Exhibit 303

Clinical Evidence related to COVID-19, potential governmental corruption, and the safety of our military and citizens.

https://renz-law.com/special-notice-regarding-evidentiary-findings-related-to-the-official-renz-law-covid-19-investigation/

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
www.renz-law.com

RENZ LAW, LLC.

Contents

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

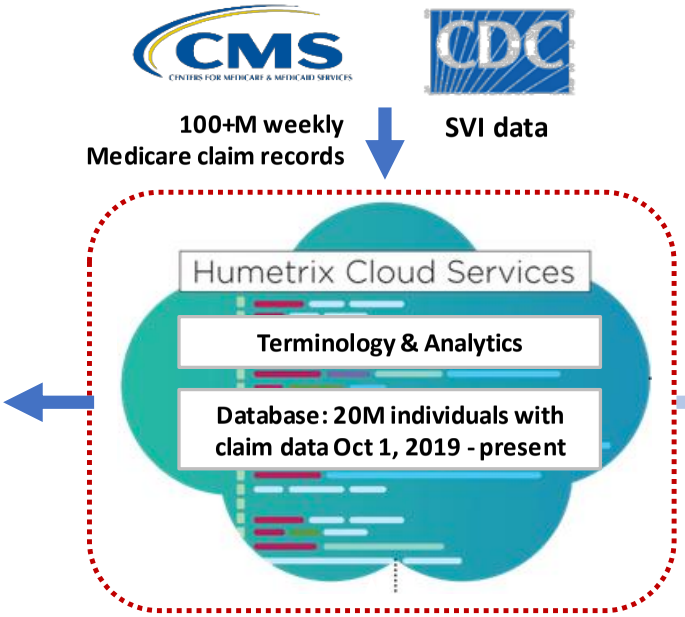
January - August 21 2021

Breakthrough Key Metrics

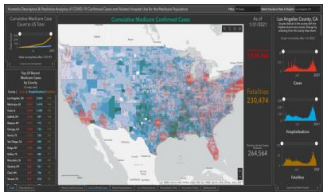
161K Breakthrough cases

33K Breakthrough hospitalizations

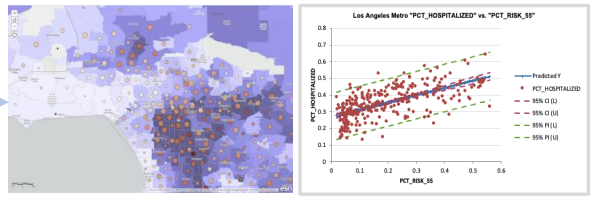
10.4K requiring ICU admissions



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*

Project Salus

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

Project Salus

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

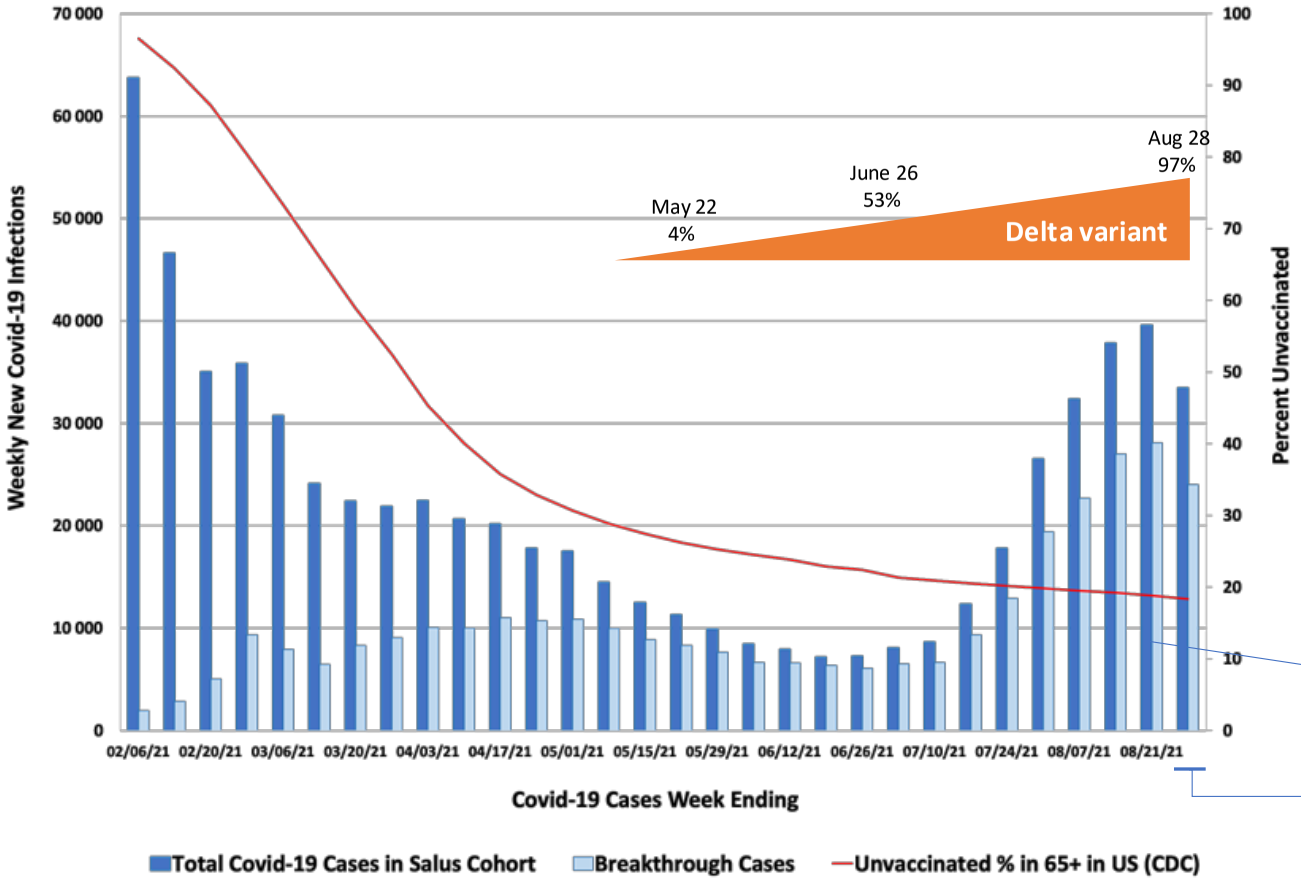
Key Breakthrough vs. Pre-Vaccination COVID-19 Metrics

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**

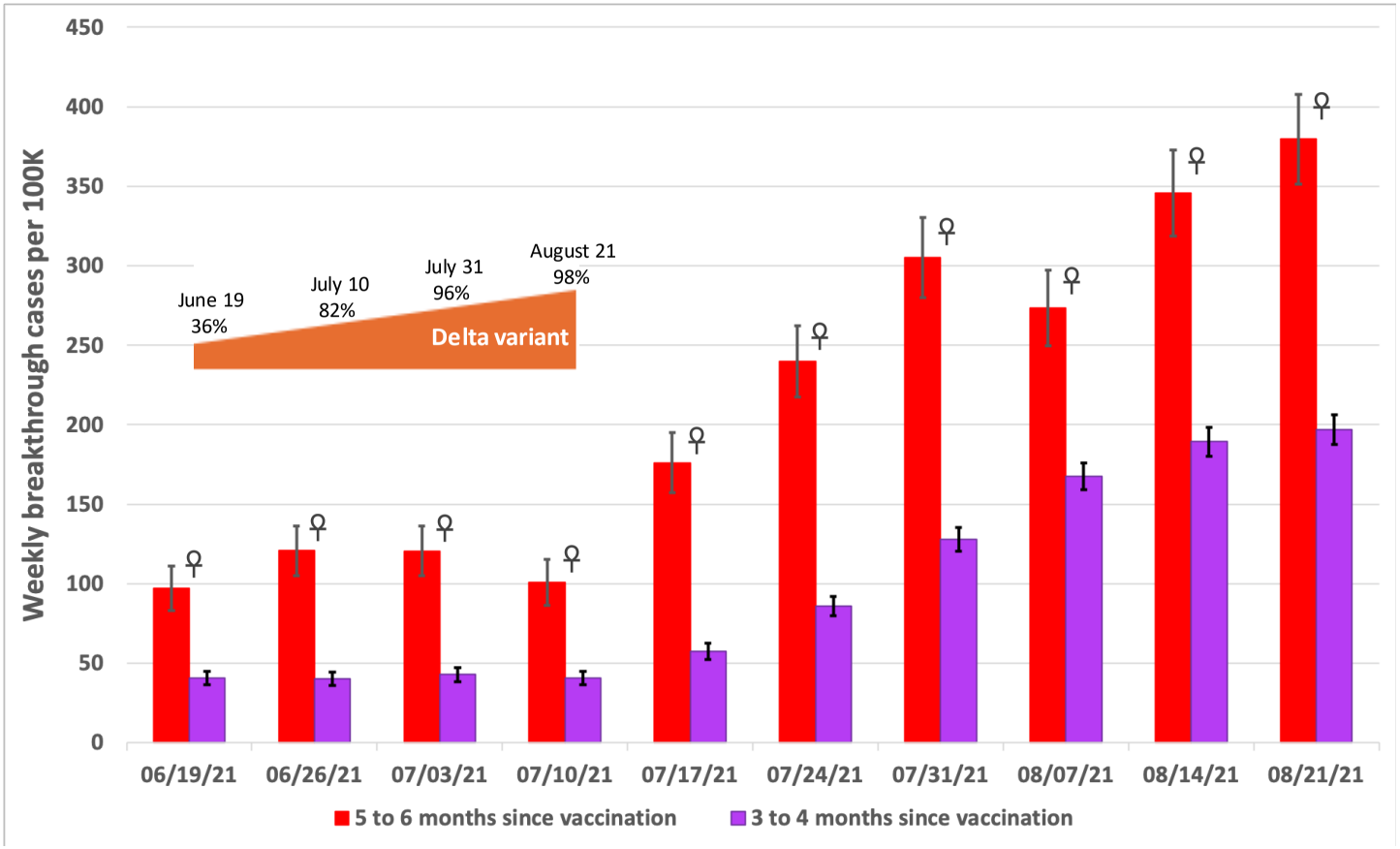
Breakthrough cases = 71% of total Covid-19 cases in cohort

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

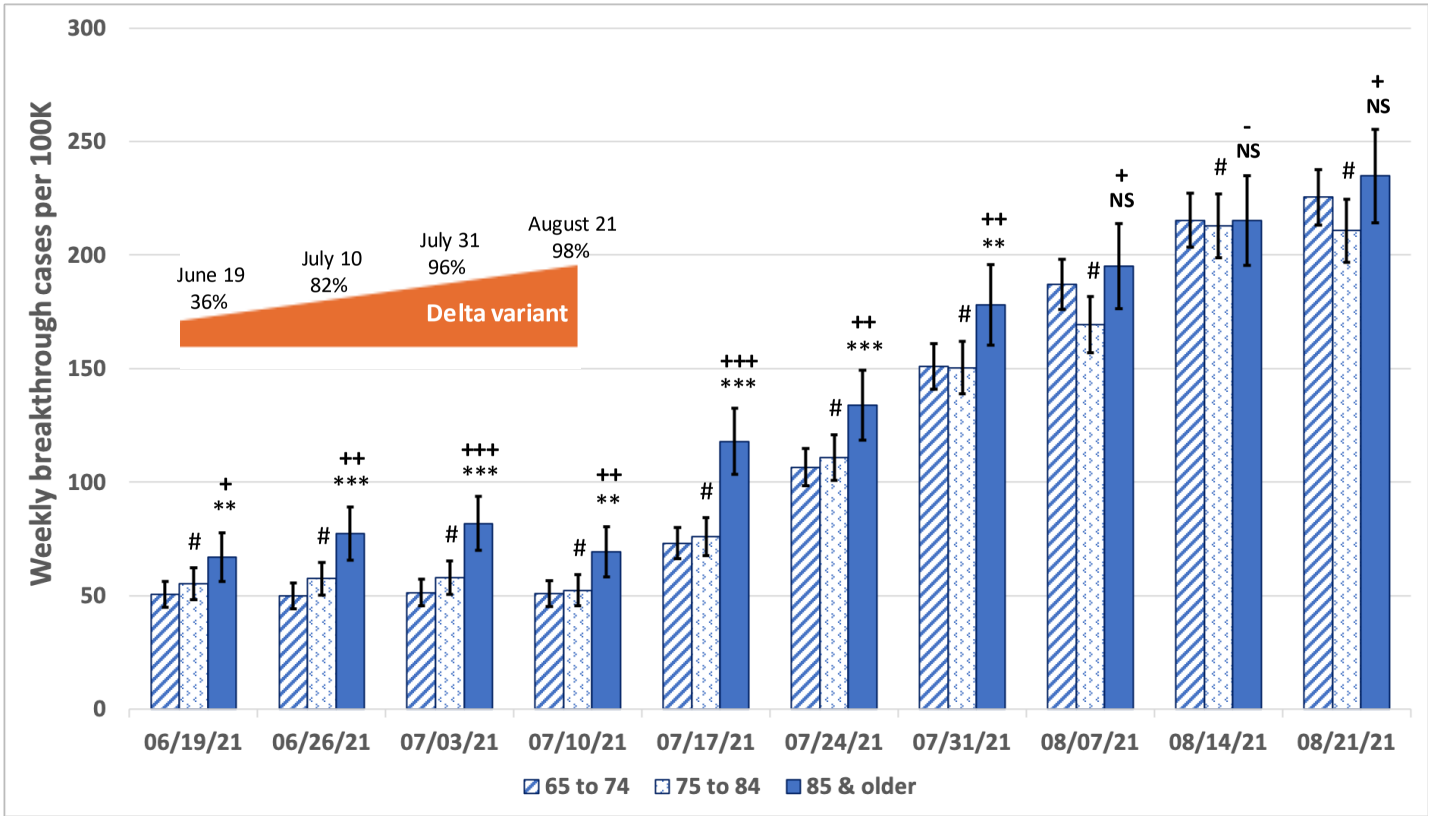
Age Distribution of Vaccinated Groups in the 65 Years and Older Cohort

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?



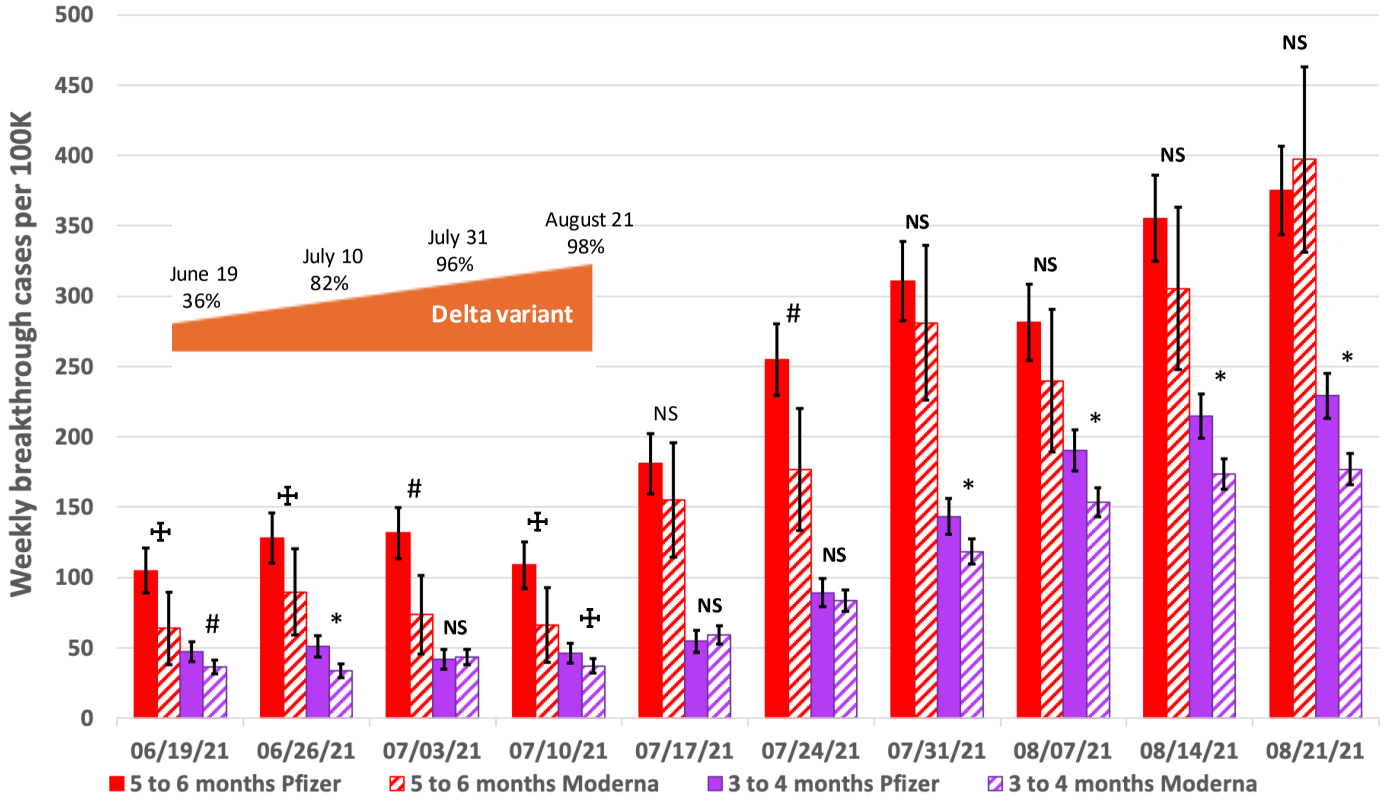
- **Age has a minor contribution to the reduced vaccine protection** seen in the group vaccinated 5-6 months ago

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 ?



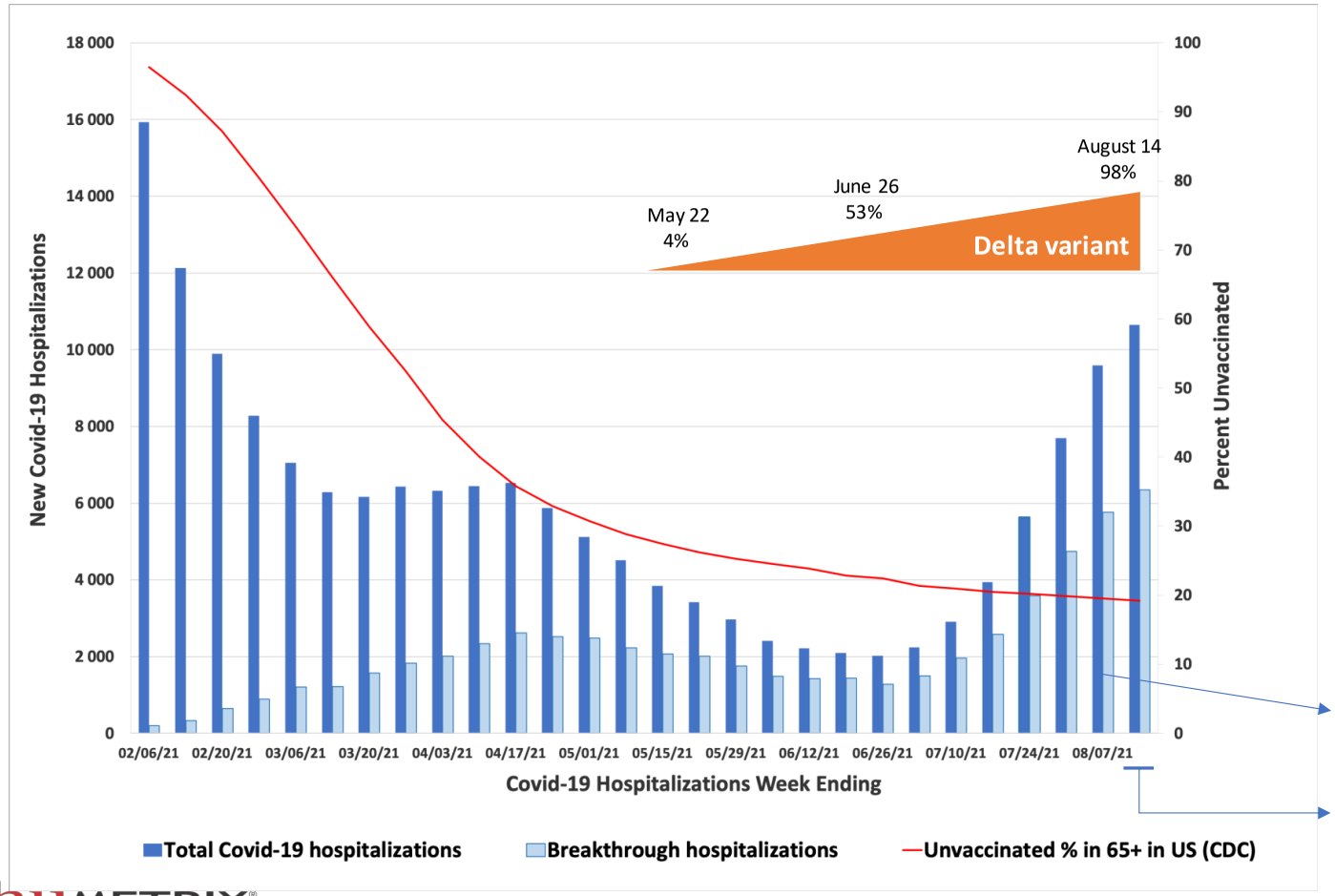
- **Waning immunity are seen with both Pfizer-BioNTech and Moderna** vaccines during Delta phase of the pandemic
- **Moderna vaccine offers better protection than Pfizer vaccine** for individuals vaccinated 4 months prior for weeks ending after July 31

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



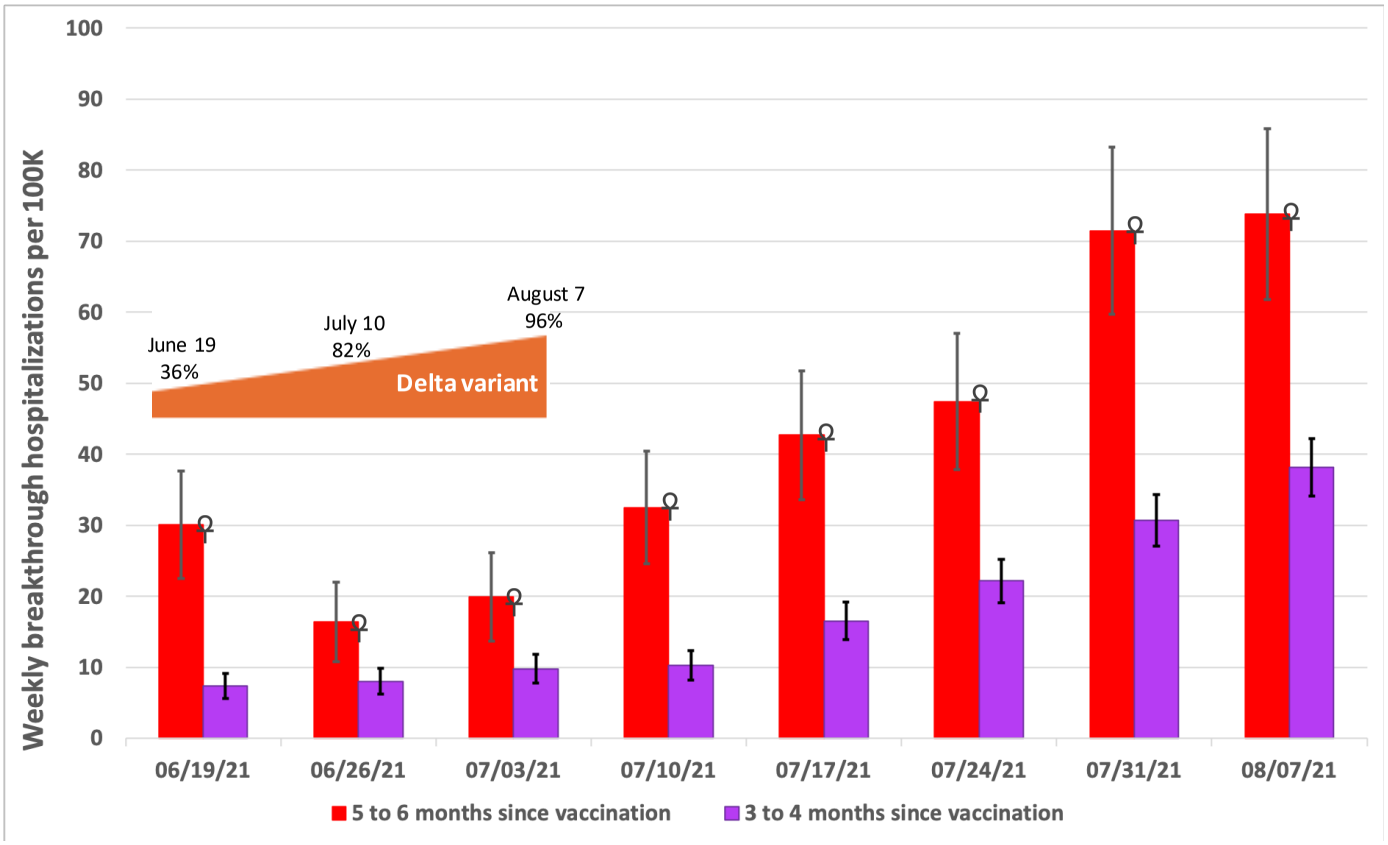
- **As Delta variant surged to over 50% in June, COVID-19 hospitalizations more than doubled, reversing the prior trend of decreasing hospitalizations since April**
- In this 80% vaccinated 65+ population, an estimated **60% of COVID-19 hospitalizations occurred in fully vaccinated individuals in the 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?



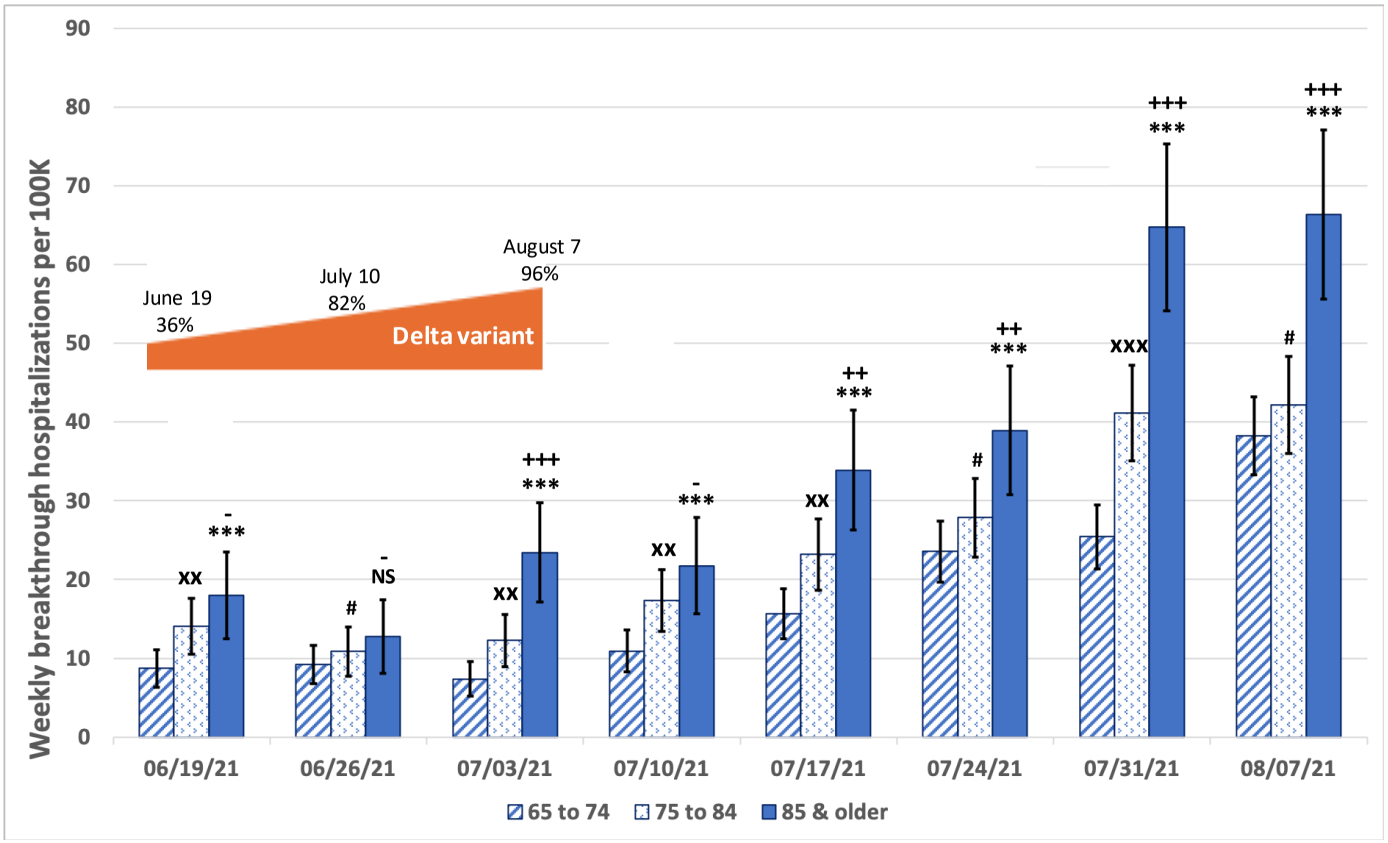
- **VE against breakthrough hospitalization is significantly lower 5-6 months post vaccination than 3-4 months post vaccination**

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?



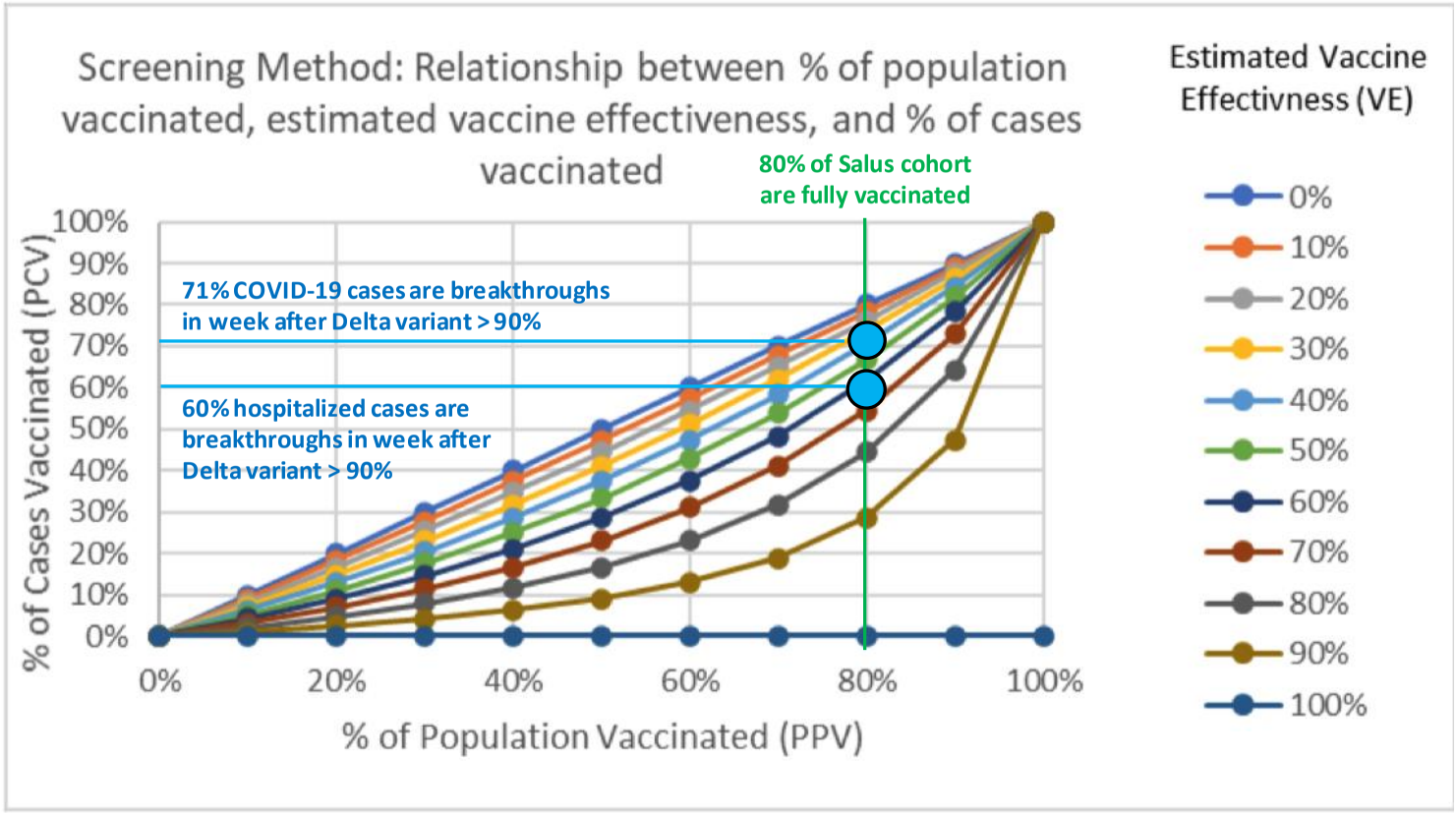
- **Older age associated with increased breakthrough hospitalization rates**

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)]

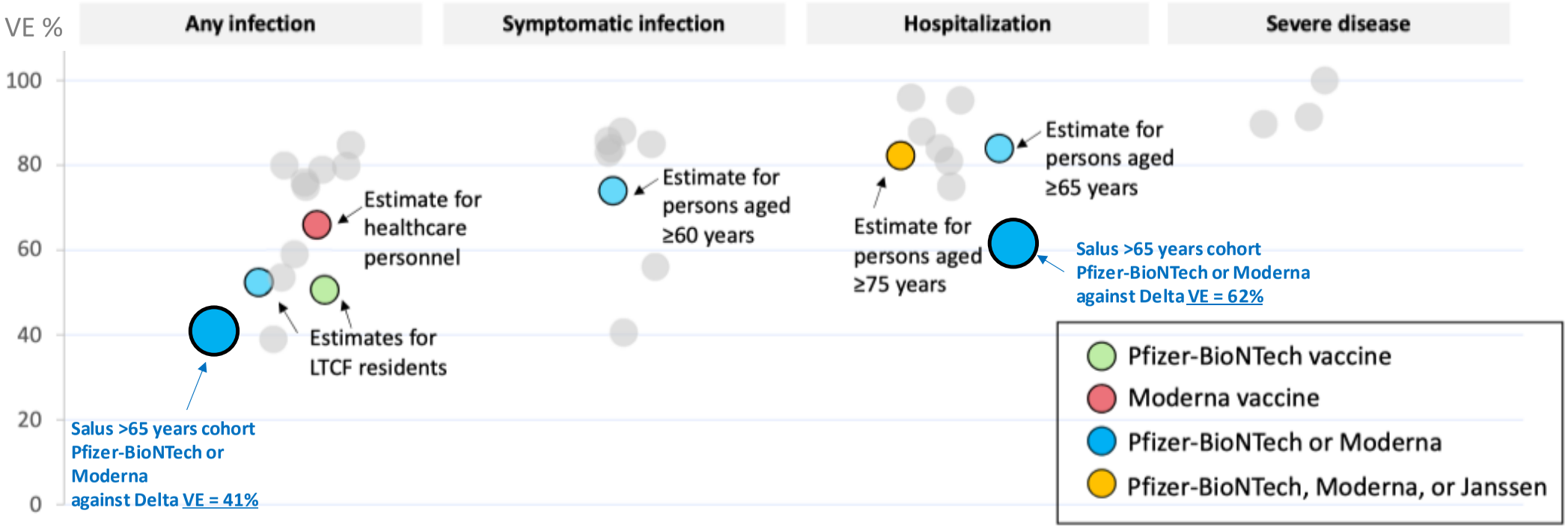
PCV = proportion cases vaccinated

PPV = proportion population vaccinated

Graphic adapted from CDC Presentation July 30, 2021
Improving communication around vaccine breakthrough and vaccine effectiveness

Project Salus

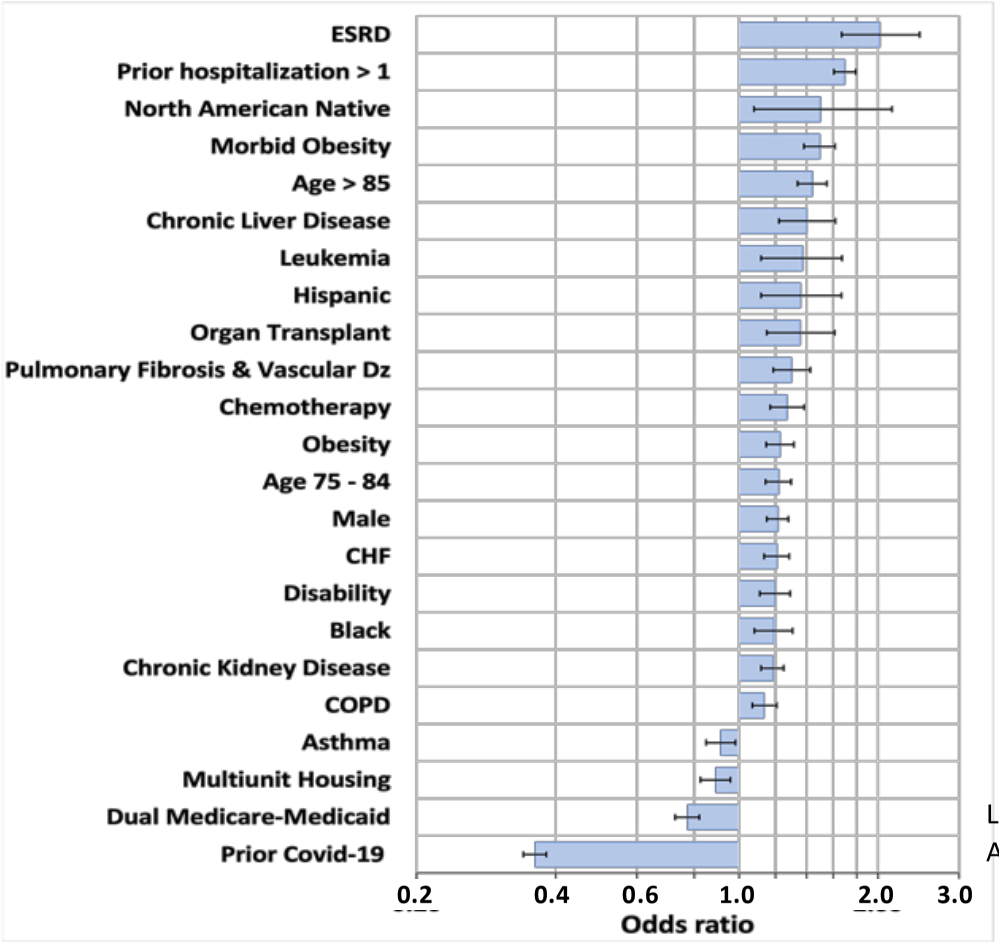
How Does mRNA Vaccine Effectiveness in 65+ Salus Cohort with 5.6M Vaccinees Compared to Published Estimates?



- **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**

Project Salus

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

Report Prepared by:

Worldwide Safety

Pfizer

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

APPENDICES

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

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

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.

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).

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%)

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

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

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.

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.

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:

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

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.

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;

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

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);

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

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;

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);

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;

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),

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

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;

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. .

- 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

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.

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.

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

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

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

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

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

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

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

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

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.

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

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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**
   - **Vaccine Adverse Event Reporting System (VAERS)**
     - **Management shared by CDC and FDA**

2. Active Surveillance Monitoring Program
   - FDA BEST
   - FDA-CMS partnership

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

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– 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

83

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

84

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

87

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

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

100

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

101

Operations

5 JAN 2021– 12 JAN 2022

OTHER SIGNIFICANT EVENTS

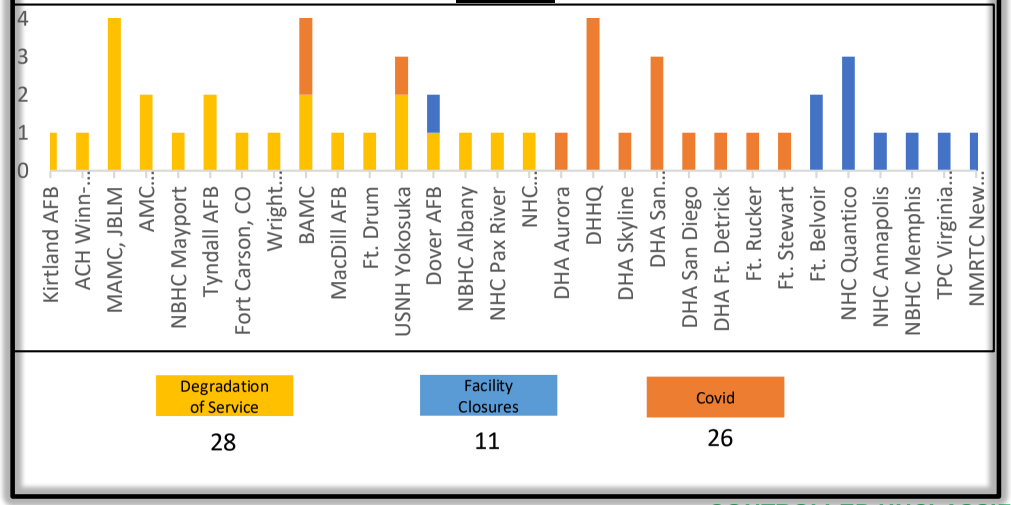
Deployment Roll-Up:

- 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

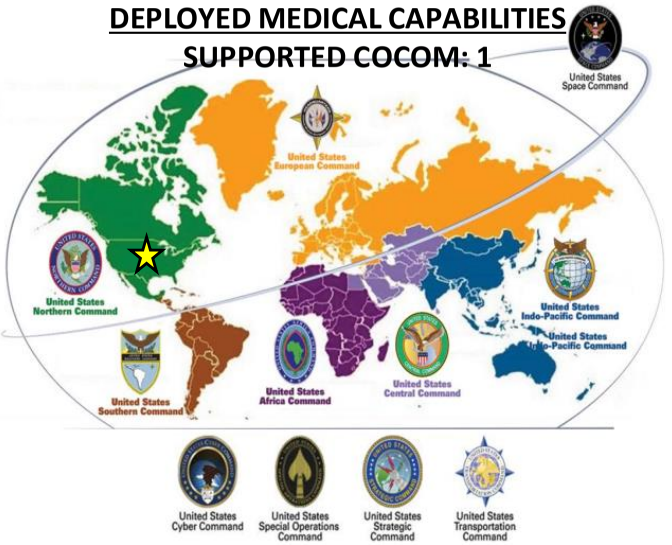
- CDRUSNORTHCOM IMMEDIATE RFF S220020 ISO DSCA COVID-19 RESONSE
  - IMMEDIATE RFF. RFF REFLECTS THE CONTENTS OF THE 30 DEC 21 SDOB. SOURCING CONFIRMED BY FORCE PROVIDERS. 1000 DoD PERSONNEL.

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.

102

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

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 In CBP custody | 227 In ORR care | 203 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 Arrived at Ports of Entry yesterday

0 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 Arrived at Safe Havens yesterday

738 Departed Safe Havens yesterday (preliminary count)

	7-day total	7-day avg.
Arrivals	6	1
Departures	4,014	573

Total population over 7 days

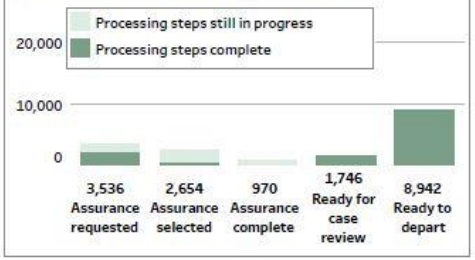
Medically Fragile and Third Trimester Pregnancies

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 Departures from Safe Havens through Resettlement Agencies yesterday (preliminary count)

45 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

104

As of 2022-01-12

POC: Col Jennifer Garrison
E-mail: jennifer.h.garrison.mil@mail.mil

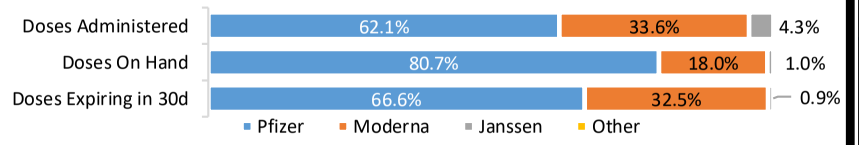
CONTROLLED UNCLASSIFIED INFORMATION (CUI)

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**



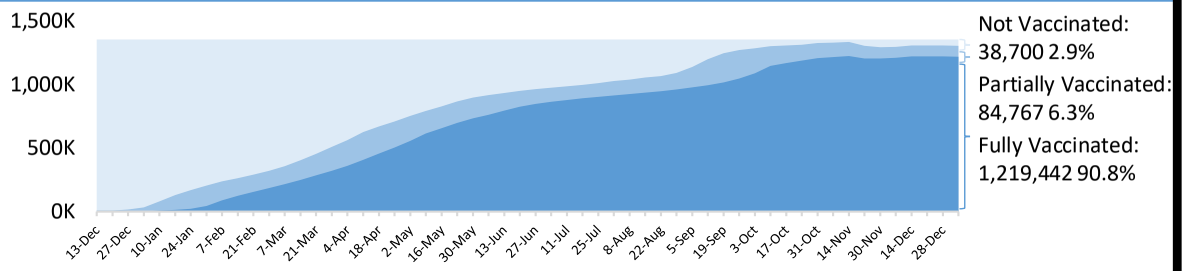
DOD & US Vaccination Statistics

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



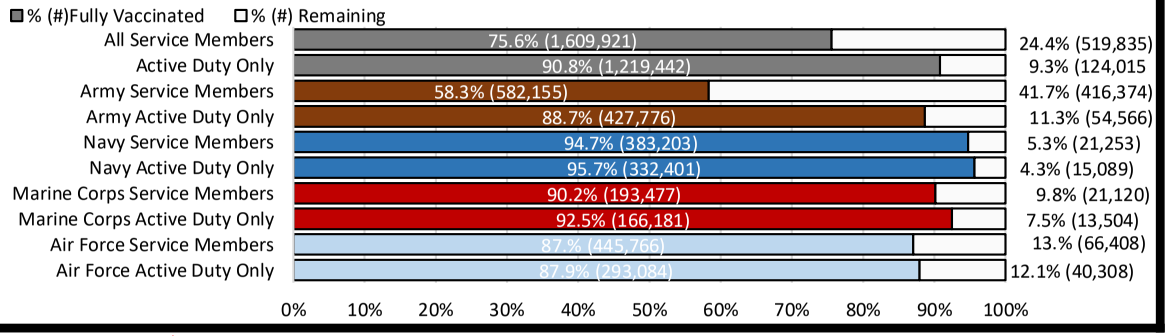
Total Force Individuals Vaccinated**

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.

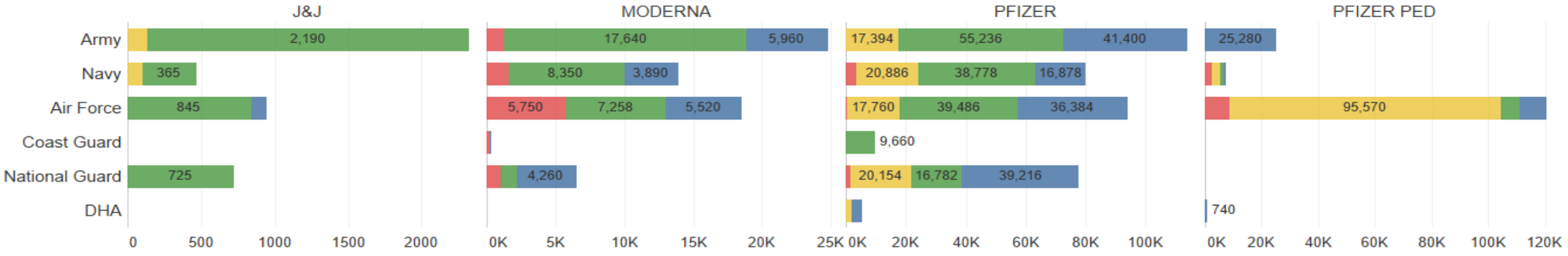
CONTROLLED UNCLASSIFIED INFORMATION

DOD COVID-19 Vaccine Doses On Hand

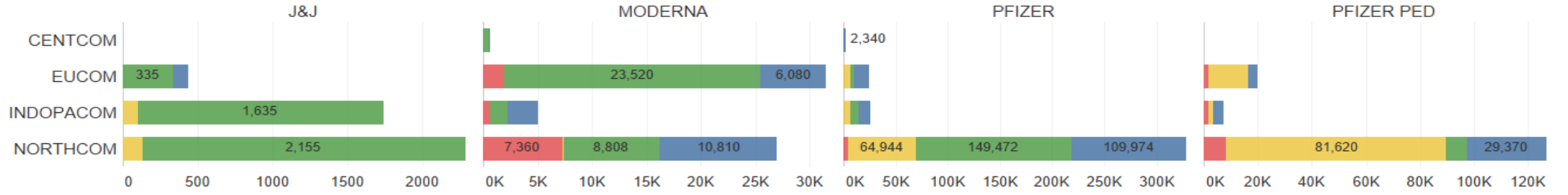
Data pulled from DMLSS/SLEP on: Tuesday, January 11, 2022

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

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106

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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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

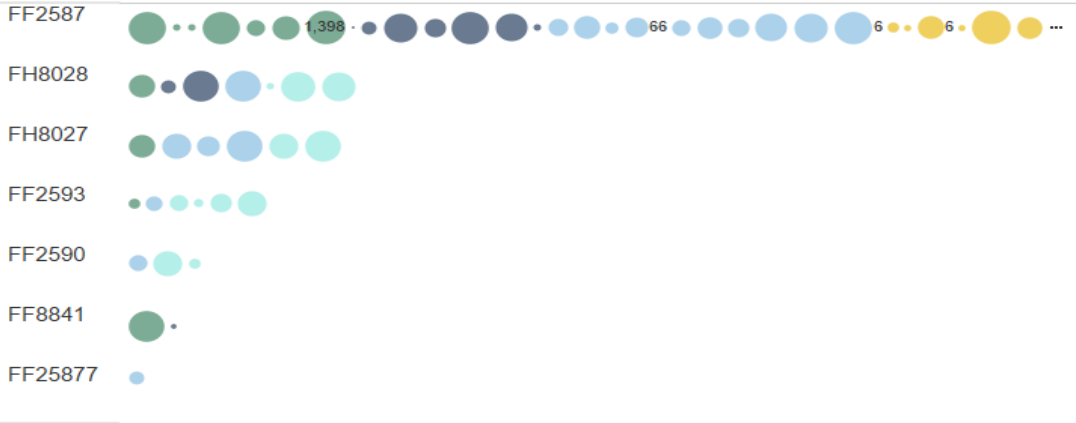
90,570 Current Serviceable BLA Doses by Service/Agency

Brush for details, click to filter

FF2587	PFIZER	NAVY	16,428
		AIR FORCE	16,194
		ARMY	15,054
		COAST GUARD	9,294
		NATIONAL GUARD	162
FF8841	PFIZER	ARMY	12,918
		NAVY	6,798
FH8028	PFIZER	NATIONAL GUARD	2,154
		NAVY	1,386
		AIR FORCE	1,170
		ARMY	588
FH8027	PFIZER	AIR FORCE	2,412
		NATIONAL GUARD	1,962
		ARMY	648
FF2593	PFIZER	NATIONAL GUARD	1,590
		AIR FORCE	288
		ARMY	102

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

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108

DMLSS/CLED

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

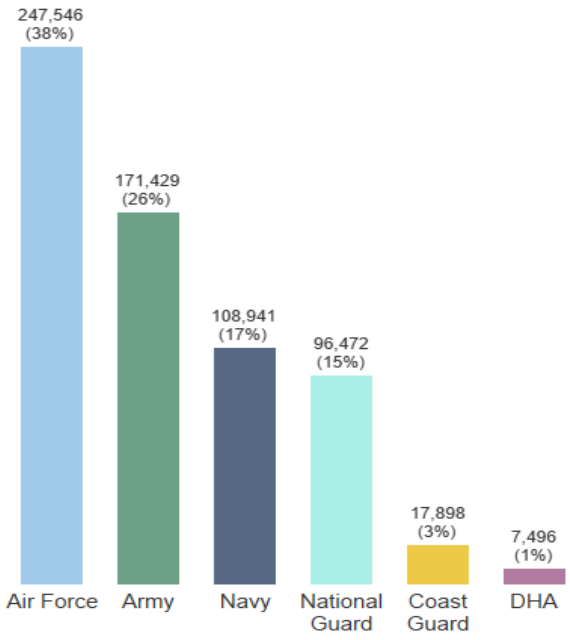
Serviceable?	Item Name	CCMD	Service/Agency	DHA Market	Main Organization	Child Organization	Lot Number	Expiration Dates
Serviceable Doses	All	All	All	All	All	All	All	Show all dates

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

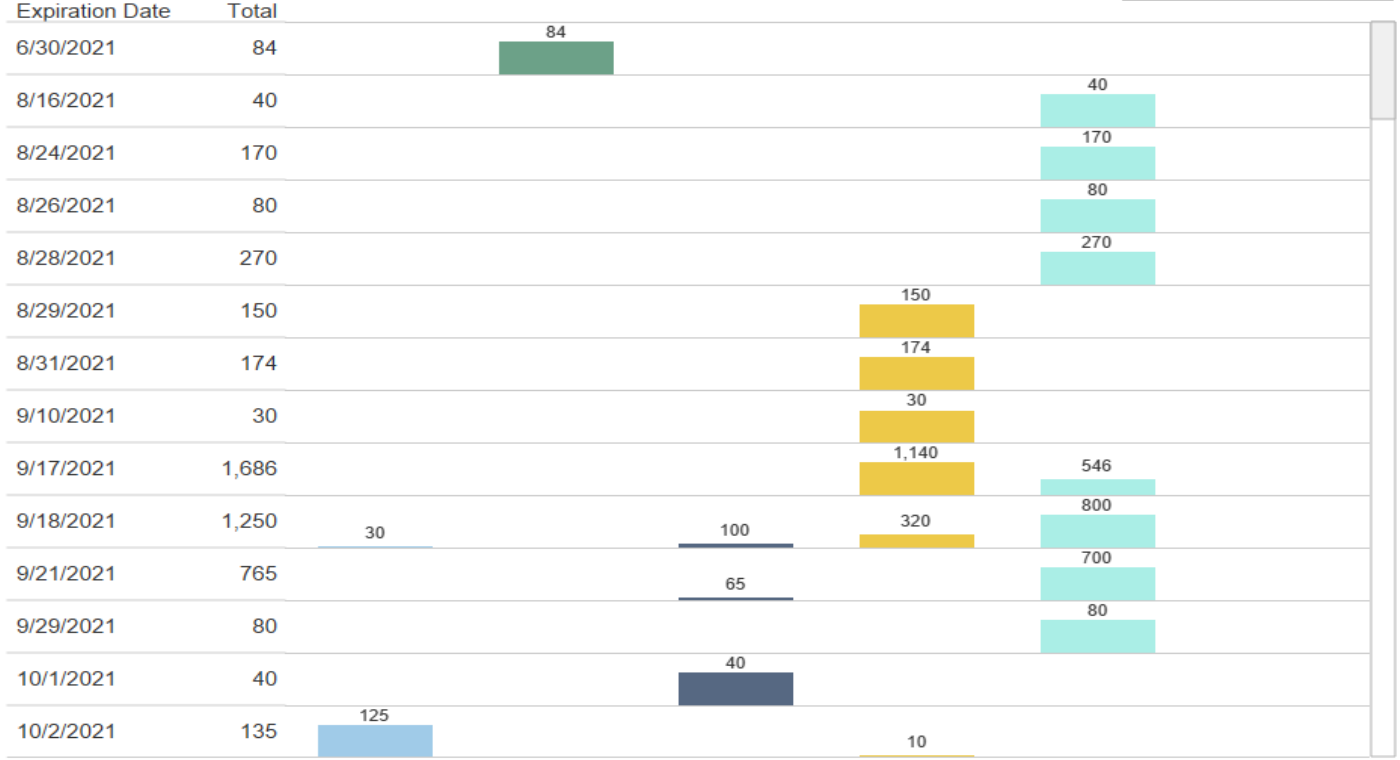
Brush for details

Data Outliers 0

Show All Data

Remove Outlier Data

Expiration Date	Total
6/30/2021	84
8/16/2021	40
8/24/2021	170
8/26/2021	80
8/28/2021	270
8/29/2021	150
8/31/2021	174
9/10/2021	30
9/17/2021	1,686
9/18/2021	1,250
9/21/2021	765
9/29/2021	80
10/1/2021	40
10/2/2021	135



CUI

As of 2022-01-11

POC: Col Jennifer Garrison
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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

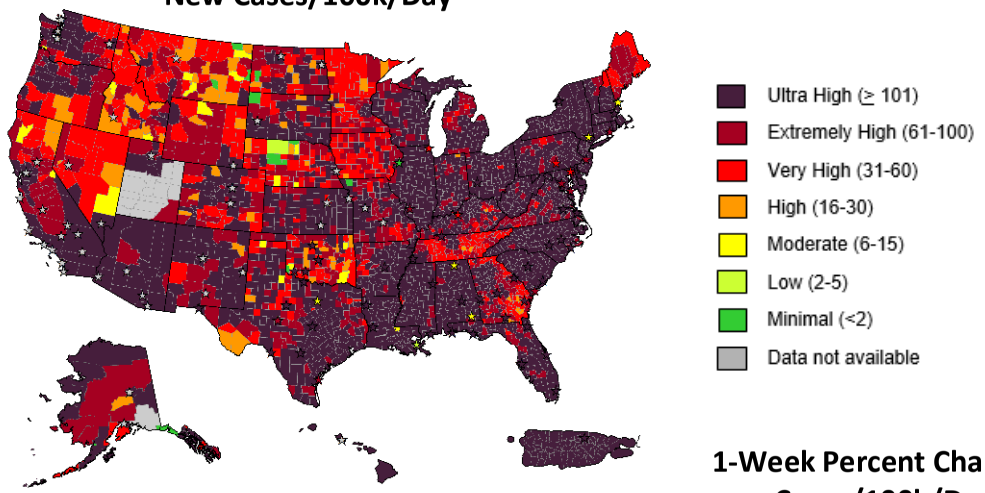
Installations of Interest

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		

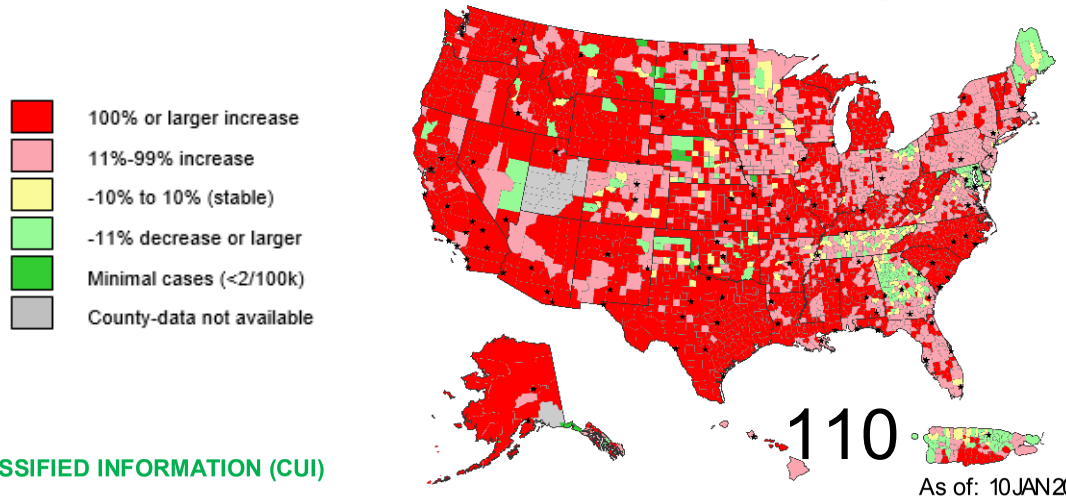
Markets/Regions to Watch

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

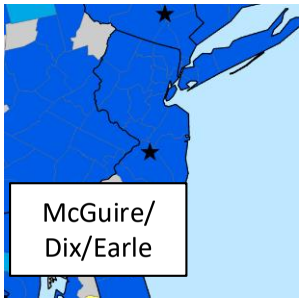


As of: 11JAN2022
Controlled by: DHA/PHD//AFHSD
CUI Category: CUI
Slide POC: Col Patrick Kennedy; patrick.w.kennedy.mil@mail.mil; (301) 619-3850

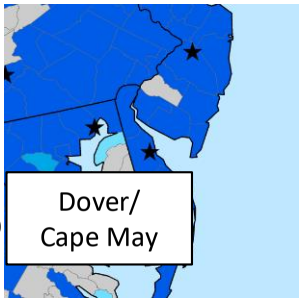
MHS Market	State	CIV COVID-19 Hosp./100k/day	CIV Cases/100k/day	CIV ICU Beds Occupied
McGuire/Dix/Earle	NJ, NY, PA	73	383	68%
Dover/Cape May	MD, NJ, DE	66	263	76%
Knox	IN, KY	59	241	81%
Great Lakes	IL, WI	59	253	69%
Leavenworth	MO, KS	55	252	78%
Scott	MO, IL	55	283	88%
Lejeune/Cherry Point	NC	53	119	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

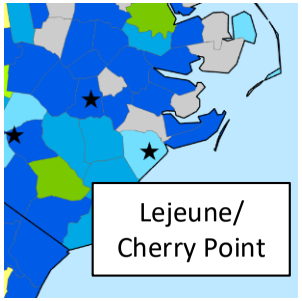
McGuire/Dix/Earle MHS Market, NJ/NY/PA
Civilian COVID-19 Hospitalizations Increasing: 73 hospitalizations/100k/day (+54%), 68% ICU/79% inpatient beds used
Civilian Cases Increasing: 383 cases/100k/day (+16%)



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%)

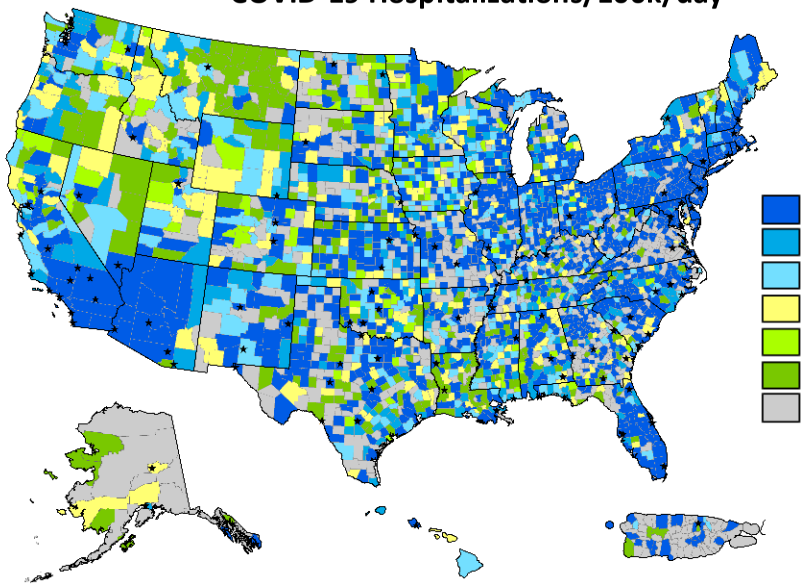


Lejeune/Cherry Point MHS Market, NC
Civilian COVID-19 Hospitalizations Increasing: 53 hospitalizations/100k/day (+22%), 65% ICU/79% inpatient beds used
Civilian Cases Increasing: 119 cases/100k/day (+145%)

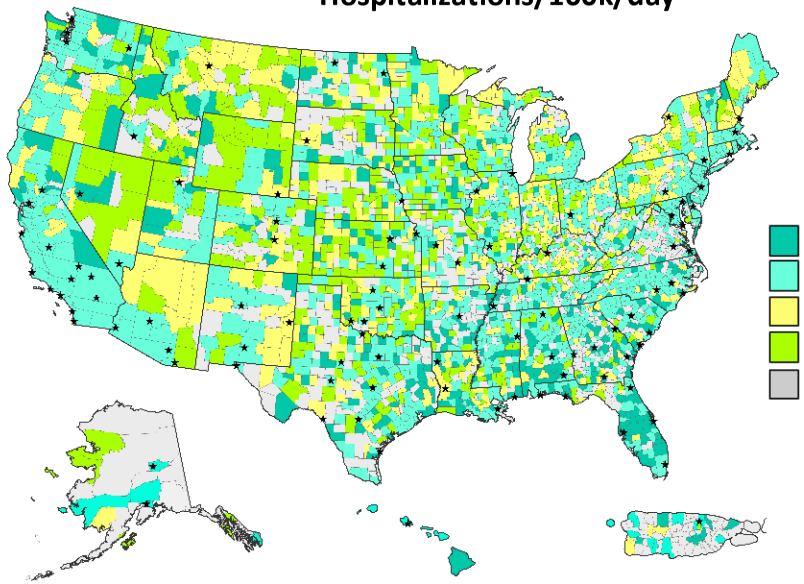


All US Counties

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.		

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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

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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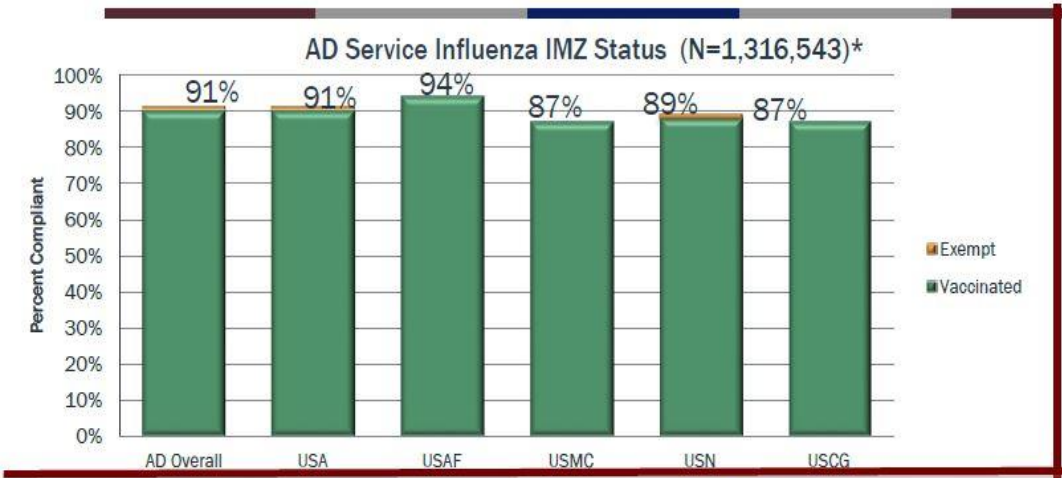
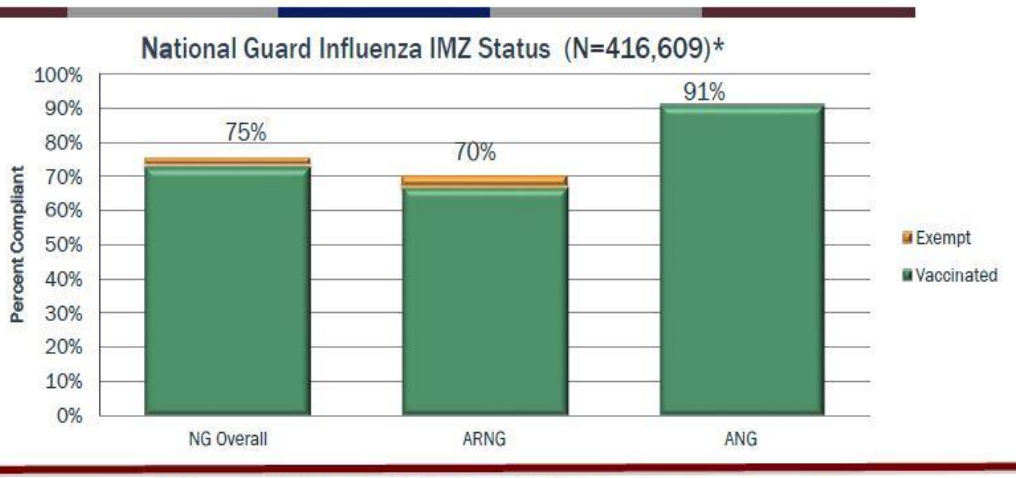
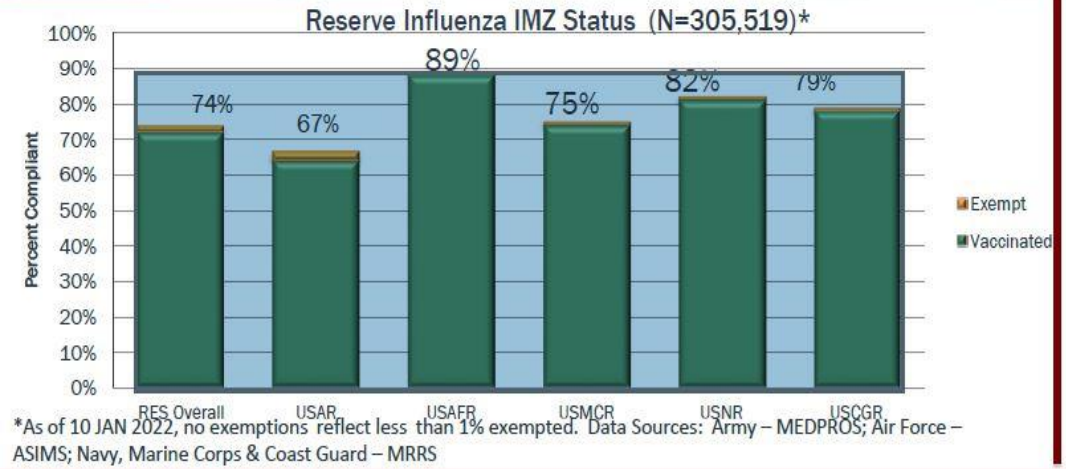
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

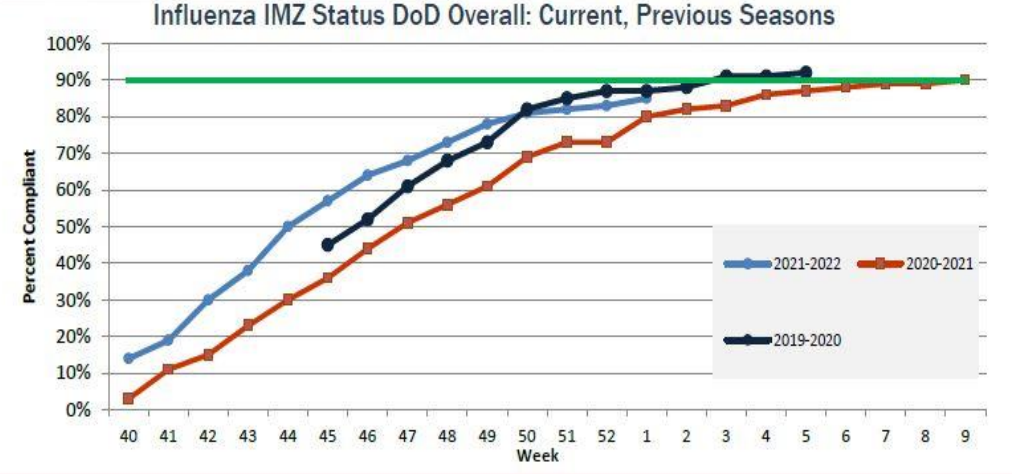
2021-2022 Seasonal Influenza Vaccine Compliance Status,

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

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

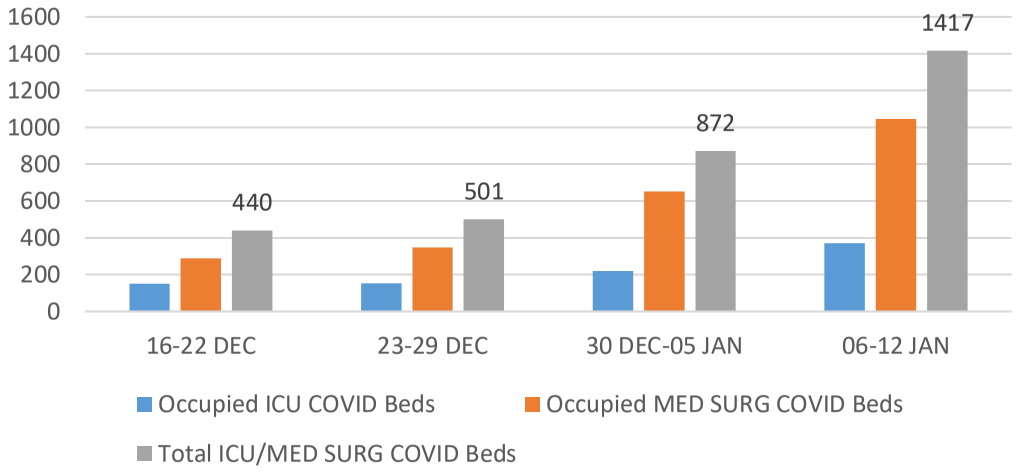
WAMC: 10 MS/SDU, 0 ICU
WBAMC: 10 MS/SDU, 5 ICU
DDEAMC: 8 MS/SDU, 3 ICU
Travis AFB, 5 MS/SDU, 5 ICU
WRNMMC: 12 MS/SDU, 5 ICU

- Total COVID Inpatients for MHS: **223** *(153)
  - MS/SDU: **171**
  - ICU: **52**

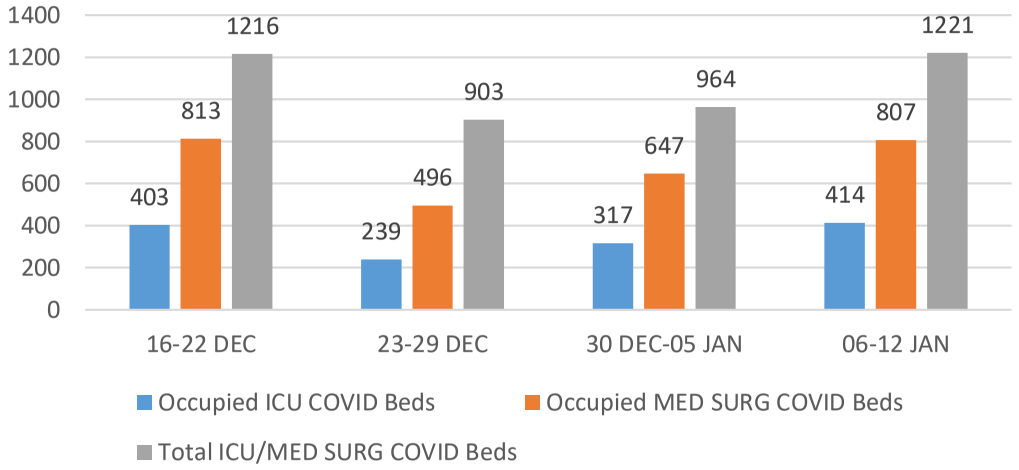
ACTIVE COVID ETMS2's

- 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

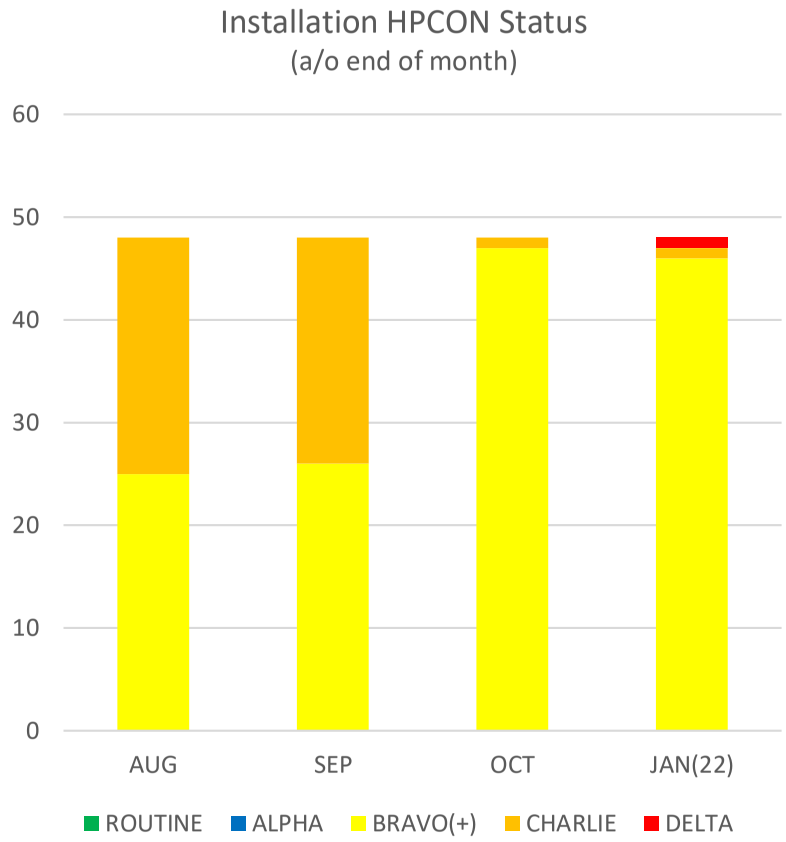
COVID-19

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)****

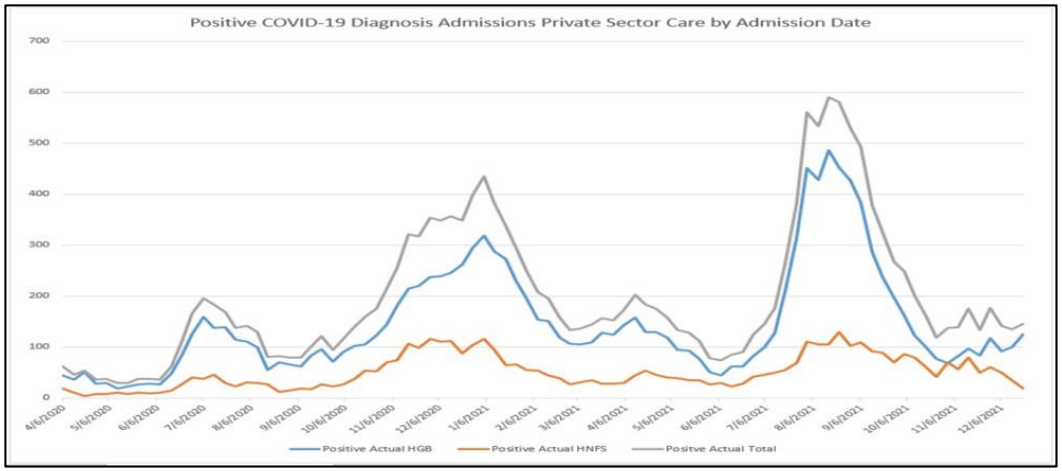
****Current updates information provided by filed DCIRs****

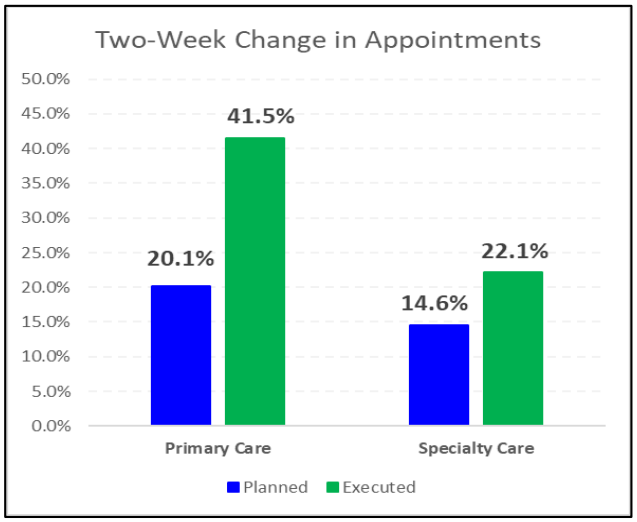
As of: 1100/ 12 JAN 2022
Slide POC: Mr. Neil Doherty
703-681-8165

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

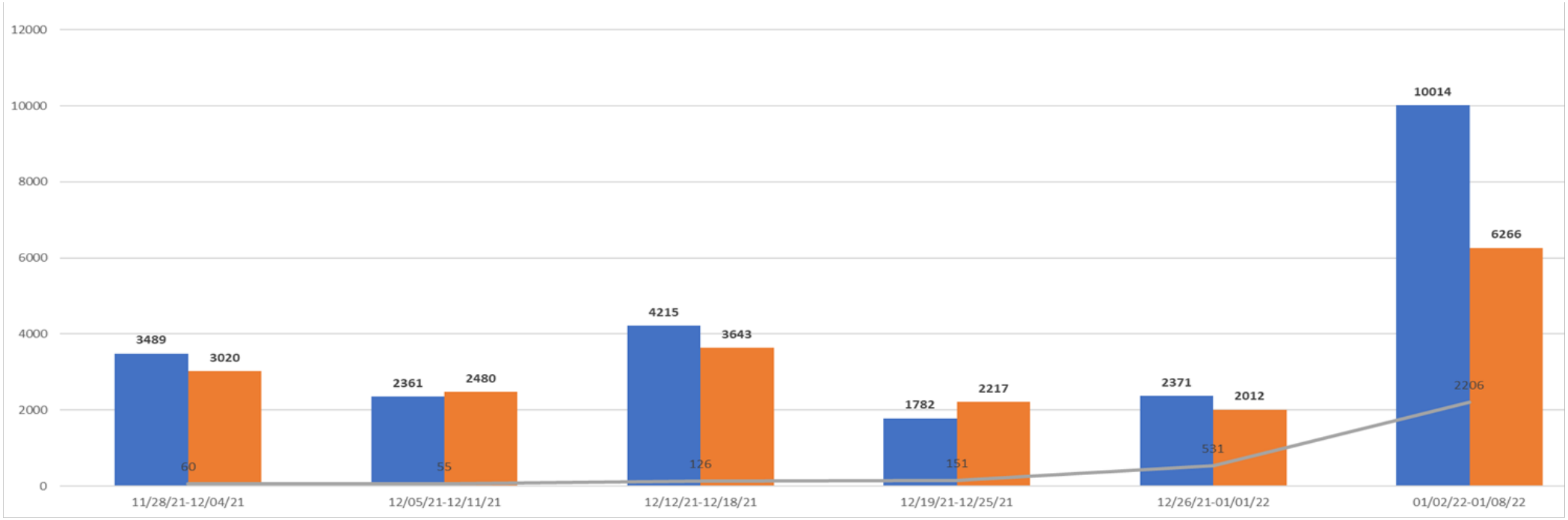
Slide POC: Maj Cooper Tatanya.l.cooper.mil@mail.mil 703-681-7317

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).

Slide POC: Maj Cooper Tatanya.l.cooper.mil@mail.mil 703-681-7317

UNCLASSIFIED//FOUO

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

UNCLASSIFIED//FOUO

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
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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.

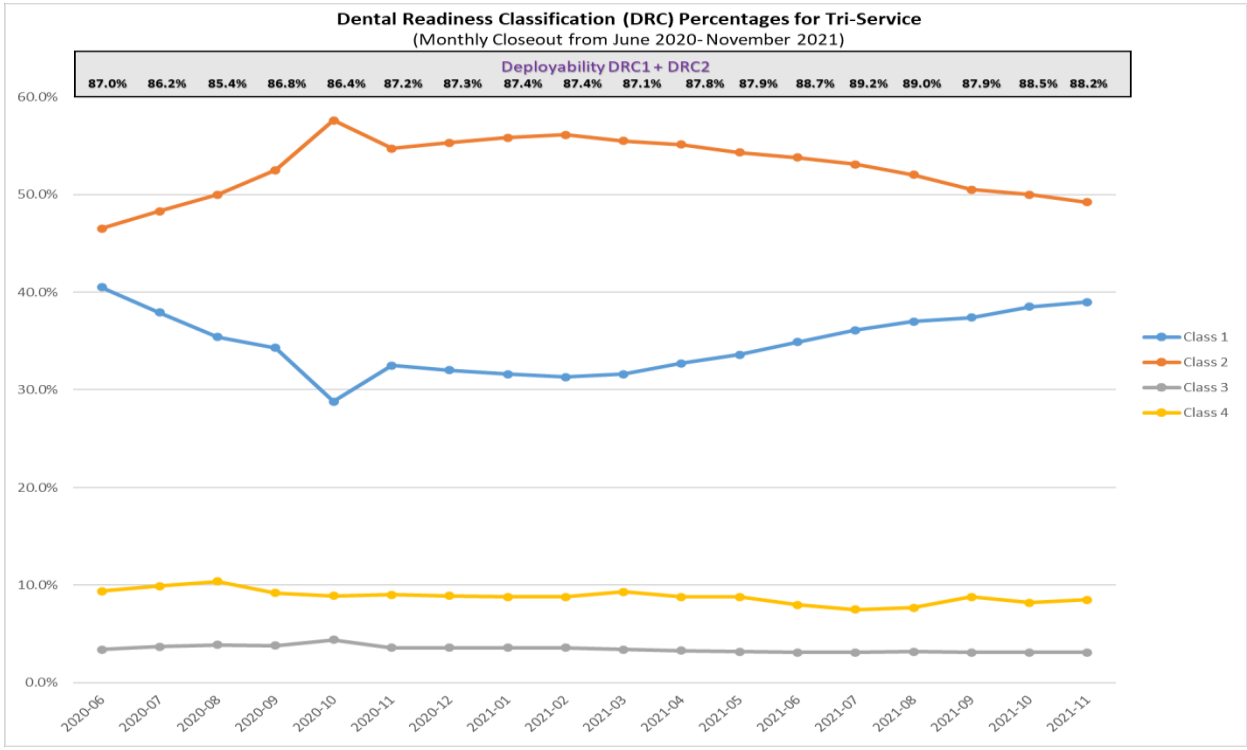
If MTFs do not have the capacity, network providers are capable of absorbing referrals from the Active Duty Dental Program (ADDP). The DHA TRICARE Dental Program Section (TDPS) under DAD-HCO is tracking market viability to ensure eligible beneficiaries under the TRICARE Dental Program and ADDP Remote 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.

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

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

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

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WHERE WE ARE

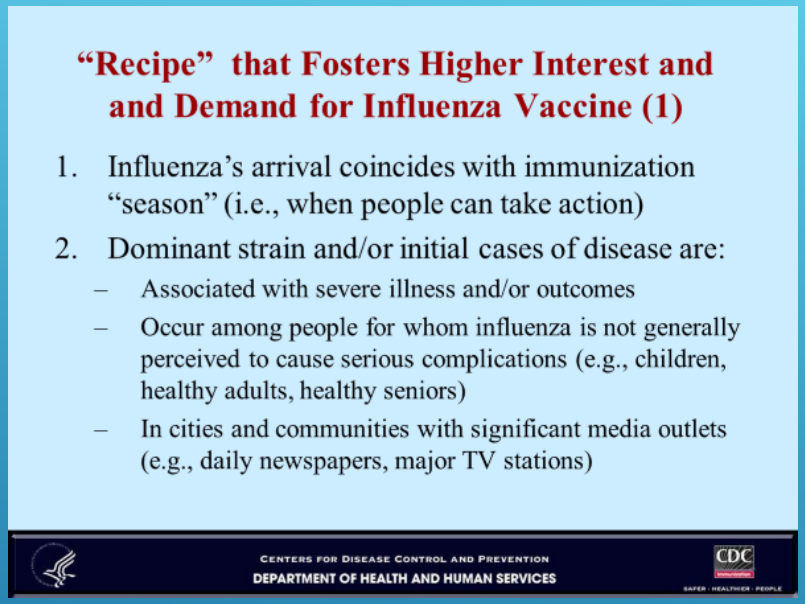
- At this point it is indisputable that the entirety of the world has been lied to about COVID-19.
- This presentation will lay out the lie and the path forward.
- This must include criminal and civil investigations by INDEPENDENT investigators, as well as prosecution where appropriate.
- At the end of this presentation we challenge anyone to suggest INDEPENDENT investigations are inappropriate with complete disclosure and transparency.

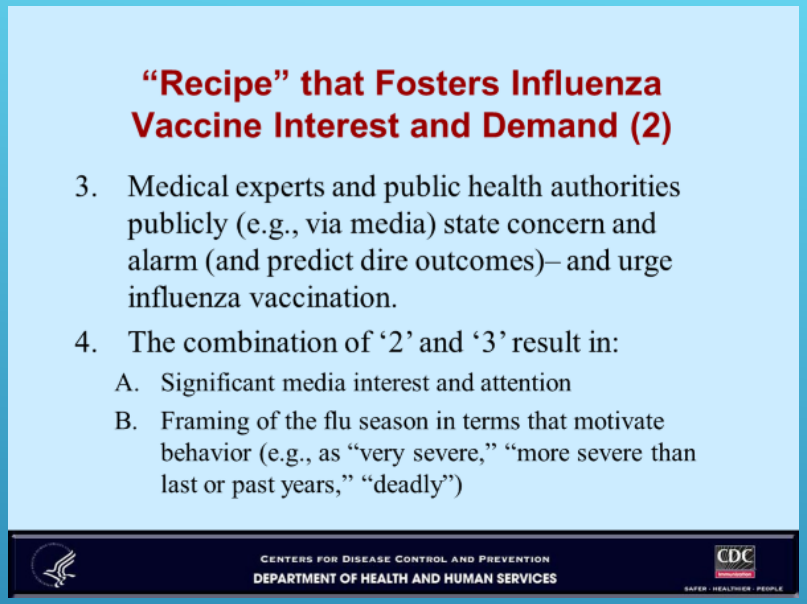
THE EVIDENCE

- 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.

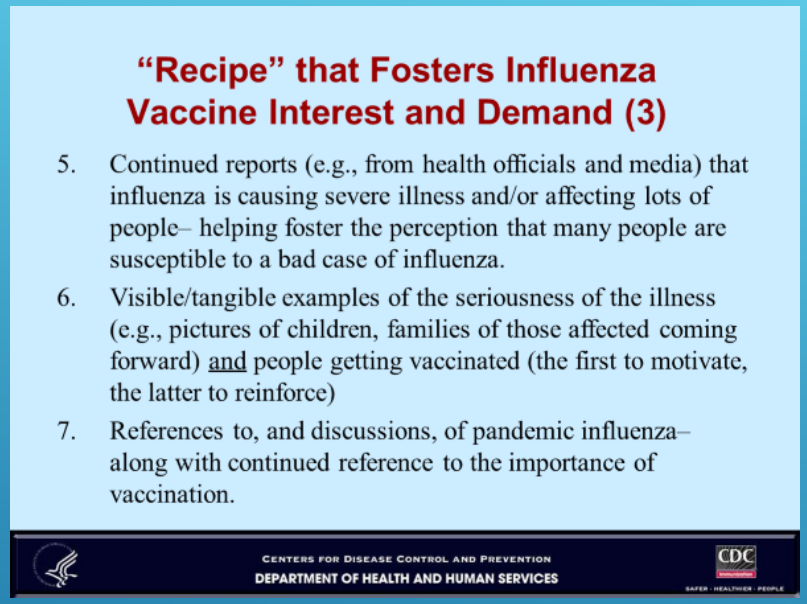
THE FEAR AND MANIPULATION PRESENTATION

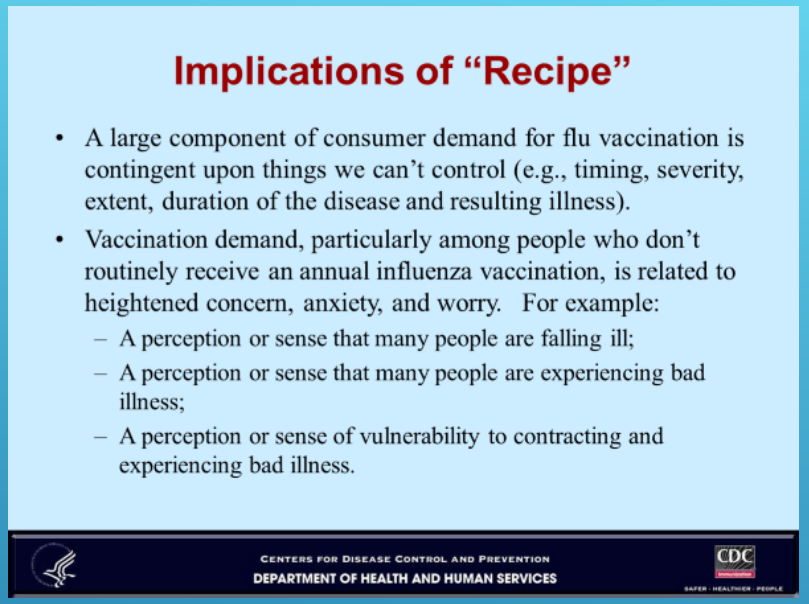
- Public health has used fear and manipulation for years against the public
- The next few slides are critical in understanding the global fraud now occurring
- These documents are from the CDC and DHHS



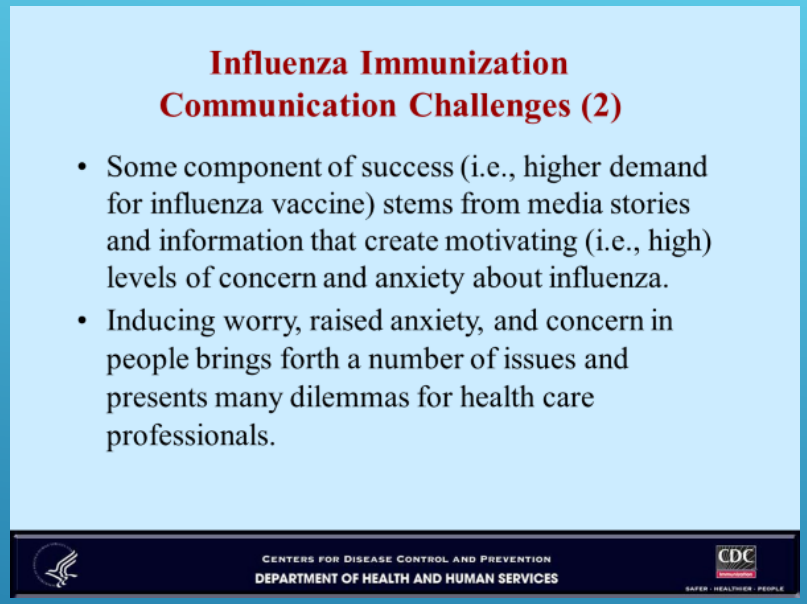


THE CDC RECIPE FOR FEAR





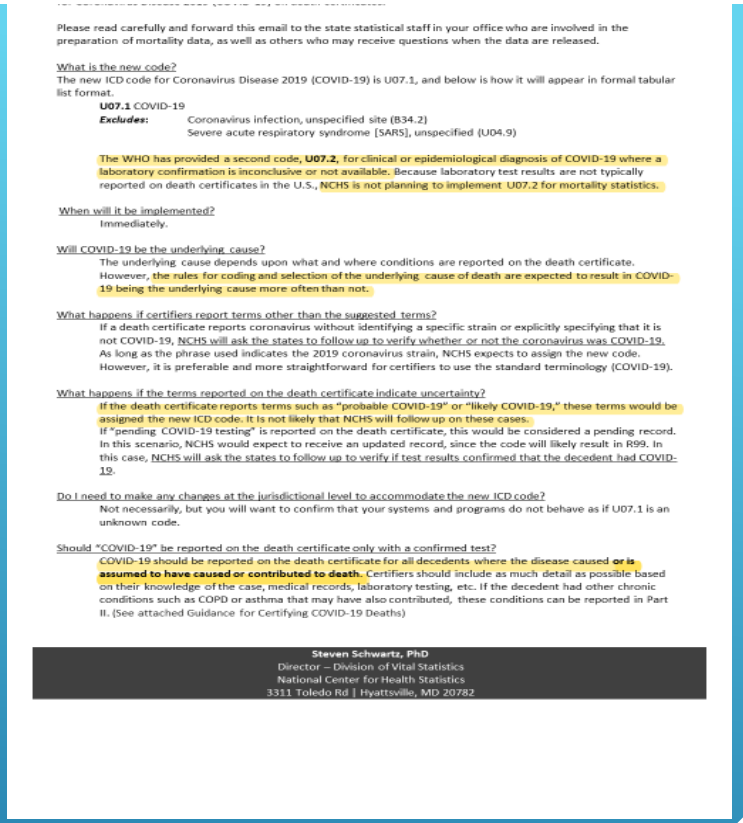
CDC AND FEAR CONT.



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.

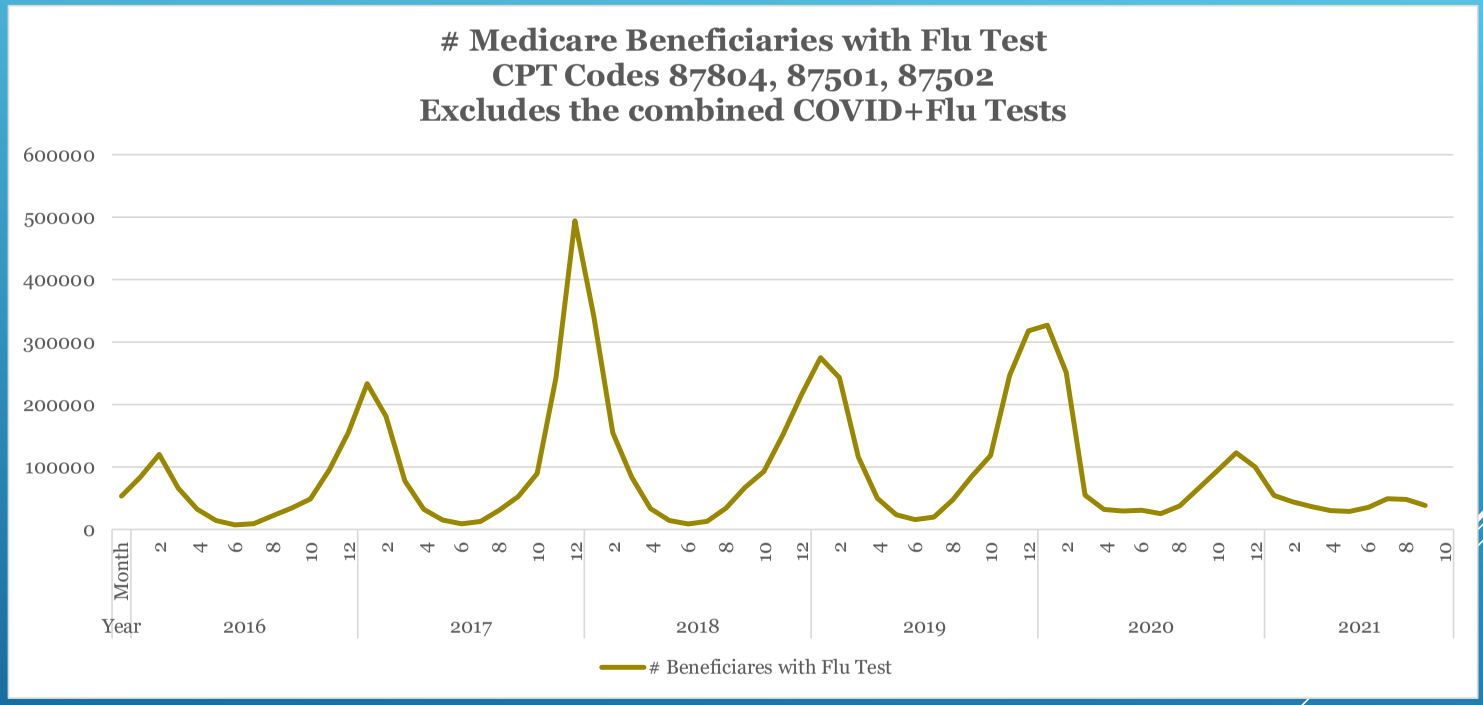
Do I need to make any changes at the jurisdictional level to accommodate the new ICD code?
Not necessarily, but you will want to confirm that your systems and programs do not behave as if U07.1 is an unknown code.

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

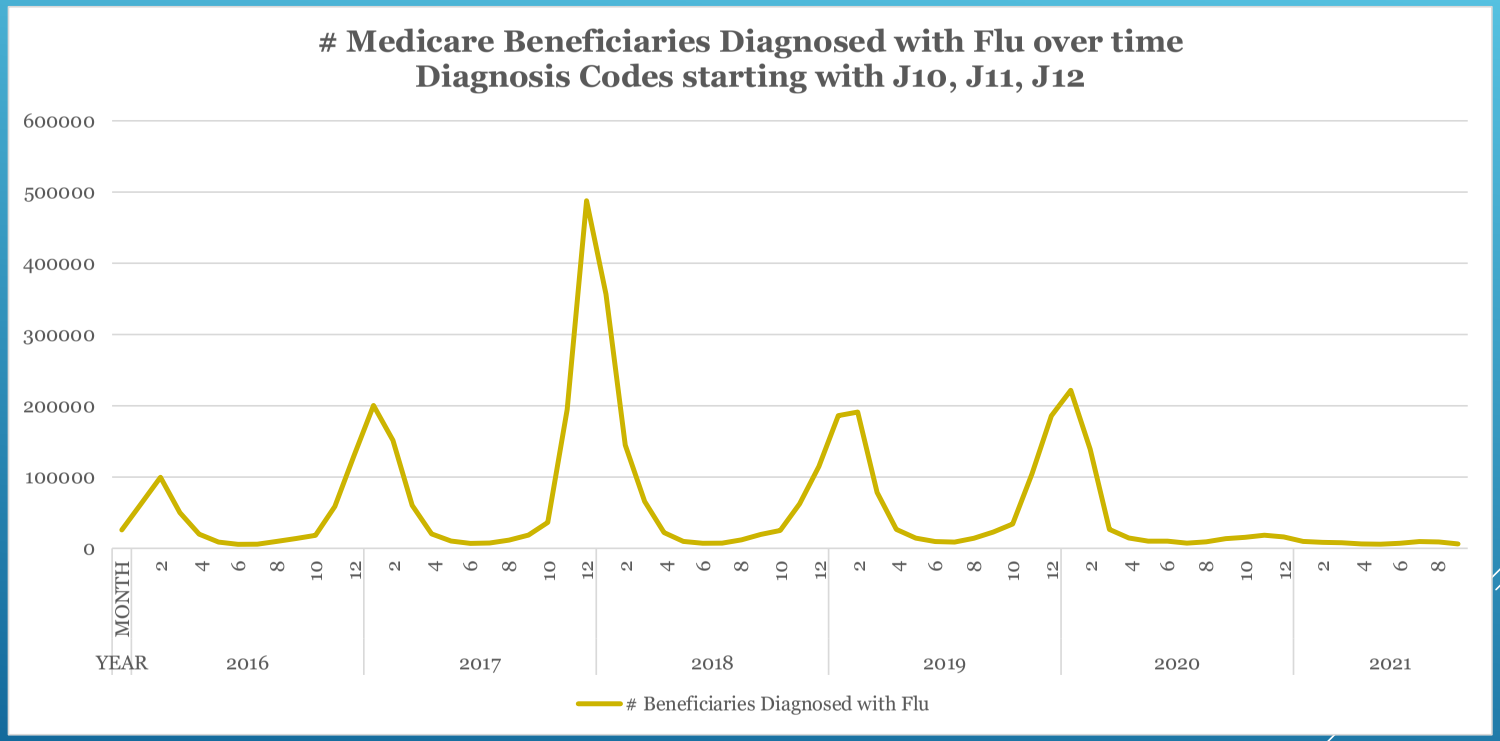
WHERE DID THE FLU GO?

Flu testing decreased significantly almost to a halt in late 2020



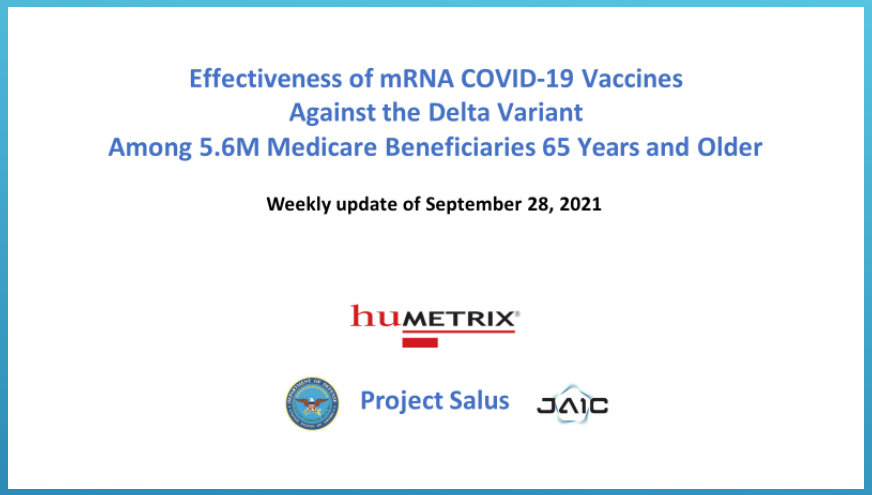
WHERE DID THE FLU GO?

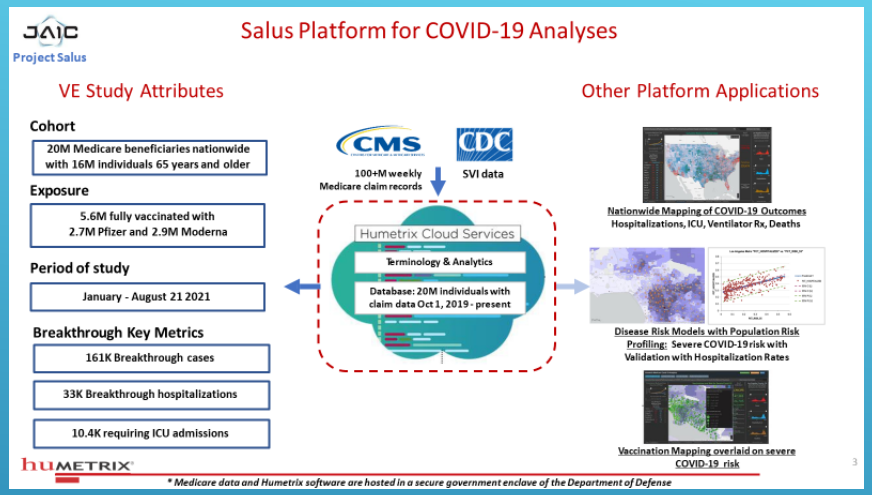
The graph below shows the number of Medicare beneficiaries who had a Diagnosis of influenza, defined as a diagnosis code starting with J10, J11, or J12. Only primary and secondary diagnosis codes were queried.



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?

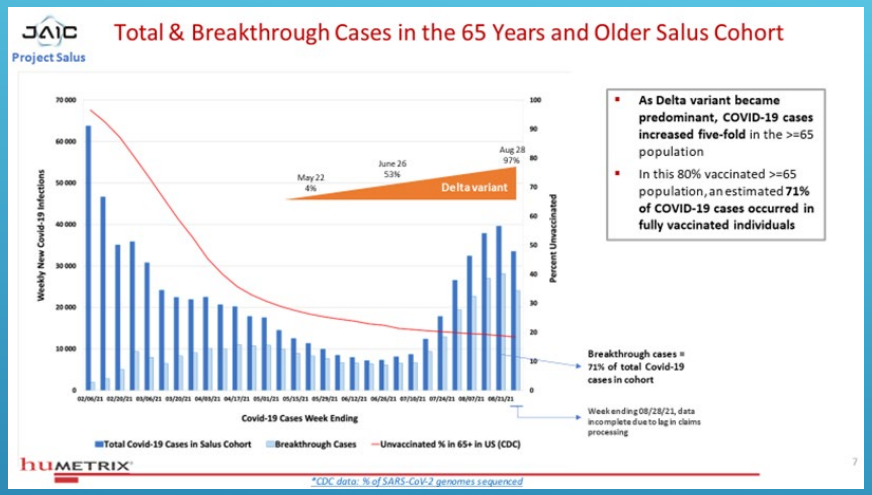


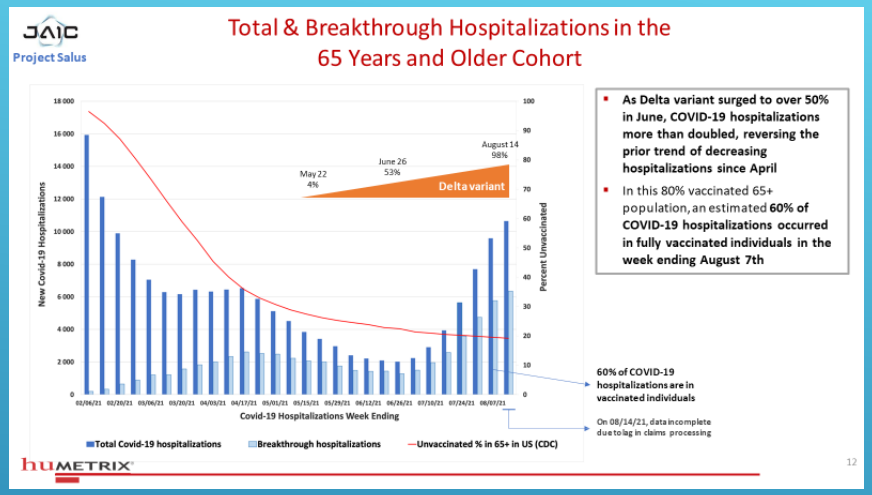


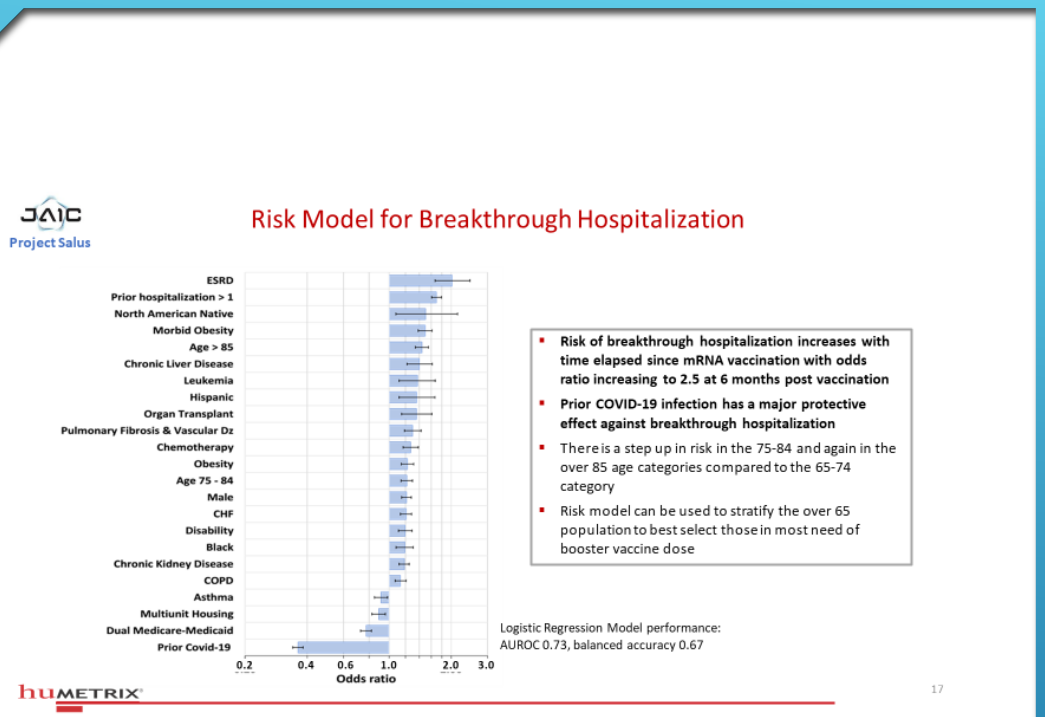
DOD EXCERPTS

- 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.

- 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.

GENERAL INFORMATION

- 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?

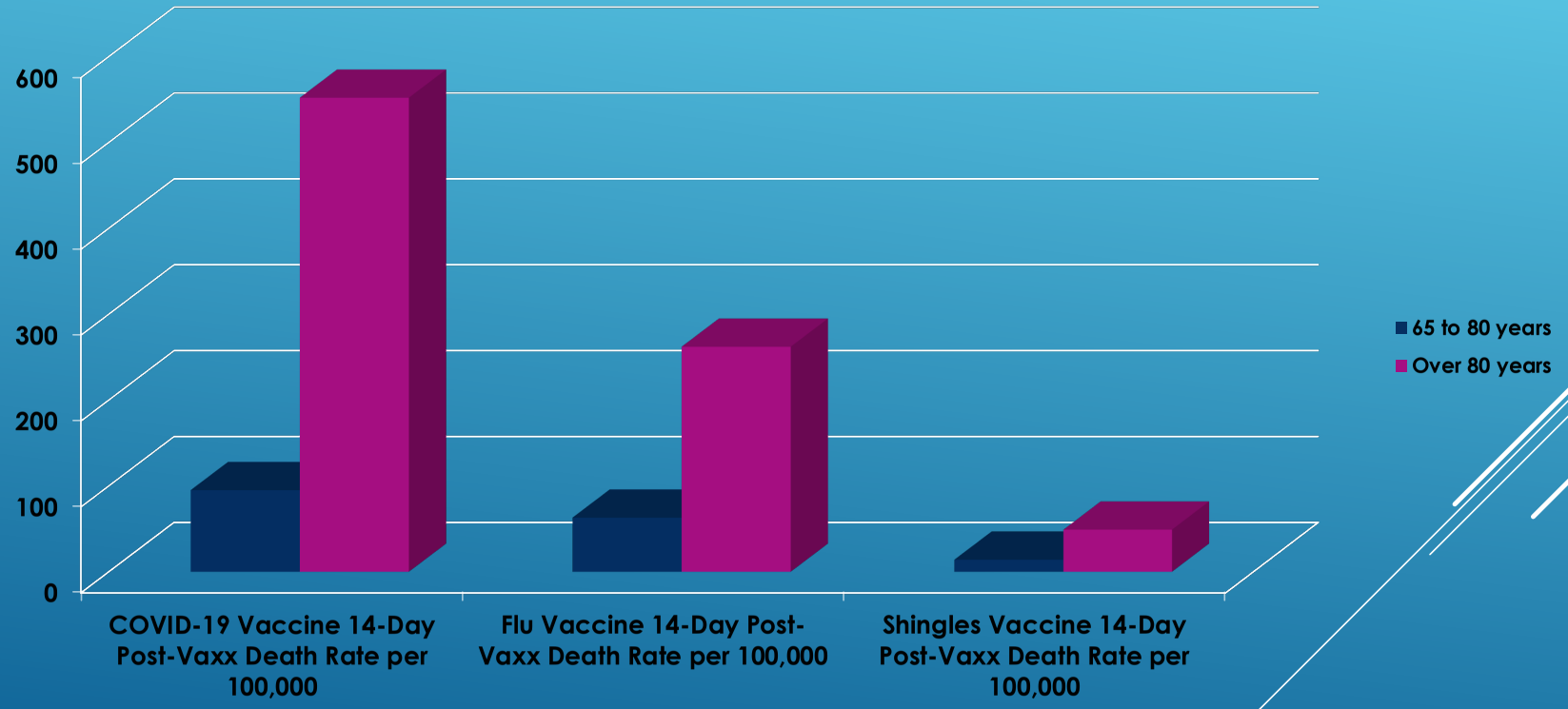
COVID-19 VACCINE COMPARED TO FLU & SHINGLES VACCINE (ALL AGES IN MEDICARE) – SOME PEOPLE RECEIVED FLU/COVID VAX AT THE SAME TIME SO THE REAL NUMBERS ARE WORSE

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

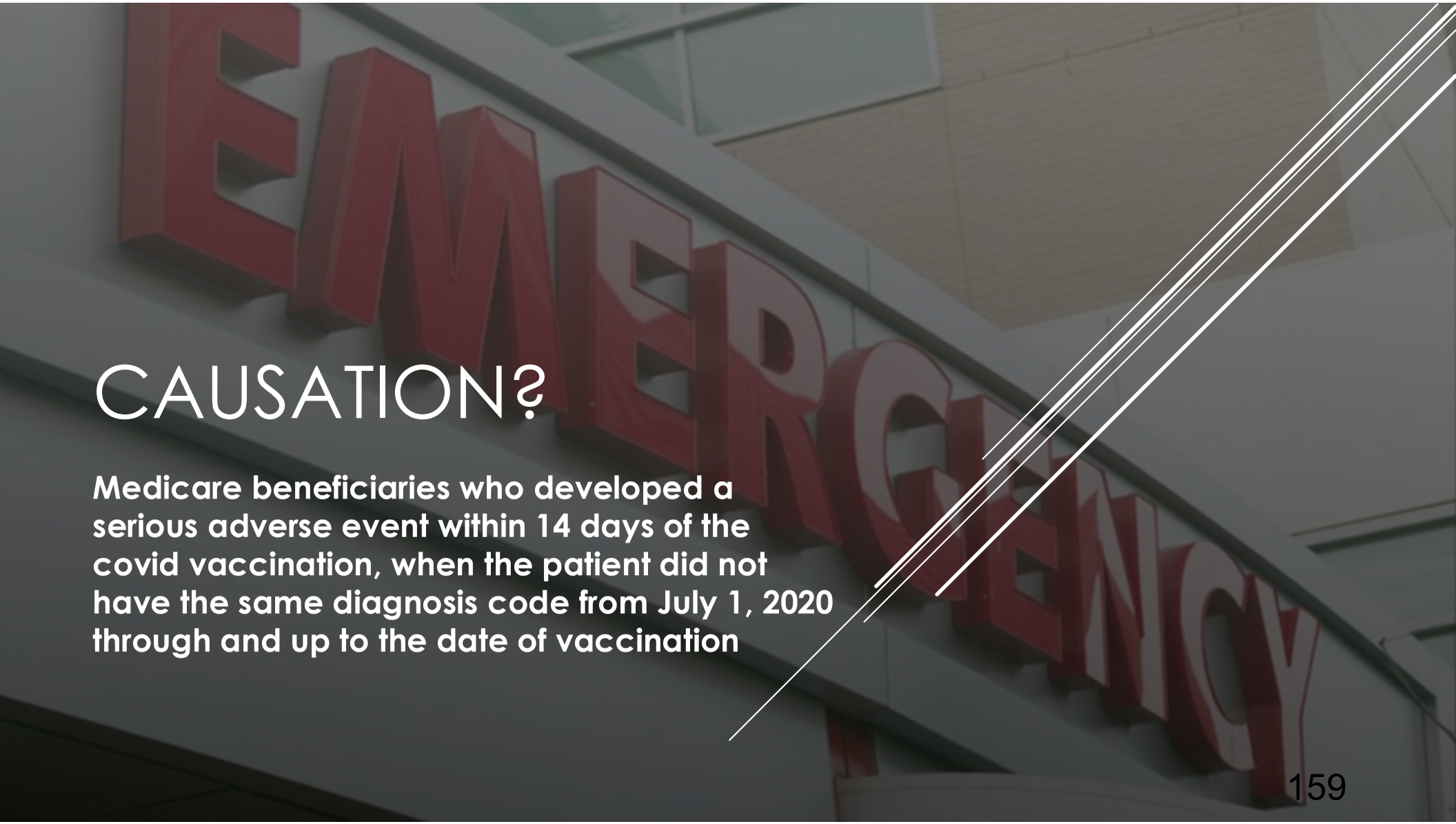
n=21,031

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

VACCINE CAUSALITY?

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…

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

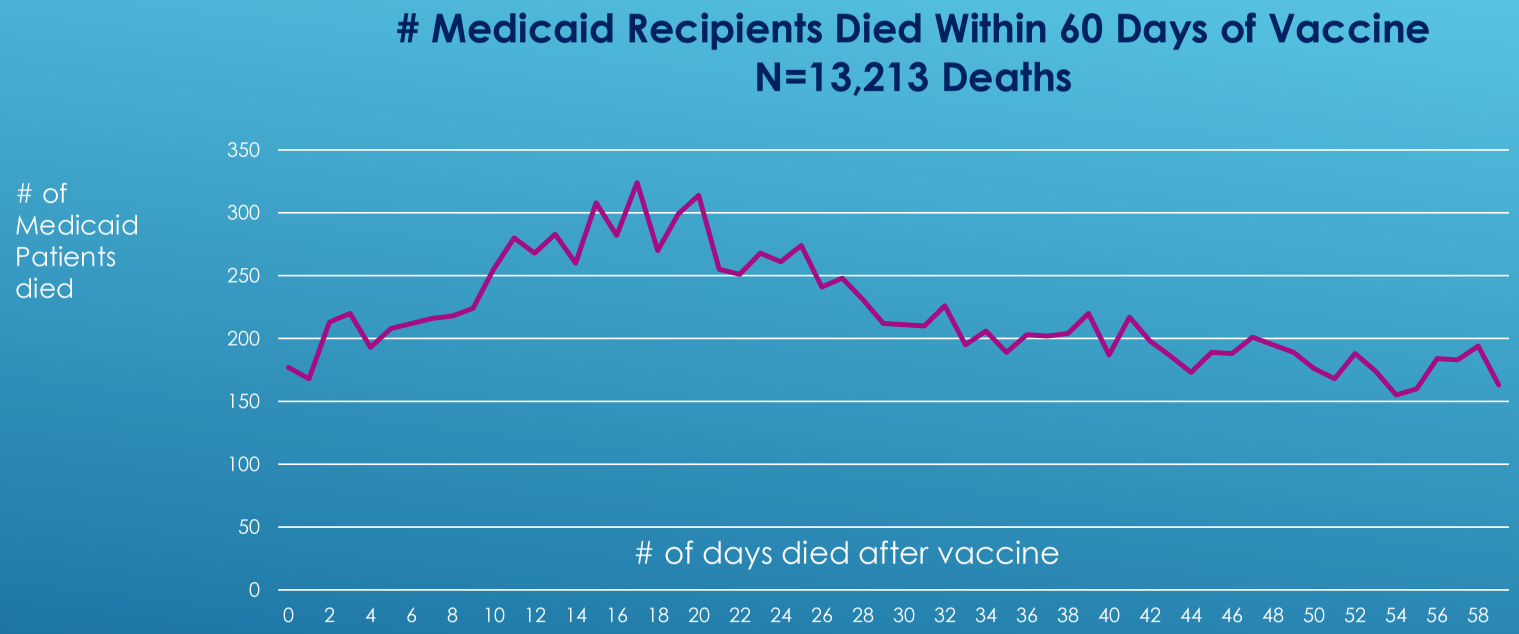
TEXAS: ADVERSE EVENTS WITHIN 14 DAYS OF VACCINE

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

"Cause of death" defined as one of last 5 diagnosis codes prior to death

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

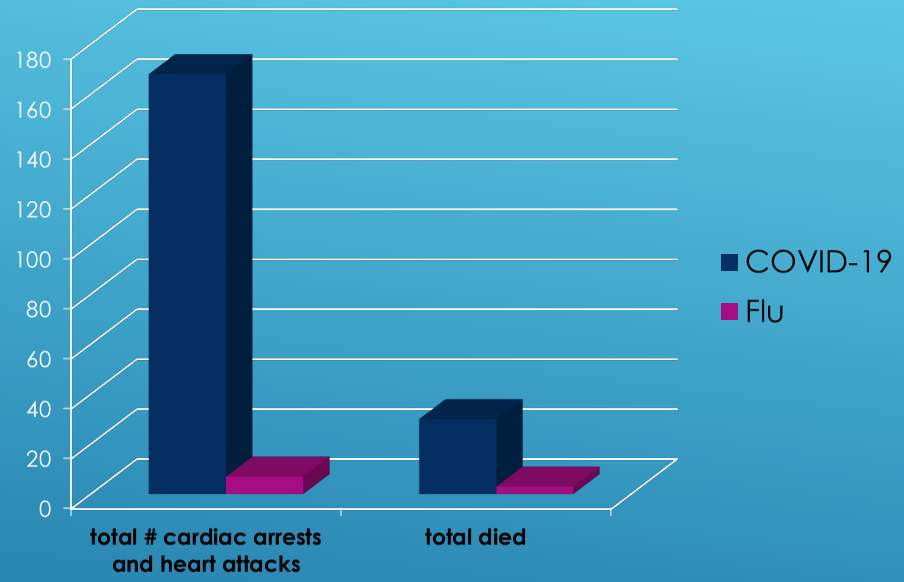
This is out of 7,036 recipients who Died within 28 post-vaccine

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.

OUR DEMANDS – THE UNITED STATES

- 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

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."

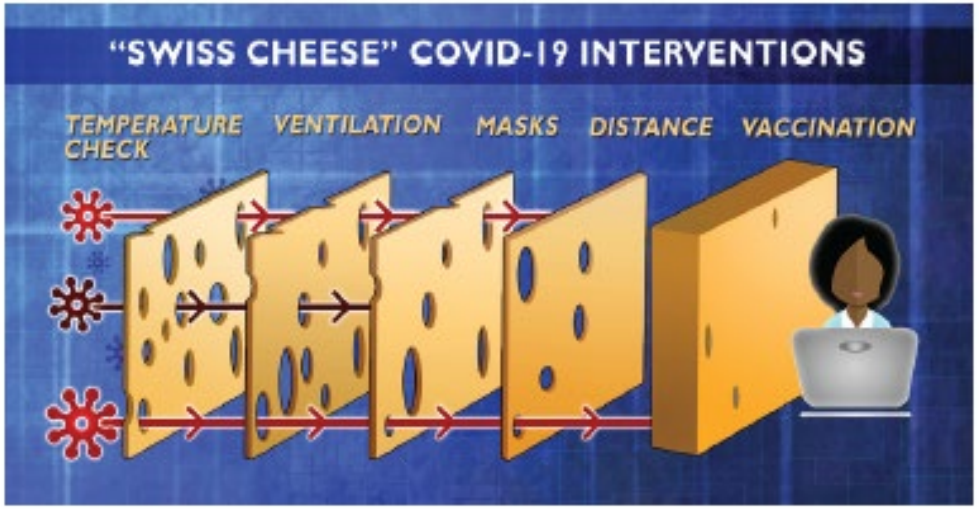
May 20, 2021: AO - *Updated Guidance Regarding Judiciary Response To Covid-19* "…fully vaccinated individuals may forego wearing masks and social distancing in federal buildings."

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

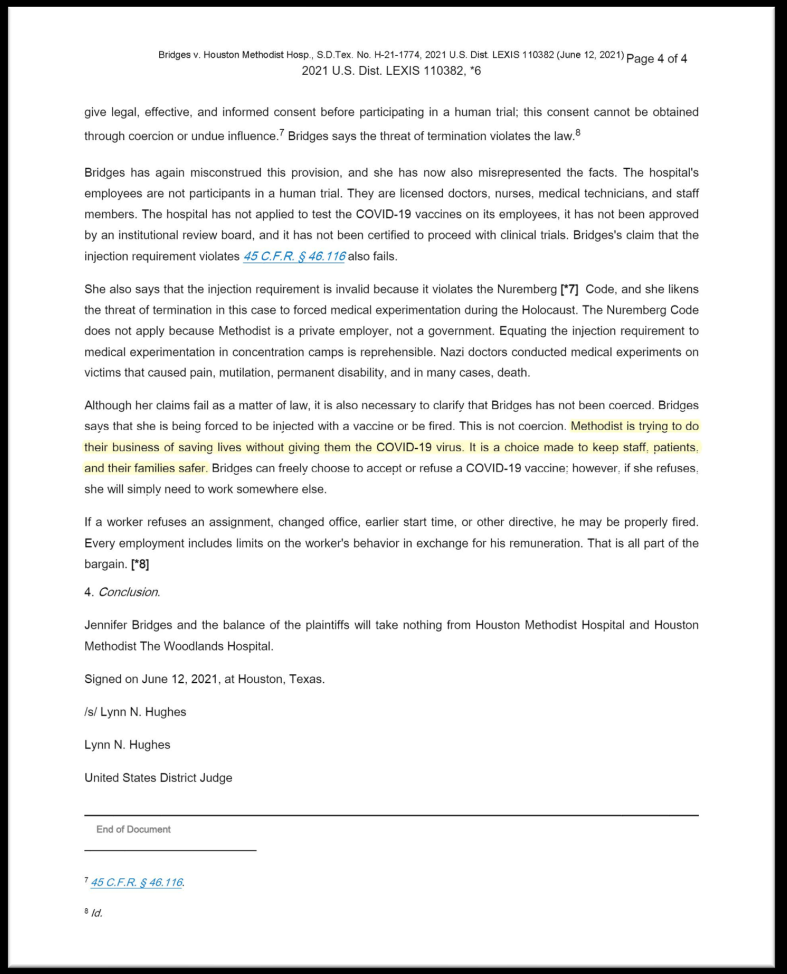
CANON 2(A) RESPECT FOR LAW. A JUDGE SHOULD RESPECT AND COMPLY WITH THE LAW AND SHOULD ACT AT ALL TIMES IN A MANNER THAT PROMOTES PUBLIC CONFIDENCE IN THE INTEGRITY AND IMPARTIALITY OF THE JUDICIARY.

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.

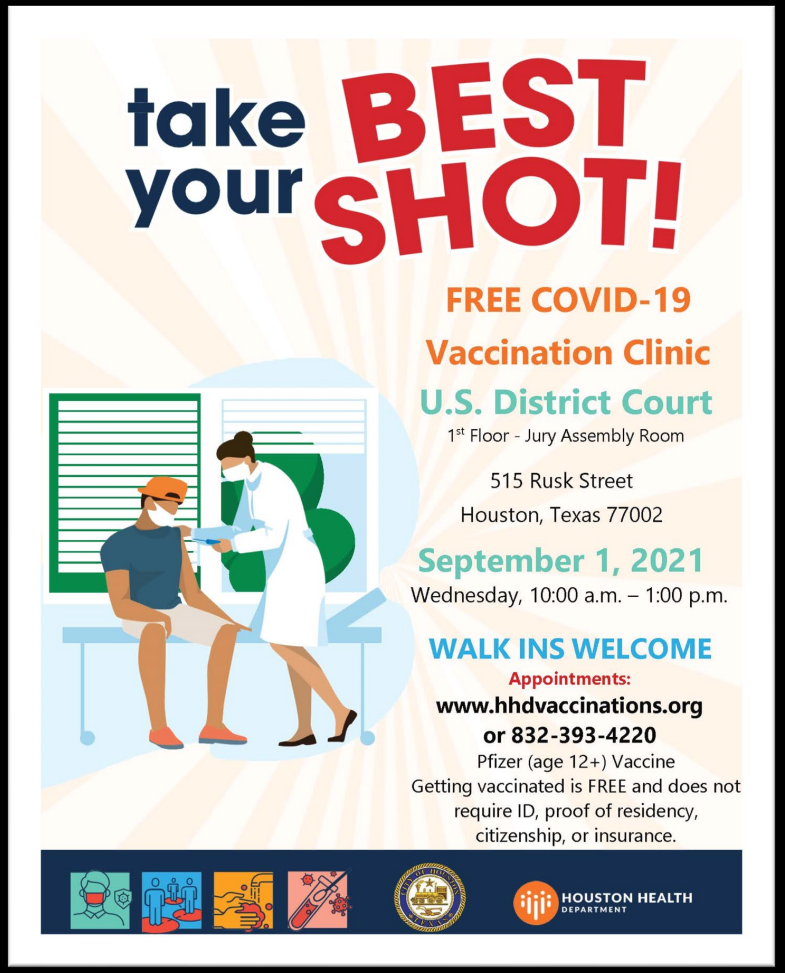
[redacted]
United States Probation Officer
515 Rusk Street, Suite 2301
Houston, TX 77002
[redacted]

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?