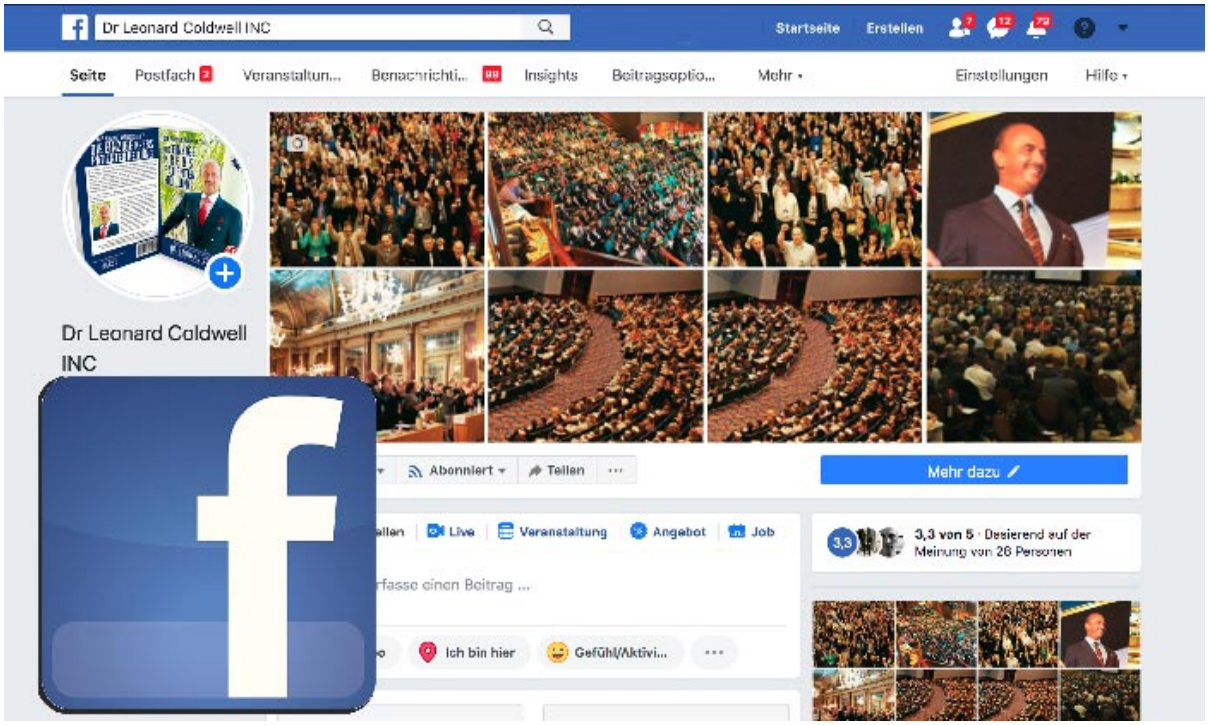
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Centers for Disease Control and Prevention

COVID-19

Workplace SARS-CoV-2 Testing: Consent Elements and Disclosures

Updated Jan. 21, 2021

Purpose

SARS-CoV-2 testing may be incorporated as part of a comprehensive approach to reducing transmission in non-healthcare workplaces. This document describes the elements of consent and recommended disclosures necessary to support employee decision-making for participating in workplace-based testing. This document expands on the disclosures outlined in "SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces."

Overview: Consent and Supporting Employee Decision-Making

Workplace-based testing should **not** be conducted without the employee's informed consent. Informed consent requires disclosure, understanding, and free choice, and is necessary for an employee to act independently and make choices according to their values, goals, and preferences.

Differences in position and authority (i.e., workplace hierarchies), as well as employment status in non-standard working arrangements (e.g., temporary help, contract help, or part-time employment), can affect an employee's ability to make free decisions. To fully support employee decision-making and consent, employers should take the following measures when developing a testing program:

- Ensure safeguards are in place to protect an employee's privacy and confidentiality.
- Provide complete and understandable information about how the employer's testing program may impact employees' lives, such as if a positive test result or declination to participate in testing may mean exclusion from work.
- Explain any parts of the testing program an employee would consider especially important when deciding whether to participate. This involves explaining the key reasons that may guide their decision.
- Provide information about the testing program in the employee's preferred language using non-technical terms. Consider obtaining employee input on the readability of the information. Employers can use this tool to create clear messages.
- Encourage supervisors and co-workers to avoid pressuring employees to participate in testing.
- Encourage and answer questions during the consent process. The consent process is active information sharing between an employer or their representative and an employee, in which the employer discloses the information, answers questions to facilitate understanding, and promotes the employee's free choice.

Disclosures for Workplace Testing

An employer's testing program (including the implementation of a testing protocol to test employees) may be complex and technical. Certain aspects of the testing program may be more relevant than others to an employee's decision whether to accept an offered test. SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces identifies disclosures important for employees contemplating testing. Many of these disclosures are addressed in the U.S. Food and Drug Administration (FDA) emergency use authorization patient fact sheet for the test, which must be provided during the consent process. Those disclosures include:

during the consent process. Those disclosures include:

- The manufacturer and name of the test
- The test's purpose
- The type of test
- How the test will be performed
- Known and potential risks of harm, discomforts, and benefits of the test
- What it means to have a positive or negative test result, including:
  - Test reliability and limitations
  - Public health guidance to isolate or quarantine at home, if applicable

Additionally, an employer should be prepared to address the following topics:

General Considerations

- Why is the employer offering to test employees?
- How frequently will employees be tested, and will they be asked to consent to each test?
- What happens if an employee declines to be tested?

Scheduling and Payment

- Is the employee obligated to schedule the test and travel to the site?
- Will the employer pay for the employee's time and travel?
- Are there any available accommodations or alternatives for an employee who declines to take the test?
- Who pays for the test, including:
  - Will the employer pay for the test?
  - Will the employee's insurance be billed for the test or will the employee be billed for a copayment?
  - Will the employee pay for the test?
  - Will the employee's insurance be billed for follow-up care if needed?
  - Will the employee pay for follow-up care if needed?

Testing Site

- Who will be administering the test and what are their qualifications?
- Where will the test be performed?
- Will the test provider require any temperature and symptom screening prior to administering the test?

Communication and Interpretation of Results

- When will the results be provided to employees, and in what confidential manner?
- Who will interpret the test and what are their qualifications?
- The test provider's obligation to report a positive result to the public health authority.
- What happens if the employee tests positive, including:
  - Who will inform the employee about guidance for employee isolation and quarantine for those who have been around the employee?
  - Is there a need for follow-up testing?
  - Is there a need for medical evaluation?
  - Will the employer take any action, including any follow-up with the employee such as contact tracing?
  - When can the employee return to the work site?
  - Are there any flexible and supportive leave and other benefit policies available to the employee?
  - Will the employee be paid for any lost work time?
  - Will the employee's benefits be affected?
- What happens if the employee tests negative, including any need for follow-up testing?

Privacy

- What personal information does the employee need to provide (e.g., name, date of birth) to the test provider?
- Will that demographic information be retained, and if so, by whom and for how long?
- How will personal information be kept confidential and secure (i.e., restricted from unauthorized access or disclosure)?
- Which employer representative(s) will have access to the employee's result?
- Whether, where, and for how long will the employer retain the result?
- How will the employer keep the result confidential and secure?

Seeking Additional Help or Reporting Injuries

- Who to contact for additional information about the employer's testing program (e.g., an employer or union representative)?
- Who to contact to explain an employee's rights?
- Who to contact if assistance is needed (e.g., language translation or transportation to and from the testing site)?
- Will the employer provide treatment for any employee injuries from the test procedure and during transport to/from the testing site?

Last Updated Jan. 21, 2021

Centers for Disease Control and Prevention

COVID-19

Interim Guidance for SARS-CoV-2 Testing in Non-Healthcare Workplaces

Updated Oct. 5, 2021

Summary of Recent Changes

Updates as of October 6, 2021

- Updated descriptions of test types.
- Updated to align with new antigen testing algorithms, one for community settings and one for congregate settings .
- Updated testing recommendations for fully vaccinated workers who are close contacts of someone with COVID-19.
- Clarified that screening testing recommendations apply to asymptomatic, unvaccinated workers.

View Previous Updates

Key Points

- Workplace-based testing for SARS-CoV-2, the virus that causes COVID-19, could identify workers with SARS-CoV-2 infection, and thus help prevent or reduce further transmission. The purpose of this guidance is to provide employers with considerations for incorporating testing for SARS-CoV-2 into a workplace COVID-19 preparedness, response, and control plan in non-healthcare workplaces.
- This guidance includes descriptions of different types of SARS-CoV-2 tests; scenarios where SARS-CoV-2 testing may be used; considerations for screening testing (testing asymptomatic and unvaccinated workers with no known or suspected exposure to SARS-CoV-2); and use of antigen tests for serial screening testing.
- Screening testing could be effective in helping to prevent transmission for workplace settings.
- These interim considerations on SARS-CoV-2 testing strategies for non-healthcare workplaces during the COVID-19 pandemic are based on what is currently known about the transmission and severity of COVID-19 and is subject to change as additional information becomes available.

Note: This document provides guidance on the appropriate use of testing and does not dictate the determination of payment decisions or insurance coverage of such testing, except as may be otherwise referenced (or prescribed) by another entity or federal or state agency.

Introduction

The purpose of this document is to provide employers with strategies to consider for incorporating testing for SARS-CoV-2, the virus that causes COVID-19, into workplace preparedness, response, and control plans in non-healthcare workplaces. For workplaces with healthcare personnel, including those that work in nursing homes, please refer to Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic and Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes.

Employers are encouraged to collaborate with state, territorial, tribal, and local health officials to determine whether and how to implement the following testing strategies and which one(s) would be most appropriate for their circumstances. These considerations are meant to supplement, not replace, any federal, state, local, territorial, or tribal health and safety laws, rules, and regulations with which workplaces must comply. These strategies should be carried out in a manner consistent with existing laws and regulations, including laws protecting employee privacy and confidentiality. They should also be carried out consistent with Equal Employment Opportunity Commission (EEOC) guidance regarding permissible testing policies and procedures. Employers providing testing of employees should put procedures in place for rapid notification of results and establish appropriate measures based on testing results, including instructions regarding self-isolation and restrictions on workplace access.

Considerations when testing

SARS-CoV-2 testing may be incorporated as part of a comprehensive approach to reducing transmission in non-healthcare workplaces. Testing identifies workers infected with SARS-CoV-2, the virus that causes COVID-19, so that actions can be taken to slow and stop the spread of the virus.

Employees undergoing testing should receive clear information on:

- the manufacturer and name of the test, the type of test, the purpose of the test, the performance specifications of the test, any limitations associated with the test, who will pay for the test, how the test will be performed, how and when they will receive test results, and;
- how to understand what the results mean, actions associated with negative or positive results, the difference between testing for workplace screening versus for medical diagnosis, who will receive the results, how the results may be used, and any consequences for declining to be tested.

Individuals tested are required to receive patient fact sheets as part of the test's emergency use authorization (EUA).

According to the Americans with Disabilities Act (ADA), when employers implement any mandatory testing of employees, it must be "job related and consistent with business necessity." In the context of the COVID-19 pandemic, the U.S. EEOC notes that testing to determine if an employee has SARS-CoV-2 infection with an "accurate and reliable test" is permissible as a condition to enter the workplace because an employee with the virus will "pose a direct threat to the health of others." EEOC notes that testing administered by employers that is consistent with current CDC guidance will meet the ADA's business necessity standard. Employers who mandate workplace testing for SARS-CoV-2 infection should discuss further with employees who decline testing and consider providing alternatives as feasible and appropriate, such as reassignment to tasks that can be performed via telework.

Under OSHA's recordkeeping requirements in 29 CFR Part 1904, COVID-19 can be a recordable illness. Thus, employers are responsible for recording cases of COVID-19, if the case meets certain requirements. Employers are encouraged to frequently check OSHA's webpage for updates.

Test types

Viral tests

Viral tests, including nucleic acid amplification tests (NAATs) and antigen tests, are used as diagnostic tests to **detect infection** with SARS-CoV-2 and to inform an individual's medical care. Viral tests can also be used as screening tests to reduce the transmission of SARS-CoV-2 by identifying infected persons who need to isolate from others. See FDA's list of In Vitro Diagnostics Emergency Use Authorizations for more information about the performance of specific authorized tests.

- NAATs, such as real-time reverse transcription-polymerase chain reaction (RT-PCR), are high-sensitivity, high-specificity tests for diagnosing SARS-CoV-2 infection. NAATs detect genetic material (nucleic acids). NAATs for SARS-CoV-2 specifically identify the ribonucleic acid (RNA) sequences that comprise the genetic material of the virus. Most NAATs need to be processed in a laboratory and time to results can vary (~1–3 days), but some NAATs are point-of-care (POC) tests with results available in about 15–45 minutes. Because laboratory-based NAATs are considered the most sensitive tests for detecting SARS-CoV-2, they can also be used to confirm the results of lower sensitivity tests, such as POC NAATs or antigen tests.
- Antigen tests are immunoassays that detect the presence of a specific viral antigen. Antigen tests generally have similar specificity but are less sensitive than most NAATs. Most can be processed at the point of care with results available in minutes and thus can be used in screening programs to quickly identify those who are likely to be contagious. Because of the performance characteristics of antigen tests, it may be necessary to confirm some antigen test results (e.g., a negative test in persons with symptoms or a positive test in persons without symptoms) with a laboratory-based NAAT. Furthermore, based on the authorization from FDA , some point-of-care NAATs cannot be used for confirmatory testing. Use of the appropriate antigen testing algorithm is recommended to determine when confirmatory testing is needed.

Antibody tests

Antibody (or serology) tests are used to detect previous infection with SARS-CoV-2 and can aid in the diagnosis of multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A). CDC does not recommend using antibody testing to diagnose current infection. Depending on the time when someone was infected and the timing of the test, the test might not detect antibodies in someone with a current infection. In addition, it is not currently known whether a positive antibody test result indicates protective immunity against SARS-CoV-2; therefore, at this time, antibody tests should not be used to determine if an individual is immune against reinfection. Antibody testing is being used for public health surveillance and epidemiologic purposes. Because antibody tests can have different targets on the virus, specific tests might be needed to assess for antibodies originating from past infection versus those from vaccination. For more information about COVID-19 vaccines and antibody test results, refer to Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.

For more information, please refer to Overview of Testing for SARS-CoV-2 (COVID-19).

Overview of testing scenarios

Diagnostic testing is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19 or when a person is asymptomatic but has a recent known or suspected exposure to SARS-CoV-2.

Examples of diagnostic testing include:

- Testing people who have symptoms consistent with COVID-19 and who present to their healthcare provider
- Testing people as a result of contact tracing efforts
- Testing people who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19.
- Testing people who attended an event where another attendee was later confirmed to have COVID-19

Screening tests are intended to identify infected people who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening helps to identify unknown cases so that measures can be taken to prevent further transmission.

Examples of screening testing include:

- Testing unvaccinated employees in a workplace setting
- Testing unvaccinated students, faculty, and staff in a K-12 school or institute of higher education setting
- Testing an unvaccinated person before or after travel

- Testing at home for someone who does not have symptoms associated with COVID-19 and no known exposures to someone with COVID-19

Choosing a test

When choosing which test to use, it is important to understand the purpose of the testing (e.g., diagnostic vs. screening), analytic performance of the test within the context of the level of community transmission, need for rapid results, and other considerations (See Table 1). The COVID-19 Viral Testing Tool helps healthcare providers and individuals understand their COVID-19 testing options. After test results are in, the tool can help interpret results and guide next steps.

Table 1 summarizes some characteristics of NAATs and antigen tests to consider. Most antigen tests that have received EUA from FDA are authorized for testing symptomatic persons within the first 5, 6, 7, 12, or 14 days of symptom onset. Accumulation of data on the performance of antigen tests in different situations has helped guide the use of these tests as screening tests in asymptomatic people to detect or exclude SARS-CoV-2 infection. See FDA's recommendations for healthcare providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19 . Also see information from the Centers for Medicare & Medicaid Services (CMS) on Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion . Laboratories that perform screening or diagnostic testing for SARS-CoV-2 must have a Clinical Laboratory Improvement Amendments (CLIA) certificate and meet regulatory requirements. Tests that have received an EUA from FDA for point of care (POC) use can be performed with a CLIA certificate of waiver.

Table 1. NAAT and Antigen Test Differences to Consider When Planning for Diagnostic or Screening Use

	NAATs	**Antigen Tests**
Intended Use	Detect *current* infection	Detect *current* infection
Analyte Detected	Viral Ribonucleic Acid (RNA)	Viral Antigens
Specimen Type(s)	Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva	Nasal, Nasopharyngeal, Saliva
Sensitivity	Varies by test, but generally high for laboratory-based tests and moderate-to-high for POC tests	Varies depending on the course of infection, but generally moderate-to-high at times of peak viral load*
Specificity	High	High
Test Complexity	Varies by test	Relatively easy to use
Authorized for Use at the Point of Care	Most are not, some are	Most are, some are not
Turnaround Time	Most 1-3 days. Some could be rapid in 15 minutes	Ranges from 15 minutes to 30 minutes
Cost/Test^	Moderate (~$75-$100/test)	Low (~$5-$50/test)
Advantages	Most sensitive test method available	Short turnaround time (approximately 15 minutes)[+]

	Short turnaround time for NAAT POC tests, but few available Usually does not need to be repeated to confirm results	When performed at or near POC, allows for rapid identification of infected people, thus preventing further virus transmission in the community, workplace, etc. Comparable performance to NAATs in symptomatic persons and/or if culturable virus present, when the person is presumed to be infectious
Disadvantages	Longer turnaround time for lab-based tests (1–3 days) Higher cost per test A positive NAAT diagnostic test should not be repeated within 90 days, because people may continue to have detectable RNA after risk of transmission has passed	May need confirmatory testing Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people

*The decreased sensitivity of antigen tests might be offset if the POC antigen tests are repeated more frequently (i.e., serial testing at least weekly).
^ Costs for: NAATs
+Refers to point-of-care antigen tests only.

Considerations for testing in different scenarios

Diagnostic testing

Testing persons with signs or symptoms consistent with COVID-19

Employers may consider conducting daily in-person or virtual health checks (e.g., symptom and temperature screening) to identify employees with signs or symptoms consistent with COVID-19 before they enter a facility. Employers should follow guidance from the EEOC regarding confidentiality of medical records from health checks.

Vaccinated and unvaccinated workers with COVID-19 symptoms should be immediately separated from other employees, customers, and visitors, and sent home or to a healthcare facility, depending on how severe their symptoms are, and follow CDC guidance for caring for oneself. To prevent stigma and discrimination in the workplace, make employee health screenings as private as possible. CDC recommends that anyone with signs or symptoms of COVID-19 be tested and follow the advice of their healthcare provider. Waiting for test results prior to returning to work is recommended to keep potentially infected workers out of the workplace.

Employers are encouraged to implement flexible sick leave and supportive policies and practices as part of a comprehensive approach to prevent and reduce transmission among employees.

Positive test results using a viral test (NAAT or antigen) in persons with signs or symptoms consistent with COVID-19 indicate that the person has COVID-19 and should not come to work and should isolate at home. Decisions to discontinue isolation for workers with COVID-19 and allow them to return to the workplace may follow either a symptom-based, time-based, or a test-based strategy (see Testing to determine resolution of infection below).

A negative antigen test in persons with signs or symptoms of COVID-19 should be confirmed by a laboratory-based NAAT, a more sensitive test. Results from NAATs are considered the definitive result when there is a discrepancy between the antigen and NAAT test. For more information, see the antigen test algorithms for community settings and congregate settings .

Testing asymptomatic persons with recent known or suspected exposure to SARS-CoV-2

Case investigation is typically initiated when a health department receives a report from a laboratory or testing site of a positive SARS-CoV-2 viral test result, or a report from a healthcare provider of a patient with a confirmed or probable diagnosis of COVID-19 .

Fully vaccinated people who have come into close contact with someone with COVID-19 should be tested 5-7 days following the date of their exposure and wear a mask in public indoor settings for 14 days or until they receive a negative test result. They should isolate if they test positive.

Viral testing is recommended for all unvaccinated close contacts. Because of the potential for asymptomatic (not having symptoms) or pre-symptomatic (not yet showing symptoms) transmission of SARS-CoV-2, it is important that unvaccinated individuals exposed to people with known or suspected COVID-19 be quickly identified and quarantined. Viral testing with NAATs or antigen tests can detect if these individuals are currently infected.

The health department may ask the employer for assistance in identifying close contacts of the worker with SARS-CoV-2 infection. Employers are encouraged to work with public health departments investigating cases of COVID-19 and tracing contacts to help reduce the spread of SARS-CoV-2 in their workplaces and communities.

Because there may be a delay between the time a person is exposed to the virus and the time that virus can be detected by testing, early testing after exposure at a single time point may miss many infections. Testing that is repeated at different points in time, also referred to as serial testing, is more likely to detect infection among close contacts of a COVID-19 case than testing done at a single point in time. Viral testing is recommended for unvaccinated close contacts of persons with COVID-19 immediately after being identified, and if negative, again in 5–7 days after last exposure or immediately if symptoms develop during quarantine.

While CDC continues to recommend a 14-day quarantine for unvaccinated individuals who are close contacts of a person with COVID-19, viral testing may also be used as part of an option to shorten the quarantine period. Local public health authorities determine and establish the quarantine options for their jurisdictions. Shortening quarantine may increase willingness to adhere to public health recommendations. However, shortened quarantines with continued symptom monitoring and masking until Day 14 may be less effective in preventing transmission of COVID-19 than the currently recommended 14-day quarantine. In jurisdictions with shortened quarantine options, workplaces with higher risk of SARS-CoV-2 introduction or transmission, or with potential for greater negative impact if employees become infected SARS-CoV-2 (see Types of workplaces below), can consider restricting unvaccinated workers from entering the workplace until 14 days after their exposure.

Viral testing may also be considered for unvaccinated persons who might have been in close contact with persons diagnosed with COVID-19 in collaboration with the local health department if resources permit. A risk-based approach to testing possible contacts of a person with confirmed COVID-19 may be applied. Such an approach should take into consideration the likelihood of exposure, which is affected by the characteristics of the workplace and the results of contact investigations. In some settings, expanded screening testing (i.e., testing beyond individually identified close contacts to those who are possible close contacts), such as targeting workers who worked in the same area and during the same shift, may be considered as part of a strategy to control the transmission of SARS-CoV-2 in the workplace. Employers are encouraged to consult with state, local, territorial, and tribal health departments to help inform decision-making about expanded screening testing.

High-risk settings that have demonstrated potential for rapid and widespread dissemination of SARS-CoV-2 include:

- Workplaces where workers are in the workplace for long periods (e.g., for 8–12 hours per shift) and have prolonged close contact with coworkers
- Workplaces where employees live in congregate settings (e.g., fishing vessels, offshore oil platforms, farmworker housing, or wildland firefighter camps)
- Workplaces with populations at increased risk for severe illness if they are infected, such as homeless shelters and workplaces with older workers

If employees are tested after close contact or suspected close contact with someone who has a confirmed or probable diagnosis of COVID-19, care should be taken to inform these employees of their possible exposure to SARS-CoV-2 in the workplace while maintaining confidentiality of the individual with COVID-19, as required by the ADA, and consistent with

workplace while maintaining confidentiality of the individual with COVID-19, as required by the ADA and consistent with EEOC guidance regarding What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws .

Testing to determine resolution of infection

The decision to end isolation and return to the workplace for employees with suspected or confirmed SARS-CoV-2 infection should be made in the context of clinical and local circumstances. NAATs have detected SARS-CoV-2 RNA in some recovered people's respiratory specimens for up to 3 months after illness onset but without direct evidence that virus that can replicate or cause disease. Consequently, evidence supports a time-based and symptom-based strategy to determine when to discontinue isolation or other precautions rather than a test-based strategy. For persons who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious disease experts. For all others, a test-based strategy is no longer recommended.

Under the ADA, employers are permitted to require a healthcare provider's note to verify that employees are healthy and able to return to work. However, as a practical matter, employers should be aware that healthcare provider offices and medical facilities may be extremely busy during periods when community COVID-19 indicators are in the moderate to high categories (Table 2) and may not be able to provide such documentation in a timely manner. In such cases, employers should consider not requiring a healthcare provider's note for employees who are sick to validate their illness, qualify for sick leave, or to return to work. Most people with COVID-19 have mild illness, can recover at home without medical care, and can follow CDC recommendations to determine when to discontinue isolation and return to the workplace.

Screening testing

Testing asymptomatic persons without known or suspected exposure to SARS-CoV-2 for early identification, isolation, and disease prevention

When to consider screening testing

Screening testing in non-healthcare settings of unvaccinated workers without known or suspected exposure to SARS-CoV-2 may be useful to detect COVID-19 early and stop transmission quickly, particularly in areas with community COVID-19 indicators in the moderate to high categories (Table 2, Table 3). Screening testing can be used in addition to symptom and temperature checks, which will miss asymptomatic or pre-symptomatic contagious workers. Persons with asymptomatic or pre-symptomatic SARS-CoV-2 infection are significant contributors to SARS-CoV-2 transmission.

In general, fully vaccinated workers should continue to follow employer guidance on screening testing.

Types of workplaces

Workplace settings for which screening testing of unvaccinated, asymptomatic workers should be considered include:

- Large workplaces
- Workplaces at increased risk of introduction of SARS-CoV-2 (e.g., workplaces where workers are in close contact with the public, such as restaurants or salons, or workplaces in communities with moderate to high transmission)
- Workplaces where there is a higher risk of SARS-CoV-2 transmission (e.g., workplaces where physical distancing is difficult and workers might be in close contact, such as manufacturing or food processing plants, or workplaces that provide congregate housing for employees such as fishing vessels, offshore oil platforms, farmworker housing or wildland firefighter camps)
- Workplaces where SARS-CoV-2 infection among employees will lead to greater negative impact, such as
  - Workplaces in remote settings where medical evaluation or treatment may be delayed
  - Workplaces where continuity of operations is a high priority (e.g., critical infrastructure sectors)
  - Workplaces with a high proportion of employees at increased risk for severe illness

Frequency of screening testing

Frequency of screening testing

Approaches may include initial testing of all workers before entering a workplace, periodic testing of workers at regular intervals, targeted testing of new workers or those returning from a prolonged absence (such as medical leave or furlough), or some combination of approaches. Given the incubation period for COVID-19 (up to 14 days), CDC recommends conducting screening testing of unvaccinated, asymptomatic workers without known or suspected exposures at least weekly. Employers may find the following factors helpful to consider when determining the interval for periodic testing:

- The availability of testing, turnaround time, and cost
- The latency time period between exposure and development of a positive SARS-CoV-2 viral test
- Type of workplace
- Level of community transmission (Table 2, Table 3)
- Number of employees who tested positive during previous rounds of testing
- Relevant experience with outbreaks at the workplace

Serial testing used in a screening program could identify workers with SARS-CoV-2 infection, and thus help prevent or reduce further transmission, which is an occupational health measure of great importance in the types of workplaces mentioned above. Outbreak prevention and control is increasingly being thought to depend largely on the frequency of testing and the speed of reporting (an advantage of antigen tests) and is only marginally improved by the higher test sensitivity of NAATs. Serial testing, if implemented, should be integrated as a component of the comprehensive workplace program and not a substitute for other measures, such as COVID-19 vaccination, physical distancing, mask wearing, hand hygiene, and cleaning and disinfection. Engineering controls and improved ventilation in settings such as office buildings and schools are also important.

Interpretation of screening SARS-CoV-2 test results

For screening testing, some antigen test results should be considered presumptive (preliminary results). A positive antigen screening test result should be considered presumptive when the pretest probability (likelihood that the person being tested actually has the infection) for COVID-19 is low for the purpose of making a clinical diagnosis (e.g., a worker who is asymptomatic and has no known exposures to COVID-19 within the last 14 days, is fully vaccinated, or has had a SARS-CoV-2 infection in the last 3 months). Please see Evaluating the Results of Antigen Testing for SARS-CoV-2.

Asymptomatic employees who have a positive antigen screening test and need a confirmatory NAAT should not come to work and should quarantine during confirmatory testing. For confirmatory testing, CDC recommends using a laboratory-based NAAT that has been evaluated against the FDA reference panel for analytical sensitivity. See FDA's SARS-CoV-2 Reference Panel Comparative Data.

NAATs that generate presumptive results are not appropriate for use in confirmatory testing.

Employees with a positive confirmatory NAAT result should isolate at home. A negative confirmatory NAAT result is interpreted as no evidence of SARS-CoV-2 infection at the time when the testing sample was collected. Employees who test negative should continue to take steps to protect themselves and others.

State, local, territorial, and tribal health departments may be able to provide assistance on any local context or guidance impacting the workplace. Before testing a large proportion of asymptomatic workers without known or suspected exposure, employers are encouraged to have a plan in place for how they will ensure access to clinical evaluation and confirmatory testing when needed, ensure test results are reported to public health departments, modify operations based on test results, collaborate with public health departments in workplace case investigation and contact tracing, and manage a higher risk of false positive results in a low prevalence population.

Table 2. Level of Community Transmission

Indicator	Low Transmission	Moderate Transmission	Substantial Transmission	High Transmission

Indicator	Low Transmission	Moderate Transmission	Substantial Transmission	High Transmission
Cumulative number of new cases per 100,000 persons within the last 7 days*	<10	10-49	50-99	≥100
Percentage of NAATs that are positive during the last 7 days†	<5%	5%-7.9%	8%-9.9%	≥10.0%

Indicators should be calculated for counties or core based statistical areas, although in rural areas with low population density, multiple jurisdictions might need to be combined to make the indicators more useful for decision-making. The indicators listed can be found by county on CDC's COVID-19 Integrated County View.

* Number of new cases in the county (or other administrative level) in the last 7 days divided by the population in the county (or other administrative level) and multiplying by 100,000.

† Number of positive tests in the county (or other administrative level) during the last 7 days divided by the total number of tests resulted in the county (or other administrative level) during the last 7 days. Calculating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Laboratory Test Percent Positivity: CDC Methods and Considerations for Comparisons and Interpretation.

Table 3. Potential Actions Based on Community Transmission Level

Prevention Strategy	Low Transmission (Blue)	Moderate Transmission (Yellow)	Substantial Transmission (Orange)	High Transmission (Red)
Facilitate diagnostic testing for symptomatic persons and all close contacts of cases				
Facilitate diagnostic testing for symptomatic persons and all close contacts of cases				
Implement screening testing of select groups at least weekly plus facilitate diagnostic testing of symptomatic persons and close contacts				
Implement screening testing of select groups at least weekly plus facilitate diagnostic testing of symptomatic persons and close contacts				

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Previous Updates

Updates from Previous Content

Updates as of March 17, 2021

- Added description of nucleic acid amplification tests (NAATs) and antigen tests as types of viral tests to align with the Overview of Testing for SARS-CoV-2.
- Added considerations on incorporating testing of asymptomatic individuals without known or suspected exposure to SARS-CoV-2 (screening testing) in select workplace settings as part of a workplace COVID-19 prevention and control plan.
- Updated considerations on frequency of testing.

Updates as of October 21, 2020

- Added links to the updated close contact definition.
- Updated language to align with updated definition.

Last Updated Oct. 5, 2021

1. *“There is not an FDA-approved COVID vaccine in the US”* — Senator Ron Johnson

https://www.foxnews.com/media/ron-johnson-no-fda-approved-covid-vaccine

“We do not have an FDA–approved vaccine being administered in the U.S. The FDA played a bait and switch. They approved the Comirnaty version of Pfizer drugs. It’s not available in the U.S. They even admit it. I sent them a letter three days later going “What are you doing?” What they did is they extended the emergency use authorization for the Pfizer drug vaccine that’s available in the U.S., here that’s more than 30 days later, they haven’t asked that very simple question. If you’re saying that the Pfizer drug is the same as the Comirnaty, why didn’t you provide FDA approval on that? So, there’s not an FDA-approved drug and, of course, they announced it so they could push through these mandates so that people actually think, “Oh, OK now these things are FDA approved. They are not …”

2. The VAXX is in clinical trials until 2023

https://clinicaltrials.gov/ct2/show/NCT04368728

Therefore, those using coercion and threats to force vaxx are attempting to mandate human subject experimentation and require, unlawfully, that individuals participate in the government medical experiment with an unsafe gene therapy that does not prevent transmission, according to CDC.

The experimental injection has killed and injured thousands of people so far according to the government's own VAERS statistics.

3. 45 CFR § 46.116 General requirements for informed consent.

https://www.law.cornell.edu/cfr/text/45/46.116

"(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative."

4. 38 U.S. Code § 7331 — Informed consent

https://www.law.cornell.edu/uscode/text/38/7331

"The Secretary, upon the recommendation of the Under Secretary for Health and pursuant to the provisions of section 7334 of this title, shall prescribe regulations establishing procedures to ensure that all medical and prosthetic research carried out and, to the maximum extent practicable, all patient care furnished under this title shall be carried out only with the full and informed consent of the patient or subject or, in appropriate cases, a representative thereof."

5. 50 U.S. Code § 1520a — Restrictions on use of human subjects for testing of chemical or biological agents

US Code Informed Consent Human Subjects Testing

https://www.law.cornell.edu/uscode/text/50/1520a

“(c)Informed consent required

The Secretary of Defense may conduct a test or experiment described in subsection (b) only if informed consent to the testing was obtained from each human subject in advance of the testing on that subject.”

6. 21 U.S. Code § 360bbb–3 - Authorization for medical products for use in emergencies

https://www.law.cornell.edu/uscode/text/21/360bbb-3

21 U.S. Code § 360bbb–3 / Go To (e) (1) (A) (ii) (III) Right to refuse product under EUA

"(III)of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

7. •••The vaxx is still in clinical trials until 2023•••

https://clinicaltrials.gov/ct2/show/NCT04368728

Informed consent for clinical trials

https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials

8. Informed consent in research_AMA

https://www.ama-assn.org/delivering-care/ethics/informed-consent-research

9. The Nuremberg Code

https://history.nih.gov/display/history/Nuremberg%2BCode

The voluntary consent of the human subject is absolutely essential.

10. Physician: Informed Consent For COVID Vaccine Requires Full Disclosure Of Risk & Liability, And Here It Is…

https://tapnewswire.com/2021/03/physician-informed-consent-for-covid-vaccine-requires-full-disclosure-of-risk-liability-and-here-it-is/

"If you have read and understood this article, and the warnings in all the scientific studies linked, you can now see that taking the COVID injection is an act of extreme and reckless self-destruction. As a physician, I strongly advise against this vaccine, regardless of brand, for everyone, without exception."

11. Federal law prohibits employers and others from requiring vaccination with a Covid-19 vaccine distributed under an EUA

https://www.statnews.com/2021/02/23/federal-law-prohibits-employers-and-others-from-requiring-vaccination-with-a-covid-19-vaccine-distributed-under-an-eua/

EUAs are clear: Getting these vaccines is voluntary

The same section of the Federal Food, Drug, and Cosmetic Act that authorizes the FDA to grant emergency use authorization also requires the secretary of Health and Human Services to *"ensure that individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product."*

Likewise, the FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances … That they have the option to accept or refuse the EUA product …"

12. Masks are neither safe nor effective

https://www.technocracy.news/masks-are-neither-effective-nor-safe-a-summary-of-the-science/

The largest, most definitive review of all facemasking studies, Kisielinski et al, 2021, concludes that facemasking is harmful and ineffective for its stated purpose. This review constitutes the most powerful piece of scientific evidence that can possibly be brought to a court under the Supreme Court Daubert Rule.

Kisielinski K, Giboni P, Prescher A, Klosterhalfen B, Graessel D, Funken S, Kempski O, Hirsch O. Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards? Int J Environ Res Public Health. 2021 Apr 20;18(8):4344. doi: 10.3390/ijerph18084344. PMID: 33923935; PMCID: PMC8072811.

https://pubmed.ncbi.nlm.nih.gov/33923935/

13. According to U.S. code, coercion of the population meets the definition of "domestic terrorism" and is a felony:

18 U.S. Code § 2331 - Definitions

https://www.law.cornell.edu/uscode/text/18/2331

(5)the term “domestic terrorism” means activities that—

(A)

involve acts dangerous to human life that are a violation of the criminal laws of the United States or of any State;

(B)appear to be intended—

(i)

to intimidate or coerce a civilian population;

The Centers for Disease Control has finally admitted that natural immunity from prior infection *exists*. But it's even worse than that for the Covid narrative: The CDC admits that natural immunity from prior infections is superior to vaccinated immunity alone.

The CDC broke its silence on natural immunity on Wednesday. It released a study called "COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021." The findings were reported by Agence France-Presse.

AFP

Natural immunity more potent than during US Delta wave: study



A nurse prepares a dose of the AstraZeneca vaccine against COVID-19 at a vaccination center in Mexico City (AFP/PE

Wed, January 19, 2022, 3:02 PM · 2 min read

"During America's last surge of the coronavirus driven by the Delta variant, people who were unvaccinated but survived Covid were better protected

than those who were vaccinated and not previously infected," AFP noted about the new study.

"The finding is the latest to weigh in on a debate on the relative strengths of natural versus vaccine-acquired immunity against SARS-CoV-2, but comes this time with the imprimatur of the US Centers for Disease Control and Prevention (CDC)," AFP added.

The study itself is heavily parsed and argues that vaccination is still the best strategy to prevent Covid hospitalizations and deaths. That may be true — but *only* for people who don't have natural immunity from prior infections.

> During May–November 2021, case and hospitalization rates were highest among persons who were unvaccinated without a previous diagnosis. Before Delta became the predominant variant in June, case rates were higher among persons who survived a previous infection than persons who were vaccinated alone. By early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone.

The CDC unsurprisingly urged all Americans to get vaccinated, regardless of prior infections. This is consistent with the agency's earlier positions.

> Although the epidemiology of COVID-19 might change as new variants emerge, vaccination remains the safest strategy for averting future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death. Primary vaccination, additional doses, and booster doses are recommended for all eligible persons. Additional future recommendations for vaccine doses might be warranted as the virus and immunity levels change.

< Previous
The Czech Republic charts its own path on Covid

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Cutting sick pay for the unvaccinated sets a dangerous precedent

BY **UNHERD STAFF**

Tuesday, 18 January 2022

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Video 16:13

Israeli vaccine advisor: “We have made mistakes”

Professor Cyrille Cohen talks herd immunity and his pandemic regrets



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Israeli vaccine advisor: "We have made mistakes"

January 18, 2022 · 30 min · Listen later

View terms

Professor Cyrille Cohen is head of Immunology at Bar Ilan University and a member of the advisory committee for vaccines for the Israeli Government. In a wide-ranging and forthright interview, the Professor tells Freddie Sayers:

- The Green Pass / vaccine passport concept is no longer relevant in the Omicron era and should be phased out (he expects it to be in short order in Israel)
- He and his colleagues were surprised and disappointed that the vaccines did not prevent transmission, as they had originally hoped
- The biggest mistake of the pandemic in Israel was closing schools and education
- Widespread infection is now an inevitable part of future immunity — otherwise known as herd immunity
- Omicron has accelerated the pandemic into the endemic phase, in which Covid will be “like flu”

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BOYD TONKIN
8 mins

Stop calling yourself a dog parent
MARY HARRINGTON
6 mins

KEY QUOTES

> Especially with Omicron, where we don't see virtually any difference, there is a very narrow gap between people vaccinated and non-vaccinated, both can get infected with a virus, more or less at the same pace
>
> - CYRILLE COHEN, UNHERDTV

On the behavioural science behind the Green Pass:

> You have also to understand that the Green Pass is not necessarily — and that's not a secret — it's not necessarily to prevent transmission. It's also to encourage people to get vaccinated. And I don't want to touch upon the political aspects of the green pass. But this is a reality
>
> - CYRILLE COHEN, UNHERDTV

On the risks and rewards of herd immunity:

> Herd immunity is a consequence for me. It's not an objective, it's not a goal. There is a thin nuance here, if I may say, that people have to grasp. I'm not saying to people go and get infected, I don't think that this is a model that we need to adopt
>
> - CYRILLE COHEN, UNHERDTV

On Israeli school closures:

> There is one mistake, I think that we made, and that I'm extremely sorry for that. We have made a few mistakes, but it was education. For me education was the thing we shouldn't have touched. Never, never
>
> - CYRILLE COHEN, UNHERDTV

On the acceleration from pandemic to endemic:

> I think it's going to be like flu, I think there is going to be bad waves and better waves, with a better immunity at the level of the population, with better vaccines with better treatment. In that sense, and I'm extremely cautious, there is a possibility that Omicron will accelerate that transition
>
> - CYRILLE COHEN, UNHERDTV

On vaccine mandates:

> I think that vaccination is a personal choice. And I always said, I believe it is so. But that choice has some consequences. And here, there is a problem in society. If you are over 50, 60, and you're saying I don't want to get vaccinated, will you be, and I'm gonna ask a provocative question, will you be willing to

renounce on the possibility of getting taken care of in hospitals?

- CYRILLE COHEN, UNHERDTV

...

Join the discussion



GI **GILES CHANCE**

So – what are the lessons ? Thinking at the beginning in April/May 2020, I thought: Vaccination- then immunity, either natural or vaccinated – then, it's like flu. First Lesson: **Scientists often don't know and should not pretend they do know.** Put another way: scientists must resist the temptation to play God. Of the tens of interviews of scientists I have watched since COVID started, how many admitted they didn't have a clue ? Yes, it's zero. Second Lesson: **Use Common Sense**. Don't "Follow the Science" which is only a political way of blaming everything bad that happens on someone else. Third: **Stay Calm and Rational, Don't Over-React.** Closing schools was a wild over-reaction.



ALEX CK

Outstanding and thank you Freddie for doing all this work – this is what journalists need to be doing. Not taking the "party line" but actually digging in, asking difficult questions, looking at all authority with a skeptical eye and *getting to the truth*.

DO **GALETI TAVAS**

Freddy forgot the BIG one to ask and Israeli – Why did the Palestinian communities all around, with great vax-hesitance in them, not all die, but rather did about the same.

To get involved in the discussion and stay up to date, become a registered user.

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CDC Director Walensky Admits She Found Out Vaccines were Effective by Watching CNN

By Jim Hoft
Published March 8, 2022 at 6:02pm
601 Comments



Robert Kennedy Jr. tweeted out a report from his organization the Children's Health Defense on Tuesday on CDC Director Dr. Rochelle Walensky's recent talk in St. Louis. Walensky spoke at a Washington University event where she admitted that the medical elites relied too much on the vaccine as a "cure-all" and disregarded treatments.

This is something the rest of us **already knew**. There was not prescribed treatment for COVID patients and now **nearly one million Americans** are

dead!

x

Dr. Walensky also said she found out about the effectiveness of the vaccines by watching CNN.
Stunning!

Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention (CDC), became the latest prominent official to contradict key aspects of the official COVID-19 narrative of the past two years.

In a March 3 appearance at Washington University in St. Louis, Missouri, Walensky was interviewed by Dr. William G. Powderly, co-director of the institution's Division of Infectious Diseases.

During the interview, Walensky said she learned COVID vaccines were effective from watching CNN. She also admitted health officials relied too heavily on vaccines as a "cure-all" of sorts for COVID, and said vaccine makers didn't warn the agency that the vaccines would be less effective against potential variants.

She also admitted that the science, far from being "settled," is "gray" instead of "black and white."

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Jim Hoft

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Jim Hoft is the founder and editor of The Gateway Pundit, one of the top conservative news outlets in America. Jim was awarded the Reed Irvine Accuracy in Media Award in 2013 and is the proud recipient of the Breitbart Award for Excellence in Online Journalism from the Americans for Prosperity Foundation in May 2016.

The Gateway Pundit is moving back to Disqus! All of your account information and comment history has been saved and will be uploaded as quickly as possible to Disqus. If you do not already have a Disqus account, you will need to create one. Please use the same email address that you used for Insticator for your comment history to be carried over. We greatly appreciate your patience and continued support!

x

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But if you dig further into the release, you get a clearer picture of how vaccinated immunity and natural immunity stack up.

> Across the entire study period, persons with vaccine- and infection-derived immunity had much lower rates of hospitalization compared with those in unvaccinated persons. These results suggest that vaccination protects against COVID-19 and related hospitalization and that surviving a previous infection protects against a reinfection. Importantly, infection-derived protection was greater after the highly transmissible Delta variant became predominant, coinciding with early declining of vaccine-induced immunity in many persons (*5*). Similar data accounting for booster doses and as new variants, including Omicron, circulate will need to be assessed.

The public healthy agency has allowed the American people to believe in the false argument that natural immunity does not work against Covid. But when you break down the numbers, you see that natural immunity from prior infection, in both the vaccinated and unvaccinated populations, is potent protection against Covid.

One might argue that natural immunity from prior infection is actually doing a lot of the heavy lifting among the vaccinated population, as will be seen below.

The CDC's press release refers specifically to California and New York. But it's another case — Rhode Island — that provides one of the best illustrations of how the data break down.

Dr. Andrew Bostom, an epidemiologist, delved into the data and provided the statistical breakdown that helps us fully understand what is going on:

There was ~6X lower risk of covid-19 hospitalization and ~28X lower risk of covid-19 death, <u>comparing those with natural immunity to covid-19, regardless of vaccination status, to those fully vaccinated…</u>

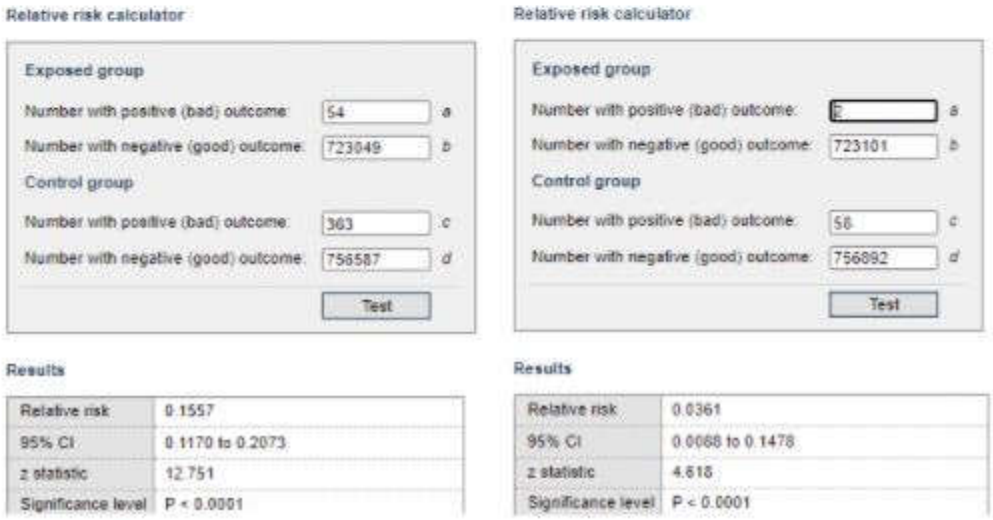
Rhode Island raw data on covid-19 infections by vaccination and prior infection status, December, 2021

Rhode Island raw data on covid-19 infections by vaccination and prior infection status, December, 2021

Rhode Island raw data on covid-19 infections by vaccination and prior infection status, December, 2021

Group	Infections (% total)	Hospitalizations (% total)	Deaths (% total)
Fully vaccinated			
-No prior infection	21,365 (46.4)	363 (29.2)	58 (38.1)
-Prior infection	2,249 (4.9)	32 (2.6)	1 (0.7)
Not fully vaccinated			
-No prior infection	20,842 (45.3)	826 (66.5)	92 (60.5)
-Prior infection	1,551 (3.4)	22 (1.8)	1 (0.7)
Totals	46,007	1,243	152

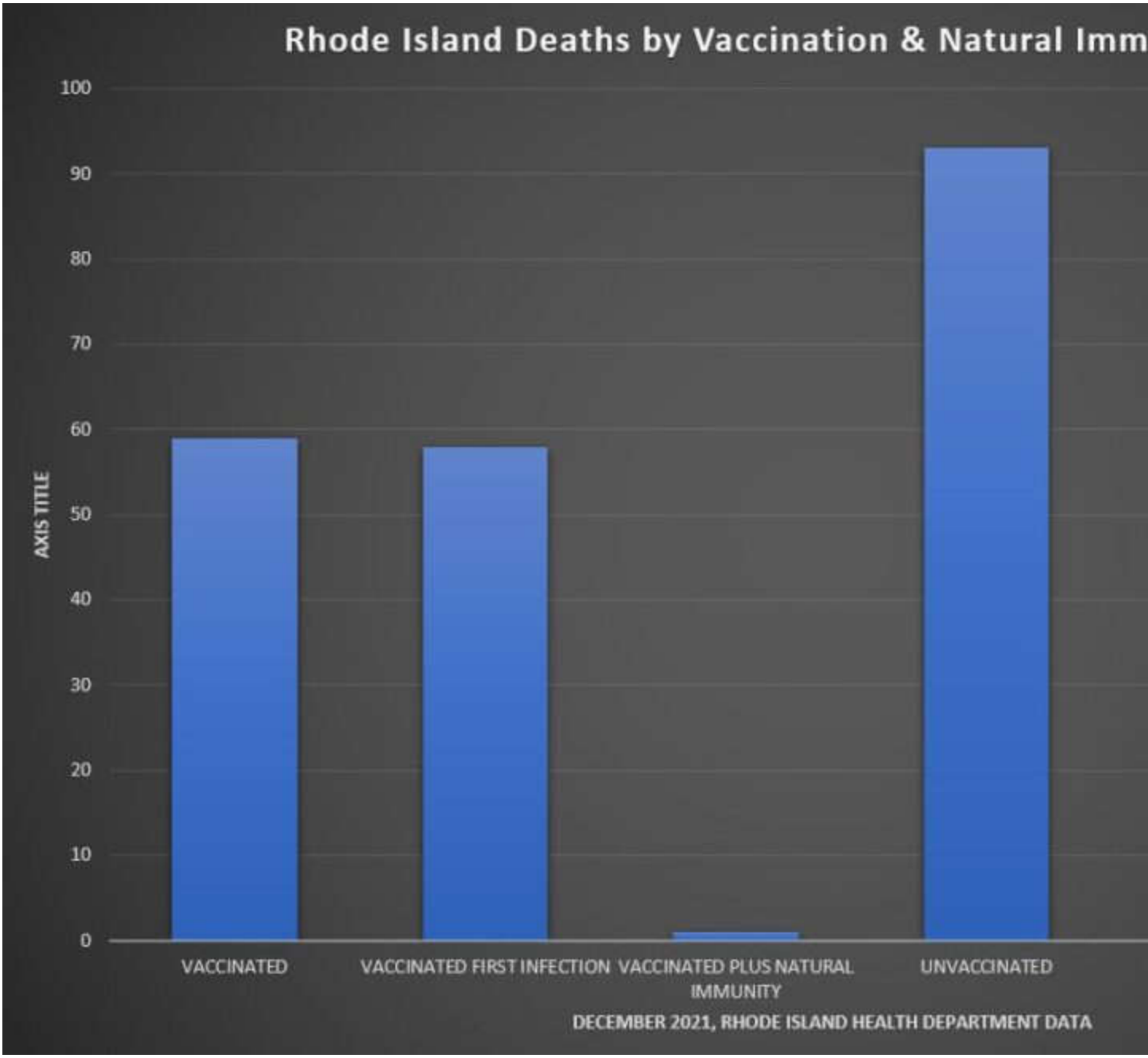
Rhode Island relative risk estimates for hospitalizations and deaths comparing fully vaccinated (n=363 hospitalizations; n=58 deaths) to those with a prior infection (n=54 hospitalizations; n=2 deaths), regardless of vaccination status, December, 2021



If you take these base numbers, which come from the Rhode Island Department of Health's website, you come to some startling conclusions. After verifying the data and the epidemiologist's methodology (Dr. Bostom changes some of the Rhode Island Health Department's terms and does

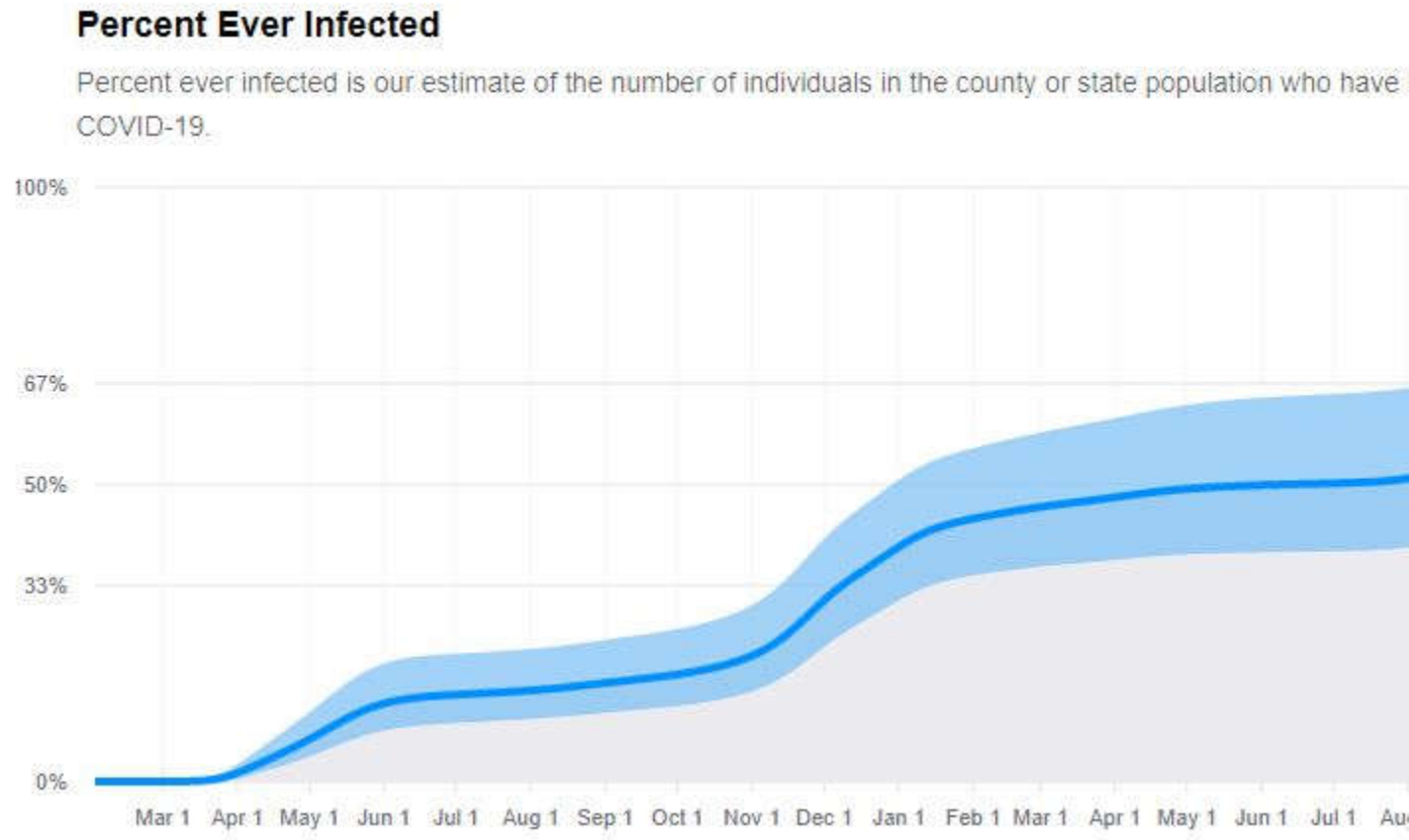
some simple math before running the statistics), you can see that cases, hospitalizations, and deaths are all greatly reduced by natural immunity.

The strongest takeaway is regarding deaths. Even when correcting for scale, survival of a prior infection was by far the greatest predictor of surviving another Covid infection.

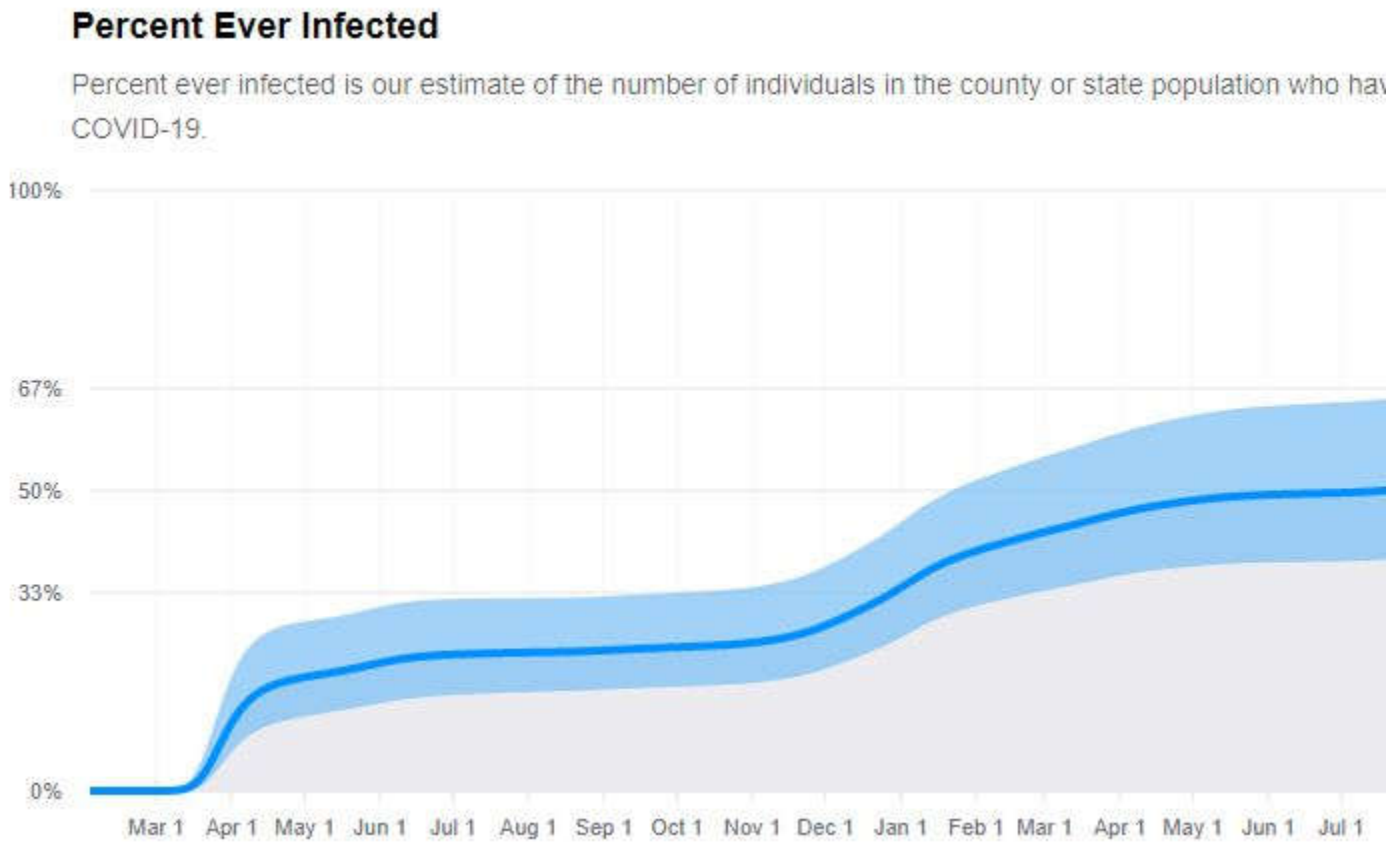


However, if one did not have a prior infection (or does not know if one had a prior infection), the argument can be made that vaccination appears to provide the best strategy of surviving one. (It is important to note that the vaccinated community in Rhode Island is much larger than the unvaccinated community; it is about twice as large, therefore the incidence rate for unvaccinated deaths is about three times as high).

Yet, even as the CDC estimated that as of September there were 146.6 million Americans with prior infections, the state-by-state breakdown, including Rhode Island, proves to be substantially higher after the Omicron surge, as Becker News had earlier predicted would be the case.
Rhode Island's percent of prior infections: 92 percent.

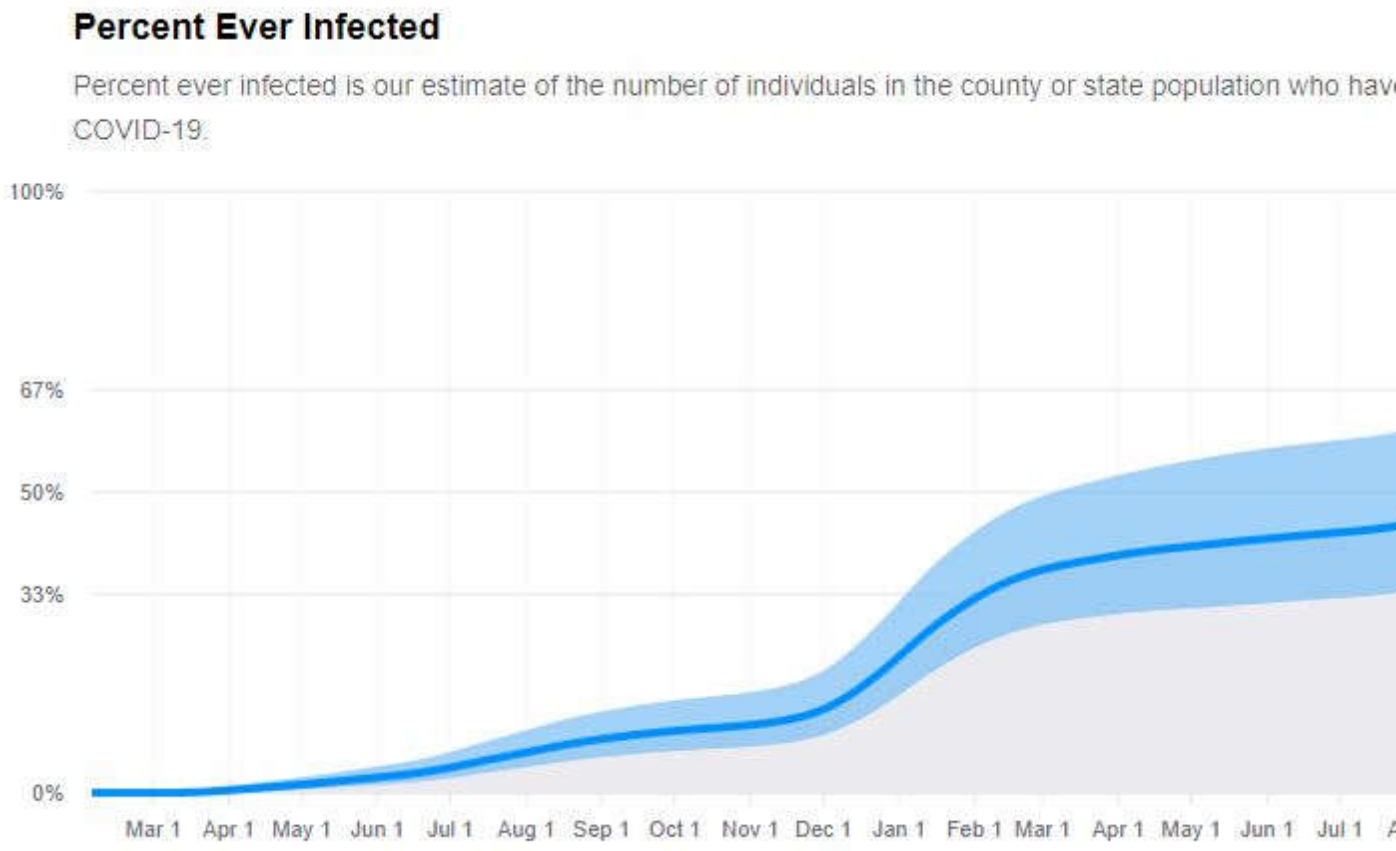


Here is New York's, for context on the CDC's latest press release. It is about 88 percent prior infections.

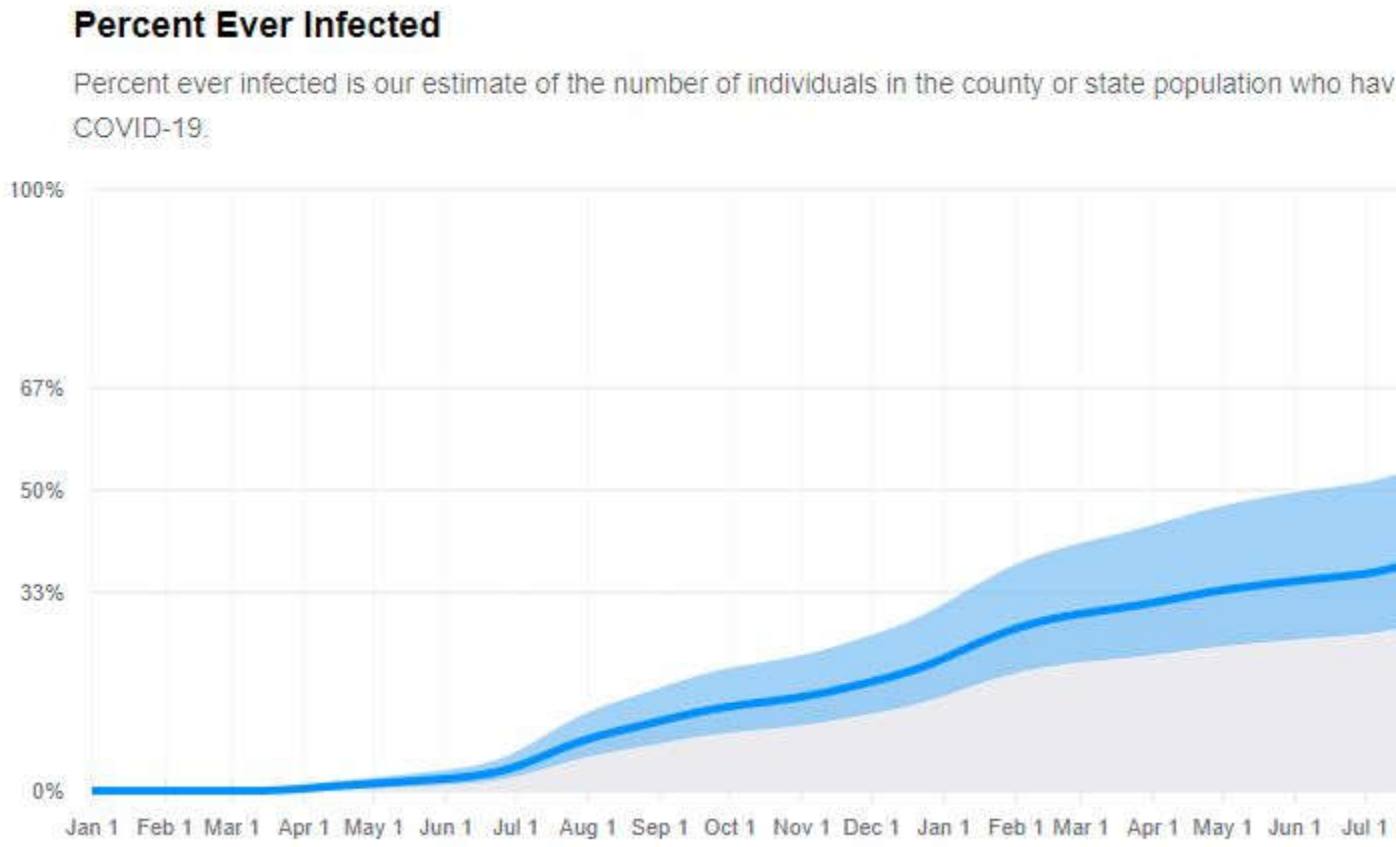


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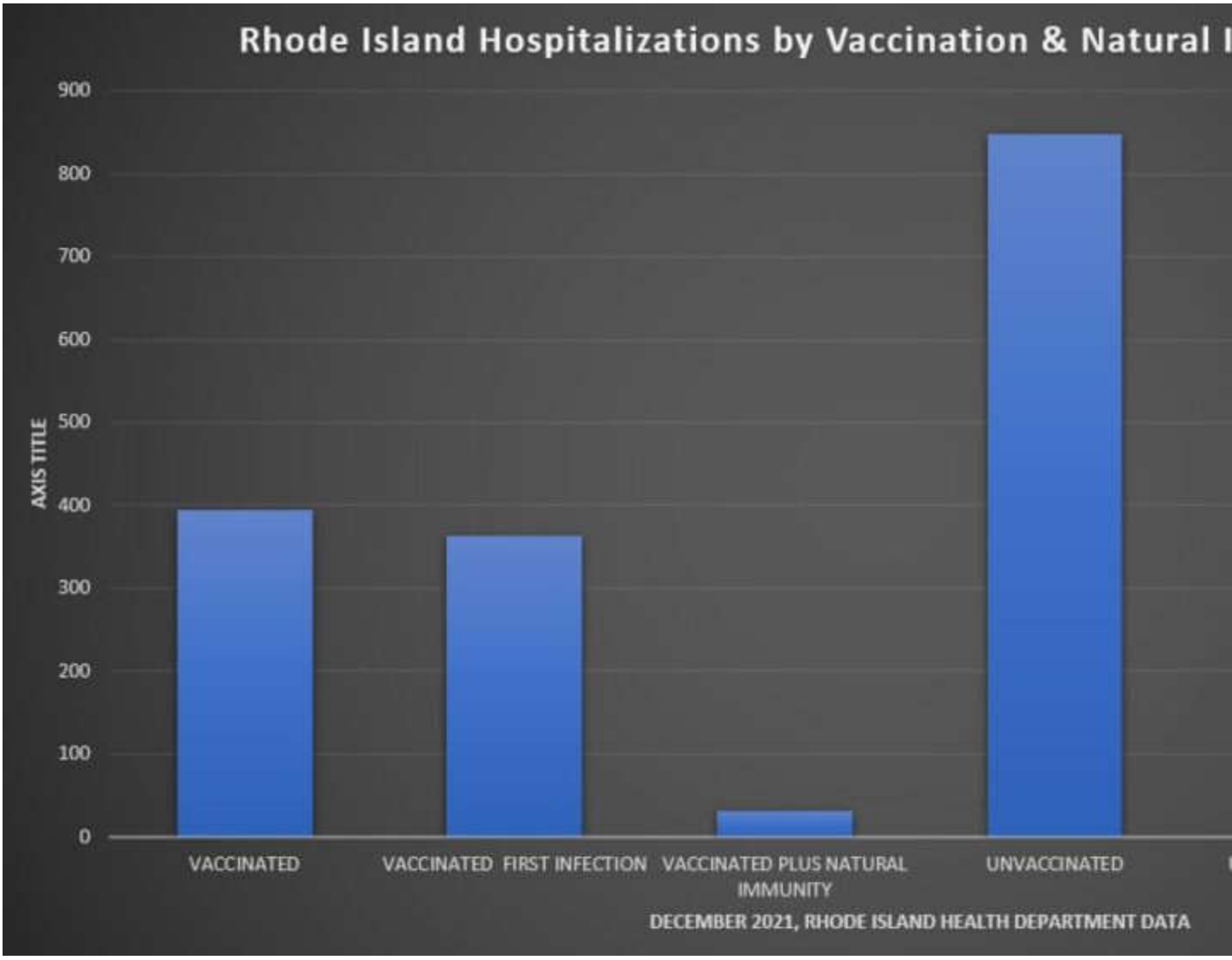
Here is California's. About 78 percent.



Just for further context, here is Florida. About 87 percent.

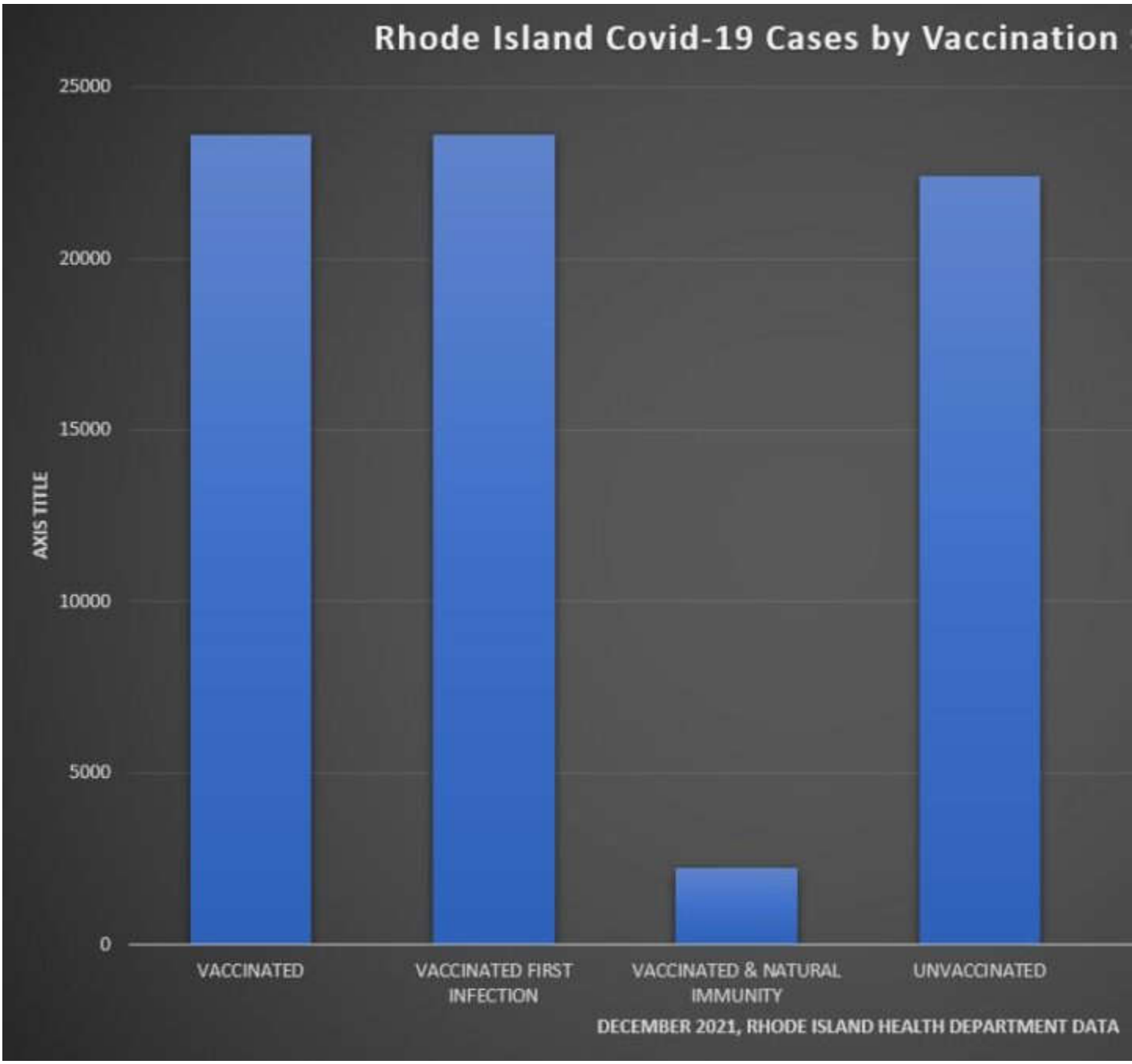


For perspective, the Mayo Clinic once considered 200 million Americans with vaccinated or natural immunity to be sufficient to claim “herd immunity.” The latest Omicron numbers, based on CDC’s Covid burden estimates, lead us to assess there may be as many as 250 million Americans with prior infections. (Cases, however, may be counted more than once.)
Rhode Island’s pattern of natural immunity being the best predictor of positive health outcomes holds up when it comes to hospitalizations.



As one can see, both the vaccinated and unvaccinated groups with prior infections had much better health outcomes. Furthermore, the health outcomes for the unvaccinated with natural immunity group was far superior to the vaccinated with no natural immunity group.

Additionally, natural immunity proved to be a far superior barrier against Covid reinfection than vaccinations alone.



The CDC release and the state-level data both indicate that natural immunity has been a powerful defense against Covid-19. Two years into the pandemic, it has taken until now for the public health agency to admit it.

It's even worse than that, however, as the data show. The vaccines are only of marginal utility, at best, to those who have had prior infections to SARS-CoV-

2. And as recent studies show, even though the vaccines and as many as two "booster shots" fail to stop the spread and infections, Omicron appears to confer natural immunity to other variants, such as Delta.
"Previous infection with SARS-CoV-2 has shown to induce effective immunity and protection against reinfections in most individuals," the *European Journal of Immunology* study said.
Nonetheless, the mainstream media have repeatedly tried to convince the American people that natural immunity is either a myth or is ineffective against Covid.

CNN "reported" on the news earlier today, but its first headline was blatantly wrong. It reported the reverse of what the CDC said. Phil Kerpen pointed out the CNN story's error.C

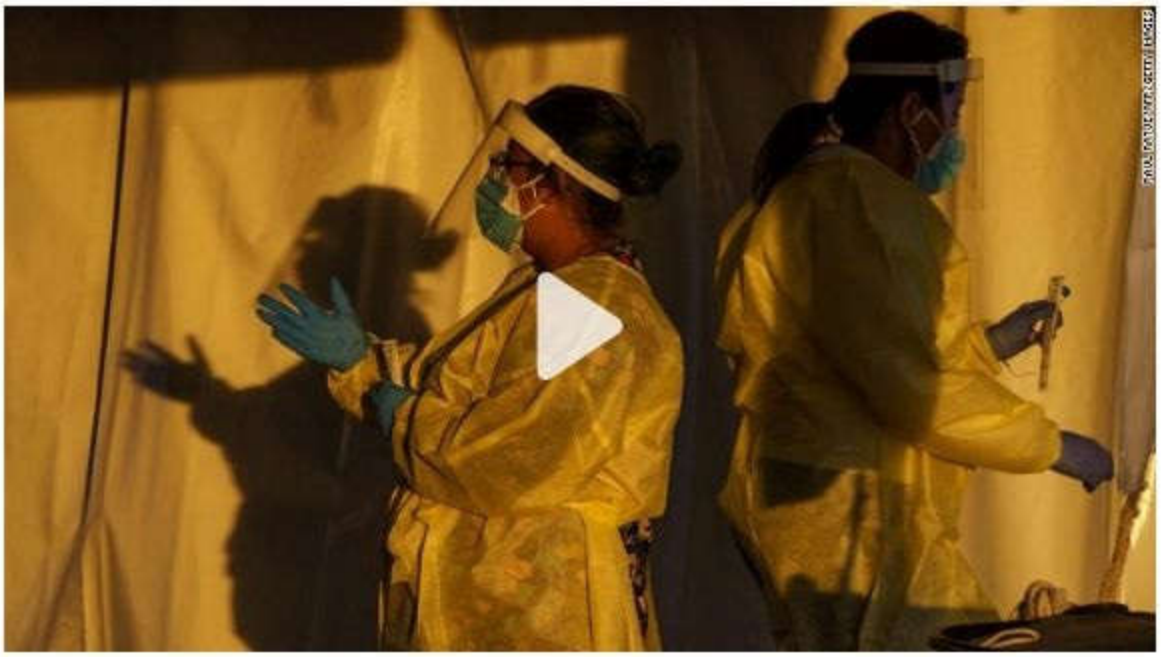
CNN then "stealth edited" the story with a new headline… which was still wildly misleading, as we saw from the analyses above.

When the Delta variant dominated, vaccinat prior infection protected against Covid-19, b vaccination was safest, study finds

NEW

By Deidre McPhillips, CNN

Updated 3:45 PM ET, Wed January 19, 2022





Doctor says 'our empathy has taken a hard hit' during covid surge



Guest corrects Joe Rogan live on his own show. See his reaction



How to get your at-home Covid-19 test for free



Why experts recommend a N95 mask to stop Covid spread



5 million st may never even thoug has reoper

(CNN) — When the Delta variant was dominant in the United States, both vaccination and prior infection helped protect against Covid-19, but vaccination was the safest way to be protected, according to a study published Wednesday by the US Centers for Disease Control and Prevention.

The data included in the study was collected before the Omicron wave in the United States, and before boosters were widely available. The CDC says it will publish additional data on Covid-19

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Vaccination was “safest” — but only if you didn’t have a prior infection. Natural immunity was the most important indicator of positive healthcomes, whether vaccinated or unvaccinated. You do not push mass vaccination for all age groups and risk profiles for extremely minimal benefits, especially among demographics that are statistically at near-zero mortality risk.

The AP was guilty of an infamous “fact check” on natural immunity in September.

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“Posts continue to circulate online falsely claiming that COVID-19 survivors don’t need vaccines because of natural immunity,” the AP claimed. “In fact, that protection is variable and not long-lasting, so vaccines are still recommended.”

But a cursory review of the scientific literature shows conclusively that natural immunity is real and it can be relied upon for strong protection against Covid-19. A Washington Post “perspective” piece from September got it right. Dr. Marty Makary, a professor at the Johns Hopkins School of Medicine and Bloomberg School of Public Health, was correct in his assessment of the situation.

“More than 15 studies have demonstrated the power of immunity acquired by previously having the virus,” he continued. “A 700,000-person study from Israel two weeks ago found that those who had experienced prior infections were 27 times less likely to get a second symptomatic covid infection than those who were vaccinated. This affirmed a June Cleveland Clinic study of health-care workers (who are often exposed to the virus), in which none who had previously tested positive for the coronavirus got reinfected. The study authors concluded that ‘**individuals who have had SARS-CoV-2 infection are unlikely to benefit from covid-19 vaccination**.’ And in May, a Washington University study found that even a mild covid infection resulted in long-lasting immunity.”

The Johns Hopkins professor referred to 15 studies on natural immunity resulting from prior infections to Covid-19. A famous article from Brownstone listed 30 such scientific studies on the benefit of Covid-19 natural immunity, in addition to adding four more to its comprehensive list of 140 scientific studies on natural immunity.
These “fact checkers” and “health agencies” are acting more like vaccine salesmen than watchdogs over the public trust.

Even when the truth comes out, they can’t help but continue to push the universal vaccination agenda. It’s sad, pathetic, and it’s getting very old.

THE EPOCH TIMES



Dr. Robert Malone in Washington on Jan. 5, 2022. (American Thought Leaders/EpochTV)

PREMIUM **VACCINES & SAFETY**

COVID-19 Vaccines May Be Enhancing Disease: Malone

By Zachary Stieber and Roman Balmakov | March 9, 2022 Updated: March 9, 2022 Print

COVID-19 vaccines may be causing enhanced disease because they target an old version of the coronavirus, Dr. Robert Malone says.

"The data are showing that vaccination can actually increase the risk of being infected with the Omicron version of this virus," Malone told The Epoch Times in a recent interview.

Malone was referring to how in some areas, including Scotland and New Zealand, patients hospitalized with COVID-19 are more likely to have received a COVID-19 vaccine than not.

A recent study, meanwhile, found that one dose of a vaccine boosted protection for people who recovered from COVID-19 but two or three doses seemed to lower protection; the authors said they weren't sure why this was the case. Another study found higher protection among naturally immune who weren't vaccinated versus those who were.

Vaccine-associated enhanced diseases (VAED) were identified (pdf) as an "important potential risk" of the COVID-19 vaccines by U.S. drug regulators, as was a similar event known as enhanced respiratory disease following COVID-19 vaccination. Some adverse events recorded following COVID-19 vaccination "could indicate" VAED (pdf), according to a Centers for Disease Control and Prevention (CDC) team.

VAED refers to disease "resulting from infection in individuals primed with non-protective immune responses against the respective wild-type viruses," researchers said last year as they set a case definition for the term. "Given that these enhanced responses are triggered by failed attempts to control the infecting virus, VAED typically presents with symptoms related to the target organ of the infection pathogen," they added.

"That's what the data has been showing now for a few months," Malone, who helped invent the messenger RNA technology that two of the three COVID-19 vaccines cleared for use in the United States is built on, told The Epoch Times.

In a Pfizer document (pdf) released this month, the vaccine manufacturer said there were a potential 138 cases with 317 relevant events of VAED reported from December 2020 to February 2021. Of the 138 cases, 71 were medically significant, 16 required hospitalization, 13 were life-threatening, and there were 38 deaths.

The most frequently reported event out of the 317 potentially relevant events was drug ineffectiveness (135). Other events included COVID-19 pneumonia, diarrhea, respiratory failure, and seizure.

"VAED may present as severe or unusual clinical manifestations of COVID-19," Pfizer concluded, adding that, "based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine" and that they will continue to monitor the syndrome.

Pfizer, Moderna, and Johnson & Johnson didn't respond to requests for comment.

A CDC spokesperson said that the agency, along with the Food and Drug Administration (FDA), are monitoring vaccine safety through surveillance systems such as the Vaccine Adverse Event Reporting System and v-safe.

Monitoring to date "has not established a causal relationship between COVID-19 vaccination and vaccine-associated enhanced disease," the spokesperson told The Epoch Times in an email.

The CDC says the vaccines are largely safe and effective but also encourages people who experience side effects after getting one of them to report the issues to one of the systems.

The FDA, meanwhile, has not at this time identified an association between enhanced respiratory disease with the three vaccines the agency has cleared, a spokesperson told The Epoch Times via email.

Meiling Lee contributed to this report.

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

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Report Prepared by:

Worldwide Safety

Pfizer

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

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1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

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proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

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Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

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Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

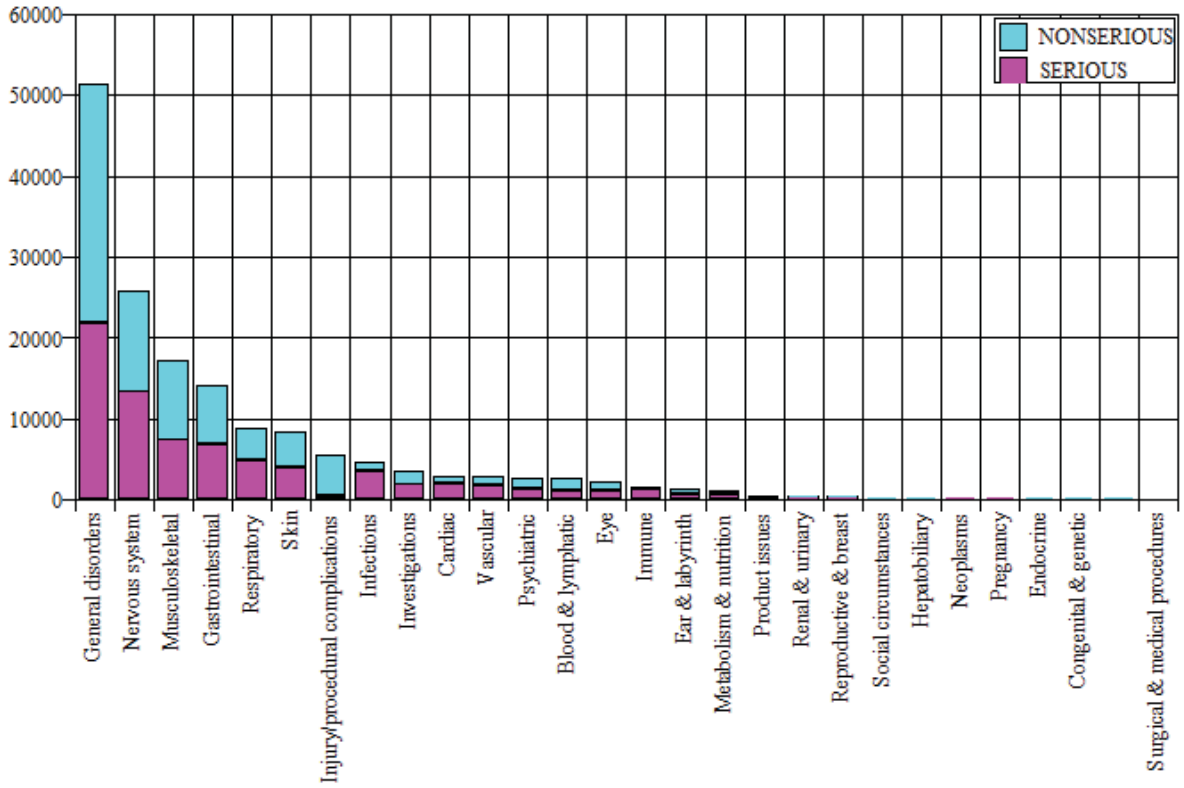


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

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Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

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Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

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Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

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3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

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3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

  Medication error case outcomes:

  - Fatal (7)[3],
  - Recovered/recovering (354, of which 4 are serious),
  - Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

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- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

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Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

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5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

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APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

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coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

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tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

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fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

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infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

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increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

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neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

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neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

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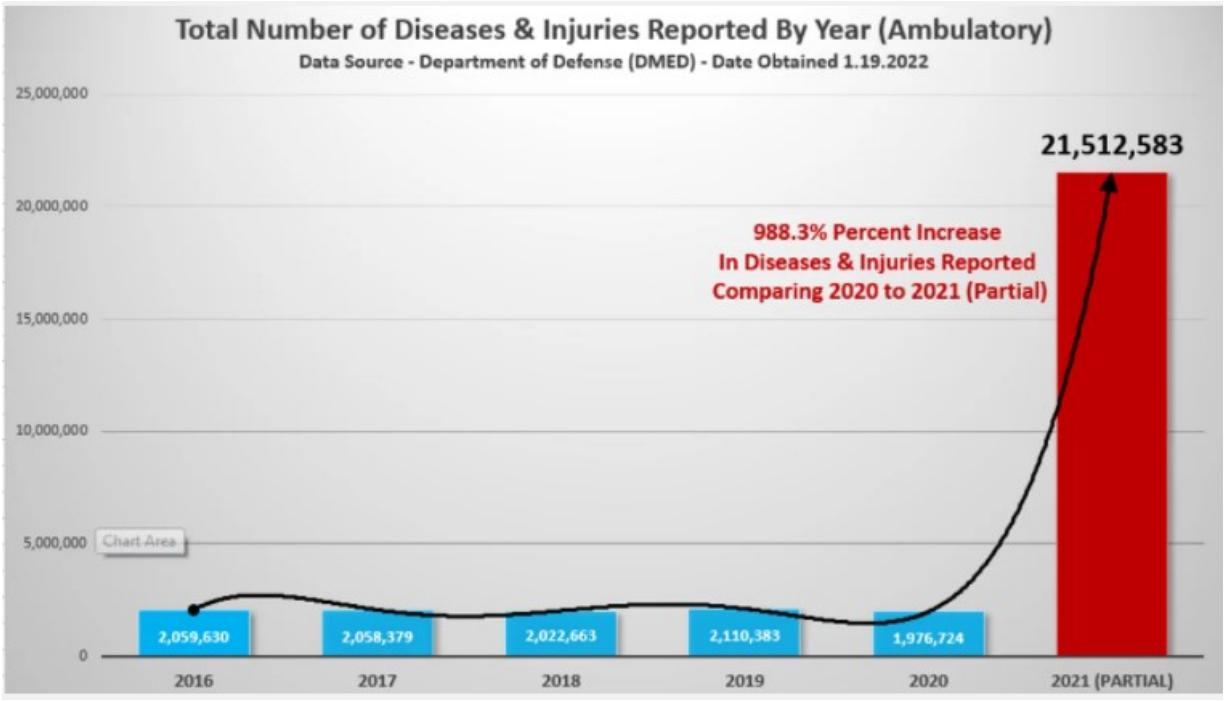
DOD Caught in MAJOR SCANDAL: US Military Caught in Severe Data Manipulation Following COVID Reveal – No Way "Revised" Numbers Are Real

By Jim Hoft
Published February 9, 2022 at 12:21pm
0 Comments



A recent report by **Daniel Horowitz** at **The Blaze** on the Department of Defense manipulating epidemiological data after the initial data for 2021 **revealed a MASSIVE increase**, by 988%, in doctor visits by US military members in 2021.

What happened in 2021? Could it be the mandatory COVID vaccines?



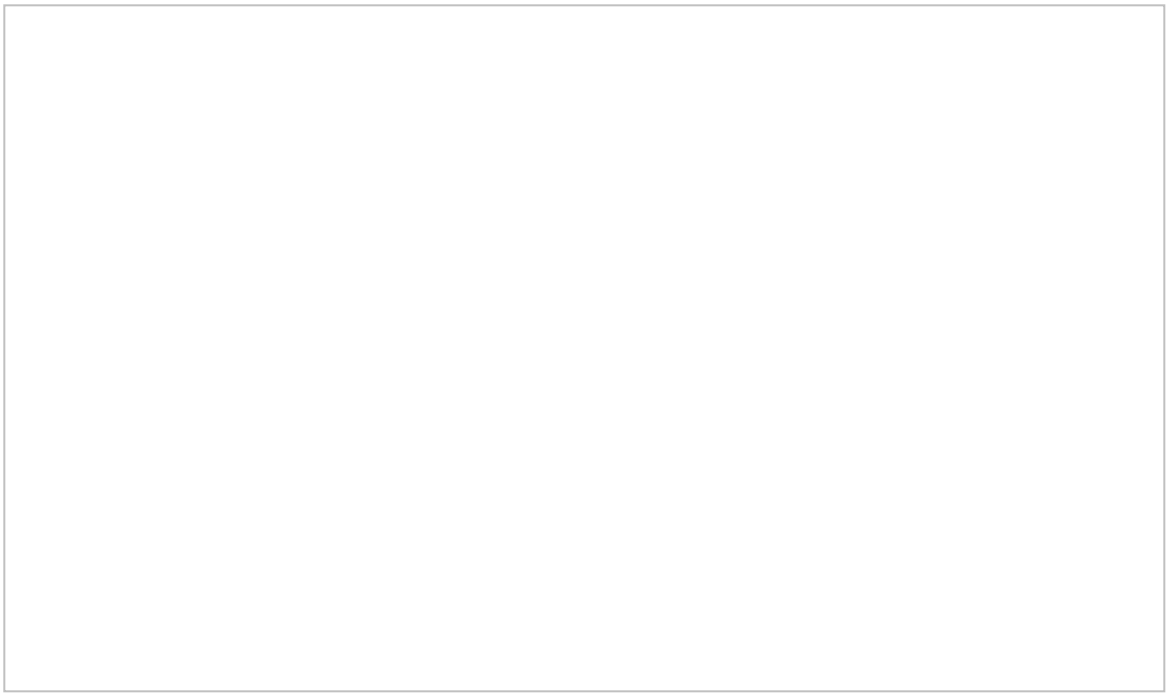
Hat Tip ***Canncon***

The initial data was presented during Sen. Ron Johnson's five-hour hearing on a **"COVID-19: Second Opinion"** by Ohio attorney **Thomas Renz**, who has been representing clients suing the vaccine mandates.

In response to the report, the US military claimed **the five previous years were plagued by a giant clitch**.

According to the Department of Defense, the actual number of doctor visits and ambulatory care in the military is at least **TEN TIMES higher** than was being reported since 2016!

The US military then provided this "corrected" chart.



So the US military in fiscal years 2019 to 2021 was over $680 billion per year. Yet, the US military could not compile a list of doctor visits for the past six years?

What the US military is admitting is that their numbers were off by 18 million a year in the number of doctor visits.

Could the US military really be this inept? Or are they covering up the actual COVID vaccine incidents?

And then there's this... There are **1.3 million serving Active Duty** in the US military today. So does that mean the average doctor visit, disease, and injury is 10 per year for our military men and women? Seriously?

This is a massive scandal. Heads should roll!

Via **The Blaze**:

> *There is undoubtedly a public health and national security crisis in the military, and the Pentagon's reaction only seems to be concerned with*

exonerating the vaccine, not fixing its own alleged problem.

It's now certain that the military's health surveillance system – DMED – showed a massive increase in sickness and injury diagnoses in 2021 over previous years, particularly in the neurological, cardiovascular, oncological, and reproductive health categories. The military, in a ***very terse and cryptic statement to PolitiFact*** *last week, admitted as much, but claimed without any further explanation that the data in the system accessed by several military doctors working with attorney Thomas Renz was only a "fraction" of the true numbers that existed. In the words of the Pentagon spokesman, it was a "glitch in the database." Where those true numbers existed, why they weren't in the system for five years, what exactly was in the system, and why the 2021 numbers were accurate according to the DOD account remain a mystery.*

However, one by one, the military public health officials have been adding back random numbers to the 2016 through 2020 codes. I'm told by Renz and two of the whistleblowers that throughout the past week, they have queried the same data again, and in most of the ICD categories, they have found that the numbers from 2016 through 2020 were "increased" exponentially to look as though 2021 was not an abnormal year. This has been done without any transparency, any press release, any statement of narrative, and sloppily in a way that makes the already unbelievable narrative simply impossible to believe.

In addition to believing that every epidemiological report for five years was somehow completely tainted with false data – including during the first year of the pandemic itself – we would have to believe that the minute they discovered this from Renz, they suddenly discovered the exact numbers. A five-year mistake fixed overnight!

Read the **rest here**.

Submit a Correction

x

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Jim Hoft

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Jim Hoft is the founder and editor of The Gateway Pundit, one of the top conservative news outlets in America. Jim was awarded the Reed Irvine Accuracy in Media Award in 2013 and is the proud recipient of the Breitbart Award for Excellence in Online Journalism from the Americans for Prosperity Foundation in May 2016.

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BLOGS

FOIA docs reveal Pfizer shot caused avalanche of miscarriages, stillborn babies

Among the first reports handed over by Pfizer was a 'Cumulative Analysis of Post-authorization Adverse Event Reports' describing events reported to Pfizer up until February 2021.



Celeste McGovern

Thu Dec 23, 2021 - 1:47 pm EST

(LifeSiteNews) – Netflix reality TV star Maya Vander told her fans last week of her devastating grief after she delivered a stillborn baby at 38 weeks of pregnancy December 9.

"Yesterday was the hardest day of my life," Vander, 39, posted on Instagram, with a picture of new baby clothes in a memory box she was taking home from hospital instead of her baby boy. "I always heard of it but never imagined I'll be part of the statistics."

Vander, a Beverly Hills real estate agent who stars on the show "Selling Sunset," had posted a photo of herself in November from a pregnancy shoot and looked the picture of health. Described as "fully vaccinated," by *US* magazine, Vander has two other children: Aiden, two, and daughter Elle, one.

After her loss, she wrote in Insider magazine that she had felt less movement from the baby a few days before she learned her baby had died and also that her husband and two children were COVID-positive, although she had tested negative. She said the baby, who was "perfect" and weighed seven pounds and four ounces, would be autopsied.

There was a flurry of sympathetic news coverage about Vander's loss, but not one article dared to ask burning questions: did COVID shots during her pregnancy have something to do with this baby's death? Or did COVID have something to do with it, and the COVID shots failed?

Data Pfizer didn't want you to see

When a group called Public Health and Medical Professionals for Transparency asked Pfizer to share the raw data from their COVID vaccine trials and post-marketing surveillance that was used to license the injection, the pharma giant linked up with the Food and Drug Administration (FDA) to refuse the Freedom of Information Act (FOIA) requests. In fact, the FDA (meant to serve and protect public health) hired Justice Department lawyers and went to court to shield the pharmaceutical giant from having to reveal its data – for 55 years. That's right. The FDA and Pfizer did not want anyone to see the numbers behind their COVID vaccine until 2076.

Fortunately, a judge ruled that the FDA and Pfizer would have to answer their FOIA requests. Among the first reports handed over by Pfizer was a "Cumulative Analysis of Post-authorization Adverse Event Reports" describing events reported to Pfizer up until February 2021. It reveals that the drug behemoth received more than 150,000 serious adverse event reports within three months of rolling out its COVID shot, but here we will focus on Table 6 of the data on pregnant and lactating women who received the shots in the first few months of the rollout, which began December 11. Most of these women would have been healthcare workers because that was who the first rounds of shots went to. As the clinical trials preceding the rollout excluded pregnant women, these would have been the first pregnant and lactating women to have ever received the vaccines.

Table 6 states that of 270 "unique pregnancies" that were exposed to the vaccine, "no outcome was provided for 238 pregnancies."

This leaves 32 pregnancies with known outcomes.

Pfizer's report states that there were 23 spontaneous abortions (miscarriages), two premature births with neonatal death, two spontaneous abortions with intrauterine death, one spontaneous abortion with neonatal death, and one pregnancy with "normal outcome." That means that of 32 pregnancies with known outcome, 28 resulted in fetal death.

Pfizer's report states that there were five pregnancies with "outcome pending" as well as the 238 with "no outcome provided." But 32 minus 28 equals four, not five.

Because of this confusion, I called Pfizer and emailed questions to their media rep. Were 28 of 32 known pregnancy outcomes actually fatal in the first 10 weeks that the vaccine became available, as their report suggests? That's an 87.5% pregnancy loss rate? And only one pregnancy outcome was "normal"? Please correct me if I'm wrong about this.

No reply.

The FDA would have had these data in their hands by the end of April. Maybe this is why they wanted to hide it for 55 years?

Ordinarily, when a new drug or medical device is put into action, the onus is, and should be, on the drug maker to prove that any unexpected events that occur afterwards are *not* related to the product. "All spontaneous reports have an implied causal relationship as per regulatory guidance, regardless of the reporter's assessment," according to adverse event reporting guidelines. But Pfizer and the FDA ignored events with temporal association and plausible cause for injury and have blithely declared the vaccine "safe and effective" for pregnant women.

Allowed it to be mandated, even.

Canadian stillbirth reports

In Canada, there have been whistleblower reports claiming spiking stillborn death rates after COVID injections. A retired doctor in British Columbia, Dr. Mel Bruchet, claimed in November that he was told by doulas that there had been 13 stillbirths in a 24-hour period at the Lion's Gate Hospital in Vancouver. A grandmother whose grandbaby was stillborn at the hospital tweeted November 21: "My daughter got that damned poison vaccine one month ago because she couldn't go to a restaurant, and people were freaking out because that she was unvaxxed. I want to sue the government." The message was scrubbed from Twitter.

Dr. Daniel Nagase, an Alberta doctor who was ordered to leave his Alberta hospital for treating three COVID patients (all of whom who went home from hospital alive) with ivermectin, told a reporter that he had been informed of 86 stillbirths in Waterloo, Ontario between January and July.

"Normally, it's only five or six stillbirths every year. So, about one stillbirth every two months is the usual rate," he said. "So, to suddenly get to 86 stillbirths in six months, that's highly unusual. But, the most important confirmation that we have from the Waterloo, Ontario report was that all of the [mothers of the] 86 stillbirths were fully vaccinated."

Fuzzy fact-checks

Media and hospitals immediately decried the claims as misinformation, but their "fact-checks" did not actually refute them. They provided data from the "last fiscal year," or from April to August.

"Data specifically from Lions Gate Hospital could not be disclosed due to privacy reasons," said Global News. They gave not-so-reassuring statements from doctor like, "There is a growing body of evidence that the vaccination is safe." The "growing body of evidence" is clearly coming from the pregnant women and their babies themselves who *are* the clinical trial.

Factcheck quoted the Centers for Disease Control and Prevention website which confirms this, stating that, according to the CDC, "the benefits of receiving a COVID-19 vaccine outweigh any *known or potential risks* of vaccination during pregnancy" (emphasis added). That's cover-your-butt language. We are not responsible until we *know* there is a problem or until we see a *potential risk* realized.

'You will die in ICU'

When independent MP Rick Nicholls raised a question about stillbirths in the Ontario legislature, the minister of health only replied that the CDC and Food and Drug Administration are recommending the jabs.

"She didn't even answer properly, just repeated what all the other puppets always say, 'it's safe,'" commented one mother, Chané Neveling. "This makes me so mad. I just had my baby girl in July [and] the amount or pressure I felt from my doctors to get the [vaccine] while pregnant almost made me go against my morals and I almost got it. My OBGYN's exact words to me were 'you are stupid for not getting it. You will die in ICU.'"

If doctors are fearmongering like that to patients, is it unreasonable to think there is at least a problem of under-reporting of adverse events following vaccination? What doctor who is so dogmatic about his latest pharma cocktail is going to consider (let alone admit) there could be a problem with it?

There are 3,604 reports of spontaneous abortions, miscarriages, stillbirths, and neonate deaths on the U.S. Vaccine Adverse Event Reporting System (VAERS) through December 10, 2021. These include thousands of miscarriages and early pregnancy losses shortly after injection of experimental gene-modifying mRNA COVID vaccines; reports of babies that abruptly stop growing, or experience a stroke in utero; of malformed babies; a baby dying from an inflamed placenta; and a baby born fatally bleeding from its mouth, nose, and lungs. A surprising number of these reports note that there was no autopsy done and admit "no further information." It's as if public health doesn't want to know what caused these babies to die – even if there are plenty of reasonable theories to explain why these events might be occurring.

VigiBase data

Given the high numbers of doses given, the number of adverse events continues to climb. VigiBase, the database of the World Health Organization, reports pregnancy complications including:

- 3,952 spontaneous abortions
- 353 foetal deaths
- 189 missed abortions
- 166 premature labours
- 160 premature babies
- 154 abortions
- 150 slow movement of unborn baby
- 146 hemorrhages in pregnancy
- 132 premature deliveries
- 123 fetal growth restriction
- 120 stillbirths
- 105 ectopic pregnancies
- 90 pre-eclampsia

Problematic studies

Public health agencies justify these dangers by claiming that women (or their babies) are more likely to experience them with exposure to the virus than to the vaccine – but they provide no evidence for this. The study they refer to most comes from the CDC itself. A comparison of stillbirth rates in 1,249,634 deliveries at 736 hospitals during March 2020–September 2021 among women with and without COVID infection, it establishes that there was indeed a surge in stillbirths – but not at the height of the first deadly wave of the virus, only "during the period of Delta variant predominance," i.e., after pregnant women were being pressured into vaccines. CDC wouldn't consider that the experimental, "novel platform" mRNA injections could be the reason that stillbirth affected only 0.98% of COVID-19–affected deliveries pre-Delta compared to 2.70% after the vaccines were introduced.

"Vaccination status was unable to be assessed in this analysis," the CDC wrote. This is the agency that is calling for vaccine mandates and introducing QR codes across the country. It can demand to know if you are vaccinated or not if you want to go to your local restaurant, or gym, or football game, but for a national study of its "most critical," supposedly lifesaving intervention during a supposedly unprecedented global pandemic, it's just not possible for the most powerful health agency in the world to determine vaccination status? Everyone knows that every pregnant woman entering a hospital for the past 18 months gets a COVID test. The CDC knows which women were vaccinated and which weren't in this, it just doesn't want to tell us.

COVID vaccine science is like their abortion 'science'

Instead, the CDC "experts" resort to platitudes. "However, because COVID-19 vaccines are *highly effective*, and COVID-19 vaccination coverage among pregnant women was *approximately* 30% as of July 2021*, most* women with COVID-19 at delivery were *likely* unvaccinated" (emphasis added). Why does that sound so unscientific? Good science isn't usually an assumption based on a slogan added to a guesstimate. Haven't we seen this kind of science before? When they told us that women don't have complications after abortion – and the CDC did their magical disappearing act of all the sepsis and the bleed outs, the perforated wombs and the post-abortion psychological sequelae? They just pay the right scientists to manipulate the data and whitewash the unwanted numbers until they vanish. Nothing to see. Vaccine science is just like abortion science. Now, they're literally fusing.

82% pregnancy loss?

Another study that's being heavily relied upon by the "experts" is from the New England Journal of Medicine. However, its authors at the CDC were forced to issue a major correction when analysts recognized their data calculations actually showed the possibility of an 82% miscarriage rate in early pregnancy, while it concluded that COVID shots were safe and effective.

Initially the study was published with Table 4 showing "Spontaneous Abortion" after vaccination. The authors claimed that 104 pregnancy losses divided by 827 pregnancies resulted in 12.6% pregnancy loss rate, which is within a normal range. However, as Deanna McLeod, a professional cancer data analyst from Kaleidoscope Strategic Inc.in Toronto, and her colleagues pointed out in a letter to the NEJM, in the tiny print below the table was a statement that a "total of 700 participants received their first eligible dose in the third trimester." Since the definition of spontaneous abortion pertains to pregnancy loss under 20 weeks gestation, that meant 700 women didn't belong in the denominator because when they were vaccinated, they were already past the point of being able to *have* a spontaneous abortion. So, properly read, the fraction changed from 104/827 to 104/127 (81.9%). Hence, an 82% pregnancy loss rate for the first trimester pregnancies.

The CDC experts wrote a correction but the New England Journal of Medicine actually just erased the faulty denominator from the original publication and kept all the same conclusions.

The 82% figure has been bandied about quite a bit, and McLeod told LifeSite that it is likely an overestimate, but the true pregnancy outcome is still not available and in fact other scientists have looked at the data and calculated a 91.2% early pregnancy loss rate. These figures fit with Pfizer's hidden data.

Researchers published a follow-up to the study but that was equally flawed. "First, they start with the absurd premise that 'there is no compelling biological reason to expect that mRNA COVID-19 vaccination (either preconception or during pregnancy) presents a risk to pregnancy'" says Jeremy Hammond, an independent journalist and political analyst who has analyzed flu shot data in pregnancy. "That's a bald-faced lie, of course, since maternal immune activation in and of itself is a compelling biological mechanism known to be associated with fetal harm."

Next, Hammond says, “they confounded their analysis of the risk of vaccination during pregnancy by including women who were vaccinated up to 30 days before conception but offered no reason for this.” Then, the defined spontaneous abortion as pregnancy loss between six and 20 weeks, thereby excluding all losses in the first five weeks (when 90% of spontaneous abortions occur).

“This means that if a woman got vaccinated, then 3 weeks later got pregnant, then made it through 6 weeks of gestation without a miscarriage, she was included;” says Hammond, “whereas if a woman got vaccinated, then 3 weeks later got pregnant, then 5 weeks later had a miscarriage, she was excluded. This obviously biases their data in favor of finding no increased risk of miscarriage.”

What all of this tells us is that we have public health agencies and scientists willing to manipulate data to protect pharmaceutical interests rather than the women and babies they exist to serve. At least some of the stories that are percolating around us of stillborn babies, hemorrhages, and miscarriages are linked to the experimental new injections – perhaps many more than we think. But it will be a long time – and many more babies’ lives will be lost – before we learn the whole truth.

LifeSiteNews has produced an extensive COVID-19 vaccines resources page. View it here.

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PREP Act Q&As

The following is intended to address an overview of the PREP Act and frequently asked questions from the manufacturing industry, the healthcare community, and state and local government officials. It is not an exhaustive review of the PREP Act's provisions in all contexts or a protocol for the HHS's implementation of the PREP Act. In addition, other legal protections may be available at the federal, state, and local government level.

The Public Readiness and Emergency Preparedness Act (PREP Act):

- adds new legal authorities to the Public Health Service (PHS) Act
- provides liability immunity related to the manufacture, testing, development, distribution, administration and use of medical countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics
- adds authority to establish a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act's immunity provisions

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) (HHS) to issue a PREP Act Declaration ("Declaration") that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency.

Liability Immunity and Compensation

In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct.

The PREP Act also authorizes a United States Treasury fund that compensates eligible individuals for serious physical injuries or deaths directly caused by administration or use of a countermeasure covered by the Declaration.

PREP Declaration

1. What Information is Included in a PREP Act Declaration?
2. Where is the Declaration Published?
3. What Factors Are Considered by the Secretary?
4. How is a PREP Act Declaration Different from a Declaration of Public Health Emergency under section 319 of the Public Health Service Act?

Immunity

1. What is Immunity from Liability?
2. Who May be Afforded Immunity from Liability under a PREP Act Declaration?
3. Are There Any Limitations on Immunity from Liability?
4. What Countermeasures May be Covered by Immunity from Liability?
5. When Does Immunity Under the PREP Act Become Available?

Claims and Compensation

PREP Act

- Public Readiness and Emergency Preparedness (PREP) Act Overview
- PREP Act Glossary of Terms
- PREP Act Question and Answers

Legal Authorities

- Legal Authorities Overview
- Legal Authority of the Secretary
- Public Health Emergency (PHE) Declaration
- PHE Frequently Asked Questions
- 1135 Waivers
- Emergency Use Authorization
- Pandemic and All-Hazards Preparedness Act of 2006
- Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

1. Is There Any Compensation for Injury?
2. How Does an Individual File a Claim for Benefits?
3. What Options does an Injured Individual have if Congress has not funded the Compensation Fund?rt. Can I receive funding priority in another way?

Litigation

1. Has there been any litigation related to the PREP Act?

PREP Declaration

1. What Information is Included in a PREP Act Declaration?

A Declaration includes:

- A determination that a disease or health condition or threat to health constitutes a public health emergency, or that there is a credible risk that it will in the future constitute an emergency;
- The category of diseases, health conditions, or health threats for which administration and use of the countermeasure is recommended. During the time period covered by the Declaration, it is presumed that the recommended countermeasure;
- The effective time period (the Secretary may specify an extended time period for manufacturers to dispose of the countermeasure and for others to cease administration and use of the countermeasure);
- The population of individuals receiving the countermeasure and the geographic area of administration and use of the countermeasure for which immunity from liability is in effect for program planners and qualified persons (manufacturers and distributors are provided liability immunity regardless of who receives the countermeasure or where it is administered or used);
- Limitations (if any) on the geographic area or areas for which immunity is in effect with respect to administration or use of the countermeasure;
- Limitations (if any) on the means of distribution;
- Any additional persons identified as qualified to prescribe, dispense, or administer the countermeasure; and
- Any other limitations or conditions.

2. Where is the Declaration Published?

The Declaration and any amendments are published in the Federal Register. It is important to note, however, that unless the Declaration specifies otherwise, it is effective upon the Secretary's signature, not upon publication in the Federal Register.

3. What Factors Are Considered by the Secretary?

In deciding whether to issue a PREP Act Declaration, HHS must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administering, licensing, and use of the countermeasure recommended in the Declaration. HHS may also consider other relevant factors.

4. How is a PREP Act Declaration Different from a Declaration of Public Health Emergency under section 319 of the Public Health Service Act?

Under section 319 of the Public Health Service Act, HHS may issue a declaration of a public health emergency based upon a determination that a:

- disease or disorder presents a public health emergency; or
- public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

Following a section 319 declaration, the HHS can take a number of emergency actions, including:

- Waiving certain Medicare, Medicaid, State Children's Health Insurance Program, and Health Insurance Portability and Accountability Act requirements;
- Allowing States and localities to temporarily reassign personnel supported with federal funds during the period of the emergency.

A determination of a public health emergency is different from a PREP Act declaration. The declarations are made on different public health determinations, and have different legal effects. A PREP Act Declaration may be made in advance of a public health emergency and may provide liability immunity for activities both before and after a declared public health emergency. A separate declaration under section 319 or other statutes is not needed for immunity under the PREP Act to take effect unless the PREP Act Declaration states that a public health or other emergency Declaration is needed to trigger immunity.

-Top-

Immunity

1. What is Immunity from Liability?

Immunity means that courts must dismiss claims brought against any entity or individual covered by the PREP Act. Claims that courts must dismiss include claims for any loss that is related to any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration. This includes, but is not limited to, claims for:

- death;
- physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability, or condition;
- any need for medical monitoring; or
- property damage or loss, including business interruption loss.

The only exception is for claims of willful misconduct. (See Question: Are There Any Limitations on Immunity From Liability?).

2. Who May be Afforded Immunity from Liability under a PREP Act Declaration?

A Declaration may provide liability immunity for covered persons. Covered persons may include, at the Secretary's discretion:

- Manufacturers of countermeasures;
- Distributors of countermeasures;
- Program planners, i.e., individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure (e.g., State or local governments, Indian tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility);
- Qualified persons, i.e., persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories of persons named in a Declaration, e.g., volunteers;
- Officials, agents, and employees of any of these entities or persons; and
- The United States.

3. Are There Any Limitations on Immunity from Liability?

Immunity from liability under the PREP Act is not available for death or serious physical injury caused by willful misconduct. A "serious physical injury" is one that is life-threatening, or results in or requires medical or surgical intervention to preclude permanent impairment of a body function or results in permanent damage to a body structure. Willful misconduct is misconduct that is greater than any form of recklessness or negligence. It is defined in the PREP Act as an act or failure to act that is taken:

- intentionally to achieve a wrongful purpose;
- knowingly without legal or factual justification; and
- in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. All three of these conditions must be proven with clear and convincing evidence. Willful misconduct cannot be found against:
- A manufacturer or distributor for actions regulated by HHS under the Public Health Service Act or the

Federal Food, Drug and Cosmetic Act, if HHS chooses not to take an enforcement action against the manufacturer or distributor, or if HHS terminates or settles an enforcement action without imposing a criminal, civil, or administrative penalty; or

- A program planner or qualified person who acts in accordance with applicable directions, guidelines, or recommendations issued by the HHS regarding administration and use of a countermeasure as long as HHS or the State or local health authority is notified about the serious injury or death within seven days of its discovery.

In addition, immunity is not available for claims based on activities that fall outside the scope of the applicable Declaration. As described below (5. "When Does Immunity Under the PREP Act Become Available?"), the Declaration can specify the conditions under which a Declaration will provide immunity, such as the effective dates and geographic area for which immunity will be available. Immunity is not available for claims that fall outside these conditions.

Immunity is not available for claims of loss unrelated to the design, development, testing, manufacture, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration.

Immunity from liability also is not available for foreign claims where the U.S. has no jurisdiction. Immunity may be available for administration or use of a countermeasure outside the United States if the claim is based on events that take place in U.S. territory or there is another link to the U.S. that makes it reasonable to apply U.S. law to the claim.

In addition, immunity is not available for claims based on activities that fall outside the scope of the applicable Declaration. As described below (5. "When Does Immunity Under the PREP Act Become Available?"), the Declaration can specify the conditions under which a Declaration will provide immunity, such as the effective dates and geographic area for which immunity will be available. Immunity is not available for claims that fall outside these conditions.

4. What Countermeasures May be Covered by Immunity from Liability?

A "covered countermeasure" may be:

- A qualified pandemic or epidemic product;
- A security countermeasure;
- An unapproved drug, biological product, or device used under an Emergency Use Authorization (EUA) issued by FDA;
- An approved drug, biological product, or device used pursuant to Federal law in conditions that are in consistent with its approval ; or
- An unapproved drug, biological product, or device, or an approved drug, biological product, or device intended for an unapproved use, that is intended for emergency use and shipped and held by a government agency or someone working on that agency's behalf for use only when that use is authorized.

In general, these are products that are approved, cleared, or licensed by FDA; authorized for investigational use, i.e. an Investigational New Drug ("IND") or Investigational Device Exemption ("IDE"), by FDA, authorized under an EUA by FDA, or otherwise permitted to be held or used for emergency use in accordance with Federal law. However, each has a specific legal definition. See the PREP Act Glossary for more information.

5. When Does Immunity Under the PREP Act Become Available?

Immunity under the PREP Act becomes available when HHS issues a Declaration, beginning on the effective date or other triggering event stated in the Declaration. For example, the Declaration may specify that activities such as manufacture and testing are covered on the effective date of the Declaration, but emergency uses such as mass dispensing are covered following a declared public health or other emergency.

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Claims and Compensation

1. Is There Any Compensation for Injury?

The PREP Act authorized a "Covered Countermeasures Process Fund" to compensate eligible individuals who suffer injuries as the direct result of a countermeasure administered or used under the Declaration. Funds must

be appropriated by Congress into this account to pay claims. If funds are appropriated, compensation for serious physical injuries may then be available to eligible requesters under the HRSA's Countermeasures Injury Compensation Program (CICP). Requests for Benefits must be made to HRSA's CICP.

Serious physical injury means an injury that warranted hospitalization (whether or not the person was actually hospitalized) or that led to a significant loss of function or disability. The CICP pays reasonable and necessary medical benefits, and/or lost wages for eligible injured countermeasure recipients. Death benefits may also be available to certain survivors of eligible individuals who died as a direct result of the administration or use of a covered countermeasure.

The CICP is payer of last resort, so benefits are reduced by the amounts payable by all other public and private third-party payers (such as health insurance and workers' compensation). The regulations implementing the CICP are at 42 CFR part 110.

2. How Does an Individual File a Claim for Benefits?

An individual who may have suffered a serious physical injury from the administration or use of a countermeasure under a Declaration may seek compensation by filing a Request for Benefits with the CICP. A Request for Benefits form must be filed within one year of receiving the countermeasure.

A legal or personal representative may file on the individual's behalf, but is generally not required unless the injured person is a minor or an adult who lacks legal capacity to receive payments. If the injured person has died (regardless of cause of death), the executor or administrator of the estate may file for benefits on behalf of the estate. If the injured person died as a direct result of receiving the countermeasure, certain survivors may file a request for death benefits.

As well as filing a Request for Benefits Form, the requester must submit all required medical records and other supporting documentation. Further information on filing a Request for Benefits is available on the CICP's website

3. What Options does an Injured Individual have if Congress has not funded the Compensation Fund?

If no funds have been appropriated to the compensation program, or the Secretary does not make a final determination on the individual's request within 240 days, or the individual decides not to accept the compensation, the injured individual or his representative may pursue a tort claim in the United States District Court for the District of Columbia, but only if the claim involves willful misconduct and meets the other requirements for suit under the PREP Act. If the individual accepts compensation from the CICP, or if there is no willful misconduct, the individual does not have a tort claim that can be filed in a United States Federal or a State court.

Any award is reduced by public or private insurance or worker's compensation available to the injured individual. Awards for non-economic damages, such as pain, suffering, physical impairment, mental anguish, and loss of consortium are also limited.

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Litigation

1. Has there been any litigation related to the PREP Act?

On November 21, 2012, the Appellate Division of the New York Supreme Court in *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (2012) upheld PREP Act protections for a county that conducted a school based vaccination clinic in response to the H1N1 outbreak.

During the clinic, a nurse employed by St. Lawrence County inadvertently vaccinated a kindergartener in the absence of parental informed consent. The child's mother filed suit, arguing that the county had committed negligence and battery. The county moved to dismiss the complaint on the basis that the claim was preempted under the PREP Act. The lower court denied the defendant's motion to dismiss, asserting that the PREP Act was not intended by Congress to protect against claims arising from failure to obtain informed consent. The county appealed and the United States submitted an amicus brief supporting the county.

The appellate court dismissed the plaintiff's claims, finding that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff's claims of negligence and battery. The court noted the alternative remedy provided by the countermeasure injury compensation program and the possibility of a federal cause of action for willful misconduct claims.

The period for appeal of the case has expired.

In another case, *Kehler v. Hood*, 2012 WL 1945952 (E.D.Mo.), plaintiffs alleged that the physician and her employing hospital were negligent in failing to obtain the adult patient's informed consent and a consult from a specialist prior to the administration of the vaccination, which resulted in a severe case of transverse myelitis to the patient, and loss of consortium to the spouse. Defendants then brought third party product liability/failure to warn claims against the manufacturer.

The parties did not dispute that the manufacturer, was protected by the PREP Act, nor did they allege that it engaged in willful misconduct. As a result, the federal Eastern District Court of Missouri dismissed the claim against the manufacturer. Finding that it had no jurisdiction over plaintiffs' remaining claims, the federal court remanded the case to state court for further consideration of the plaintiffs' claims.

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This page last reviewed: January 13, 2021

RENZ LAW, LLC.

SPECIAL NOTICE REGARDING EVIDENTIARY FINDINGS RELATED TO THE OFFICIAL RENZ LAW COVID-19 INVESTIGATION

Herein is notice regarding critical evidence related to COVID-19, potential governmental corruption, and the safety of our military and citizens. We would like to thank Make Americans Free Again for their assistance in ensuring this document is provided to every congressperson, governor, state attorney general, and as many other elected officials as possible throughout the nation.

This document includes a substantial amount of evidence. While we believe it should be analyzed in its entirety, we have included overview documents that provide bullet-point information on critical items for easy reference (*see* the Table of Contents).

RENZ LAW, LLC.

Date: March 7, 2022

Dear Sir or Madam,

For approximately two years now, two presidents, congress, the federal and state court systems, and the American public have been lied to, manipulated, and injured. What started as one of the most egregious over-reaches of executive power in American history – 14 days to flatten the curve – quickly morphed into an anathema to the principles upon which our republic was founded. These lies and manipulation have resulted in an economic crisis, a mental health crisis, the erosion of freedoms fundamental to all Americans, and the debilitation of our military.

A combination of unelected and totally corrupt bureaucrats, big tech and big pharma billionaires, the mainstream media, and the healthcare/pharmaceutical industry have successfully perpetrated the greatest fraud in the history of the world. Make no mistake, we do not deny the existence of COVID-19 nor the fact that it has killed too many people. We can, however, show how the COVID fraud was carried out through data manipulation, terrible public health policy, and political manipulation that made a disease with approximately the same case fatality rate as the seasonal flu in most people appear to be the end of the world.

Renz Law and its associated experts and attorneys will make evidence of all of this available in the future, but this document will focus on the crisis faced by our most essential citizen heroes – our military. For those that do not know, a number of whistleblowers recently came forth with terrifying data related to the impact of the COVID-19 injections on our military. These decorated heroes have queried the Defense Military Epidemiological Database (DMED) and found that after the implementation of the vaccine mandates in the military there were terrifying increases – over 1000% in several cases – of severe disease in our soldiers.

The DMED database is considered the premier epidemiological database in the world, monitored by an entire division of the military, part of the data feeding into the DHHS related to vaccine safety, and frequently cited by public health professionals in peer reviewed publications. Yet, after we presented this data to Senator Johnson in a public hearing, and after he wrote a letter to the Secretary of Defense regarding this information, the only response from the DoD was to a "fact-checking" organization stating that a glitch occurred in this database affecting the data from 2016-2020. If there was truly a glitch, the database, that our DHHS, DoD, public health professionals around the world, and Anthony Fauci's crew of scientific gurus that have been monitoring DMED to "follow the science" of COVID were wrong for 5 years including 2020 – the year Fauci followed the science to keep us safe from COVID. The glitch then magically repaired itself in 2021 despite the fact that the error went unnoticed until we shared this information in 2022.

The DoD has still not, to my knowledge, responded to Senator Johnson, nor have they responded to the team representing the whistleblowers that shared this information. They have, however, continually changed the numbers in the DMED database on a regular basis, some by hundreds of percent. Given what

is probably in the vicinity of the hundreds of millions of dollars per year we spend on maintaining this database and monitoring our soldier's health, what has occurred represents negligence on an unprecedented level and, more likely, a clear cover-up. The likelihood of this being a cover-up is made even clearer in light of the fact that this data was part of the data Fauci (who has declared himself to represent science) and the DHHS was using to determine both our COVID response in 2020 and the vaccine safety in 2021.

Enclosed are supporting documents that demonstrate our claims. The evidence available is far too voluminous to include so we have focused on several key documents. Each document will be preceded by a bullet-point summary to ease the reading. The documents show:

1. Evidence submitted to federal court regarding the DMED data;
2. A DoD document demonstrating that Fauci was lying in claiming this to be a "crisis of the unvaxxed" and showing that the injections are even less effective in minority populations;
3. A Pfizer document demonstrating that the dangers of these injections were known very early on and that potential side effects have been covered up since the creation of the injections;
4. An FDA presentation showing categories of expected side effects which were never disclosed to the public as well as a list of data sources that are being withheld from public disclosure;
5. A DoD Senior Leader Briefing that shows that a full 25% of the active duty and reserves have not completed the "vaccination" process and thus are subject to being dismissed from the military;
6. Presentations that summarize the included information as well as provide additional context; and
7. While not included, we can provide documentation from Pfizer and Moderna that these injections are in fact gene therapies.

Ultimately, we are requesting that immediate action be taken to lift any and all mandates for military personnel to receive these dangerous injections and also for passage of legislation repealing immunity for vaccine manufacturers – if vaccines are truly safe and effective no one should oppose this. Finally, we are requesting the immediate rescission of the EUA and illegal approvals of these injections until such time as the public can be properly informed of the real risks of the "vaccines" and of COVID-19; no one can provide informed consent if they do not know the potential risks and benefits of these injections.

We finish by asking you, our elected officials, the following question: Given the attached evidence of a cover-up related to the danger of the COVID "vaccines", will you stand with our soldiers and the American people or with billionaires, big pharma, and special interests?

Sincerely,

Thomas Renz
Renz Law, LLC
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RENZ LAW, LLC.

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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA

AMERICA'S FRONTLINE DOCTORS, et al,	)	
Plaintiffs,	)	
v.	)	Case No. 2:21-cv-702-CLM
The UNITED STATES OF AMERICA, et al,	)	Supplement to Plaintiffs' Brief (ECF 43)
Defendants.	)	

COME NOW the Plaintiffs, by and through their undersigned attorneys, and as their supplemental filing explaining the relevance of the Excel file presented to the Court on February 8, 2022 (*see* Order entered on February 8, 2022, ECF 46), do hereby submit the following:

1. The Excel spread sheet file first presented to the Court on February 8, 2022 (the "File") is now attached as Exhibit A to this Supplement.

2. The File contains a table of data that has been carefully downloaded from the Defense Medical Epidemiological Database ("DMED") by senior military personnel who are risking everything to serve their country in the best way they know how, now as whistleblowers.

3. These personnel are LT COL Theresa M. Long, LT COL Peter Chambers, 1LT Mark Bashaw and MAJ Samuel Sigoloff (the "Whistleblowers"). The

Whistleblowers are U.S. Army medical officers with regular authorized access to DMED. Each of them regularly accesses DMED as a part of their job. Each of them has provided undersigned counsel with a declaration under 28 U.S.C. § 1746(2).[1]

4. The DMED website[2] explains:

> DMED is available to authorized users such as U.S. military providers, epidemiologists, medical researchers, safety officers or medical operations / clinical support staff for serving health conditions in the U.S. military.
>
> The purpose of DMED is to standardize the epidemiologic methodology used to collect, integrate and analyze active component service member personnel and medical event data, to provide authorized users with remote access to the summarized data.

5. Each of the Whistleblowers independently queried the DMED database using the same queries. Each of the Whistleblowers obtained the same shocking results. Each of the Whistleblowers attempted to discredit and find an alternate explanation for the results, and each failed. The queries and results are reflected in the File. The File is populated exclusively with, and faithfully reflects, the DMED data.

6. The File reveals that prior to the commencement of vaccination within the DOD with the mRNA COVID-19 vaccines, the incidence of certain diseases and

[1] The declarations exceed the 10-page limit imposed by the Court in its February 8 Order, however, counsel will provide them to the Court upon request.
[2] https://health.mil/Military-Health-Topics/Combat-Support/Armed-Forces-Health-Surveillance-Division/Data-Management-and-Technical-Support/Defense-Medical-Epidemiology-Database

medical conditions among DOD personnel was predictable and constant at a certain level over a number of years from 2016 to 2020; HOWEVER, after the commencement of vaccination within the DOD with the mRNA COVID-19 vaccines in 2021, the incidence of these diseases and medical conditions among DOD personnel spiked dramatically.

7. For example, the File shows a 456% increase in acute myocardial infarction, a 468% increase in pulmonary embolism, a 296% increase in all cancers, a 275% increase in myocarditis.

8. The data in the File was first disclosed to the general public at a roundtable hosted by U.S. Senator Ron Johnson (R-WI) on January 24, 2022.[1] Following the exposé, the DOD responded with a statement that the dramatic spike in disease and medical conditions in DOD personnel immediately following the vaccine rollout in DOD was purely coincidental, and the result of a previously unannounced "glitch" in its DMED database, and had nothing to do with the vaccines themselves. The DOD maintains that the database glitch resulted in artificially low incidence numbers in the years 2016-2020, but that the 2021 data is accurate.

9. The DOD "glitch" story is absurd. It strains credulity that such a breathtaking error in the DMED database, which is heavily scrutinized by personnel

[1] https://www.ronjohnson.senate.gov/2022/2/sen-johnson-to-secretary-austin-has-dod-seen-an-increase-in-medical-diagnoses-among-military-personnel

throughout the DOD and other federal agencies, including the agencies employing the named Defendants, could have gone unnoticed for so long, including during the height of the pandemic in 2020. It is equally unconvincing that the DMED database would have magically corrected itself prior to 2021, while leaving all of the old erroneous data in the system.

10. Further, Plaintiffs have conducted their own investigation, and offer the attached Declarations of Mathew Crawford (Exhibit B) and Dr. Andrew Huff (Exhibit C), which are further illuminating and suggest deliberate agency misconduct and fraud (abuse of discretion).

Respectfully submitted this the 16th day of February, 2021.

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Exhibit A

Defense Medical Surveillance System (DMSS) Defense Medical Epidemiology Database (DMED) DoD Data - January 2022

Diagnosis or Injury	Query Date	2016	2017	2018	2019	2020	Total 2016-2020	Avg Injuries Per Year 2016-2020	2021 (Partial Year)	Percent Increase in 2021
All Diseases & Injuries										
All Disease & Injuries (Amb)	1/19/2022	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	10,227,779	2,045,555.80	**21,512,583**	**1052%**
All Disease & Injuries (Hosp)	1/19/2022	43,786	43,338	42,024	43,493	40,052	212,693	42,538.60	**54,776**	**129%**
Cancer										
Neoplasms (ALL CANCERS)	1/19/2022	41,557	39,139	37,756	38,889	36,050	193,391	38,678.20	**114,645**	**296%**
Malignant Neoplasms of Digestive Organs	1/19/2022	660	654	633	602	704	3,253	650.60	**4,060**	**624%**
Malignant Neoplasms of Thyroid & Other Endocrine Glands	1/19/2022	550	394	369	374	372	2,059	411.80	**1,950**	**474%**
Malignant Neuroendocrine tumors	1/19/2022	167	135	98	113	117	630	126.00	**440**	**349%**
Testicular Cancer (Amb)	1/10/2022	1,156	1,008	866	880	889	4,799	959.80	**3,537**	**369%**
Ovarian Cancer (Amb)	1/10/2022	121	88	73	82	69	433	86.60	**181**	**209%**
Breast Cancer (Amb)	1/10/2022	934	810	766	792	766	4,068	813.60	**4,357**	**536%**
Malignant Neoplasm of Esophagus	1/19/2022	29	36	35	20	26	146	29.20	**261**	**894%**
Mental Health & Metabolic Function										
Anxiety (Amb)	1/10/2022	37,011	36,667	36,145	37,762	37,870	185,455	37,091.00	**931,791**	**2512%**
Anxiety (Hosp)	1/10/2022	2,478	2,577	2,534	2,666	2,642	12,897	2,579.40	**6,496**	**252%**
Suicide	1/10/2022	359	496	530	570	550	2,505	501.00	**1,798**	**359%**
Endocrine Nutritional & Metabolic Diseases (Amb)	1/19/2022	33,140	31,825	30,814	31,504	30,506	157,789	31,557.80	**134,053**	**425%**
Disorders of Thyroid Gland	1/19/2022	8,078	7,694	7,357	7,289	6,893	37,311	7,462.20	**24,769**	**332%**
Malasie & Fatigue (Amb)	1/10/2022	3,851	3,842	3,832	3,885	3,735	19,145	3,829.00	**26,416**	**690%**
Thyroid Dysfunction (Amb)	1/10/2022	8,074	7,696	7,357	7,289	6,891	37,307	7,461.40	**22,620**	**303%**
Diabetes Type 1 (Amb)	1/10/2022	1,319	1,167	1,072	1,036	960	5,554	1,110.80	**5,269**	**474%**
Disease of Liver (Amb)	1/10/2022	1,994	2,053	2,063	2,234	2,322	10,666	2,133.20	**6,187**	**290%**
Narcolepsy & Cataplexy										
Narcolepsy & Cataplexy	1/19/2022	995	898	864	830	766	4,353	870.60	**2,097**	**241%**
Neuromuscular & Skeletal Systems										
Diseases of the Nervous System	1/19/2022	82,435	81,998	81,382	85,012	80,786	411,613	82,322.60	**863,013**	**1048%**
Diseases of the Eye & Adnexa	1/19/2022	88,091	87,712	86,417	91,503	79,529	433,252	86,650.40	**280,206**	**323%**
Migraine	1/19/2022	15,734	15,714	16,462	17,116	16,331	81,357	16,271.40	**73,490**	**452%**
Seizures (Amb)	1/10/2022	196	148	130	150	123	747	149.40	**489**	**327%**
Guillian-Bare Syndrome (Amb)	1/10/2022	66	79	71	85	65	366	73.20	**403**	**551%**

Exhibit A

Defense Medical Surveillance System (DMSS) Defense Medical Epidemiology Database (DMED) DoD Data - January 2022

Diagnosis or Injury	Query Date	2016	2017	2018	2019	2020	Total 2016-2020	Avg Injuries Per Year 2016-2020	2021 (Partial Year)	Percent increase in 2021
Acute Transverse Myelitis in Demyelinating Disease of CNS	1/19/2022	46	57	48	35	34	220	44.00	**202**	**459%**
Demyelinating Diseases of the CNS	1/19/2022	785	737	690	677	648	3,537	707.40	**3,444**	**487%**
Multiple Sclerosis	1/19/2022	479	391	367	400	385	2,022	404.40	**2,750**	**680%**
Rhabdomyolysis (Hosp)	1/10/2022	216	209	227	222	198	1,072	214.40	**440**	**205%**
Rhabdomyolysis (Amb)	1/10/2022	706	696	740	755	669	3,566	713.20	**5,162**	**724%**
Eye Disorder (Amb)	1/10/2022	6,044	6,013	5,647	6,312	5,623	29,639	5,927.80	**11,892**	**201%**
Extra Pyramidal (Amb)	1/10/2022	1,509	1,474	1,339	1,371	1,338	7,031	1,406.20	**3,669**	**261%**
Bell's Palsy (Amb)	1/10/2022	483	462	457	447	450	2,299	459.80	**1,338**	**291%**
Cardiovascular System										
Diseases of the Blood & Blood-forming Organs & Certain Disorders Involving the Immune Mechanism	1/19/2022	11,533	11,122	10,851	11,773	11,429	56,708	11,341.60	**34,486**	**304%**
Acute Myocardial Infarction (Amb)	1/10/2022	324	370	376	366	372	1,808	361.60	**1,650**	**456%**
Hypertension (Amb)	1/10/2022	2,308	2,323	2,363	2,392	2,415	11,801	2,360.20	**53,846**	**2281%**
Acute Myocarditis (Amb)	1/21/2022	84	92	116	159	108	559	111.80	**307**	**275%**
Acute Pericarditis (Amb)	1/10/2022	535	538	522	531	499	2,625	525.00	**850**	**162%**
Nontraumatic subarachnoid hemorrhage	1/19/2022	219	139	134	170	196	858	171.60	**640**	**373%**
Pulmonary Embolism (Amb)	1/19/2022	678	701	668	716	968	3,731	746.20	**3,489**	**468%**
Tachycardia (Amb)	1/10/2022	845	814	893	903	849	4,304	860.80	**2,595**	**301%**
Disease of the Arteries (Amb)	1/10/2022	3,164	2,965	2,938	3,096	2,860	15,023	3,004.60	**6,069**	**202%**
Cerebral Infarction (Amb)	1/10/2022	887	848	858	888	887	4,368	873.60	**3,136**	**359%**
Reproductive System & Birth										
Spontaneous Abortion (First Occurrence)	1/19/2022	2,668	2,532	2,475	2,608	2,404	12,687	2,537.40	**2,164**	**85%**
Spontaneous Abortion (All Occurences)	1/10/2022	1,431	1,518	1,493	1,578	1,477	7,497	1,499.40		**0%**
Congenital Malformations (Amb)	1/19/2022	11,710	11,131	10,456	11,081	10,153	54,531	10,906.20	**18,951**	**174%**
Infertility, Female (Amb)	1/19/2022	2,261	2,262	2,243	2,340	2,262	11,368	2,273.60	**11,748**	**517%**
Infertility, Male (Amb)	1/19/2022	2,187	2,287	2,037	2,152	1,990	10,653	2,130.60	**8,365**	**393%**
Ovarian Dysfunction (Amb)	1/19/2022	862	936	908	945	1,022	4,673	934.60	**4,086**	**437%**
Dysmenorrhea (Amb)	1/10/2022	3,104	3,403	3,481	3,943	3,900	17,831	3,566.20	**12,539**	**352%**
Vaccine Adminstration										
T50.B95A Adverse Effect of Other Viral Vaccine, Initial Encounter	Unassigned						914	182.80	**1,281**	**701%**

Exhibit B

To whom it may concern:

On Monday, January 24, attorney Thomas Renz addressed Senator Ron Johnson and those at a special five-hour hearing on COVID-19 issues. Renz spoke about alarming increases in miscarriages, cancers, and neurological conditions based on reports put together by whistleblowers with access to the Defense Medical Epidemiology Database (DMED).

The Department of Defense (DoD) responded that the increases in rates of illness and disease reported by Renz were due to a “glitch” in DMED. The DMED was then taken offline for some time. After DMED was put back online, query reports showed large changes to data queries for the 2016 through 2020 date range.

Tracking down the glitch reveals an unexplained change of data that can be observed in Medical Surveillance Monthly Reports (MSMR) published openly online. The May 2021 MSMR displays annual summaries of major diagnostic categories of ambulatory and hospitalization reports from 2016, 2018, and 2020. These major diagnostic categories are defined as the categories with the greatest number of reported events and constitute the vast majority of medical diagnoses. When comparing the numbers of ambulatory reports to the May 2019 MSMR (which displays summaries from 2014, 2016, and 2018), the totals for these diagnostic categories for 2016 and 2018 were substantially revised to display increases in all forms of illness by an average of 17.5% (16.3% after excluding one category called “Other” that included a change in definition). Presumably these changes took place for all data from 2016 through 2020. Strangely, no such large revisions were made to hospitalization data, which would be expected if the revisions were due to a large cache of “lost and found” patient reports in which a proportion of the conditions resulted in hospitalization.

A review of the past decade of MSMR reports show a small handful of revisions larger than 2%, with nearly all changes in summary data far smaller than 1%. No major systemic data revisions were observed prior to the May 2021 MSMR. At the time of this report, no explanation was given for the massive changes in health data that would surely affect biomedical studies on these diagnostic categories. Best practices would dictate a detailed explanation for large and sudden changes---particularly as it pertains to one of the world’s most important medical databases. Further, the changes in all but one of the 16 major diagnostic categories fit the changes observed from queries performed after the DMED was put back online, purportedly to fix the “glitch”. This leads me to believe that the DMED “glitch” clearly corresponds to the large revisions that appeared in the May 2021 MSMR.

Further, and perhaps more disturbing, the data revisions are not randomly distributed as one might expect of “lost and found” reports added to a system, or many methods for recalibrating report definitions. These revisions are most prominent in the categories most heavily researched as injuries or adverse events associated with the COVID-19 quasi-vaccines, including those that Renz spoke about in the January 24 hearing.

There are enough signs to conclude with a high probability that the large-scale MSMR revisions published in May 2021 and associated DMED alterations made in January 2022 were made to mask illness data from early 2021 associated with vaccine rollouts, and likely fraudulent. An examination of the data should quickly reveal whether this is the case.

Exhibit B

I, Mathew Crawford, declare under penalty of perjury, pursuant to 28 U.S.C. §1746, that the foregoing facts are true and correct.

Respectfully submitted this the 16th day of February 2022.



Mathew Crawford
Statistical and Data Analyst

Exhibit C

DECLARATION OF ANDREW HUFF PH.D., M.S.

To whom it may concern:

On February 16th, I participated in a presentation by Mathew Crawford from Renz Law Firm where he explained numerous anomalies in the DMED reports published by the Department of Defense (DoD). After his presentation, I personally examined the Defense Medical Epidemiology Database (DMED) data and two different versions of the reported data. The purpose of DMED is "to standardize the epidemiologic methodology used to collect, integrate and analyze active component service member personnel and medical event data, and to provide authorized users with remote access to the summarized data." DMED contains the reasons why DoD personnel were evaluated by medical personnel reported in the form of International Diagnostic Codes (IDC) revisions 9 and 10. The two reports in question are from one that was available online prior to January 24, 2022, and second that was published after a "glitch" was identified and corrected by the DoD. As DMED is one of the most comprehensive and accurate health record databases in the world, the database contains any potential vaccine injury data related to mRNA vaccines. After, analyzing both versions of the data, it is my opinion that the data were altered to distort and hide the true extent of the harm caused to the US Armed Forces by the mRNA vaccines that were uniformly administered to the population.

In the absence, of any large or major changes in the exposures of DoD personnel to any other substance, chemical, toxin, physical, or environmental hazard, there should not be substantial deviations between the years of reported data. Due to the "glitch" correction, it appears that DMED was altered in a way to obfuscate mRNA vaccine injuries by increasing the illnesses in the previous years to match the projected injuries in 2021. Most, notably that such a major correction of this "glitch" would have triggered these actions by DoD:

- An addendum to the report to be issued that explains why the glitch occurred, the changes to the data that occurred due to correcting the glitch, an explanation of how the glitch was identified, and the methods used to correct the glitch by DoD personnel.
- Due to the large differences in diseases incidence and prevalence, it would normally trigger investigations into the diseases and health conditions which dramatically increased due to correcting the "glitch" in previous years. At the time of this letter there appears to be no investigation to the diseases that dramatically increased incidence, which would be typical for public health officials and officers reviewing the DMED data.

Due to the circumstances and timing surrounding of the glitch, the lack of proper reporting related to the glitch's correction, and the large increases in health conditions reported in previous years data, it appears that the data were manipulated to obfuscate injuries and diseases caused by mRNA vaccines in DMED.

I, Andrew Huff, declare under penalty of perjury, pursuant to 28 U.S.C. §1746, that the foregoing facts are true and correct.

Respectfully submitted this the 16th day of February 2022.

Andrew Huff, Ph.D., M.S.

Project Salus

Attached is a document from the DoD related to Project Salus. This document shows:

- The DoD and DHHS are monitoring the safety and effectiveness of the vaccines using complex AI and providing weekly updates to relevant personnel;
- This data is not shared with the public nor, to our knowledge, with elected officials;
- The document we have is dated September 28, 2021
    - At that time there are numerous public statements from Anthony Fauci and others claiming this to be a "crisis of the unvaxxed" and that our hospitals are 90%+ filled with unvaxxed people;
    - Our military was also continuing to push the vaccine mandates despite this document showing the lack of efficacy of the vaccines;
- Slide 3 shows that the CDC and CMS data are being analyzed as part of this project through the DoD;
- Slides 4-5 show that side effects are being excluded from statistics if they occur within 14 days of full vaccination:
    - It is well known that most side effects occur within 14 days of receiving these injections;
    - This also excludes any side effects that occur after the first dose of Pfizer or Moderna as they are considered a two shot series;
- Slide 7 states that in the Medicare population, "**an estimated 71% of COVID-19 cases occurred in fully vaccinated individuals.";**
- Slide 12 states that in the Medicare population, **"an estimated 60% of COVID-19; hospitalizations occurred in fully vaccinated individuals in the week ending August 7th."**
- Finally, slide 17 shows that the injections are substantially less effective in minority populations. Despite this, and despite the risk of side effects, DHHS has made a concerted effort to market these injections to minorities.
- This document definitively demonstrates that the DoD and DHHS have known for quite some time that the injections are ineffective but have continued to force them on our military and healthcare workers, while also falsely promoting the "safe and effective" narrative to Congress, the courts, and the public.

Effectiveness of mRNA COVID-19 Vaccines Against the Delta Variant Among 5.6M Medicare Beneficiaries 65 Years and Older

Weekly update of September 28, 2021

huMETRIX®

Project Salus

JAIC

Project Salus

Executive Summary

Basic questions which require data-driven answers

- Is vaccine effectiveness (VE) **waning** over time?
- Is VE **reduced** for the **Delta variant**?
- Does the need vary by **sub-population**?

Project Salus provides answers to these questions

- **VE of both mRNA vaccines appears to wane over time in this large 5.6M US-based 65 & over vaccinated cohort**
- **Risk of breakthrough hospitalization increases with time elapsed since mRNA vaccination with odds ratio increasing to 2.5 at 6 months post vaccination**
- **VE against Delta breakthrough hospitalization (62%) exceeds VE against Delta infection (41%)**
- **Prior COVID-19 infection has a major protective effect against breakthrough hospitalization**
- **Older age groups** (75-84 & 85 and older) **experienced further reduction in vaccine protection against hospitalization**
- **Hospitalization rate (21% vs 32%) and death rate (2% vs 12%) of breakthrough infections lower than rates observed in Covid-19 cases in pre-vaccination pandemic phase in 2020**

Graphic adapted from CDC Presentation ACIP Meeting August 30, 2021
Oliver, S. Framework for Booster Doses of COVID-19 Vaccines

Project Salus

Salus Platform for COVID-19 Analyses

VE Study Attributes

Cohort

20M Medicare beneficiaries nationwide with 16M individuals 65 years and older

Exposure

5.6M fully vaccinated with 2.7M Pfizer and 2.9M Moderna

Period of study

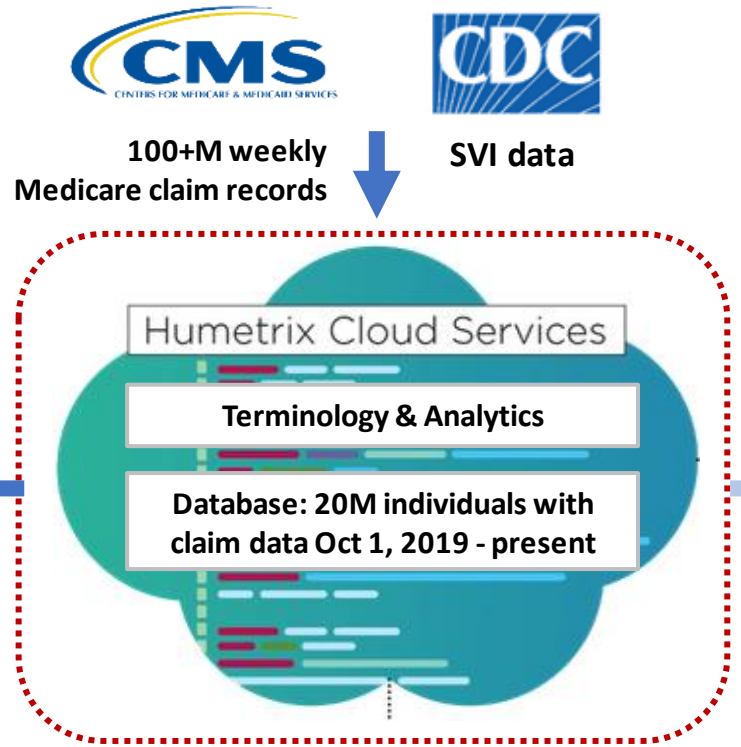
January - August 21 2021

Breakthrough Key Metrics

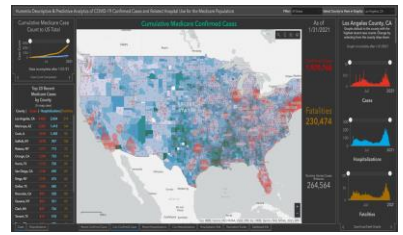
161K Breakthrough cases

33K Breakthrough hospitalizations

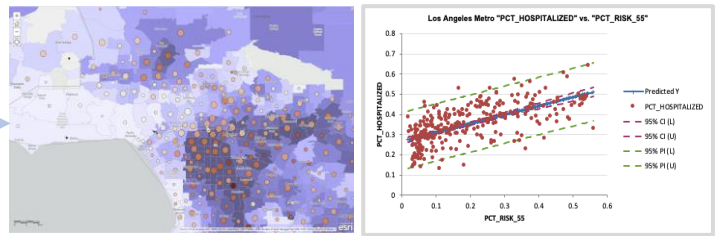
10.4K requiring ICU admissions



Other Platform Applications



Nationwide Mapping of COVID-19 Outcomes
Hospitalizations, ICU, Ventilator Rx, Deaths



Disease Risk Models with Population Risk Profiling: Severe COVID-19 risk with Validation with Hospitalization Rates



Vaccination Mapping overlaid on severe COVID-19 risk

humetrix®

** Medicare data and Humetrix software are hosted in a secure government enclave of the Department of Defense*

Salus Breakthrough Analysis Methodology and Limitations

- **Breakthrough case definition**: new COVID-19 diagnosis (by COVID-19 ICD-10 code) occurring no earlier than 2-weeks post the second vaccine dose (see appendix for more details on case definition)

- **Breakthrough analysis methodology**: to estimate weekly breakthrough cases and hospitalizations we multiplied our Medicare claim-based weekly breakthrough case counts and hospitalization counts by the corresponding weekly ratio of the claims-based vaccination rate to the CDC vaccination rate to compensate for missing COVID-19 vaccination data from Medicare claim data (Medicare claims only provide ~45% of the published CDC vaccination rate in the 65 and over age group)

- **Breakthrough data limitations**:
  - Possible overestimation of breakthrough rates due to breakthroughs clinically defined with a COVID-19 diagnosis but not confirmed by PCR or antigen test (unavailable in claim data)
  - Possible overestimation of breakthrough rates due to assuming identical breakthrough rates between individuals with claim-based vaccination data and those lacking vaccination data in their claims
  - Overestimation of breakthrough rates would lead to underestimating vaccine VE against breakthrough infections and breakthrough hospitalizations

COVID-19 Case Definitions

- **COVID-19 case definition**: COVID-19 ICD-10-CM code U071 found in any claim type. Date of diagnosis based on first claim with U071. Note: 29% have either a COVID-19 PCR or antigen test in a claim.
- **COVID-19 breakthrough infection definition**: COVID-19 diagnosis more than 2 weeks after second dose of mRNA vaccine or single dose of J&J vaccine with no COVID-19 ICD-10 code U071 between first and second dose of mRNA vaccine. Note: 36% of breakthrough cases have either a COVID-19 PCR or antigen test in a claim.
- **COVID-19 hospitalization definitions**: (1) Inpatient claim with primary admitting diagnosis ICD-10-C code U071 with data of admission within 14 days after COVID-19 diagnosis or date of discharge within 10 days of post hospitalization COVID-19 diagnosis OR (2) Carrier claim with ICD10 code U071 and place of service code = 21 and date of service either 14 days after COVID-19 diagnosis or 10 days before COVID-19 diagnosis.
- **COVID-19 associated death definitions**: (1) Inpatient claim patient discharge status code = 41 (expired in facility) OR (2) MBSF file Date of Death are within 60 days of COVID-19 diagnosis. 85% of COVID-19 deaths using this definition occurred within 30 days and 72% within 20 days of COVID-19 diagnosis

Project Salus

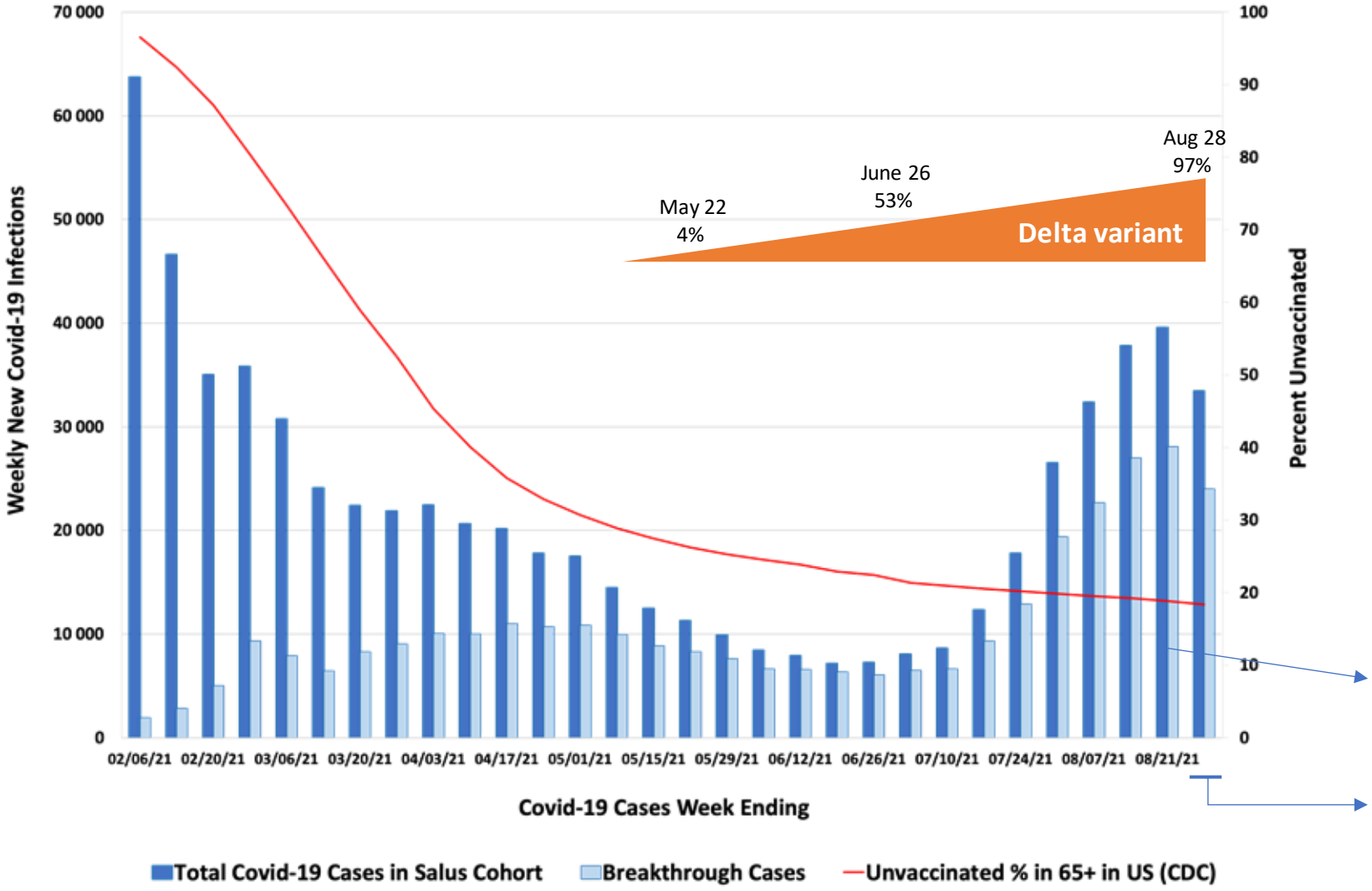
Key Breakthrough vs. Pre-Vaccination COVID-19 Metrics

Among 5.6M fully vaccine immunized Salus cohort members aged 65 and older (2.7M Pfizer and 2.9M Moderna), as of September 10, 2021:

- **2.9% cumulative breakthrough rate**
- **21% hospitalization rate** in breakthrough infections, reduced by one third of 32% hospitalization rate March – December 2020
- **31% breakthrough hospitalizations include ICU care,** equivalent to 32% ICU rate March – December 2020
- **2.1% death rate** in breakthrough infections, reduced six-fold from 12% death rate March – December 2020

Project Salus

Total & Breakthrough Cases in the 65 Years and Older Salus Cohort



- **As Delta variant became predominant, COVID-19 cases increased five-fold** in the >=65 population
- In this 80% vaccinated >=65 population, an estimated **71% of COVID-19 cases occurred in fully vaccinated individuals**

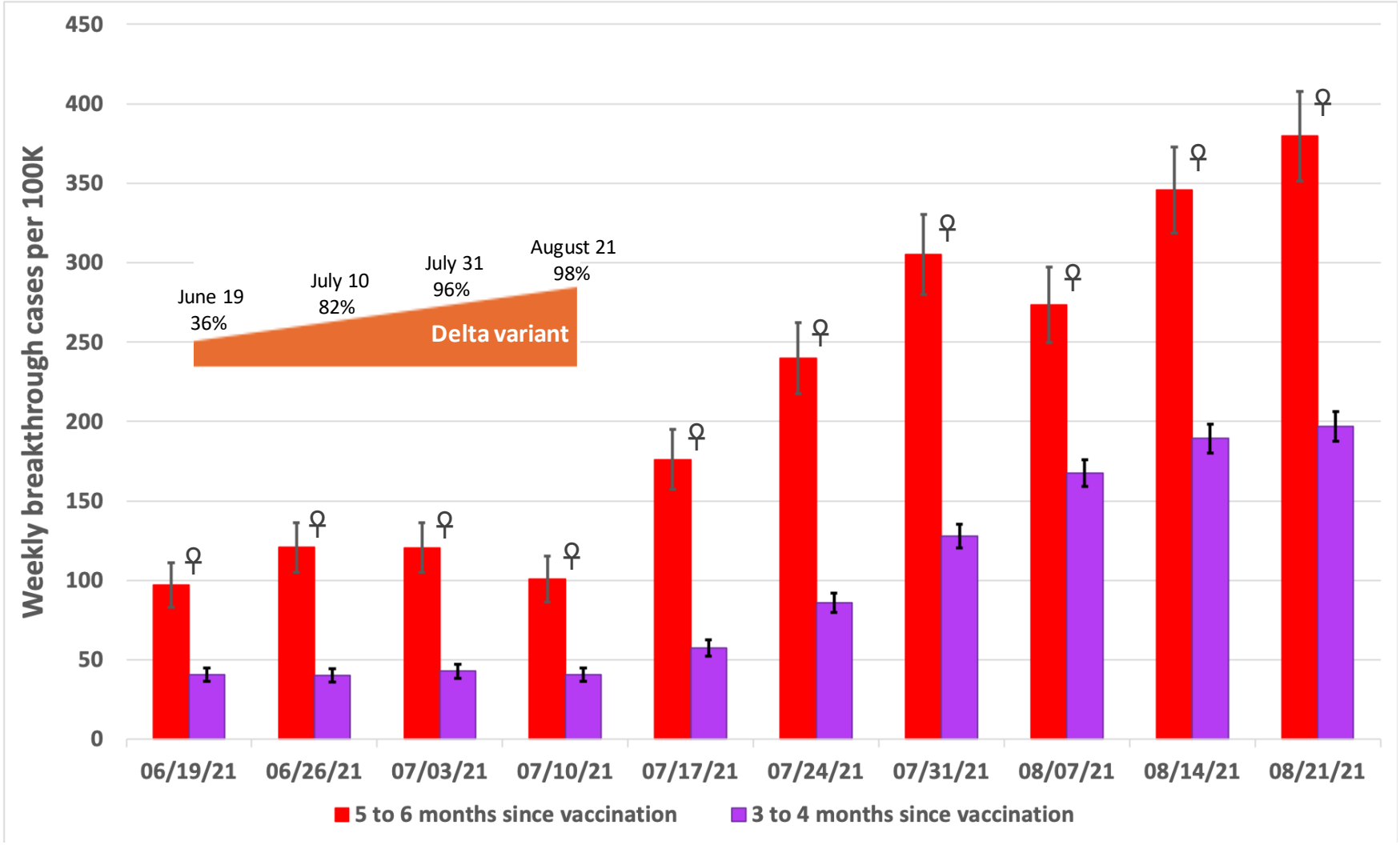
Breakthrough cases = 71% of total Covid-19 cases in cohort

Week ending 08/28/21, data incomplete due to lag in claims processing

*CDC data: % of SARS-CoV-2 genomes sequenced

Project Salus

Is mRNA Vaccine Effectiveness Against Delta Breakthrough Infection Waning Over Time in 65 Years and Older Salus Cohort?



- **Breakthrough infection rates 5-6 months post vaccination are twice as high as 3-4 months post vaccination**

95% CI

♀ Breakthrough infection rates 5-6 months since vaccination > 3-4 months since vaccination
P < 0.001

Project Salus

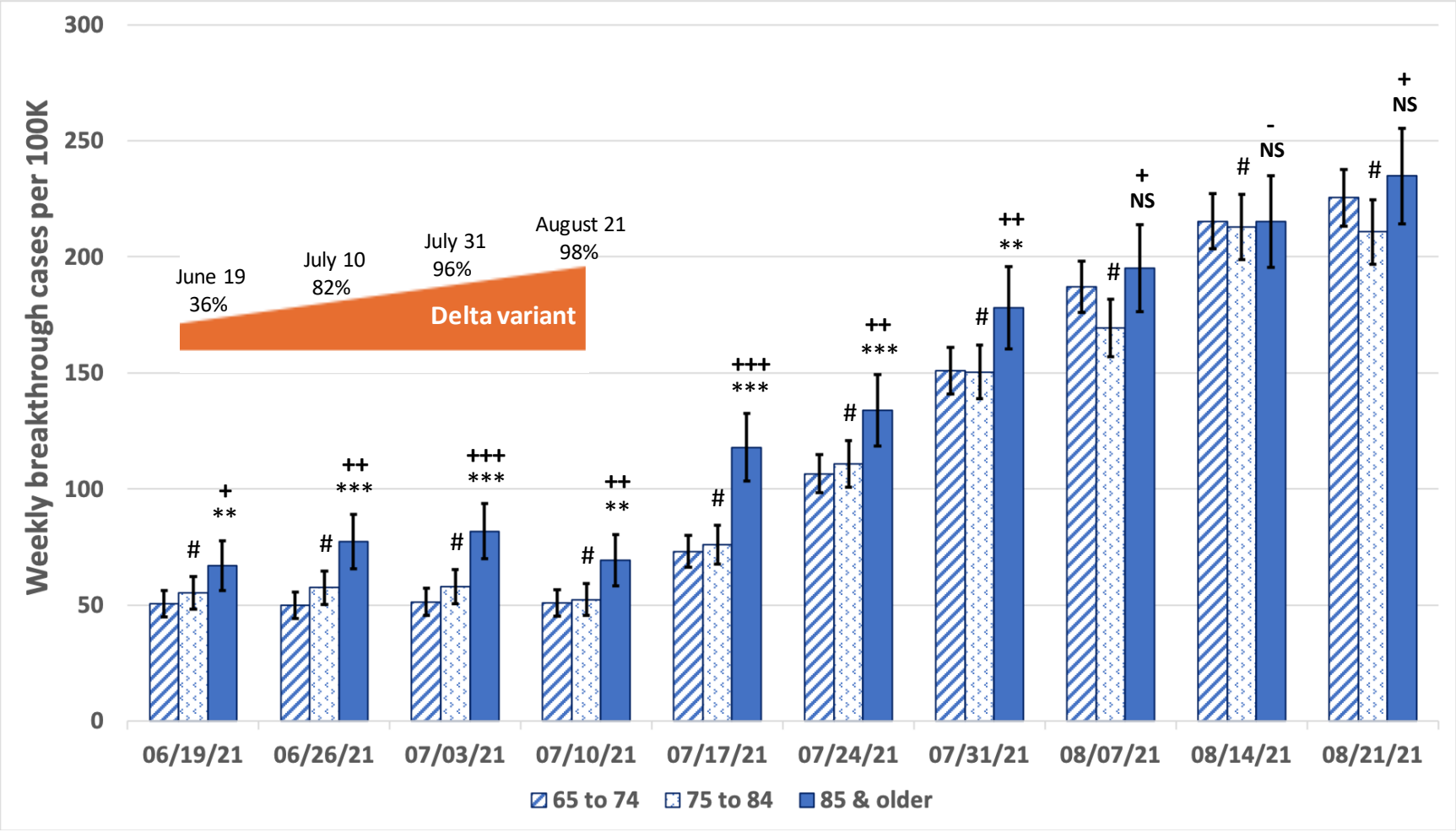
Age Distribution of Vaccinated Groups in the 65 Years and Older Cohort

Vaccinee Group		
5-6 months post vaccination		
age groups	65 to 74	24%
	75 to 84	33%
	85 & older	43%
3-4 months post vaccination		
age groups	65 to 74	51%
	75 to 84	35%
	85 & older	14%

- **Could higher proportion of 85 years and older members in first vaccinated group explain reduced VE?**

Project Salus

Does Age Affect Vaccine Effectiveness Against Breakthrough Infections in the 65 Years and Older Cohort?



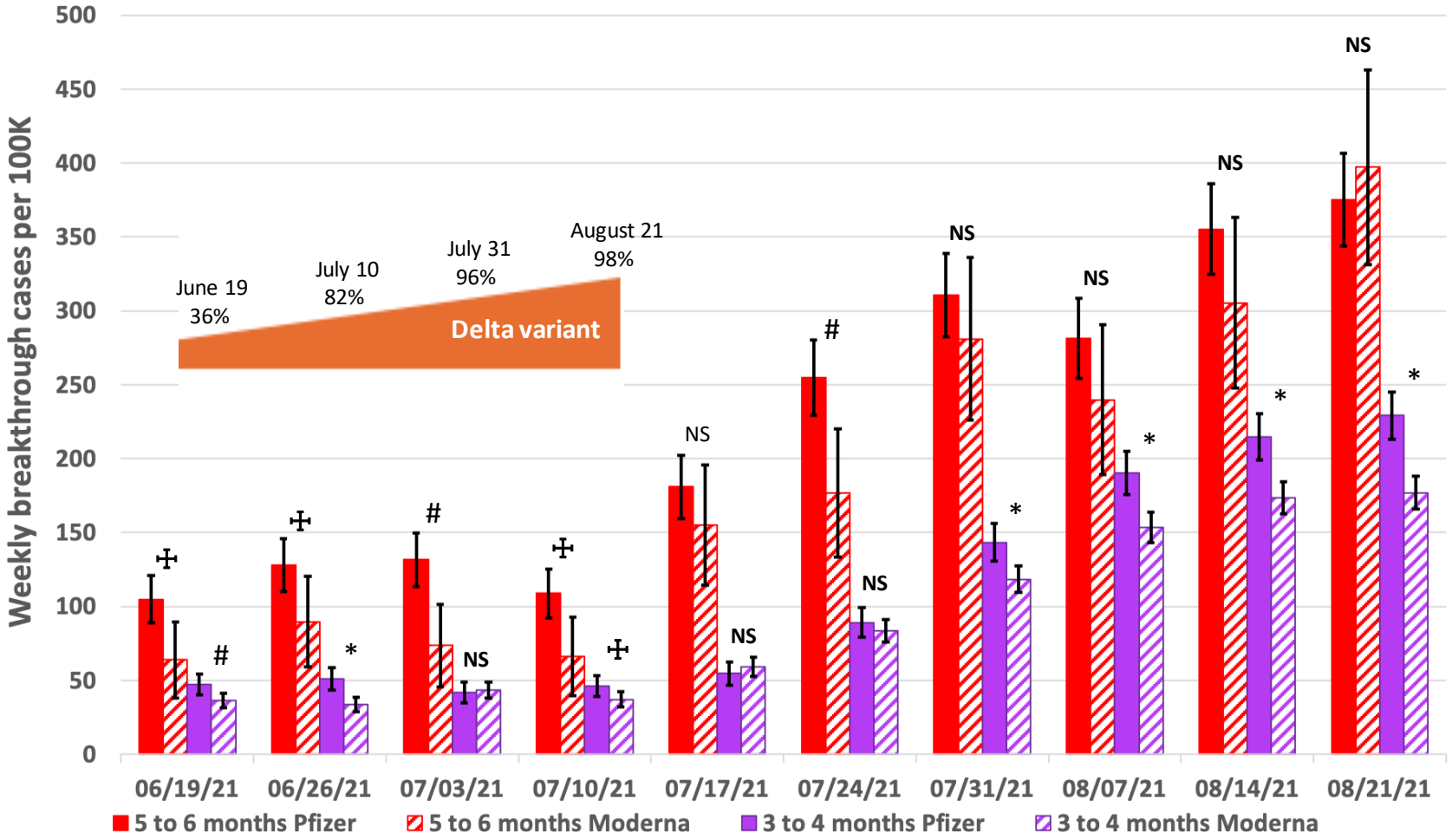
- **Age has a minor contribution to the reduced vaccine protection** seen in the group vaccinated 5-6 months ago

95% CI

	Over 85 > 75 to 84	Over 85 > 65 to 74	75 to 84 > 65 to 74
P < 0.001	+++	***	none
P < 0.01	++	**	none
P < 0.05	+	none	none
P > 0.05	-	NS	#

Project Salus

Are There Differences in Waning Effectiveness Between Pfizer-BioNTech and Moderna Vaccines in the 65 Years and Older Cohort ?



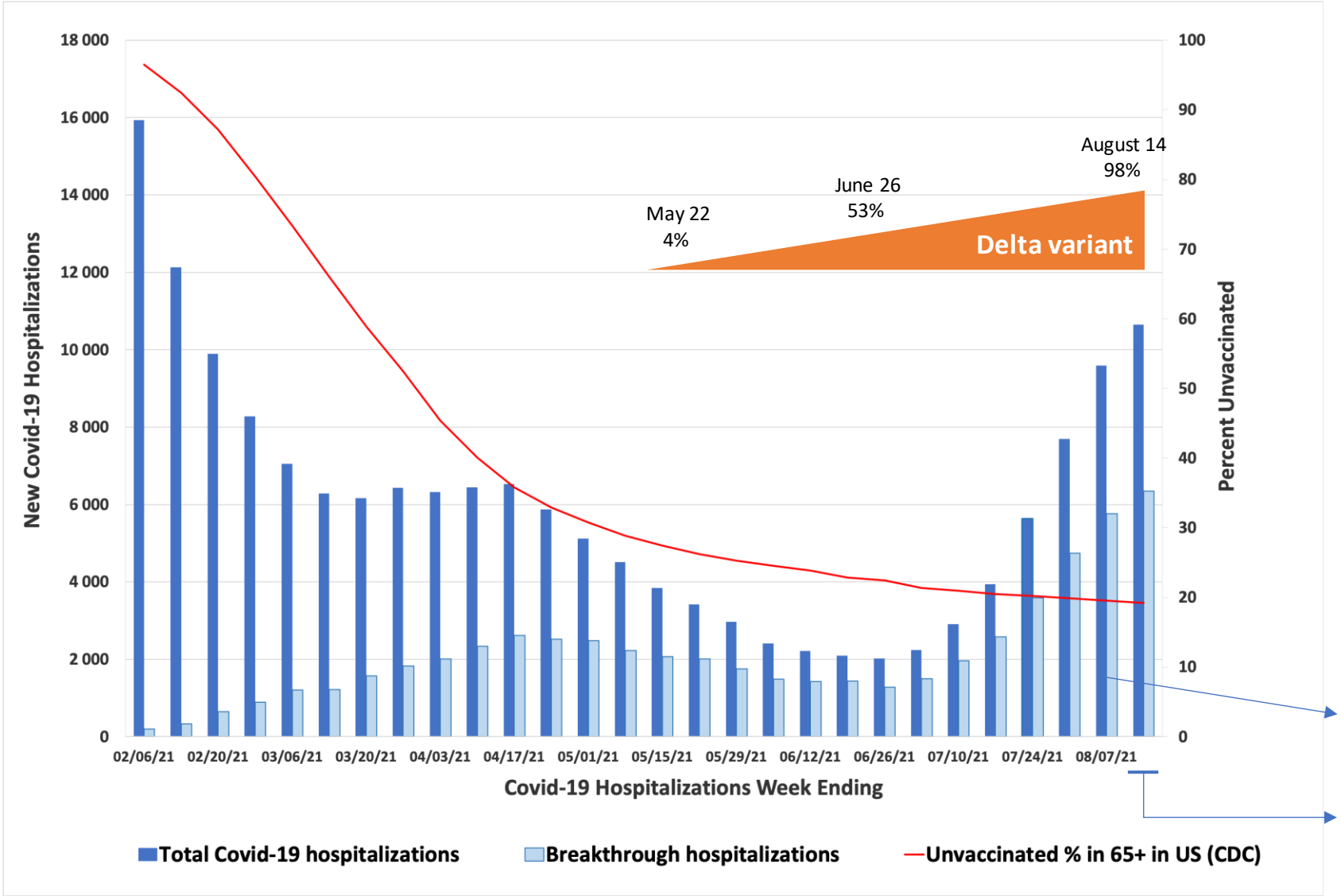
- **Waning immunity are seen with both Pfizer-BioNTech and Moderna** vaccines during Delta phase of the pandemic
- **Moderna vaccine offers better protection than Pfizer vaccine** for individuals vaccinated 4 months prior for weeks ending after July 31

95% CI

Breakthrough infection rate Pfizer > Moderna	
P < 0.001	*
P < 0.01	#
P < 0.05	✢
P > 0.05	NS

Project Salus

Total & Breakthrough Hospitalizations in the 65 Years and Older Cohort



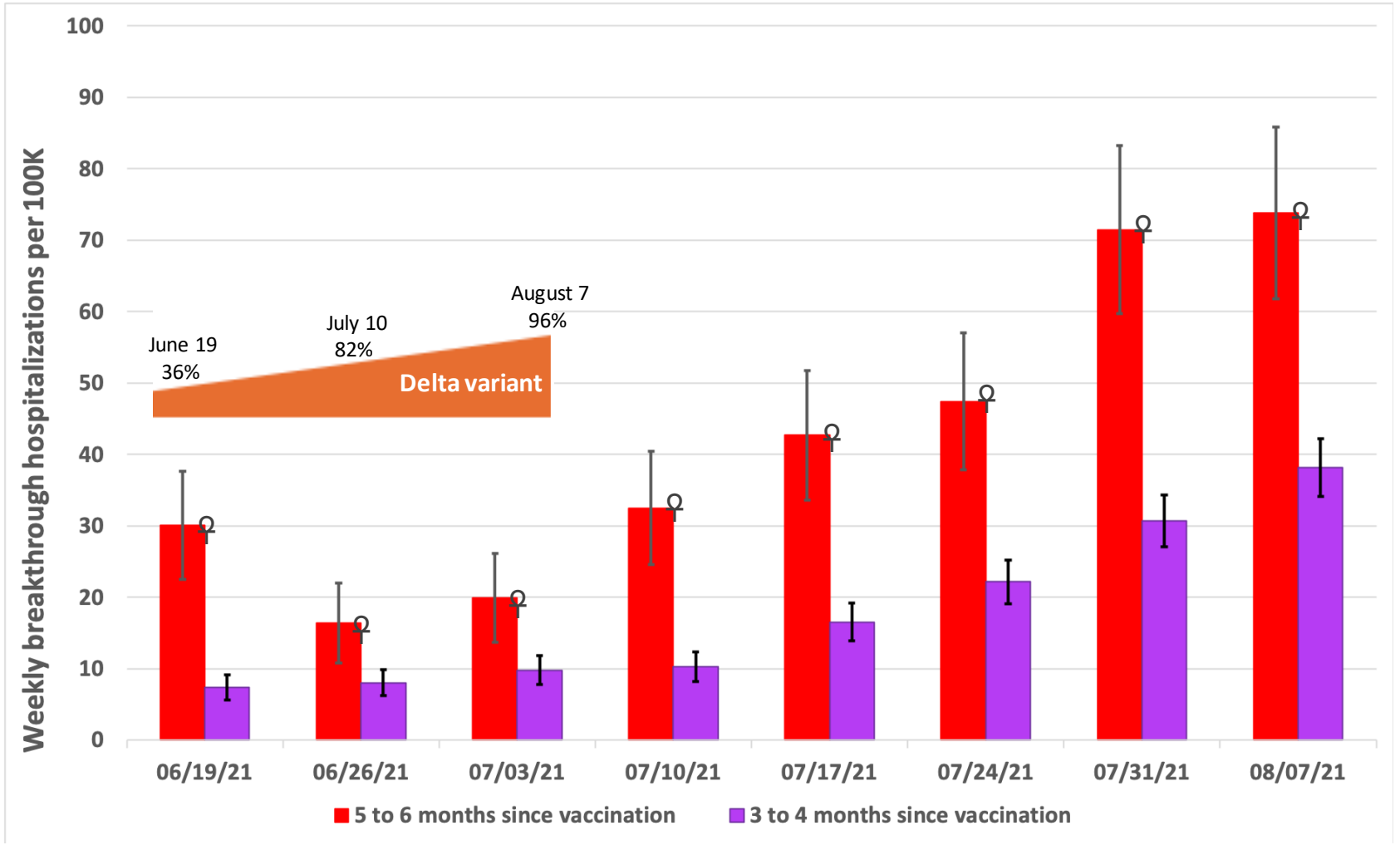
- **As Delta variant surged to over 50% in June, COVID-19 hospitalizations more than doubled, reversing the prior trend of decreasing hospitalizations since April**
- In this 80% vaccinated 65+ population, an estimated **60% of COVID-19 hospitalizations occurred in fully vaccinated individuals in the week ending August 7th**

60% of COVID-19 hospitalizations are in vaccinated individuals

On 08/14/21, data incomplete due to lag in claims processing

Project Salus

Is Vaccine Protection Against Breakthrough Hospitalization Waning Over Time in the 65 Years and Older Cohort?



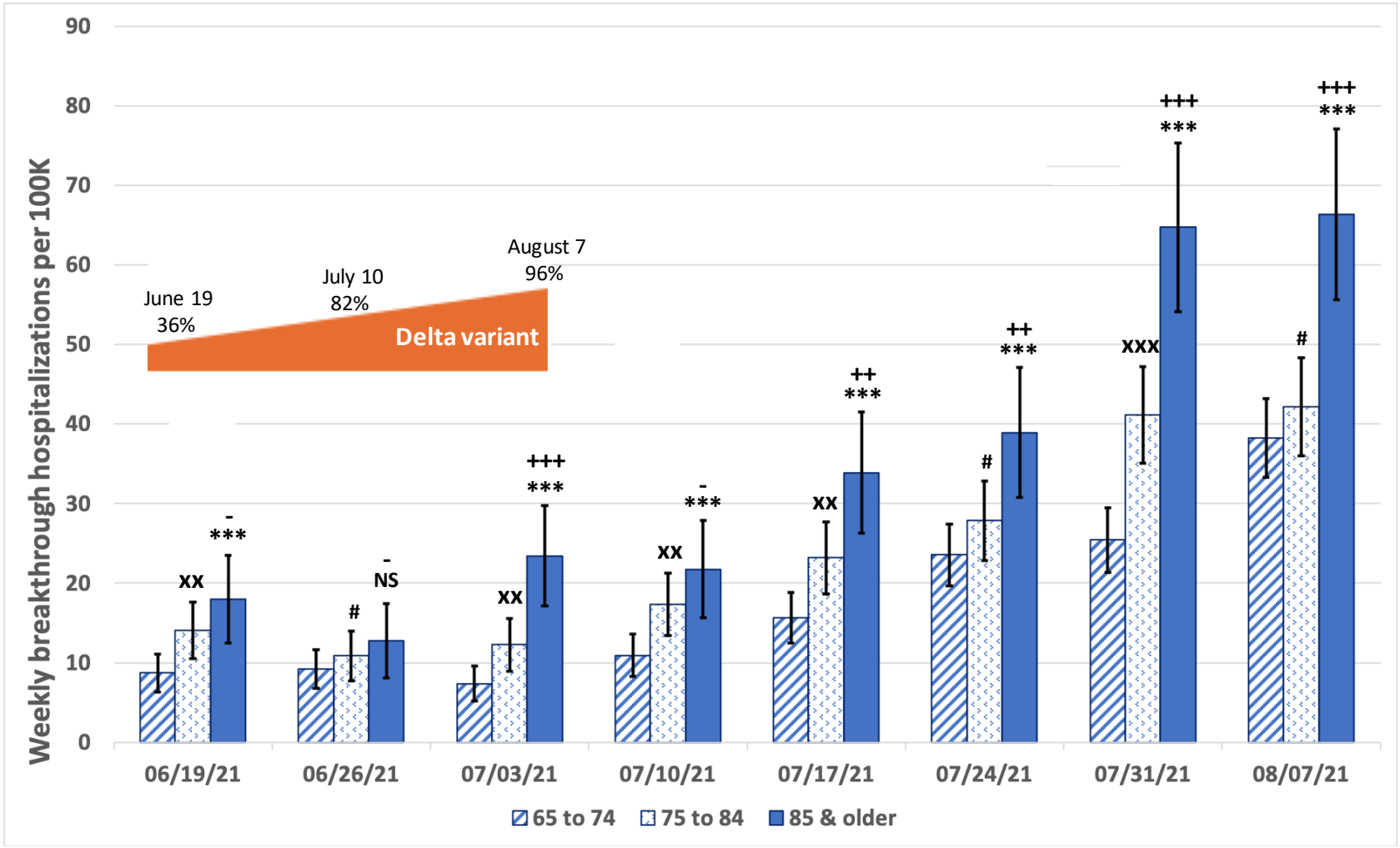
- **VE against breakthrough hospitalization is significantly lower 5-6 months post vaccination than 3-4 months post vaccination**

95% CI

♀ Breakthrough hospitalization rate for 5-6 months since vaccination > 3-4 months
P < 0.001

Project Salus

Are there Age Differences in Vaccine Protection Against Breakthrough Hospitalizations in the 65 Years and Older Cohort?



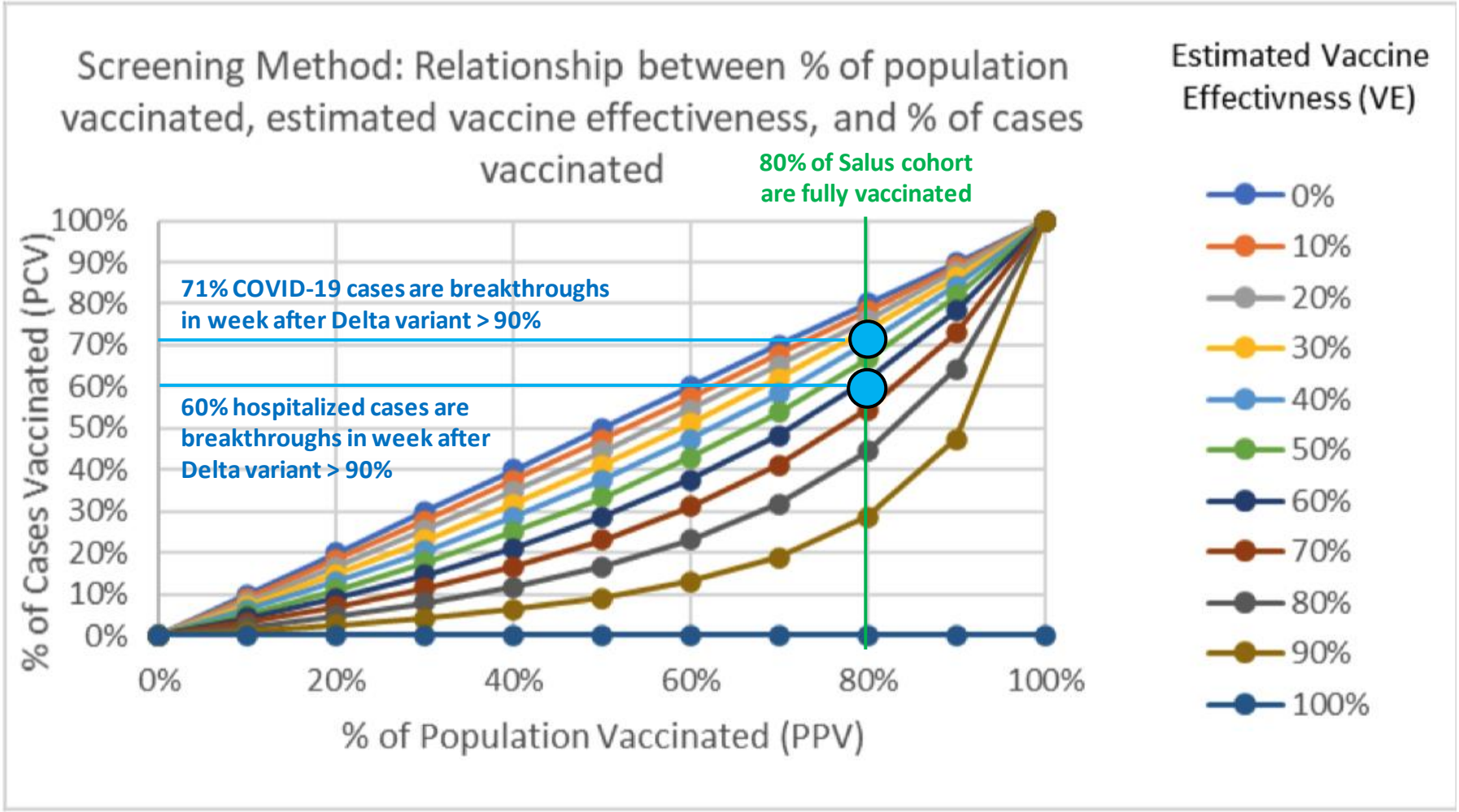
- **Older age associated with increased breakthrough hospitalization rates**

95% CI

	Over 85 > 75 to 84	Over 85 > 65 to 74	75 to 84 > 65 to 74
P < 0.001	+++	***	xxx
P < 0.01	++	none	xx
P < 0.05	+	none	x
P > 0.05	-	NS	#

Project Salus

What is the Vaccine Effectiveness Against the Delta Variant in the Salus Cohort? – Using the CDC Screening Approach



- **41% calculated VE against infection**
- **62% calculated VE against hospitalization**

VE Screening method

VE = 1- [(PCV/(1-PCV))((1-PPV)/PPV)]

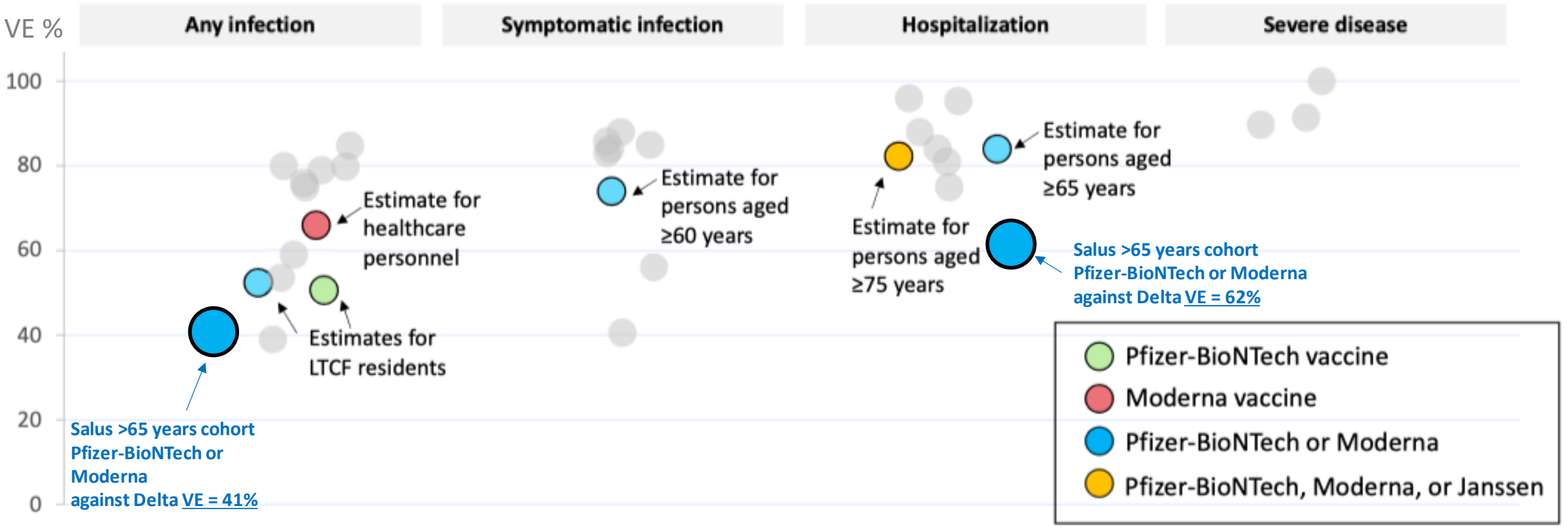
PCV = proportion cases vaccinated

PPV = proportion population vaccinated

Graphic adapted from CDC Presentation July 30, 2021
Improving communication around vaccine breakthrough and vaccine effectiveness

Project Salus

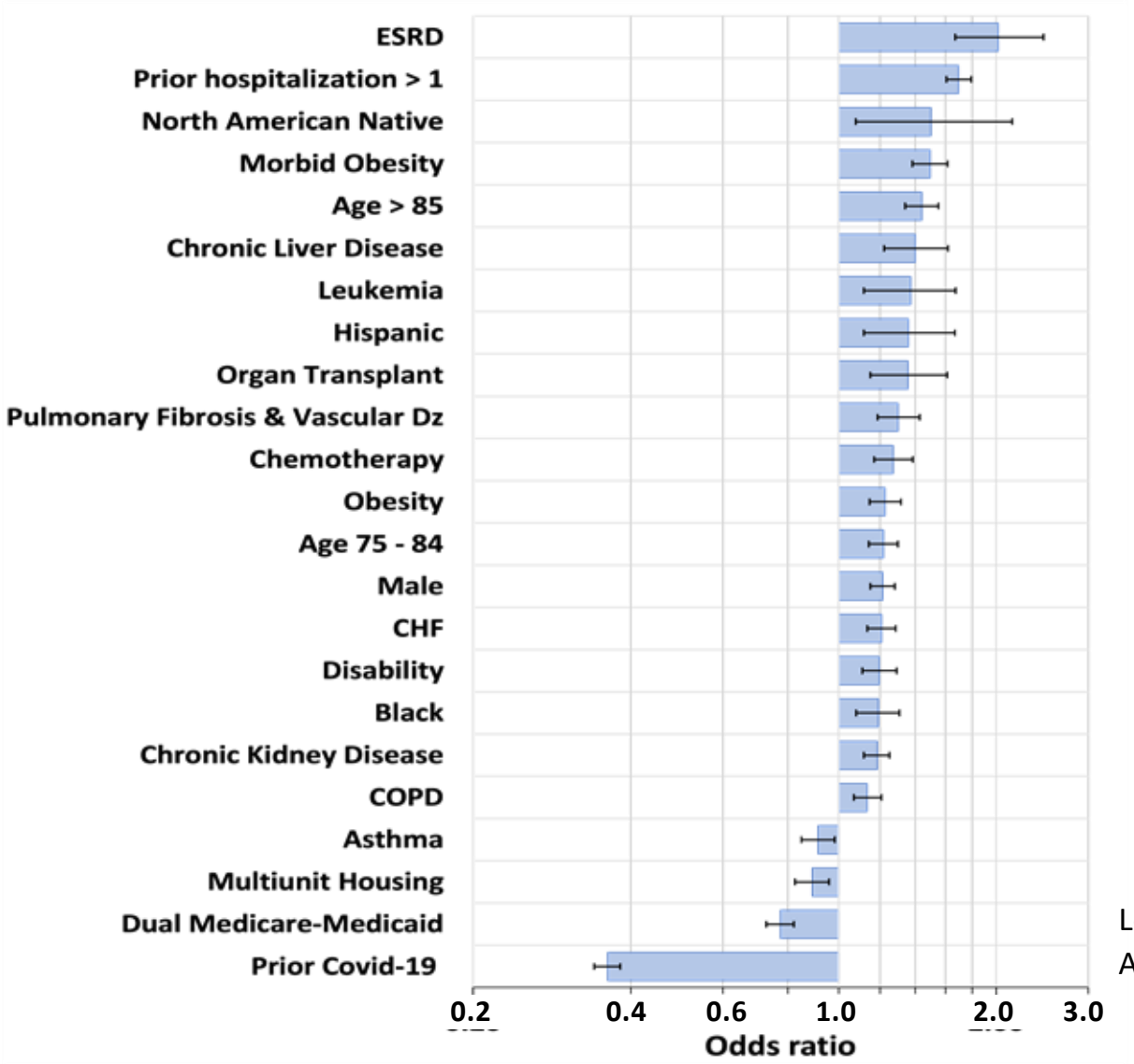
How Does mRNA Vaccine Effectiveness in 65+ Salus Cohort with 5.6M Vaccinees Compared to Published Estimates?



- **VE of both mRNA vaccines in this 65+ cohort is lower than previously reported in smaller study sizes for both COVID-19 infection and hospitalization**
- **VE for mRNA vaccines is higher against hospitalization than against infection**

Graphic adapted from CDC Presentation ACIP Meeting August 30, 2021, Oliver, S. Framework for Booster Doses of COVID-19 Vaccines

Risk Model for Breakthrough Hospitalization



- **Risk of breakthrough hospitalization increases with time elapsed since mRNA vaccination with odds ratio increasing to 2.5 at 6 months post vaccination**
- **Prior COVID-19 infection has a major protective effect against breakthrough hospitalization**
- There is a step up in risk in the 75-84 and again in the over 85 age categories compared to the 65-74 category
- Risk model can be used to stratify the over 65 population to best select those in most need of booster vaccine dose

Logistic Regression Model performance:
AUROC 0.73, balanced accuracy 0.67

Pfizer – Cumulative Analysis of Post-Authorization Adverse Event Reports

This Pfizer analysis discusses post emergency authorization adverse event reports and is dated April 30, 2021. The dates covered in the analysis only cover through February 28, 2021. This means the adverse events included only cover about 2.5 months of general availability and only Pfizer products. This document shows:

- As of Feb. 28, 2021, there were a total of 42,086 case reports containing 158,893 events with 13,739 of the cases coming from the United States;
- Of these cases there had already been 1,223 fatalities and 9,400 outcomes were unknown. Compare this with ANY other consumer product on the market and/or the Swine Flu vaccine which was pulled from market after 26 fatalities. As a comparative, we recently saw a recall of the Chevy Volt due to the potential for a battery fire – no deaths were reported to our knowledge;
- Page 16 discusses the Adverse Events of Special Interest (AESIs) stating:

  > "The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).
  >
  > The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general."

- It should be noted that the "vaccines" were intended to prevent severe COVID-19 and so any AESIs occurring after "vaccination" should be associated with the injections rather than COVID-19 unless we assume the "vaccines" to be ineffective;
- Pages 16-24 share the number of cases of many of the AESIs. This should not be viewed to be a complete list as the numbers would likely increase over time for some slower developing diseases;
- Pages 30-38 of the document provide the very long list of potential AESIs. Given that these injections were only authorized – as opposed to approved – and that they were a new category of drugs (gene therapies), why were these not listed as potential side effects?

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

090177e196ea1800\Approved\Approved On: 30-Apr-2021 09:26 (GMT)

Report Prepared by:

Worldwide Safety

Pfizer

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FDA-CBER-2021-5683-0000054

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APPENDICES

APPENDIX 1 LIST OF ADVERSE EVENTS OF SPECIAL INTEREST....30

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

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FDA-CBER-2021-5683-0000057

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

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proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

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Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

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Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

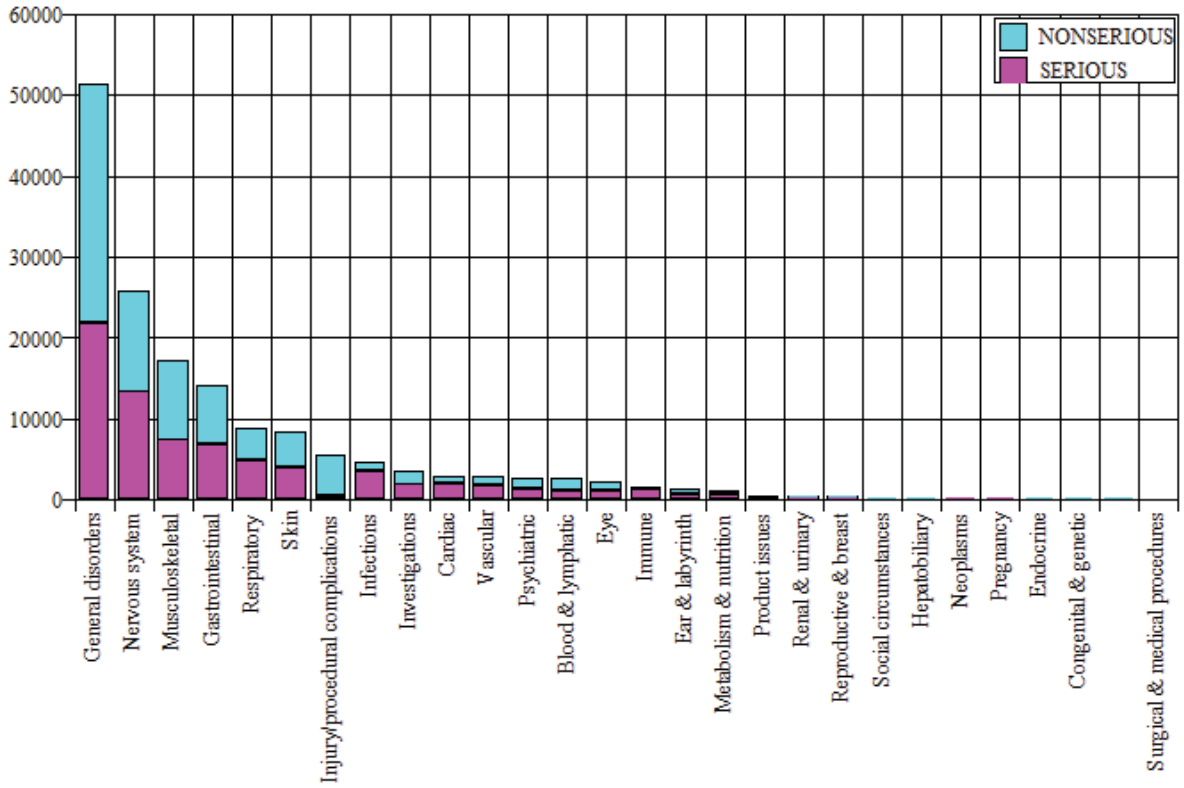


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

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Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

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Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

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Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

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3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

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3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

  Medication error case outcomes:

  - Fatal (7)[3],
  - Recovered/recovering (354, of which 4 are serious),
  - Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

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- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

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Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

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5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

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APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

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coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

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tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

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fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

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infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

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increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

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neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

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neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

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Vaccines and Related Biological Products Advisory Committee (VRBPAC) Presentation

Attached is a presentation from the FDA's VRBPAC. This presentation was dated October 22, 2020 and shows:

- The FDA has been monitoring the safety and efficacy of the "vaccines" through a number of systems that have been hidden from the public and, to our knowledge, elected officials;
- The monitoring program included:
    - VAERS;
    - FDA BEST – which includes partners such as Acumen, IBM, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, and "Academic organizations";
    - FDA-CMS partnership;
    - Sentinel;
    - Veterans Affairs;
    - National Institutes of Health;
    - DoD;
    - Indian Health Services; and
    - Numerous data sources listed on slides 12-13;
- According to slide 16 the FDA planned to use CMS data for "near real-time" surveillance;
- Pursuant to 21 U.S. Code § 360bbb–3 the Secretary must, to the extent necessary to protect public health, ensure that both health care professional and those who may receive the product are made aware "of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown."
    - People must also be made aware of the fact that these are experimental and "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."
- Slide 17 lists a working list of possible adverse event outcomes. This list is not part of the informed consent packets shared with the public nor has the public been made aware of the real potential for these outcomes. Instead we have heard a constant drumbeat of "safe and effective" along with the misleading statements about side effects including a bump, soreness, and potentially feeling sick for a few days.;
- Slide 20 notes that "there may be limited information available at licensure on level and duration of effectiveness." If that is the case why was the license granted in light of the serious potential side effects?; and
- Slide 25 claims that there are "weekly meetings" and near real time surveillance with these agencies. Why is none of this data available?

Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

U.S. FOOD & DRUG ADMINISTRATION

CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Steve Anderson, PhD, MPP
Director, Office of Biostatistics & Epidemiology, CBER

VRBPAC Meeting
October 22, 2020

FDA Vaccine Surveillance: Pre-licensure Pharmacovigilance Planning

"Safety throughout the lifecycle" approach for vaccines (pre- and post-licensure):

- Manufacturer submits pharmacovigilance plans (PVP) of proposed post-licensure surveillance activities
  - Submitted for BLA and for EUA
  - Post-licensure commitment (PMC) – studies, registries for general safety concern
  - Post-licensure requirement (PMR) – clinical study, epidemiological study, registries, etc. to verify a specific safety signal
  - Routine pharmacovigilance – Passive surveillance (VAERS), review of safety literature, available studies, etc.

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**
   - Vaccine Adverse Event Reporting System (VAERS)
     - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**
   - FDA BEST
   - FDA-CMS partnership

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**
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   - FDA BEST
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VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

CDC + FDA

http://vaers.hhs.gov



VAERS – FDA CBER Efforts

- CDC presentation covered VAERS so will provide summary of FDA efforts
- **FDA and CDC have weekly and bi-weekly coordination meetings** on VAERS and Pharmacovigilance activities between CBER OBE and OBE Division of Epidemiology (DE) and CDC Immunization Safety Office
- **CBER DE Physicians will be reviewing the serious adverse event reports** from VAERS for COVID-19 vaccines – review of individual reports, death reports, conduct aggregate analyses, case-series, etc.
- **FDA will utilize statistical data-mining methods** to detect disproportional reporting of specific vaccine-adverse event combinations to identify AEs that are more frequently reported

FDA Vaccine Surveillance Programs: Post-Licensure

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   - Vaccine Adverse Event Reporting System (VAERS)
     - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**
   - **FDA BEST**
   - **FDA-CMS partnership**

FDA Vaccine– Legislative Authorization Active Surveillance

Legislation, mandates and Current Surveillance

FDA Amendments Act of 2007:

- Directed FDA to develop an active risk identification and analysis system – such as Sentinel, and later BEST, and others and covers ≥100 million persons

Prescription Drug User Fee Act VI (2017)

- Discussion between FDA and Industry on Priority Areas - Renewed every 5 yrs
- Provides resources/funding for Sentinel, BEST, real-world evidence, etc

COVID-19 Vaccine Monitoring Data Considerations

- **Rapid data access** for near real time surveillance
- **Large databases of tens of millions of patients** for evaluating vaccine rare serious adverse events
- **Data representing integrated care spectrum** – outpatient, physician, inpatient, etc.
- **High quality data** to assess and confirm potential adverse events or safety concerns for COVID-19 vaccines
- **Data with significant clinical detail** or medical chart access

1. FDA Biologics Effectiveness and Safety (BEST) System

- Several partners – Acumen, IBM Watson, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, Academic organizations
- Represents variety of healthcare settings – inpatient, emergency department, outpatient, etc.

BEST Initiative Expansion

CLAIMS Data Sources

Data Sources	Type	Patients (millions)
MarketScan	Claims	254
Blue Health Intelligence	Claims	33.6
Optum	Claims	70
HealthCore	Claims	56
Healthagen	Claims	26
OneFlorida Clinical Research Consortium (Medicaid)	Claims	6.7

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Data lag: 1-12 months depending on data source

BEST Initiative Expansion
EHR Data Sources

Data Sources	Type	Patients (millions)
MedStar Health	EHR	6
IBM Explorys	EHR	90
Regenstrief Institute	Claims and EHR	20.2
Columbia University	EHR	6.6
University of Colorado	EHR	17
University of California San Francisco	EHR	3.2
PEDSnet Clinical Research Consortium	EHR	6.2
Optum EHR	EHR	105
OneFlorida Clinical Research Consortium	EHR	5.6
OneFlorida Clinical Research Consortium	Linked EHR-Claims	1.5
MarketScan Explorys Claims-EHR (CED)	Linked EHR-Claims	5.5
Optum	Linked EHR-Claims	50

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Data lag: 1-2 weeks to 4 months depending on data source

2. CMS (Center for Medicare & Medicaid Services)

- **Federal Partners**
  - Ongoing FDA-CMS partnership on vaccine safety since 2002
  - Data cover very large population of approximately 55 million elderly US beneficiaries ≥65yrs of age
  - >92% of US elderly use Medicare so database represents the elderly population and not a sample
  - Represents variety of healthcare settings – inpatient, outpatient, etc.
  - Consists of claims data with access to medical charts

Limitations of Data Systems

- Not all claims and EHR data systems can be used to address a vaccine safety or effectiveness regulatory question

- Each data system has its limitations
  - Populations, healthcare settings, clinical detail, necessary parameters, data lag, exposures and outcomes that are captured

FDA COVID-19 vaccine safety surveillance planning

“Near real-time surveillance” or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using CMS data for COVID-19 vaccine RCA – near real time with efforts

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FDA Safety Surveillance of COVID-19 Vaccines : DRAFT Working list of possible adverse event outcomes ***Subject to change***

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

FDA Experience with Near Real Time Surveillance / RCA

FDA and CMS - RCA

- Conduct "near real-time" surveillance for annual influenza vaccine and Guillain-Barre Syndrome(GBS) since 2007
- Support confirmation of CDC rapid-cycle analyses of safety for seasonal influenza vaccine, Shingrix, and others

FDA Sentinel – Rapid Surveillance

- Near real-time, rapid surveillance in 2017-2018 seasonal influenza vaccine – evaluation of 6 health outcomes of interest

FDA COVID-19 vaccine safety surveillance Plans

- **Epidemiological analyses**
  - Need capability to resolve potential safety signals identified from near real-time surveillance, TreeScan and other sources
  - Rapid queries and small epidemiological studies
  - Larger self-controlled, cohort, comprehensive protocol-based studies

COVID-19 Vaccine Effectiveness Surveillance Plans

- COVID-19 vaccine(s) – there may be limited information available at licensure on level and duration of effectiveness
- Manufacturers may conduct certain COVID-19 vaccine effectiveness post-licensure studies
- FDA may conduct COVID-19 vaccine effectiveness studies
  - General effectiveness studies – including subpopulations of interest
  - Duration of protection studies
  - Others
- FDA coordinating COVID-19 Vaccine Effectiveness efforts with the CDC NCIRD through monthly, bi-monthly meetings

FDA-CMS-CDC Vaccine Effectiveness Experience

- Extensive experience with the data and methods needed to conduct vaccine effectiveness studies
- Produced several vaccine effectiveness and relative vaccine effectiveness studies for influenza and zoster vaccines
- Conducted duration of effectiveness analysis of Zostavax vaccine

FDA-CMS Vaccine Effectiveness Experience

- Actively studying risk factors for COVID-19 and preparing to study safety and effectiveness of vaccines and biologics therapies
- More than 30 publications since 2012
- Results included in Congressional testimony

CBER COVID-19 Vaccine Monitoring Transparency Considerations

- Master Protocols for Safety and Effectiveness outcomes
- Posting of draft protocols for public comment
- Posting of final protocols and final study reports on the BESTinitiative.org website

US Government-wide Efforts
COVID-19 Vaccine Monitoring

Large US Government Effort

FDA Coordinating its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies:

- Centers for Disease Control (CDC)
- Centers for Medicare& Medicaid Services (CMS)
- Veterans Administration (VA)
- National Institutes of Health
- Department of Defense
- Indian Health Services

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US Government-wide Efforts
COVID-19 Vaccine Monitoring (2)

Large US Government Effort

- Weekly meetings between FDA and CDC, regular meetings with VA and CMS
- Planned sharing of protocols, discussion safety and effectiveness outcomes of interest
- Coordinated planning and conduct of surveillance activities such as near real time surveillance/ RCA between FDA, CDC, CMS, VA, and DOD 96

Acknowledgments

- Richard Forshee
- Azadeh Shoaibi
- Hui-Lee Wong
- CBER Surveillance Team
- Manette Niu
- CBER OBE Colleagues
- CDC Colleagues
- CMS Colleagues
- VA Colleagues
- FDA Partners: Acumen, IBM Watson – and new partners in FY2021

U.S. FOOD & DRUG ADMINISTRATION

Thank you!

Questions?

Senior Leaders Brief Document

Attached is a document from the DoD related to Project Salus. This document shows:

- This document is a briefing to senior leaders of the military/DoD and dated January 12, 2022 – it is unclassified;
- President Biden and the DoD have said that any military personnel not fully "vaccinated" against COVID-19 will be removed from the service;
- Slide 6 of the document shows:
    - The total number of active duty and reserve service members numbers 2,129,756;
    - 24.4% or 519,835 service members are not fully "vaccinated" or of unknown status;
    - A full 1.3 million or 71.4% of civilian and contractors supporting our military are also not fully "vaccinated";
- Slide 13 shows that the military is lying or covering up the fact that our service members are not getting the licensed "vaccines";
    - It notes that there are supply shortages for the Pfizer-BioNTech injections and that this shortage may impact the "vaccine" mandate;
    - It goes on to provide an alternative solution to deal with the shortage stating, "Provide "Comirnaty"-labeled vaccine";
    - It is plainly illegal to mandate an experimental injection such as this.

Given the international security issues facing our nation and the world, is it wise to fire 24.4% of our military and 71.4% of our civilian and contractor support force?

Senior Leaders Brief
COVID-19

12 JAN 2022

Controlled by: AD-CS/CCOS
CUI Category(ies): **OPSEC**
Limited Dissemination Control: FEDCON
POC: CDR Karen Alexander, 703-681-4600

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Agenda

Briefers

- ❑ OPS
- ❑ EUCOM
- ❑ Operation Allies Welcome
- ❑ DOD Vaccine Operations Update
- ❑ DOD Vaccine Doses On Hand
- ❑ AFHSD
- ❑ IHD
- ❑ Market Operations
- ❑ CLMS
- ❑ MEDLOG
- ❑ ASBP

By Exception

- ❑ SERVICES (Army, Marines, Navy, Air Force)
- ❑ DENTAL
- ❑ ADMIN & PERSONNEL J-1
- ❑ LESSONS LEARNED
- ❑ PHARMACY OPS

Service Components Comments
ADs Guidance

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Operations

5 JAN 2021– 12 JAN 2022

OTHER SIGNIFICANT EVENTS

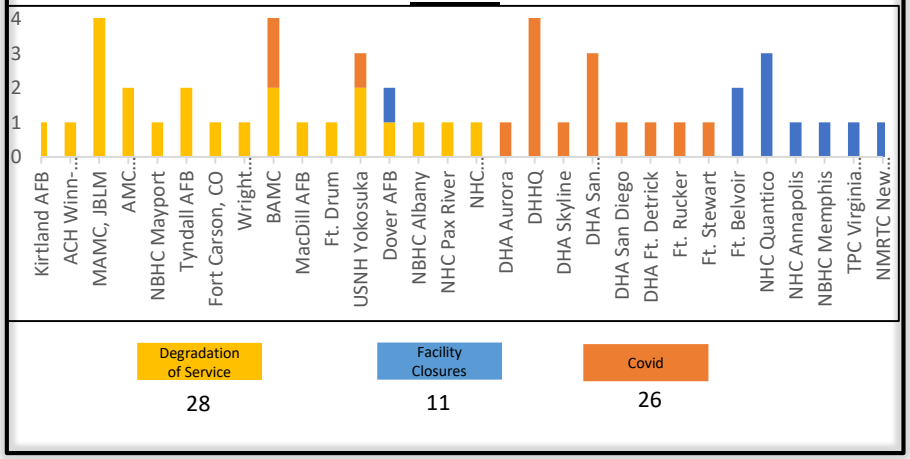
Deployment Roll-Up:

- PTDO ISO COVID-19 OMICRON MEDICAL RESPONSE
  - ESTABLISHING ADDITIONAL MEDICAL RESPONSE ON 96 HOUR PTDO AND EXTENSION OF CURRENT MRTS TO 31MAR22
  -
- CDRUSNORTHCOM CAPABILITY REQUREMENT MESSAGE 045 (FY22)
  - 1x MMT Extend deployment 6FEB to 14FEB Farmington, NM

- PREPARE TO DEPLOY ORDERS ISO COVID-19 OMICRON MEDICAL RESPONSE TEAM//
  - PTDO for 1 LMT ready to mobilize on 15 JAN 22 EOM 31 Mar 22
  - PTDO for 1 LMT and 1 MMT with 96 hours of notice to move and ready to mobilize on 30 JAN 22 EOM 31 Mar 22

- CDRUSNORTHCOM IMMEDIATE RFF S220020 ISO DSCA COVID-19 RESONSE
  - IMMEDIATE RFF. RFF REFLECTS THE CONTENTS OF THE 30 DEC 21 SDOB. SOURCING CONFIRMED BY FORCE PROVIDERS. 1000 DoD PERSONNEL.

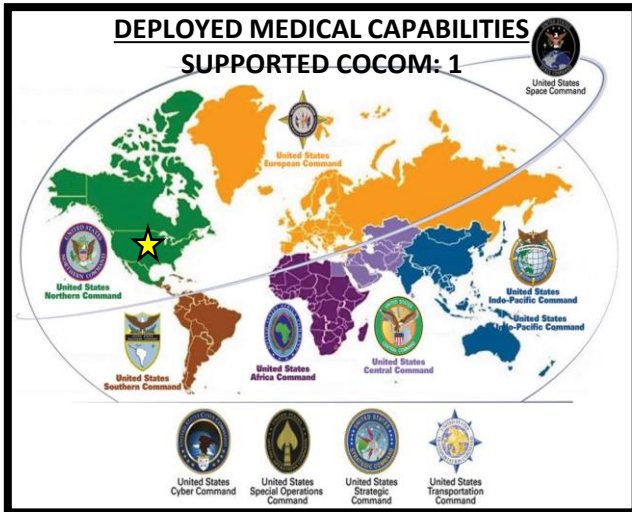
DCIRs



Global Force Management Weekly Rollup

DEPLOYED MEDICAL CAPABILITIES

SUPPORTED COCOM: 1



Task Support Rollup

Geographic COCOMs

- AFRICOM: 0
- CENTCOM: 0
- EUCOM: 0
- INDOPACOM: 0
- NORTHCOM: 1
- SOUTHCOM: 0
- SPACECOM: 0

Functional COCOMs

- CYBERCOM: 0
- SOCOM: 0
- STRATCOM: 0
- TRANSCOM: 0

ORDERS/DIRECTIVES: 12 TOTAL

- CRMs: 3
- EXORD: 0
- SDOB: 0
- FRAGOs: 2
- RFS: 3
- MODS: 2
- OPORD: 0
- IAS: 0
- PTDO: 2
- RFF: 0
- GEN ADMIN: 0
- DEPORD: 0

PATIENT MOVEMENTS

- Mission ID JLWGF200A010:
  - Depart Ramstein 14 JAN 1740
  - Arrive to Andrews AFB 15 JAN 0310.
  - 19 US patients, and 4 attendants.

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EUCOM

OPERATION ALLIES WELCOME MEDCOP

As of 12 JAN 2022 **USEUCOM OPERATION ALLIES WELCOME MEDCOP**



Current Population	INFP	Family members	AMCITs	Medically Fragile
CBS: **211**	82	129	14	8
LRMC: 0	0	0	0	0

Traveler Care	Last 24	Current/ Ongoing	# Complete	ISOS Docs Received
CBS 557 encounters	11	N/A	1066	N/A
HN (Kosovo) Inpatient	N/A	0	2	1 (1 was AMCIT)
HN (Kosovo)	N/A	0	5	30

Battle Rhythm	Reporting
1200L NIPR SG Synch Mon/Thu	0700L Daily MEDCOP Data: Pt encounters, PMRs, Vax Status
1500L EUCOM OAW/WG Thu	0700L Daily HN care & PMR
1000L DHA/ISOS/CBS synch Thu	Info sharing only

D&I	Last 24	Total
Measles	-	0
Varicella	-	0
Mumps	-	0
Rubella	-	0
COVID-19	-	0
Pertussis	-	0
Tuberculosis	-	0
Diphtheria	-	0
Hepatitis A	-	0
GI - Infectious	-	0
Polio	-	0
Typhoid Fever	-	0
Malaria	-	0
Cholera	-	0
Meningococcal	-	0
Total:	-	**0**

Vaccination	# Complete/ Eligible	# Declined
MMR	206/206	0
Varicella	205/205	0
COVID-19	134/187	0
Influenza	202/210	5
Polio	109/109	0
Hep B	208/211	0
DTaP	35/35	0
HiB	31/31	0
MenACV	46/47	0
PCV	32/32	0
TD	174/176	0
Rotavirus	3/3	0
Hep A	58/77	0

*** DoS Panel Physicians anticipated to commence screenings (off site) on/about 20 JAN.**

CUI

POC: LCDR Robert Bartholomew robert.a.bartholomew16.mil@mail.mil, DSN: 324-412-4306

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OAW

Operation Allies Welcome Daily Report - as of Tuesday, January 11

Lily Pads

Population & Capacity



2,167 evacuees at Lily Pads

12% capacity | Max is 18,000

15,833 beds remaining

	Population	Capacity	UCs
Abu Dhabi, UAE	1,913	14%	7
Doha, Qatar	254	6%	2

Unaccompanied Children

9 Known unaccompanied children at lily pads

0	227	203
In CBP custody	In ORR care	Discharged from ORR

In addition, ORR has kept 1,031 children together with their relatives and caregivers by conducting screening and case management at airports and safe havens.

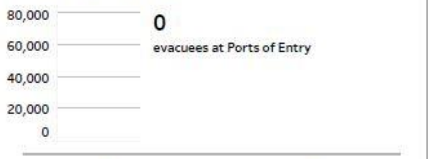
Total Population



All locations	86,762	
Lily Pads	2,167	2.5%
Ports of Entry	0	0.0%
Safe havens	17,272	19.9%
Departures	67,323	77.6%

Ports of Entry

Population & Capacity



0 evacuees at Ports of Entry

1	0
Arrived at Ports of Entry yesterday	Departed Ports of Entry yesterday

	7-day total	7-day avg.
Arrivals	1	0
Departures	0	0

Total population over 7 days

Total U.S. Arrivals

All arrivals	84,595	
U.S. Citizens	4,639	5%
Lawful permanent residents	3,597	4%
Afghans with U.S. visas	3,415	4%
Afghan parolees (including SIV applicants)	72,625	86%
Other third country nationals or unknown	319	0%

Demographics	Adults	Minors
Male	28,322 (33%)	19,498 (23%)
Female	18,308 (22%)	17,310 (20%)

Safe Havens

Population & Capacity



17,272 evacuees at Safe Havens

71% capacity | Max is 24,206

6,934 beds remaining

0	738
Arrived at Safe Havens yesterday	Departed Safe Havens yesterday (preliminary count)

	7-day total	7-day avg.
Arrivals	6	1
Departures	4,014	573

Total population over 7 days



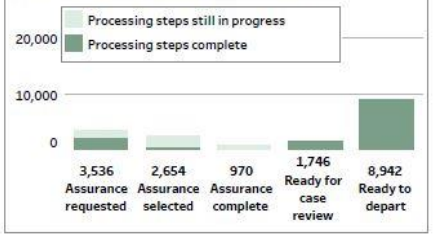
Medically Fragile and Third Trimester Pregnancies

Current cases	Change in past day	Change in past 7 days	All-time
233	16	87	2,342

Processing steps (All Locations)

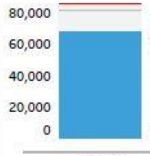
	Current population with step complete		Completed yesterday	Completed in past 7 days
Medicals complete	16,538	92%	TBD	TBD
Work authorization submitted	17,506	97%	TBD	TBD

Assurance & Resettlement (All Locations)



Departures

All Departures



67,323 total departures from POE and Safe Havens

80% complete | Total evacuees in U.S. is 84,595

17,272 persons awaiting departure

693	45
Departures from Safe Havens through Resettlement Agencies yesterday (preliminary count)	Independent Departures from Safe Havens yesterday (preliminary count)

	7-day total	7-day avg.
Safe Haven R.A. Departures	3,763	538
Safe Haven Ind. Departures	250	36

Safe Haven departures past 7 days



	Past day	Past 7 days	All-time
Departures through Resettlement Agencies	693	3,763	47,905
Afghan Parolees and SIV Holders from Safe Havens	693	3,763	46,110
SIV Holders from Ports of Entry	0	0	1,795

	Past day	Past 7 days	All-time
Independent Departures from Safe Havens	45	250	10,786
U.S. Citizens, Lawful Permanent Residents, and Third-Country Nationals	0	4	425
Afghans who departed without the assistance of Resettlement Agencies	45	246	10,361

	Past day	Past 7 days	All Time
Independent Departures from Ports of Entry	TBD	TBD	8,632
U.S. Citizens, Lawful Permanent Residents, and Third-Country Nationals	TBD	TBD	TBD
Afghans who departed without the assistance of Resettlement Agencies	TBD	TBD	TBD

Data Sources:
DOS Site Lead Reporting
CBP Arrival Records
NORTHCOM Reporting
Hummingbird
CBP Spot Counts
ORR UC Portal
WRAPS

As of 12 Jan 2022

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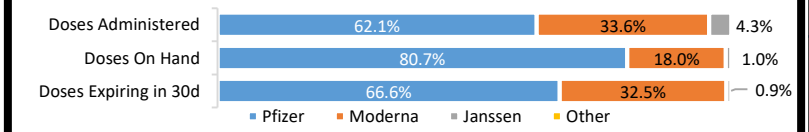
As of 2022-01-12
POC: Col Jennifer Garrison
E-mail: jennifer.h.garrison.mil@mail.mil

Data pull from ADVANA 1800 11 JAN
Data current as of 10 JAN

DOD COVID-19 VACCINE OPERATIONS UPDATE

Vaccine Throughput & Inventory

Metrics	Two-dose vaccine (Pfizer, Moderna, Other)		Single-dose vaccine (Janssen)	Total
Total Doses Administered	6,391,239	*Initial Dose:* 3,590,981 *Second Dose:* 2,800,258	286,037	6,677,276
Doses Lost to Waste/Error	9,940		79	*10,019*
Doses On Hand	Adult 490,567	Pediatric 154,200	5,015	649,782
Past Expiration Date	45,924 9.4%	170 0%	545 10.9%	**46,639**
Expiring in next 7 days	51,910 10.6%	250 0%	545 10.9%	**52,705**
Expiring in next 14 days	55,725 11.4%	790 1%	545 10.9%	**57,060**
Expiring in next 30 days	60,969 12.4%	11,320 7%	545 10.9%	**72,834**
Total Doses Ordered	5,833,890		210,700	**6,044,590**
Total Doses Deliv. To Sites	5,540,710		210,200	**5,750,910**
Additional Doses Ordered	**293,180**		**500**	**293,680**



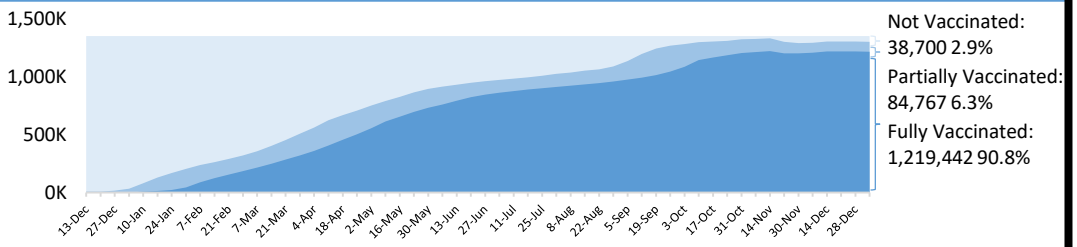
DOD & US Vaccination Statistics

Metrics	DOD	All Other U.S.[2]
Doses Shipped (10 JAN)	6,042,590	638,449,040
Total Doses Admin (09-JAN)	6,669,979	510,663,157
+ New Doses Admin (10-JAN)	7,297	6,292,839
Total Doses Admin (10-JAN)	6,677,276	516,955,996
Admin (10-JAN) / Doses Shipped	110.5%	81.0%
% of Adult Population[2] with at Least 1 Dose	97.1%	86.2%
% of Adult Population[2] Fully Vaccinated	90.8%	73.1%
Doses Shipped (10 JAN)	6,042,590	638,449,040

National & Global Headlines

- Facebook's parent company, Meta Platforms, announced that eligible employees will be required to get booster shots.
- In a sweeping speech on the pandemic and other global issues, Pope Francis called for widespread vaccination in all countries and suggested the global coronavirus response was being complicated by "baseless information or poorly documented facts."
- India administered nearly 1 million booster doses to its eligible population on Monday, as the country continues to witness a sharp rise in cases driven by the highly transmissible Omicron variant.
- Canadian PM Justin Trudeau said the government secured enough vaccines to offer all eligible Canadians a booster shot and a fourth dose.

Active Duty Vaccination Rate Trend



Not Vaccinated: 38,700 2.9%
Partially Vaccinated: 84,767 6.3%
Fully Vaccinated: 1,219,442 90.8%

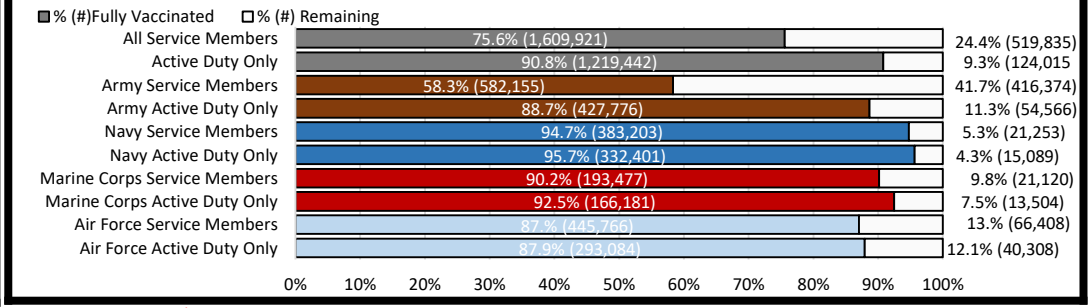
Total Force Individuals Vaccinated**

Personnel Category	Eligible Population	Fully Vaccinated[4] # Individuals	Fully Vaccinated[4] % of Total[4]	Partially Vaccinated # Individuals	Partially Vaccinated % of Total[4]	Not Vaccinated or Unknown # Individuals	Not Vaccinated or Unknown % of Total[4]
Active Duty (USA, USN, USAF, USMC)	**1,342,909**	**1,219,442**	**90.8%**	**84,767**	**6.3%**	**38,700**	**2.9%**
Reserves & National Guard	786,847	390,479	49.6%	255,116	32.4%	141,252	18.0%
Total Service Members	**2,129,756**	**1,609,921**	**75.6%**	**339,883**	**16.0%**	**179,952**	**8.4%**
Other Active Duty	112,345	42,318	**74.6%**	3,920	**13.9%**	12,889	**11.5%**
Other Guard/Reserve		41,506		11,712			
Civilians & Contractors	1,820,642	441,313	**24.2%**	79,218	**4.4%**	1,300,111	**71.4%**
Beneficiaries – All vaccination sites	2,616,959	1,062,167	40.6%	625,118	23.9%	929,674	35.5%
Other/Unknown		142,130		51,520			
TOTAL	**6,679,702**	**3,339,355**	**50.0%**	**1,111,371**	**16.6%**	**2,228,976**	**33.4%**

Enrolled Beneficiaries <18 Fully Vaccinated by Region

Population Group	U.S. Population[5]	U.S. Fully Vaccinated[6]		INTERNATIONAL Population	INTERNATIONAL Fully Vaccinated	
Beneficiaries 5-11	262,862	15,372	5.8%	30,725	5,047	16.4%
Beneficiaries 12-15	138,457	35,567	25.7%	12,897	6,107	47.4%
Beneficiaries 16-17	65,734	24,640	37.5%	4,558	3,019	66.2%

Active Duty Only & Service Members Fully Vaccinated by Service



** Inconsistent methodologies for reporting vaccination records and population denominators of Active Duty vs National Guard/Reserve Service members and DMDC data timing discrepancies have resulted in decrements to vaccination rates for Service members reported since 24 NOV. EIDS and ADVANA are working to synchronize delivery and updates of DMDC data files and align reporting methodologies in order to resolve these issues.

1. Dose utilized can exceed 100% due to excess do ses obtained from vials. 2. U.S data from CDC, does not include DOD doses : https://covid.cdc.gov/covid-data-tracker/#vaccinations
3. DoD Adult Population includes Active Duty Only; US Adult Population includes individuals 18+ years of age 4. Individuals who have received both doses when two doses are required. 5. CONUS population includes beneficiaries enrolled to DOD Military Treatment Facilities 6. Includes doses administered in US DOD vaccination sites and retail pharmacies; does not include doses administered through mass vaccination sites, school districts or non-DoD clinics.

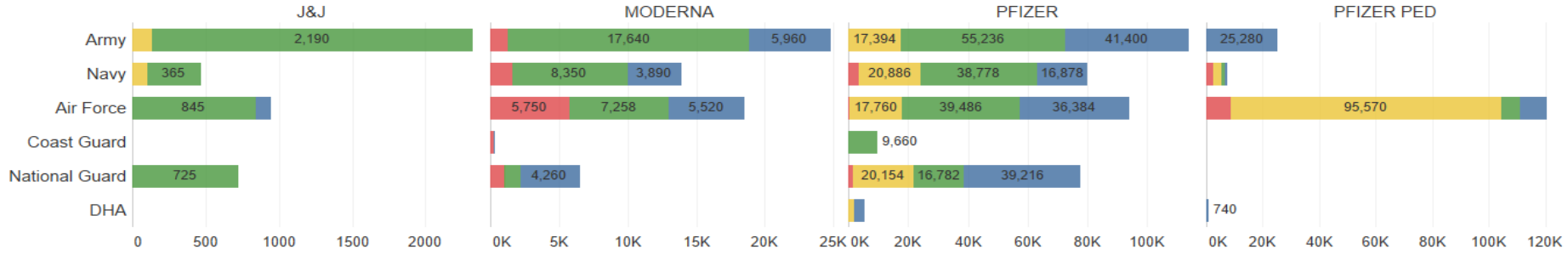
CONTROLLED UNCLASSIFIED INFORMATION

DOD COVID-19 Vaccine Doses On Hand

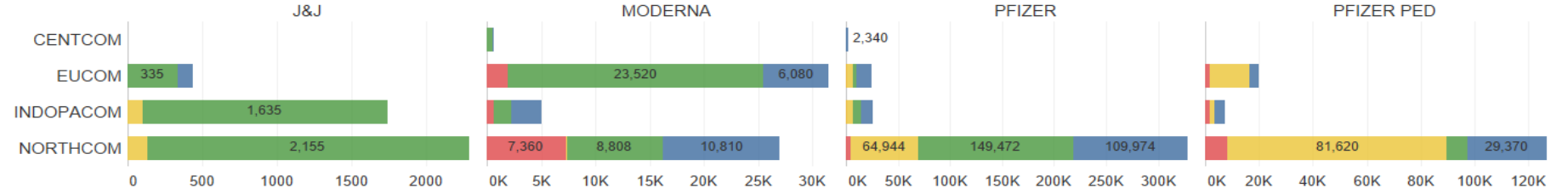
Data pulled from DMLSS/SLEP on: **Tuesday, January 11, 2022**

Expiring <=30 days	Expiring 31-60 days	Expiring 61-90 days	Expiring > 90 days
26,195 Doses (**4%**)	**176,964** Doses (**29%**)	**206,415** Doses (**34%**)	**193,545** Doses (**32%**)

By Service



By Geographic Region



As of 2022-01-11
POC: Col Jennifer Garrison
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DMLSS/SLEP
Data current as of 11 Jan 22

CONTROLLED UNCLASSIFIED INFORMATION

DOD COVID-19 Vaccine Doses On Hand

Data Outliers 0

Data pulled from DMLSS/SLEP on: Tuesday, January 11, 2022

		Army	Navy	Air Force	Coast Guard	National Guard	DHA	Grand Total
J&J	Expiring 31-60 days	135	105					240
	Expiring 61-90 days	2,190	365	845		725		4,125
	Expiring > 90 days			105				105
MODERNA	Expiring <=30 days	1,235	1,650	5,750	240	1,010		9,885
	Expiring 31-60 days					20		20
	Expiring 61-90 days	17,640	8,350	7,258		1,210		34,458
	Expiring > 90 days	5,960	3,890	5,520	100	4,260		19,730
PFIZER	Expiring <=30 days		3,336	198		1,626		5,160
	Expiring 31-60 days	17,394	20,886	17,760		20,154	1,920	78,114
	Expiring 61-90 days	55,236	38,778	39,486	9,660	16,782		159,942
	Expiring > 90 days	41,400	16,878	36,384		39,216	3,432	137,310
PFIZER PED	Expiring <=30 days		2,370	8,780				11,150
	Expiring 31-60 days		3,020	95,570				98,590
	Expiring 61-90 days		1,380	6,510				7,890
	Expiring > 90 days	25,280	600	9,780			740	36,400
Grand Total		166,470	101,608	233,946	10,000	85,003	6,092	603,119

		CENTCOM	EUCOM	INDOPACOM	NORTHCOM	Grand Total
J&J	Expiring 31-60 days			105	135	240
	Expiring 61-90 days		335	1,635	2,155	4,125
	Expiring > 90 days		105			105
MODERNA	Expiring <=30 days		1,919	606	7,360	9,885
	Expiring 31-60 days				20	20
	Expiring 61-90 days	510	23,520	1,620	8,808	34,458
	Expiring > 90 days	50	6,080	2,790	10,810	19,730
PFIZER	Expiring <=30 days		306	504	4,350	5,160
	Expiring 31-60 days		6,576	6,594	64,944	78,114
	Expiring 61-90 days		2,874	7,596	149,472	159,942
	Expiring > 90 days	2,340	14,364	10,632	109,974	137,310
PFIZER PED	Expiring <=30 days		1,540	1,570	8,040	11,150
	Expiring 31-60 days		14,890	2,080	81,620	98,590
	Expiring 61-90 days				7,890	7,890
	Expiring > 90 days		3,430	3,600	29,370	36,400
Grand Total		2,900	75,939	39,332	484,948	603,119

As of 2022-01-11

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CONTROLLED UNCLASSIFIED INFORMATION (CUI)

CONTROLLED UNCLASSIFIED INFORMATION

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DMLSS/SLEP
Data current as of 11 Jan 22

DOD COVID-19 VACCINE Doses on Hand

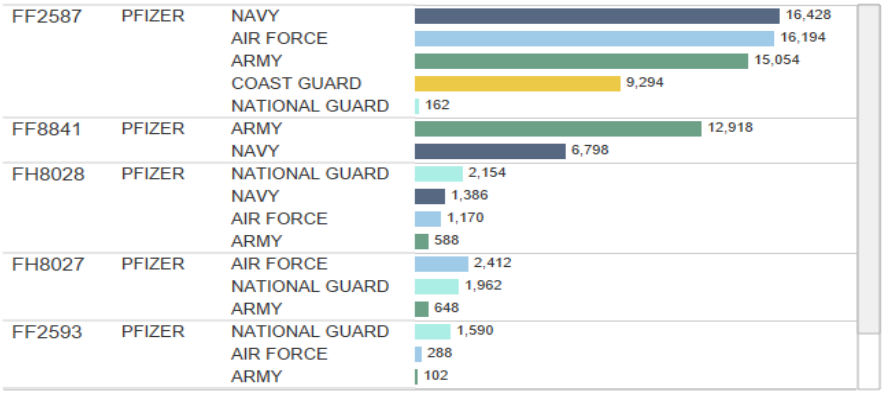
Biologic License Agreement Vaccine Quantities

Data as of: **Jan 11, 2022**

Doses or Vials	DHA Managed	CCMD	Service/Agency	DHA Market	Main Organization	BLA Lot Number	Expiration Dates
Doses	All	All	All	All	All	Multiple values	All

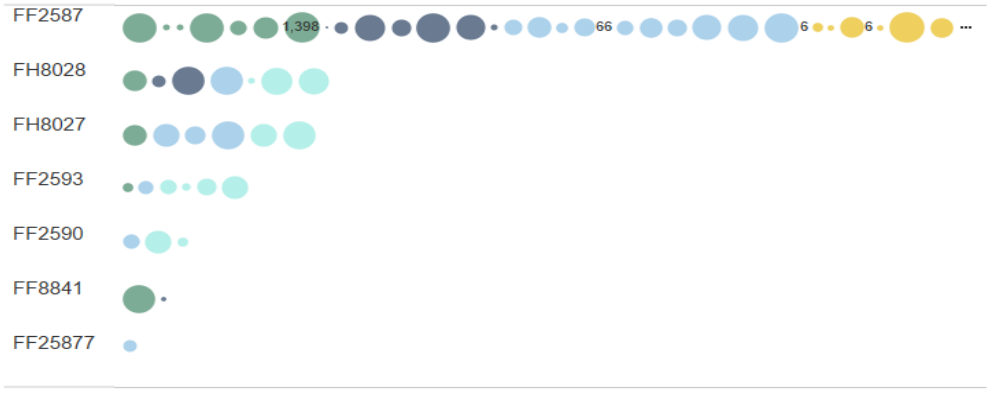
90,570 Current Serviceable BLA Doses by Service/Agency

Brush for details, click to filter



Current Serviceable BLA Doses by Main Organizations

Brush for details. Each circle is a main organization, listed in alphabetical order. The larger the circle, the greater the vaccine quantity.



Serviceable BLA Vials Recent Trend

BLA Lot Number	Item Name	1/11/2022	1/10/2022	1/7/2022	1/6/2022	1/5/2022	1/4/2022	1/3/2022	12/29/2021	12/28/2021	12/27/2021	12/23/2021	12/22/2021	12/21/2021
FF2587	PFIZER	57,132	57,954	59,784	60,534	60,960	61,758	62,094	64,068	64,224	64,590	64,680	65,550	67,038
FF25877	PFIZER	204	204	204	204	204	204	204	204	204	204	204	204	204
FF2590	PFIZER	1,218	1,368	1,368	1,368	1,368	1,608	1,608	1,608	1,608	1,608	1,608	1,968	1,968
FF2593	PFIZER	1,980	1,980	1,980	1,980	1,980	1,980	1,980	1,992	1,992	1,992	1,992	1,692	1,692
FF8841	PFIZER	19,716	19,824	20,532	20,736	20,976	21,072	21,096	21,300	21,444	21,444	21,528	21,702	21,840
FH8027	PFIZER	5,022	5,658	5,664	6,060	6,510	6,570	7,812	8,346	8,502	8,868	8,868	9,990	10,212
FH8028	PFIZER	5,298	5,406	5,406	5,418	5,418	5,484	5,484	5,538	5,592	5,592	5,796	6,276	6,306

As of 2022-01-11

POC: Col Jennifer Garrison
E-mail: jennifer.h.garrison.mil@mail.mil

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DMLSS/CLD

Data current as of 11 Jan 22

DOD COVID-19 VACCINE Doses on Hand

CUI

Vaccine Quantities by Expiration Date

Item Name: All

Data as of: Tue, Jan 11, 2022

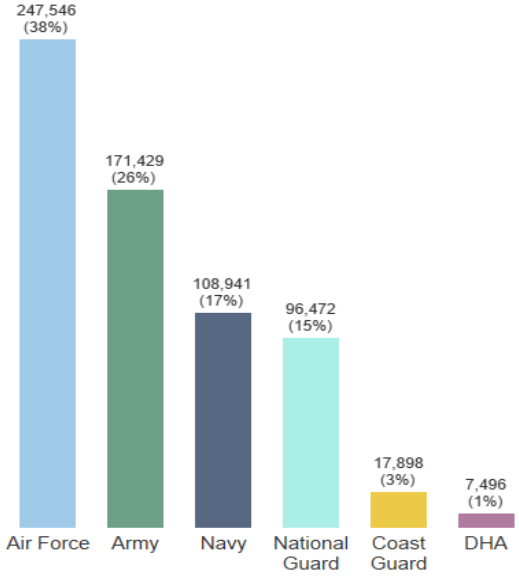
Serviceable?	Item Name	CCMD	Service/Agency	DHA Market	Main Organization	Child Organization	Lot Number	Expiration Dates
Serviceable Doses	All	All	All	All	All	All	All	Show all dates

649,782 Serviceable Doses

25,050 Unserviceable Doses

Serviceable Doses by Service/Agency

Brush for details, click to filter



Serviceable Doses by Expiration Date and Service/Agency

Brush for details

Data Outliers 0

Show All Data

Remove Outlier Data

Expiration Date	Total	Air Force	Army	Navy	Coast Guard	National Guard	DHA
6/30/2021	84		84				
8/16/2021	40					40	
8/24/2021	170					170	
8/26/2021	80					80	
8/28/2021	270					270	
8/29/2021	150				150		
8/31/2021	174				174		
9/10/2021	30				30		
9/17/2021	1,686				1,140	546	
9/18/2021	1,250	30		100	320	800	
9/21/2021	765			65		700	
9/29/2021	80					80	
10/1/2021	40			40			
10/2/2021	135	125			10		

CUI

As of 2022-01-11

POC: Col Jennifer Garrison
E-mail: jennifer.h.garrison.mil@mail.mil

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DMLSS/SLED

Data current as of 11 Jan 22

AFHSD

SUMMARY

- **Global Civilian Cases: 313,890,009 (+3,258,914)**
  - *278 MHS Omicron cases in U.S. (198), Japan (36), ROK (34), Germany (5), & Guantánamo Bay, Cuba (5) since DEC*
- **Total MHS Cases: 445,816 (+10,483)**
  - **AD 282,803 (+6,748)**
- **Countries/Territories of DoD Interest (past week)**
  - *Italy MHS cases ↑ 250 to 542; civ ↑ 49% (286 cases/100k/day)*
  - *Japan MHS cases ↑ 1,257 to 2,896, w/ Omicron implicated in Okinawa outbreak; civ ↑ 942%*
  - *Guam MHS cases ↑ 124 to 504; civ ↑ 311%*
  - *Germany MHS cases ↑ 736 to 1,561; civ ↑ 42%*
- **U.S. Cases: 62,308,472 (+752,387)**
  - *CONUS MHS cases ↑ 85% (4,748/day) in past week; civ ↑ 47% (751k/day), w/ "Ultra High" incidence rates in 47 states & D.C.*
  - *HI MHS cases ↑ 350 to 628; civ ↑ 41% in past week*

https://go.intelink.gov/gIKcynv

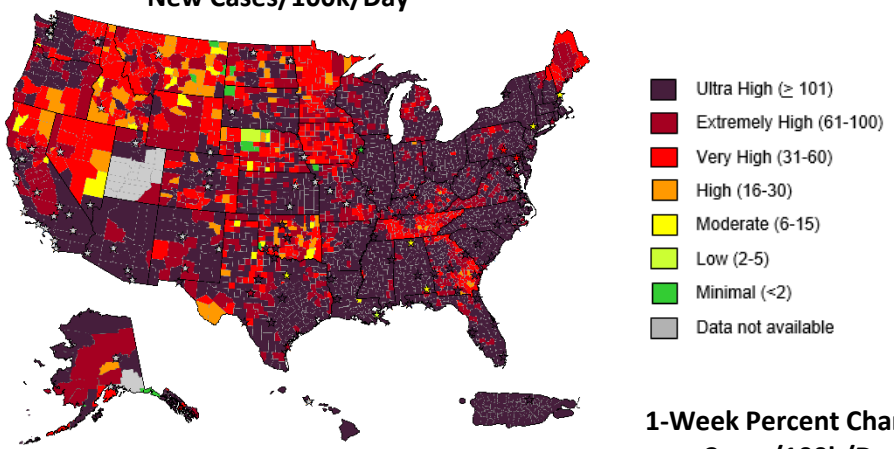
Installations of Interest

State	Installation name	Cumulative Case Total	Cases onset past 14d
VA	PORTSMOUTH	19,205	4850
TX	JOINT (AF) SAN ANTONIO*	22,370	4811
TX	FT HOOD	19,332	4004
NC	FT BRAGG	18,421	3849
CA	SAN DIEGO*	16,844	2609
TX	FT BLISS	11,272	2491
Japan	OKINAWA	4,903	2079
WA	JOINT (AF) BASE LEWIS-MCCHORD	11,957	1980
KY	FT CAMPBELL	11,612	1965
NC	CAMP LEJEUNE	13,494	1812
South Korea	CAMP HUMPHREYS	2,891	1534
CO	FT CARSON	10,120	1534
GA	FT BENNING*	14,402	1518
VA	JOINT (AF) BASE LANGLEY-EUSTIS	5,344	1488
HI	HAWAII-OAHU	8,248	1431
	*Initial training/Service Academy		

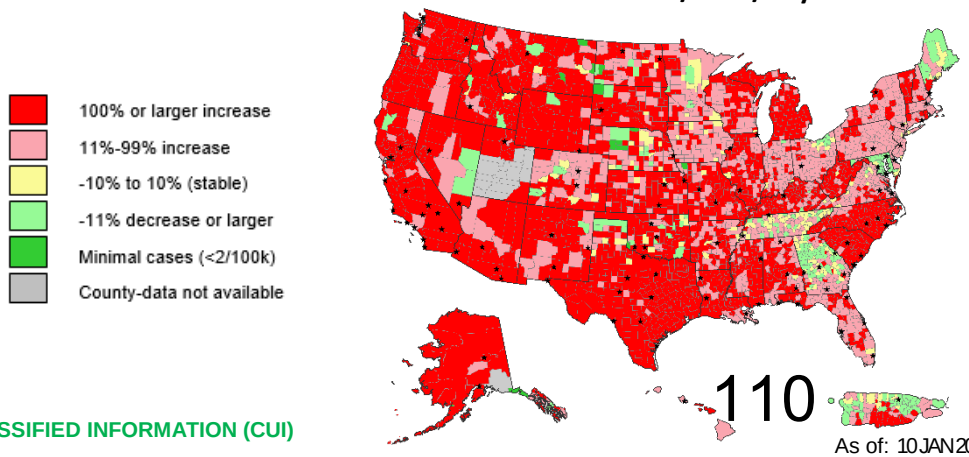
Markets/Regions to Watch

MHS Market	State	Total AD	Total MHS Beneficiaries	AD Cases/ 100k/day	Total Civ Cases/ 100k/day
Moody	GA, FL	5,129	9,766	652	102
Hood	TX	45,787	140,801	543	214
Polk	LA, TX	8,945	21,633	497	158
Keesler/Gulfport	LA, MS	9,702	33,006	443	212
Bliss/White Sands	TX, NM	32,277	118,667	384	129
Patrick	FL	2,490	11,557	442	240
Dover/Cape May	MD, NJ, DE	4,077	11,221	410	263

New Cases/100k/Day



1-Week Percent Change in Cases/100k/Day



110

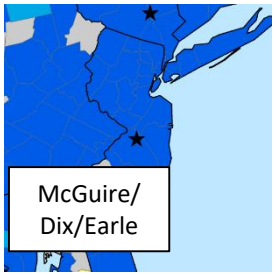
As of: 11JAN2022
Controlled by: DHA/PHD//AFHSD
CUI Category: CUI
Slide POC: Col Patrick Kennedy; patrick.w.kennedy.mil@mail.mil; (301) 619-3850

As of: 10JAN2022

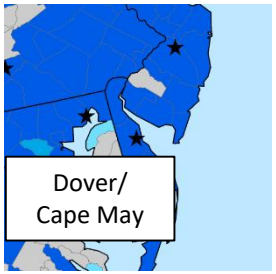
MHS Market	State	CIV COVID-19 Hosp./100k/day	CIV Cases/100k/day	CIV ICU Beds Occupied
McGuire/Dix/Earle	NJ, NY, PA	73	383	68%
Dover/Cape May	MD, NJ, DE	66	263	76%
Knox	IN, KY	59	241	81%
Great Lakes	IL, WI	59	253	69%
Leavenworth	MO, KS	55	252	78%
Scott	MO, IL	55	283	88%
Lejeune/Cherry Point	NC	53	119	65%
Harrisburg	PA, WV, MD	52	208	85%
West Point	NY, CT, NJ	52	343	54%
Patuxent River	MD, VA	51	199	66%

Featured Markets to Watch

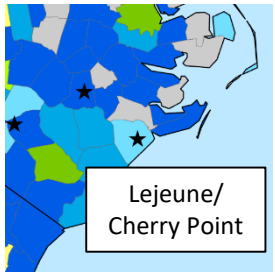
McGuire/Dix/Earle MHS Market, NJ/NY/PA
Civilian COVID-19 Hospitalizations Increasing: 73 hospitalizations/100k/day (+54%), 68% ICU/79% inpatient beds used
Civilian Cases Increasing: 383 cases/100k/day (+16%)



Dover/Cape May MHS Market, MD/NJ/DE
Civilian COVID-19 Hospitalizations Increasing: 66 hospitalizations/100k/day (+44%), 76% ICU/74% inpatient beds used
Civilian Cases Increasing: 263 cases/100k/day (+23%)

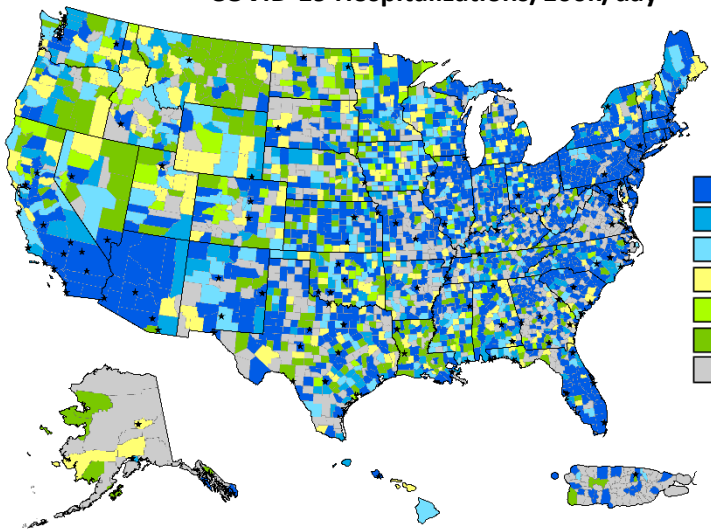


Lejeune/Cherry Point MHS Market, NC
Civilian COVID-19 Hospitalizations Increasing: 53 hospitalizations/100k/day (+22%), 65% ICU/79% inpatient beds used
Civilian Cases Increasing: 119 cases/100k/day (+145%)

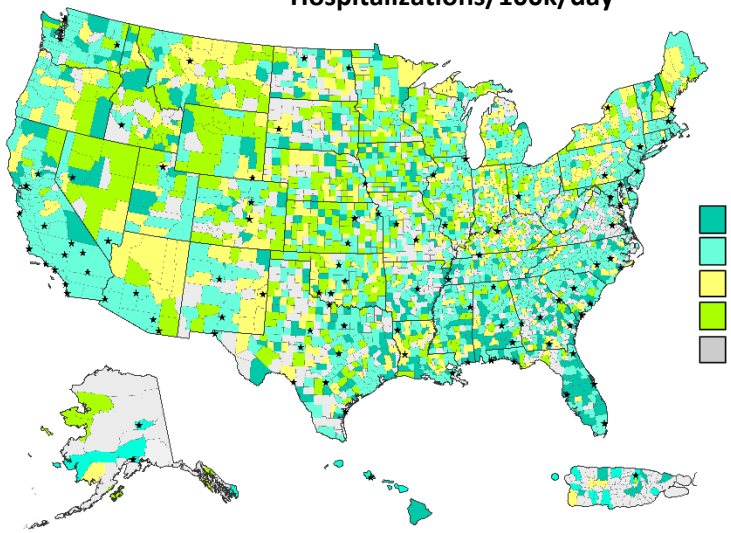


All US Counties

COVID-19 Hospitalizations/100k/day



1-Week Percent Change in COVID-19 Hospitalizations/100k/day



As of: 10JAN2022
Controlled by: DHA/AD-CS/PHD/AFHSD
CUI Category: CUI
POC: Col Patrick Kennedy; patrick.w.kennedy.mil@mail.mil; (301) 619-3850

IHD

COVID vaccine implementation updates 12 Jan 2022

- Potential issue: Pfizer-BioNTech supply to support mandate
  - 350K "plus up" of purple-cap was approved by DHA and by CAG
  - CAG now pushing back, stating that the purple and gray cap products are interchangeable
  - Current status
    - ✓ Estimated SM need to reach 100%: **700K doses**; for ADSM: **162K doses**
    - ✓ Pfizer product on the shelf which may be used for mandate: **390K total doses**
      - EUA-manufactured, EUA-labeled: 300K doses
      - BLA-manufactured, EUA-labeled: 90K doses
    - ✓ Requested mtng with CAG/CDC/OGC/DHA 11 Jan 2022
    - ✓ Alternatives:
      - Immediate ceasing of administering purple cap for non-SM
        - » Tris be ordered and directed to non-SM
      - Strongly encourage Pfizer/CDC to publically identify BLA-approved Tris lots
      - Provide "Comirnaty"-labeled vaccine
      - Await Moderna BLA approval by FDA

IHD

PFIZER

Indication	Dose, concentration, interval	< 5 years	5-11 years	12-15 years	16-17 years	18-49 years	50-64 years	≥ 65 years
Primary series ≥ 12 year olds PURPLE OR GRAY CAP Mix and match not authorized	2 doses, 30 mcg/dose (0.3mL/dose) Interval between doses: 21 days Repeat dose 2 if given earlier than the 4 day grace period	< 12 years - do not give		12-15 years	≥16 years - FDA licensed			
Primary series 5-11 year olds ORANGE CAP	2 doses, 10 mcg/dose (0.2mL/dose) Interval between doses: 21 days	< 5 years - do not give	5-11 years	≥12 years - do not give				
Additional primary dose for those who are immunocompromised Mix and match not authorized	≥ 12 years: Single 30 mcg (0.3mL) dose at least 28 days after Pfizer dose 2 5-11 years: Single 10 mcg (0.2mL) dose at least 28 days after Pfizer dose 2 Repeat addn primary dose if given earlier than 4 day grace period	< 5 years - do not give	5-11 years with certain immunocompromising conditions	≥ 12 years who have certain immunocompromising conditions				
Booster Dose Mix and match authorized but mRNA vaccine is recommended over Janssen	Options for booster in those ≥ 18 years Pfizer: single 30 mcg dose (same dose as Pfizer primary dose) OR Moderna: single 50 mcg dose (HALF-DOSE of Moderna primary series) OR Janssen: single 5x10e10 viral particles dose (same dose as Janssen primary dose) If the booster is given earlier than the 4 day grace period, it does not need to be repeated	< 12 years - do not give		12-17 year olds should get a Pfizer booster dose 5 months after Pfizer primary series	All those ≥ 18 years who received a complete mRNA primary series should get a booster dose at least 5 months after last dose. All those ≥ 18 years who received a complete series Janssen vaccine should get a booster dose at least 2 months after last dose.			

GREEN BOX = FDA APPROVED | YELLOW BOX = FDA EMERGENCY USE AUTHORIZATION | GRAY BOX = NO INDICATION FOR THIS AGE GROUP | 9 Jan 2022

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

IHD

	Indication	Dose, concentration, interval	< 5 years	5-11 years	12-15 years	16-17 years	18-49 years	50-64 years	≥ 65 years
MODERNA	Primary series Mix and match not authorized	2 doses; 100 mcg/dose (0.5mL) Interval between doses: 28 days 2 doses, 30 mcg/dose (0.3mL/dose) Interval between doses: 21 days Repeat dose 2 if given earlier than the 4 day grace period	< 18 years - do not give				≥ 18 years		
	Additional primary dose for those who are immunocompromised Mix and match not authorized	Single 100 mcg (0.5mL) dose at least 28 days after Moderna dose 2 Repeat additional primary dose if given earlier than the 4 day grace period	< 18 years - do not give				≥ 18 years who have certain immunocompromising conditions		
	Booster Mix and match authorized but mRNA vaccine is recommended over Janssen	Options for booster in those ≥ 18 years: Pfizer: single 30 mcg dose (same dose as Pfizer primary dose) OR Moderna: single 50 mcg dose (HALF-DOSE of Moderna primary series) OR Janssen: single 5x10e10 viral particles dose (same dose as Janssen primary dose) If the booster is given earlier than 4 day grace period, it does not need to be repeated.	< 18 years - do not give				All those ≥ 18 years who received a complete mRNA primary series should get a booster dose at least 5 months after last dose. All those ≥ 18 years who received a complete series Janssen vaccine should get a booster dose at least 2 months after last dose.		

GREEN BOX = FDA APPROVED | YELLOW BOX = FDA EMERGENCY USE AUTHORIZATION | GRAY BOX = NO INDICATION FOR THIS AGE GROUP

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

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IHD

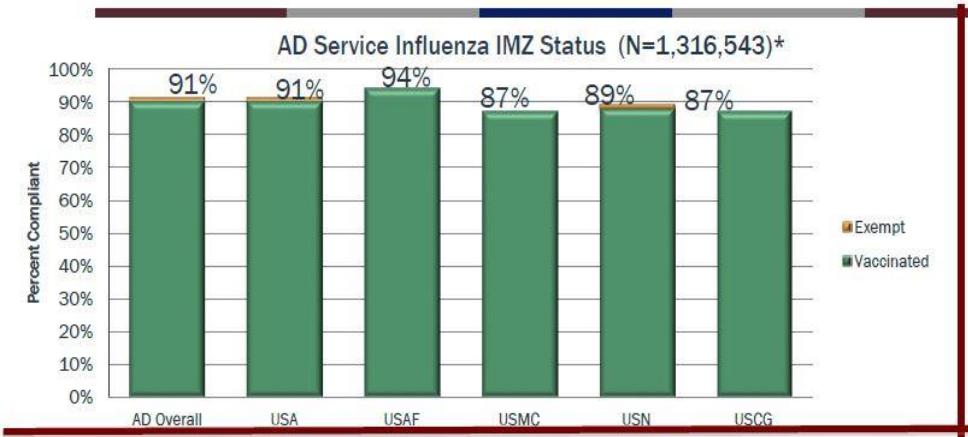
	Indication	Dose, concentration, interval	< 5 years	5-11 years	12-15 years	16-17 years	18-49 years	50-64 years	≥ 65 years
JANSSEN	Primary series per CDC, mRNA is preferred over Janssen	5x10e10 viral particles (0.5mL)	< 18 years - do not give				≥ 18 years FDA EUA		
	Additional primary dose for those who are immunocompromised	Not Indicated	Janssen additional doses for those moderately/severely immunocompromised are not authorized or approved by the FDA due to insufficient data.						
	Booster per CDC, mRNA is preferred over Janssen Mix and match authorized but mRNA vaccine is recommended over Janssen	Options for booster in those ≥ 18 years Pfizer: single 30 mcg dose (same dose as Pfizer primary dose) OR Moderna: single 50 mcg dose (HALF-DOSE of Moderna primary series) OR Janssen: single 5x10e10 viral particles dose (same dose as Janssen primary dose) If the booster is given earlier than the 4 day grace period, it does not need to be repeated	< 18 years - do not give				All those ≥ 18 years who received a complete mRNA primary series should get a booster dose at least 5 months after last dose. All those ≥ 18 years who received a complete series Janssen vaccine should get a booster dose at least 2 months after last dose.		

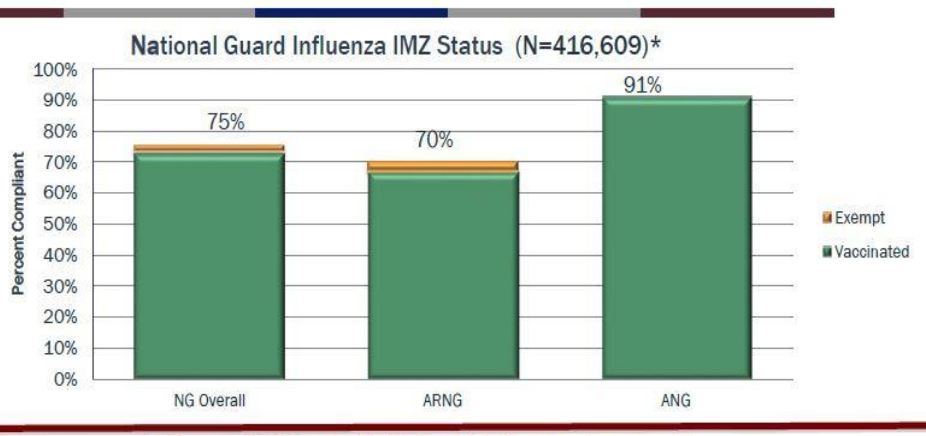
	Indication	Dose, concentration, interval	< 5 years	5-11 years	12-15 years	16-17 years	18-49 years	50-64 years	≥ 65 years
WHO EUL TRIAL	Additional primary dose for those who are immunocompromised Only Pfizer is authorized	Pfizer: single 30 mcg dose at least 28 days after 2nd dose in primary series Repeat additional primary dose if given earlier than the 4 day grace period	< 12 years - do not give		Under the Emergency Use Instructions, those ≥ 12 years who received a complete series of a WHO-Emergency Use List vaccine or clinical trial vaccine should receive an additional primary dose of Pfizer-BioNTech COVID-19 vaccine (30 µg) at least 28 days after receiving the second vaccine dose of their primary series				
	Booster Only Pfizer is authorized	Pfizer: single 30 mcg dose at least 6 months after 2nd dose in primary series If the booster is given earlier than the 4 day grace period, it does not need to be repeated	< 12 years - do not give		Under the Emergency Use Instructions, those ≥ 12 years those who received a complete series of a WHO-Emergency Use List vaccine or clinical trial vaccine should receive a booster dose of Pfizer-BioNTech COVID-19 vaccine (30 µg) at least 6 months after receiving the second vaccine dose of their primary series				

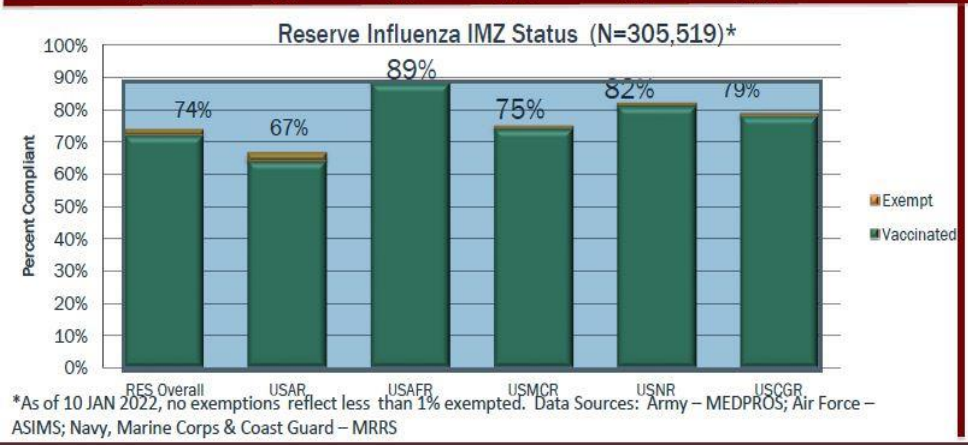
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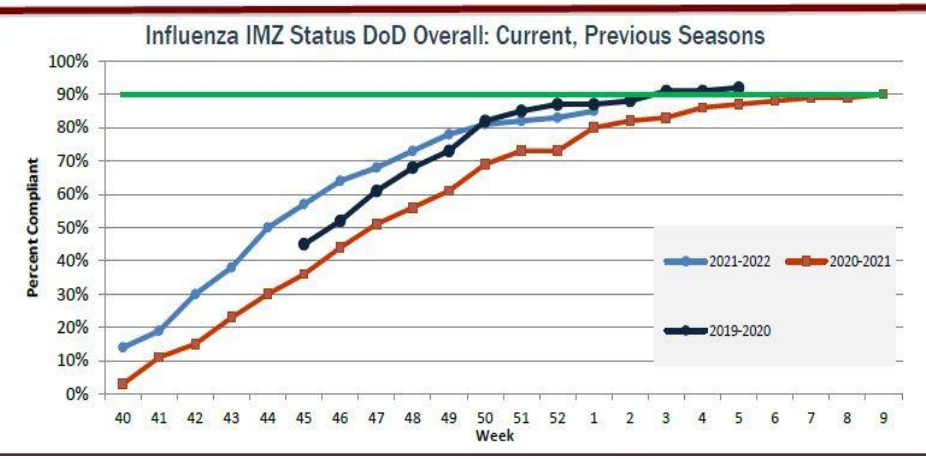
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

2021-2022 Seasonal Influenza Vaccine Compliance Status,
AD/NG/RES 11 JAN 2022









*As of 10 JAN 2022, no exemptions reflect less than 1% exempted. Data Sources: Army – MEDPROS; Air Force – ASIMS; Navy, Marine Corps & Coast Guard – MRRS

*As of 3 JAN 2022, no exemptions reflect less than 1% exempted. Data Sources: Army – MEDPROS; Air Force – ASIMS; Navy, Marine Corps & Coast Guard – MRRS; Army and USCG suspense for 90% is 15 Jan

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Market Operations

COVID-19

MHS BEDCAPABILITY

- Hospitals with **10 or more** COVID Inpatients:

BAMC: 35 MS/SDU, 8 ICU
NMCP: 14 MS/SDU, 1 ICU
FT Belvoir: 8 MS/SDU, 3 ICU
NMCSD: 21 MS/SDU, 4 ICU
MAMC: 13 MS/SDU, 7 ICU
TAMC: 9 MS/SDU, 3 ICU

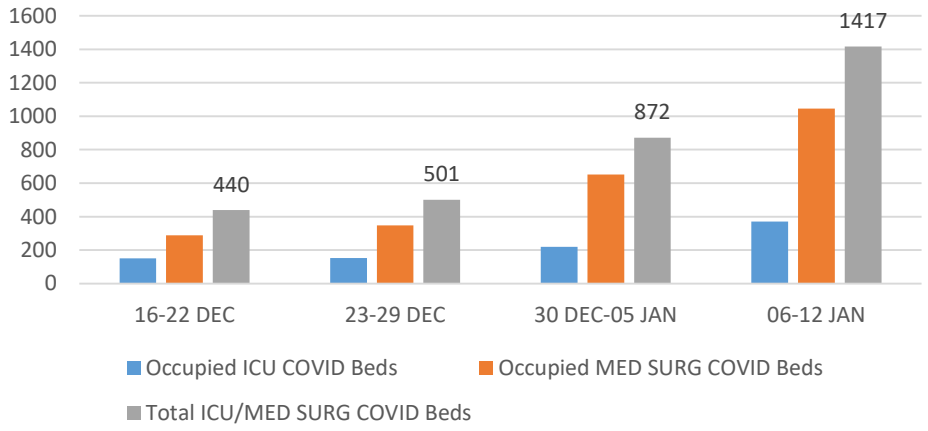
WAMC: 10 MS/SDU, 0 ICU
WBAMC: 10 MS/SDU, 5 ICU
DDEAMC: 8 MS/SDU, 3 ICU
Travis AFB, 5 MS/SDU, 5 ICU
WRNMMC: 12 MS/SDU, 5 ICU

- Total COVID Inpatients for MHS: **223** *(153)
  - MS/SDU: **171**
  - ICU: **52**

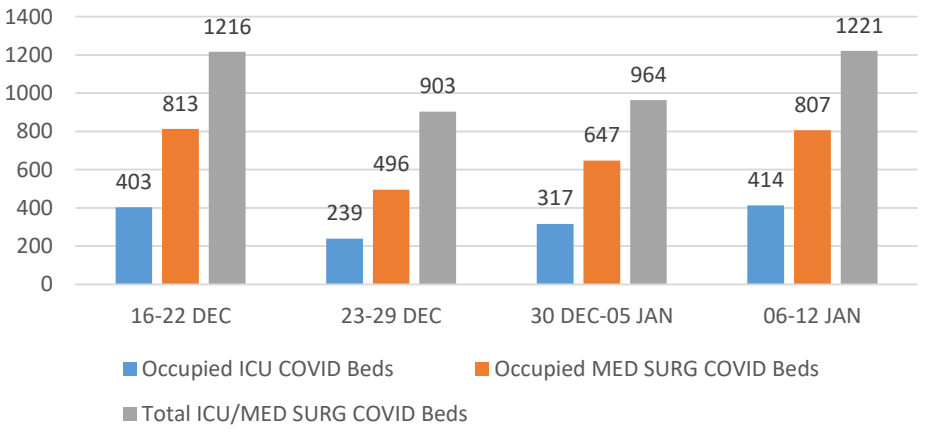
ACTIVE COVID ETMS2's

- Force Health Protection Guidance (Supplement 20) Revision 1 – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic
- Force Health Protection Guidance (Supplement 18) Revision 1 – Department of Defense Guidance for Protecting All Personnel in Department of Defense Workplaces during the Coronavirus Disease 2019 Pandemic

Occupied COVID ICU, MED SURG, Total ICU/MED SURG COVID Beds 2021



Occupied COVID ICU, MED SURG, Total ICU/MED SURG COVID Beds 2020



As of: 1205 / 12 JAN 2022
Slide POC: Mr. Neil Doherty
703-681-8165

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COVID-19

DHA Status Overview

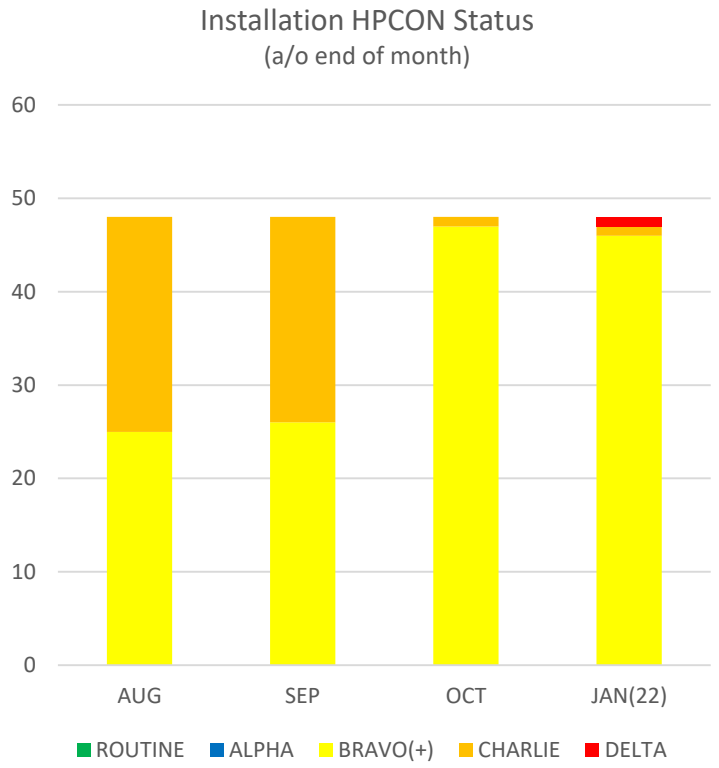
DHA Hospital Bed Capacity (25 MTFs)

12-Jan-22 10:24

	Type Bed	Bed Capacity					Equipped Beds			Staffed Beds			C-19 Pts ↑↓	
		Equipped		Expansion		Total	Staffed ↑↓		Unstaff.	Occupied ↑↓		% Occ	651d Trend	
CONUS (25)	MS/SDU	1,447	-	1,571	-1	3,018	953	-48	494	725	7	76%	171	28
	ICU	332	-	--		332	219	-9	113	147	-3	67%	52	-5
	OB/Peds	903	-	--		903	624	-3	279	324	16	52%		
	MH	340	-	--		340	249	-	91	156	1	63%		
	TOTAL	**3,022**	**-**	**1,571**	**-1**	**4,593**	**2,045**	**-60**	**977**	**(60)**	**21**	**66%**	**223**	**23**
OCONUS (0)	MS/SDU	-	-	-	-	-	-	-	-	-	-	--	-	-
	ICU	-	-	--		-	-	-	-	-	-	--	-	-
	OB/Peds	-	-	--		-	-	-	-	-	-	--		
	MH	-	-	--		-	-	-	-	-	-	--		
	TOTAL	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**--**	**-**	**-**
DHA (25)	MS/SDU	1,447	-	1,571	-1	3,018	953	-48	494	725	7	76%	171	28
	ICU	332	-	--		332	219	-9	113	147	-3	67%	52	-5
	OB/Peds	903	-	--		903	624	-3	279	324	16	52%		
	MH	340	-	--		340	249	-	91	156	1	63%		
	TOTAL	**3,022**	**-**	**1,571**	**-1**	**4,593**	**2,045**	**-60**	**977**	**(60)**	**21**	**66%**	**223**	**23**

✓ 23 (Today) 2 (<24 hrs) 0 (24-48 hrs) 0 (>48 hrs)

Installation HPCON Status (Inpatient MTFs)				
Installation Name	AUG	SEP	OCT	JAN(22)
ACH BASSETT-WAINWRIGHT	BRAVO	BRAVO	BRAVO+	BRAVO+
ACH BAYNE-JONES-POLK	BRAVO	BRAVO	BRAVO	BRAVO
ACH BLANCHFIELD-CAMPBELL	BRAVO	BRAVO	BRAVO	BRAVO
ACH BRIAN ALLGOOD-SEOUL	BRAVO	BRAVO	BRAVO	BRAVO
ACH EVANS-CARSON	BRAVO	BRAVO	BRAVO	BRAVO
ACH IRWIN-RILEY	BRAVO	BRAVO	BRAVO	BRAVO
ACH KELLER-WEST POINT	BRAVO	BRAVO	BRAVO	BRAVO
ACH LEONARD WOOD	CHARLIE	BRAVO	BRAVO	BRAVO
ACH MARTIN-BENNING	BRAVO	BRAVO	BRAVO	BRAVO
ACH WEED-IRWIN	CHARLIE	BRAVO	BRAVO	BRAVO
ACH WINN-STEWART	BRAVO	BRAVO	BRAVO	BRAVO
AF-H-35th MED GRP-MISAWA	CHARLIE	BRAVO	BRAVO	BRAVO
AF-H-374th MED GRP-YOKOTA	CHARLIE	BRAVO	BRAVO	BRAVO
AF-H-48th MED GRP-LAKENHEATH	CHARLIE	BRAVO	BRAVO	BRAVO
AF-H-51st MED GRP-OSAN	BRAVO	BRAVO	BRAVO	BRAVO
AF-H-633rd MED GRP LANG-EUSTIS	CHARLIE	BRAVO	BRAVO	BRAVO
AF-H-673rd-ELMENDORF	BRAVO	BRAVO	BRAVO+	BRAVO+
AF-H-96th MED GRP-EGLIN	CHARLIE	BRAVO	BRAVO	BRAVO
AF-MC-60th MED GRP-TRAVIS	BRAVO	BRAVO	BRAVO	BRAVO
AF-MC-81st MED GRP-KEESLER	BRAVO	BRAVO	BRAVO	BRAVO
AF-MC-88th MED GRP-WRIGHT-PAT	CHARLIE	CHARLIE	CHARLIE	DELTA
AF-MC-99th MED GRP-NELLIS	CHARLIE	BRAVO	BRAVO+	BRAVO+
AMC BAMC-FSH	CHARLIE	BRAVO	BRAVO+	BRAVO+
AMC DARNALL-HOOD	CHARLIE	BRAVO	BRAVO+	BRAVO+
AMC EISENHOWER-GORDON	CHARLIE	BRAVO	BRAVO+	BRAVO+
AMC MADIGAN-LEWIS	BRAVO	BRAVO	BRAVO	BRAVO
AMC TRIPLER-SHAFTER	CHARLIE	BRAVO	BRAVO	BRAVO
AMC WILLIAM BEAUMONT-BLISS	CHARLIE	BRAVO	BRAVO+	BRAVO+
AMC WOMACK-BRAGG	BRAVO	BRAVO	BRAVO	BRAVO
FORT BELVOIR COMMUNITY HOSPITAL	BRAVO	BRAVO	BRAVO+	CHARLIE
LANDSTUHL REGIONAL MEDCEN	BRAVO	BRAVO	BRAVO+	BRAVO+
NH BEAUFORT	CHARLIE	BRAVO	BRAVO	BRAVO
NH BREMERTON	BRAVO	BRAVO	BRAVO	BRAVO
NH CAMP LEJEUNE - source USN	BRAVO	BRAVO	BRAVO+	BRAVO+
NH CAMP PENDLETON	CHARLIE	BRAVO	BRAVO+	BRAVO+
NH GUAM-AGANA	CHARLIE	BRAVO	BRAVO	BRAVO
NH GUANTANAMO BAY	BRAVO	BRAVO	BRAVO+	BRAVO+
NH JACKSONVILLE	CHARLIE	BRAVO	BRAVO	BRAVO
NH NAPLES	CHARLIE	BRAVO	BRAVO	BRAVO
NH OAK HARBOR	BRAVO	BRAVO	BRAVO	BRAVO
NH OKINAWA	BRAVO	BRAVO	BRAVO	BRAVO
NH ROTA	CHARLIE	BRAVO	BRAVO	BRAVO
NH SIGONELLA	CHARLIE	BRAVO	BRAVO	BRAVO
NH TWENTYNINE PALMS	BRAVO	BRAVO	BRAVO	BRAVO
NH YOKOSUKA	BRAVO	BRAVO	BRAVO	BRAVO
NMC PORTSMOUTH	CHARLIE	BRAVO	BRAVO	BRAVO
NMC SAN DIEGO	CHARLIE	BRAVO	BRAVO	BRAVO
WALTER REED NATL MIL MED CNTR	BRAVO	BRAVO	BRAVO+	BRAVO+
	AUG	SEP	OCT	JAN(22)
ROUTINE	0	0	0	0
ALPHA	0	0	0	0
BRAVO(+)	25	26	47	46
CHARLIE	23	22	1	1
DELTA	0	0	0	1



****COVID Dashboard Refresh is Suspended as of 10/14/2021, Due to COVID-19 Funding (Last Refresh Date: 10/13/21)****

****Current updates information provided by filed DCIRs****

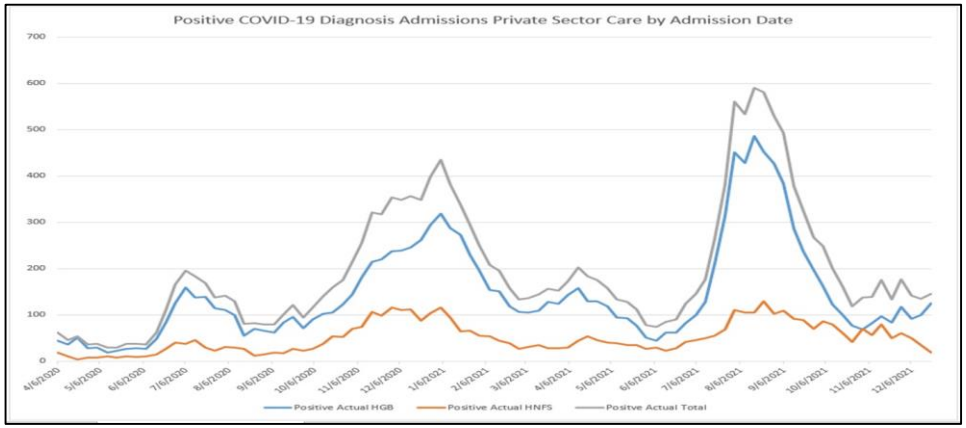
As of: 1100/ 12 JAN 2022
Slide POC: Mr. Neil Doherty
703-681-8165

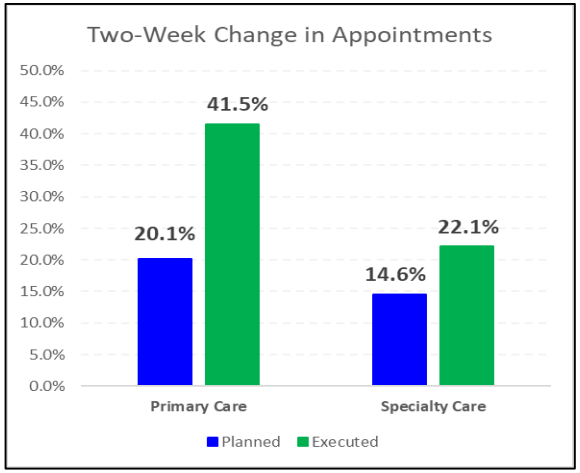
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Market Operations

Access to Care

Updated Daily	Feb 20 - Daily (Baseline) Daily	6 Jan 22 (Thurs)	7 Jan 22 (Fri)	Average Daily Week 3-7 Jan (Last Week)	Average Daily Week 10-14 Jan (This Week)	Average Daily Week 17-21 Jan (Next Week)	Avg Daily This Week vs. Last Week	Avg Daily Next Week vs. This Week
Number of Primary Care Appointments TEMPLATED Daily	44,859	33,553	31,462	**31,479**	**33,208**	**27,067**	**5.5%**	**-18.5%**
Number of Primary Care Appointments SEEN Daily	42,992	32,605	29,052	This week, average utilization is 94% (below target range) compared to 69% in April 2020.				
Number of Specialty Appointments TEMPLATED Daily	62,100	39,098	32,203	**37,876**	**39,353**	**30,625**	**3.9%**	**-22.2%**
Number of Specialty Care Appointments SEEN Daily	66,969	34,999	26,235	This week, average utilization is 84% compared to 69% in April 2020, indicating more demand than supply.				
Number of MTF ER and UC Visits	4,048	2,859	2,718					





Positive COVID-19 Civilian Admissions			Two-Week Change	Percent Change
	22-Dec-21	5-Jan-22		
Total	18,125	18,640	515	3%
HNFS	4,247	4,370	123	3%
HGB	13,878	14,270	392	3%

Data Sources: Appointments: 12 Jan 22; Purchased Care: THP: 5 Jan 22

LAB COVID – 19

Center for Laboratory Medicine Services (CLMS)

SUMMARY:

- 171 DoD COVID testing sites
- **56%** of Sites Reported via MHS Survey **as of 11 Jan 2022**
- No COVID-19 related CLIP certificates issued

CONCERNS/REQUIRED ASSISTANCE:

- Request that the Services remind labs to enter accurate data on a daily basis, and report only once by 0900 for last 24 hours of testing.
- **CARES Act: DoD Compliance with HHS SARS-CoV-2 Lab Data Reporting**
- All units reminded CLIP Certificates are required prior to testing.
- **All MTF clinical lab testing must be reported.**

NEXT 30 DAYS:

- Creating COVID-19 training platform
- CARES Act SARS-CoV-2/COVID-19 Test Result Reporting
  - Awarded Sep 2021
  - Working the format to ensure PHI is protected
  - Modification submitted to adjust the format to report results until IT use HL7 format

DATA/CAPABILITY STATUS:

LAB COVID-19 testing data– DoD In House Testing (data from MHS Survey) as of 11 Jan 2022

# DoD Labs Performing COVID19 Testing	# Specimens Tested Last 24 Hours	# Specimens Tested last 7 Days	DoD Cumulative # Tests Performed to Date	MAX # Tests with Current Inventory (w/o restock)	Daily Test Capacity
171	15,670	112,525	4,163,059	658,514	40,333

Cumulative DoD Testing in Labs Outside DoD (Commercial/Non-DoD Labs) April 2020 – 08 January 2022

# COVID Lab Tests Ordered	# COVID Lab Tests Rec'd	# COVID Positive Tests	% COVID-19 Positive Test Results
625,893	594,378	26,795	5%

As of: 12 Jan 2022

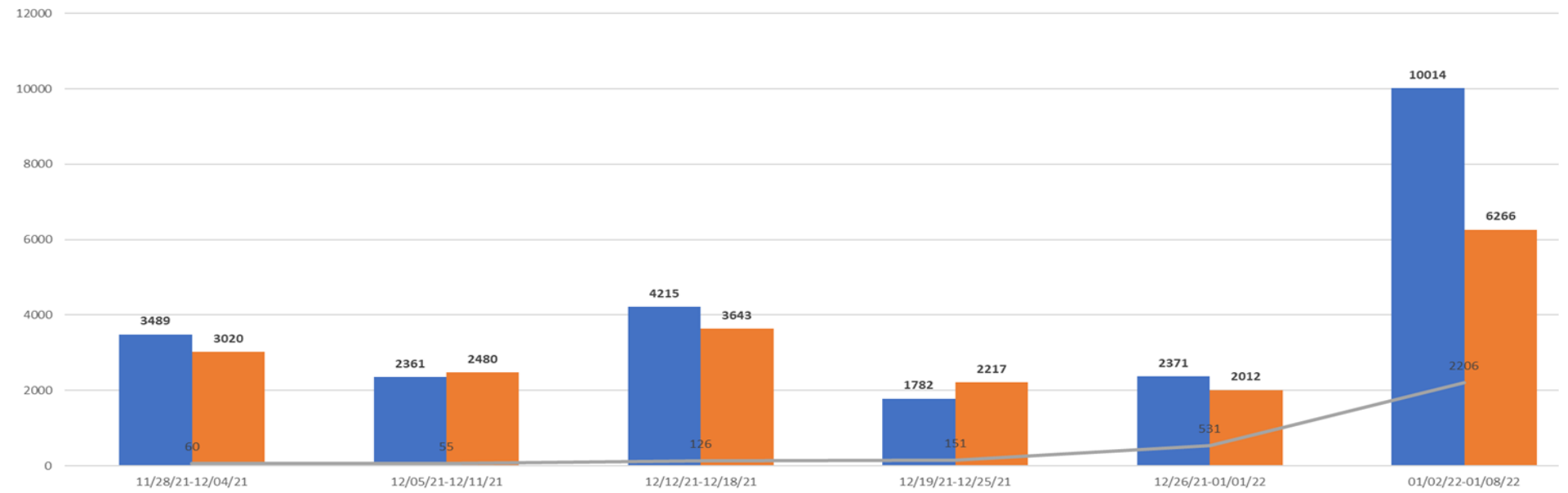
Slide POC: Maj Cooper Tatanya.l.cooper.mil@mail.mil 703-681-7317

LAB COVID – 19

Center for Laboratory Medicine Services (CLMS)

Last 6 Weeks DoD Testing in Labs Outside the DoD (Commercial & Non-DoD Labs)

Data from MHS Daily Laboratory Status Report Survey as of 9 Jan 2022



Report Week	Outside DoD Labs COVID-19 Tests Ordered	Outside DoD Labs COVID-19 Tests Received	Outside DoD Labs COVID-19 Positive Test Results	% COVID-19 Positive Test Results
11/28/21-12/04/21	3489	3020	60	2%
12/05/21-12/11/21	2361	2480	55	2%
12/12/21-12/18/21	4215	3643	126	3%
12/19/21-12/25/21	1782	2217	151	7%
12/26/21-01/01/22	2371	2012	531	26%
01/02/22-01/08/22	10014	6266	2206	35%
Grand Total	24232	19638	3129	16%

For the week of 2 January 2021, the top five highest number of tests ordered came from Portsmouth (2745), Bragg (1257), Pendleton (1101), Pyeongtaek (1020), and Drum (852).

As of: 12 Jan 2022

Slide POC: Maj Cooper Tatanya.l.cooper.mil@mail.mil 703-681-7317

MEDLOG

SUMMARY:

- **PPE Reconstitution Update:**
  - NSTR all items are tracking
- **COVID-19 Testing Materiel**
  - Validating COVID testing inventory, at-home and point of care tests, working on a dashboard to include lab survey
- **Oversight of DCIRs; MTFs using YPPE/SG05/H200 (65)**
- Added DLA Depot Stocked Items

DHA Pandemic PPE Assemblage

Item	% = Qty/Allowance	On Hand Qty	% Daily Delta	On Hand Daily Delta
Eye Protection Goggles	239%	220,086	0.0%	-75
Gloves	2142%	41,467,487	0.0%	0
Gowns	166%	12,861,822	0.0%	-200
Masks	1234%	11,926,877	-0.3%	-36,000
N-95 Respirators	116%	72,505,610	0.0%	-30,260

OH/Allowance % Color Guide:
Green (90% or >); Amber (80-89%); Red (<80%)

DLA Depot-Stocked Supplies: Specimen Collection & Handling

Item	Qty On-Hand	Qty On-Hand Delta
BINAX POC	21,680	-13,920
Nasopharyngeal collection swab (polystyrene)	5,706,600	-20,950
Transport medium	1,515,792	-24,576

DHA MTF On-Hand Inventory (PPE & Associated Items)

Item	On Hand Qty*	DDR**	DOS*	DOS Delta*
Face Shields	166,738	455	366	-2
Gloves	56,550,564	493,335	115	0
Goggles	127,381	827	154	-2
Gowns	1,138,993	9,865	115	-1
Hand Sanitizers	303,217	93	3,260	-11
Masks	6,180,784	39,618	156	1
N-95 Respirators	2,303,038	4,230	545	0
Specimen Swab***	790,889	2,517	314	64
Transport Medium***	333,663	3,600	93	15
Viral Transport Kit***	193,117	335	576	242

DOS Color Guide:
Green (30 days or >); Amber (16-29 days); Red (15 days or less)
**** Updated daily ** Updated weekly every Monday *** Data provided by CLMS Lab Survey***

As of: 12 Jan 2022
Slide POC: Lt Col Dwayne Baca, dwayne.a.baca.mil@mail.mil, 301-619-6689

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Armed Services Blood Program

COVID-19

MTF Support

MTF Transfusion Services Daily Inventory Status (CONUS & OCONUS)

	# of Products	PAR Level	Status
Total Products	9,824	9,073	108%
Total Red Cells	2,043	1,628	125%

Note: Inventory status for non- MHS GENESIS MTFs.

MTF Transfusion Services Daily Inventory Status (MHS GENESIS Sites)

	# of Products	PAR Level	Status
Total Products	1,948	2,288	85%
Total Red Cells	622	815	76%

This inventory is for MHS GENESIS sites. New PAR levels have been implemented to capture sites that have transitioned to MHSG.

COVID-19 Convalescent Plasma (CCP) as of 30 December 2021

Inventory of CCP Units	# of Patients transfused	# of units transfused*
1,571	337	502

*The patients may receive multiple CCP units as part of their treatment.



Donor Support

Weekly Donor Collections Dec 31 – Jan 6

Collection Goal	# of Collections	% of Goal Achieved
2,030	722	36%

Overall blood donations did not meet compliance for the week of Dec 31 – Jan 6.

Theater Support

Weekly Quota Compliance (Support to Theater) Dec 31 – Jan 6

	Goal	# of units received	% Compliance
RBCs	475	184	39%
LTOWB	233	63	27%

PAR Levels (Theater Support)

	PAR Levels	
CCMD	RBCs	LTOWB
CENTCOM	291	351
AFRICOM	214	272
EUCOM	288	4
INDOPACOM	382	3

*PAR Levels do not reflect current inventory.

Frozen Inventory CONUS & OCONUS

	Number of Units	Deglyc Capability
CONUS	2,708	35%
OCONUS	6,287	75%

ASBP Highlights:

1. Donor collections were low this last week due to reduced number of donors. The ASBP team released a message to promote donations.
2. National blood supply status is RED (less than 1 day supply).
3. AFRICOM PAR level status is amber due to flight availability and delayed flights.

DoD COVID-19 Convalescent Plasma (CCP) Program Updates:

- CCP capability at all 20 Blood Donor Centers (BDCs): Apheresis and/or Whole Blood; however many testing center will cease testing on 31Dec2021.
- FDA EUA: On 4 February 2021, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of CCP; specifies additional testing platforms required to label CCP as "High Titer" and the use of only "High Titer" CCP in hospitalized patients early in the course of disease. Cut-off for Ortho Vitros IgG is now >9.5.
- DOD EUA CCP (Tested on Ortho VITROS IgG Platform): Current DoD CCP inventory is EUA compliant.

As of 12JAN2022
Slide POC: COL Taylor, Audra

SERVICES


DEPARTMENT OF THE ARMY
UNITED STATES OF AMERICA
1775


DEPARTMENT OF THE NAVY
UNITED STATES MARINE CORPS


DEPARTMENT OF THE NAVY
UNITED STATES OF AMERICA


DEPARTMENT OF THE AIR FORCE
MCMXLVII
UNITED STATES OF AMERICA

Alibis

Guidance and Closing Remarks

COVID-19
WAY-FORWARD

Next Assistant Director's Update Brief

- 20220112
- Dial-in: 888-453-0468
- Pin: 62946640#

SharePoint Links

- ADUB Slides - https://info.health.mil/hco/j35/CAT/Pages/JOC-Daily-Briefs.aspx
- CAT SharePoint - https://info.health.mil/hco/j35/CAT/Pages/Home.aspx

By Exception Briefs

Dental Operations

COVID-19

SUMMARY:

The military dental enterprise continues to provide readiness-related dental care in the military treatment facilities (MTFs) to ensure the readiness of the Force while safeguarding the health and well-being of clinic personnel and patients.

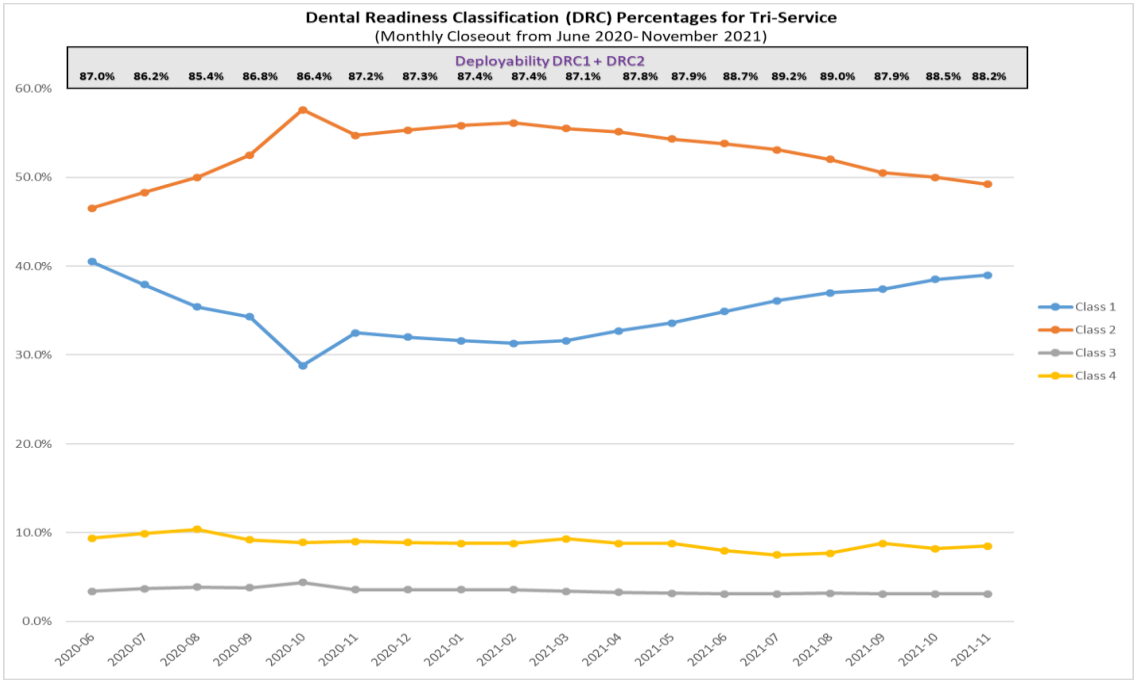
If MTFs do not have the capacity, network providers are capable of absorbing referrals from the Active Duty Dental Program (ADDP). The DHA TRICARE Dental Program Section (TDPS) under DAD-HCO is tracking market viability to ensure eligible beneficiaries under the TRICARE Dental Program and ADDP Remote have access to care to include areas in the remote regions. If a large number of activated NG/Reservists are attempting to seek direct care in MTFs with limited capacity, the Dental Directors/Commanders can request DHA TDPS to designate certain units as ADDP Remote and receive care through network providers.

PRIORITIES:

(1) Increasing operations following 8 Mar 21 Consolidated Outpatient Guidance and local conditions
(2) Maintaining visibility on possible COVID related degradation of services
(3) Ensuring any local COVID-related patient backlog is appropriately adjudicated
(4) Supporting operations WRT possible variant impacts

HPCON Status (CONUS & OCONUS)

DTFs align with Installation HPCON Status. The majority of military dental clinics continue to provide readiness-related dental care and expand services as permitted by their available local resources.



CONCERNS:

As OCONUS DTFs expand services and address dental readiness of the force, military family members will more likely depend on the TOPD network providers for dental services. Currently, access to dental care for family members overseas is available through the TOPD and space A in the MTF/DTFs.

REQUIRED ASSISTANCE:

- Continued support by MEDLOG to ensure PPE accessibility as dental services continue to increase throughout the MHS.

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Updated as of 1300, 12 JAN 2022
Col Jay Graver/jay.d.graver.mil@mail.mil/703-681-5339

J-1 Administration & Management

COVID-19

SUMMARY:

Return To Workplace

- FPCON Bravo
- **HPCON BRAVO Plus**
- **Pentagon HPCON Bravo Plus**
- DHHQ Phase 2, since 6 July 2020
- Gym open: 0530-1800, (Monday – Friday) CAC is needed after 1800-0530 and weekends/holidays
- Showers are available – Multi Purpose Room open
- Personnel with METRO Subsidy may park at DHHQ on a TEMPORARY basis
- Conference Rooms – Limit gatherings to fewer than 25 persons
- **Facility Occupancy – No more than 40% of normal occupancy; supervisors will provide maximum telework opportunities to all current telework eligible personnel.**
- **As of 28 July 2021, service members, federal employees and onsite contractor employees will wear a mask in indoor settings on Pentagon Reservation regardless of vaccinated status. DOES NOT include the MTF/DTF/VTFs**
- **NCR Administrative Offices - HPCON BRAVO PLUS (9 Sept 2021)**
- Effective November 1, 2021, all visitors entering the Defense Health Headquarters will be required to present a completed and signed Department of Defense Form 3150 "CERTIFICATION OF VACCINATION", indicating their current vaccination status.

CONCERNS/REQUIRED ASSISTANCE

- Continue COVID-19 mitigations by hand washing, wearing a mask, distancing, and avoiding large gatherings.

-The following face coverings are not authorized: Neck Gaiter; Mask with Values; Bandanas

LAST 24 HOURS

- NSTR

NEXT 24 HOURS

- NSTR

CAPABILITY STATUS

- NSTR

As of: 0900, 12 January 2022
Slide POC: scott.a.legge.civ@mail.mil

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Pharmacy Operations Division (POD)

COVID-19

SUMMARY:

The role of the POD is to assist established Markets, Services, and MTFs in provisions of the pharmacy benefit. Knowledge of current and changing capabilities of MTF Pharmacies across the enterprise allows DHA to be more responsive as situations dictate.

CONCERNS/REQUIRED ASSISTANCE:

- Allocated Medications
  - Acetaminophen oral
  - Advair and Flovent
  - Chloroquine
  - Albuterol and Levalbuterol
  - Azithromycin
  - Insulin
  - Dexamethasone
  - Inpatient Medications
    - Dexamethasone injectable, Methylprednisolone injectable, Propofol, Fentanyl, Midazolam, and Paralytics

Previous 7 Days

- COVID-19 Closures
  - NBHC Key West (January 7th and 10th)
- RTS Waivers
  - Washington State, 2 counties due to flooding; through 20JAN22

Next 7 Days

- DHA POD World Wide Webinar (19 JAN 22 @ 1300)

Capability Status:

- COVID-19 Closures
  - None
- Operational Limitations/Restrictions
  - NBHC Temecula Pharmacy (4NOV21)
    - Flooding in Pharmacy caused by burst water pipe
    - Leased building
      - Expected closure 6-8 weeks (optimistic timeline)

As of: 1130 12JAN22
Slide POC: COL Randy D. Dorsey @ randy.d.dorsey.mil@mail.mil 703-681-8808

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Backup

LAB COVID – 19

Center for Laboratory Medicine Services (CLMS)

Current as of 11 January 2022	Available	Operational
DoD Lab Facilities	171	171
Total Labs Reported	56%	
New Sites Performing COVID Testing: 0	NA	
Sites w/New Expansions: 0	NA	
Daily Testing Capacity:		40,333
Max Number of Tests w/Current Inventory - *(w/o restock)*		658,514
Specimens Tested		
MTFs: Specimens Tested in Last 24 Hrs		15,670
MTFs: Total number of Specimens Tested in the Last 7 days		112,525
MTFs: Total Number of specimens Tested To-Date: *		**4,137,195**
DoD Cumulative Tests To-Date per CVTF D&T		4,163,059
Operational Significance	**** (3,605)*** ***Added to MTFs Total Number of Specimens Tested to Date***	

NUREMBURG 2.0 IN AMERICA – IT IS TIME

Renz Law

Renz-Law.com

WHERE WE ARE

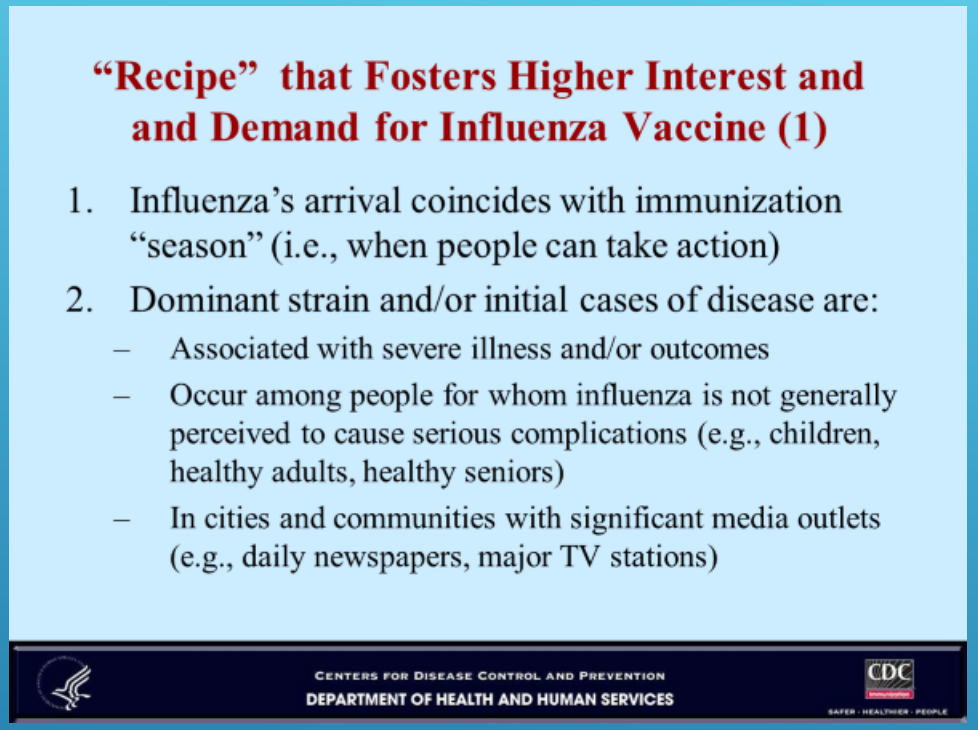
- At this point it is indisputable that the entirety of the world has been lied to about COVID-19.
- This presentation will lay out the lie and the path forward.
- This must include criminal and civil investigations by INDEPENDENT investigators, as well as prosecution where appropriate.
- At the end of this presentation we challenge anyone to suggest INDEPENDENT investigations are inappropriate with complete disclosure and transparency.

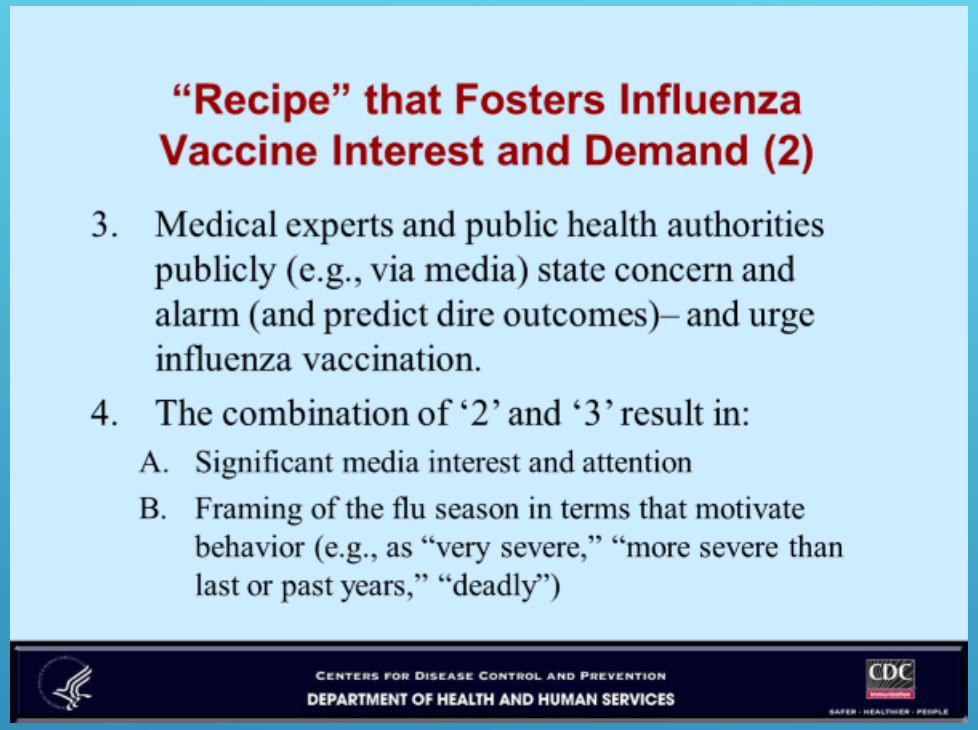
THE EVIDENCE

- At this point it is indisputable that everything about the "pandemic" and the "vaccines" is a lie.
- While there is more evidence than could be presented in any single presentation, we will discuss data from four primary sources here.
  - The United States Department of Defense Document
  - The Pfizer Analysis of Post-Authorization of Adverse Event Reports
  - A CDC presentation promoting the use of fear to manipulate the public
  - Whistleblower data from the Center for Medicare and Medicaid Services
- We also touch on the COVID Consumer Protection Act and some other potential legal issues.

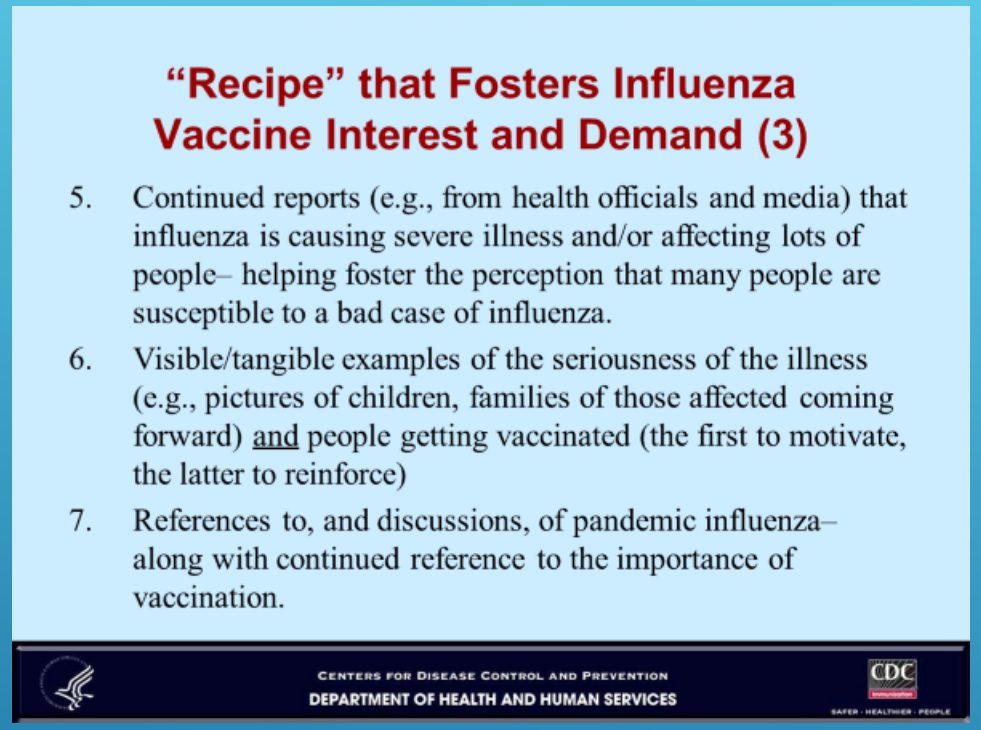
THE FEAR AND MANIPULATION PRESENTATION

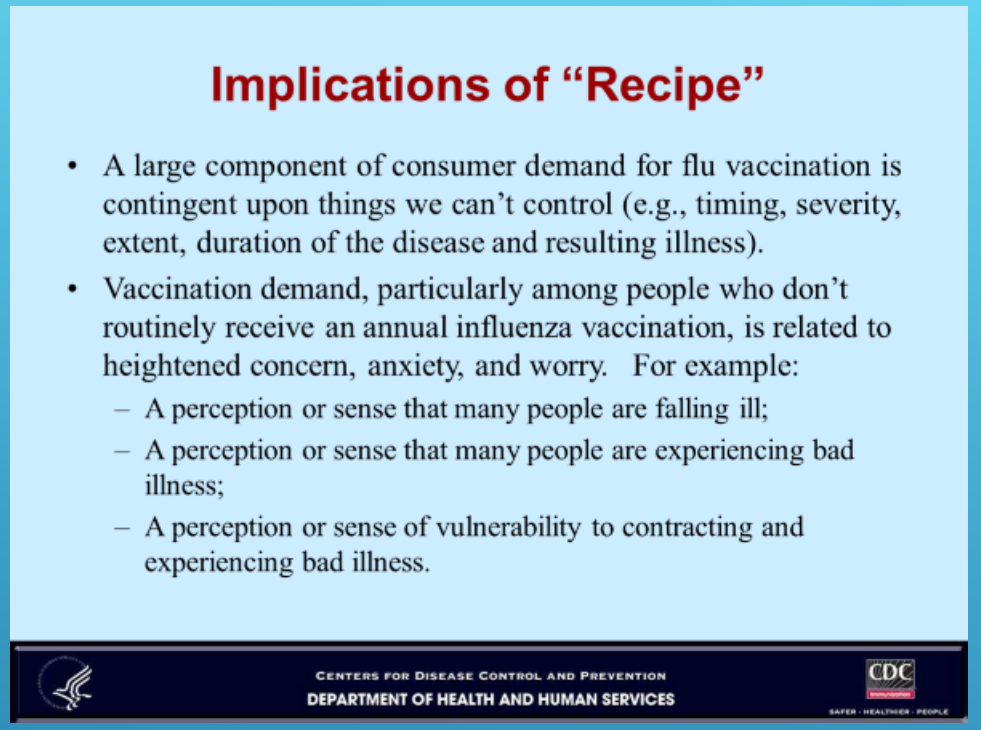
- Public health has used fear and manipulation for years against the public
- The next few slides are critical in understanding the global fraud now occurring
- These documents are from the CDC and DHHS



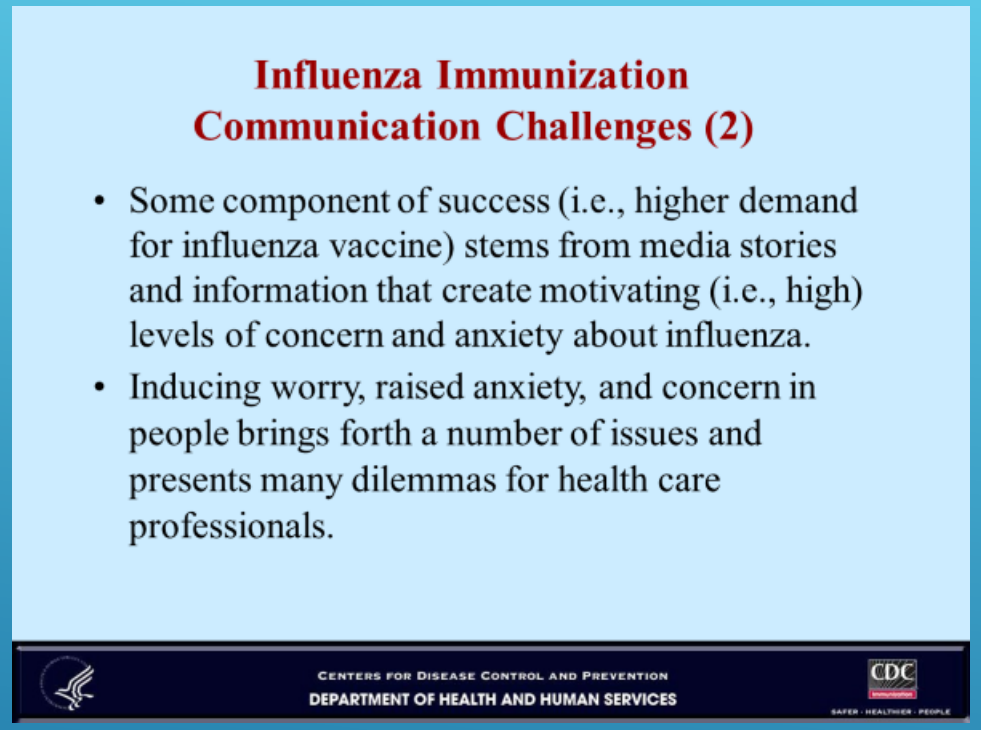


THE CDC RECIPE FOR FEAR





CDC AND FEAR CONT.

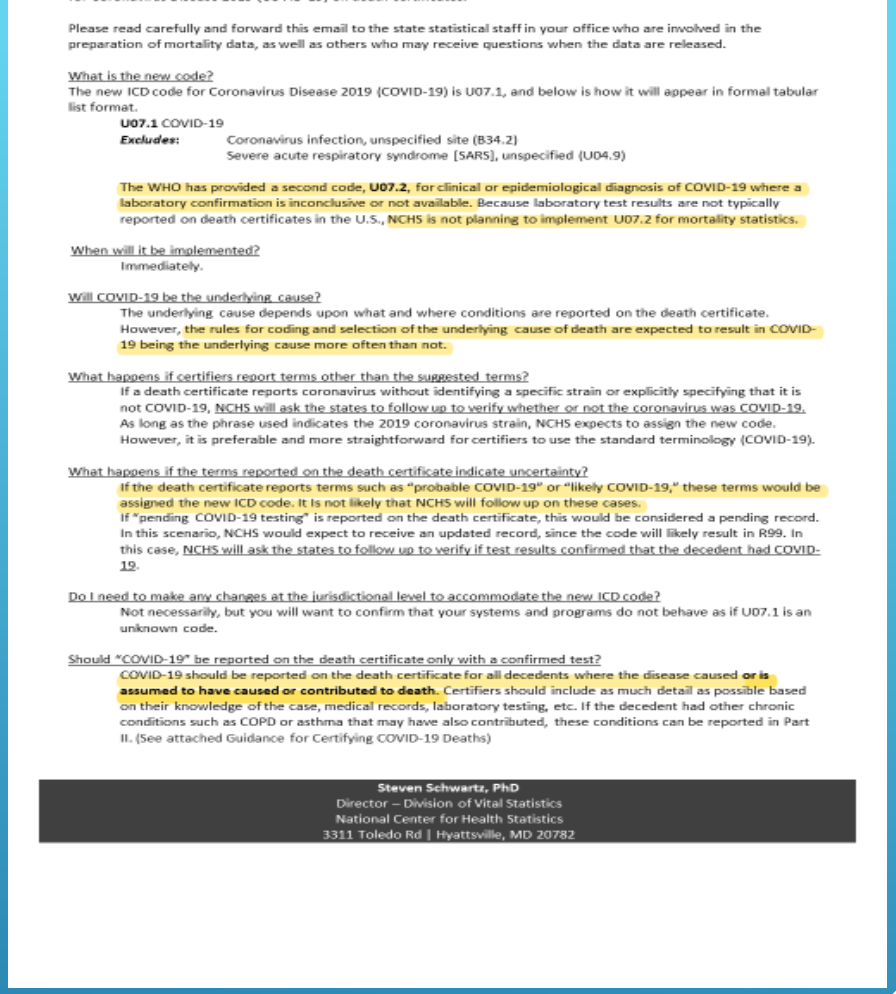




CDC SUCCESS = CREATING FEAR

THE USE OF FEAR IS NOT NEW - BUT HAS NOW BEEN MASTERED

- This presentation was well developed and based on years of work related to the use of fear in public health
- The presentation was presented by the CDC regarding the 2004-2005 flu season
- The use of fear and manipulation in public health has been mastered and leveraged to the maximum extent possible with COVID
- Truth does not matter – only creating "heightened concern, anxiety, and worry."
- The document shown here is one of the primary methods the CDC has used to promote fear of COVID – they wanted every death to be called a COVID death



Please read carefully and forward this email to the state statistical staff in your office who are involved in the preparation of mortality data, as well as others who may receive questions when the data are released.

What is the new code?
The new ICD code for Coronavirus Disease 2019 (COVID-19) is U07.1, and below is how it will appear in formal tabular list format.

U07.1 COVID-19
Excludes: Coronavirus infection, unspecified site (B34.2)
Severe acute respiratory syndrome [SARS], unspecified (U04.9)

The WHO has provided a second code, **U07.2**, for clinical or epidemiological diagnosis of COVID-19 where a laboratory confirmation is inconclusive or not available. Because laboratory test results are not typically reported on death certificates in the U.S., NCHS is not planning to implement U07.2 for mortality statistics.

When will it be implemented?
Immediately.

Will COVID-19 be the underlying cause?
The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not.

What happens if certifiers report terms other than the suggested terms?
If a death certificate reports coronavirus without identifying a specific strain or explicitly specifying that it is not COVID-19, NCHS will ask the states to follow up to verify whether or not the coronavirus was COVID-19. As long as the phrase used indicates the 2019 coronavirus strain, NCHS expects to assign the new code. However, it is preferable and more straightforward for certifiers to use the standard terminology (COVID-19).

What happens if the terms reported on the death certificate indicate uncertainty?
If the death certificate reports terms such as "probable COVID-19" or "likely COVID-19," these terms would be assigned the new ICD code. It is not likely that NCHS will follow up on these cases.
If "pending COVID-19 testing" is reported on the death certificate, this would be considered a pending record. In this scenario, NCHS would expect to receive an updated record, since the code will likely result in R99. In this case, NCHS will ask the states to follow up to verify if test results confirmed that the decedent had COVID-19.

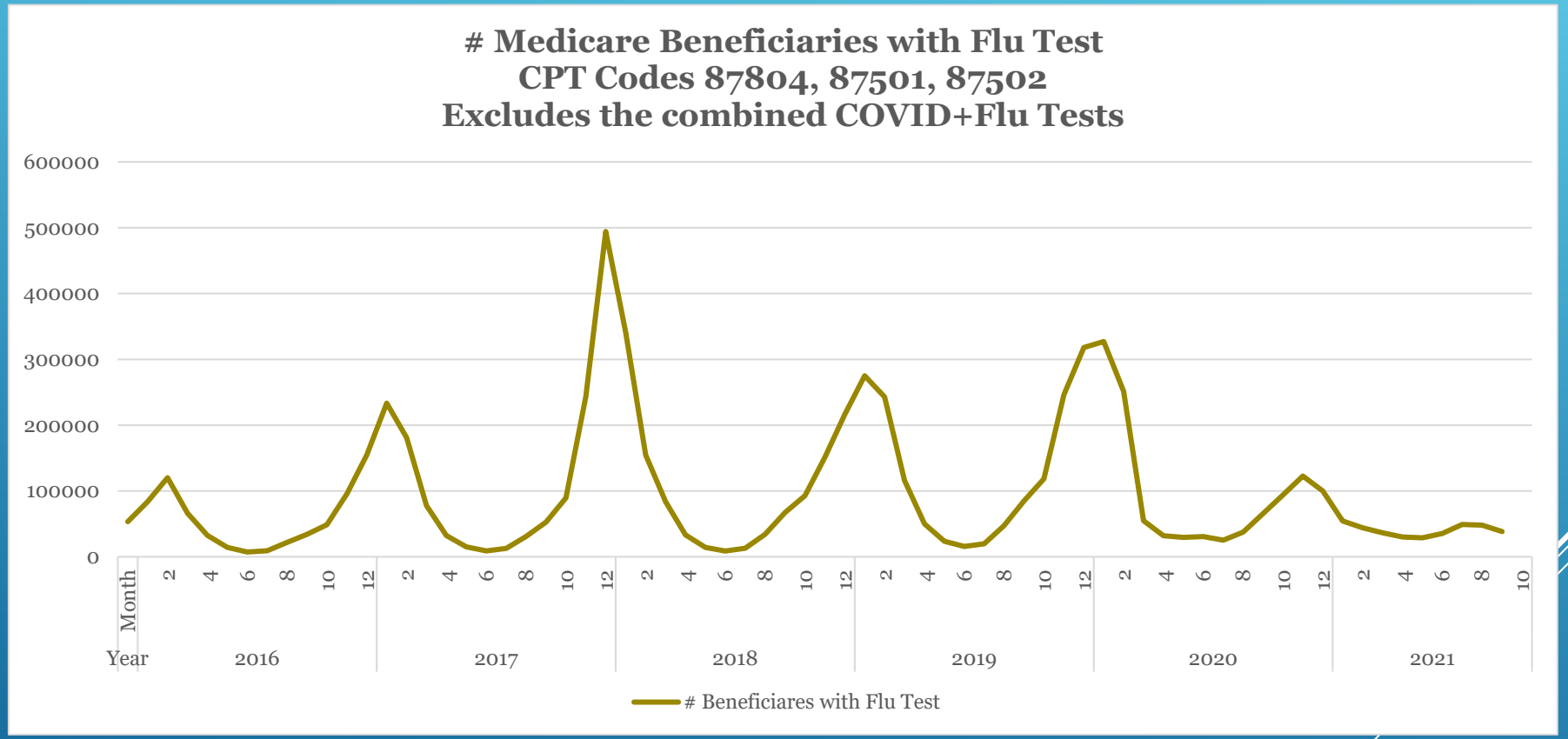
Do I need to make any changes at the jurisdictional level to accommodate the new ICD code?
Not necessarily, but you will want to confirm that your systems and programs do not behave as if U07.1 is an unknown code.

Should "COVID-19" be reported on the death certificate only with a confirmed test?
COVID-19 should be reported on the death certificate for all decedents where the disease caused **or is assumed to have caused or contributed to death.** Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II. (See attached Guidance for Certifying COVID-19 Deaths)

Steven Schwartz, PhD
Director – Division of Vital Statistics
National Center for Health Statistics
3311 Toledo Rd | Hyattsville, MD 20782

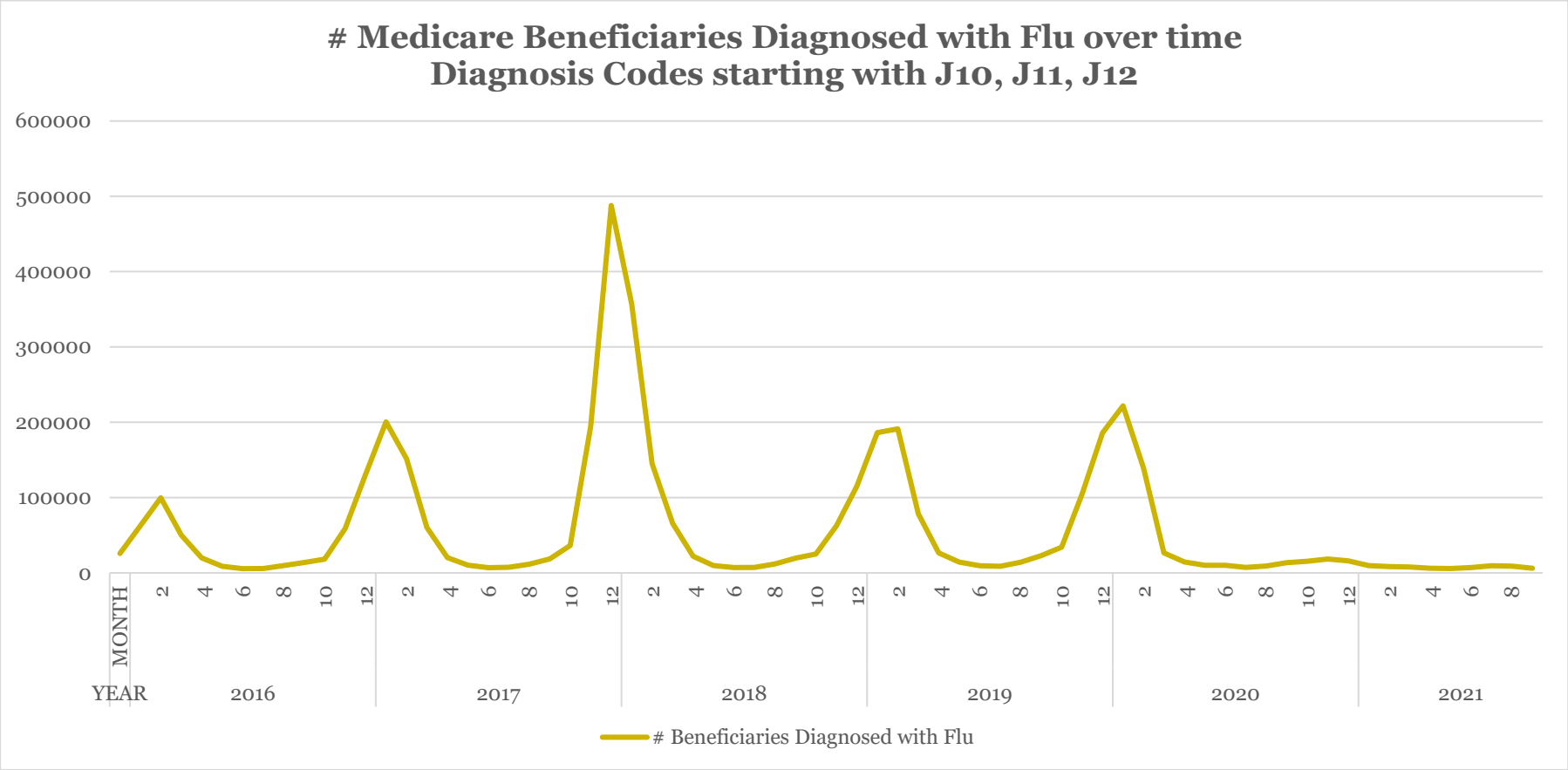
WHERE DID THE FLU GO?

Flu testing decreased significantly almost to a halt in late 2020



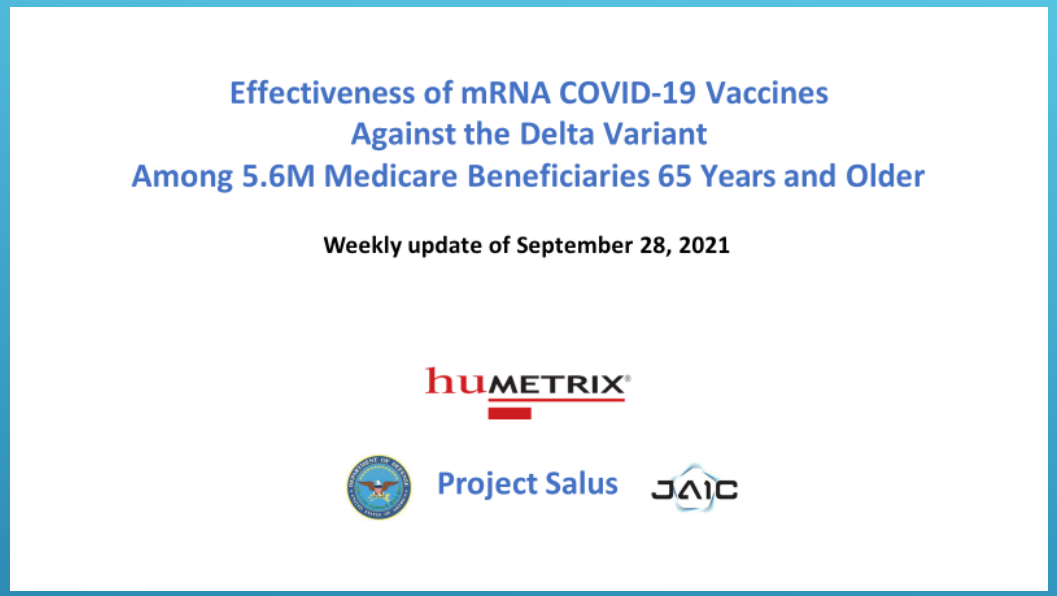
WHERE DID THE FLU GO?

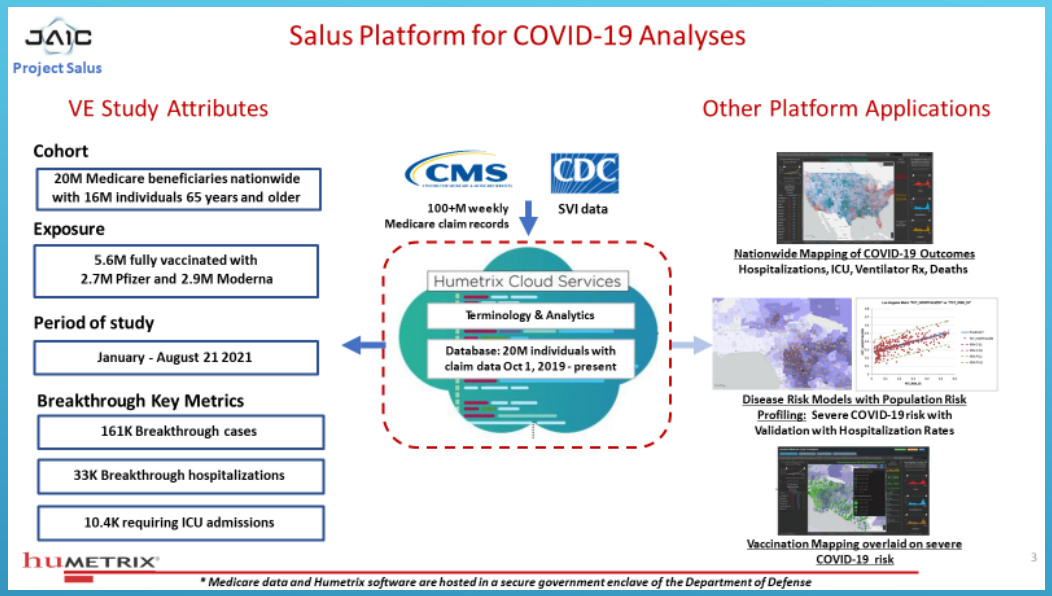
The graph below shows the number of Medicare beneficiaries who had a Diagnosis of influenza, defined as a diagnosis code starting with J10, J11, or J12. Only primary and secondary diagnosis codes were queried.



THE DOD DOCUMENT

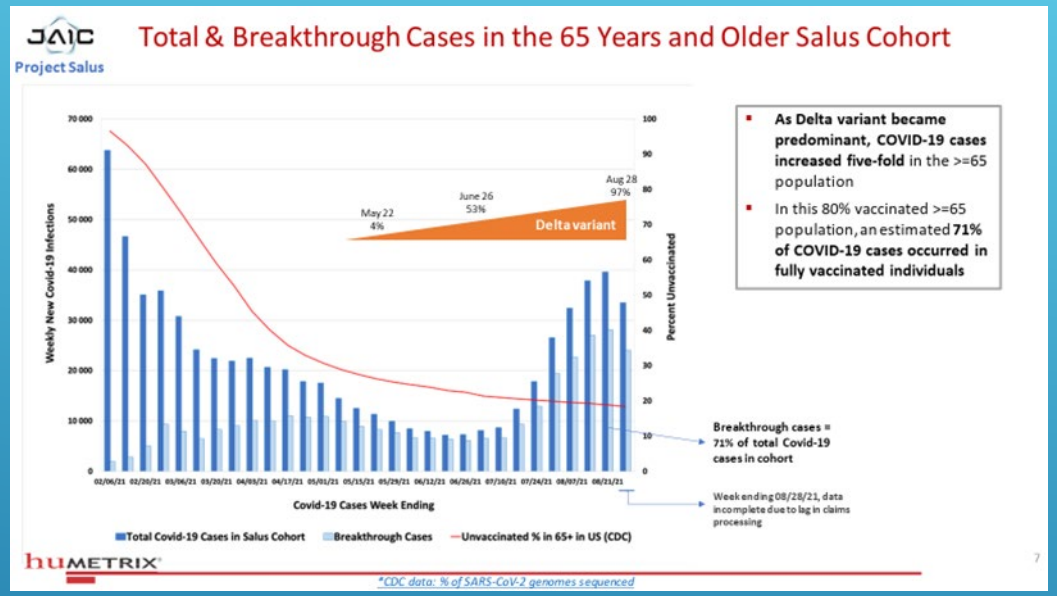
- Several weeks ago we publicized a document from the United States Department of Defense.
- That document was publicly available on the internet and was a "weekly report" regarding the "vaccines"
- Prior to that time and even occasionally since, some of our elected leaders, the media, and many bureaucrats have stated that we are seeing a crisis of the unvaxxed and that the hospitals were overflowing with unvaxxed patients. They lied.
- According to the DoD, 60% of hospitalizations and 71% of new cases were in fully vaccinated individuals.
- It also showed the vaccines fared even worse in people of color than in white people.
- Why aren't all of these "weekly reports" public?

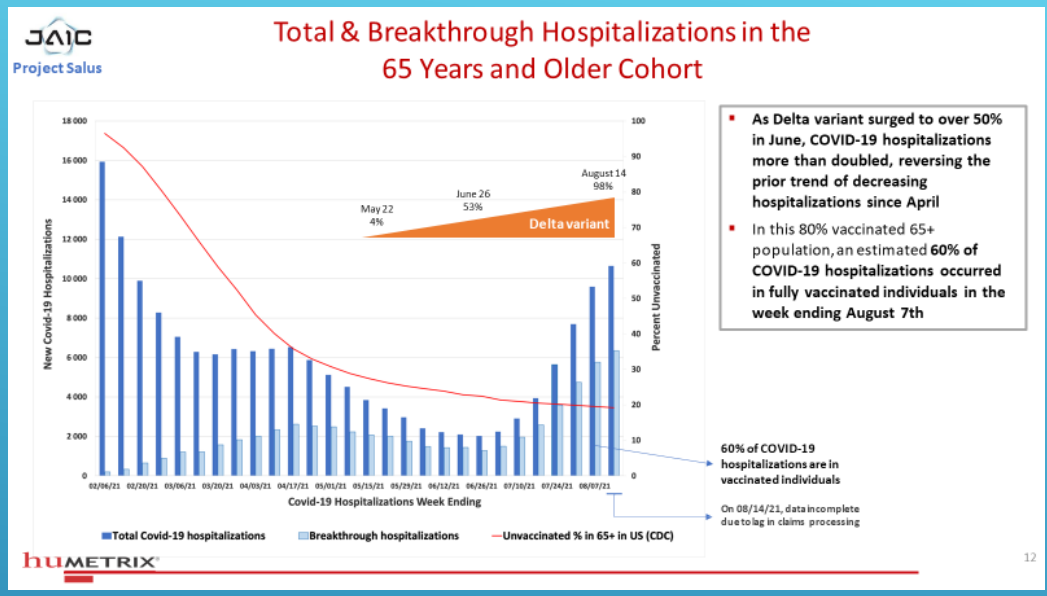




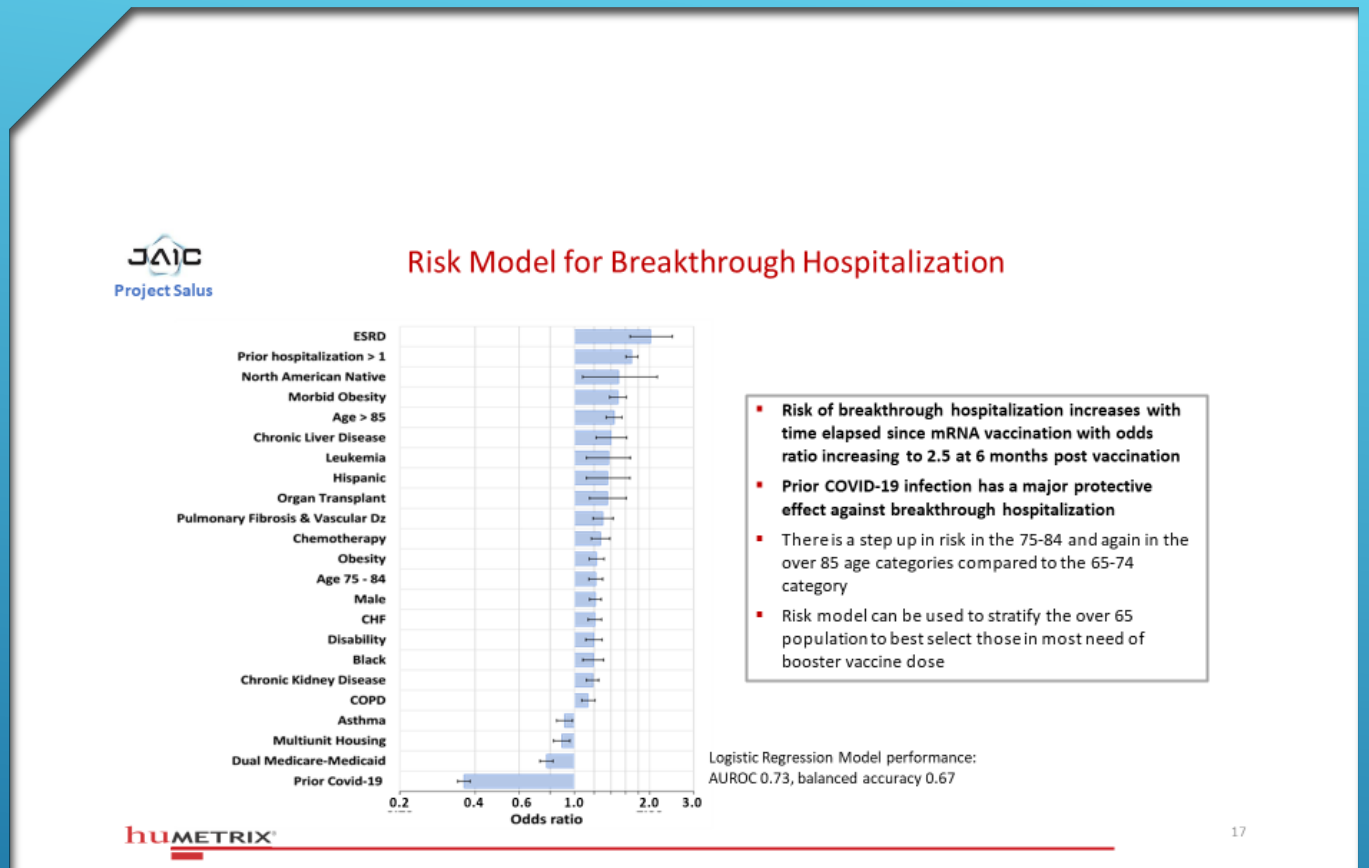
DOD EXCERPTS

- NOTE THE DOD SEAL AND THAT THEY ANALYZE CMS





DOD EXCERPTS 2



DOD EXCERPTS 3

Why is this less effective against North American Natives, Hispanics, and "Blacks"

THE PFIZER REPORT

- The government fought in court to hide the Pfizer document.
- Thanks to the actions of a group known as Public Health and Medical Professionals for Transparency and their attorney Aaron Siri, this document was made public.
- This document notes that there may be underreporting of adverse events.

GENERAL INFORMATION

- The Pfizer document only analyzes adverse event reports through February 28, 2021.
- The Pfizer vaccine was only authorized in the USA just over 2 months prior to this date on December 11, 2020. The document notes shipping began December 1st, 2020.
- In that time, the document admits the following about this safe and effective "vaccine" – please note these numbers do not include the other available "vaccines":
  - 42,086 cases reported including 158,893 adverse events.
  - This includes 1,223 deaths.
  - This despite the fact that there were 9,400 unknown case outcomes which could have included additional deaths.

- Anaphylaxis – which can result in death – occurred in 1883 of the 42,086 cases. This indicates a very high risk of immediate danger to anyone receiving a jab.
- COVID infection post vaccination was reported in 3,067 cases, this was 7.3% of the data set. 136 of these cases resulted in death.
- There were 1,403 "cardiovascular AESIs (Adverse Events of Special Interest) including heart attacks, heart failure, etc. (3.3% of the data set). 136 of these cases resulted in death. Pfizer concluded that "This cumulative case review does not raise new safety issues." We hope that is comfort to those 1,403 people.
- While there are a number of other horrendous facts included, we find the development of Herpes being listed amongst "Other AESIs" particularly noteworthy. It is unclear whether Pfizer was tracking the potential of the "vaccine" to facilitate herpes infection; however, herpes was listed as an AESI in several hundred cases.

INFO CONTINUED 1

- Though the jab was not generally authorized for pregnant women a small number but unknown number received it. Of the women that received it there were 274 case reports in women and their babies/fetuses.
- Within these 274 case reports there were 23 spontaneous abortions.
- No outcome was provided for 238 of the pregnancies.
- The document seems to indicate that exposure via breast milk is a legitimate concern and that there were 17 reported cases of adverse events for the babies exposed in this way.

INFO – PREGNANCY AND BABIES

IMPORTANT NOTE:

- Data was gathered at different points in time so some numbers may not agree. This is because each day that goes by means more are hurt or injured without informed consent by these dangerous jabs and so the numbers continue to increase.
- Key take-away is that these shots are dangerous and our elected officials, AG's, and prosecutors MUST take action.



COVID-19 VACCINE DEATHS & ADVERSE EVENTS

An analysis of COVID-19 vaccine deaths derived from CMS Medicare and Medicaid data – Causality?

The real issue is where is the INDEPENDENT investigation?

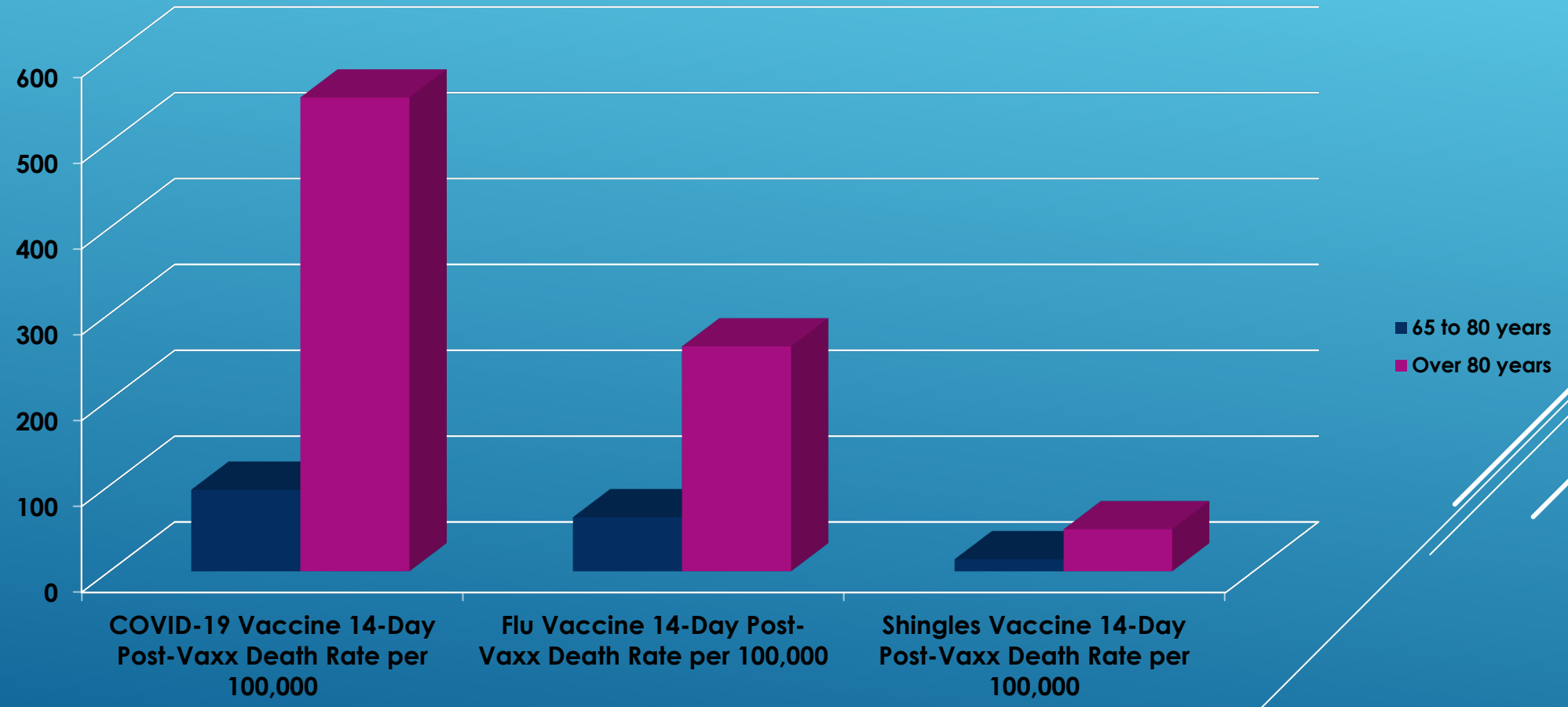
COVID-19 VACCINE COMPARED TO FLU & SHINGLES VACCINE (ALL AGES IN MEDICARE) – SOME PEOPLE RECEIVED FLU/COVID VAX AT THE SAME TIME SO THE REAL NUMBERS ARE WORSE

Year	# of Benes with COVID-19 Vaccine	# Benes who died within 14 days of COVID-19 vaccine	# Benes who died within 14 days of COVID-19 vaccine PER 100,000	# Benes who had Flu Vaccine	# Benes who died within 14 days of Flu Vaccine	# Benes who died within 14 days of Flu Vaccine PER 100,000
2021	27,431,845	52,030	189	N/A	N/A	N/A
2020	N/A	N/A	N/A	23,441,863	25,473	108
2019	N/A	N/A	N/A	22,810,724	23,740	104
2018	N/A	N/A	N/A	23,023,803	25,591	111

Year	# of Benes with COVID-19 Vaccine	# Benes who died within 14 days of COVID-19 vaccine	# Benes who died within 14 days of COVID-19 vaccine PER 100,000	# Benes who had Shingles Vaccine	# Benes who died within 14 days of Shingles Vaccine	# Benes who died within 14 days of Shingles Vaccine PER 100,000
2021	27,431,845	52,030	189	N/A	N/A	N/A
2020	N/A	N/A	N/A	548,757	117	21.3
2019	N/A	N/A	N/A	528,975	105	19.8
2018	N/A	N/A	N/A	347,007	81	23.3

Comparison of COVID-19 Vaccine with Other Vaccine: Death Rates per 100,000

Death rates per 100,000 where death occurred within *14 days of the vaccine*



MEDICARE DEATHS WITHIN 14 DAYS OF 1ST VACCINE DOSE

n=29,398

Total deaths 14 days after 1st dose: 29,398

Total deaths 14 days after 2nd dose: 21,031

Total: 50,429

Days Died After 1st Dose	# Beneficiaries Died	% Beneficiaries Died	Cumulative Number	Cumulative Percentage
0	555	1.89	555	1.89
1	1,137	3.87	1,692	5.76
2	1,492	5.08	3,184	10.83
3	1,654	5.63	4,838	16.46
4	1,750	5.95	6,588	22.41
5	1,876	6.38	8,464	28.79
6	1,924	6.54	10,388	35.34
7	2,095	7.13	12,483	42.46
8	2,099	7.14	14,582	49.60
9	2,244	7.63	16,826	57.24
10	2,266	7.71	19,092	64.94
11	2,458	8.36	21,550	73.30
12	2,593	8.82	24,143	82.12
13	2,595	8.83	26,738	90.95
14	2,660	9.05	**29,398**	100.00

MEDICARE DEATHS WITHIN 14 DAYS OF 2ND VACCINE DOSE

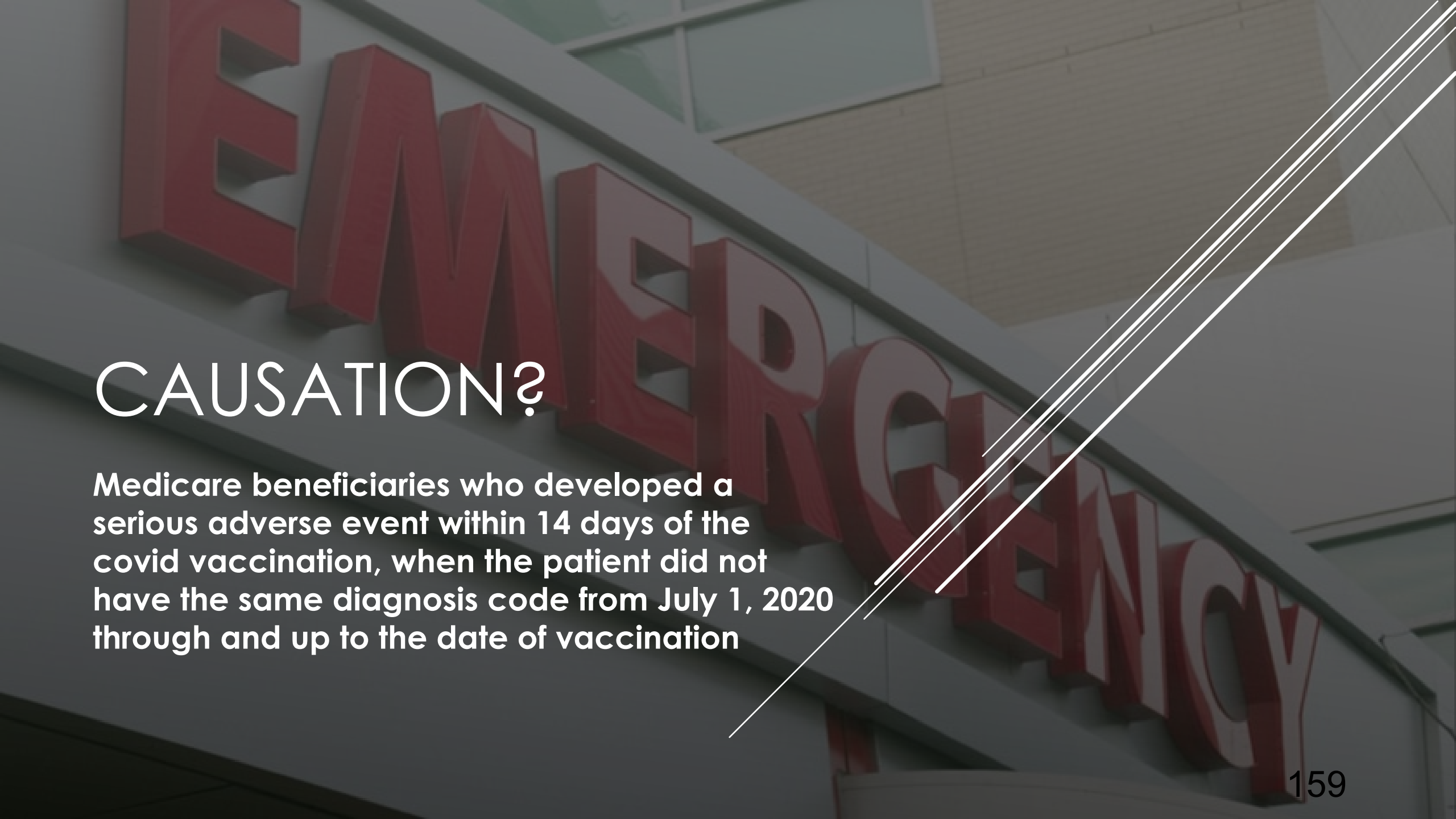
n=21,031

Total deaths 14 days after 1st dose: 29,398

Total deaths 14 days after 2nd dose: 21,031

Total: 50,429

Days Died After 2nd Dose	# Beneficiaries Died	% Beneficiaries Died	Cumulative Number	Cumulative Percentage
0	362	1.72	362	1.72
1	1023	4.86	1385	6.59
2	1186	5.64	2571	12.22
3	1218	5.79	3789	18.02
4	1326	6.30	5115	24.32
5	1398	6.65	6513	30.97
6	1426	6.78	7939	37.75
7	1508	7.17	9447	44.92
8	1541	7.33	10988	52.25
9	1570	7.47	12558	59.71
10	1602	7.62	14160	67.33
11	1708	8.12	15868	75.45
12	1678	7.98	17546	83.43
13	1740	8.27	19286	91.70
14	1745	8.30	**21031**	100.00



CAUSATION?

Medicare beneficiaries who developed a serious adverse event within 14 days of the covid vaccination, when the patient did not have the same diagnosis code from July 1, 2020 through and up to the date of vaccination

This section analyzes Medicare beneficiaries who did NOT have selected serious adverse events from July 1 2020 to the date of vaccination, then developed the adverse event (AE) within 14 days of the COVID-19 vaccine. This is as close to causality as we can get in the data. The patient did not have any Medicare claims with the select diagnosis codes, then had a sudden onset of the condition within 14 days of the shot. Refer to table 1 for the list of adverse events



14 days later…

VACCINE CAUSALITY?

List Serious Adverse Event (AE)
ACUTE KIDNEY FAILURE
ANAPHYLAXIS
CARDIAC ARREST
CEREBROVASCULAR EVENT
COVID-19
EMBOLISM
ENCEPHALITIS/MYELITIS/ENCHEPHALOMYELITIS /MENINGITIS/ENCEPHOLATPATHY
GUILLAIN-BARRE SYNDROME
INTRAVASCULAR COAGULATION
KAWASKI DISEASE
MYO-ENDO-PERI-CARDITIS
MYOCARDIAL INFARCTION
NARCOLEPSY/CATAPLEXY
PLEGIA/PALSY/PARALYSIS
PNEUMONIA
RESPIRATORY DISTRESS
RESPIRATORY FAILURE
RESPIRATORY INFECTION
RESPIRATORY SYNCYTIAL VIRUS
SEIZURE/CONVULSION
STROKE/CEREBRAL INFARCTION
THROMBOCYTOPENIA
THROMBOSIS

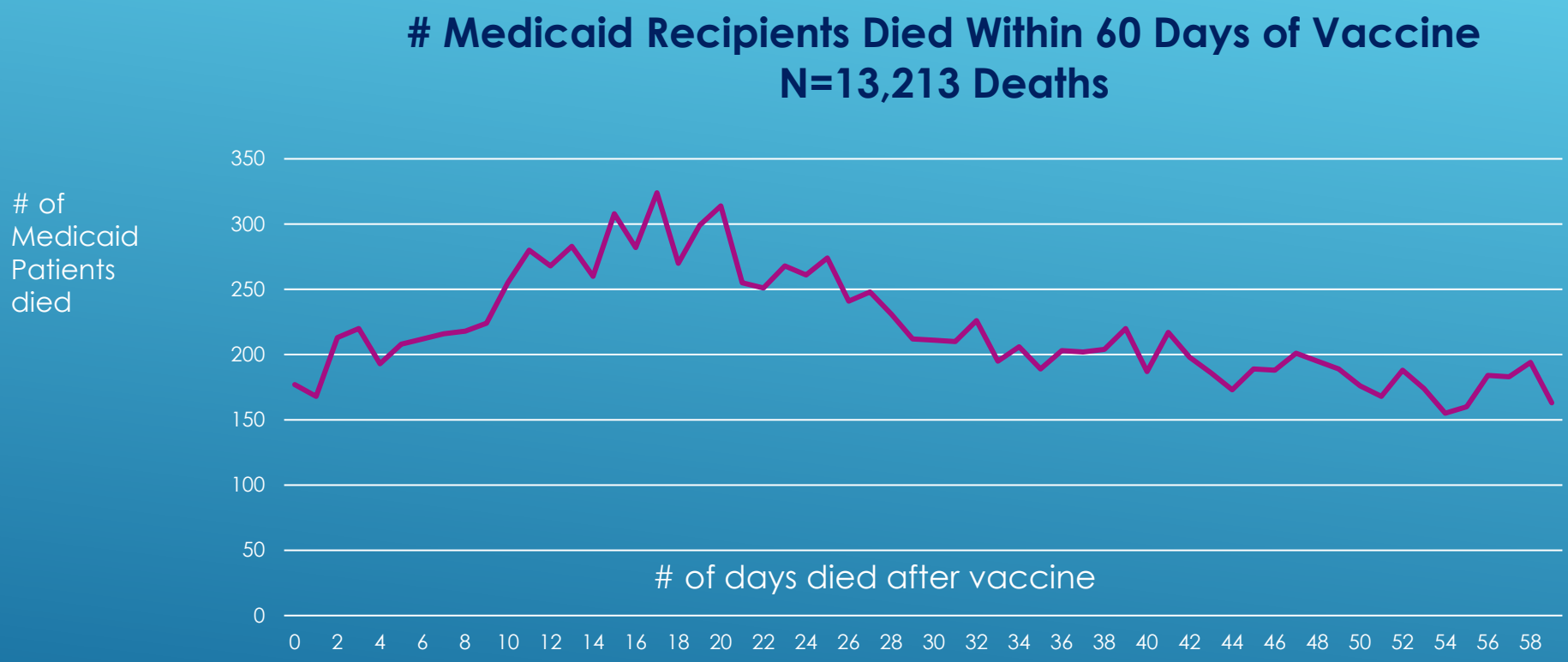
TEXAS: ADVERSE EVENTS WITHIN 14 DAYS OF VACCINE

TEXAS Serious Adverse Event (AE)	# Beneficiaries Developed the Adverse Event	# Beneficiaries who Developed the AE and Died	% Beneficiaries who Developed the AE and Died
ACUTE KIDNEY FAILURE	3633	1004	27.6%
ANAPHYLAXIS	161	6	3.7%
CARDIAC ARREST	***609***	***488***	***80.1%***
CEREBROVASCULAR EVENT	1330	201	15.1%
COVID-19	10271	1286	12.5%
EMBOLISM	2320	373	16.1%
ENCEPHALITIS/MYELITIS/ENCHEPHALOMYELITIS/ MENINGITIS/ENCEPHOLATPATHY	63	10	15.9%
GUILLAIN-BARRE SYNDROME	22	1	4.5%
INTRAVASCULAR COAGULATION	35	27	77.1%
KAWASKI DISEASE	2		
MYO-ENDO-PERI-CARDITIS	290	39	13.4%
MYOCARDIAL INFARCTION	2694	457	17.0%
NARCOLEPSY/CATAPLEXY	38	5	13.2%
PLEGIA/PALSY/PARALYSIS	1753	329	18.8%
PNEUMONIA	4141	1176	28.4%
SEIZURE/CONVULSION	1173	171	14.6%
STROKE/CEREBRAL INFARCTION	3638	472	13.0%
THROMBOCYTOPENIA	2973	370	12.4%
THROMBOSIS	2114	309	14.6%

CALIFORNIA: ADVERSE EVENTS WITHIN 14 DAYS OF VACCINE

CALIFORNIA Serious Adverse Event (AE)	# Beneficiaries Developed the Adverse Event	# Beneficiaries who Developed the AE and Died	% Beneficiaries who Developed the AE and Died
ACUTE KIDNEY FAILURE	4700	1286	27.4%
ANAPHYLAXIS	184	11	6.0%
CARDIAC ARREST	***608***	***439***	***72.2%***
CEREBROVASCULAR EVENT	1792	275	15.3%
COVID-19	7541	944	12.5%
EMBOLISM	3282	471	14.4%
ENCEPHALITIS/MYELITIS/ENCHEPHALOMYELITIS /MENINGITIS/ENCEPHOLATPATHY	128	23	18.0%
GUILLAIN-BARRE SYNDROME	47	2	4.3%
INTRAVASCULAR COAGULATION	53	38	71.7%
KAWASKI DISEASE	1		
MYO-ENDO-PERI-CARDITIS	380	62	16.3%
MYOCARDIAL INFARCTION	4412	586	13.3%
NARCOLEPSY/CATAPLEXY	42	2	4.8%
PLEGIA/PALSY/PARALYSIS	2806	344	12.3%
PNEUMONIA	4550	1278	28.1%
SEIZURE/CONVULSION	1503	166	11.0%
STROKE/CEREBRAL INFARCTION	5573	631	11.3%
THROMBOCYTOPENIA	11445	662	5.8%
THROMBOSIS	2774	389	14.0%

MEDICAID DEATHS WITHIN 60 DAYS OF COVID-19 VACCINE*



*Please note, the majority of CMS-covered vaccinations were covered by Medicare, as Medicaid is the "payer of last resort"

CMS estimates that only 48% of all vaccinations were captured

In the Integrated Data Repository (IDR),
because many providers and mass vaccinations centers
were providing vaccinations for free. These numbers are largely under-reported.

MEDICAID PATIENTS WHO DIED WITHIN 28 DAYS OF COVID-19 VACCINE, BY AGE GROUP

Age Group	# of Patients Died within 28 Days of COVID Vaccine	Percent of Total	Cumulative #	Cumulative %
1: 0-30 YEARS	101	1.44	101	1.44
2: 31-65 YEARS	2,162	30.73	2,263	32.16
3: 65-80 YEARS	1,985	28.21	4,248	60.38
4: OVER 80 YEARS	2,788	39.62	7,036	100.00

- N=7,036 Medicaid patients died within 28 days of the COVID-19 vaccine
- Roughly 1/3 were under the age of 65

MEDICAID PATIENTS WHO DIED WITHIN 28 DAYS OF COVID-19 VACCINE, CAUSES OF DEATH

Top 10 Causes of Death* for patients who died within 28 days after vaccine, when The patient did NOT have the exact diagnosis from Oct 1 2020 to time of vaccination

Diagnosis Code	Diagnosis Description (1st or 2nd diagnosis code only)	# Recipients
Z23	Encounter for immunization	3122
I469	Cardiac arrest, cause unspecified	755
A419	Sepsis, unspecified organism	429
U071	COVID-19	418
J9601	Acute respiratory failure with hypoxia	408
J189	Pneumonia, unspecified organism	235
N179	Acute kidney failure, unspecified	230
I10	Essential (primary) hypertension	229
R4182	Altered mental status, unspecified	177

Interpretation:

For *3,122 (44%)* recipients, One of the last 5 diagnosis Codes prior to death Was the COVID-19 vaccine.

For *755* recipients, One of the last 5 diagnosis Codes prior to death was Cardiac Arrest

This is out of 7,036 recipients who Died within 28 post-vaccine

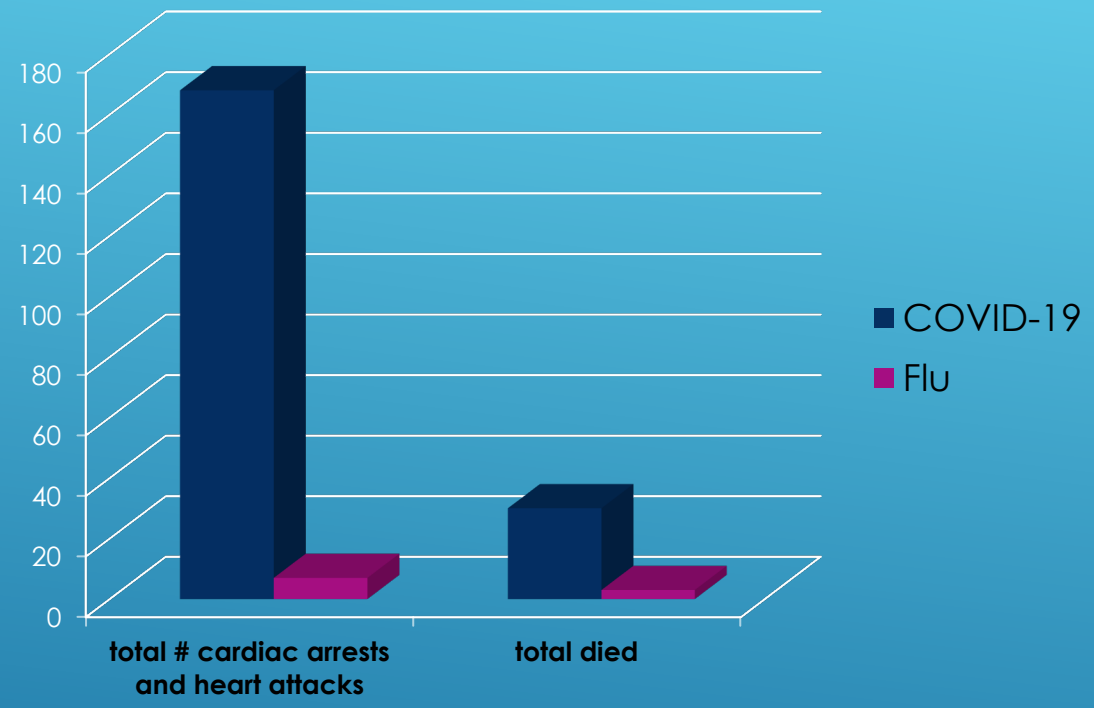
"Cause of death" defined as one of last 5 diagnosis codes prior to death

MEDICAID PATIENTS WHO DIED WITHIN 28 DAYS OF COVID-19 VACCINE, WHO SUFFERED CARDIAC ARREST

N=778 Medicaid patients died within 28 days of the COVID-19 vaccine with diagnosis of Cardiac Arrest - Death was almost always immediate
56% were under the age of 65

Age Group	# of Patients Died within 28 Days of COVID Vaccine from Cardiac Arrest	Percent of Total	Cumulative #	Cumulative %
1: 0-30 YEARS	26	3.34	26	3.34
2: 31-65 YEARS	436	56.04	462	59.38
3: 65-80 YEARS	212	27.25	674	86.63
4: OVER 80 YEARS	104	13.37	778	100.00

778 out of 7,036 **(11.1%)** died from cardiac arrest,
Where cardiac arrest was the 1st or 2nd diagnosis code,
All within 28 days of the vaccine (1st or 2nd dose, whichever was under 28 days)



- COVID Vaccine: 168
- Flu Vaccine: 7

- COVID Vaccine Deaths: 30
- Flu Vaccine Deaths: 3

- 10X AS MANY DEATHS!!

MEDICAID CARDIAC ARRESTS & HEART ATTACKS: UNDER AGE 30

THE COVID CONSUMER PROTECTION ACT

- The entirety of the COVID Consumer Protection Act reads:
  - For the duration of the COVID-19 public health emergency declared pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), this Act makes it unlawful under Section 5 of the Federal Trade Commission Act for any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID–19 or a government benefit related to COVID–19. The Act provides that such a violation shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under Sec. 18(a)(1)(B) of the FTC Act.

DR. ERIC NEPUTE

- Dr. Eric Nepute is being sued by the FTC for millions of dollars under the CCPA
- His crime: he gave away hundreds of thousands of dollars or more of vitamin D and zinc and talked about its value in keeping people safe from viruses.
- Both vitamin D and zinc have been confirmed in numerous studies to be valuable in keeping people safe from viruses – this is indisputable.
- With the information in this presentation, I look forward to seeing the public apology to him and the prosecution of those that are actually violating this law.
- Renz Law is not representing Dr. Nepute in this case and speaking only as to its importance as a public matter.

WHO MIGHT THE CCPA ACTUALLY APPLY TO?

Fauci: "We've shown that boosters are safe and effective…" Fact Check-Misleading headlines with Fauci statement about booster shots | Reuters

Pfizer CEO: "The additional data 'provide further confidence in our vaccine's safety and effectiveness profile in adolescents…'" Pfizer's Covid vaccine was 100% effective in kids in longer-term study (statnews.com)

Moderna: "We are encouraged" that the vaccine "was highly effective at preventing COVID-19 in adolescents," Moderna CEO Stéphane Bancel said in a statement. "It is particularly exciting to see that the Moderna COVID-19 vaccine can prevent SARS-CoV-2 infection."Moderna vaccine safe and highly effective in kids ages 12 to 17, company says (nbcnews.com)

The Trusted News Initiative: The entirety of the Trusted News Initiative and Big Tech appear to be actively working to affect commerce related to the treatment of COVID-19 by censoring some data and promoting other.

WHERE ARE THE DoJ AND FTC?

THE PATH FORWARD

What to do

THE PATH FORWARD

- Litigation
- We are busy in the courts but need help.
- We need more lawyers and more people paying those lawyers to continue bringing this before the courts.
  - Remember state AGs and local prosecutors/law enforcement may be able to take action.
- I will do everything possible to make myself available to assist in major litigation related to COVID.
- We have the data, we have the experts, we need the big and respected firms/lawyers to have the courage to fight.

- We are also ardent supporters of free speech.
- BUT - The mainstream media and particularly the "Trusted News Initiative" are not acting as "news media" with regards to COVID
- They have misbranded themselves as "news" while censoring ANY stories related to the dangers of the "vaccines"
- This has been done because of massive contracts, conflicts, and funding by Pharma
- Specifically in regards to the COVID "vaccines" these companies are acting as marketing organizations not news media and may be liable for misbranding themselves and also for knowingly promoting dangerous products while covering up the risks.
- I support and will assist in any appropriate litigation to stop the dangerous promotion of these unsafe products by groups that are NOT actually presenting news but, rather, acting as marketing arms of these multi-billion dollar companies that are becoming even richer and more powerful off of the suffering of people without their privilege.

SUING THE MEDIA

THE LETTER – PLEASE SHARE EVERYWHERE

- I have put together a letter that is now up on www.renz-law.com
- This presentation will be up on the website as soon as possible as well.
- We need EVERYONE to share these as far and wide as possible.
- We need as many people as possible to mail (certified is best but any is good), email, and share this letter with EVERY federal, state, and local elected official in the United States and around the world.
- The media has taken numerous high-dollar deals with pharma and pharma related entities and will cover this up; it is up to we the people to ensure it is seen. Remember, lives are at stake.
- Share this with EVERY media outlet and demand that they share the truth.

THE PEOPLE

- Martin Luther King and Jesus Christ both created change using peaceful resistance; we MUST do the same.
- We can not capitulate to those that have remained willfully ignorant or simply sold out any longer. We simply must stand and peacefully and properly say NO, I will NOT comply.
- We can no longer fear whether someone will judge us for speaking truth. It is time that we stand together as free people of the world. Peaceful protests, local activism, being involved in local politics, refusing to financially support those that oppose individual freedom, and supporting those that support freedom are absolutely necessary steps.

- We the free and united people of America, DEMAND the following:
  - 1. The resignation/termination of Anthony Fauci, the FDA commissioner, Director of CDC, and the US Surgeon General as well as civil/criminal investigation of their actions by a truly INDEPENDENT prosecutor
  - Investigations – criminal and civil – into the deceptive and misleading push for the gene therapy injections that have been falsely labeled as vaccines (only after the definition of "vaccine" was changed)
    - This should include RICO claims involving the "Trusted News Initiative", the drug companies, hospital systems, and some government actors
  - Transparency legislation that gives the public immediate access to the raw data and submitted documents related to the vaccines and COVID "pandemic" – If there is nothing to hide NO ONE should oppose transparency.
    - This should be passed on the state level as well.
  - Liability for injury from vaccines under the same rules as any other product – if they are safe there should be no opposition to liability to help those that have been injured
  - NO on vaccination status tracking legislation

OUR DEMANDS – THE UNITED STATES

NUREMBURG 2.0 - ACCOUNTABILITY

- We can and must demand that those behind this be held accountable.
- Legally, a Nuremburg style trial can only happen with the support of the governments of the world – IT IS TIME WE DEMAND ACCOUNTABILITY.
- Whether we have a global tribunal or simply demand our governments begin to hold people accountable, it is time for our elected officials to represent the health and safety of the PEOPLE rather than the financial interests of the rich and powerful.

THE REAWAKENING TOUR - OHIO

A Culture of Corruption

Thomas Renz

www.renz-law.com

Defense Medical Surveillance System (DMSS) Defense Medical Epidemiology Database (DMED) DoD Data - January 2022

Diagnosis or Injury	Query Date	2016	2017	2018	2019	2020	Total 2016-2020	Avg Injuries Per Year 2016-2020	2021 (Partial Year)	Percent Increase in 2021
All Diseases & Injuries										
All Disease & Injuries (Amb)	1/19/2022	2,059,630	2,058,379	2,022,663	2,110,383	1,976,724	10,227,779	2,045,555.80	**21,512,583**	**1052%**
All Disease & Injuries (Hosp)	1/19/2022	43,786	43,338	42,024	43,493	40,052	212,693	42,538.60	**54,776**	**129%**
Cancer										
Neoplasms (ALL CANCERS)	1/19/2022	41,557	39,139	37,756	38,889	36,050	193,391	38,678.20	**114,645**	**296%**
Malignant Neoplasms of Digestive Organs	1/19/2022	660	654	633	602	704	3,253	650.60	**4,060**	**624%**
Malignant Neoplasms of Thyroid & Other Endocrine Glands	1/19/2022	550	394	369	374	372	2,059	411.80	**1,950**	**474%**
Malignant Neuroendocrine tumors	1/19/2022	167	135	98	113	117	630	126.00	**440**	**349%**
Testicular Cancer (Amb)	1/10/2022	1,156	1,008	866	880	889	4,799	959.80	**3,537**	**369%**
Ovarian Cancer (Amb)	1/10/2022	121	88	73	82	69	433	86.60	**181**	**209%**
Breast Cancer (Amb)	1/10/2022	934	810	766	792	766	4,068	813.60	**4,357**	**536%**
Malignant Neoplasm of Esophagus	1/19/2022	29	36	35	20	26	146	29.20	**261**	**894%**
Mental Health & Metabolic Function										
Anxiety (Amb)	1/10/2022	37,011	36,667	36,145	37,762	37,870	185,455	37,091.00	**931,791**	**2512%**
Anxiety (Hosp)	1/10/2022	2,478	2,577	2,534	2,666	2,642	12,897	2,579.40	**6,496**	**252%**
Suicide	1/10/2022	359	496	530	570	550	2,505	501.00	**1,798**	**359%**
Endocrine Nutritional & Metabolic Diseases (Amb)	1/19/2022	33,140	31,825	30,814	31,504	30,506	157,789	31,557.80	**134,053**	**425%**
Disorders of Thyroid Gland	1/19/2022	8,078	7,694	7,357	7,289	6,893	37,311	7,462.20	**24,769**	**332%**
Malasie & Fatigue (Amb)	1/10/2022	3,851	3,842	3,832	3,885	3,735	19,145	3,829.00	**26,416**	**690%**
Thyroid Dysfunction (Amb)	1/10/2022	8,074	7,696	7,357	7,289	6,891	37,307	7,461.40	**22,620**	**303%**
Diabetes Type 1 (Amb)	1/10/2022	1,319	1,167	1,072	1,036	960	5,554	1,110.80	**5,269**	**474%**
Disease of Liver (Amb)	1/10/2022	1,994	2,053	2,063	2,234	2,322	10,666	2,133.20	**6,187**	**290%**
Narcolepsy & Cataplexy										
Narcolepsy & Cataplexy	1/19/2022	995	898	864	830	766	4,353	870.60	**2,097**	**241%**
Neuromuscular & Skeletal Systems										
Diseases of the Nervous System	1/19/2022	82,435	81,998	81,382	85,012	80,786	411,613	82,322.60	**863,013**	**1048%**
Diseases of the Eye & Adnexa	1/19/2022	88,091	87,712	86,417	91,503	79,529	433,252	86,650.40	**280,206**	**323%**
Migraine	1/19/2022	15,734	15,714	16,462	17,116	16,331	81,357	16,271.40	**73,490**	**452%**
Seizures (Amb)	1/10/2022	196	148	130	150	123	747	149.40	**489**	**327%**
Guillian-Bare Syndrome (Amb)	1/10/2022	66	79	71	85	65	366	73.20	**403**	**551%**

Defense Medical Surveillance System (DMSS) Defense Medical Epidemiology Database (DMED) DoD Data - January 2022

Diagnosis or Injury	Query Date	2016	2017	2018	2019	2020	Total 2016-2020	Avg Injuries Per Year 2016-2020	2021 (Partial Year)	Percent increase in 2021
Acute Transverse Myelitis in Demyelinating Disease of CNS	1/19/2022	46	57	48	35	34	220	44.00	202	459%
Demyelinating Diseases of the CNS	1/19/2022	785	737	690	677	648	3,537	707.40	3,444	487%
Multiple Sclerosis	1/19/2022	479	391	367	400	385	2,022	404.40	2,750	680%
Rhabdomyolysis (Hosp)	1/10/2022	216	209	227	222	198	1,072	214.40	440	205%
Rhabdomyolysis (Amb)	1/10/2022	706	696	740	755	669	3,566	713.20	5,162	724%
Eye Disorder (Amb)	1/10/2022	6,044	6,013	5,647	6,312	5,623	29,639	5,927.80	11,892	201%
Extra Pyramidal (Amb)	1/10/2022	1,509	1,474	1,339	1,371	1,338	7,031	1,406.20	3,669	261%
Bell's Palsy (Amb)	1/10/2022	483	462	457	447	450	2,299	459.80	1,338	291%
Cardiovascular System										
Diseases of the Blood & Blood-forming Organs & Certain Disorders Involving the Immune Mechanism	1/19/2022	11,533	11,122	10,851	11,773	11,429	56,708	11,341.60	34,486	304%
Acute Myocardial Infarction (Amb)	1/10/2022	324	370	376	366	372	1,808	361.60	1,650	456%
Hypertension (Amb)	1/10/2022	2,308	2,323	2,363	2,392	2,415	11,801	2,360.20	53,846	2281%
Acute Myocarditis (Amb)	1/21/2022	84	92	116	159	108	559	111.80	307	275%
Acute Pericarditis (Amb)	1/10/2022	535	538	522	531	499	2,625	525.00	850	162%
Nontraumatic subarachnoid hemorrhage	1/19/2022	219	139	134	170	196	858	171.60	640	373%
Pulmonary Embolism (Amb)	1/19/2022	678	701	668	716	968	3,731	746.20	3,489	468%
Tachycardia (Amb)	1/10/2022	845	814	893	903	849	4,304	860.80	2,595	301%
Disease of the Arteries (Amb)	1/10/2022	3,164	2,965	2,938	3,096	2,860	15,023	3,004.60	6,069	202%
Cerebral Infarction (Amb)	1/10/2022	887	848	858	888	887	4,368	873.60	3,136	359%
Reproductive System & Birth										
Spontaneous Abortion (First Occurrence)	1/19/2022	2,668	2,532	2,475	2,608	2,404	12,687	2,537.40	2,164	85%
Spontaneous Abortion (All Occurences)	1/10/2022	1,431	1,518	1,493	1,578	1,477	7,497	1,499.40		0%
Congenital Malformations (Amb)	1/19/2022	11,710	11,131	10,456	11,081	10,153	54,531	10,906.20	18,951	174%
Infertility, Female (Amb)	1/19/2022	2,261	2,262	2,243	2,340	2,262	11,368	2,273.60	11,748	517%
Infertility, Male (Amb)	1/19/2022	2,187	2,287	2,037	2,152	1,990	10,653	2,130.60	8,365	393%
Ovarian Dysfunction (Amb)	1/19/2022	862	936	908	945	1,022	4,673	934.60	4,086	437%
Dysmenorrhea (Amb)	1/10/2022	3,104	3,403	3,481	3,943	3,900	17,831	3,566.20	12,539	352%
Vaccine Adminstration										
T50.B95A Adverse Effect of Other Viral Vaccine, Initial Encounter	Unassigned						914	182.80	1,281	701%

THE COVER-UP

- …Peter Graves, spokesperson for the Defense Health Agency's Armed Forces Surveillance Division, told PolitiFact by email that "in response to concerns mentioned in news reports" the division reviewed data in the DMED "and found that the data was incorrect for the years 2016-2020…"
- …The 2021 numbers, however, were up-to-date, giving the "appearance of significant increased occurrence of all medical diagnoses in 2021 because of the underreported data for 2016-2020," Graves said.
- https://www.politifact.com/factchecks/2022/jan/31/instagram-posts/numbers-were-based-faulty-data-military-spokespers/

SERIOUSLY? IS ANYONE THAT STUPID?

- So this means we are to believe that:
  - DoD believes 2021 is accurate but did not notice the other issues until AFTER whistleblower testimony in 2022.
  - Apparently, despite the fact that they could not fix an error they were unaware of – the database magically fixed itself after 2020
  - Anthony Fauci, the DHHS, the DoD, the CDC, the entire Armed Services Health Survalience Devision, the contractor responsible for DMED, and all of the health professionals that cite to DMED in peer reviewed scientific articles failed to notice that the records from 2016-2020 were off by thousands of percent
    - And – by the way – 2020 was the year of COVID when EVERYONE was supposed to be looking at this data so we could "follow the science"
  - And – they have a bridge to sell us (that Fauci will get rich from selling)

CONFLICTS?

- In 2018 the Secretary of Defense was appointed to the Board of Directors of Tenet Healthcare Corp
- 20 years ago Tenet almost went bankrupt due to a Medicare fraud billing issue
- Tenet appears to benefit directly from government assistance related to Covid
- In 2020… "As a member of Board of Directors at TENET HEALTHCARE CORP, Lloyd J. Austin, III made $288,627 in total compensation…" https://www.salary.com/research/executive-compensation/lloyd-j-austin-iii-board-member-of-tenet-healthcare-corp
- In light of the DMED data we have to ask, are we protecting our soldiers or our pockets?

BIDEN'S MILITARY PURGE… AND WAR?

Total Force Individuals Vaccinated**		Fully Vaccinated[4]		Partially Vaccinated		Not Vaccinated or Unknown	
Personnel Category	*Eligible Population*	*# Individuals*	*% of Total[4]*	*# Individuals*	*% of Total[4]*	*# Individuals*	*% of Total[4]*
Active Duty (USA, USN, USAF, USMC)	**1,342,909**	**1,219,442**	**90.8%**	**84,767**	**6.3%**	**38,700**	**2.9%**
Reserves & National Guard	786,847	390,479	49.6%	255,116	32.4%	141,252	18.0%
Total Service Members	**2,129,756**	**1,609,921**	**75.6%**	**339,883**	**16.0%**	**179,952**	**8.4%**
Other Active Duty	112,345	42,318	**74.6%**	3,920	**13.9%**	12,889	**11.5%**
Other Guard/Reserve		41,506		11,712			
Civilians & Contractors	1,820,642	441,313	**24.2%**	79,218	**4.4%**	1,300,111	**71.4%**
Beneficiaries – All vaccination sites	2,616,959	1,062,167	40.6%	625,118	23.9%	929,674	35.5%
Other/Unknown		142,130		51,520			
TOTAL	**6,679,702**	**3,339,355**	**50.0%**	**1,111,371**	**16.6%**	**2,228,976**	**33.4%**

So the real questions are:

1. Is it wise to purge 25% of our military and 71% of our civilian and contractor supporters given the issues with China and elsewhere?
2. Does Biden plan to kick a quarter of our military out before or during his bogus war with Russia?

OH – AND NO, OUR SOLDIERS ARE NOT GETTING A LICENSED JAB

- Note that the potential issue listed here is the shortage of supply of Pfizer-BioNTech for the mandate.
- BioNTech is NOT licensed and NOT legally interchangeable with any licensed Jab
- Note the alternative solution suggested "Provide 'Cominarty' labeled vaccine"
- We have numerous witnesses that have seen the military records change after the BioNTech injections to show that Cominarty was used – MORE COVER-UP

COVID vaccine implementation updates 12 Jan 2022

- Potential issue: Pfizer-BioNTech supply to support mandate
  - 350K "plus up" of purple-cap was approved by DHA and by CAG
  - CAG now pushing back, stating that the purple and gray cap products are interchangeable
  - Current status
    - ✓ Estimated SM need to reach 100%: **700K doses**; for ADSM: **162K doses**
    - ✓ Pfizer product on the shelf which may be used for mandate: **390K total doses**
      - EUA-manufactured, EUA-labeled: 300K doses
      - BLA-manufactured, EUA-labeled: 90K doses
    - ✓ Requested mtng with CAG/CDC/OGC/DHA 11 Jan 2022
    - ✓ Alternatives:
      - Immediate ceasing of administering purple cap for non-SM
        - » Tris be ordered and directed to non-SM
      - Strongly encourage Pfizer/CDC to publically identify BLA-approved Tris lots
      - Provide "Comirnaty"-labeled vaccine
      - Await Moderna BLA approval by FDA

CAN A JUDICIARY THAT EMBRACES CDC GUIDANCE ON COVID-19 MAINTAIN IMPARTIALITY IN MATTERS CHALLENGING THE CDC AND THE EXECUTIVE BRANCH'S COVID NARRATIVE?

The Administrative Office of the U.S. Courts (AO), Senior Circuit Court Judges, and the Executive Office of the President issued scores of memoranda outlining the Federal Judiciary's approach to COVID-19. These documents reflect the judiciary's adoption of the Center for Disease Control (CDC) and the National Institute of Health (NIH) COVID narratives and guidance.

If a judge that will preside over a case where they have even an appearance of impropriety then that judge must recuse him/herself from the case. Do these documents imply a bias?

JUDICIAL DEFERENCE TO THE ADMINISTRATIVE STATE

July 6, 2020: *Federal Judiciary COVID-19 Recovery Guidelines:* "The Administrative Office is closely monitoring government policy changes, Centers for Disease Control and Prevention (CDC) guidelines…"

March 10, 2021: *AO – Judiciary COVID-19 Vaccination Plan*: "I have communicated with the National COVID-19 Response Coordinator at the White House and with the Acting Secretary of the Department of Health and Human Services (HHS) regarding the urgency of obtaining vaccinations for the judicial branch."

April 12, 2021: *AO - Updated Guidance Regarding Judiciary Response To Covid-19 And Judiciary Vaccination Plan:* "…court orders are limiting USMS courtroom access to vaccinated Deputy United States Marshals (DUSM)."

April 22, 2021: *AO - Updated Guidance Regarding Judiciary Response To Covid-19 And Judiciary Vaccination Plan:* "The United States Marshals Service (USMS) has directed all CSO contract vendors to have and enforce policies requiring all CSOs to wear appropriate personal protection equipment (e.g. masks) while in the courthouse or other court facilities."

May 2021: *U.S. Courts Safe Return to the Workplace Handbook*: "The courts and the AO continue to closely monitor government policy changes, Centers for Disease Control and Prevention (CDC) guidelines, and public health advancements."

May 14, 2021: *AO - Updated Guidance Regarding Judiciary Response To Covid-19* "On May 13, 2021, the CDC issued new guidance on indoor mask use, social distancing, and testing requirements for fully vaccinated people."

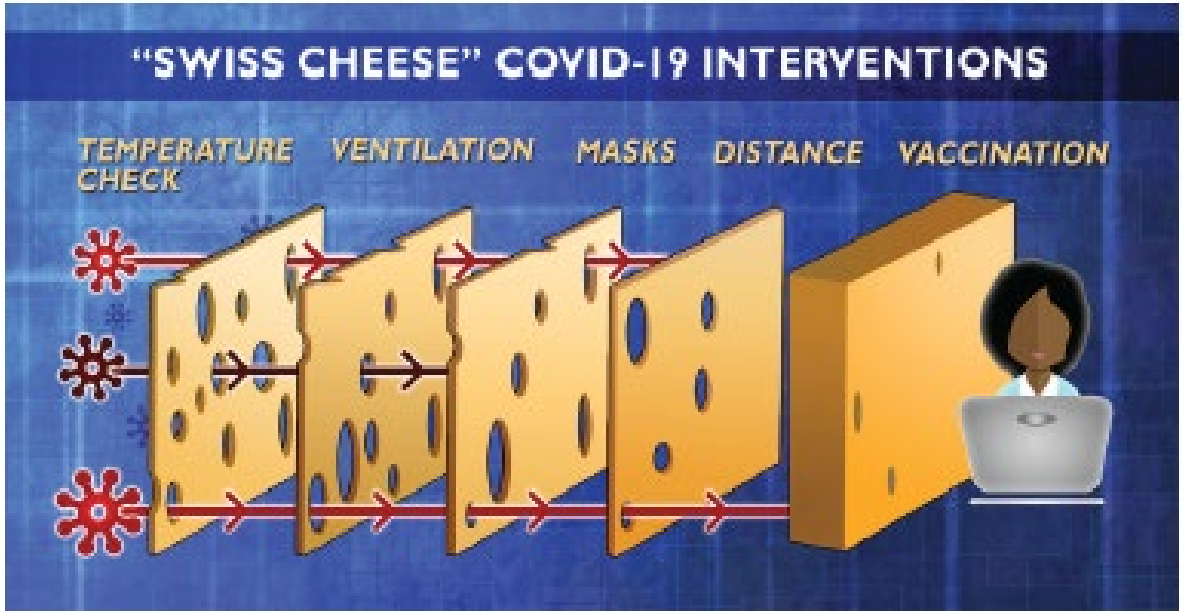
May 20, 2021: AO - *Updated Guidance Regarding Judiciary Response To Covid-19* "…fully vaccinated individuals may forego wearing masks and social distancing in federal buildings."

July 29, 2021: *COVID-19 Workplace Safety: Agency Model Safety Principles:* "The principles presented here are aligned with the latest guidance from the Centers for Disease Control and Prevention (CDC) for employers and for fully vaccinated people and the Occupational Safety and Health Administration (OSHA) on protecting workers, based on evolving understanding of the pandemic.

July 30, 2021: AO – *Updated Guidance Regarding the Judiciary Response to COVID-19:* "…CDC advised all people, regardless of vaccination status to wear a mask in public indoor settings in areas of substantial or high transmission to further reduce spread of the coronavirus."

January 13, 2022: *U.S. Court of Appeal for Federal Circuit – Revised Protocols for In-Person Arguments:* "To enter the National Courts Building and the courtrooms, counsel and attendees will be required to show proof of having received a negative polymerase chain reaction [PCR] COVID-19 test administered withing the prior 72 hours of oral argument."

TRUST THE "SCIENCE" ?



Think of the interventions to reduce the risk of transmission of the virus as a series of slices of Swiss Cheese. Each slice provides a barrier, but it's not perfect, it has some holes. So we add another slice, and another. The thickest slice, with the fewest holes, is vaccination.

– Dr. William Schaffner, Safe Return to the Workplace video

U.S. Courts Safe Return to the Workplace Handbook, May 2021

CODE OF CONDUCT FOR UNITED STATES JUDGES

Canon 1: A Judge Should Uphold the Integrity and Independence of the Judiciary. An independent and honorable judiciary is indispensable to justice in our society. A judge should maintain and enforce high standards of conduct and should personally observe those standards, so that the integrity and independence of the judiciary may be preserved. The provisions of this Code should be construed and applied to further that objective

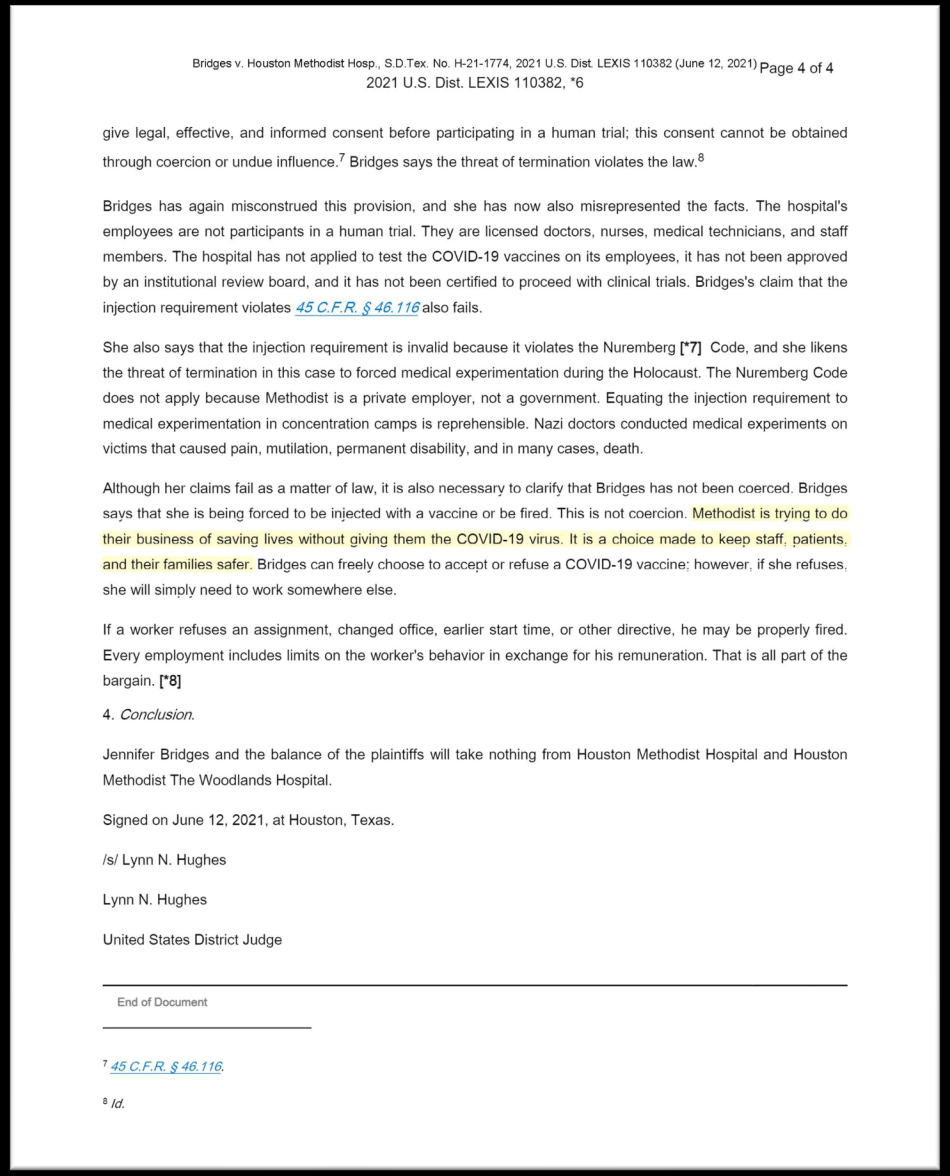
CANON 2(A) RESPECT FOR LAW. A JUDGE SHOULD RESPECT AND COMPLY WITH THE LAW AND SHOULD ACT AT ALL TIMES IN A MANNER THAT PROMOTES PUBLIC CONFIDENCE IN THE INTEGRITY AND IMPARTIALITY OF THE JUDICIARY.

Judge Hughes: the FDA's approval or disapproval is an approximation. I don't think any one of them would say we get it right every time...

Mr. Woodfill: You're correct. But you're more likely to get it right after it's made it through that EUA process and received approval.

Judge Hughes: No, no, no. Look, **that's just another rubber stamp on the folder**.

Bridges v. Houston Methodist Hosp., S.D.Tex. No. H-21-1774, 2021 U.S. Dist. LEXIS 110382 (June 12, 2021), RE. 23. P. 34, *Transcript Of Motion Proceedings Heard Before The Honorable Lynn N. Hughes United States District Judge*, June 11, 2021



Bridges v. Houston Methodist Hosp., S.D.Tex. No. H-21-1774, 2021 U.S. Dist. LEXIS 110382 (June 12, 2021) Page 4 of 4
2021 U.S. Dist. LEXIS 110382, *6

give legal, effective, and informed consent before participating in a human trial; this consent cannot be obtained through coercion or undue influence.[7] Bridges says the threat of termination violates the law.[8]

Bridges has again misconstrued this provision, and she has now also misrepresented the facts. The hospital's employees are not participants in a human trial. They are licensed doctors, nurses, medical technicians, and staff members. The hospital has not applied to test the COVID-19 vaccines on its employees, it has not been approved by an institutional review board, and it has not been certified to proceed with clinical trials. Bridges's claim that the injection requirement violates *45 C.F.R. § 46.116* also fails.

She also says that the injection requirement is invalid because it violates the Nuremberg **[*7]** Code, and she likens the threat of termination in this case to forced medical experimentation during the Holocaust. The Nuremberg Code does not apply because Methodist is a private employer, not a government. Equating the injection requirement to medical experimentation in concentration camps is reprehensible. Nazi doctors conducted medical experiments on victims that caused pain, mutilation, permanent disability, and in many cases, death.

Although her claims fail as a matter of law, it is also necessary to clarify that Bridges has not been coerced. Bridges says that she is being forced to be injected with a vaccine or be fired. This is not coercion. Methodist is trying to do their business of saving lives without giving them the COVID-19 virus. It is a choice made to keep staff, patients, and their families safer. Bridges can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else.

If a worker refuses an assignment, changed office, earlier start time, or other directive, he may be properly fired. Every employment includes limits on the worker's behavior in exchange for his remuneration. That is all part of the bargain. **[*8]**

4. *Conclusion.*

Jennifer Bridges and the balance of the plaintiffs will take nothing from Houston Methodist Hospital and Houston Methodist The Woodlands Hospital.

Signed on June 12, 2021, at Houston, Texas.

/s/ Lynn N. Hughes

Lynn N. Hughes

United States District Judge

End of Document

[7] *45 C.F.R. § 46.116.*

[8] *Id.*

CAN A JUDICIARY THAT TOLERATES DISCRIMINATION AGAINST THE UNVACCINATED REMAIN IMPARTIAL IN A MANDATE CASE?

- COMMENTARY Canon 2A. "An appearance of impropriety occurs when reasonable minds, with knowledge of all the relevant circumstances disclosed by a reasonable inquiry, would conclude that the judge's honesty, integrity, impartiality, temperament, or fitness to serve as a judge is impaired… A judge must avoid all impropriety and appearance of impropriety."

From: [redacted]
Subject: ***URGENT - PLEASE READ*** Unvaccinated employees in court
Date: Tuesday, August 3, 2021 9:09:48 AM
Attachments: image001.png

Good morning:

We have recently received communication from some of the courts in the Houston/Galveston Divisions that the judges in those courts prefer not to have employees who have not yet been vaccinated for COVID-19 to be present in their respective courts or chambers. I have spoken individually with the SUSPOs and advised them which courts have made this request. If you still have not been fully vaccinated, please reach out to your SUSPO to discuss your schedule of upcoming hearings and court coverage duties, so that we can individually work out a plan to find alternative coverage.

Please understand that we are trying to approach this request from the courts in a manner that best preserves your confidentiality. Thank you in advance for your understanding and your cooperation with this effort. If you have any questions or concerns about it, please don't hesitate to contact me. Have a good day.

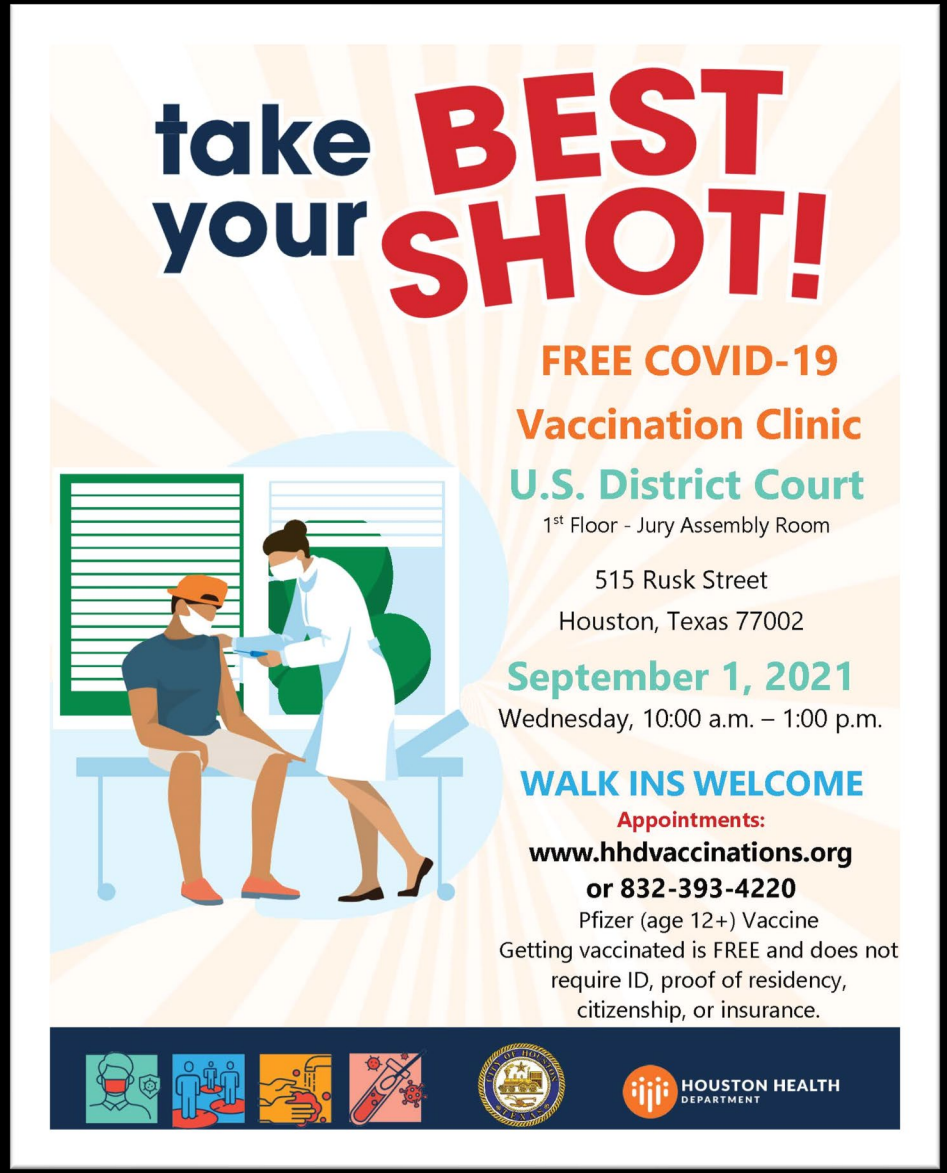
[redacted]
United States Probation Officer
515 Rusk Street, Suite 2301
Houston, TX 77002
[redacted]

Top 5 Strengths: Relator, Analytical, Responsibility, Context, Restorative

CANON 3: A JUDGE SHOULD PERFORM THE DUTIES OF THE OFFICE FAIRLY, IMPARTIALLY AND DILIGENTLY

Canon 3 (C)(1)(a) *Disqualification:* A judge shall disqualify himself or herself in a proceeding in which the judge's impartiality might reasonably be questioned, including but not limited to instances in which (a) the judge has a personal bias or prejudice concerning a party, or personal knowledge of disputed evidentiary facts concerning the proceeding.

"I hope that all who can be completely vaccinated, including boosterized, have done so, or have it on the holiday to-do list for every family member and friend. My new motto is 'friends don't let friends who can be vaccinated stay unvaccinated.'" – Chief Judge Lee H. Rosenthal, U.S. District Court for the Southern District of Texas. *Southern District of Texas Status Report*, December 16, 2021



ABA MODEL RULE 8.3: REPORTING PROFESSIONAL MISCONDUCT

- Rule 8.3(b) A lawyer who knows that a judge has committed a violation of applicable rules of judicial conduct that raises a substantial question as to the judge's fitness for office shall inform the appropriate authority.
- We are not charging professional misconduct but merely asking the question, is there bias, conscious or otherwise, in our courts.
- We have similar documents from other courts and so now we ask – WHAT IF THE CDC LIED?

From: steph parker [redacted]
Sent: Tuesday, March 22, 2022 4:14 PM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: PEBP Meeting March 24, 2022 Public Comment

I am asking that this Committee do everything within its power to reduce the projected increases for FY23. I received a notification at work that our healthcare administrator is changing but I am not able to find out if I can even keep my same providers. I had to change some last year due to the AETNA fiscal. I had to pay new patient rates for the doctors I had to change and delayed in getting the medical services that I needed. I cannot currently get my medically recommended mammogram in my own city so I am waiting to see if it will be covered under the new plan. This cannot continue, many of us cannot go through this annually. I should know now if my healthcare providers will be covered as in network.

The problem is that the cost of living has gone up but my wages have not kept up. While I can use some of my benefits, I know several of my fellow employees cannot afford to as they are below the poverty line with the wages paid by the state. We are seeing the impact of the diminishing of all around compensation as demonstrated by the Great Resignation.

You know as that staff from the Governors office, I believe his name is Duane said, they are aware that they don't pay fair wages to state employees and the benefits package is not up to par either. Unlike him and other administrators, I am not a member of the 6-figure club.

Respectfully submitted,
Stephanie Parker
AFSCME Local 4041 Member, Nevada Classified Employee
Carson City, Nevada

From: Annie Wong [redacted]
Sent: Wednesday, March 23, 2022 8:37 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: March 24, 2022 Board Meeting Public Comment

.

Dear Ms. Lunz,

Please include this email and its attachments as public comment for the March 24, 2022 Board Meeting. I am a state employee and PEBP member. On March 23, 2022, the Office of the Governor issued a memorandum ending the employee testing program effective March 25, 2022 (attached). I ask you to repeal the surcharge implemented on your unvaccinated members and their dependents.

Pfizer released a report listing all adverse events (attached). Deaths and injuries from Covid-19 are indisputably tragic. Deaths and injuries from the vaccine are indisputably tragic. Ignoring the right to informed consent, despite this information, is unfathomable.

The passage of this surcharge targeting unvaccinated employees and their unvaccinated dependents was unprecedented, coercive, and parallel to financial extortion. Please ask yourselves as Board Members and as Nevadans, if you will hold yourselves accountable for the vaccine injuries that occur as a result of implementing this surcharge. If not, it is time to acknowledge that this vaccine is not a one-size-fits-all solution. Repeal this surcharge and restore the right to informed consent.

Annie W.

STEVE SISOLAK
GOVERNOR

STATE OF NEVADA
OFFICE OF GOVERNOR STEVE SISOLAK
One Hundred One North Carson Street
Carson City, Nevada 89701

MEMORANDUM

Date:	March 22, 2022
To:	All State Agencies
From:	Office of the Governor
Subject:	Employee COVID-19 Testing Program

When the state began its first of a kind vaccination or testing program, nearly 50% of the state workforce was testing weekly. This meant that almost 10,000 tests were administered per week. Now less than 10% of the state workforce is testing, and positive case results have dropped significantly to less than 1% of the workforce. The employee vaccination/testing program was designed as public safety measure to ensure the health of our workforce, and it has achieved that result.

The employee testing program will end effective March 25,2022. To continue to protect each other's health and safety we ask that employees regardless of vaccination status continue to test when ill to rule out COVID and help contain any spread. Along with the sharp increase in vaccinations the state has seen a decline in both the number of employees with COVID and the severity of those needing treating. This coupled with the end of a formalized testing program lessens any need for a future surcharge on unvaccinated employees or their dependents. PEBP will be asking its board at its upcoming March meeting to consider a repeal of the surcharge scheduled to begin in July.

We thank you all for your continued dedication and diligence during a very difficult time of two COVID surges. It was because of your efforts in utilizing the tools of mitigation we were able as an organization to continue to weather the storm and serve Nevadans.

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

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Report Prepared by:

Worldwide Safety

Pfizer

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FDA-CBER-2021-5683-0000054

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LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

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FDA-CBER-2021-5683-0000057

1. INTRODUCTION

Reference is made to the Request for Comments and Advice submitted 04 February 2021 regarding Pfizer/BioNTech's proposal for the clinical and post-authorization safety data package for the Biologics License Application (BLA) for our investigational COVID-19 Vaccine (BNT162b2). Further reference is made to the Agency's 09 March 2021 response to this request, and specifically, the following request from the Agency.

"Monthly safety reports primarily focus on events that occurred during the reporting interval and include information not relevant to a BLA submission such as line lists of adverse events by country. We are most interested in a cumulative analysis of post-authorization safety data to support your future BLA submission. Please submit an integrated analysis of your cumulative post-authorization safety data, including U.S. and foreign post-authorization experience, in your upcoming BLA submission. Please include a cumulative analysis of the Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in your Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). Please also include distribution data and an analysis of the most common adverse events. In addition, please submit your updated Pharmacovigilance Plan with your BLA submission."

This document provides an integrated analysis of the cumulative post-authorization safety data, including U.S. and foreign post-authorization adverse event reports received through 28 February 2021.

2. METHODOLOGY

Pfizer is responsible for the management post-authorization safety data on behalf of the MAH BioNTech according to the Pharmacovigilance Agreement in place. Data from BioNTech are included in the report when applicable.

Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment.

The limitations of post-marketing adverse drug event reporting should be considered when interpreting these data:

- Reports are submitted voluntarily, and the magnitude of underreporting is unknown. Some of the factors that may influence whether an event is reported include: length of time since marketing, market share of the drug, publicity about a drug or an AE, seriousness of the reaction, regulatory actions, awareness by health professionals and consumers of adverse drug event reporting, and litigation.

- Because many external factors influence whether or not an AE is reported, the spontaneous reporting system yields reporting proportions not incidence rates. As a result, it is generally not appropriate to make between-drug comparisons using these

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proportions; the spontaneous reporting system should be used for signal detection rather than hypothesis testing.

- In some reports, clinical information (such as medical history, validation of diagnosis, time from drug use to onset of illness, dose, and use of concomitant drugs) is missing or incomplete, and follow-up information may not be available.

- An accumulation of adverse event reports (AERs) does not necessarily indicate that a particular AE was caused by the drug; rather, the event may be due to an underlying disease or some other factor(s) such as past medical history or concomitant medication.

- Among adverse event reports received into the Pfizer safety database during the cumulative period, only those having a complete workflow cycle in the safety database (meaning they progressed to Distribution or Closed workflow status) are included in the monthly SMSR. This approach prevents the inclusion of cases that are not fully processed hence not accurately reflecting final information. Due to the large numbers of spontaneous adverse event reports received for the product, the MAH has prioritised the processing of serious cases, in order to meet expedited regulatory reporting timelines and ensure these reports are available for signal detection and evaluation activity. The increased volume of reports has not impacted case processing for serious reports, and compliance metrics continue to be monitored weekly with prompt action taken as needed to maintain compliance with expedited reporting obligations. Non-serious cases are entered into the safety database no later than 4 calendar days from receipt. Entrance into the database includes the coding of all adverse events; this allow for a manual review of events being received but may not include immediate case processing to completion. Non-serious cases are processed as soon as possible and no later than 90 days from receipt. Pfizer has also taken a multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately (b) (4) additional full-time employees (FTEs). More are joining each month with an expected total of more than (b) (4) additional resources by the end of June 2021.

3. RESULTS

3.1. Safety Database

3.1.1. General Overview

It is estimated that approximately (b) (4) doses of BNT162b2 were shipped worldwide from the receipt of the first temporary authorisation for emergency supply on 01 December 2020 through 28 February 2021.

Cumulatively, through 28 February 2021, there was a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Most cases (34,762) were received from United States (13,739), United Kingdom (13,404) Italy (2,578), Germany (1913), France (1506), Portugal (866) and Spain (756); the remaining 7,324 were distributed among 56 other countries.

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Table 1 below presents the main characteristics of the overall cases.

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

As shown in Figure 1, the System Organ Classes (SOCs) that contained the greatest number (≥2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693).

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Figure 1. Total Number of BNT162b2 AEs by System Organ Classes and Event Seriousness

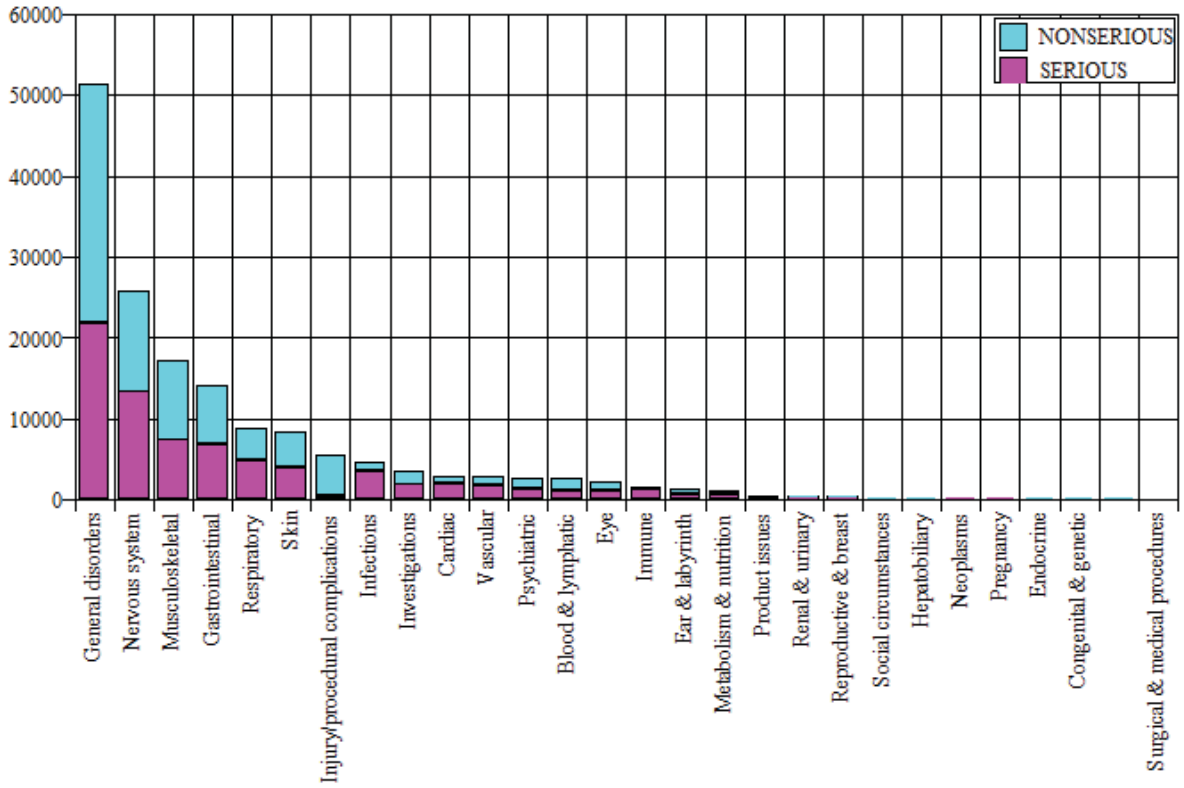


Table 2 shows the most commonly (≥2%) reported MedDRA (v. 23.1) PTs in the overall dataset (through 28 February 2021),

Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
Blood and lymphatic system disorders		
	Lymphadenopathy	1972 (4.7%)
Cardiac disorders		
	Tachycardia	1098 (2.6%)
Gastrointestinal disorders		
	Nausea	5182 (12.3%)
	Diarrhoea	1880 (4.5%)
	Vomiting	1698 (4.0%)
General disorders and administration site conditions		
	Pyrexia	7666 (18.2%)
	Fatigue	7338 (17.4%)
	Chills	5514 (13.1%)
	Vaccination site pain	5181 (12.3%)

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Table 2. Events Reported in ≥2% Cases

		Cumulatively Through 28 February 2021
MedDRA SOC	**MedDRA PT**	**AEs (AERP%) N = 42086**
	Pain	3691 (8.8%)
	Malaise	2897 (6.9%)
	Asthenia	2285 (5.4%)
	Drug ineffective	2201 (5.2%)
	Vaccination site erythema	930 (2.2%)
	Vaccination site swelling	913 (2.2%)
	Influenza like illness	835 (2%)
Infections and infestations		
	COVID-19	1927 (4.6%)
Injury, poisoning and procedural complications		
	Off label use	880 (2.1%)
	Product use issue	828 (2.0%)
Musculoskeletal and connective tissue disorders		
	Myalgia	4915 (11.7%)
	Pain in extremity	3959 (9.4%)
	Arthralgia	3525 (8.4%)
Nervous system disorders		
	Headache	10131 (24.1%)
	Dizziness	3720 (8.8%)
	Paraesthesia	1500 (3.6%)
	Hypoaesthesia	999 (2.4%)
Respiratory, thoracic and mediastinal disorders		
	Dyspnoea	2057 (4.9%)
	Cough	1146 (2.7%)
	Oropharyngeal pain	948 (2.3%)
Skin and subcutaneous tissue disorders		
	Pruritus	1447 (3.4%)
	Rash	1404 (3.3%)
	Erythema	1044 (2.5%)
	Hyperhidrosis	900 (2.1%)
	Urticaria	862 (2.1%)
Total number of events		**93473**

3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan

Table 3. Safety concerns

Important identified risks	Anaphylaxis
Important potential risks	Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-associated Enhanced Respiratory Disease (VAERD)
Missing information	Use in Pregnancy and lactation Use in Paediatric Individuals <12 Years of Age Vaccine Effectiveness

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Table 4. Important Identified Risk

<table>
<tr><th>Topic</th><th>Description</th></tr>
<tr><td>Important Identified Risk</td><td>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021)
Total Number of Cases in the Reporting Period (N=42086)</td></tr>
<tr><td>Anaphylaxis</td><td>Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 1833 potentially relevant cases were retrieved from the Anaphylactic reaction SMQ (Narrow and Broad) search strategy, applying the MedDRA algorithm. These cases were individually reviewed and assessed according to Brighton Collaboration (BC) definition and level of diagnostic certainty as shown in the Table below:

<table>
<tr><td>Brighton Collaboration Level</td><td>Number of cases</td></tr>
<tr><td>BC 1</td><td>290</td></tr>
<tr><td>BC 2</td><td>311</td></tr>
<tr><td>BC 3</td><td>10</td></tr>
<tr><td>BC 4</td><td>391</td></tr>
<tr><td>BC 5</td><td>831</td></tr>
<tr><td>Total</td><td>1833</td></tr>
</table>
Level 1 indicates a case with the highest level of diagnostic certainty of anaphylaxis, whereas the diagnostic certainty is lowest for Level 3. Level 4 is defined as “reported event of anaphylaxis with insufficient evidence to meet the case definition” and Level 5 as not a case of anaphylaxis.

There were 1002 cases (54.0% of the potentially relevant cases retrieved), 2958 potentially relevant events, from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy, meeting BC Level 1 to 4:

Country of incidence: UK (261), US (184), Mexico (99), Italy (82), Germany (67), Spain (38), France (36), Portugal (22), Denmark (20), Finland, Greece (19 each), Sweden (17), Czech Republic , Netherlands (16 each), Belgium, Ireland (13 each), Poland (12), Austria (11); the remaining 57 cases originated from 15 different countries.
Relevant event seriousness: Serious (2341), Non-Serious (617);
Gender: Females (876), Males (106), Unknown (20);
Age (n=961) ranged from 16 to 98 years (mean = 54.8 years, median = 42.5 years);
Relevant even outcome[a]: fatal (9)[b], resolved/resolving (1922), not resolved (229), resolved with sequelae (48), unknown (754);
Most frequently reported relevant PTs (≥2%), from the Anaphylactic reaction SMQ (Broad and Narrow) search strategy: Anaphylactic reaction (435), Dyspnoea (356), Rash (190), Pruritus (175), Erythema (159), Urticaria (133), Cough (115), Respiratory distress, Throat tightness (97 each), Swollen tongue (93), Anaphylactic shock (80), Hypotension (72), Chest discomfort (71), Swelling face (70), Pharyngeal swelling (68), and Lip swelling (64).

Conclusion: Evaluation of BC cases Level 1 - 4 did not reveal any significant new safety information. Anaphylaxis is appropriately described in the product labeling as are non-anaphylactic hypersensitivity events. Surveillance will continue.</td></tr>
</table>

a Different clinical outcome may be reported for an event that occurred more than once to the same individual.
b There were 4 individuals in the anaphylaxis evaluation who died on the same day they were vaccinated. Although these patients experienced adverse events (9) that are potential symptoms of anaphylaxis, they all had serious underlying medical conditions, and one individual appeared to also have COVID-19 pneumonia, that likely contributed to their deaths

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Table 5. Important Potential Risk

Topic	Description
Important Potential Risk	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

a. Search criteria: Standard Decreased Therapeutic Response Search AND PTs Dyspnoea; Tachypnoea; Hypoxia; COVID 19 pneumonia; Respiratory Failure; Acute Respiratory Distress Syndrome; Cardiac Failure; Cardiogenic shock; Acute myocardial infarction; Arrhythmia; Myocarditis; Vomiting; Diarrhoea; Abdominal pain; Jaundice; Acute hepatic failure; Deep vein thrombosis; Pulmonary embolism; Peripheral Ischaemia; Vasculitis; Shock; Acute kidney injury; Renal failure; Altered state of consciousness; Seizure; Encephalopathy; Meningitis; Cerebrovascular accident; Thrombocytopenia; Disseminated intravascular coagulation; Chillblains; Erythema multiforme; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
Use in Pregnancy and lactation	• Number of cases: 413[a] (0.98% of the total PM dataset); 84 serious and 329 non-serious; • Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries. Pregnancy cases: 274 cases including: • 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins). • Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted). • 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2). • 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs Abortion spontaneous (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and Foetal death (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases). • 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and Death neonatal (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester. Breast feeding baby cases: 133, of which: • 116 cases reported exposure to vaccine during breastfeeding (PT Exposure via breast milk) without the occurrence of any clinical adverse events; • 17 cases, 3 serious and 14 non-serious, reported the following clinical events that occurred in the infant/child exposed to vaccine via breastfeeding: Pyrexia (5), Rash (4), Infant irritability (3), Infantile vomiting, Diarrhoea, Insomnia, and Illness (2 each), Poor feeding infant, Lethargy, Abdominal discomfort, Vomiting, Allergy to vaccine, Increased appetite, Anxiety, Crying, Poor quality sleep, Eructation, Agitation, Pain and Urticaria (1 each). Breast feeding mother cases (6): • 1 serious case reported 3 clinical events that occurred in a mother during breast feeding (PT Maternal exposure during breast feeding); these events coded to the PTs Chills, Malaise, and Pyrexia • 1 non-serious case reported with very limited information and without associated AEs.

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	• In 4 cases (3 non-serious; 1 serious) Suppressed lactation occurred in a breast feeding women with the following co-reported events: Pyrexia (2), Paresis, Headache, Chills, Vomiting, Pain in extremity, Arthralgia, Breast pain, Scar pain, Nausea, Migraine, Myalgia, Fatigue and Breast milk discolouration (1 each). Conclusion: There were no safety signals that emerged from the review of these cases of use in pregnancy and while breast feeding.
Use in Paediatric Individuals <12 Years of Age	<u>Paediatric individuals <12 years of age</u> • Number of cases: 34[d] (0.1% of the total PM dataset), indicative of administration in paediatric subjects <12 years of age; • Country of incidence: UK (29), US (3), Germany and Andorra (1 each); • Cases Seriousness: Serious (24), Non-Serious (10); • Gender: Females (25), Males (7), Unknown (2); • Age (n=34) ranged from 2 months to 9 years, mean = 3.7 years, median = 4.0; • Case outcome: resolved/resolving (16), not resolved (13), and unknown (5). • Of the 132 reported events, those reported more than once were as follows: Product administered to patient of inappropriate age (27, see Medication Error), Off label use (11), Pyrexia (6), Product use issue (5), Fatigue, Headache and Nausea (4 each), Vaccination site pain (3), Abdominal pain upper, COVID-19, Facial paralysis, Lymphadenopathy, Malaise, Pruritus and Swelling (2 each). Conclusion: No new significant safety information was identified based on a review of these cases compared with the non-paediatric population.
Vaccine Effectiveness	Company conventions for coding cases indicative of lack of efficacy: The coding conventions for lack of efficacy in the context of administration of the COVID-19 vaccine were revised on 15 February 2021, as shown below: • PT "Vaccination failure" is coded when ALL of the following criteria are met: o The subject has received the series of two doses per the dosing regimen in local labeling. o At least 7 days have elapsed since the second dose of vaccine has been administered. o The subject experiences SARS-CoV-2 infection (confirmed laboratory tests). • PT "Drug ineffective" is coded when either of the following applies: o The infection is not confirmed as SARS-CoV-2 through laboratory tests (irrespective of the vaccination schedule). This includes scenarios where LOE is stated or implied, e.g., "the vaccine did not work", "I got COVID-19". o It is unknown: ▪ Whether the subject has received the series of two doses per the dosing regimen in local labeling; ▪ How many days have passed since the first dose (including unspecified number of days like" a few days", "some days", etc.); ▪ If 7 days have passed since the second dose; o The subject experiences a vaccine preventable illness 14 days after receiving the first dose up to and through 6 days after receipt of the second dose. Note: after the immune system as had sufficient time (14 days) to respond to the vaccine, a report of COVID-19 is considered a potential lack of efficacy even if the vaccination course is not complete. Summary of the coding conventions for onset of vaccine preventable disease versus the vaccination date:

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**

1st dose (day 1-13)	From day 14 post 1st dose to day 6 post 2nd dose	Day 7 post 2nd dose
Code only the events describing the SARS-CoV-2 infection	Code "Drug ineffective"	Code "Vaccination failure"
Scenario Not considered LOE	Scenario considered LOE as "Drug ineffective"	Scenario considered LOE as "Vaccination failure"

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;
- Number of lack of efficacy events: 1665 [PT: Drug ineffective (1646) and Vaccination failure (19)[f]].
- Country of incidence: US (665), UK (405), Germany (181), France (85), Italy (58), Romania (47), Belgium (33), Israel (30), Poland (28), Spain (21), Austria (18), Portugal (17), Greece (15), Mexico (13), Denmark (8), Canada (7), Hungary, Sweden and United Arab Emirates (5 each), Czech Republic (4), Switzerland (3); the remaining 12 cases originated from 9 different countries.
- COVID-19 infection was suspected in 155 cases, confirmed in 228 cases, in 1 case it was reported that the first dose was not effective (no other information).
- COVID-19 infection (suspected or confirmed) outcome was reported as resolved/resolving (165), not resolved (205) or unknown (1230) at the time of the reporting; there were 65 cases where a fatal outcome was reported.

Drug ineffective cases (1649)

- Drug ineffective event seriousness: serious (1625), non-serious (21)[e];
- Lack of efficacy term was reported:
  - after the 1st dose in 788 cases
  - after the 2nd dose in 139 cases
  - in 722 cases it was unknown after which dose the lack of efficacy occurred.
- Latency of lack of efficacy term reported after the first dose was known for 176 cases:
  - Within 9 days: 2 subjects;
  - Within 14 and 21 days: 154 subjects;
  - Within 22 and 50 days: 20 subjects;
- Latency of lack of efficacy term reported after the second dose was known for 69 cases:
  - Within 0 and 7 days: 42 subjects;
  - Within 8 and 21 days: 22 subjects;
  - Within 23 and 36 days: 5 subjects.
- Latency of lack of efficacy term reported in cases where the number of doses administered was not provided, was known in 409 cases:
  - Within 0 and 7 days after vaccination: 281 subjects.
  - Within 8 and 14 days after vaccination: 89 subjects.
  - Within 15 and 44 days after vaccination: 39 subjects.

According to the RSI, individuals may not be fully protected until 7 days after their second dose of vaccine, therefore for the above 1649 cases where lack of efficacy was reported after the 1st dose or the

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Table 6. Description of Missing Information

Topic	Description
Missing Information	**Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)**
	2nd dose, the reported events may represent signs and symptoms of intercurrent or undiagnosed COVID-19 infection or infection in an individual who was not fully vaccinated, rather than vaccine ineffectiveness. ***Vaccination failure cases (16)*** • Vaccination failure seriousness: all serious; • Lack of efficacy term was reported in all cases after the 2nd dose: • Latency of lack of efficacy was known for 14 cases: o Within 7 and 13 days: 8 subjects; o Within 15 and 29 days: 6 subjects. COVID-19 (10) and Asymptomatic COVID-19 (6) were the reported vaccine preventable infections that occurred in these 16 cases. Conclusion: No new safety signals of vaccine lack of efficacy have emerged based on a review of these cases.

a. From a total of 417 cases, 4 cases were excluded from the analysis. In 3 cases, the MAH was informed that a 33-year-old and two unspecified age pregnant female patients were scheduled to receive bnt162b2 (PT reported Off label use and Product use issue in 2 cases; Circumstance or information capable of leading to medication error in one case). One case reported the PT Morning sickness; however, pregnancy was not confirmed in this case.
b. 558 additional cases retrieved in this dataset were excluded from the analysis; upon review, 546 cases cannot be considered true lack of efficacy cases because the PT Drug ineffective was coded but the subjects developed SARS-CoV-2 infection during the early days from the first dose (days 1 – 13); the vaccine has not had sufficient time to stimulate the immune system and, consequently, the development of a vaccine preventable disease during this time is not considered a potential lack of effect of the vaccine; in 5 cases the PT Drug ineffective was removed after data lock point (DLP) because the subjects did not develop COVID-19 infection; in 1 case, reporting Treatment failure and Transient ischaemic attack, the Lack of efficacy PT did not refer to BNT162b2 vaccine; 5 cases have been invalidated in the safety database after DLP; 1 case has been deleted from the discussion because the PTs reported Pathogen resistance and Product preparation issue were not indicative of a lack of efficacy. to be eliminated.
c. Upon review, 31 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects
d. Upon review, 28 additional cases were excluded from the analysis as the data reported (e.g. clinical details, height, weight, etc.) were not consistent with paediatric subjects.
e. Different clinical outcomes may be reported for an event that occurred more than once to the same individual
f. In 2 cases the PT Vaccination failure was replaced with Drug ineffective after DLP. Another case was not included in the discussion of the Vaccination failure cases because correct scheduling (21 days apart between the first and second dose) cannot be confirmed.

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3.1.3. Review of Adverse Events of Special Interest (AESIs)

Please refer to Appendix 1 for the list of the company's AESIs for BNT162b2.

The company's AESI list takes into consideration the lists of AESIs from the following expert groups and regulatory authorities: Brighton Collaboration (SPEAC), ACCESS protocol, US CDC (preliminary list of AESI for VAERS surveillance), MHRA (unpublished guideline).

The AESI terms are incorporated into a TME list and include events of interest due to their association with severe COVID-19 and events of interest for vaccines in general.

The AESI list is comprised of MedDRA PTs, HLTs, HLGTs or MedDRA SMQs and can be changed as appropriate based on the evolving safety profile of the vaccine.

Table 7 provides a summary review of cumulative cases within AESI categories in the Pfizer safety database. This is distinct from safety signal evaluations which are conducted and included, as appropriate, in the Summary Monthly Safety Reports submitted regularly to the FDA and other Health Authorities.

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
Anaphylactic Reactions *Search criteria: Anaphylactic reaction SMQ (Narrow and Broad, with the algorithm applied), selecting relevant cases according to BC criteria*	Please refer to the Risk 'Anaphylaxis' included above in Table 4.
Cardiovascular AESIs *Search criteria: PTs Acute myocardial infarction; Arrhythmia; Cardiac failure; Cardiac failure acute; Cardiogenic shock; Coronary artery disease; Myocardial infarction; Postural orthostatic tachycardia syndrome; Stress cardiomyopathy; Tachycardia*	• Number of cases: 1403 (3.3% of the total PM dataset), of which 241 are medically confirmed and 1162 are non-medically confirmed; • Country of incidence: UK (268), US (233), Mexico (196), Italy (141), France (128), Germany (102), Spain (46), Greece (45), Portugal (37), Sweden (20), Ireland (17), Poland (16), Israel (13), Austria, Romania and Finland (12 each), Netherlands (11), Belgium and Norway (10 each), Czech Republic (9), Hungary and Canada (8 each), Croatia and Denmark (7 each), Iceland (5); the remaining 30 cases were distributed among 13 other countries; • Subjects' gender: female (1076), male (291) and unknown (36); • Subjects' age group (n = 1346): Adult[c] (1078), Elderly[d] (266) Child[e] and Adolescent[f] (1 each); • Number of relevant events: 1441, of which 946 serious, 495 non-serious; in the cases reporting relevant serious events; • Reported relevant PTs: Tachycardia (1098), Arrhythmia (102), Myocardial infarction (89), Cardiac failure (80), Acute myocardial infarction (41), Cardiac failure acute (11), Cardiogenic shock and Postural orthostatic tachycardia syndrome (7 each) and Coronary artery disease (6); • Relevant event onset latency (n = 1209): Range from <24 hours to 21 days, median <24 hours;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome[g]: fatal (136), resolved/resolving (767), resolved with sequelae (21), not resolved (140) and unknown (380); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Ageusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[h] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Dermatological AESIs *Search criteria: PT Chillblains; Erythema multiforme*	• Number of cases: 20 cases (0.05% of the total PM dataset), of which 15 are medically confirmed and 5 are non-medically confirmed; • Country of incidence: UK (8), France and Poland (2 each), and the remaining 8 cases were distributed among 8 other different countries; • Subjects' gender: female (17) male and unknown (1 each); • Subjects' age group (n=19): Adult (18), Elderly (1); • Number of relevant events: 20 events, 16 serious, 4 non-serious

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Hepatic AESIs *Search criteria: Liver related investigations, signs and symptoms (SMQ) (Narrow and Broad) OR PT Liver injury*	• Number of cases: 70 cases (0.2% of the total PM dataset), of which 54 medically confirmed and 16 non-medically confirmed; • Country of incidence: UK (19), US (14), France (7), Italy (5), Germany (4), Belgium, Mexico and Spain (3 each), Austria, and Iceland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (43), male (26) and unknown (1); • Subjects' age group (n=64): Adult (37), Elderly (27);

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Number of relevant events: 94, of which 53 serious, 41 non-serious; • Most frequently reported relevant PTs (≥3 occurrences) include: Alanine aminotransferase increased (16), Transaminases increased and Hepatic pain (9 each), Liver function test increased (8), Aspartate aminotransferase increased and Liver function test abnormal (7 each), Gamma-glutamyltransferase increased and Hepatic enzyme increased (6 each), Blood alkaline phosphatase increased and Liver injury (5 each), Ascites, Blood bilirubin increased and Hypertransaminasaemia (3 each); • Relevant event onset latency (n = 57): Range from <24 hours to 20 days, median 3 days; • Relevant event outcome: fatal (5), resolved/resolving (27), resolved with sequelae (1), not resolved (14) and unknown (47). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Facial Paralysis *Search criteria: PTs Facial paralysis, Facial paresis*	• Number of cases: 449[i] (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed; • Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3),Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender: female (295), male (133), unknown (21); • Subjects' age group (n=411): Adult (313), Elderly (96), Infant[j] and Child (1 each); • Number of relevant events[k]: 453, of which 399 serious, 54 non-serious; • Reported relevant PTs: Facial paralysis (401), Facial paresis (64); • Relevant event onset latency (n = 404): Range from <24 hours to 46 days, median 2 days; • Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97); Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C4591001, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorisation safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	2021). Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.
Immune-Mediated/Autoimmune AESIs *Search criteria: Immune-mediated/autoimmune disorders (SMQ) (Broad and Narrow) OR Autoimmune disorders HLGT (Primary Path) OR PTs Cytokine release syndrome; Cytokine storm; Hypersensitivity*	• Number of cases: 1050 (2.5 % of the total PM dataset), of which 760 medically confirmed and 290 non-medically confirmed; • Country of incidence (>10 cases): UK (267), US (257), Italy (70), France and Germany (69 each), Mexico (36), Sweden (35), Spain (32), Greece (31), Israel (21), Denmark (18), Portugal (17), Austria and Czech Republic (16 each), Canada (12), Finland (10). The remaining 74 cases were from 24 different countries. • Subjects' gender (n=682): female (526), male (156). • Subjects' age group (n=944): Adult (746), Elderly (196), Adolescent (2). • Number of relevant events: 1077, of which 780 serious, 297 non-serious. • Most frequently reported relevant PTs (>10 occurrences): Hypersensitivity (596), Neuropathy peripheral (49), Pericarditis (32), Myocarditis (25), Dermatitis (24), Diabetes mellitus and Encephalitis (16 each), Psoriasis (14), Dermatitis Bullous (13), Autoimmune disorder and Raynaud's phenomenon (11 each); • Relevant event onset latency (n = 807): Range from <24 hours to 30 days, median <24 hours. • Relevant event outcome[l]: resolved/resolving (517), not resolved (215), fatal (12), resolved with sequelae (22) and unknown (312). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Musculoskeletal AESIs *Search criteria: PTs Arthralgia; Arthritis; Arthritis bacterial[n]; Chronic fatigue syndrome; Polyarthritis; Polyneuropathy; Post viral fatigue syndrome; Rheumatoid arthritis*	• Number of cases: 3600 (8.5% of the total PM dataset), of which 2045 medically confirmed and 1555 non-medically confirmed; • Country of incidence: UK (1406), US (1004), Italy (285), Mexico (236), Germany (72), Portugal (70), France (48), Greece and Poland (46), Latvia (33), Czech Republic (32), Israel and Spain (26), Sweden (25), Romania (24), Denmark (23), Finland and Ireland (19 each), Austria and Belgium (18 each), Canada (16), Netherlands (14), Bulgaria (12), Croatia and Serbia (9 each), Cyprus and Hungary (8 each), Norway (7), Estonia and Puerto Rico (6 each), Iceland and Lithuania (4 each); the remaining 21 cases originated from 11 different countries; • Subjects' gender (n=3471): female (2760), male (711); • Subjects' age group (n=3372): Adult (2850), Elderly (515), Child (4), Adolescent (2), Infant (1); • Number of relevant events: 3640, of which 1614 serious, 2026 non-serious; • Reported relevant PTs: Arthralgia (3525), Arthritis (70), Rheumatoid arthritis (26), Polyarthritis (5), Polyneuropathy, Post viral fatigue syndrome, Chronic fatigue syndrome (4 each), Arthritis bacterial (1); • Relevant event onset latency (n = 2968): Range from <24 hours to 32 days, median 1 day;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
	• Relevant event outcome: resolved/resolving (1801), not resolved (959), resolved with sequelae (49), and unknown (853). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Neurological AESIs (including demyelination) *Search criteria: Convulsions (SMQ) (Broad and Narrow) OR Demyelination (SMQ) (Broad and Narrow) OR PTs Ataxia; Cataplexy; Encephalopathy; Fibromyalgia; Intracranial pressure increased; Meningitis; Meningitis aseptic; Narcolepsy*	• Number of cases: 501 (1.2% of the total PM dataset), of which 365 medically confirmed and 136 non-medically confirmed. • Country of incidence (≥9 cases): UK (157), US (68), Germany (49), Mexico (35), Italy (31), France (25), Spain (18), Poland (17), Netherlands and Israel (15 each), Sweden (9). The remaining 71 cases were from 22 different countries. • Subjects' gender (n=478): female (328), male (150). • Subjects' age group (n=478): Adult (329), Elderly (149); • Number of relevant events: 542, of which 515 serious, 27 non-serious. • Most frequently reported relevant PTs (>2 occurrences) included: Seizure (204), Epilepsy (83), Generalised tonic-clonic seizure (33), Guillain-Barre syndrome (24), Fibromyalgia and Trigeminal neuralgia (17 each), Febrile convulsion, (15), Status epilepticus (12), Aura and Myelitis transverse (11 each), Multiple sclerosis relapse and Optic neuritis (10 each), Petit mal epilepsy and Tonic convulsion (9 each), Ataxia (8), Encephalopathy and Tonic clonic movements (7 each), Foaming at mouth (5), Multiple sclerosis, Narcolepsy and Partial seizures (4 each), Bad sensation, Demyelination, Meningitis, Postictal state, Seizure like phenomena and Tongue biting (3 each); • Relevant event onset latency (n = 423): Range from <24 hours to 48 days, median 1 day; • Relevant events outcome: fatal (16), resolved/resolving (265), resolved with sequelae (13), not resolved (89) and unknown (161); Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Other AESIs *Search criteria: Herpes viral infections (HLT) (Primary Path) OR PTs Adverse event following immunisation; Inflammation; Manufacturing laboratory analytical testing issue; Manufacturing materials issue; Manufacturing production issue; MERS-CoV test; MERS-CoV test negative; MERS-CoV test positive; Middle East respiratory syndrome; Multiple organ dysfunction syndrome; Occupational exposure to communicable disease; Patient*	• Number of cases: 8152 (19.4% of the total PM dataset), of which 4977 were medically confirmed and 3175 non-medically confirmed; • Country of incidence (> 20 occurrences): UK (2715), US (2421), Italy (710), Mexico (223), Portugal (210), Germany (207), France (186), Spain (183), Sweden (133), Denmark (127), Poland (120), Greece (95), Israel (79), Czech Republic (76), Romania (57), Hungary (53), Finland (52), Norway (51), Latvia (49), Austria (47), Croatia (42), Belgium (41), Canada (39), Ireland (34), Serbia (28), Iceland (25), Netherlands (22). The remaining 127 cases were from 21 different countries; • Subjects' gender (n=7829): female (5969), male (1860); • Subjects' age group (n=7479): Adult (6330), Elderly (1125), Adolescent, Child (9 each), Infant (6);

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
isolation; Product availability issue; Product distribution issue; Product supply issue; Pyrexia; Quarantine; SARS-CoV-1 test; SARS-CoV-1 test negative; SARS-CoV-1 test positive	• Number of relevant events: 8241, of which 3674 serious, 4568 non-serious; • Most frequently reported relevant PTs (≥6 occurrences) included: Pyrexia (7666), Herpes zoster (259), Inflammation (132), Oral herpes (80), Multiple organ dysfunction syndrome (18), Herpes virus infection (17), Herpes simplex (13), Ophthalmic herpes zoster (10), Herpes ophthalmic and Herpes zoster reactivation (6 each); • Relevant event onset latency (n =6836): Range from <24 hours to 61 days, median 1 day; • Relevant events outcome: fatal (96), resolved/resolving (5008), resolved with sequelae (84), not resolved (1429) and unknown (1685). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue
Pregnancy Related AESIs *Search criteria: PTs Amniotic cavity infection; Caesarean section; Congenital anomaly; Death neonatal; Eclampsia; Foetal distress syndrome; Low birth weight baby; Maternal exposure during pregnancy; Placenta praevia; Pre-eclampsia; Premature labour; Stillbirth; Uterine rupture; Vasa praevia*	For relevant cases, please refer to Table 6, Description of Missing Information, *Use in Pregnancy and While Breast Feeding*
Renal AESIs *Search criteria: PTs Acute kidney injury; Renal failure.*	• Number of cases: 69 cases (0.17% of the total PM dataset), of which 57 medically confirmed, 12 non-medically confirmed; • Country of incidence: Germany (17), France and UK (13 each), US (6), Belgium, Italy and Spain (4 each), Sweden (2), Austria, Canada, Denmark, Finland, Luxembourg and Norway (1 each); • Subjects' gender: female (46), male (23); • Subjects' age group (n=68): Adult (7), Elderly (60), Infant (1); • Number of relevant events: 70, all serious; • Reported relevant PTs: Acute kidney injury (40) and Renal failure (30); • Relevant event onset latency (n = 42): Range from <24 hours to 15 days, median 4 days; • Relevant event outcome: fatal (23), resolved/resolving (10), not resolved (15) and unknown (22). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Stroke *Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents*	• Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed; • Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9),

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] **Category**	**Post-Marketing Cases Evaluation**[b] **Total Number of Cases (N=42086)**
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries; • Subjects' gender (n= 273): female (182), male (91); • Subjects' age group (n=265): Adult (59), Elderly (205), Child[m] (1); • Number of relevant events: 300, all serious; • Most frequently reported relevant PTs (>1 occurrence) included: o PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunal infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); o PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranical and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); • Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; • Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Vasculitic Events *Search criteria: Vasculitides HLT*	• Number of cases: 32 cases (0.08% of the total PM dataset), of which 26 medically confirmed and 6 non-medically confirmed; • Country of incidence: UK (13), France (4), Portugal, US and Spain (3 each), Cyprus, Germany, Hungary, Italy and Slovakia and Costa rica (1 each); • Subjects' gender: female (26), male (6); • Subjects' age group (n=31): Adult (15), Elderly (16); • Number of relevant events: 34, of which 25 serious, 9 non-serious; • Reported relevant PTs: Vasculitis (14), Cutaneous vasculitis and Vasculitic rash (4 each), (3), Giant cell arteritis and Peripheral ischaemia (3 each), Behcet's syndrome and Hypersensitivity vasculitis (2 each) Palpable purpura, and Takayasu's arteritis (1 each); • Relevant event onset latency (n = 25): Range from <24 hours to 19 days, median 3 days; • Relevant event outcome: fatal (1), resolved/resolving (13), not resolved (12) and unknown (8). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue

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Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)

a. For the complete list of the AESIs, please refer to Appendix 5;
b. Please note that this corresponds to evidence from post-EUA/conditional marketing authorisation approval data sources;
c. Subjects with age ranged between 18 and 64 years;
d. Subjects with age equal to or above 65 years;
e. Subjects with age ranged between 2 and 11 years;
f. Subjects with age ranged between 12 and less than 18 years;
g. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events;
h. Subjects with age ranged between 1 (28 days) and 23 months;
i. Twenty-four additional cases were excluded from the analysis as they were not cases of peripheral facial nerve palsy because they described other disorders (stroke, cerebral haemorrhage or transient ischaemic attack); 1 case was excluded from the analysis because it was invalid due to an unidentifiable reporter;
j. This UK case report received from the UK MHRA described a 1-year-old subject who received the vaccine, and had left postauricular ear pain that progressed to left-sided Bell's palsy 1 day following vaccination that had not resolved at the time of the report;
k. If a case included both PT Facial paresis and PT Facial paralysis, only the PT Facial paralysis was considered in the descriptions of the events as it is most clinically important;
l. Multiple episodes of the same PT event were reported with a different clinical outcome within some cases hence the sum of the events outcome exceeds the total number of PT events
m. This UK case report received from the UK MHRA described a 7-year-old female subject who received the vaccine and had stroke (unknown outcome); no follow-up is possible for clarification.
n. This PT not included in the AESIs/TME list was included in the review as relevant for ACCESS protocol criteria;

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3.1.4. Medication error

Cases potentially indicative of medication errors[1] that cumulatively occurred are summarized below.

- Number of relevant medication error cases: 2056[2] (4.9%) of which 1569 (3.7%) are medically confirmed.
- Number of relevant events: 2792
- Top 10 countries of incidence:
  - US (1201), France (171), UK (138), Germany (88), Czech Republic (87), Sweden (49), Israel (45), Italy (42), Canada (35), Romania (33), Finland (21), Portugal (20), Norway (14), Puerto Rico (13), Poland (12), Austria and Spain (10 each).

  Medication error case outcomes:

  - Fatal (7)[3],
  - Recovered/recovering (354, of which 4 are serious),
  - Recovered with sequelae (8, of which 3 serious)

[1] MedDRA (version 23.1) Higher Level Terms: Accidental exposures to product; Product administration errors and issues; Product confusion errors and issues; Product dispensing errors and issues; Product label issues; Product monitoring errors and issues; Product preparation errors and issues; Product selection errors and issues; Product storage errors and issues in the product use system; Product transcribing errors and communication issues, OR Preferred Terms: Accidental poisoning; Circumstance or information capable of leading to device use error; Circumstance or information capable of leading to medication error; Contraindicated device used; Deprescribing error; Device use error; Dose calculation error; Drug titration error; Expired device used; Exposure via direct contact; Exposure via eye contact; Exposure via mucosa; Exposure via skin contact; Failure of child resistant product closure; Inadequate aseptic technique in use of product; Incorrect disposal of product; Intercepted medication error; Intercepted product prescribing error; Medication error; Multiple use of single-use product; Product advertising issue; Product distribution issue; Product prescribing error; Product prescribing issue; Product substitution error; Product temperature excursion issue; Product use in unapproved therapeutic environment; Radiation underdose; Underdose; Unintentional medical device removal; Unintentional use for unapproved indication; Vaccination error; Wrong device used; Wrong dosage form; Wrong dosage formulation; Wrong dose; Wrong drug; Wrong patient; Wrong product procured; Wrong product stored; Wrong rate; Wrong route; Wrong schedule; Wrong strength; Wrong technique in device usage process; Wrong technique in product usage process.

[2] Thirty-five (35) cases were exclude from the analysis because describing medication errors occurring in an unspecified number of individuals or describing medication errors occurring with co suspects were determined to be non-contributory.

[3] All the medication errors reported in these cases were assessed as non-serious occurrences with an unknown outcome; based on the available information including the causes of death, the relationship between the medication error and the death is weak. .

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- Not recovered (189, of which 84 are serious),
- Unknown (1498, of which 33 are serious).

1371 cases reported only MEs without any associated clinical adverse event. The PTs most frequently reported (≥12 occurrences) were: Poor quality product administered (539), Product temperature excursion issue (253), Inappropriate schedule of product administration (225), Product preparation error (206), Underdose (202), Circumstance or information capable of leading to medication error (120), Product preparation issue (119), Wrong technique in product usage process (76), Incorrect route of product administration (66), Accidental overdose (33), Product administered at inappropriate site (27), Incorrect dose administered and Accidental exposure to the product (25 each), Exposure via skin contact (22), Wrong product administered (17), Incomplete course of vaccination, and Product administration error (14 each) Product administered to patient of inappropriate age (12).

In 685 cases, there were co-reported AEs. The most frequently co- associated AEs (> 40 occurrences) were: Headache (187), Pyrexia (161), Fatigue (135), Chills (127), Pain (107), Vaccination site pain (100), Nausea (89), Myalgia (88), Pain in extremity (85) Arthralgia (68), Off label use (57), Dizziness (52), Lymphadenopathy (47), Asthenia (46) and Malaise (41). These cases are summarized in Table 8.

Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Accidental exposure to product	0	0	0	5
Accidental overdose	4	1	9	6
Booster dose missed	0	0	0	1
Circumstance or information capable of leading to medication error	0	0	5	11
Contraindicated product administered	1	0	0	2
Expired product administered	0	0	0	2
Exposure via skin contact	0	0	0	5
Inappropriate schedule of product administration	0	2	8	264
Incorrect dose administered	1	1	0	0

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Table 8. ME PTs by seriousness with or without harm co-association (Through 28 February 2021)

	Serious		Non-Serious	
ME PTs	**With Harm**	**Without Harm**	**With Harm**	**Without Harm**
Incorrect route of product administration	2	6	16	127
Lack of vaccination site rotation	1	0	0	0
Medication error	0	0	0	1
Poor quality product administered	1	0	0	34
Product administered at inappropriate site	2	1	13	29
Product administered to patient of inappropriate age	0	4	0	40
Product administration error	1	0	0	3
Product dose omission issue	0	1	0	3
Product preparation error	1	0	4	11
Product preparation issue	1	1	0	14

Overall, there were 68 cases with co-reported AEs reporting Harm and 599 cases with co-reported AEs without harm. Additionally, Intercepted medication errors was reported in 1 case (PTs Malaise, clinical outcome unknow) and Potential medication errors were reported in 17 cases.

4. DISCUSSION

Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.

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5. SUMMARY AND CONCLUSION

Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.

Pfizer will continue routine pharmacovigilance activities on behalf of BioNTech according to the Pharmacovigilance Agreement in place, in order to assure patient safety and will inform the Agency if an evaluation of the safety data yields significant new information for BNT162b2.

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APPENDIX 1. LIST OF ADVERSE EVENTS OF SPECIAL INTEREST

1p36 deletion syndrome;2-Hydroxyglutaric aciduria;5'nucleotidase increased;Acoustic neuritis;Acquired C1 inhibitor deficiency;Acquired epidermolysis bullosa;Acquired epileptic aphasia;Acute cutaneous lupus erythematosus;Acute disseminated encephalomyelitis;Acute encephalitis with refractory, repetitive partial seizures;Acute febrile neutrophilic dermatosis;Acute flaccid myelitis;Acute haemorrhagic leukoencephalitis;Acute haemorrhagic oedema of infancy;Acute kidney injury;Acute macular outer retinopathy;Acute motor axonal neuropathy;Acute motor-sensory axonal neuropathy;Acute myocardial infarction;Acute respiratory distress syndrome;Acute respiratory failure;Addison's disease;Administration site thrombosis;Administration site vasculitis;Adrenal thrombosis;Adverse event following immunisation;Ageusia;Agranulocytosis;Air embolism;Alanine aminotransferase abnormal;Alanine aminotransferase increased;Alcoholic seizure;Allergic bronchopulmonary mycosis;Allergic oedema;Alloimmune hepatitis;Alopecia areata;Alpers disease;Alveolar proteinosis;Ammonia abnormal;Ammonia increased;Amniotic cavity infection;Amygdalohippocampectomy;Amyloid arthropathy;Amyloidosis;Amyloidosis senile;Anaphylactic reaction;Anaphylactic shock;Anaphylactic transfusion reaction;Anaphylactoid reaction;Anaphylactoid shock;Anaphylactoid syndrome of pregnancy;Angioedema;Angiopathic neuropathy;Ankylosing spondylitis;Anosmia;Antiacetylcholine receptor antibody positive;Anti-actin antibody positive;Anti-aquaporin-4 antibody positive;Anti-basal ganglia antibody positive;Anti-cyclic citrullinated peptide antibody positive;Anti-epithelial antibody positive;Anti-erythrocyte antibody positive;Anti-exosome complex antibody positive;Anti-GAD antibody negative;Anti-GAD antibody positive;Anti-ganglioside antibody positive;Antigliadin antibody positive;Anti-glomerular basement membrane antibody positive;Anti-glomerular basement membrane disease;Anti-glycyl-tRNA synthetase antibody positive;Anti-HLA antibody test positive;Anti-IA2 antibody positive;Anti-insulin antibody increased;Anti-insulin antibody positive;Anti-insulin receptor antibody increased;Anti-insulin receptor antibody positive;Anti-interferon antibody negative;Anti-interferon antibody positive;Anti-islet cell antibody positive;Antimitochondrial antibody positive;Anti-muscle specific kinase antibody positive;Anti-myelin-associated glycoprotein antibodies positive;Anti-myelin-associated glycoprotein associated polyneuropathy;Antimyocardial antibody positive;Anti-neuronal antibody positive;Antineutrophil cytoplasmic antibody increased;Antineutrophil cytoplasmic antibody positive;Anti-neutrophil cytoplasmic antibody positive vasculitis;Anti-NMDA antibody positive;Antinuclear antibody increased;Antinuclear antibody positive;Antiphospholipid antibodies positive;Antiphospholipid syndrome;Anti-platelet antibody positive;Anti-prothrombin antibody positive;Antiribosomal P antibody positive;Anti-RNA polymerase III antibody positive;Anti-saccharomyces cerevisiae antibody test positive;Anti-sperm antibody positive;Anti-SRP antibody positive;Antisynthetase syndrome;Anti-thyroid antibody positive;Anti-transglutaminase antibody increased;Anti-VGCC antibody positive;Anti-VGKC antibody positive;Anti-vimentin antibody positive;Antiviral prophylaxis;Antiviral treatment;Anti-zinc transporter 8 antibody positive;Aortic embolus;Aortic thrombosis;Aortitis;Aplasia pure red cell;Aplastic anaemia;Application site thrombosis;Application site vasculitis;Arrhythmia;Arterial bypass occlusion;Arterial bypass thrombosis;Arterial thrombosis;Arteriovenous fistula thrombosis;Arteriovenous graft site stenosis;Arteriovenous graft thrombosis;Arteritis;Arteritis

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coronary;Arthralgia;Arthritis;Arthritis enteropathic;Ascites;Aseptic cavernous sinus thrombosis;Aspartate aminotransferase abnormal;Aspartate aminotransferase increased;Aspartate-glutamate-transporter deficiency;AST to platelet ratio index increased;AST/ALT ratio abnormal;Asthma;Asymptomatic COVID-19;Ataxia;Atheroembolism;Atonic seizures;Atrial thrombosis;Atrophic thyroiditis;Atypical benign partial epilepsy;Atypical pneumonia;Aura;Autoantibody positive;Autoimmune anaemia;Autoimmune aplastic anaemia;Autoimmune arthritis;Autoimmune blistering disease;Autoimmune cholangitis;Autoimmune colitis;Autoimmune demyelinating disease;Autoimmune dermatitis;Autoimmune disorder;Autoimmune encephalopathy;Autoimmune endocrine disorder;Autoimmune enteropathy;Autoimmune eye disorder;Autoimmune haemolytic anaemia;Autoimmune heparin-induced thrombocytopenia;Autoimmune hepatitis;Autoimmune hyperlipidaemia;Autoimmune hypothyroidism;Autoimmune inner ear disease;Autoimmune lung disease;Autoimmune lymphoproliferative syndrome;Autoimmune myocarditis;Autoimmune myositis;Autoimmune nephritis;Autoimmune neuropathy;Autoimmune neutropenia;Autoimmune pancreatitis;Autoimmune pancytopenia;Autoimmune pericarditis;Autoimmune retinopathy;Autoimmune thyroid disorder;Autoimmune thyroiditis;Autoimmune uveitis;Autoinflammation with infantile enterocolitis;Autoinflammatory disease;Automatism epileptic;Autonomic nervous system imbalance;Autonomic seizure;Axial spondyloarthritis;Axillary vein thrombosis;Axonal and demyelinating polyneuropathy;Axonal neuropathy;Bacterascites;Baltic myoclonic epilepsy;Band sensation;Basedow's disease;Basilar artery thrombosis;Basophilopenia;B-cell aplasia;Behcet's syndrome;Benign ethnic neutropenia;Benign familial neonatal convulsions;Benign familial pemphigus;Benign rolandic epilepsy;Beta-2 glycoprotein antibody positive;Bickerstaff's encephalitis;Bile output abnormal;Bile output decreased;Biliary ascites;Bilirubin conjugated abnormal;Bilirubin conjugated increased;Bilirubin urine present;Biopsy liver abnormal;Biotinidase deficiency;Birdshot chorioretinopathy;Blood alkaline phosphatase abnormal;Blood alkaline phosphatase increased;Blood bilirubin abnormal;Blood bilirubin increased;Blood bilirubin unconjugated increased;Blood cholinesterase abnormal;Blood cholinesterase decreased;Blood pressure decreased;Blood pressure diastolic decreased;Blood pressure systolic decreased;Blue toe syndrome;Brachiocephalic vein thrombosis;Brain stem embolism;Brain stem thrombosis;Bromosulphthalein test abnormal;Bronchial oedema;Bronchitis;Bronchitis mycoplasmal;Bronchitis viral;Bronchopulmonary aspergillosis allergic;Bronchospasm;Budd-Chiari syndrome;Bulbar palsy;Butterfly rash;C1q nephropathy;Caesarean section;Calcium embolism;Capillaritis;Caplan's syndrome;Cardiac amyloidosis;Cardiac arrest;Cardiac failure;Cardiac failure acute;Cardiac sarcoidosis;Cardiac ventricular thrombosis;Cardiogenic shock;Cardiolipin antibody positive;Cardiopulmonary failure;Cardio-respiratory arrest;Cardio-respiratory distress;Cardiovascular insufficiency;Carotid arterial embolus;Carotid artery thrombosis;Cataplexy;Catheter site thrombosis;Catheter site vasculitis;Cavernous sinus thrombosis;CDKL5 deficiency disorder;CEC syndrome;Cement embolism;Central nervous system lupus;Central nervous system vasculitis;Cerebellar artery thrombosis;Cerebellar embolism;Cerebral amyloid angiopathy;Cerebral arteritis;Cerebral artery embolism;Cerebral artery thrombosis;Cerebral gas embolism;Cerebral microembolism;Cerebral septic infarct;Cerebral thrombosis;Cerebral venous sinus thrombosis;Cerebral venous thrombosis;Cerebrospinal thrombotic

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tamponade;Cerebrovascular accident;Change in seizure presentation;Chest discomfort;Child-Pugh-Turcotte score abnormal;Child-Pugh-Turcotte score increased;Chillblains;Choking;Choking sensation;Cholangitis sclerosing;Chronic autoimmune glomerulonephritis;Chronic cutaneous lupus erythematosus;Chronic fatigue syndrome;Chronic gastritis;Chronic inflammatory demyelinating polyradiculoneuropathy;Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids;Chronic recurrent multifocal osteomyelitis;Chronic respiratory failure;Chronic spontaneous urticaria;Circulatory collapse;Circumoral oedema;Circumoral swelling;Clinically isolated syndrome;Clonic convulsion;Coeliac disease;Cogan's syndrome;Cold agglutinins positive;Cold type haemolytic anaemia;Colitis;Colitis erosive;Colitis herpes;Colitis microscopic;Colitis ulcerative;Collagen disorder;Collagen-vascular disease;Complement factor abnormal;Complement factor C1 decreased;Complement factor C2 decreased;Complement factor C3 decreased;Complement factor C4 decreased;Complement factor decreased;Computerised tomogram liver abnormal;Concentric sclerosis;Congenital anomaly;Congenital bilateral perisylvian syndrome;Congenital herpes simplex infection;Congenital myasthenic syndrome;Congenital varicella infection;Congestive hepatopathy;Convulsion in childhood;Convulsions local;Convulsive threshold lowered;Coombs positive haemolytic anaemia;Coronary artery disease;Coronary artery embolism;Coronary artery thrombosis;Coronary bypass thrombosis;Coronavirus infection;Coronavirus test;Coronavirus test negative;Coronavirus test positive;Corpus callosotomy;Cough;Cough variant asthma;COVID-19;COVID-19 immunisation;COVID-19 pneumonia;COVID-19 prophylaxis;COVID-19 treatment;Cranial nerve disorder;Cranial nerve palsies multiple;Cranial nerve paralysis;CREST syndrome;Crohn's disease;Cryofibrinogenaemia;Cryoglobulinaemia;CSF oligoclonal band present;CSWS syndrome;Cutaneous amyloidosis;Cutaneous lupus erythematosus;Cutaneous sarcoidosis;Cutaneous vasculitis;Cyanosis;Cyclic neutropenia;Cystitis interstitial;Cytokine release syndrome;Cytokine storm;De novo purine synthesis inhibitors associated acute inflammatory syndrome;Death neonatal;Deep vein thrombosis;Deep vein thrombosis postoperative;Deficiency of bile secretion;Deja vu;Demyelinating polyneuropathy;Demyelination;Dermatitis;Dermatitis bullous;Dermatitis herpetiformis;Dermatomyositis;Device embolisation;Device related thrombosis;Diabetes mellitus;Diabetic ketoacidosis;Diabetic mastopathy;Dialysis amyloidosis;Dialysis membrane reaction;Diastolic hypotension;Diffuse vasculitis;Digital pitting scar;Disseminated intravascular coagulation;Disseminated intravascular coagulation in newborn;Disseminated neonatal herpes simplex;Disseminated varicella;Disseminated varicella zoster vaccine virus infection;Disseminated varicella zoster virus infection;DNA antibody positive;Double cortex syndrome;Double stranded DNA antibody positive;Dreamy state;Dressler's syndrome;Drop attacks;Drug withdrawal convulsions;Dyspnoea;Early infantile epileptic encephalopathy with burst-suppression;Eclampsia;Eczema herpeticum;Embolia cutis medicamentosa;Embolic cerebellar infarction;Embolic cerebral infarction;Embolic pneumonia;Embolic stroke;Embolism;Embolism arterial;Embolism venous;Encephalitis;Encephalitis allergic;Encephalitis autoimmune;Encephalitis brain stem;Encephalitis haemorrhagic;Encephalitis periaxialis diffusa;Encephalitis post immunisation;Encephalomyelitis;Encephalopathy;Endocrine disorder;Endocrine ophthalmopathy;Endotracheal intubation;Enteritis;Enteritis leukopenic;Enterobacter pneumonia;Enterocolitis;Enteropathic spondylitis;Eosinopenia;Eosinophilic

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fasciitis;Eosinophilic granulomatosis with polyangiitis;Eosinophilic oesophagitis;Epidermolysis;Epilepsy;Epilepsy surgery;Epilepsy with myoclonic-atonic seizures;Epileptic aura;Epileptic psychosis;Erythema;Erythema induratum;Erythema multiforme;Erythema nodosum;Evans syndrome;Exanthema subitum;Expanded disability status scale score decreased;Expanded disability status scale score increased;Exposure to communicable disease;Exposure to SARS-CoV-2;Eye oedema;Eye pruritus;Eye swelling;Eyelid oedema;Face oedema;Facial paralysis;Facial paresis;Faciobrachial dystonic seizure;Fat embolism;Febrile convulsion;Febrile infection-related epilepsy syndrome;Febrile neutropenia;Felty's syndrome;Femoral artery embolism;Fibrillary glomerulonephritis;Fibromyalgia;Flushing;Foaming at mouth;Focal cortical resection;Focal dyscognitive seizures;Foetal distress syndrome;Foetal placental thrombosis;Foetor hepaticus;Foreign body embolism;Frontal lobe epilepsy;Fulminant type 1 diabetes mellitus;Galactose elimination capacity test abnormal;Galactose elimination capacity test decreased;Gamma-glutamyltransferase abnormal;Gamma-glutamyltransferase increased;Gastritis herpes;Gastrointestinal amyloidosis;Gelastic seizure;Generalised onset non-motor seizure;Generalised tonic-clonic seizure;Genital herpes;Genital herpes simplex;Genital herpes zoster;Giant cell arteritis;Glomerulonephritis;Glomerulonephritis membranoproliferative;Glomerulonephritis membranous;Glomerulonephritis rapidly progressive;Glossopharyngeal nerve paralysis;Glucose transporter type 1 deficiency syndrome;Glutamate dehydrogenase increased;Glycocholic acid increased;GM2 gangliosidosis;Goodpasture's syndrome;Graft thrombosis;Granulocytopenia;Granulocytopenia neonatal;Granulomatosis with polyangiitis;Granulomatous dermatitis;Grey matter heterotopia;Guanase increased;Guillain-Barre syndrome;Haemolytic anaemia;Haemophagocytic lymphohistiocytosis;Haemorrhage;Haemorrhagic ascites;Haemorrhagic disorder;Haemorrhagic pneumonia;Haemorrhagic varicella syndrome;Haemorrhagic vasculitis;Hantavirus pulmonary infection;Hashimoto's encephalopathy;Hashitoxicosis;Hemimegalencephaly;Henoch-Schonlein purpura;Henoch-Schonlein purpura nephritis;Hepaplastin abnormal;Hepaplastin decreased;Heparin-induced thrombocytopenia;Hepatic amyloidosis;Hepatic artery embolism;Hepatic artery flow decreased;Hepatic artery thrombosis;Hepatic enzyme abnormal;Hepatic enzyme decreased;Hepatic enzyme increased;Hepatic fibrosis marker abnormal;Hepatic fibrosis marker increased;Hepatic function abnormal;Hepatic hydrothorax;Hepatic hypertrophy;Hepatic hypoperfusion;Hepatic lymphocytic infiltration;Hepatic mass;Hepatic pain;Hepatic sequestration;Hepatic vascular resistance increased;Hepatic vascular thrombosis;Hepatic vein embolism;Hepatic vein thrombosis;Hepatic venous pressure gradient abnormal;Hepatic venous pressure gradient increased;Hepatitis;Hepatobiliary scan abnormal;Hepatomegaly;Hepatosplenomegaly;Hereditary angioedema with C1 esterase inhibitor deficiency;Herpes dermatitis;Herpes gestationis;Herpes oesophagitis;Herpes ophthalmic;Herpes pharyngitis;Herpes sepsis;Herpes simplex;Herpes simplex cervicitis;Herpes simplex colitis;Herpes simplex encephalitis;Herpes simplex gastritis;Herpes simplex hepatitis;Herpes simplex meningitis;Herpes simplex meningoencephalitis;Herpes simplex meningomyelitis;Herpes simplex necrotising retinopathy;Herpes simplex oesophagitis;Herpes simplex otitis externa;Herpes simplex pharyngitis;Herpes simplex pneumonia;Herpes simplex reactivation;Herpes simplex sepsis;Herpes simplex viraemia;Herpes simplex virus conjunctivitis neonatal;Herpes simplex visceral;Herpes virus

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infection;Herpes zoster;Herpes zoster cutaneous disseminated;Herpes zoster infection neurological;Herpes zoster meningitis;Herpes zoster meningoencephalitis;Herpes zoster meningomyelitis;Herpes zoster meningoradiculitis;Herpes zoster necrotising retinopathy;Herpes zoster oticus;Herpes zoster pharyngitis;Herpes zoster reactivation;Herpetic radiculopathy;Histone antibody positive;Hoigne's syndrome;Human herpesvirus 6 encephalitis;Human herpesvirus 6 infection;Human herpesvirus 6 infection reactivation;Human herpesvirus 7 infection;Human herpesvirus 8 infection;Hyperammonaemia;Hyperbilirubinaemia;Hypercholia;Hypergammaglobulinaemia benign monoclonal;Hyperglycaemic seizure;Hypersensitivity;Hypersensitivity vasculitis;Hyperthyroidism;Hypertransaminasaemia;Hyperventilation;Hypoalbuminaemia;Hypocalcaemic seizure;Hypogammaglobulinaemia;Hypoglossal nerve paralysis;Hypoglossal nerve paresis;Hypoglycaemic seizure;Hyponatraemic seizure;Hypotension;Hypotensive crisis;Hypothenar hammer syndrome;Hypothyroidism;Hypoxia;Idiopathic CD4 lymphocytopenia;Idiopathic generalised epilepsy;Idiopathic interstitial pneumonia;Idiopathic neutropenia;Idiopathic pulmonary fibrosis;IgA nephropathy;IgM nephropathy;IIIrd nerve paralysis;IIIrd nerve paresis;Iliac artery embolism;Immune thrombocytopenia;Immune-mediated adverse reaction;Immune-mediated cholangitis;Immune-mediated cholestasis;Immune-mediated cytopenia;Immune-mediated encephalitis;Immune-mediated encephalopathy;Immune-mediated endocrinopathy;Immune-mediated enterocolitis;Immune-mediated gastritis;Immune-mediated hepatic disorder;Immune-mediated hepatitis;Immune-mediated hyperthyroidism;Immune-mediated hypothyroidism;Immune-mediated myocarditis;Immune-mediated myositis;Immune-mediated nephritis;Immune-mediated neuropathy;Immune-mediated pancreatitis;Immune-mediated pneumonitis;Immune-mediated renal disorder;Immune-mediated thyroiditis;Immune-mediated uveitis;Immunoglobulin G4 related disease;Immunoglobulins abnormal;Implant site thrombosis;Inclusion body myositis;Infantile genetic agranulocytosis;Infantile spasms;Infected vasculitis;Infective thrombosis;Inflammation;Inflammatory bowel disease;Infusion site thrombosis;Infusion site vasculitis;Injection site thrombosis;Injection site urticaria;Injection site vasculitis;Instillation site thrombosis;Insulin autoimmune syndrome;Interstitial granulomatous dermatitis;Interstitial lung disease;Intracardiac mass;Intracardiac thrombus;Intracranial pressure increased;Intrapericardial thrombosis;Intrinsic factor antibody abnormal;Intrinsic factor antibody positive;IPEX syndrome;Irregular breathing;IRVAN syndrome;IVth nerve paralysis;IVth nerve paresis;JC polyomavirus test positive;JC virus CSF test positive;Jeavons syndrome;Jugular vein embolism;Jugular vein thrombosis;Juvenile idiopathic arthritis;Juvenile myoclonic epilepsy;Juvenile polymyositis;Juvenile psoriatic arthritis;Juvenile spondyloarthritis;Kaposi sarcoma inflammatory cytokine syndrome;Kawasaki's disease;Kayser-Fleischer ring;Keratoderma blenorrhagica;Ketosis-prone diabetes mellitus;Kounis syndrome;Lafora's myoclonic epilepsy;Lambl's excrescences;Laryngeal dyspnoea;Laryngeal oedema;Laryngeal rheumatoid arthritis;Laryngospasm;Laryngotracheal oedema;Latent autoimmune diabetes in adults;LE cells present;Lemierre syndrome;Lennox-Gastaut syndrome;Leucine aminopeptidase increased;Leukoencephalomyelitis;Leukoencephalopathy;Leukopenia;Leukopenia neonatal;Lewis-Sumner syndrome;Lhermitte's sign;Lichen planopilaris;Lichen planus;Lichen sclerosus;Limbic encephalitis;Linear IgA disease;Lip oedema;Lip swelling;Liver function test abnormal;Liver function test decreased;Liver function test increased;Liver induration;Liver injury;Liver iron concentration abnormal;Liver iron concentration

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increased;Liver opacity;Liver palpable;Liver sarcoidosis;Liver scan abnormal;Liver tenderness;Low birth weight baby;Lower respiratory tract herpes infection;Lower respiratory tract infection;Lower respiratory tract infection viral;Lung abscess;Lupoid hepatic cirrhosis;Lupus cystitis;Lupus encephalitis;Lupus endocarditis;Lupus enteritis;Lupus hepatitis;Lupus myocarditis;Lupus myositis;Lupus nephritis;Lupus pancreatitis;Lupus pleurisy;Lupus pneumonitis;Lupus vasculitis;Lupus-like syndrome;Lymphocytic hypophysitis;Lymphocytopenia neonatal;Lymphopenia;MAGIC syndrome;Magnetic resonance imaging liver abnormal;Magnetic resonance proton density fat fraction measurement;Mahler sign;Manufacturing laboratory analytical testing issue;Manufacturing materials issue;Manufacturing production issue;Marburg's variant multiple sclerosis;Marchiafava-Bignami disease;Marine Lenhart syndrome;Mastocytic enterocolitis;Maternal exposure during pregnancy;Medical device site thrombosis;Medical device site vasculitis;MELAS syndrome;Meningitis;Meningitis aseptic;Meningitis herpes;Meningoencephalitis herpes simplex neonatal;Meningoencephalitis herpetic;Meningomyelitis herpes;MERS-CoV test;MERS-CoV test negative;MERS-CoV test positive;Mesangioproliferative glomerulonephritis;Mesenteric artery embolism;Mesenteric artery thrombosis;Mesenteric vein thrombosis;Metapneumovirus infection;Metastatic cutaneous Crohn's disease;Metastatic pulmonary embolism;Microangiopathy;Microembolism;Microscopic polyangiitis;Middle East respiratory syndrome;Migraine-triggered seizure;Miliary pneumonia;Miller Fisher syndrome;Mitochondrial aspartate aminotransferase increased;Mixed connective tissue disease;Model for end stage liver disease score abnormal;Model for end stage liver disease score increased;Molar ratio of total branched-chain amino acid to tyrosine;Molybdenum cofactor deficiency;Monocytopenia;Mononeuritis;Mononeuropathy multiplex;Morphoea;Morvan syndrome;Mouth swelling;Moyamoya disease;Multifocal motor neuropathy;Multiple organ dysfunction syndrome;Multiple sclerosis;Multiple sclerosis relapse;Multiple sclerosis relapse prophylaxis;Multiple subpial transection;Multisystem inflammatory syndrome in children;Muscular sarcoidosis;Myasthenia gravis;Myasthenia gravis crisis;Myasthenia gravis neonatal;Myasthenic syndrome;Myelitis;Myelitis transverse;Myocardial infarction;Myocarditis;Myocarditis post infection;Myoclonic epilepsy;Myoclonic epilepsy and ragged-red fibres;Myokymia;Myositis;Narcolepsy;Nasal herpes;Nasal obstruction;Necrotising herpetic retinopathy;Neonatal Crohn's disease;Neonatal epileptic seizure;Neonatal lupus erythematosus;Neonatal mucocutaneous herpes simplex;Neonatal pneumonia;Neonatal seizure;Nephritis;Nephrogenic systemic fibrosis;Neuralgic amyotrophy;Neuritis;Neuritis cranial;Neuromyelitis optica pseudo relapse;Neuromyelitis optica spectrum disorder;Neuromyotonia;Neuronal neuropathy;Neuropathy peripheral;Neuropathy, ataxia, retinitis pigmentosa syndrome;Neuropsychiatric lupus;Neurosarcoidosis;Neutropenia;Neutropenia neonatal;Neutropenic colitis;Neutropenic infection;Neutropenic sepsis;Nodular rash;Nodular vasculitis;Noninfectious myelitis;Noninfective encephalitis;Noninfective encephalomyelitis;Noninfective oophoritis;Obstetrical pulmonary embolism;Occupational exposure to communicable disease;Occupational exposure to SARS-CoV-2;Ocular hyperaemia;Ocular myasthenia;Ocular pemphigoid;Ocular sarcoidosis;Ocular vasculitis;Oculofacial paralysis;Oedema;Oedema blister;Oedema due to hepatic disease;Oedema mouth;Oesophageal achalasia;Ophthalmic artery thrombosis;Ophthalmic herpes simplex;Ophthalmic herpes zoster;Ophthalmic vein thrombosis;Optic neuritis;Optic

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neuropathy;Optic perineuritis;Oral herpes;Oral lichen planus;Oropharyngeal oedema;Oropharyngeal spasm;Oropharyngeal swelling;Osmotic demyelination syndrome;Ovarian vein thrombosis;Overlap syndrome;Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection;Paget-Schroetter syndrome;Palindromic rheumatism;Palisaded neutrophilic granulomatous dermatitis;Palmoplantar keratoderma;Palpable purpura;Pancreatitis;Panencephalitis;Papillophlebitis;Paracancerous pneumonia;Paradoxical embolism;Parainfluenzae viral laryngotracheobronchitis;Paraneoplastic dermatomyositis;Paraneoplastic pemphigus;Paraneoplastic thrombosis;Paresis cranial nerve;Parietal cell antibody positive;Paroxysmal nocturnal haemoglobinuria;Partial seizures;Partial seizures with secondary generalisation;Patient isolation;Pelvic venous thrombosis;Pemphigoid;Pemphigus;Penile vein thrombosis;Pericarditis;Pericarditis lupus;Perihepatic discomfort;Periorbital oedema;Periorbital swelling;Peripheral artery thrombosis;Peripheral embolism;Peripheral ischaemia;Peripheral vein thrombus extension;Periportal oedema;Peritoneal fluid protein abnormal;Peritoneal fluid protein decreased;Peritoneal fluid protein increased;Peritonitis lupus;Pernicious anaemia;Petit mal epilepsy;Pharyngeal oedema;Pharyngeal swelling;Pityriasis lichenoides et varioliformis acuta;Placenta praevia;Pleuroparenchymal fibroelastosis;Pneumobilia;Pneumonia;Pneumonia adenoviral;Pneumonia cytomegaloviral;Pneumonia herpes viral;Pneumonia influenzal;Pneumonia measles;Pneumonia mycoplasmal;Pneumonia necrotising;Pneumonia parainfluenzae viral;Pneumonia respiratory syncytial viral;Pneumonia viral;POEMS syndrome;Polyarteritis nodosa;Polyarthritis;Polychondritis;Polyglandular autoimmune syndrome type I;Polyglandular autoimmune syndrome type II;Polyglandular autoimmune syndrome type III;Polyglandular disorder;Polymicrogyria;Polymyalgia rheumatica;Polymyositis;Polyneuropathy;Polyneuropathy idiopathic progressive;Portal pyaemia;Portal vein embolism;Portal vein flow decreased;Portal vein pressure increased;Portal vein thrombosis;Portosplenomesenteric venous thrombosis;Post procedural hypotension;Post procedural pneumonia;Post procedural pulmonary embolism;Post stroke epilepsy;Post stroke seizure;Post thrombotic retinopathy;Post thrombotic syndrome;Post viral fatigue syndrome;Postictal headache;Postictal paralysis;Postictal psychosis;Postictal state;Postoperative respiratory distress;Postoperative respiratory failure;Postoperative thrombosis;Postpartum thrombosis;Postpartum venous thrombosis;Postpericardiotomy syndrome;Post-traumatic epilepsy;Postural orthostatic tachycardia syndrome;Precerebral artery thrombosis;Pre-eclampsia;Preictal state;Premature labour;Premature menopause;Primary amyloidosis;Primary biliary cholangitis;Primary progressive multiple sclerosis;Procedural shock;Proctitis herpes;Proctitis ulcerative;Product availability issue;Product distribution issue;Product supply issue;Progressive facial hemiatrophy;Progressive multifocal leukoencephalopathy;Progressive multiple sclerosis;Progressive relapsing multiple sclerosis;Prosthetic cardiac valve thrombosis;Pruritus;Pruritus allergic;Pseudovasculitis;Psoriasis;Psoriatic arthropathy;Pulmonary amyloidosis;Pulmonary artery thrombosis;Pulmonary embolism;Pulmonary fibrosis;Pulmonary haemorrhage;Pulmonary microemboli;Pulmonary oil microembolism;Pulmonary renal syndrome;Pulmonary sarcoidosis;Pulmonary sepsis;Pulmonary thrombosis;Pulmonary tumour thrombotic microangiopathy;Pulmonary vasculitis;Pulmonary veno-occlusive disease;Pulmonary venous thrombosis;Pyoderma gangrenosum;Pyostomatitis vegetans;Pyrexia;Quarantine;Radiation leukopenia;Radiculitis

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brachial;Radiologically isolated syndrome;Rash;Rash erythematous;Rash pruritic;Rasmussen encephalitis;Raynaud's phenomenon;Reactive capillary endothelial proliferation;Relapsing multiple sclerosis;Relapsing-remitting multiple sclerosis;Renal amyloidosis;Renal arteritis;Renal artery thrombosis;Renal embolism;Renal failure;Renal vascular thrombosis;Renal vasculitis;Renal vein embolism;Renal vein thrombosis;Respiratory arrest;Respiratory disorder;Respiratory distress;Respiratory failure;Respiratory paralysis;Respiratory syncytial virus bronchiolitis;Respiratory syncytial virus bronchitis;Retinal artery embolism;Retinal artery occlusion;Retinal artery thrombosis;Retinal vascular thrombosis;Retinal vasculitis;Retinal vein occlusion;Retinal vein thrombosis;Retinol binding protein decreased;Retinopathy;Retrograde portal vein flow;Retroperitoneal fibrosis;Reversible airways obstruction;Reynold's syndrome;Rheumatic brain disease;Rheumatic disorder;Rheumatoid arthritis;Rheumatoid factor increased;Rheumatoid factor positive;Rheumatoid factor quantitative increased;Rheumatoid lung;Rheumatoid neutrophilic dermatosis;Rheumatoid nodule;Rheumatoid nodule removal;Rheumatoid scleritis;Rheumatoid vasculitis;Saccadic eye movement;SAPHO syndrome;Sarcoidosis;SARS-CoV-1 test;SARS-CoV-1 test negative;SARS-CoV-1 test positive;SARS-CoV-2 antibody test;SARS-CoV-2 antibody test negative;SARS-CoV-2 antibody test positive;SARS-CoV-2 carrier;SARS-CoV-2 sepsis;SARS-CoV-2 test;SARS-CoV-2 test false negative;SARS-CoV-2 test false positive;SARS-CoV-2 test negative;SARS-CoV-2 test positive;SARS-CoV-2 viraemia;Satoyoshi syndrome;Schizencephaly;Scleritis;Sclerodactylia;Scleroderma;Scleroderma associated digital ulcer;Scleroderma renal crisis;Scleroderma-like reaction;Secondary amyloidosis;Secondary cerebellar degeneration;Secondary progressive multiple sclerosis;Segmented hyalinising vasculitis;Seizure;Seizure anoxic;Seizure cluster;Seizure like phenomena;Seizure prophylaxis;Sensation of foreign body;Septic embolus;Septic pulmonary embolism;Severe acute respiratory syndrome;Severe myoclonic epilepsy of infancy;Shock;Shock symptom;Shrinking lung syndrome;Shunt thrombosis;Silent thyroiditis;Simple partial seizures;Sjogren's syndrome;Skin swelling;SLE arthritis;Smooth muscle antibody positive;Sneezing;Spinal artery embolism;Spinal artery thrombosis;Splenic artery thrombosis;Splenic embolism;Splenic thrombosis;Splenic vein thrombosis;Spondylitis;Spondyloarthropathy;Spontaneous heparin-induced thrombocytopenia syndrome;Status epilepticus;Stevens-Johnson syndrome;Stiff leg syndrome;Stiff person syndrome;Stillbirth;Still's disease;Stoma site thrombosis;Stoma site vasculitis;Stress cardiomyopathy;Stridor;Subacute cutaneous lupus erythematosus;Subacute endocarditis;Subacute inflammatory demyelinating polyneuropathy;Subclavian artery embolism;Subclavian artery thrombosis;Subclavian vein thrombosis;Sudden unexplained death in epilepsy;Superior sagittal sinus thrombosis;Susac's syndrome;Suspected COVID-19;Swelling;Swelling face;Swelling of eyelid;Swollen tongue;Sympathetic ophthalmia;Systemic lupus erythematosus;Systemic lupus erythematosus disease activity index abnormal;Systemic lupus erythematosus disease activity index decreased;Systemic lupus erythematosus disease activity index increased;Systemic lupus erythematosus rash;Systemic scleroderma;Systemic sclerosis pulmonary;Tachycardia;Tachypnoea;Takayasu's arteritis;Temporal lobe epilepsy;Terminal ileitis;Testicular autoimmunity;Throat tightness;Thromboangiitis obliterans;Thrombocytopenia;Thrombocytopenic purpura;Thrombophlebitis;Thrombophlebitis migrans;Thrombophlebitis

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neonatal;Thrombophlebitis septic;Thrombophlebitis superficial;Thromboplastin antibody positive;Thrombosis;Thrombosis corpora cavernosa;Thrombosis in device;Thrombosis mesenteric vessel;Thrombotic cerebral infarction;Thrombotic microangiopathy;Thrombotic stroke;Thrombotic thrombocytopenic purpura;Thyroid disorder;Thyroid stimulating immunoglobulin increased;Thyroiditis;Tongue amyloidosis;Tongue biting;Tongue oedema;Tonic clonic movements;Tonic convulsion;Tonic posturing;Topectomy;Total bile acids increased;Toxic epidermal necrolysis;Toxic leukoencephalopathy;Toxic oil syndrome;Tracheal obstruction;Tracheal oedema;Tracheobronchitis;Tracheobronchitis mycoplasmal;Tracheobronchitis viral;Transaminases abnormal;Transaminases increased;Transfusion-related alloimmune neutropenia;Transient epileptic amnesia;Transverse sinus thrombosis;Trigeminal nerve paresis;Trigeminal neuralgia;Trigeminal palsy;Truncus coeliacus thrombosis;Tuberous sclerosis complex;Tubulointerstitial nephritis and uveitis syndrome;Tumefactive multiple sclerosis;Tumour embolism;Tumour thrombosis;Type 1 diabetes mellitus;Type I hypersensitivity;Type III immune complex mediated reaction;Uhthoff's phenomenon;Ulcerative keratitis;Ultrasound liver abnormal;Umbilical cord thrombosis;Uncinate fits;Undifferentiated connective tissue disease;Upper airway obstruction;Urine bilirubin increased;Urobilinogen urine decreased;Urobilinogen urine increased;Urticaria;Urticaria papular;Urticarial vasculitis;Uterine rupture;Uveitis;Vaccination site thrombosis;Vaccination site vasculitis;Vagus nerve paralysis;Varicella;Varicella keratitis;Varicella post vaccine;Varicella zoster gastritis;Varicella zoster oesophagitis;Varicella zoster pneumonia;Varicella zoster sepsis;Varicella zoster virus infection;Vasa praevia;Vascular graft thrombosis;Vascular pseudoaneurysm thrombosis;Vascular purpura;Vascular stent thrombosis;Vasculitic rash;Vasculitic ulcer;Vasculitis;Vasculitis gastrointestinal;Vasculitis necrotising;Vena cava embolism;Vena cava thrombosis;Venous intravasation;Venous recanalisation;Venous thrombosis;Venous thrombosis in pregnancy;Venous thrombosis limb;Venous thrombosis neonatal;Vertebral artery thrombosis;Vessel puncture site thrombosis;Visceral venous thrombosis;VIth nerve paralysis;VIth nerve paresis;Vitiligo;Vocal cord paralysis;Vocal cord paresis;Vogt-Koyanagi-Harada disease;Warm type haemolytic anaemia;Wheezing;White nipple sign;XIth nerve paralysis;X-ray hepatobiliary abnormal;Young's syndrome;Zika virus associated Guillain Barre syndrome.

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From: JON CARPINETA [redacted]
Sent: Wednesday, March 23, 2022 9:33 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: PEBP Board Meeting 3/23/22 Agenda Item VI COVID-19 Update

Good morning. My name is Jon Carpineta (C-A-R-P-I-N-E-T-A). I am opposed to the COVID surcharges for unvaccinated members. PEBP will be eliminating these surcharges due to funding allocated by the Governor. However, PEBP should never have passed the discriminatory surcharge in the first place. By now, most of the public realizes that we have been lied to and deceived about the "safety and efficacy" of the shots and that they are not based on immunity to COVID-19 or any of the SARS-CoV-2 variants. On September 1st 2021, the CDC had to change (downgrade) the definition of "vaccine" and "vaccination" to continue to qualify the Pfizer, Moderna, and Janssen shots as "vaccines". Information and research about nutritional deficiencies, such as Vitamin D and Zinc, and other ways of boosting the human immune system were treated as "misinformation" and kept silent. People who actually had been infected by the entire virus were regarded as not having immunity while people who get shots containing only the original spike protein were deemed to have protection. Injecting people with the spike protein makes them more susceptible to infection from SARS-CoV-2 (or any other virus for that matter) while the spike protein is still in their system. The spike protein is what gives the SARS-CoV-2 virus easier accessibility into human cells.
People were, and still are, categorized as unvaccinated:
Pfizer = a minimum of 35 days after the first shot.
Moderna = a minimum of 42 days after the first shot.
Janssen = 14 days after the shot.

As of January 10, 2022 Pfizer CEO Albert Bourla even admitted that the "two doses of the vaccine offer very limited protection, if any". At this point, why are we still pretending or going along with the idea that people who received the shots are "vaccinated"? We need to get back to reality and stop manipulating science to manipulate people. If a truly safe and effective vaccine is created and provides real immunity, then PEBP would have some justification for proposing COVID surcharges. But, that is not the case. These shots have failed miserably and have given people a dangerous false sense of security. Put and end to the discrimination that has been based on manipulated science and coercion.

Thank you.
Jon Carpineta

From: Bart Alexander [redacted]
Sent: Wednesday, March 23, 2022 11:51 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Rate Increase for Health Benefits

My Name is Bart Alexander. I have been employed by DETR since 5/4/2008. In the 14 years that I have been with the State of Nevada, we have endured unpaid furloughs, frozen pay scales, and increased work loads.
Currently with soaring costs of fuel, housing, and cost of living, the last thing the employees of the State of Nevada need is an increase in the healthcare costs. Many people are leaving State employment due to the inability to make ends meet. Heaping additional burdens will force more people out of the public sector into the private sector. I implore you to please give some relief to State Employees and hold the current rates in place.

Thank you,

Bart Alexander

From: Brooke Maylath [redacted]
Sent: Wednesday, March 23, 2022 3:32 PM
To: Wendi Lunz <wlunz@peb.nv.gov>
Cc: PEBP Member Services <memberservices@peb.nv.gov>
Subject: Public Comment for the PEBP Board Meeting of March 24th, 2022

Public Employees' Benefits Program Board
901 S. Stewart Street
Suite 1001
Carson City, NV 89701

Dear Members of the Board;

Once again, I must call out the inaction of the Executive Officer to provide remedies on the Master Plan Document's exclusions that are discriminatory towards transgender persons. Under the Affordable Care Act and as interpreted by the Nevada Insurance Commissioner in 2015, "the denial, exclusion, or limitation of benefits relating to coverage of medically necessary health care services on the basis of sex as it relates to gender identity or expression" is prohibited. The Supreme Court of the United States' ruling under *Bostock* clarifies employment law under Title VII that sex discrimination includes discrimination on the basis of sexual orientation or gender identity. I have been bringing this matter to the board's attention for over one year, and there has yet to be any action taken.

Let's be very clear. Excluding transgender-related health care is discriminatory. Singling out transgender health care for exclusion is form of discrimination. Just as it would be sex discrimination if a plan were to exclude all coverage for gynecological care, and it would be disability discrimination if a plan were to exclude all treatments for HIV, it is both sex and disability discrimination when a health plan carves out and excludes medically necessary care simply because it is for the purpose of treating gender dysphoria.

Transgender employees pay the same premiums as other employees yet receive unequal benefits in return. Employees who are transgender or have transgender dependents subsidize the health care of their co-workers yet are denied doctor recommended care for themselves or their families.

Transgender-related care is medically necessary, and there is no legitimate, nondiscriminatory basis to single out transgender care for exclusion. It is precisely for that reason that insurance companies developed explicit exclusions for transgender-related care—because it would otherwise fall under standard surgical, mental health, physician, diagnostic, or pharmaceutical benefits. Transgender care is neither experimental nor cosmetic, and existing plan definitions of medical necessity are sufficient to ensure that only medically necessary services are provided.

I urge the Board to make this a priority for the Executive Officer to address, immediately, so that the those in need can access the medical interventions that they need to mitigate the symptoms of Gender Dysphoria. Every day lost is another day of agony and anxiety for people with specific needs. Every day lost is another day closer to the Board having legal action taken that will force the plan to comply and add significant financial penalties, as well. The supposed pennies that you are saving today will cost thousands of dollars in the future if you continue to delay.

Respectfully,

Brooke Maylath

From: Stephanie Dube <Stephanie.Dube@nvafscme.org>
Sent: Wednesday, March 23, 2022 9:32 PM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Public Comment

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My name is Stephanie Dube. I am a state of Nevada employee and also a member of AFSCME Local 4041. I ask you to vote no on any rate increases to employee health insurance. PEBP continues to increase health insurance rates while cutting services. We are paying more for less insurance coverage than the year before, and the year before that.

I am a state employee who can not afford to have the HMO plan. I also can not afford the out-of-pocket costs that are incurred while being on the PPO plan. I do not want to continue to make life decisons based on if I can afford to get sick. There have been numerous times when I have decided to pass on going to the doctors because of the cost that I fear will take place.

We deserve better. We want better. Please remember our voices when making decisions for state of Nevada employees.

Thank you for your time.
Stephanie Dube
State of Nevada Employee, DHHS
AFSCME Local 4041 member

From: Rocio Perez [redacted]
Sent: Wednesday, March 23, 2022 10:58 PM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: State employees insurance health inctease

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We are paying more for less insurance. As a single parent with a college student and a middle school child with 27 years in and no more pay increases. I vote No on any rates increase to State employees health insurance.

Rocio Travez
AFSCME UNION MEMBER

From: Brent Slobe <bslobe81@gmail.com>
Sent: Thursday, March 24, 2022 6:05 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Non-Vaccinated Surcharge

Dear PEBP Board Members,

Again, I am writing about the surcharge. Asking the board to rethink the decision that the majority of the board voted in favor for on Dec. 2nd. Even though this surcharge is not in effect yet, just the thought of employees having to pay a surcharge has changed morale across all divisions. This one decision that the majority of the board voted in favor of has changed many peoples life's. Many have already found employment outside of public employment and many are looking to leave all because of a decision of this board. I do believe being selected to be a board member you have a duty to do what is right for the public employees. You also have a duty to look at all the material presented prior to making that final decision. This decision that was made was not thought through nor were all the facts presented prior to the board voting in favor of it.

Let's start with the testing. There was no plan or a vender or a cost per employee but to our surprise all non vaccinated employees had to start testing again and our "wonderful" insurance was going to be the one to set this up. This was an absolute disaster. Once our employees were signed into the testing app which wasn't easy. They called into to begin testing. They demanded to have a state issued ID showing your picture date of birth and name. I personally decided to black out all of the non-pertinent information. The last test I took the guy decided he needed to see my expiration date of my drivers license. Every time we tested they wanted something else. Most of us were not comfortable giving this personal information out but were forced to because we were being threatened with our jobs.

Then we are told that we are going to be charged a surcharge for the non vaccinated employees and the non vaccinated dependents. You as a board voted this in without any consideration of the effects of this surcharge. Did it ever cross your minds that this would cause more people to leave public employment which in turn effects PEBP? The less employees we have the

less people are paying into the benefits program. Well this one vote did just that. We have lost a ton of institutional knowledge that we will never get and still have employees looking to leave because of one decision you as a board made.

I truly hope the PEBP board will reconsider the decision they made on Dec. 2nd. I also hope that going forward this board will listen to the people they are on the board making these decisions for. Please remember every decisions you vote on effects many people.

Thank you

Brent Slobe

From: Detelin Georgiev [redacted]
Sent: Thursday, March 24, 2022 6:15 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: PEBP premium rates change.

Good morning. I'm a public employee and AFSCME local 4041 member for 10years. Through all this time I've seen nothing, but higher rates for less coverage and I'm expected to put my life and we'll being in danger in my line of duty. Benefits and pay for state public employees is so incopettative that there are only few people applying for those jobs and many resign every day because of it. Please consider all that, before you make a decision. Thank you.

From: Lisa Dehart [redacted]
Sent: Thursday, March 24, 2022 8:21 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Please support our State with no rate hikes or surcharges- avoid litigation

The effect of the surcharge has possible violations of NRS statutes . Please consider the possible fiscal impact that increasing rates and surcharges for employees may have. Charging a surcharge to unvaccinated employees opens the door for litigation unless the Board also initiates surcharges for other health- lifestyle decisions for example- if the surcharge is enacted with the reasoning unvaccinated incur higher medical costs if they get ill then the Board would also have to consider other personal choices that may lead to higher costs such as - smoking, dangerous hobbies like dirt biking or not taking birth control ... re: birthing costs.

As A dedicated public servant of 16 years and one that takes being a guardian of taxpayer money seriously, I am referring to NRS 281.611 , which encourages state employees to disclose improper governmental action. Since the implementation of the surcharge will cause many state employees with families to have to quit their jobs-- 55.00 a month per family member has been suggested as reported in the media . This action can be viewed as a violation of 281.661 1. "Improper governmental action" by 4. Local governmental officer" means a person elected or appointed to a position with a local government. as the action is 5. "Reprisal or retaliatory action"(if the employee is not vaccinated they are charged) which causes : (b) Frequent replacement of members of the staff.

Also testing only unvaccinated seems a waste of taxpayer money because odds are 2 in 10 if I catch COVID from someone here at work it will be from a vaccinated person that was not tested or a customer. It seems a waste of taxpayer funds to only test unvaccinated under those circumstances. As NRS 281.611 encourages I am bringing this up to disclose improper governmental action – 281.611 e. gross waste of public money.

Here is evidence vaccinated persons have "breakthrough "cases . For example per Washoe County Per the website there has been 21,339 "breakthrough " cases – those are vaccinated people.
Total Washoe County confirmed cases are 102,813 and 21,339 are break through. That means **20.75 of cases are vaccinated people**
https://www.washoecounty.gov/health/programs-and-services/ephp/communicable-diseases-and-epidemiology/educational-materials/COVID-19.php

The order for unvaccinated employees to be tested weekly or face disciplinary action even when they are asymptomatic appears to be coercion to make them take a vaccine. The action of implementing a SURCHARGE when other bad habits and unhealthy life choices are not Per Dictionary.com : The act of coercing; use of force or intimidation to obtain compliance. Under NRS 207.190, the Nevada crime of coercion is defined as intentionally using intimidation, deprivation, or violence to compel another person to do something that he or she is not legally obligated to do. Prosecutors may file this charge as a misdemeanor or a felony. Deprivation is also an issue by allowing only vaccinated to use admin time and mandating unvaccinated use their own sick leave. Also new evidence was presented to Congress on 2/2/2022 by Senator Ron Johnson obtained by the Department of Defense that there is an identified significant increase in health issues for veterans that were vaccinated so encouraging employees to be vaccinated against their will could eventually lead to further litigation if the findings prove to be valid. The United States and the Great State of Nevada are built on hard work and free choice . Please support our choice of medical decisions.

Please consider these thoughts in your voting today. The State Employees have been getting less and less while being asked to do more and more. While others got stimulus money from COVID funds from the Feds we were having our wages taken away in the form of unpaid furloughs. Many of our clerical , front line staff and correctional officers starting wages are so low that if they have a family they make so low income they are eligible for food stamps. It would be a good study to break out our front line workers from the administrators and educators when considering cuts and raises by pay grade as we get lumped in with people making 6 digits as administrators and college professors and football coaches.
Thank goodness we are now in the GREEN- https://www.washoecounty.gov/health/programs-and-services/ephp/communicable-diseases-and-epidemiology/educational-materials/COVID-19.php
Thank- you and Kind Regards,
Lisa DeHart LSW - SWII at RDO DWSS

From: Brian Miller [redacted]
Sent: Thursday, March 24, 2022 8:22 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Public comment

Hello,
My name is Brian Miller. I am a proud member of AFSCME local 4041.
I hope you vote to repeal any unjust surcharge that is bias towards workers and families.
Has PEBP considered the fact that such discriminatory fees and surcharges, may lead to litigations from insurance holders?
Thank you.

From: Carmen Cortez [redacted]
Sent: Thursday, March 24, 2022 8:25 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: PEBP

Good morning,
My name is Carmen Cortez and I am a state employee and member of AFSCME Local 4041.
I ask you to vote no on any rate increases to states employee health insurance.
PEBP continues to increase health insurance rates while cutting services. For example, PEBP stopped cover some medications this year and now, I have to pay in full.
Thank you for your time,
Sincerely,
Carmen Cortez, LSW.

From: Pam Freestone [redacted]
Sent: Thursday, March 24, 2022 8:29 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: public comment on Health Insurance rates for State Employees

I am a State of NV employee of 15 yrs and a member of AFSCME Local 4041. I am writing this statement today to ask you to vote No on any rate increases to State Employee Health Insurance. PEBP continues to increase our insurance rates and cut our benefits. I grew up on the State insurance my mother was a State Employee for 2 decades. I have seen the States Health Insurance go from being one of the best to The WORST Health Insurance. People on Medicare have better benefits than STATE EMPLOYEES. This is a disgrace & you should be ashamed of yourselves. We are constantly Paying more for less insurance coverage that the previous year & it has gotten worse each year!. Being a single income person each time you raise our rates I have to re evaluate my budget to be able to afford premiums, co-pays, & doctor. bills I cannot imagine what a Single parent family is going through to cover medical costs for themselves and their family. Your lack of understanding and willingness to work for the State Employees instead of against them is a disgrace.

From: Christine B Emmons [redacted]
Sent: Thursday, March 24, 2022 9:03 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Public Comment

This health insurance is not good. Mental health is awful, I had to stop seeing my therapist because, them like many, are treated so poorly by this insurance company that they will not work with them. Mental health, for everyone, is so important right now. Additionally, my doctor just stopped taking this insurance effective as of March for the same reason. You need to stop increasing rates and decreasing benefits. We need insurance that is good and actually takes care of our needs. We are not paid well at the state level, this should be a benefit to offset some of that and it is not and every year it is getting worse.

-Chrissy

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From: JON CARPINETA
Sent: Wednesday, March 23, 2022 9:32 AM
To: wlunz@peb.nv.gov <wlunz@peb.nv.gov>
Subject: PEBP Board Meeting 3/23/22 Agenda Item VI COVID-19 Update

Good morning. My name is Jon Carpineta (last name spelled C-A-R-P-I-N-E-T-A). I am opposed to the COVID surcharges for unvaccinated members. PEBP will be eliminating these surcharges due to funding allocated by the Governor. However, PEBP should never have passed the discriminatory surcharge in the first place. By now, most of the public realizes that we have been lied to and deceived about the "safety and efficacy" of the shots and that they are not based on immunity to COVID-19 or any of the SARS-CoV-2 variants. On September 1st 2021, the CDC had to change (downgrade) the definition of "vaccine" and "vaccination" to continue to qualify the Pfizer, Moderna, and Janssen shots as "vaccines". Information and research about nutritional deficiencies, such as Vitamin D and Zinc, and other ways of boosting the human immune system were treated as "misinformation" and kept silent. People who actually had been infected by the entire virus were regarded as not having immunity while people who get shots containing only the original spike protein were deemed to have protection. Injecting people with the spike protein makes them more susceptible to infection from SARS-CoV-2 (or any other virus for that matter) while the spike protein is still in their system. The spike protein is what gives the SARS-CoV-2 virus easier accessibility into human cells.
People were, and still are, categorized as unvaccinated:
Pfizer = a minimum of 35 days after the first shot.
Moderna = a minimum of 42 days after the first shot.
Janssen = 14 days after the shot.

As of January 10, 2022 Pfizer CEO Albert Bourla even admitted that the "two doses of the vaccine offer very limited protection, if any". At this point, why are we still pretending or going along with the idea that people who received the shots are "vaccinated"? We need to get back to reality and stop manipulating science to manipulate people. If a truly safe and effective vaccine is created and provides real immunity, then PEBP would have some justification for proposing COVID surcharges. But, that is not the case. These shots have failed miserably and have given people a dangerous false sense of security. Put and end to the discrimination that has been based on manipulated science and coercion.

Thank you.
Jon Carpineta

From: Patricia Reyes-Parra [redacted]
Sent: Thursday, March 24, 2022 9:10 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Health Coverage

Good morning. My name is Patricia Reyes-Parra. I am DMV employee. I am 55 years of age. What is being done to my healthcare coverage is reprehensible. This is the time in my life when I need health insurance the most. I am also a COVID survivor. The virus has left me with health issues. By raising premiums and lowering coverage makes it very stressful plus put me in a financial situation.

I'm asking to please reconsider. I am the sole income provider in my family. It is an honor to work for the state but our benefits are declining yearly. Our salaries have not been increased therefore making it difficult to afford healthcare. This rent crisis has hurt me and many others in the community.

I'm praying for you, the Legislator's to reconsider and make things right for me and my state employee family.

Thank you.

Patricia Reyes-Parra

From: Lisa DeHart [redacted]
Sent: Thursday, March 24, 2022 9:21 AM
To: Wendi Lunz <wlunz@peb.nv.gov>
Subject: Please support our State employees with no rate hikes or surcharges- avoid litigation

The effect of the surcharge has possible violations of NRS statutes . Please consider the possible fiscal impact that increasing rates and surcharges for employees may have. Charging a surcharge to unvaccinated employees opens the door for litigation unless the Board also initiates surcharges for other health- lifestyle decisions for example- if the surcharge is enacted with the reasoning unvaccinated incur higher medical costs if they get ill then the Board would also have to consider other personal choices that may lead to higher costs such as - smoking, dangerous hobbies like dirt biking or not taking birth control ... re: birthing costs.

As A dedicated public servant of 16 years and one that takes being a guardian of taxpayer money seriously, I am referring to NRS 281.611 , which encourages state employees to disclose improper governmental action. Since the implementation of the surcharge will cause many state employees with families to have to quit their jobs-- 55.00 a month per family member has been suggested as reported in the media . This action can be viewed as a violation of 281.661 1. "Improper governmental action" by 4. Local governmental officer" means a person elected or appointed to a position with a local government. as the action is 5. "Reprisal or retaliatory action"(if the employee is not vaccinated they are charged) which causes : (b) Frequent replacement of members of the staff.

Also testing only unvaccinated seems a waste of taxpayer money because odds are 2 in 10 if I catch COVID from someone here at work it will be from a vaccinated person that was not tested or a customer. It seems a waste of taxpayer funds to only test unvaccinated under those circumstances. As NRS 281.611 encourages I am bringing this up to disclose improper governmental action – 281.611 e. gross waste of public money.

The order for unvaccinated employees to be tested weekly or face disciplinary action even when they are asymptomatic appears to be coercion to make them take a vaccine. The action of implementing a SURCHARGE when other bad habits and unhealthy life choices are not Per Dictionary.com : The act of coercing; use of force or intimidation to obtain compliance. Under NRS 207.190, the Nevada crime of coercion is defined as intentionally using intimidation, deprivation, or violence to compel another person to do something that he or she is not legally obligated to do. Prosecutors may file this charge as a misdemeanor or a felony. Deprivation is also an issue by allowing only vaccinated to use admin time and mandating unvaccinated use their own sick leave. Also new evidence was presented to Congress on 2/2/2022 by Senator Ron Johnson obtained by the Department of Defense that there is an identified significant increase in health issues for veterans that were vaccinated so encouraging employees to be vaccinated against their will could eventually lead to further litigation if the findings prove to be valid. The United States and the Great State of Nevada are built on hard work and free choice . Please support our choice of medical decisions.

Here is evidence vaccinated persons have "breakthrough "cases . For example per Washoe County Per the website there has been 21,339 "breakthrough " cases – those are vaccinated people.
Total Washoe County confirmed cases are 102,813 and 21,339 are break through. That means 20.75 of cases are vaccinated people

https://www.washoecounty.gov/health/programs-and-services/ephp/communicable-diseases-and-epidemiology/educational-materials/COVID-19.php

Please consider these thoughts in your voting today. The State Employees have been getting less and less while being asked to do more and more. While others got stimulus money from COVID funds from the Feds we were having our wages taken away in the form of unpaid furloughs. Many of our clerical , front line staff and correctional officers starting wages are so low that if they have a family the wage is so low income they are eligible for food stamps. It would be a good study to break out our front line workers from the administrators and educators when considering cuts and raises by pay grade as we get lumped in with people making 6 digits as administrators and college professors and football coaches.

Thank goodness we are in the Green
Thank- you for any consideration.
Kind Regards,
Lisa De Hart LSW