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Testimony before the Senate Committee on Human Services, Children and Families
State Senator André Jacque
January 21, 2021

Committee Members,

Thank you for the opportunity to testify before you as the author of Senate Bill 4.

Rep. Thiesfeldt and I have introduced this legislation to ensure Public Health Officers and the Wisconsin Department of Health Services (DHS) are not able to require vaccination or require a person to show proof of vaccination for COVID-19.

While Wisconsin citizens are rightly concerned about the lagging roll-out by DHS of COVID-19 vaccine availability in our state, there remains public apprehension about the COVID vaccines by the general public, particularly given that their approval was expedited at breakneck speed and not as robustly examined and tested for long-term effects. At this point in time, there is little to no information about the use of these vaccines in infants and children, or in pregnant or breastfeeding women. Vaccines can kill or make some people with auto-immune disorders, such as Guillain-Barre Syndrome, very sick. Forcing the vaccination of millions of young and healthy citizens who perceive themselves to be at an acceptably low risk from COVID-19 is ethically disputed.

We don't know how long immunity conferred by the vaccines lasts, none of the trials were designed to tell us if the vaccine prevents serious disease or virus transmission, and, we don't yet know if they have any adverse effects on various subpopulations. It is critical to protect individual freedom in medical decisions- government coercion in relation to a vaccine will do nothing to protect the public trust and assure citizens that their rights are being protected.

It is important to recall that through the inherent complexity and novelty of the virus, but also human error, the pandemic has created no shortage of uncertainty and misinformation, which has at times reflected poorly on government and cast doubt on both scientific and governmental authority. It should also be noted that mandatory vaccination does not automatically increase vaccine uptake. A European Union-funded project on epidemics and pandemics, which took place several years before COVID-19, found no evidence to support this notion. Looking at Baltic and Scandinavian countries, the project's report noted that countries "where a vaccination is mandatory do not usually reach better coverage than neighbour or similar countries where there is no legal obligation".

A successful roll-out of COVID-19 vaccines will require time, communication, and trust, not heavy-handed big government mandates.

Thank you for your consideration of Senate Bill 4.

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TESTIMONY IN SUPPORT OF SENATE BILL 4 & SENATE BILL 5
SENATE COMMITTEE ON HUMAN SERVICES, CHILDREN AND FAMILIES
THURSDAY, JANUARY 21, 2021
JULAINE K. APPLING, PRESIDENT

Thank you, Chairman Jacque and committee members, for the opportunity to testify on Senate Bills 4 and 5. Wisconsin Family Action supports these bills that address a critical issue in our state.

At the outset, I want to be perfectly clear that we take no position on whether or not an individual should take the COVID-19 vaccine or any other vaccine for that matter. We are not in any way dismissive of the virus. Like virtually everyone in our state, we have been affected by its reach in our own families and organization. We are not making any kind of judgment in this testimony as to the efficacy of or the necessity for the vaccine. That is not the point or purpose of these bills.

One issue we do have with any vaccine, including the COVID-19 vaccine, is whether or not the research and/or testing has involved the use of the cells or tissue or any body part of an aborted baby. And that reality does play into our position on these bills because people should be able to choose not to take a vaccine that in its development violates a person's core, deep-seated beliefs and convictions. That choice should be protected—and we believe it is—by the First Amendment of the US Constitution and by Article I, Section 18 of our Wisconsin Constitution, which gives unequivocal protection to the right of conscience:

> *Article I, Section 18, Wisconsin Constitution*
> *Freedom of worship; liberty of conscience; state religion; public funds. SECTION 18. [As amended Nov. 1982] The right of every person to worship Almighty God according to the dictates of conscience shall never be infringed; nor shall any person be compelled to attend, erect or support any place of worship, or to maintain any ministry, without consent;* ***nor shall any control of, or interference with, the rights of conscience be permitted,*** *or any preference be given by law to any religious establishments or modes of worship; nor shall any money be drawn from the treasury for the benefit of religious societies, or religious or theological seminaries. [1979 J.R. 36, 1981 J.R. 29, vote Nov. 1982] [emphasis added]*

We believe deciding to take a vaccine is a personal matter, even a matter of conscience. Individuals might also involve a doctor in their decision, but even that choice is up to the individual. No vaccine should ever be forced on people, not even during a declared "emergency." As you will hear today and as you know, vaccines are potent pharmaceuticals. Every vaccine has a risk-benefit associated with it, and people are entitled to determine for themselves whether they want to assume the risk for any benefit the vaccine may bring.

In a country where the rule of law is supposed to be at the heart of how we do government, we cannot set aside the Constitution, both the US Constitution and our state constitution, even during a health crisis. To the contrary, constitutions are meant to ensure protections even during the worst of times. Giving government officials at any level of government the authority to mandate a vaccine threatens the rights of individuals. These bills appropriately restrict that authority and ensure that the rule of law is respected.

When it comes to employers, we firmly believe employees do not forego their constitutional or legal rights when they sign on to work at a given company. Receiving a vaccine should not be a condition of employment.

Consider the precedent that would be set if this prohibition in Senate Bill 5 is not put in place. Right now, COVID-19 is the virus we are fighting. Tomorrow it could be something different for which scientists develop a vaccine. We could have situations where a person would need to get multiple vaccines just to have a job. To not prohibit this vaccine mandate would put us on the proverbial slippery slope—which seems to always take us further and take us faster than we ever imagined.

For those who would say that Wisconsin has three vaccine exemption options and that should be sufficient to cover the current vaccine situation, thereby making these bills unnecessary, I respond that we have learned over the last year that once a state or local official declares an "emergency," safeguards and options we thought were available can be quickly set aside, legal or not. We have no confidence that without these specific prohibitions for vaccine mandates that an employee claiming the personal conviction, religious or even medical exemption could be told that those are not applicable during a declared emergency. Likewise, for an individual citizen who decides to invoke one of these exemptions in general. Simply put, we need these specific safeguards.

Frankly, our only concern with these bills is that they are specific to the COVID-19 vaccine. We believe they should be more generally applicable so that we do not have to revisit this issue for any future health crisis we face in the state.

Individuals and families are being asked to deal with a great deal right now. They should not have to be concerned that they will be violating a law if they decide not to take the COVID-19 vaccine, and they should not have to be concerned that their employment would be in jeopardy should they decline the vaccine. Enacting Senate Bills 4 and 5 would ensure authority would not be abused, would uphold the rule of law, and would help families avoid additional stress. We urge this committee to pass these bills quickly and move them to the full Senate where we hope they will receive swift passage.

Thank you for your attention and thoughtful consideration of our position on these bills.

Wisconsin United for Freedom

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Oral Testimony for Tara Czachor of Wisconsin United For Freedom
Thursday, January 21, 2021: Senate Committee on Human Services, Children, and Families

Good afternoon! I just wanted to thank this committee, especially my own Senator André Jacque, for having a public hearing on these very important bills. On behalf of my family and the organization Wisconsin United For Freedom, of which I represent, and on behalf of thousands of Wisconsinites, I sincerely thank you.

Wisconsin United For Freedom is in strong support of **SB4, which would Prohibit Public Health Officers & DHS from mandating Covid-19 Vaccination.** It is very apparent to us, that Chapter 252 of Wisconsin's State Statutes are far too vague, and gives far too much power and control to unelected bureaucrats, of whom have no accountability in our state. Vague interpretation of the law is a huge issue.

It is also incredibly apparent from the multiple accounts from across this country, how truly dangerous vaccinations can be for some individuals, and how we must never rush the process of approving medical procedures that will be widely used by millions of individuals across our nation. History has taught us this very lesson with regards to the Swine Flu Vaccination catastrophe in 1976, of which it was found that there was an increased risk of Guillian-Barre syndrome (GBS) after vaccine administration.[1]

Not FDA Approved

Our organization also firmly supports SB5, Prohibiting Mandatory COVID-19 Vaccination for Employment.

Wisconsin citizens should never be forced into a medical procedure that carries very real risks, in order to maintain their employment and feed their families. Vaccinations, like any medical procedure, carry risks, and not only are the Covid-19 vaccinations only approved for Emergency Use, **currently, they are not FDA approved vaccines.** [2]

Public vaccine policies, that include mandates, constitute an assault on the rights of individuals to receive full and informed consent. Informed consent includes the right to decide what goes into our own bodies, and the right as a parent to choose what is injected into our children's bodies

I have provided you with a copy of the Fact Sheet given to Healthcare Providers administering the Pfizer Covid-19 Vaccine for your review. I have highlighted the section at the bottom of page 7, which states that those receiving the vaccine must receive additional information, including, 1) that the Pfizer vaccine is not FDA approved, 2) that the recipient or their caregiver has the option to accept or refuse the vaccine, 3) the significant known and potential risks and benefits of the vaccine, 4) Information about available alternative vaccines and the risks and

benefits of those alternatives.

This issue of mandatory vaccination for employment is incredibly pertinent, considering the recent Milwaukee Journal Sentinel report of Rock Haven, a Rock County-owned Janesville nursing home, laying off their staff for refusing the Covid-19 vaccine. The article states that a memo to employees informed them that the covid-19 vaccine was "a requirement for all staff" and that employees who failed to get the vaccine would be laid off. They also stated that a laid off employee would not be eligible to return to work until they received 2 doses of the vaccine.

According to the article,

> *Michelle Lynch, a secretary at Rock Haven, said employees should not be forced to get the vaccine.*
>
> *"We have staff that are having side-effects from it, and they're being told, 'Too bad,' " she said.*
>
> *In letters to Rock County supervisors, two employees said they suffered high fevers and other side-effects from getting the vaccine on Jan. 5, the first day the nursing home conducted vaccinations. One of them wrote that the side-effects were so bad she had to go to the doctor and was advised not to get the second shot of the vaccine."*[3]

Prior Felony and Criminal Negligence

Aside from the issue of informed consent and bodily autonomy, individuals may also have other rational and valid arguments for rejecting this new emergency use Covid-19 vaccination. Some individuals, may look at Pfizers track record for example, and decide that in their opinion, they are not a trustworthy company, and they do not wish to receive the products they are offering, or they may not wish to receive the first market product from Moderna. [4]

For example, according to the Department of Justice in 2009, [5]

> *"Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products."*

I could go on and on in detail about the wrong doings Pfizer admitted to, but the point of this is that Pfizer has been caught red handed before, and will be caught again. If this same situation were to happen with the Covid-19 vaccine from Pfizer, there would be no lawsuits, no court proceedings, no discovery phases, because the Covid-19 vaccine manufacturers are exempt from liability. A federal law establishes that the only option for compensation for COVID-19 vaccine victims is the Countermeasures Injury Compensation Program (CICP).[6] Only eight percent of all petitioners since 2010 have been awarded compensation through the CICP. No legal or medical expert fees are covered, no pain and suffering is awarded, lost wages are capped at $50,000, and there is no judicial appeal. Vaccination must be voluntary.

Safety Concerns

With mass vaccination of the Covid-19 vaccines starting a few weeks ago, there have been multiple safety issues that have come to light within the first few weeks. Within our own state of Wisconsin, according to MedAlerts, an interface built from the governments raw data from the VAERS search engine, CDC Wonder, there have been 89-vaccine injury reports since Covid-19 vaccinations in Wisconsin have been administered, including 2 deaths.[7] While a report to VAERS does not mean that the vaccine was responsible for the death, it also does not rule out an association. If Public Health officials seem to report on every Covid-19 death, one has to ask oneself why they are not reporting on deaths following vaccine administration.

One specific vaccine injury in Wisconsin stood out to me, of a 22-year-old male who received the vaccine on December 17, and just four days later, he was admitted to the hospital. The write up for his vaccine injury report states: *"Patient received Pfizer COVID 19 vaccine last Thursday 12/17. Admitted today (12/21) with bleeding and low platelet count - working up for* ITP (a disorder that can lead to easy or excessive bruising and bleeding[8]) *and TTP* (which is another blood disorder[9]). *Given recency of vaccination and no known contributory allergy or medical history, physician thought potentially associated with vaccination."*[10]

It is entirely possible that serious reactions occurring after Covid-19 vaccine administration are significantly higher given that historically, vaccine reactions are rarely reported. A 2011 report by Harvard Pilgrim Health Care, Inc. for the U.S. Department of Health and Human Services (HHS) stated **that fewer than one percent of all vaccine adverse events are reported to the government.** This report states the following -

> *"Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."*[11]

Given that both the Pfizer and Moderna vaccinations have just been released, it is entirely possible that the risks associated with these particular vaccines might outweigh the benefit. Theses vaccines *must not be mandated.* Health care providers and public health officials *must* ensure that the public is aware of the risks of this vaccine, provide informed consent, and allow individuals the right to decide to choose which medical procedures are right for them, if any.

It is not right of the state to use its power to compel or mandate the use of liability free pharmaceutical products. Medical procedures, that carry very real risks, should always be voluntary, and citizens in our state should not face the threat of losing their financial security over making an informed medical decision. Our organization supports individual choices, and if someone feels that receiving the Covid-19 vaccine is in their best interest, we fully support, and even advocate, for their right to do so, however, **we take a firm and unwavering stance against mandatory vaccinations**.

I also wanted to mention our support for **SB7, which would prohibit local health officers from closing or forbidding gatherings in places of worship to control outbreaks and epidemics of the 2019 novel coronavirus.** Our organization stands for constitutional freedoms, and the right to worship is certainly included.

Thank you very much, for your time, for your service to this great state, and for preserving the freedoms our founding fathers have bestowed upon us. As a mother of 4, as a wife, and speaking on behalf of over 10,000 Wisconsinites who are a part of our organization, I very strongly encourage you all to vote yes on these bills. I also encourage you all to work together with the Wisconsin Assembly to pass good legislation, even if that means adding these same standalone provisions back into the Assembly Bill 1 and placing it onto the Governor's desk. Thank you!

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[3] Wisconsin nursing home staff laid off for refusing COVID-19 vaccine

[4] Moderna nears its first-ever FDA authorization, for its COVID-19 vaccine

[5] JUSTICE DEPARTMENT ANNOUNCES LARGEST HEALTH CARE FRAUD SETTLEMENT IN ITS HISTORY (Sept. 2, 2009)

[6] Countermeasures Injury Compensation Program (CICP)

[7] Vaccine Adverse Events Reporting System (VAERS) accessed with Medalerts - Vaccine Reactions Reported to VAERS from December 2020-January 7, 2021 (Accessed 1/20/21)

[8] Definition of Thrombocytopenic purpura - ITP

[9] Definition of Thrombotic thrombocytopenic purpura - TTP

[10] Vaccine Adverse Events Reporting System (VAERS) accessed with Medalerts – VAERS ID Number 905345 (Accessed 1/20/21)

[11] AHRQ Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS) Dec 1, 2007-Sep. 30, 2010

DAYSPRING
BAPTIST CHURCH AND SCHOOLS

Thursday, January 21, 2021

Dear Committee Members,

I appreciate all of you working so hard on behalf of the citizens of our state. Thank you for taking the time to read this. I'm writing to encourage you on the importance of SB 4,5,6, & 7.

We are a Church with a Preschool and K-12 School. We are located on 36 acres in Town of Delafield. If you drive to Milwaukee, you see our campus on the south side of I-94 as you enter into Waukesha.

I'm sure you understand why SB7 is extremely important to all churches in Wisconsin. A "Church" is a "Called out Assembly", meaning in order for us to be the "Church", we must "assemble" in person. Online meetings may work for a short time, but failure to consistently assemble is a failure of the "Church" to do its work. Assembling together is a main tenant of our faith. To not assemble goes against the will and desire of our Lord as taught in the Bible.

We believe the Church is essential, and no government agency has the unlimited power to force churches to close indefinitely. As we all know so well: "Congress shall make no law respecting an establishment of religion or prohibiting the exercise thereof."

In my experience this past year, ALL the churches in our area DID want to cooperate with the government in mitigating the spread of Covid. I do not know of a single church in our area that was disrespectful or flippant about following the guidelines setup by our government. We have followed all the rules and went to extreme lengths and great expense to adhere to CDC guidelines to protect our students and members. The Church desires to work alongside of and peacefully with our government.

Covid lockdowns have led to an alarming rise in overdose and suicides in our state. One of the main outreach programs that our church offers is an "Addiction Recovery Program". This program meets in person on Fridays where we work with "Functioning Addicts" in our area. Hundreds of people have come to our meetings. Many people have found freedom and recovery. I'm proud that our community calls DaySpring the "Church of the Former Addict". This year, due to Covid and the "Stay Home" orders, we have seen a spike in our addiction recovery students "falling off the wagon" and getting deeper into their addiction. This year alone, we have had 3 students die of overdose and suicide. In comparison, we haven't had an overdose or suicide death among our students for the past 4 years. Assembling together in person is essential to people that struggle with mental health and addictive tendencies.

Thank you again for your service to our great state.

Daniel Reehoff

Founder & Lead Pastor

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Testimony in Support of Senate Bill 4: prohibiting DHS and local health officers from mandating vaccination against the 2019 novel coronavirus

Testimony in Support of Senate Bill 5: prohibiting employers from mandating vaccination against the 2019 novel coronavirus

Senate Committee on Human Services, Children and Families
By Matt Sande, Director of Legislation

January 21, 2021

Good afternoon Chairman Jacque and Committee members. My name is Matt Sande and I serve as director of legislation for Pro-Life Wisconsin (PLW). Thank you for this opportunity to express our support for Senate Bill (SB) 4, legislation prohibiting the state Department of Health Services (DHS) and local public health officers from requiring individuals to receive vaccination against the 2019 novel coronavirus, and our support for Senate Bill (SB) 5, legislation prohibiting employers from requiring employees or prospective employees to receive vaccination against the 2019 novel coronavirus, or show proof of having received such vaccination as a condition of an offer of employment or continued employment.

As Operation Warp Speed races forward in the production and deployment of safe and effective vaccines for the novel coronavirus, it is imperative that we lay down firm ethical parameters around this effort. On October 13, 2020, the national Personhood Alliance (PA) published its official position on vaccine ethics, the culmination of two months of work by PA affiliate representatives from eight states, both Catholic and evangelical, and independent physician reviewers including Alan B. Moy, MD, President and Scientific Director of the John Paul II Medical Research Institute in Iowa.

As a founding board member of the Personhood Alliance, I participated in crafting the position throughout August and September as a working member of the PA Vaccine Ethics Committee. Our position was formally approved by the PA Board of Directors and subsequently by the PLW Board of Directors.

The Personhood Alliance vaccine ethics position **1) opposes**, and deems morally unacceptable, the production and testing of vaccines using the remains of aborted human beings, and **2) affirms** the rights of all people to refuse medical treatment and to reject violations of their and their family members' bodily integrity, moral conscience, and Constitutional protections through forced or coerced vaccines.

(OVER)

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Senate Bill(s) 4 and 5 specifically reinforce our second position opposing coerced vaccination. Whether or not a vaccine is ethically produced and tested, it is unethical, and highly offensive, for the state, an employer, or anyone to force it on an individual who may strongly resist it for a variety of health, conscience, religious or personal reasons. It is a direct, physical assault on that person's bodily integrity. Such an assault can leave a deep emotional and psychological impact, inducing intense fear, distrust, and anger. For the many Wisconsinites who earnestly avoid any entanglement in the abortion industry, forcing them to receive a vaccine produced from or tested on an aborted baby is *especially* repugnant – a total violation of conscience.

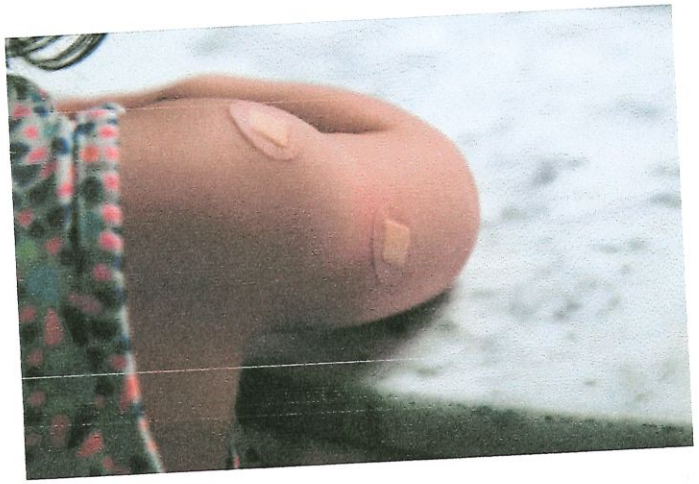
The recent Pfizer/BioNTech and Moderna Covid-19 vaccine development and deployment are a case in point. While both are ethically derived/produced, both are being unethically tested using HEK293 aborted fetal cells harvested from the kidney of a preborn baby aborted in the Netherlands in 1973. One can see this clearly, under the "Confirmatory Lab Tests" column, on the Charlotte Lozier Institute website at https://lozierinstitute.org/update-covid-19-vaccine-candidates-and-abortion-derived-cell-lines/ The PA/PLW standard is high, eschewing both unethical *production* and *testing*, because if we continue to allow the use of aborted human beings in therapeutic development, *in any manner*, legal abortion will continue unabated. Accordingly, many pro-life Wisconsinites reject use of the Pfizer and Moderna vaccines and would vehemently oppose any state or employer mandate of their use.

Persuasion is the way vaccine campaigns must be conducted, especially in America where our civil liberties are sacrosanct...where personal autonomy and medical informed consent are bedrock principles. Coercion tramples on our cherished rights and severely undermines the public trust in our medical and public health authorities.

Thank you for your consideration, and I am happy to answer any questions committee members may have for me.

VACCINE ETHICS

The Personhood Alliance's official position on vaccine ethics



The most current information on unethical and ethical COVID-19 vaccine candidates can be found here.

The Personhood Alliance's official position on vaccine ethics is a culmination of 2 months of committee work, which included affiliate representatives from eight states, both Catholic and evangelical, and independent physician reviewers. The committee's recommendation was unanimously approved by the Personhood Alliance's national board of directors.

To read and share our press release, click here. For questions or clarification, please contact us at info@personhood.org.

10 foundational tenets

WHEREAS:

1. Many vaccines are still produced and/or tested[1] using human diploid cell cultures originally harvested from aborted human beings (hereby referenced as

unethical vaccines),[2] [3] [4] which in turn, has had an impact on families' access to common, ethically produced vaccines at present; Researchers have developed several new fetal cell lines from aborted human beings to supplement or replace the original fetal cell lines.[5] [6] [7] [8]

2. Remnants of the DNA of aborted human beings are present in unethical vaccines[9] and researchers are currently studying the level of risk to patients receiving these vaccines and the manufacturing protocols necessary to reduce this risk,[10] with guidance from the FDA.[11]
3. Some pharmaceutical companies are moving away from unethical production and testing of vaccines because of public pressure,[12] but more must be done to produce ethical vaccines–that is, derived from animal, plant, synthetic, or human cells from consenting adults–and demand ethical alternatives of more companies, particularly when taxpayer funding is involved.[13]
4. Interdenominational church positions on the use of unethical vaccines may differ,[14] [15] [16] [17] [18] [19] but our common goal of ethical production and testing of vaccines remains. The Personhood Alliance seeks to find unity among various positions, where biblical personhood and the Word of God can be our foundation and where the rights of persons remain intact–the rights of born persons not to be forced to violate their own bodily integrity and/or moral conscience and the rights of pre-born persons not to be trafficked, commodified, and/or experimented upon without their consent.
5. There are religious arguments that permit and sometimes encourage participation in vaccinations that use the originally aborted fetal cell lines; These arguments include, but are not limited to, the amount of time that has passed since the original abortions and the intent of the original abortions not being for vaccine production.[20] [21] We find these arguments to be in error. Christians must demand an end to the trafficking and commodification of human beings at all stages of life and must not participate or accept practices that perpetuate and encourage the relationship between abortion, biomedical science, and human trafficking, no matter when that connection was initiated or how long a practice has been socially accepted.
6. The production and testing of vaccines using the remains of aborted human beings, regardless of manner of conception and without their consent, is morally unacceptable and must be opposed. The Personhood Alliance strongly urges the rejection of such vaccines.
7. The right of bodily integrity and the right to refuse medical treatments for moral, religious, health, or other reasons,[22] must remain intact and protected by law when an individual considers whether to vaccinate or not. Bodily integrity emphasizes the importance of self-ownership and self-determination of human beings over their own physical bodies. The Personhood Alliance regards the violation of bodily integrity as unethical and intrusive.
8. Humans are made in the image and likeness of Almighty God (Genesis 1:26-27); We have a duty to honor and care for the body God has given us as a temple of the Holy Spirit (Romans 12:1, 1 Corinthians 3:16, 1 Corinthians 6:20, 1 Corinthians 10:31) and therefore, to force or coerce a person to administer a substance into their body against their will is a violation of their biblical personhood. Such mandates and coercions are also a violation of the dignity of the human person, because freedom of religion and freedom of conscience are fundamental to human dignity.[23]
9. Parental decisions regarding vaccinations of children must be determined by the family and not by the State, according to biblical mandate (Romans 13:1-7) and legal precedent;[24] [25] the family and the Church are legitimate authorities distinct from the civil magistrate and as such, the Personhood Alliance rejects the subordination of the family and Church to the State in these matters.
10. Threats to religious freedom, as well as compelled speech,[26] [27] in relation to forced or coerced vaccinations,[28] [29] are already a reality in several states.[30] [31] [32] [33] [34] [35] [36] The Personhood Alliance is seeing increasing trends toward mandated vaccines with little to no exemptions for moral or religious objection. We stand against these Constitutional violations. The Christian conscience, bodily integrity, and the personhood of the human being must be protected.

On the basis of these 10 points, BE IT RESOLVED that:

The production of a vaccine or any medical therapy derived from the remains of a human being intentionally killed is wholly unethical and should be made unlawful. The Personhood Alliance affirms the inalienable right to life of pre-born human beings, regardless of the manner of conception, and thus, their right not to be trafficked, commodified, and/or experimented upon. The Personhood Alliance also affirms the rights of all people to refuse medical treatment and to reject violations of their and their family members' bodily integrity, moral conscience, and Constitutional protections through forced or coerced vaccines.

Be it FURTHER RESOLVED that:

The Personhood Alliance affirms that, while the family, the Church, and the State have distinct spheres of authority, the State is subordinate to the family and the Church in matters of vaccination. Therefore, we acknowledge that Christians of all stations have a duty to reject unethical vaccines, to inform others of the connection between abortion, human trafficking, and biomedical science, and to publicly demand that ethical alternatives be produced, tested, and brought to market by pharmaceutical companies and public health officials.

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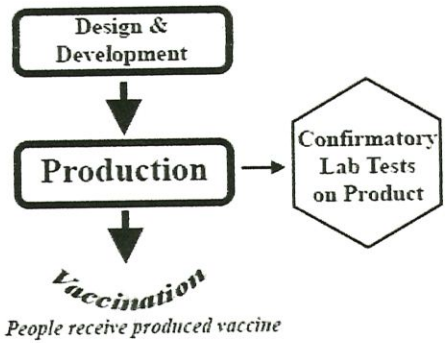
Update: COVID-19 Vaccine Candidates and Abortion-Derived Cell Lines

Accurate information about the development and production of COVID-19 vaccines is essential, especially because many proposed candidates use newer molecular technologies for production of a viral vaccine. One concern regarding the ethical assessment of viral vaccine candidates is the potential use of abortion-derived cell lines in the development, production or testing of a vaccine. This analysis utilizes data from the primary scientific literature when available, along with data from clinical trial documents, reputable vaccine tracking websites, and published commercial information.[1] It is the hope that by providing accurate data, recipients can make well-informed decisions regarding vaccine choices.

For additional background and guidance, please see:
* A Visual Aid to Viral Infection and Vaccine Production for a visual primer on the various strategies for viral vaccine production.
* COVID-19 Vaccines & Fetal Cell Lines for an infographic description of how fetal cell lines are sometimes used to produce vaccines.
* Chart of Operation Warp Speed Vaccines streamlined view of the leading vaccine candidates.



Flow Chart for Creation and Testing of Vaccines
Design & Development: conceptualization, preparatory experiments, and specification for how vaccine will be constructed and produced.
Production: process used to manufacture final vaccine to be given to people.
Confirmatory Lab Tests on Product: tests to analyze quality, nucleic acid or protein sequence, protein confirmation, antibody reactivity, etc. of final vaccine product.
Vaccination: giving final produced vaccine to people.

Analysis of SARS-CoV-2 (COVID-19) Vaccine Candidates

Last Updated 4 January 2021

DOES NOT USE abortion-derived cell line
DOES USE abortion-derived cell line
SOME tests DO NOT use abortion-derived cells, SOME DO.
Currently undetermined

Sponsor(s)[1]	Country	Strategy[2]	Clinical Trial Status[3]	Public Funding[4]	Design & Development	Production	Confirm-atory Lab Tests
WHOLE VIRUS VACCINE – LIVE ATTENUATED or INACTIVATED							
Beijing Institute of Biological Products/ Sinopharm	China	Inactivated virus "BBIBP-CorV" Given: Intramuscular	Phase 3		Vero monkey cells	Vero monkey cells	Cytopathic test

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		2 doses (2 weeks apart)	*Early approval in China* **Phase 3** **Phase 1/2**		Wang *et al., Cell* 182, P713, 6Aug2020	Wang *et al., Cell* 182, P713, 6Aug2020	Vero monkey cells Wang *et al., Cell* 182, P713, 6Aug2020
Wuhan Institute of Biological Products/ Sinopharm	China	Inactivated virus "New Crown COVID-19" Given: Intramuscular 2 doses (2 weeks apart)	**Phase 3** *Early approval in China* **Phase 1/2**		Vero monkey cells Xia *et al., JAMA* 324, 951, 13Aug2020	Vero monkey cells Xia *et al., JAMA* 324, 951, 13Aug2020	Plaque reduction neutralization test Vero monkey cells Xia *et al., JAMA* 324, 951, 13Aug2020
Bharat Biotech/Indian Council of Medical Research	India	Inactivated virus "COVAXIN" "BBV152" Given: Intramuscular 2 doses (2 weeks apart)	*India EUA granted* **Phase 3** **Phase 1/2** **Phase 1/2** **Phase 1/2**		Vero monkey cells Yadav *et al., ResearchSquare 10Sept2020*	Vero monkey cells Yadav *et al., ResearchSquare 10Sept2020*	Antibody ELISA Plaque reduction Vero monkey cells Yadav *et al., ResearchSquare 10Sept2020*
John Paul II Medical Research Institute	USA	Live attenuated virus	Pre-clinical		Ethical cell lines as a matter of policy	Perinatal human cells (term umbilical cord and placental)	?
Sinovac Biotech Co., Ltd.	China	Inactivated virus "PiCoVacc" Given: Intramuscular 2 doses (2 weeks apart)	**Phase 3** *Early approval in China* **Phase 3** **Phase 1/2** **Phase 1/2** **Phase 1/2**		Vero monkey cells	Vero monkey cells Gao *et al., Science* 369, 77, 3July2020	protein test HEK293 cells Supplement Gao *et al., Science* 369, 77, 3July2020
Valneva and Dynavax	France USA UK	Inactivated Virus "VLA2001" plus adjuvant CpG1018 Given: Intramuscular	Pre-clinical		Vero monkey cells	Vero monkey cells Same platform as IXIARO, Valneva press release, 22April2020	?

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VIRAL VECTOR-BASED VACCINE							
Altimmune	USA	Replication-deficient Adenovirus vector "AdCOVID" Given: Intranasal	Pre-clinical		PER.C6 cells	PER.C6 cells Same platform as NasoVAX NasoVAX uses PER.C6 Licensed PER.C6 from Janssen	
AstraZeneca University of Oxford	USA UK	Replication-deficient Adenovirus vector "AZD1222" "ChAdOX1nCoV-19" Given: Intramuscular 2 doses (4 weeks apart)	***UK EUA granted*** *India EUA granted* **Phase 3** **Phase 3** **Phase 3** **Phase 2/3** **Phase 2/3** **Phase 1/2** **Phase 1/2**	*Operation Warp Speed* HHS-BARDA $1.2 Billion CEPI up to $384 Million	HEK293 cells	HEK293 cells van Doremalen *et al., Nature* preprint, 30July2020	
CanSino Biologics, Inc. Beijing Institute of Biotechnology, Academy of Military Medical Sciences, PLA of China	China	Replication-deficient Adenovirus vector "Ad5-nCoV" Given: Intramuscular 1 dose	**Phase 3** **Phase 3** **Phase 2** **Phase 2** **Phase 2** **Phase 1** **Phase 1**		HEK293 cells	HEK293 cells Biospace, 12May2020	
Gamaleya Research Institute	Russia	Replication-deficient Adenovirus vectors (rAd26-S+rAd5-S) "Sputnik V" Given: Intramuscular 2 doses (3 weeks apart)	**Phase 3** *Early approval in Russia August 2020* **Phase 1/2** **Phase 1/2**		HEK293 cells	HEK293 cells	
ImmunityBio and NantKwest	USA	Replication-deficient Adenovirus vector recombinant "hAd5 S-Fusion + N-ETSD" Given: Subcutaneous	**Phase 1**		E.C7 cells (derivative of HEK293 cells) Rice *et al., bioRxiv* 30July2020	E.C7 cells (derivative of HEK293 cells) Rice *et al., bioRxiv* 30July2020	Protein and antibody tests HEK293T cells

							Rice *et al.*, *bioRxiv* 30July2020 Seiling *et al.*, *medRxiv* 6Nov2020
Institut Pasteur and Themis and Merck	USA France	Replication-competent recombinant measles virus "V591" (formerly "TMV-083") Given: Intramuscular 1 or 2 doses (4 weeks apart)	**Phase 1/2** **Phase 1**	CEPI up to $4.9 Million	HEK293T Development and rescue of recombinant measles virus Hörner *et al., PNAS* 22Dec2020 Hörner *et al.* Supplement "SARS-CoV-2 S-encoding vaccine candidates… were generated as described previously"	Vero monkey cells Hörner *et al., PNAS* 22Dec2020 Hörner *et al.* Supplement	Lentiviral vectors for antigenic DC Fusogenic test HEK293T Fusogenic test S protein expression Vero monkey cells Hörner *et al., PNAS* 22Dec2020 Hörner *et al.* Supplement
Israel Institute for Biological Research (IIBR)	Israel	Replication-competent recombinant vesicular stomatitis virus (VSVΔG) "IIBR-100" Given: Intramuscular 1 dose	**Phase 1**		BHK hamster cells Vero monkey cells Yahalom-Ronen *et al., bioRxiv* 19June2020	Vero monkey cells Yahalom-Ronen *et al., bioRxiv* 19June2020	Plaque reduction; immunofluorescence Vero monkey cells Yahalom-Ronen *et al., bioRxiv* 19June2020
Janssen Research & Development, Inc. Johnson & Johnson	USA	Replication-deficient Adenovirus vector "Ad26.COV2-S" Given: Intramuscular 1 or 2 doses (8 weeks apart)	**Phase 3** **Phase 3** **Phase 1/2**	*Operation Warp Speed* HHS-BARDA $1,457,887,081 total	PER.C6 cells	PER.C6 cells Tostanoski *et al., Nature Medicine,* 3Sept2020; Mercado *et al., Nature* 30July2020 J&J, 30March2020; Janssen Vaccine Technologies	
Merck and IAVI	USA	Replication-competent recombinant vesicular stomatitis virus (VSVΔG) "V590" Given: Intramuscular	**Phase 1**	*Operation Warp Speed* HHS-BARDA $38,033,570	Vero monkey cells	Vero monkey cells Use rVSV Ervebo platform	?

						Ervebo uses Vero cell culture-11 Description	
Shenzhen Geno-immune Medical Institute	China	Lentivirus minigenes + Adult human APC (antigen-presenting cells)	Phase 1		?		?
Shenzhen Geno-immune Medical Institute	China	Lentivirus minigenes + Adult human CD/T cells (dendritic cells and T cells) "LV-SMENP-DC"	Phase 1/2		?		?
Vaxart	USA	Replication-deficient Adenovirus vector "VXA-CoV2-1" plus dsRNA adjuvant Given: Oral	Phase 1		HEK293 cells	HEK293 cells Moore *et al., bioRxiv 6Sept2020*	
PROTEIN-BASED VACCINE							
Anhui Zhifei Longcom Biopharmaceutical/Institute of Microbiology, Chinese Academy of Sciences	China	Protein vaccine Recombinant RBD dimer plus adjuvant Given: Intramuscular 2 or 3 doses (30 days apart)	Phase 3 Phase 2 Phase 1/2 Phase 1		HEK293T cells Dai *et al., Cell* 6Aug2020	CHO hamster cells Dai *et al., Cell* 6Aug2020	Pseudovirus HEK293T cells Dai *et al., Cell* 6Aug2020
Clover Biopharmaceuticals, Inc.	China	Protein vaccine "SCB-2019" plus adjuvant CpG 1018 Given: Intramuscular	Phase 1	CEPI up to $69.5 Million	cDNA in expression vector; transfect CHO hamster cells Liang *et al., bioRxiv*, 24Sept2020 Trimer-Tag system; Liu *et al., Scientific Reports* 2017	CHO hamster cells Liang *et al., bioRxiv*, 24Sept2020	Pseudovirus HEK293 cells Ref'd: Nie *et al., Emerging Microbes & Infections* 24Mar2020 Cytopathic effect Vero monkey cells Liang *et al., bioRxiv*, 24Sept2020
Federal Budgetary Research Institution State Research Center of Virology and Biotechnology "Vektor"	Russia	Protein vaccine "EpiVacCorona" chemically synthesized peptide antigens of	*Early approval in Russia Oct 2020*		?	chemically synthesized peptide antigens	?

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		SARS-CoV-2, conjugated to a carrier protein adsorbed on an aluminum-containing adjuvant Given: Intramuscular 2 doses (3 weeks apart)	Phase 1 Phase 1				
John Paul II Medical Research Institute	USA	Recombinant Protein Perinatal human cells (term umbilical cord and placental)	Pre-clinical		Ethical cell lines as a matter of policy	Perinatal human cells (term umbilical cord and placental)	?
Kentucky BioProcessing, Inc. (British American Tobacco)	USA	Protein vaccine "KBP-201" Plant-expressed RBD Given: Intramuscular 2 doses (3 weeks apart)	Phase 1/2		Recombinant DNA sequence for RBD of SARS-CoV-2	Plant expression of RBD peptide	?
Medicago	Canada	Protein on Virus-Like Particle "CoVLP" Plant-expressed spike protein particle with adjuvant, CpG1018 or AS03 Given: Intramuscular 2 doses (3 weeks apart)	Phase 2/3 Phase 2 Phase 1		Recombinant DNA sequence in *Agrobacterium*, transformation of plant cells	Plant expression of protein and VLP Ward *et al., medRxiv* 6Nov2020	Pseudovirus HEK293 cells Ward *et al., medRxiv* 6Nov2020
Novavax	USA	Protein vaccine "NVX-CoV2373" Baculovirus expression plus Matrix M adjuvant Given: Intramuscular 2 doses (3 weeks apart)	Phase 3 Phase 3 Phase 2 Phase 1	*Operation Warp Speed* HHS-BARDA $1,600,434,523 CEPI up to $388 Million		Sf9 insect cells Bangaru *et al., bioRxiv* preprint, 6Aug2020; Graphical view	Pseudovirus HEK293 cells Bangaru *et al., bioRxiv* preprint, 6Aug2020
Sanofi and GSK Protein Sciences	USA France	Protein vaccine Baculovirus expression plus AS03 adjuvant Given: Intramuscular 2 doses (3 weeks apart)	Phase 1/2	*Operation Warp Speed* HHS-BARDA $2,072,775,336 total		Sf9 insect cells Baculovirus expressed recombinant protein ;	?
Sorrento	USA	Protein vaccine	Pre-clinical				

		"T-VIVA-19" SARS-Cov-2 spike protein S1 domain fused with human IgG-Fc Given: Intramuscular			DNA fragment developed in lab Herrmann *et al.*, *bioRxiv* preprint, 30June2020	CHO cells Herrmann *et al.*, *bioRxiv* preprint, 30June2020	Antibody ELISA; Neutralization assays Vero monkey cells Herrmann *et al.*, *bioRxiv* preprint, 30June2020
Sorrento	USA	Protein vaccine "STI-6991" SARS-Cov-2 spike protein expressed on K562 cells	Pre-clinical		?	K562 cells Concept: Ji *et al.*, *Medicine in Drug Discovery* March2020	?
University of Pittsburgh	USA	Protein vaccine Adenovirus-expressed recombinant proteins "PittCoVacc" Given: Microneedle arrays	Pre-clinical		HEK293 cells	HEK293 cells Kim *et al.*, *EBioMedicine* , 2April2020	
University of Queensland and CSL Ltd.	Australia	Protein vaccine "V451" Recombinant protein with proprietary molecular clamp Given: Intramuscular	**HALTED** **Phase 1** **Phase 1** **Phase 1**	CEPI up to $4.5 Million		expiCHO hamster cells	?
RNA VACCINE							
Arcturus Therapeutics	USA	mRNA vaccine self-transcribing, replicating "LUNAR-CoV19" ("ARCT-021") *in vitro* transcription reaction with T7 RNA polymerase from STARR plasmid template LUNAR proprietary lipid nanoparticle encapsulated Given: Intramuscular 1 dose	**Phase 2** **Phase 1/2**		Sequence designed on computer	No cells used de Alwis *et al.*, *bioRxiv* 3Sept2020	protein test HEK293 de Alwis *et al.*, *bioRxiv* 3Sept2020

CureVac	Germany	mRNA vaccine non-replicating "CVnCoV" *in vitro* transcription lipid nanoparticle encapsulated Given: Intramuscular 2 doses (4 weeks apart)	**Phase 2/3** **Phase 2** **Phase 1**	CEPI up to $15.3 Million	Sequence designed on computer	No cells used Rauch *et al., bioRxiv* 23Oct2020	Protein test Reticulocyte lysate, HeLa cells Rauch *et al., bioRxiv* 23Oct2020
Moderna, Inc. with National Institutes of Health	USA	mRNA vaccine non-replicating "mRNA-1273" T7 RNA polymerase-mediated transcription from DNA plasmid template LNP (lipid nanoparticle) encapsulated Given: Intramuscular 2 doses (4 weeks apart)	***FDA Emergency Use Authorization Approved*** **Phase 3** **Phase 2** **Phase 1**	*Operation Warp Speed* HHS-BARDA $2,479,894,979 total CEPI up to $1 Million	Sequence designed on computer	No cells used Corbett *et al., Nature* , 5Aug2020	protein test & pseudovirus HEK293 cells Corbett *et al., Nature* , 5Aug2020
Pfizer and BioNTech	USA Germany	mRNA vaccine non-replicating "BNT-162a1,b1,b2,b3,c2" nucleoside-modified mRNA *in vitro* transcribed by T7 polymerase from a plasmid DNA template LNP (lipid nanoparticle) encapsulated Given: Intramuscular 2 doses (3 weeks apart)	***FDA Emergency Use Authorization Approved*** *UK EUA granted* **Phase 2/3** **Phase 1/2** **Phase 1/2** **Phase 1** **Phase 1**	*Operation Warp Speed* HHS-BARDA $1.95 Billion	Sequence designed on computer	No cells used Vogel *et al., bioRxiv* 8Sept2020	protein test & pseudovirus HEK293 cells Vogel *et al., bioRxiv* 8Sept2020
Sanofi Pasteur and Translate Bio	USA France	mRNA vaccine non-replicating "MRT5500" synthesized by in vitro transcription employing RNA polymerase with a plasmid DNA template	Pre-clinical		Sequence designed on computer	No cells used Kalnin *et al., bioRxiv* 14Oct2020 mRNA production in the lab ; Translate Bio scientific platform	protein test & pseudovirus HEK293 cells Kalnin *et al., bioRxiv* 14Oct2020

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		LNP (lipid nanoparticle) encapsulated Given: Intramuscular					
DNA VACCINE							
Genexine	Korea	DNA vaccine "GX-19" DNA synthesized in vitro, placed in plasmid vector Given: Intramuscular and Electroporation 2 doses (4 weeks apart)	**Phase 1/2**		Sequence designed on computer	No cells used Seo *et al., bioRxiv 10Oct2020*	?
Inovio Pharmaceuticals	USA	DNA vaccine "INO-4800" DNA synthesized in vitro, placed in plasmid vector Given: Intradermal Electroporation 2 doses (4 weeks apart)	**Phase 2/3** **Phase 1/2** **Phase 1**	*Operation Warp Speed* CEPI up to $22.5 Million	Sequence designed on computer	No cells used Smith *et al., Nature* 20May2020	protein test & pseudovirus HEK293 cells Smith *et al., Nature* 20May2020
Symvivo Corporation	Canada	DNA vaccine Genetically engineered *Bifidobacterium longum* "bacTRL-spike" Given: Oral, bacteria bind to gut lining 1 dose	**Phase 1**		?	No cells used	?

1. Data accumulated from primary literature as referenced in the Chart; AND "COVID-19 Treatment and Vaccine Tracker," Milken Institute, https://covid-19tracker.milkeninstitute.org/ ; AND "Draft landscape of COVID-19 candidate vaccines," World Health Organization (WHO), https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines
NOTE that patents are not considered because they are unreliable sources; even the most relevant patents are prospective documents that provide examples of potential use, but do not provide information about actual, current application of an invention or technology.
2. Prentice, DA and Sander Lee, T. June 15, 2020. A Visual Aid to Viral Infection and Vaccine Production. *On Science Series 1. Accessed 19 June 2020* at: https://lozierinstitute.org/a-visual-aid-to-viral-infection-and-vaccine-production/
3. Phases of Clinical Trials: Pre-clinical- laboratory and animal studies; Phase I- 10-100 people, study safety and dosage; Phase II- tens to hundreds of people, study efficacy, dosage, side effects; Phase III- hundreds to thousands of people, study efficacy and adverse reactions.
4. HHS-BARDA = U.S. Health and Human Services-Biomedical Advanced Research and Development Authority; CEPI = Coalition of Epidemic Preparedness Innovations; BARDA's rapidly-expanding COVID-19 medical countermeasure portfolio. *Accessed 29 Sept 2020* at https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx; CEPI's COVID-19 Vaccine Portfolio, *Accessed 29 Sept 2020* at https://cepi.net/COVAX/

Thank you so much for this opportunity to make our voices heard here in WI and this beloved free land of America!

I know that the Corona Virus has caused a serious health challenge for many individuals around the world and for us here in America. I do not want to underestimate the serious health challenges some, especially elderly and those with pre-existing conditions, have faced with this virus. At the same time, I urge government leaders to allow citizens to choose for themselves how they want to protect themselves from a virus instead of government forcing their ideas upon us. One reason America is so wonderful is that we have defended and fought for more individual freedom and not more government mandates and control.

I strongly urge that WI lead the way for other states to preserve our wonderful freedoms in this state and country by providing legislation in the recent Assembly 1 bill that would:

1) Prohibit employers and state (primarily the Department of Health Services) and/or local health officials from mandating that a person receive a COVID-19 vaccine
2) Prohibit the state Department of Health Services and/or local health officials from closing or prohibiting gatherings in places of worship. ***Bars and abortion centers are being allowed to stay open and they are NOT essential!
3) Limit the amount of time a public school can close down in-person instruction.**

Thank you again for allowing this opportunity. I trust we will all work our hardest and look to Almighty God for help to promote, preserve and increase true freedom in this country as originally presented in our beloved constitution.

For God and a free USA,
Stephen Rains
Mukwonago, WI

Dear Senator Jacque, Senator Ballweg, and members of the Senate Committee on Human Services, Children and Families,

My name is Judith Jolly and I am a wife, mother of 2, a resident of Pardeeville Wisconsin and a constituent of Senator Ballweg. I am a registered nurse with a Bachelor of Science in nursing who has been in active practice for over 25 years. Additionally, I am the Wisconsin State Director and the Director of Diseases and Vaccine Website Content for the National Vaccine Information Center, the nation's oldest vaccine safety and informed consent advocacy organization. I am here today representing Vaccine Choice Wisconsin – an organization dedicated to ensuring that vaccination remains a choice for all Wisconsinites, from their first to last heartbeat.

Vaccine Choice Wisconsin supports both SB 4 and SB 5 and respectfully request that the Senate make it a priority to ensure that no one is forced to receive any pharmaceutical product as a condition of employment, education or as a condition to participating in society.

While we realize that these bills are specific to vaccines targeting the SARS-CoV-2 virus, we would like to request that this committee consider amending these bills to prohibit mandates for all vaccines.

As you are likely aware, vaccines are liability-free pharmaceutical products. If you or your loved one are injured or die as a result of vaccination, you can't sue the drug maker for damages. Instead, you must file for compensation from the government through the Federal Vaccine Injury Compensation Program or VICP. However, two-thirds of people who file a VICP claim never receive any compensation and are left to pick up the pieces of their life without any assistance.

What's worse is that even though pursuing compensation through the VICP is an uphill battle for nearly all who submit claims, it is, in fact, a cakewalk compared to what a person who is injured from a COVID-19 vaccine will face.

In the U.S., vaccine manufacturers are shielded from liability under the 2005 Public Readiness and Emergency Preparedness (PREP) Act if a vaccine or drug developed in response to a health emergency like a pandemic causes the death or permanent injury of an individual who receives it. COVID-19 vaccines fall into this category and those persons harmed by these vaccines are prevented from suing the drug maker. Instead, they must file a claim with the Countermeasures Injury Compensation Program, or CICP, within 1 year of injury or death of a loved one.

Here's a few facts about the CICP program that you may not be aware of –

Unlike the VICP where attorneys' fees are covered by the program, anyone who attempts to file a claim with the CICP must pay their own fees for any legal representation or medical experts. Dependent on the situation, these fees could cost a person tens or hundreds of thousands of dollars. Few people have the means to cover these costs, which is likely why only about seven percent of people who have filed a claim with the CICP have been successful in obtaining any financial compensation.

Additionally, the CICP does not award compensation for pain or suffering caused by the injury. While the program covers lost wages, compensation for future lost wages is capped at $50,000. In other words, less than what the average healthcare professional earns in a single year.

One of the saddest pieces of the CICP is that it is the payer of last resort. The U.S. Health Resources and Services Administration (HRSA), which is the administrator of the program, can wait to see any life insurance or private insurance coverage pays first, then Medicaid/Medicare and Social Security disability. Only after all other payer sources have paid out benefits will the CICP compensate.

So if your loved one dies as a result of the COVID-19 vaccine and CICP determines the death benefit to be $250,000, the estate may not receive anything close to that amount if other benefits pay first. For example, if private life insurance pays the estate $200,000, CICP would only be required to pay the difference - $50,000.

Further, if HRSA, the program's administrator, declines to compensate a claim, there is no appeals process. Given that a person would be required to pay all legal costs and costs associated with medical expert testimonies, most who are injured may not even bother to risk losing more, especially given the fact that so few people who file ever receive any assistance.

According to the Vaccine Adverse Events Reporting System, as of January 7, 2021, COVID19 vaccines have been associated with nearly 1,400 emergency room visits and 225 hospitalizations. 362 reports were classified as serious, 99 were reported as life-threatening, and there have been 66 deaths that have occurred following vaccinations. Several of these deaths occurred within an hour or two of vaccination.

There are still so many unknowns regarding COVID-19 vaccines. In pre-licensing clinical trials of both the Pfizer and Moderna vaccines, as well as other experimental COVID-19 vaccines, assessments were not conducted to determine whether these vaccines would prevent infection with and transmission of the SARS-CoV-2 virus but rather how well they could prevent or minimize symptoms of COVID-19 disease. There is no evidence to suggest the vaccines will have any effect in terms of protecting people from getting the virus and spreading it.

There's no long-term safety or effectiveness data on COVID 19 vaccines and as we are all unique, in most cases, there is no way to know who might be harmed from these products.

Again, Vaccine Choice Wisconsin urges this committee and the Senate as a whole to make it their priority to ensure that no one is forced to receive a COVID-19 vaccine – or any vaccine or pharmaceutical product – as a condition of living freely in our great state.

Thank you for your time.

Judith Jolly

Pardeeville, Wisconsin

judith@vaccinechoicewi.org

VACCINE CHOICE WISCONSIN

January 21, 2021

Good afternoon. My name is Denise Brusveen. I am a wife and mother of three, residing near Poynette, Wisconsin. I earned my master's degree from UW-Madison focusing my research on reproductive physiology and have served the greater Madison area as a birth doula and childbirth educator since 2010. I am also a co-founder of the organization Vaccine Choice Wisconsin. I am here today in support of SB4 and SB5.

I am deeply concerned at the thought of any government official requiring individuals to be vaccinated against their will. I was actually put in a position to do just that last year. I am a member of the Columbia County Board of Supervisors, and I was appointed to our county's Ad Hoc Ordinance Review and Recodification Committee in July. Our healthcare center director attempted to slip language into our ordinances during that process that would have required not only a COVID vaccination but ALL CDC recommended vaccinations for county employees working at the healthcare center. Her proposed revision completely left out any provision for religious, philosophical, or medical exemptions. The language stated that failure to receive these vaccinations would be considered voluntary resignation. Just a few days later, an area doctor reached out to me asking if I was aware of this attempt to change policy because several of her patients had come to her highly concerned. Thankfully I was able to answer her that our committee voted NOT to add the language to our ordinances because they, too, value an individual's right to choose what goes into their body.

I am here today asking you to strengthen our state's legislation so that this isn't even an option to consider in our counties, municipalities, and private businesses. In fact, I implore you to go one step farther with your legislation. I would ask that you amend SB4 and SB5 to include not just the COVID vaccine, but ALL vaccines. We know that this is not going to end with COVID. It is only a matter of time before another virus or variation of this virus is on the horizon, and we will be back here all over again fighting for the same rights during the next public health emergency unless you broaden this language now.

Additionally, by broadening the language in both bills to include all vaccines, people would be protected from being forced to receive any other vaccine that already exists. Statewide, we are experiencing a shortage of nurses, however, individuals who are unwilling to receive the CDC-recommended vaccines are prohibited from entering nursing school, and most hospitals and clinics require annual flu shots in order to remain employed at their facility. So, then, is it any wonder that the only messaging we hear from the medical community is that we ALL need all vaccines?

The medical community is setting the tone for other employers in Wisconsin. In fact, during our discussions on my county board committee, an individual justified adding the vaccine requirements to our ordinances because her son works at a hospital, and they require them.

This is not ok. It is time that we let individuals make decisions for themselves. I have personally witnessed corruption between pharmaceutical companies and researchers. In graduate school, a

pharmaceutical company funded a study for our lab to compare their product to several competitors' products, fully expecting that their product would be best. When it wasn't, they threatened to pull their funding from our lab if my professor published the research. Thankfully, he did the right thing and published the research anyway. How many times is information being swept under the rug in the high stakes area of vaccines though? As I read the studies that ARE published, I find myself becoming more and more angry at the manipulation of parameters and results. It is these faulty studies that the CDC relies on to make their recommendations.

To an individual that has been injured or has had a family member injured, those studies really don't matter though. Their personal experience is enough for them to choose to forego one or more vaccines. That is their sovereign right, and it is time that our legislation upholds that right.

Again, I ask you to please pass SB4 and SB5, with the inclusion of all vaccines in the language.

Respectfully submitted,

Denise Brusveen
Poynette, WI
denise@vaccinechoicewi.org

Dear Senator Jacques, Senator Ballweg and members of the Senate Committee on Human Services, Children and Families.

My name is Andrew Bengston. I am a resident of Pardeeville Wisconsin and a constituent of Senator Ballweg.

I am here today to testify in support of Senate Bills 4, 5 and 7. I support Senate bills 4 and 5 because it allows people to make their own educated decisions.

COVID 19 is primarily serious and potentially deadly virus to a known group of people: the older generation and people with preexisting health conditions.

Safety Data is very limited on this vaccine and we do not know the long-term consequences that messenger RNA vaccines will have on our health and whether they will alter our DNA. It should be your choice to get this Vaccine (and any Vaccine for that matter) No one should be forced to get any pharmaceutical product as a condition of employment or living in this country. If the government has power to mandate Vaccines, then it can have power to do many other bad things to the people. This bill is a step in the right direction to limit the power of government. Something the founding fathers wanted to begin with.

Whether or not you get this Vaccine is your choice. I'm not stopping anyone from getting it if they want to. But if you don't, you are entitled to that choice as well. Back in March, the Governor ordered the closure of businesses and since then, we have seen counties put significant restrictions on the number of people who can be in a place at one time, with fines imposed on those who violate. If this can be done, then there's no reason why the government can't protect employees from being forced to receive these liability-free vaccines.

Totalitarian governments give you no choice – not governments of a constitutional republic who have taken an oath to uphold the Constitution. Too much government control and laws lead to censorship of information and even to the discrimination and even hunting down of people who disagree. The founding fathers wanted the people to be afforded as much freedom as possible. This must include the choice of not having to get a vaccine that could cause them harm. I know first hand about vaccine injury because I was seriously harmed by vaccines as a child and continue to have issues because of this harm.

Senate Bill 7 protects freedom of religion in the first amendment of the US constitution. This makes sure people of religion can worship however they would like. Totalitarian governments are the ones who fine and arrest people for practicing their religious beliefs in a manner of their choosing. We can't allow this to happen in our state. It is your choice to go to a church in this pandemic. If you don't want to, that's completely fine. But freedom of religion is a basic right and shouldn't be violated.

Thank you for your time.

Andrew Bengston

Pardeeville, Wisconsin

Dear Senator Jacques, Senator Ballweg and members of the Senate Committee on Human Services, Children and Families. My name is Anneka Bengston. I am a resident of Pardeeville Wisconsin and a constituent of Senator Ballweg. My brother my mom and I have come to the capital today in support of SB4 and SB5. As a child who grew up with a vaccine injured brother I have witnessed the negative effects that come with vaccines. That is why we are here today to support families like ours and families who have fought through much worse whose children suffered through the unfavorable events caused by these vaccines. We along with many others are concerned about the side effects that come with these vaccines. That is why we are in support of this bill. I believe if anyone wants to get this vaccine they can get it. I also believe that people have the choice to not get the vaccines if they don't feel that they are safe. For instance if my friend wanted to climb on the roof of his or hers house and wanted me to join them in doing so, do I have the right to refuse, Yes. Am I going to turn around and tell them not to do it? I could but I couldn't force them not to because it is their choice. I am not telling everyone to run out and get the vaccine, and I am not telling everyone to not get the vaccine. The people should choose what is best for them and not let the government tell them what they can or cannot do to their body.

Thank you for your time.

Anneka Bengston

Pardeeville, Wisconsin

Thank you very much for the opportunity to speak before this committee on some Senate Bills 4, 5, 6, and 7.

I Strongly urge you to approve and pass each of these bills through the Legislature. Our liberties have been encroached upon more than any other time in our nations history as they have been in these last ten months. We have seen churches unconstitutionally ordered to shutter their doors, families and groups of people told they cannot gather together, people and businesses forced to require mask compliance with respect to personal liberties, the government intrusion into people's lives, and many more specifics could be mentioned. Although these bills are not perfect, they are a start on many pieces of legislation that must be passed and signed by Governor Evers to stop and limit the encroachment of government upon our personal liberties given to us by God and spelled out in the Constitution. Far too long the legislature has sat idly by while people have faced personal liberties taken away, lockdowns and school closure have had drastic consequences on mental and physical health, and the very essence of what America is being trampled under foot.

If these bills are not passed, they will have many possible consequences that will further erode away our personal liberties, and unnecessarily put the people under pressure to make decisions that they do not want to make.

We must prohibit government officials from mandating vaccination at all levels of government, We must prohibit mandatory vaccination for employment, We must open up our schools as so many students are suffering horribly, and we must, I repeat, must forbid any future closures of places of worship and education by the government. Please remember what our state Constitution says, "The right of every person to worship Almighty God according to the dictates of conscience shall never be infringed; nor shall any person be compelled to attend, erect or support any place of worship, or to maintain any ministry, without consent; nor shall any control of, or interference with, the rights of conscience be permitted, or any preference be given by law to any religious establishments or modes of worship; nor shall any money be drawn from the treasury for the benefit of religious societies, or religious or theological seminaries."

In conclusion, I would like to mention that these bills should have been combined with the COVID bill instead of as stand along bills.

Thank you for listening to my thoughts and concerns regarding these bills.

Micah Roberts

Mukwonago, WI

Gmail

Samantha Kohlstedt <samanthakohlstedt@gmail.com>

Public Hearing Today

Thu, Jan 21, 2021 at 10:26 AM

Samantha Kohlstedt <samanthakohlstedt@gmail.com>
Draft To: Sen.Jacque@legis.wisconsin.gov

Senator Jacque,
This is my testimony regarding the Public Hearing today by the Senate Committee on Human Services, Children and Families:

I am 19 years old and live in Jefferson County. I support the Senate Bills 4, 5 and 7.

Regarding 4 and 5, I believe that decisions concerning vaccines and health care are the rights of every individual. The Government has no right under the Constitution to force vaccines or any other health treatment. The side-effects of the Covid 19 vaccine in particular are very disconcerting, and the long-term consequences cannot be known at this time. I should have the right to research any vaccines and make an informed decision for myself. I also believe that my health history is private, and that I should not be required to present any such information (especially regarding past vaccinations) when applying for a job.
Please pass Senate Bills 4 and 5 to protect my health rights and privacy.

Regarding Bill 7:
I believe that it is unconstitutional to close churches or other houses of worship for any reason. The first amendment clearly states that *no* law may be made 'respecting an establishment of religion or prohibiting the free exercise thereof'. The coronavirus is no reason for exception. It is my right to decide whether I am comfortable going to a church or not. Please pass Senate Bill 7 to protect my right to worship freely.

Thank you,
Samantha Kohlstedt

James & Susan Dziak
320 McGrath Lane
Hartland, WI 53029
262-397-4031

Chairman Sen Andrè Jacque - 608-266-3512
Vice-Chair Sen Joan Ballweg - 608-266-0751
Sen Eric Wimberger - 608-266-5670
Sen. LaTonya Johnson - 608-266-2500
Sen Melissa Agard - 608-266-9170

My wife and I both contracted COVID in March of 2020 and during this period the medical services refused us any medical assistance and ordered us to stay in our home. These services included our Aurora primary care doctors of over 30 years. We are both in our 70's and the point of being isolated and cut off was deeply concerning to put it mildly.

We and many others absolutely believe the lockdowns were the most devastating to personal well-being and the financial welfare of many especially the hourly worker and hourly.

The continued actions by government officials to lock down schools, churches and social gatherings is without a doubt the most harmful to our society.

The misguided thought that lockdowns will protect us from the virus is absolutely wrong. The Virus will touch everyone at some point and "managing the curve" is nothing more then evil control over the most freedom loving country in the world.

The information flowing even from medical workers incudes lying about statistics to continue the control. States with the most stringent controls are reporting the worst results.

Churches are essential to everyone person of faith and those looking for community support. In light of other so called essential enterprises including abortion clinic that take life, casino's etc. it exposes the real intent of government officials.

Free thinking people know what is happening and why it is happening you must make the right decision to declare churches and all places of worship essential.

Thank you,

Jim and Susan Dziak

From: Stephanie H <stephaniehammar.rn@hotmail.com>
Sent: Thursday, January 21, 2021 9:58 AM
To: Sen.Ballweg <Sen.Ballweg@legis.wisconsin.gov>; Sen.Wimberger <Sen.Wimberger@legis.wisconsin.gov>; Sen.Johnson <Sen.Johnson@legis.wisconsin.gov>; Sen.Agard <Sen.Agard@legis.wisconsin.gov>
Cc: Sen.Jacque <Sen.Jacque@legis.wisconsin.gov>
Subject: Choose your poison - SB 4,5,6, & 8 Committee on Human Services
Importance: High

Choose your poison...an experimental vaccine which currently has a 2.79% risk of a severe adverse reaction, can cause antibody dependent enhancement of disease, has no long term studies on safety, has 66 deaths reported in the U.S. to the FDA VAERS system (within days of vaccination) as of 1/7/21, and is not proven to reduce transmission of Coronavirus OR risk getting a virus that has a lethality of .008% - 2.5% depending on your age and comorbidities? That is what you are talking about today. You are talking about allowing the people of this state to pick their poison.

We must not forget that these vaccines are still experimental. The "trust science" rhetoric is ridiculous, science isn't something you believe, it is something that is PROVEN. These vaccines are not proven. They are still in a clinical trial state and that is why they have been issued an emergency use authorization and not a biological license (BLA) to distribute. It has not been granted a BLA because it does not meet the rigor of approval, it is still experimental. We must heed the warning of the 5 scientists who sat on the 22 member FDA panel to grant EUA of these vaccines and voted NO that the potential benefits do not outweigh the risks of this experimental vaccine to authorize emergency use. This is enough trusted scientific opinion to tell us we must not allow government or employers to force any person to participate in this general population clinical trial in which the risks outweigh the benefits. Using the body as a scientific vehicle is a personal choice, not the governments and certainly not the employers.

Furthermore, IF you plan to vote in favor of giving government entities and employers the power to mandate an experimental vaccine then you must allow the recipient of the vaccine an avenue for legal recourse and recovery in the event of injury. To force upon someone an experimental vaccine while holding their job over their head is black mail, but then to take zero responsibility if they suffer an injury as a result of such an ultimatum is unconscionable. You cannot have it both ways. Employers who want to mandate this as a condition of employment then must assume the liability of injury as they do with any other work related injury that occurs as a condition of employment. The fact that these manufacturers are protected from liability by our government is disgusting. Telling the American people they must take something and if they get hurt "too bad, so sad" is outright wrong. This is not American freedom; this is an egregious infringement on our rights.

A very prominent pulmonary doctor in this state said to me, "bad things can happen with the vaccine and bad things can happen with COVID". This is true and where there is this risk, one must have the freedom to choose. I urge you to vote in favor of protecting the right to choose and prohibiting any government or employer vaccine mandate. Picture yourself as one of the unlucky ones that suffers a severe life threatening adverse event from this vaccine and ask yourself if that risk is worth it to you. As

a RN, a person who has suffered a severe immunologic reaction to a flu vaccine, and a child who has been severely injured by a pharmaceutical I urge you to vote to protect our freedom to choose.

Thank you Senator Jacque for bringing forth such important bills and caring to protect our freedoms.

Sincerely,

Stephanie Hammar

In addition...open the schools. The people yelling at us to "trust science" of an unproven experimental vaccine seem to be the people who don't want to "trust the science" that schools are not the major vehicle of viral spread AND the chances of a person under 20 dying from COVID is around .008%. Our kids deserve the right to in person education that meets the educational thresholds of adequacy to prepare them for adulthood. Those uncomfortable sending their children to school have the option to home school. Those teachers afraid to teach in fear of the virus have the choice to get an unproven vaccine to help protect them, the choice to wear personal protective equipment, and the choice to find alternative employment. We need to wake up WI! The emotional and mental health fall out from this on our children is going to be felt for years to come if we don't right this ship.

WALHDAB
Public Health In Action
Wisconsin Association of Local Health Departments and Boards

WPHA
Wisconsin Public Health Association

DATE: January 21, 2021
TO: Members of the Senate Committee on Human Services, Children and Families
FROM: The Wisconsin Association of Local Health Departments and Boards (WALHDAB)
The Wisconsin Public Health Association (WPHA)
RE: Oppose Senate Bill 4

WALHDAB is the statewide organization of city, county and tribal local board of health members and health department administrators. WALHDAB members provide a unified forum for public health leadership development, advocacy, education, and forging of community partnerships for the improvement of public health at the local level.

WPHA is the largest statewide association of public health professionals in Wisconsin. WPHA was established in 1948 and serves as the collective voice for public health in Wisconsin and is committed to building a healthier, safer state through policy, partnership and professional development of our members.

Together, WPHA and WALHDAB represent over 1,200 public health professionals in communities across Wisconsin, striving to prevent, promote, and protect the health of Wisconsin citizens.

WALHDAB and WPHA share the following concerns on Senate Bill 4:

Senate Bill 4 – Prohibiting Local Health Officers and DHS from Mandating COVID-19 Vaccination

- Wisconsin Statute 252.041, which states DHS can "order any individual to receive a vaccination ***unless the vaccination is reasonably likely to lead to serious harm to the individual or unless the individual, for reasons of religion or conscience, refuses to obtain the vaccination."***

- It is unclear what the bill's intent is, and since current law already allows individuals to object to mandatory vaccinations, this bill is unnecessary.

The middle of a pandemic is no time to interrupt the work of local health officers. We need to support local health officers and remain committed to the local decision-making as the keys to governance in Wisconsin. State leaders from both parties and all branches of state government have described the importance of local response to this unprecedented pandemic. We ask your support to provide the same tools our local health officers need to continue their work.

If you have any questions, contact call Tim Hoven (414-305-2011) or Erik Kanter (608-310-8833).

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *(see Storage and Handling)*.
- Refer to thawing instructions in the panels below.

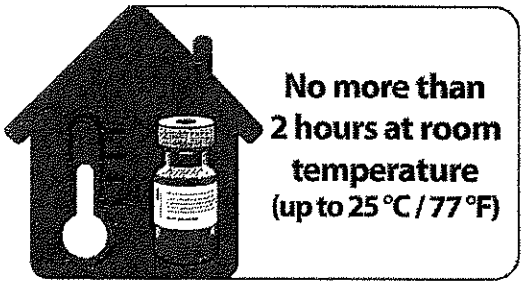
Dilution

Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

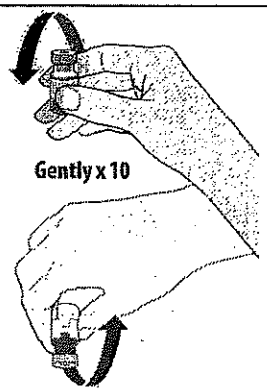
After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION

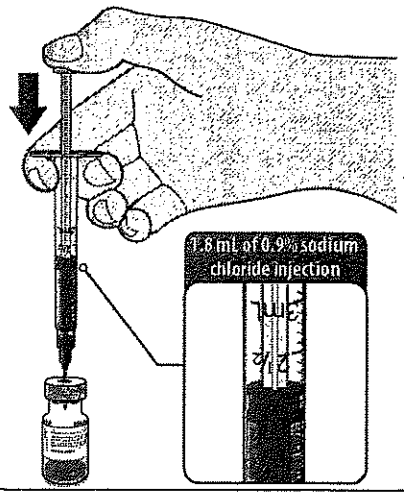


- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

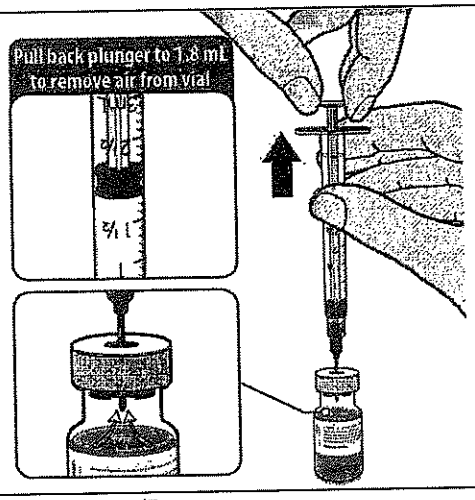
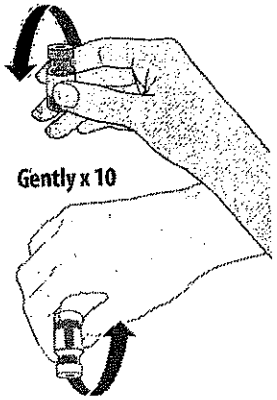
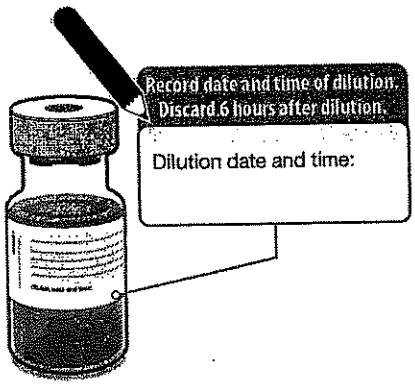


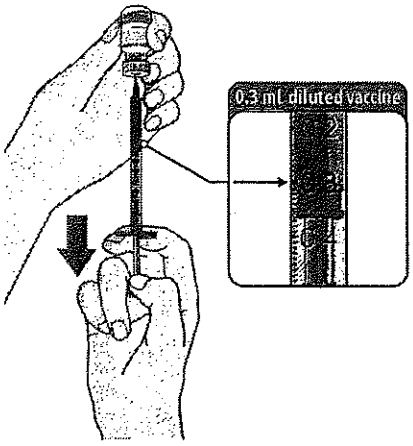
- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

DILUTION



- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs

following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events* (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting

to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
  - Death;
  - A life-threatening adverse event;
  - Inpatient hospitalization or prolongation of existing hospitalization;
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
  - A congenital anomaly/birth defect;
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-4.0

Revised: January 2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

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4 CONTRAINDICATIONS
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* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

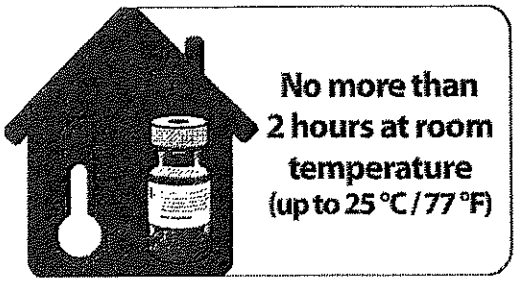
Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

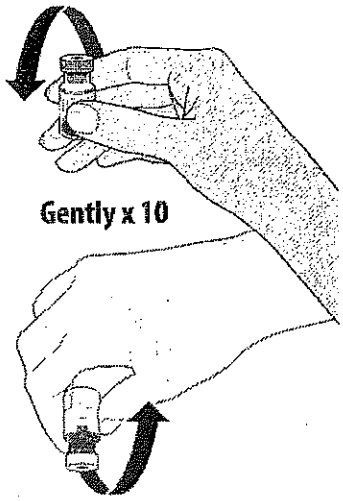
Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION

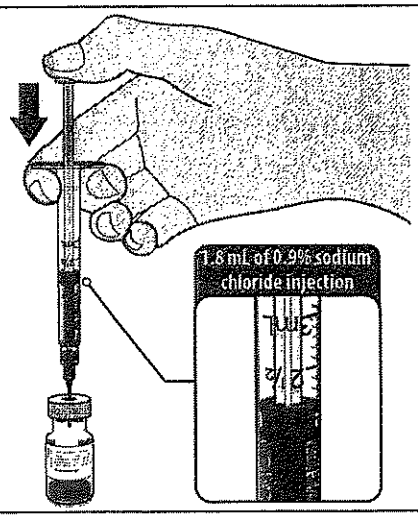


- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

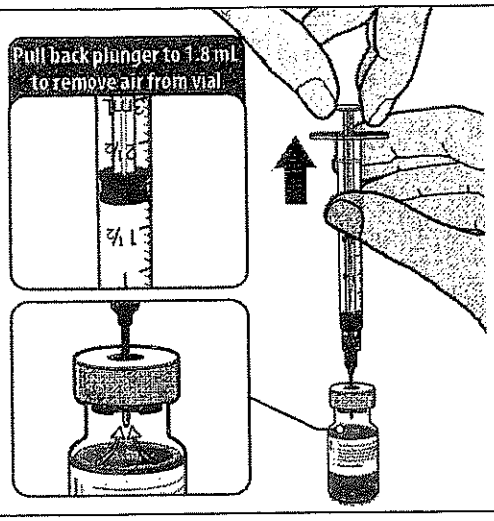
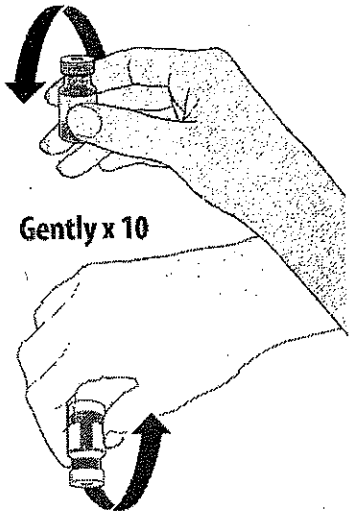
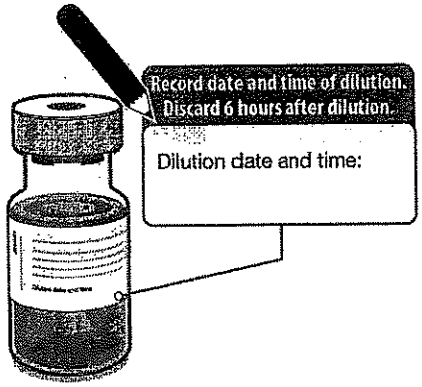


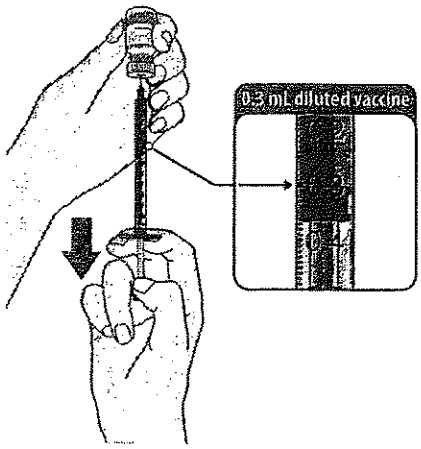
- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

DILUTION



- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule for Individuals 16 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.3 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 44,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively).

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older have been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020. Participants 18 years and older in the reactogenicity subset are monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo in the subset of participants 18 to 55 years of age included in the EUA safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo for participants 56 years of age and older.

Across both age groups, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

‡ Eight participants were between 16 and 17 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

‡ Eight participants were between 16 and 17 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 to 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7960, placebo = 7934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Overall in Study 2 in which 10,841 participants 16 to 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. The higher frequency of reported unsolicited non-serious adverse events among Pfizer BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 16 and 17 years of age is based on extrapolation of safety and effectiveness from adults 18 years of age and older. Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine does not include use in individuals younger than 16 years of age.

Comparison of Countermeasures Injury Compensation Program (CICP) to the National Vaccine Injury Compensation Program (VICP)

Program Categories	CICP	VICP
Program Authorization	Public Readiness and Emergency Preparedness Act (PREP Act) (42 U.S.C. §§ 247d-6d, 247d-6e)	National Childhood Vaccine Injury Act of 1986, as amended (42 U.S.C. § 300aa-10, et seq.)
Filing Deadlines	• One (1) year filing deadline • Filing deadline when a countermeasures injury table is developed or changed	• Injury claim filing deadline • Death claim filing deadline • Filing deadline when changes are made to the Vaccine Injury Table
Products Covered	Covered countermeasures are identified by the Secretary of the Department of Health and Human Services (HHS) in declarations published under the PREP Act. Covered Countermeasures	Vaccines recommended for routine administration to children and/or pregnant women by the Centers for Disease Control and Prevention, subject to a Federal excise tax, and added to the Vaccine Injury Table by the Secretary of HHS. Covered Vaccines
Process for Adding Covered Vaccines/ Countermeasures	Covered countermeasures are identified by the Secretary of HHS in declarations published under the PREP Act.	For a category of vaccines to be covered by the VICP, the category of vaccines must be recommended for routine administration to children and/or pregnant women by the Centers for Disease Control and Prevention, subject to an excise tax by federal law, and added to the Vaccine Injury Table by the Secretary of Health and Human Services. This has not been done for any U.S. licensed COVID-19 vaccines, which have not been developed to date.
Type of Injury Covered	• Serious physical injuries • Deaths	• Injuries with effects lasting for more than 6 months after the vaccine was given or resulted in inpatient hospitalization and surgery, or • Deaths
Benefits Available	Types of Benefits	Types of Compensation
Payment of Legal	Attorneys' fees and costs	Attorneys' fees and costs may be available if certain requirements are met (petition

Fees and Costs	are not paid by the program.	filed in good faith and on a reasonable basis)
Persons who can file Requests/ Petitions	Types of Eligible Requesters	Who Can File a Petition?
Process for Filing a Request/Petition	File the Request Form and documentation with the Secretary of HHS.	File petition and documentation with the U.S. Court of Federal Claims and the Secretary of HHS.
Process for Resolving Requests/ Petitions	Administrative Process	Judicial Process
Covered Injury Determinations	HHS makes decision. Criteria to Demonstrate that a Covered Injury Occurred	Special Masters (or judges) of U.S. of Court of Federal Claims make decision. Criteria to be Found Eligible to Receive Compensation
Appeal Rights	One step administrative reconsideration possible. No judicial appeal permitted.	Judicial appeal by either party to higher courts possible.
Program Funding	Appropriated Funds	Vaccine Injury Compensation Trust Fund funded through excise taxes on covered vaccines.

Date Last Reviewed: November 2020

Grant Final Report

Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

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Submitted to:
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Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

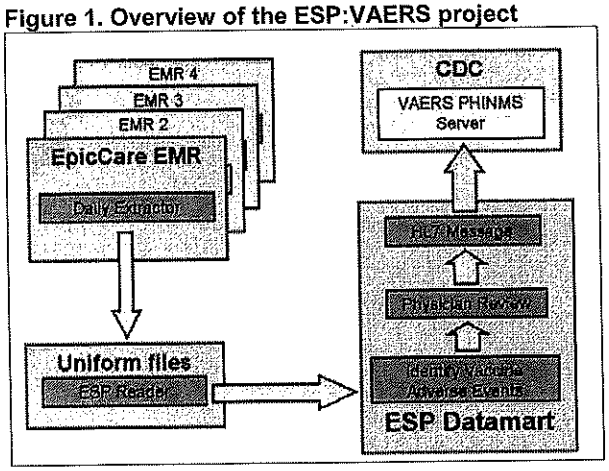
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration*, and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect.* A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS.* The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.*

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at: http://esphealth.org/trac/ESP/wiki/ESPVAERS.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

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Search Results

From the 1/7/2021 release of VAERS data:

This is VAERS ID 905345

Case Details

VAERS ID:	905345 (history)	**Vaccinated:**	2020-12-17
Form:	Version 2.0	**Onset:**	2020-12-20
Age:	22.0	**Days after vaccination:**	3
Sex:	Male	**Submitted:**	0000-00-00
Location:	Wisconsin	**Entered:**	2020-12-21

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / IM

Administered by: Private **Purchased by:** ?
Symptoms: Haemorrhage, Platelet count decreased, SARS-CoV-2 test negative
SMQs:, Haematopoietic thrombocytopenia (narrow), Haemorrhage terms (excl laboratory terms) (narrow), Systemic lupus erythematosus (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), COVID-19 (broad)
Life Threatening? No
Birth Defect? No
Died? No
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? Yes
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications: None reported by patient
Current Illness: No known past medical history
Preexisting Conditions: None
Allergies: No known allergies
Diagnostic Lab Data: COVID (-) Platelets 2000 cells/mcL
CDC Split Type:

Write-up: Patient received Pfizer COVID 19 vaccine last Thursday 12/17. Admitted today (12/21) with bleeding and low platelet count - working up for ITP, TTP. Given recency of vaccination and no known contributory allergy or medical history, physician thought potentially associated with vaccination.

New Search

Link To This Search Result:
https://www.medalerts.org/vaersdb/findfield.php?IDNUMBER=905345

Feature

Will covid-19 vaccines save lives? Current trials aren't designed to tell us

BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m4037 (Published 21 October 2020)Cite this as: BMJ 2020;371:m4037

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Author affiliations

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The world has bet the farm on vaccines as the solution to the pandemic, but the trials are not focused on answering the questions many might assume they are. **Peter Doshi** reports

As phase III trials of covid-19 vaccines reach their target enrolments, officials have been trying to project calm. The US coronavirus czar Anthony Fauci and the Food and Drug Administration leadership have offered public assurances that established procedures will be followed.[1234] Only a "safe and effective" vaccine will be approved, they say, and nine vaccine manufacturers issued a rare joint statement pledging not to prematurely seek regulatory review.[5]

But what will it mean exactly when a vaccine is declared "effective"? To the public this seems fairly obvious. "The primary goal of a covid-19 vaccine is to keep people from getting very sick and dying," a National Public Radio broadcast said bluntly.[6]

Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine in Houston, said, "Ideally, you want an antiviral vaccine to do two things . . . first, reduce the likelihood you will get severely ill and go to the hospital, and two, prevent infection and therefore interrupt disease transmission."[7]

Yet the current phase III trials are not actually set up to prove either (**table 1**). None of the trials currently under way are designed to detect a reduction in any serious outcome such as hospital admissions, use of intensive care, or deaths. Nor are the vaccines being studied to determine whether they can interrupt transmission of the virus.

Table 1

Characteristics of ongoing phase III covid-19 vaccine trials

- View popup
- View inline

Evaluating mild, not severe, disease

In a September interview Medscape editor in chief Eric Topol pondered what counts as a recorded "event" in the vaccine trials. "We're not talking about just a PCR [polymerase chain reaction test]-positive mild infection. It has to be moderate to severe illness to qualify as an event, correct?" he asked.[8]
"That's right," concurred his guest, Paul Offit, a vaccinologist who sits on the FDA advisory committee that may ultimately recommend the vaccines for licence or emergency use authorisation.

But that's not right. In all the ongoing phase III trials for which details have been released, laboratory confirmed infections even with only mild symptoms qualify as meeting the primary endpoint definition.[9][10][11][12] In Pfizer and Moderna's trials, for example, people with only a cough and positive laboratory test would bring those trials one event closer to their completion. (If AstraZeneca's ongoing UK trial is designed similarly to its "paused" US trial for which the company has released details, a cough and fever with positive PCR test would suffice.)
Part of the reason may be numbers. Severe illness requiring hospital admission, which happens in only a small fraction of symptomatic covid-19 cases, would be unlikely to occur in significant numbers in trials. Data published by the US Centers for Disease Control and Prevention in late April reported a symptomatic case hospitalisation ratio of 3.4% overall, varying from 1.7% in 0-49 year olds and 4.5% in 50-64 year olds to 7.4% in those 65 and over.[13] Because most people with symptomatic covid-19 experience only mild symptoms,[14] even trials involving 30 000 or more patients would turn up relatively few cases of severe disease.
In the trials, final efficacy analyses are planned after just 150 to 160 "events,"—that is, a positive indication of symptomatic covid-19, regardless of severity of the illness.

Yet until vaccine manufacturers began to release their study protocols in mid-September, trial registries and other publicly released information did little to dispel the notion that it was severe covid-19 that the trials were assessing. Moderna, for example, called hospital admissions a "key secondary endpoint" in statements to the media.[15] And a press release from the US National Institutes of Health reinforced this impression, stating that Moderna's trial "aims to study whether the vaccine can prevent severe covid-19" and "seeks to answer if the vaccine can prevent death caused by covid-19."[16]
But Tal Zaks, chief medical officer at Moderna, told *The BMJ* that the company's trial lacks adequate statistical power to assess those outcomes. "The trial is precluded from judging [hospital admissions], based on what is a reasonable size and duration to serve the public good here," he said.
Hospital admissions and deaths from covid-19 are simply too uncommon in the population being studied for an effective vaccine to demonstrate statistically significant differences in a trial of 30 000 people. The same is true of its ability to save lives or prevent transmission: the trials are not designed to find out.

Zaks said, "Would I like to know that this prevents mortality? Sure, because I believe it does. I just don't think it's feasible within the timeframe [of the trial]—too many would die waiting for the results before we ever knew that."

Stopping transmission

What about Hotez's second criterion, interrupting virus transmission, which some experts have argued[17] should be the most important test in phase III studies?

"Our trial will not demonstrate prevention of transmission," Zaks said, "because in order to do that you have to swab people twice a week for very long periods, and that becomes operationally untenable."

He repeatedly emphasised these "operational realities" of running a vaccine trial. "Every trial design, especially phase III, is always a balancing act between different needs," he said. "If you wanted to have an answer on an endpoint that happens at a frequency of one 10th or one fifth the frequency of the primary endpoint, you would need a trial that is either 5 or 10 times larger or you'd need a trial that is 5 or 10 times longer to collect those events. Neither of these, I think, are acceptable in the current public need for knowing expeditiously that a vaccine works."

Zaks added, "A 30 000 [participant] trial is already a fairly large trial. If you're asking for a 300 000 trial then you need to talk to the people who are paying for it, because now you're talking about not a $500m to $1bn trial, you're talking about something 10 times the size. And I think the public purse and operational capabilities and capacities we have are rightly spent not betting the farm on one vaccine but, as Operation Warp Speed [the US government's covid-19 vaccine plan] is trying to do, making sure that we're funding several vaccines in parallel."

Debating endpoints

Still, it's fair to say that most of the general public assumes that the whole point of the current trials, besides testing safety (**box 1**), is to see whether the vaccine can prevent bad outcomes.

"How do you reconcile that?" *The BMJ* asked Zaks.

Box 1

Safety and side effects

History shows many examples of serious adverse events from vaccines brought to market in periods of enormous pressure and expectation. There were contaminated polio vaccines in 1955, cases of Guillain-Barré syndrome in recipients of flu vaccines in 1976, and narcolepsy linked to one brand of influenza vaccine in 2009.[18][19]

"Finding severe rare adverse events will require the study of tens of thousands of patients, but this requirement will not be met by early adoption of a product that has not completed its full trial evaluation," Harvard drug policy researchers Jerry Avorn and Aaron Kesselheim recently wrote in *JAMA*.[20]

Covid-19 vaccine trials are currently designed to tabulate final efficacy results once 150 to 160 trial participants develop symptomatic covid-19—and most trials have specified at least one interim analysis allowing for the trials to end with even fewer data accrued.

Medscape's Eric Topol has been a vocal critic of the trials' many interim analyses. "These numbers seem totally out of line with what would be considered stopping rules," he says. "I mean, you're talking about giving a vaccine with any of these programmes to tens of millions of people. And you're going to base that on 100 events?"[8]

Great uncertainty remains over how long a randomised trial of a vaccine will be allowed to proceed. If efficacy is declared, one possibility is that the thousands of volunteers who received a saline placebo would be offered the active vaccine, in effect ending the period of randomised

follow-up. Such a move would have far reaching implications for our understanding of vaccines' benefits and harms, rendering uncertain our knowledge of whether the vaccines can reduce the risk of serious covid-19 disease and precluding any further ability to compare adverse events in the experimental versus the placebo arm.

"It'll be a decision we'll have to take at that time. We have not committed one way or another," Moderna's Tal Zaks told *The BMJ*. "It will be a decision where FDA and NIH will also weigh in. And it will be probably a very difficult decision, because you will be weighing the benefit to the public in continuing to understand the longer term safety by keeping people on placebo and the expectation of the people who have received placebo to be crossed over now that it has been proved effective."
RETURN TO TEXT

"Very simply," he replied. "Number one, we have a bad outcome as our endpoint. It's covid-19 disease." Moderna, like Pfizer and Janssen, has designed its study to detect a relative risk reduction of at least 30% in participants developing laboratory confirmed covid-19, consistent with FDA and international guidance.[2122]
Number two, Zaks pointed to influenza vaccines, saying they protect against severe disease better than mild disease. To Moderna, it's the same for covid-19: if its vaccine is shown to reduce symptomatic covid-19, it will be confident it also protects against serious outcomes.

But the truth is that the science remains far from clear cut, even for influenza vaccines that have been used for decades. Although randomised trials have shown an effect in reducing the risk of symptomatic influenza, such trials have never been conducted in elderly people living in the community to see whether they save lives.

Only two placebo controlled trials in this population have ever been conducted, and neither was designed to detect any difference in hospital admissions or deaths.[23] Moreover, dramatic increases in use of influenza vaccines has not been associated with a decline in mortality (**box 2**).[26]
Box 2

Not enrolling enough elderly people or minorities

A vaccine that has been proved to reduce the risk of symptomatic disease by a certain proportion should, you might think, reduce serious outcomes such as hospital admissions and deaths in equal proportion.

Peter Marks, an FDA official with responsibility over vaccine approvals, recently stated as much about influenza vaccination, which "only prevents flu in about half the people who get it. And yet that's very important because that means that it leads to half as many deaths related to influenza each year."[24]
But when vaccines are not equally effective in all populations the theory breaks down.

If frail elderly people, who are understood to die in disproportionate numbers from both influenza[25] and covid-19, are not enrolled into vaccine trials in sufficient numbers to determine whether case numbers are reduced in this group, there can be little basis for assuming any benefit in terms of hospital admissions or mortality. Whatever reduction in cases is seen in the overall study population (most of which may be among healthy adults), this benefit may not apply to the frail elderly subpopulation, and few lives may be saved.

This is hard to evaluate in the current trials because there are large gaps in the types of people being enrolled in the phase III trials (**table 1**). Despite recruiting tens of thousands, only two trials are enrolling children less than 18 years old. All exclude immunocompromised people and pregnant or breastfeeding women, and though the trials are enrolling elderly people, few or perhaps none of the studies would seem to be designed to conclusively answer whether there is a benefit in this population, despite their obvious vulnerability to covid-19.

"Adults over 65 will be an important subgroup that we will be looking at," Moderna's Zaks told *The BMJ*. "That said . . . any given study is powered for its primary endpoint—in our case covid-19 disease irrespective of age."

Al Sommer, dean emeritus of the Johns Hopkins School of Public Health, told *The BMJ*, "If they have not powered for evidence of benefit in the elderly, I would find that a significant, unfortunate shortcoming." He emphasised the need for "innovative follow-up studies that will enable us to better determine the direct level of protection immunisation has on the young and, separately, the elderly, in addition to those at the highest risk of severe disease and hospitalisation."

One view is that trial data should be there for all target populations. "If we don't have adequate data in the greater than 65 year old group, then the greater than 65 year old person shouldn't get this vaccine, which would be a shame because they're the ones who are most likely to die from this infection," said vaccinologist Paul Offit.[8] "We have to generate those data," he said. "I can't see how anybody—the Data and Safety Monitoring Board or the FDA Vaccine Advisory Committee, or FDA decision-makers—would ever allow a vaccine to be recommended for that group without having adequate data."

"I feel the same way about minorities," Offit added. "You can't convince minority populations to get this vaccine unless they are represented in these trials. Otherwise, they're going to feel like they're guinea pigs, and understandably so."

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Acknowledgments

Sarah Tanveer helped research the design of studies and identify quotations, and Ulrich Keil provided comments on an early draft of this article.

Footnotes

- Competing interests: I co-wrote an op-ed on this topic with Eric Topol, who is quoted in this article, I have been pursuing the public release of vaccine trial protocols, and I co-signed an open letter to the FDA calling for independence and transparency in covid-19 vaccine related decision making.
- Provenance and peer review: Commissioned; externally peer reviewed.

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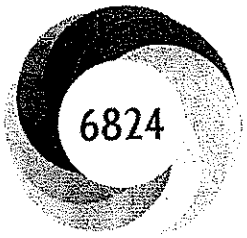

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3. At ASM Microbe, White House's Deborah Birx Urges COVID-19 Test Pooling and Community Outreach

   Madeleine Johnson, GenomeWeb

4. New Colorectal Cancer Screening Guidelines From USPSTF May Benefit Exact Sciences' Cologuard

   Ben Butkus et al., 360Dx, 2016

5. Luminex Receives FDA Emergency Use Authorization for Coronavirus Multiplex Panel

   staff reporter, 360Dx, 2020

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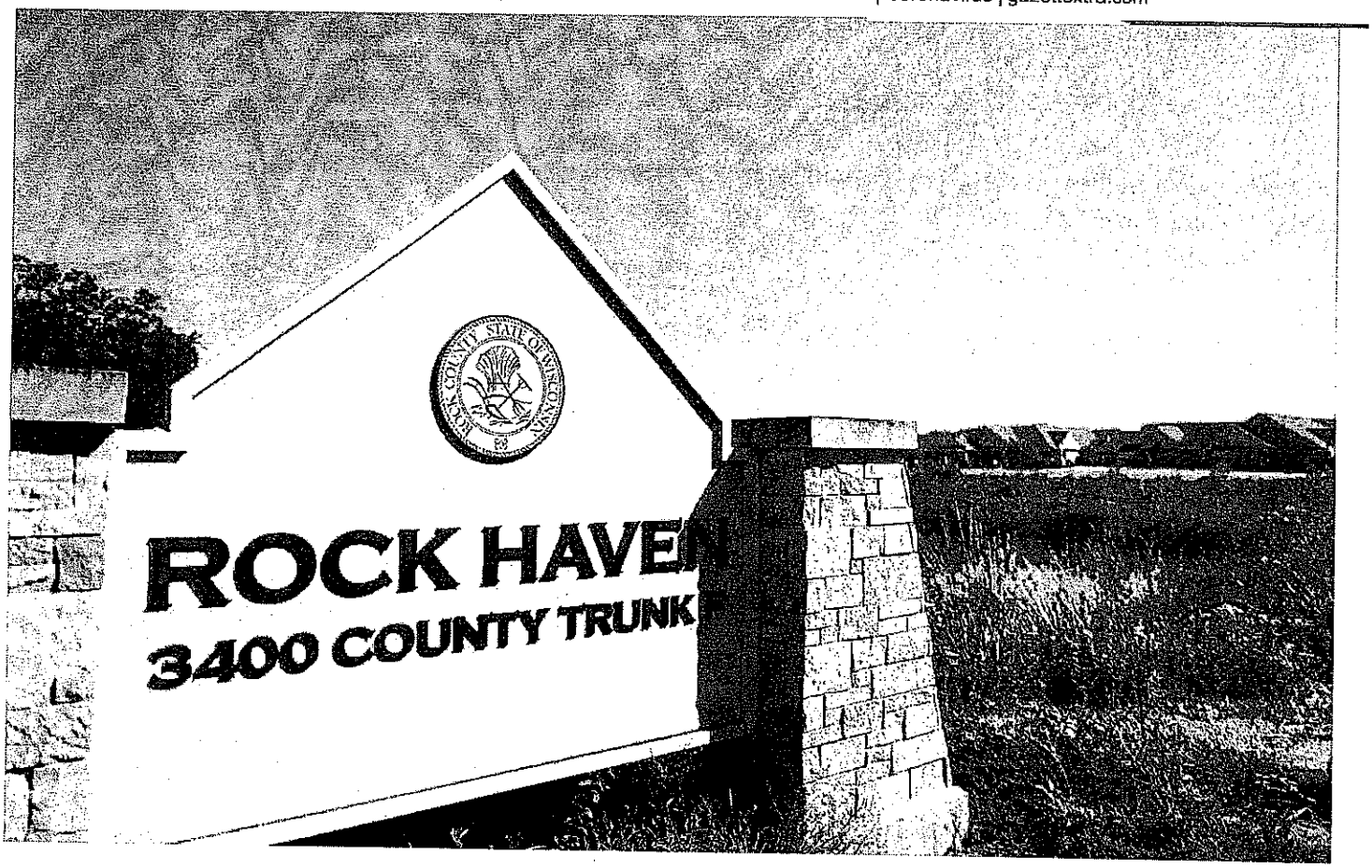
TOP STORY

Rock Haven lays off staff who decline COVID-19 vaccine

By Neil Johnson njohnson@gazettextra.com
Jan 14, 2021

Josh Smith
Dan Lassiter



Rock Haven

JANESVILLE

As Rock County rolls out a COVID-19 vaccination program for workers at Rock Haven, employees at the county's nursing home are being required to get the vaccine or face layoff.

Rock County Administrator Josh Smith said the county has drawn a hard line on vaccination at the county-run nursing home, and he said a handful of Rock Haven employees have been laid off this month after they declined to receive the new Moderna COVID-19 vaccine.

Smith and Rock Haven officials said the mandate is to protect the nursing home's elderly residents. The county's decision is drawing fire from some Rock Haven employees, who said they are not comfortable getting a vaccine that got emergency

federal approval and has caused adverse reactions in some people out of millions vaccinated so far.

As the county rolls out the Moderna version that requires two doses, Smith said most Rock Haven workers scheduled to get initial doses of the vaccine Jan. 5 complied with the mandate.

Smith said the county has written no formal rule or policy on COVID-19 vaccination, and he said other county departments with frontline workers, such as the sheriff's office, do not intend to make COVID-19 vaccination mandatory.

But a Dec. 23 memo from Rock Haven administration to employees obtained by The Gazette informs nursing home employees that they are required to receive the Moderna vaccine or face layoff.

The memo says layoffs would be enacted for any employee under a provision of a Rock County employment ordinance that "The Appointing (county) authority may lay off an employee when an employee can no longer perform the essential functions of the job."

The memo also states a laid-off employee "will not be allowed to return to work until they have completed the COVID-19 vaccine series."

One Rock Haven employee spoke to The Gazette but asked to remain anonymous citing concerns of being fired for speaking publicly about the situation. The employee said about a half-dozen co-workers either took "voluntary" layoffs or quit their jobs after they decided to refuse vaccination.

Smith said he has been told "three or four" Rock Haven employees have accepted layoffs after declining the vaccine, and he said one person retired. More employees are scheduled to get a first dose of the vaccine in early February, according to the memo.

The employee who spoke to The Gazette is slated to get a first dose of the vaccine in February. The employee doesn't want to receive the vaccine and said 27 other employees at the nursing home this month had sent the county's Health Services Committee letters explaining their concerns over the vaccination mandate.

The employee said some co-workers are concerned the vaccine might have unknown, long-term side effects and said some Rock Haven workers who already have received the vaccine reported adverse reactions.

"There have been individuals who have had pretty severe reactions. We have had multiple worker's comp claims needing to be filed because of them having to go out because of what has happened after the vaccine," the employee told The Gazette.

The employee said a co-worker who went home ill with a reaction after receiving the vaccine at work wanted to get a doctor's note that exempts them from being required to get a second dose of the vaccine.

The employee said Rock Haven's administration has refused to bend on its mandate.

"We were told by our human resources directly that it was required for all staff," the employee said.

Media reports indicate that statewide some private health care groups have been surprised to learn some frontline staff don't want the COVID-19 vaccine. Health care groups have reported some employees who are being offered the vaccine are declining or aren't showing up to appointments to get vaccinated.

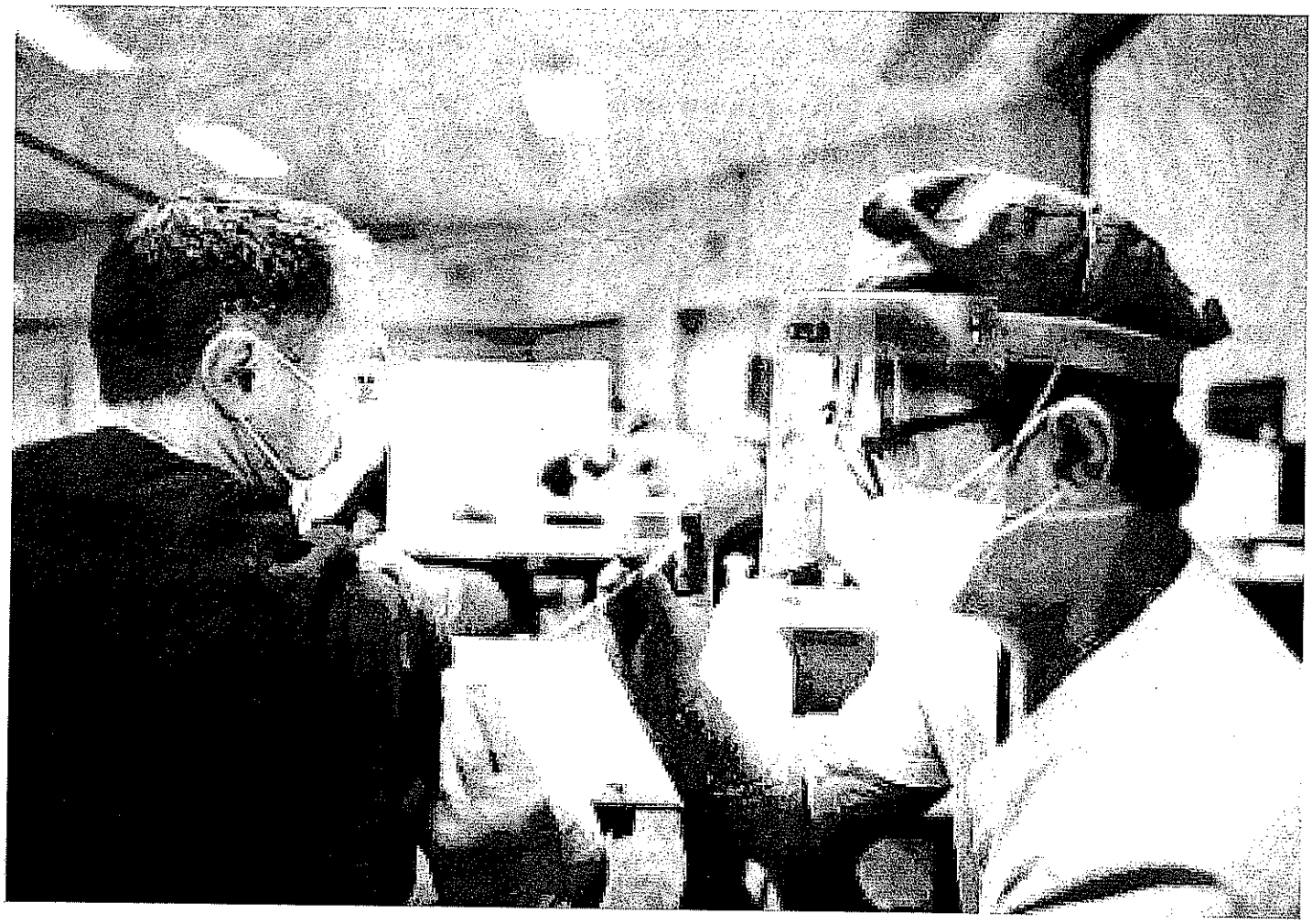
Smith said he is concerned about potential "misinformation" over COVID-19 vaccines. He acknowledged that during the rollout across the U.S., some people have had adverse reactions to the vaccine. But he said he doesn't think that means the vaccines are "unsafe."

Smith said Rock Haven is requiring employees at the nursing home to get a vaccine because nursing homes, including Rock Haven, have had COVID-19 outbreaks among residents and staff in recent months. Some nursing homes in neighboring states already have begun vaccinating residents who are considered at-risk for COVID-19 infection.

"These are difficult decisions and very personal decisions, so I don't want it to come across as we don't care about our staff. Certainly, some staff are not happy about it," Smith said.

"What I'd emphasize to people is that the decision that was made was based on concern about our (Rock Haven) residents who are entrusted with our care. Those residents should always be our No. 1 priority."

MORE INFORMATION



What we know, and don't know, about COVID-19 vaccines in Rock County

Some private nursing homes aren't requiring worker vaccinations

Neil Johnson
Reporter - Business

ASSET REPORTS

COMPULSORY VACCINATION AND RATES OF COVERAGE IMMUNISATION IN EUROPE

Introduction

High rates of vaccination coverage in childhood are main indicators for public health. However, reaching and maintaining such a target is not always an easy task for public health institutions, and the spread of vaccine refusal and hesitancy is making this even harder.

Enforcing mandatory vaccinations is one of the strategies that some countries adopted and others are considering in order to face this issue. Depending on local legislations, legal consequences for those who do not accept the uptake can be very different, ranging from pecuniary penalties to hurdles to attend public schools. In some cases, parents may even incur penal consequences; as it recently happened in France, were two parents refusing to vaccinate their children risked a jail sentence. Nevertheless, the efficacy of such an approach has been questioned.

ASSET performed an analysis on the issue, comparing coverage rates of immunisation against polio (Pol3), measles

(MCV1) and pertussis containing vaccines (DTP3)* in European Union/European Economic Area (EU/EEA) countries, where, according to different policies, these vaccinations are either mandatory or recommended.

This comparison cannot confirm any relationship between mandatory vaccination and rates of childhood immunization in the EU/EEA countries.

* In some countries, such as Italy, vaccination against pertussis is highly recommended but not compulsory, while those against diphteria and tetanus on the contrary are, but the three are usually administered in one single shot.

Methods

Information on policies of mandatory or recommended vaccinations in the EU/EEA countries were gathered by VENICE project (eurosurveillance.org).

Data on childhood immunisation coverage in the EU/EEA countries were taken from the UNICEF official website (data.unicef.org). They refer to the period from 2007 to 2013, so that the visualization can show temporal trends in immunisation rate in each country, as well.

As defined by VENICE project, vaccinations are recommended when included in the national immunisation programme for all or some specific groups independent of being funded or not. A vaccine is defined as mandatory if every child must receive it by law without the possibility for the parent to choose to accept the uptake or not, regardless of whether a legal or economical implication exists for the refusal. Law enforcement and legal consequences may be very different but, since the national contexts are difficult to evaluate, the VENICE survey did not collect any information about them.

We chose three relevant vaccinations, on which different policies have been adopted in different countries. While polio vaccine is mandatory in many countries, pertussis vaccine is more often only recommended, even in countries where other vaccinations are compulsory. Measles vaccination is an important indicator of hesitancy and refusal, since misinformation accusing it of causing autism, despite evidence of its fraudulent source, is still going on.

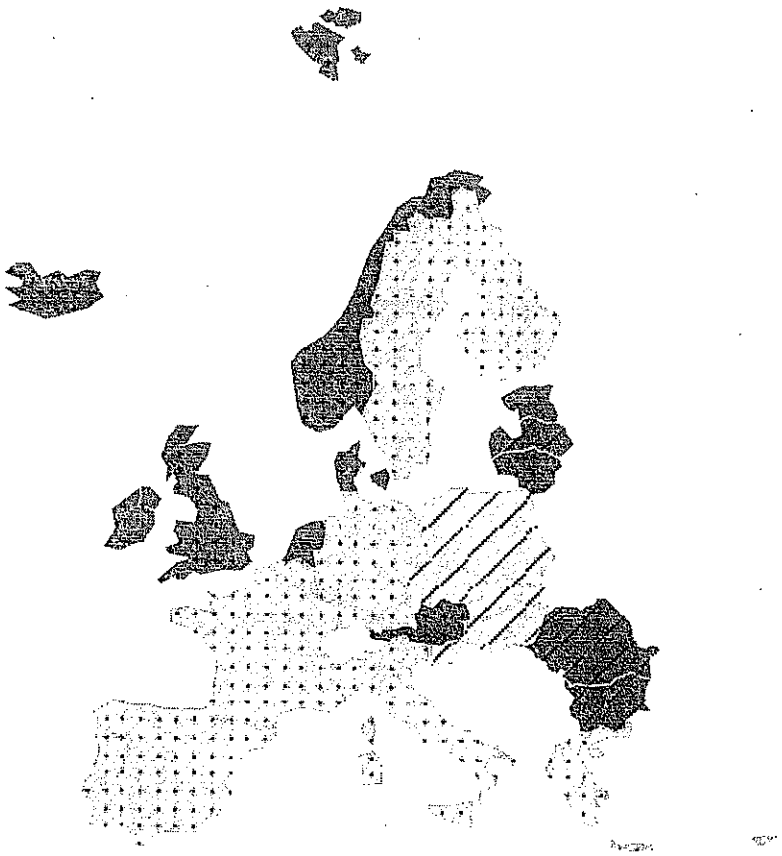
Data Visualization

In the following maps, one for each vaccine, countries where a vaccination is **mandatory** has been marked with a **lined background**, while those where the same vaccination is recommended have a **spotted background**.

Countries coloured in **green** have had an average higher vaccine coverage than the EU/EEA average – evaluated on

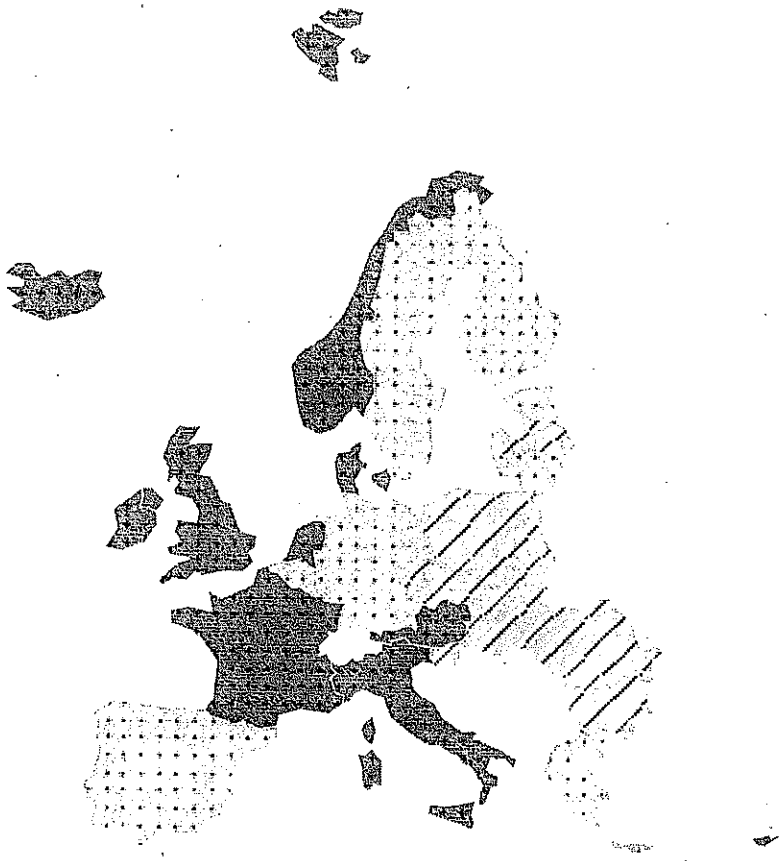
all the countries over the period considered – while the coverage is lower than the average in the **blue** ones.

No evident correlation between colours and different backgrounds appears from the maps.



Pertussis vaccination coverage in EU/EEA. Blue/green countries are below/above the European average. Mandatory vaccination has been marked with a lined background.

Polio vaccination coverage in EU/EEA. Blue/green countries are below/above the European average. Mandatory vaccination has been marked with a lined background.



Measles vaccination coverage in EU/EEA. Blue/green countries are below/above the European average. Mandatory vaccination has been marked with a lined background.

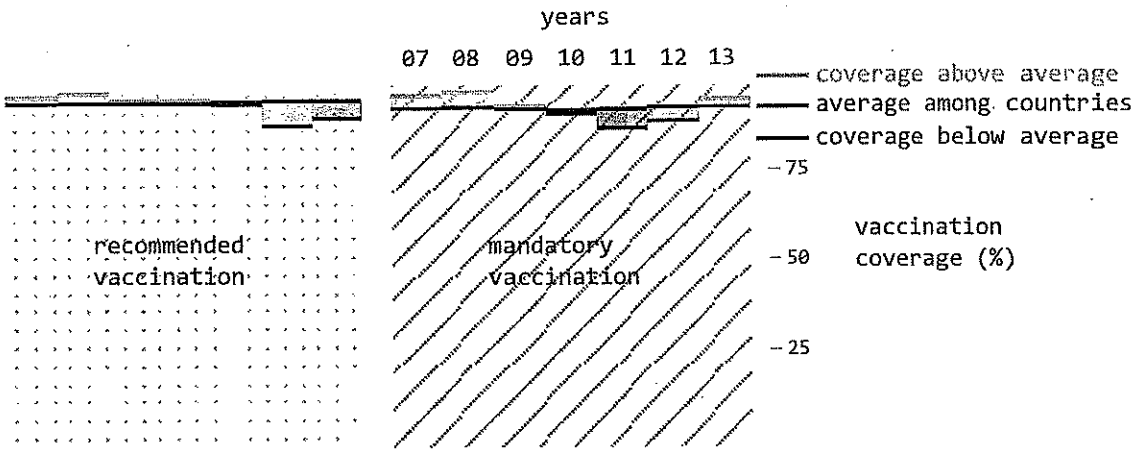
While maps can give a first, general overview at a glance, the following graphs further analyse the situation by showing the rates of immunization for Pol3, MCV1 and DTP3

vaccines in all EU/EEA countries from 2007 to 2013.

The **black line** shows the EU/EEA average, evaluated on all the countries, at the time, **while green and blue areas** indicate coverage, respectively higher or lower than the average, for each country and each vaccine.

The choice of showing the whole 0-100% range in the immunization rates, even if differences are always smaller, highlights countries where the vaccination coverage is significantly different from the average. As with previous maps, graphs consider if a vaccine is either mandatory or recommended: for each country, a **spotted background** indicates that a vaccine is recommended, while a **lined background** indicates that it is mandatory.

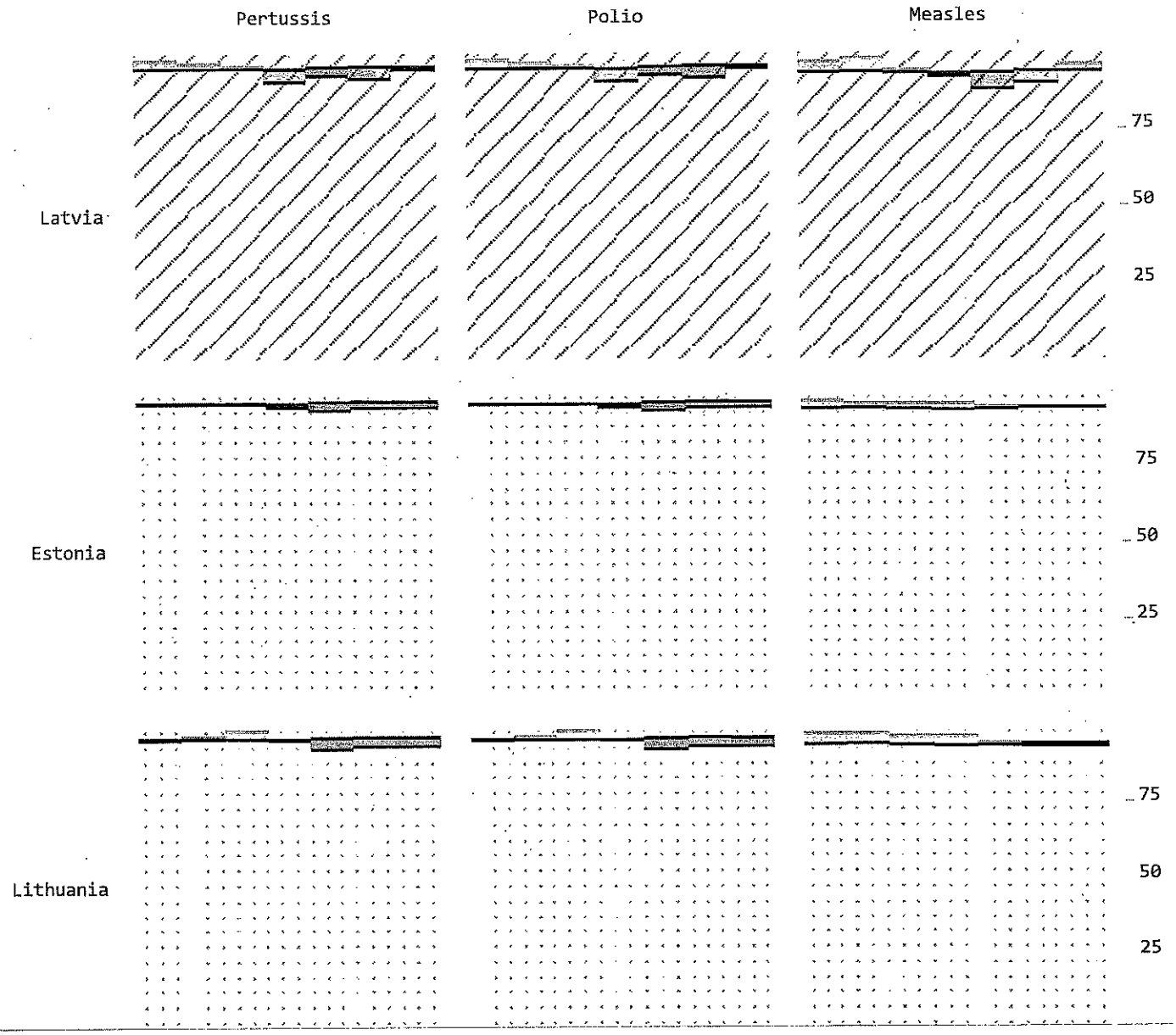
See graphs for all countries.



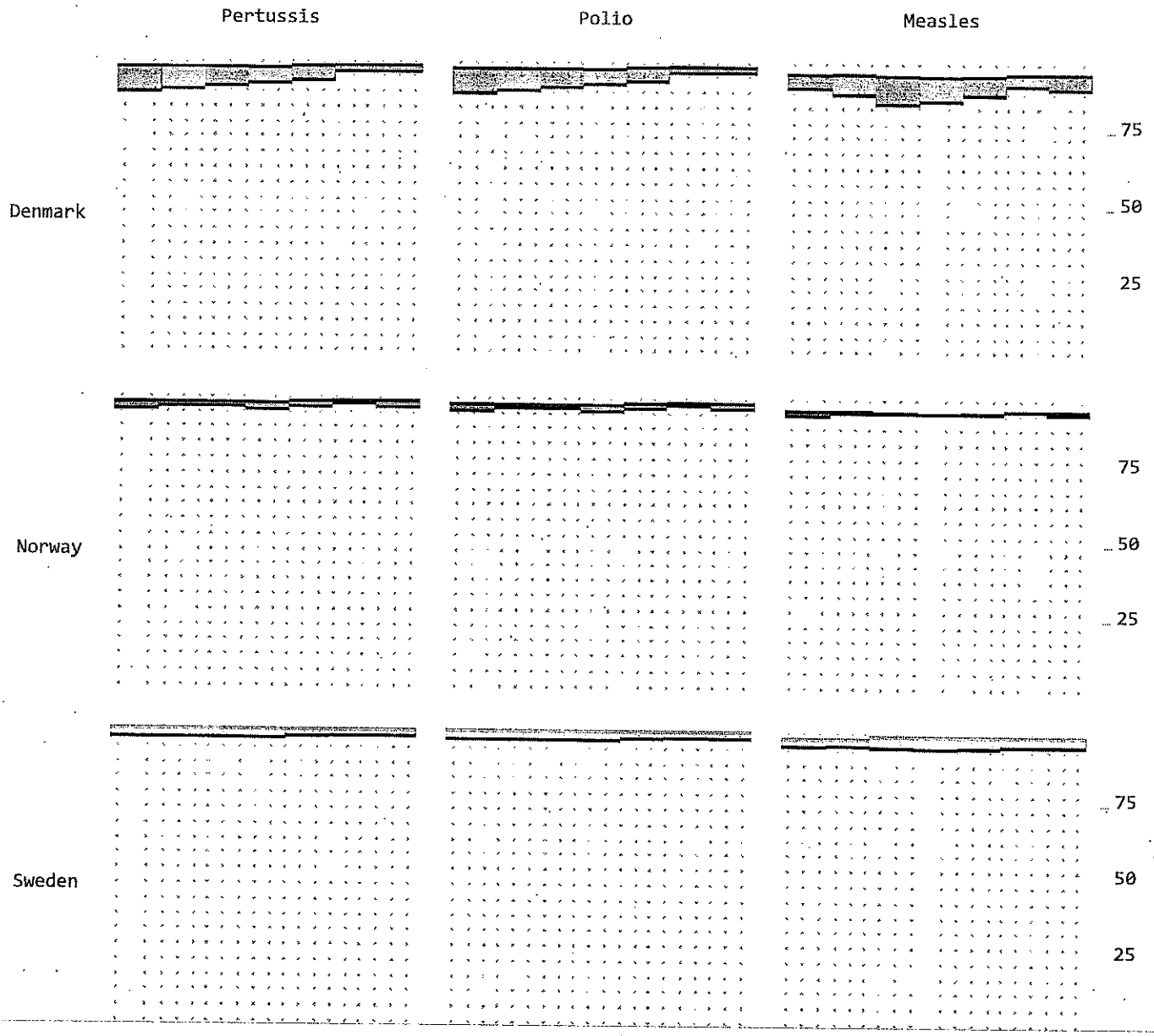
Discussion

This data visualization, showing temporal trends in immunisation rates in the EU/EEA countries in the last years for 3 main vaccines, does not suggest any evident relationship between vaccination coverage and national policies on compulsory vaccinations.

Some examples from the graphs confirm this idea. On one side, countries where a vaccination is mandatory do not usually reach better coverage than neighbour or similar countries where there is no legal obligation, as one can see comparing both Baltic and Scandinavian countries.



Baltic countries. Latvia, where vaccinations are mandatory, does not reach better coverage than other Baltic countries.

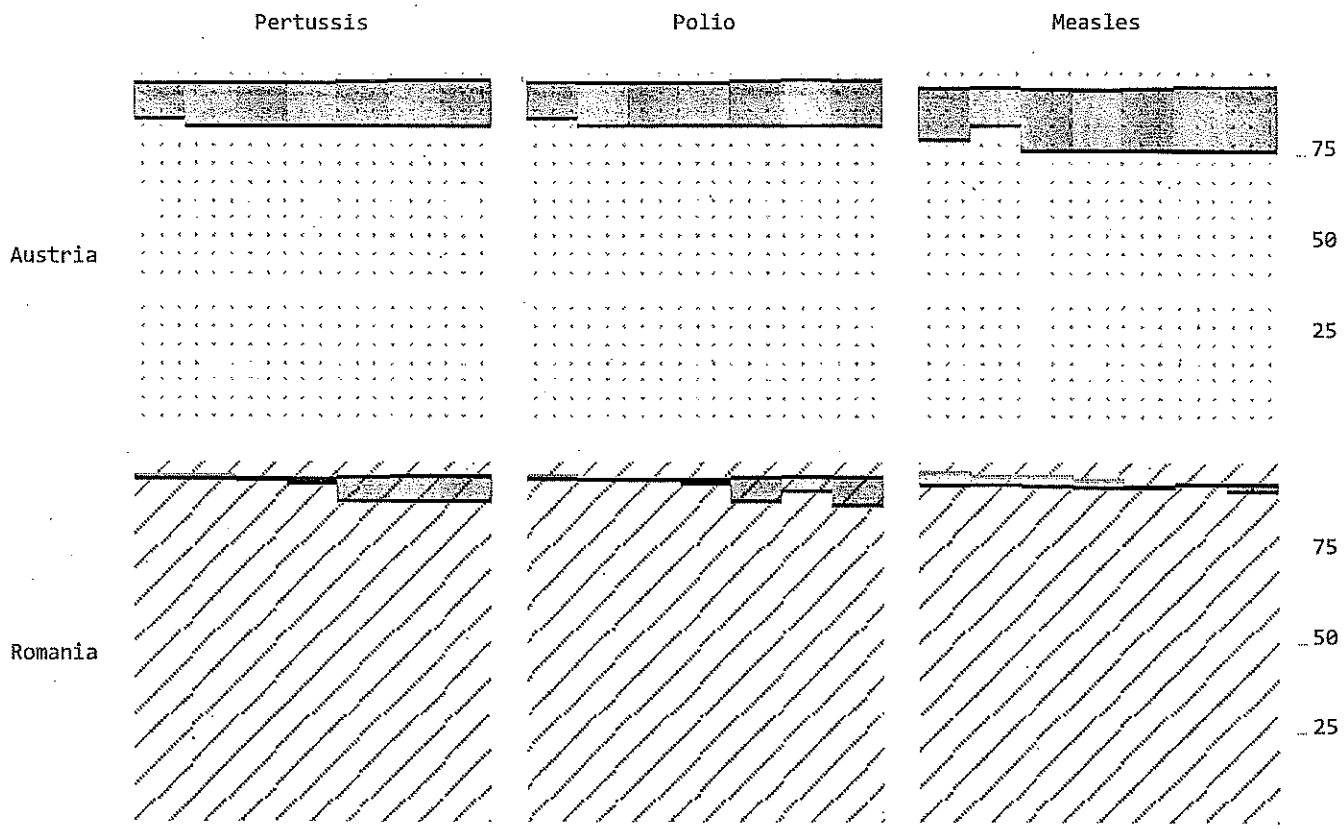


Scandinavian countries. Similar countries can show different scenarios despite same policy about recommended vaccination.

On the other side, similarly negative trends in very different

countries, with different policies about compulsory vaccination, suggest that other factors could be involved, ie.

not only hesitancy in parents, but also difficulties of healthcare systems in reaching all children.



Austria and Romania. Despite different policies about compulsory vaccination, Austria and Romania face similarly negative trends in immunization coverage.

Conclusions

This analysis has some limits. One is the lack of information on possible changes in national vaccination policies (recommended or mandatory) over the years, so preventing the possibility to understand if, in any case, a different approach could have influenced trends of immunisation. Thus, gathering these data will be a key step for future analysis.
We analysed data from only three relevant childhood vaccinations, assuming that they can reflect a general situation of immunisation rates in the EU/EEA countries. Anyway, the analysis could be extended to other vaccinations in the future. Even if this data visualization cannot provide full evidence of the efficacy or inefficacy of mandatory vaccinations on immunisation rates, it shows that this approach does not appear to be relevant in determining childhood immunisation rate in the EU/EEA countries.

Further analysis of maps and graphs could suggest new directions for further investigation.

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