COURT FILE NUMBER	
COURT	COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL CENTRE	WETASKIWIN
PLAINTIFFS	DR. BLAINE ACHEN, DR. GERT GROBLER DR. NADR JOMHA AND DR. TYLER MAY
DEFENDANT	ALBERTA HEALTH SERVICES
DOCUMENT	**AFFIDAVIT OF DR. TYLER MAY**

Clerk's Stamp

ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT

Ackroyd LLP
Barristers and Solicitors
1500, 10665 Jasper Avenue
Edmonton, Alberta T5J 3S9
Attention: Richard C. Secord

Justice Centre for Constitutional Freedoms
#253, 7620 Elbow Drive SW
Calgary, Alberta T2V 1K2
Attention: Eva Chipiuk

[redacted]

AFFIDAVIT OF DR. TYLER MAY
Sworn on December 7, 2021

I, Dr. Tyler May, of the Town of Manning, in the Province of Alberta, SWEAR AND SAY THAT:

1. I have personal knowledge of the facts herein deposed except where based on information and belief, in which case I verily believe same to be true.

Background Personal Information

2. I am a rural General Medical Practitioner ("GP") and the acting Community Medical Director ("CMD") at the Manning Community Health Centre in Manning, Alberta (the "Hospital"). The Manning Community Health Centre is comprised of an AHS-operated hospital and clinic. I practice in both locations. I was born and raised in Manning, Alberta, and have lived in Manning my entire life apart from the years I was away at University and Residency.

3. My late father's construction company was responsible for preparing the site for the Hospital, and I worked on the construction of the site in high school. I am, I believe, one of a handful of people in Canada who have grown up in, and subsequently returned to, a community of fewer than 2000 people as a practicing physician. I returned to Manning and performed my first locum here in October of 2012.

4. There was no permanent physician located in Manning when I arrived, and the community was in dire need of a physician.

5. I began practicing in Manning full-time in May of 2013. Alberta Health Services published two news releases congratulating me and welcoming me to the community. Attached hereto and marked **Exhibit "A"** to this my Affidavit are the two AHS News Releases.

6. I have practiced medicine full-time since my arrival. The scope of my practice entails the evaluation and management of acute inpatients, long-term care patients, lodge patients, emergency patients, urgent patients, and clinic patients. I work stretches of 24 hours on-call, typically ranging from 3 to 14 days where I am the physician solely responsible for all the duties.

7. In addition to my clinical work, I am also responsible for administrative tasks as the CMD for the Hospital. These tasks typically include on-call scheduling (there is one permanent physician in addition to me, as well as several locums that support us) and community advocacy.

8. For nearly 9 years I have covered every open shift at the Hospital because I could not find another physician that would work in Manning.

9. I spend much of my administrative time communicating with local and provincial politicians, as well as AHS administrators and Hospital staff, in an effort to ensure we do not suffer from service reductions or interruptions.

10. I have a Bachelor of Science Degree in General Sciences, with a minor in Political Science, from the University of Alberta. I have an MBBCh (MD equivalent) degree from the Royal College of Surgeons in Ireland in Dublin. My residency was completed at the University of British Columbia in Family Medicine. I passed the examination for certification from the College of Family Physicians of Canada (CCFP).

11. My experience as a physician in a rural outpost like Manning has been unique and varied. From run-of-the-mill chronic conditions like hypertension and diabetes to life-threatening traumas and heart attacks, the sole practicing rural GP must be prepared at any moment, for any situation.

12. My particular situation is perhaps more unique than most, in that many of these people are lifelong friends and family members. This perhaps both elevates the risk and the reward. In addition to my patients being close to me personally, they are also generally unhealthier than the average Albertan.

13. Epidemiological reporting from several years ago demonstrated our county had much higher incidences of Coronary Artery Disease, Diabetes, and Cancer than the Alberta average. Northern Alberta also suffers rates of suicide and depression that are above the Alberta average. In addition, we have lower numbers of physicians per capita than the Alberta average. What this information paints is a high risk, underserved population, in dire need of whatever services can be offered

14. AHS routinely fails to find coverage for rural Emergency Departments province wide. I've been acutely aware of the inequality in medical care for rural Alberta since I began practicing. I've advocated on multiple occasions for increased allied health staff and in particular mental health and physiotherapy.

15. After several years armed with this knowledge, I was particularly worried when I learned of the Covid pandemic in early 2020. The reports out of Italy were terrifying, and we were working in an under-resourced system with an at-risk population.

16. I was an early advocate of "two weeks to flatten the curve" as I'd never been through a pandemic before and was often practicing alone. However, it became apparent early on that the hysteria did not match what was witnessed at our facility, or in our community. And the harms of the lockdown policy were likely to be devastating and long-lasting.

17. We did not hospitalize our first Covid patients until the Spring of 2021 and since that time has had zero deaths in our practice due to Covid (there was one covid death at our hospital, but the patient was visiting our community).

18. We have had several sick people present with Covid, and some have had to be transferred to a higher level of care, but we have not had any of our patients die. There

have also been no patients that contracted Covid in the Hospital - despite 40% of our county being unvaccinated, and many of our staff being unvaccinated.

19. Given the specific data in the Hospital and our community, myself, and many of my working colleagues at the hospital found the AHS vaccine mandate announced in September ridiculous and unjustified.

My Covid Experience and My Request for Accommodation

20. I contracted Covid in late August of 2021, likely from my brother - as we operate a farm together. Attached hereto and marked **Exhibit "B"** to this my Affidavit is copy of my Covid-19 PCR test. As per AHS Guidelines, I was isolated for 10 days and nobody I have come into contact with since my recovery has been sick. Once my brother tested positive, I immediately self-isolated on my farm. I developed symptoms 3 days after him and was confirmed positive through a PCR test. I was contacted by AHS and occupational health and followed the protocols outlined by them. I made sure I drank lots of fluid and homemade bone broth from our grass-fed, free-range cows and chickens, took vitamin C, D, and Zinc, as well as raw honey from our hives. I began feeling improved after 2 days.

21. On September 14, 2021, AHS Policy 1189 was put in place effective October 31, 2021 (the "Policy").

22. I only heard about this new Policy through Facebook. On or about September 15th, 2021, I was contacted by telephone by Dr. Karen Lundgard, who is my Supervisor at AHS North Zone, asking me if I was going to be vaccinated. I informed her I was not vaccinated, nor was I planning to be. On or about September 16th, 2021, I was contacted by Dr. Brian Muir and Dr. Braeden Manns by telephone.

23. On or about October 15, 2021, I submitted a request for a religious exemption to AHS. I requested a religious exemption based on my rights of conscience, my sincere belief in personal autonomy, informed consent, non-maleficence, and the principle of first do no harm. I am also baptized Roman Catholic and believe that my rights are God-given. Attached hereto and marked as **Exhibit "C"** to this my Affidavit is a copy of my religious exemption. On October 18, 2021, I received a response from AHS denying my request

for exemption. Attached hereto and marked as **Exhibit "D"** to this my Affidavit is a copy of the denial from AHS.

24. On November 27, 2021, I had a meeting with Dr. Manns, via videoconference, following AHS' rejection of my request for religious accommodation. I also received an email from Dr. Muir but did not respond as it was not copied to the email from where I had sent my request for exemption - only to my AHS email - which I do not check regularly as I've always used my uAlberta email.

25. On November 27, 2021, Dr. Manns and I had a professional verbal discussion via zoom whereby he presented me with 4 options following the passing of the deadline:

    a. I could get vaccinated;

    b. I could change my practice from the Hospital to community only;

    c. I could go on a temporary Leave of Absence ("LOA"); or

    d. I could choose none of the first 3 options and AHS would sanction me and report me to the College of Physicians and Surgeons of Alberta.

26. I explained several things to Dr. Manns at our meeting: I felt a rapid testing option or, preferably, the recognition of natural immunity by AHS and my continued practicing would be most well aligned with the scientific evidence and best for all parties, but most of all, the patients, who suffer needlessly from the constant threat of losing their doctor and the continuity of care. I also said I was not happy with the short timeline to establish my own clinic as 2 weeks is not time enough (my EMR said it would take 2 months to move the files and Dr. Manns said there was likely nothing AHS could do in the interim to assist me).

27. I further explained to Dr. Manns that I suffer from a medical condition for which my primary care provider would provide me a medical exemption, but I chose not to submit one because I believe that my personal health is not the business of AHS. Dr. Manns proceeded to ask me if I was opposed to telling AHS my vaccination status or if I had concerns with the safety of the vaccine. I said "both". I then went on to discuss how the all-cause mortality data from the Pfizer trial was not favorable for the vaccine, that I'd seen and reported what I believe to be adverse reactions from the vaccine that I do not

believe were taken seriously by AHS and that I have significant concerns about the harms reported in the VAERS reporting system in the US (among countless other studies that cast doubt on vaccine efficacy and safety).

28. I also described to Dr. Manns a telephone call I had with Dr. Muir early in 2021: I received an anonymous complaint about my reservations on the supposed benefit of public masking and vaccine safety. Dr. Muir called me to discuss the complaint. I said that I had been reading reports out of Europe on blood clotting issues with the AstraZeneca vaccine and that I didn't feel comfortable prescribing it. In fact, I felt that I should tell people not to get it. I reiterated to him that it had always been my practice to avoid prescribing new or improperly researched medications to my patients and that this advice came from a mentor during my residency who avoided harming anyone with thalidomide by adopting this policy. Dr. Muir, while somewhat sympathetic, went on to relay to me that it would be my peers judging me and that I'd be better off doing what everyone else was doing rather than following the most up-to-date science. AstraZeneca was pulled from the market in Canada less than a month later over those very safety concerns.

29. Dr. Manns then reiterated that it is not a health policy, it is a vaccination policy. I asked for some time to consider my options and he gave me 48 hours. I responded that I would take the reduced privileges to community practice only.

30. I was then contacted by the North Zone supervisor to change my privileges. However, I chose to wait it out before I signed my privileges away as AHS had changed its mind last time, so I was still hopeful for an exemption.

31. On Monday, AHS announced that there would be an exception to the Policy for certain sites - mine being one of them. I was made aware of this in a meeting with Dr. Muir on December 3, 2021. Dr. Muir said I would have a rapid testing option every 48 hours. However, I would only be able to work in the Hospital, not the AHS-funded clinic - as only the Hospital, not the clinic, had been deemed a facility in need.

32. AHS' decision is completely arbitrary and absurd, as the facilities are intimately linked, and it provides another example of AHS putting ideology and policy before patient care - much like the Policy itself. I am to meet with Dr. Muir next week to discuss the negative impacts this will have on my community, but the Policy is unlikely to change. AHS' decision leaves my patients without a medical home until at least February - which is

unforgivable and will inevitably have a negative impact because continuity of care is one of the cornerstones of quality, patient-centered, medical practice.

33. As for the ongoing hospital privileges, Dr. Muir said they can be revoked at any time if AHS finds enough vaccinated staff to work at this site. Tentatively, I can continue working until the March 29th policy review, but there is no guarantee. You can imagine how difficult all this unnecessary uncertainty has been on my patients and myself.

My Professional Judgement

34. There are multiple and varied reasons I have thus far for deciding not to take the vaccine. Firstly, I have a sincere belief in the principles of personal autonomy, informed consent, and duty to disclose. This is a basic medical premise and I do not believe what AHS is doing is in line with established medical principles. I believe the criteria for informed consent and duty to disclose cannot be met, as the vaccine trials were completed in months (rather than years) and arrived at hastily drawn conclusions. Thus, the medicine is experimental.

35. The all-cause mortality in the Pfizer trial was higher in the treatment group (15 deaths) than the placebo group (14 deaths) before unblinding - which is the exact opposite effect one would expect to find with a safe, effective vaccine during a pandemic. Attached hereto and marked **Exhibit "E"** to this my Affidavit is a copy of that study. The benefit from the vaccine to those at low risk of severe outcome was negligible - on the order of 0.7-1.2% absolute risk reduction in symptoms (interestingly, the relative risk reduction was the metric chosen by public health to communicate drug efficacy to the public - going against the best practice advice in communicating drug efficacy to patients from previous research).

36. The vaccine does not prevent all covid deaths, as there was a covid death in the vaccinated cohort. Attached hereto and marked **Exhibit "F"** to this my Affidavit is an article regarding vaccine safety. There also is no long-term data on persistent versus waning vaccine efficacy, or the efficacy of the vaccine against future variants. It also does not prevent the transmission of the virus. Given the totality of evidence from the vaccine trials, and subsequent research, it's reasonable to conclude that the vaccines confer minimal absolute benefit to a low-risk, Covid recovered person, while being accompanied by a multitude of unknown potential harms. The massive spike in adverse events and

death reporting to VAERS and the yellow card adverse events reporting systems in the US and UK further lends weight to this. Attached hereto and marked **Exhibit "G"** to this my Affidavit is the VAERS reporting system webpage.

37. There are too many unknowns for me to be truly and adequately informed. Additionally, I previously had Covid. This confers upon me incredible immunity to the virus and its variants, as demonstrated in the most up-to-date scientific research. Attached hereto and marked **Exhibit "H"** to this my Affidavit is a recent research article. My risk of re-infection is lower than that of vaccinated individuals, making me the safest person to be practicing medicine in a clinical setting. Natural immunity is recognized in multiple jurisdictions, including in the United States, as well as by prominent epidemiologists from Stanford, Oxford, and Harvard. Attached hereto and marked **Exhibit "I"** to this my Affidavit is an article from a Harvard epidemiologist.

38. There is also evidence that getting vaccinated after having had Covid increases your risk of vaccine-related adverse events. Attached hereto and marked **Exhibit "J"** to this my Affidavit is a copy of a study evidencing this. Thus, the vaccine offers me no protection with potential harm. It is completely irresponsible and reckless to force someone into taking the vaccine at this time with so many unknowns and so many risks.

39. Lastly, I have a medical condition for which there are no studies on how the vaccine might affect it. Because of this, I am reluctant to take any medication without long-term safety data with respect to the condition. There is evidence that those with chronic illnesses may have their conditions exacerbated by vaccination and no one is liable for any negative impacts that might happen to me. I would rather not be one of those cases. I further worry about how this vaccination will affect my immunity to other viruses such as influenza - as research shows receiving an influenza vaccine increases your risk for acquiring coronavirus.

40. Given all the above and exercising my rights of personal autonomy and informed consent, I choose not to be part of an experiment of dubious benefit, and potential harm, simply because it's an administrative "vaccination policy".

41. AHS' indiscriminate and arbitrary Policy is causing irreparable harm to me personally, and the public health care system in Alberta generally, particularly in my community where there has always been a persistent problem of understaffing.

42. I undertake to indemnify the Defendant in the event of a loss of this application.

43. I swear this affidavit *bona fide*, in support of the within action and injunction application and for no improper purpose.

SWORN BEFORE ME at)
Mannville, Alberta, this 8th,)
day of December 2021.)
[redacted])
A Commissioner for Oaths)
in and for the Province of Alberta)

[redacted]

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

Exhibit "A"

This is **Exhibit "A"** referred to in the
Affidavit of Tyler May
sworn (or affirmed) before me at
Grande Prairie, Alberta, this
8th day of December, 2021.

A Commissioner/Notary Public in and
for the Province of Alberta

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

A CMOH order remains in effect that requires continuous masking at all AHS and Covenant facilities provincewide.

Family physician comes home and sets up practice

July 24, 2013

MANNING — Patients are now being accepted by a new local physician, who has returned to his hometown to practise family medicine.

Dr. Tyler May was born and raised in Manning. He moved to Dublin, Ireland, to receive his medical training, and completed his medical residency in Dawson Creek, B.C. He is now accepting patients at the Manning Community Health Centre.

"It's a pleasure to welcome Dr. May back to Manning," says Frank Oberle, Associate Minister of Services for Persons with Disabilities, and MLA for Peace River. "Albertans must have access to a family doctor so they can remain healthy and enjoy a good quality of life. Dr. May's return will benefit his hometown and surrounding communities for years to come."

Susan Smith, North Zone physician resource planner with Alberta Health Services (AHS), says Dr. May's goal was always to return home and practise medicine. She worked closely with him to ensure his return as smooth as possible.

"We are very lucky to have him working in Manning," Smith says. "I would like to especially thank Jo Keleman, site manager for the Manning Community Health Centre. She played a very important role in the arrival of Dr. May and with thanks to her efforts, residents who don't have a family doctor now have an opportunity to see Dr. May. That's good for the overall health of our community."

AHS has three physician resource planners dedicated to identifying and pursuing international and domestic physician recruitment opportunities in the North Zone of AHS. They work closely with the Government of Alberta and various community partners and organizations, such as the Rural Physician Action Plan, Health Advisory Councils and independent community physician recruitment and retention committees, to recruit international and domestic physicians to communities across the AHS North Zone.

“While some Albertans head overseas or out of province to secure their medical training, we are always very excited to have them come back home. Having worked with Tyler, I can personally attest to the exceptional skills he brings to Manning – we’re lucky to have him,” say Dr Karen Lundgard, Deputy Associate Zone Medical Director/Senior Physician Leader overseeing Manning.

In his spare time, Dr. May enjoys cattle farming, hunting and fishing, and staying active with a number of activities, including running, cycling and snowboarding. He said he is looking forward to be able to enjoy life in a small community again.

Alberta Health Services is the provincial health authority responsible for planning and delivering health supports and services for more than 3.9 million adults and children living in Alberta. Its mission is to provide a patient-focused, quality health system that is accessible and sustainable for all Albertans.

- 30 -

A CMOH order remains in effect that requires continuous masking at all AHS and Covenant facilities provincewide.

New family physician accepting patients in Manning

July 12, 2016

MANNING — A newly recruited family physician is now accepting patients, increasing local access to primary care for residents.

Dr. Ansie Capon is a family medicine physician with a sub-specialty in emergency medicine. Trained in her native South Africa, Dr. Capon started practising in the community in May and is providing care at the Manning Medical Clinic and Manning Community Health Centre.

Dr. Capon joins Dr. Tyler May as Manning's second permanent physician.

"Between Dr. May and now Dr. Capon, I think we have a very envious complement of resident doctors," says Terry Ungarian, Chair of the Manning Community Physician Attraction & Retention Coalition. "We're very excited about Dr. Capon. She's young and enthusiastic, and has embraced our community right away."

Dr. Capon says she and her husband Murray visited the community and clinic last year, and left feeling like this is where they belong.

"The people just blew us away with their sincere hospitality and welcoming attitude," Dr. Capon says. "On our site visits, we saw other bigger, busier towns with bigger, busier hospitals and more things to do. But, in the end, it was the people of Manning who stole our hearts."

Dr. Capon was recruited through a joint effort by Alberta Health Services (AHS); the Manning Community Physician Attraction & Retention Coalition; Dr. May; Manning Community Health Centre site manager Jo Kelemen; and community partners.

“The community engagement and support has been second to none as has the Capons’ enthusiasm and eagerness to settle into Manning,” says Susan Smith, AHS Physician Resource Planner, North Zone. “They have received many dinner invitations since arriving in the community, and Murray has already been recruited to join the local fire department.”

The community is going to benefit from Dr. Capon’s experience, says Dr. Karen Lundgard, Associate Zone Medical Director Area 2. “We’re always looking for ways to improve patient care in the community,” she says. “We're very pleased that Dr. Capon is here and know that she is looking forward to providing medical care and getting to know the people of Manning.”

Alberta Health Services is the provincial health authority responsible for planning and delivering health supports and services for more than four million adults and children living in Alberta. Its mission is to provide a patient-focused, quality health system that is accessible and sustainable for all Albertans.

- 30 -

For media inquiries, contact:

Erika Dart
AHS Communications
780-538-6146

Exhibit "B"

COVID-19 Variant NAT --

Order: [redacted]

Status: Edited Result - FINAL Visible to patient: No (not released)

Component	3 mo ago
COVID-19 (RNA) Variant NAT	**Positive !**

Comment: Information and Comments:
Specimen: Swab - Throat

INTERPRETATION: This specimen is confirmed positive for a variant of concern.
This is the final result. See https://www.albertahealthservices.ca/topics/Page17381.aspx for more information on COVID-19 variants of concern.
METHOD: This nucleic acid test (NAT) detects the presence of mutations associated with SARS-CoV-2 variants of concern using real-time reverse-transcriptase PCR assays developed and validated at ProvLab. Nucleic
acid sequencing may be used to determine the lineage.
DISCLAIMER: These methods are for surveillance purposes, not clinical diagnostic purposes. They have not been cleared or approved by the US FDA or
Health Canada and results should be interpreted in the clinical and epidemiological context.

COVID-19 (RNA) Lineage B.1.617.2

Resulting Agency MILLENNIUM LAB INFORMATION SYSTEM

Narrative

Performed by: MILLENNIUM

Copy To: MOH, North Zone West Area Public Health; MOH, Alberta Health CDC

Reported to Health Agency Patient Address: [redacted]

Performed at ProvLab Edmonton

Specimen Collected: 31/08/21 10:00 Last Resulted: 01/09/21 20:14

Order Details | View Encounter | Lab and Collection Details | Routing | Result History - Result Edited

Result Care Coordination

Patient Communication

Not Released ✖ Not seen

This is **Exhibit "B"** referred to in the Affidavit of Tyler May sworn (or affirmed) before me at Morinville, Alberta, this 8th day of December, 2021.

A Commissioner/Notary Public in and for the Province of Alberta

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

Lab IDs

Specimen # [redacted]

Accession # [redacted]

Collection Information

Exhibit "C"

This is **Exhibit "C"** referred to in the
Affidavit of Tyler May
sworn (or affirmed) before me at
Mundare, Alberta, this
8 th day of December, 2021.

A Commissioner/Notary Public in and
for the Province of Alberta

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

In keeping with AHS' mission and values and to protect AHS' workers, patients and others accessing the health system and at all AHS sites, AHS leadership has established the Immunization of Workers for COVID-19 Policy (Policy 1189) (the "Policy"). As of October 31, 2021, Alberta Health Services, Alberta Precision Laboratories, Carewest, CapitalCare, and Covenant Health employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on their behalf will be required to be fully vaccinated and have provided proof of vaccination to AHS.

This questionnaire may be submitted by any AHS Medical or Midwifery Staff member who is not an AHS, Alberta Precision Lab or Covenant Health employee who wishes to be granted an exception under the Policy. It may also be used by medical residents or fellows who are not AHS employees. If the request includes a medical exception request (Part 2 of this form), it must also be filled in and signed by a regulated Primary Care Provider. If the Medical or Midwifery Staff member is an AHS, Alberta Precision Lab or Covenant Health employee, the employee process must be followed and not this exception request process.

Completed forms should be submitted by email to md.midwife.covidvacc@ahs.ca

Part 1. Medical or Midwifery Staff Member Identification

Last Name	First Name
May	Tyler

Regulatory College	Registration Number
☑ CPSA ☐ ADAC ☐ Podiatry ☐ Midwifery	019422

Nature of Exception Request

☐ Medical Exception *(Part 2 to be completed by Primary Care Practitioner)*
☑ Other Exception *(Part 3 to be completed the Medical or Midwifery Staff member)*

Part 2: Medical Exception Details

To be completed by the Primary Care Provider providing care to the Medical or Midwifery Staff Member named in Part 1. The Medical or Midwifery Staff member is responsible for any costs the Primary Care Provider may charge to complete this form.

☑ **I acknowledge** that I have reviewed the information on contraindications and recommended precautions for COVID-19 vaccines and links to resources *(pages 4 and 5 of this form).*

Number of years you have known the individual named in Part 1 as a patient of yours? _____

Does the patient have any of the contraindications or recommended precautions to receiving COVID-19 vaccine that are noted in the references provided? ☐ Yes ☐ No

If yes, please specify reason _____

Do you feel that the patient should not receive the COVID-19 vaccine due to a medical condition that **is not** listed as a contraindication or recommended precaution? ☐ Yes ☐ No

If yes, please specify reason _____

If your patient has a medical condition that precludes COVID-19 immunization, then what is the anticipated timeframe?

☐ Permanent ☐ Temporary *(if checked, specify time to resolution)* _____

Has your patient previously received a dose of COVID-19 vaccine? ☐ Yes ☐ No

If yes, details related to vaccine below ▼

Date Vaccine Received *(dd-Mon-yyyy)*	Type of Vaccine
	☐ Pfizer ☐ Moderna ☐ AstraZeneca ☐ Other *(specify)* _____

Alberta Health Services

Medical or Midwifery Staff Request for Exception
COVID-19 Mandatory Immunization for Workers

Part 3. Other Reason for Exception Request
To be completed by the Medical or Midwifery Staff member named in Part 1.

If there are any grounds other than medical on which you are requesting an exception under the Policy, please describe those grounds and any relevant, associated context.

I believe I am eligible for an exemption the vaccine mandate policy imposed by AHS based on my religious beliefs, my rights of conscience and sound medical evidence that contradicts AHS policy.

I am baptized Roman Catholic. I believe, and have always believed, that my individual rights are granted by God, not by AHS or the government. Those rights include: the right to personal autonomy, the right to informed consent, the right to refuse medical treatment and the right life, liberty and security of the person. These rights are also granted to me in the Canadian Charter of RIghts and Freedoms, and have been affirmed by the Supreme Court of Canada. The Charter guarantees my right to freedom of conscience, and freedom of religion, and to manifest these beliefs in my daily life without fear of reprisal or undue hardship.

Addtionally, there is a plethora of established and emerging medical evidence that effectively nullifies the rationale for AHS adopting such a restrictive policy regarding COVID vaccination. Examples include but are not limited to: unfavourable all cause mortality data in the Pfizer vaccine trial, inability of the vaccines to reduce transmission or infection rates, waning efficacy of the vaccines against the Delta variant, robust natural immunity that is superior to vaccine derived immunity, incomplete vaccine trial data, no long term study of non-specific vaccine side effects, alarming trend toward harm in VAERS data from the US and yellowcard data from the UK, and the US FDA recommending against booster shots for those under 65 years of age. That list is by no means exhaustive.

Finally, there are solutions outside of mandatory vaccination to AHS concerns surrounding patient safety. Those include regular, rapid testing while on shift, or antibody testing for evidence of past infection. Both are easily attainable, and probably enhance patient safety to a greater extent than mandatory vaccination policy - given that the vaccinated can still aquire and spread COVID. In fact, a mandatory rapid testing policy for all employees, vaccinated or unvaccinated, is in line with the best medical evidence currently available.

I have had COVID recently. The most robust evidence to date demostrates that I am less likely than my vaccinated peers to catch or transmit COVID. Patients are more safe in my care than in the care of my vaccinated colleagues. It is my hope that this sound medical science will be respected.

Sincerely,

DR TYLER MAY.

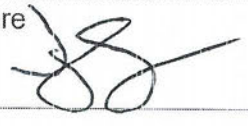
Medical or Midwifery Staff Member Signature	Date *(dd-Mon-yyyy)*
	15-OCT-2021

Exhibit "D"

Alberta Health Services

Healthy Albertans.
Healthy Communities.
Together.

Confidential

October 18, 2021

DELIVERED VIA EMAIL

This is **Exhibit "D"** referred to in the
Affidavit of Tyler May
sworn (or affirmed) before me at
Manning, Alberta, this
8th day of December, 2021.

A Commissioner/Notary Public in and
for the Province of Alberta

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

Dr. Tyler May
[redacted]
[redacted]

Dear Dr. May,

Re: Request for Exception to Immunization of Workers for COVID-19 Policy

I write with respect to your request for an exception to the Immunization of Workers for COVID-19 Policy (Policy), dated October 15, 2021, and received October 15, 2021.

All exception requests for members of the Medical Staff are reviewed by the AHS Medical and Midwifery Exception Review Panel at first instance, which makes a recommendation to me in my role as Zone Medical Director, North Zone. In this regard, please find enclosed with this letter, a copy of the report of the Exception Review Panel.

As set out in the enclosed report, the Exception Review Panel has recommended that your exception request be denied.

I agree with the recommendation of the Exception Review Panel. While I understand that you have expressed a religious belief against receiving a Covid-19 vaccine, AHS' foremost concern is to ensure the safety and wellbeing of its staff and the patients under its care. As a result, AHS will not be granting you a religious exception as mandatory vaccination is necessary to protect the patients and staff at its facilities and to ensure the continued delivery of healthcare in a safe manner.

As a result of your request being denied, in accordance with section 3.4.4.5 of the Medical Staff Rules, I have determined that further action or investigation is required by my office. Please contact my assistant, Ms. Karen Burdick to schedule a brief online or telephone meeting this week to discuss whether you intend to become fully immunized, and the path forward.

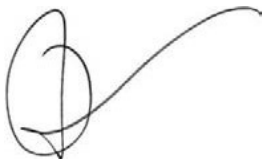
In accordance with section 4 of the Policy, at this meeting, we can also discuss any concerns you may have regarding COVID-19 vaccination and any information that would assist you in making your decision.

Zone Medical Director, North
Rm 124, Box 3520, 205 Diamond Avenue,
Spruce Grove, AB T7X 3A8
Email: Brian.Muir@ahs.ca

Additionally, I can also arrange a discussion with Dr. Koliaska, Medical Officer Health, North Zone who has expertise in the area of COVID-19 vaccines, in this regard. Please let me know if you would like me to facilitate a meeting between you and Dr. Koliaska.

If you would like to request an exception for medical reasons, you may do so by following the same process and providing the appropriate information.

Sincerely,



Dr. Brian Muir
Zone Medical Director, North – AHS

Encl. Exception Review Panel Report

North Zone
RECOMMENDATION by the AHS MEDICAL and MIDWIFERY STAFF EXCEPTION REVIEW PANEL on an EXCEPTION REQUEST of the IMMUNIZATION OF WORKERS FOR COVID-19 POLICY 1189

CONFIDENTIAL

Name of Medical Staff Member: Dr. Tyler May
College & Registration Number: [redacted]
ID: [redacted]

Date: October 15, 2021

I. Nature of the Request

On October 15, 2021 Dr. Tyler May submitted a request for an exception of the AHS Immunization of Workers for COVID-19 Policy 1189 (Policy), in accordance with paragraph 3.4 of the Policy. The request for exception was for Non-Medical Reasons.

II. Supporting Documentation Provided

On October 15, 2021 Dr. Tyler May submitted the following documents in support of the exception request:

a. Dr. May Religious Exemption.pdf

III. Recommendation

In considering the request dated October 15, 2021 and the documents provided, the Panel recommends that an exception on the basis of Non-Medical Reasons **not be approved** by the North Zone Medical Director.

IV. Reasons

The applicant has applied for a **non-medical exception** to receiving the COVID-19 vaccination. The request was reviewed by the members of the Physician & Midwifery COVID-19 Vaccination Exemption Review Panel who reached a unanimous decision that the exception **is not recommended.**

AHS is committed to protecting the health and safety of its workers, patients, visitors, and others accessing AHS sites. Immunization against COVID-19 is the most effective means to prevent the spread of COVID-19, to prevent outbreaks in AHS facilities, to preserve workforce capacity to support the health care system, and to protect our workers, patients, visitors, and others accessing AHS sites. Immunization against COVID-19 also supports AHS' Values of Compassion, Accountability, Respect, Excellence, and Safety.

On September 14, 2021, AHS implemented the Policy to address immunization requirements for COVID-19 as a measure to protect the health and safety of workers, patients, and the communities AHS serves. The Policy applies to all AHS employees and members of the Medical and Midwifery Staff, except as otherwise indicated.

The Policy requires that all workers (as defined the Policy) must be fully immunized against COVID-19 by October 31, 2021. Fully immunized means having received two doses of a vaccine considered valid by Alberta Health in a two dose COVID-19 vaccine series or one dose of a vaccine considered valid by Alberta Health in a one dose COVID-19 vaccine series; and for whom fourteen days have elapsed since the date on which the person received the second dose of the COVID-19 vaccine considered valid by Alberta Health of a two dose series or one dose of the COVID-19 vaccine considered valid by Alberta Health in a one dose vaccine series.

The Policy contemplates that there may be instances in which a member of the Medical Staff is unable to be immunized due to a medical reason. In such instances, and upon the request of the individual, this Panel has evaluated the exception request.

V. Next Steps

This recommendation will be provided to Dr. Brian Muir, North Zone Medical Director.

Exhibit "E"

ORIGINAL ARTICLE

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

S.J. Thomas, E.D. Moreira, Jr., N. Kitchin, J. Absalon, A. Gurtman, S. Lockhart, J.L. Perez, G. Pérez Marc, F.P. Polack, C. Zerbini, R. Bailey, K.A. Swanson, X. Xu, S. Roychoudhury, K. Koury, S. Bouguermouh, W.V. Kalina, D. Cooper, R.W. Frenck, Jr., L.L. Hammitt, Ö. Türeci, H. Nell, A. Schaefer, S. Ünal, Q. Yang, P. Liberator, D.B. Tresnan, S. Mather, P.R. Dormitzer, U. Şahin, W.C. Gruber, and K.U. Jansen, for the C4591001 Clinical Trial Group*

ABSTRACT

BACKGROUND

BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike protein. BNT162b2 is highly efficacious against coronavirus disease 2019 (Covid-19) and is currently approved, conditionally approved, or authorized for emergency use worldwide. At the time of initial authorization, data beyond 2 months after vaccination were unavailable.

METHODS

In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy trial, we randomly assigned 44,165 participants 16 years of age or older and 2264 participants 12 to 15 years of age to receive two 30-μg doses, at 21 days apart, of BNT162b2 or placebo. The trial end points were vaccine efficacy against laboratory-confirmed Covid-19 and safety, which were both evaluated through 6 months after vaccination.

RESULTS

BNT162b2 continued to be safe and have an acceptable adverse-event profile. Few participants had adverse events leading to withdrawal from the trial. Vaccine efficacy against Covid-19 was 91.3% (95% confidence interval [CI], 89.0 to 93.2) through 6 months of follow-up among the participants without evidence of previous SARS-CoV-2 infection who could be evaluated. There was a gradual decline in vaccine efficacy. Vaccine efficacy of 86 to 100% was seen across countries and in populations with diverse ages, sexes, race or ethnic groups, and risk factors for Covid-19 among participants without evidence of previous infection with SARS-CoV-2. Vaccine efficacy against severe disease was 96.7% (95% CI, 80.3 to 99.9). In South Africa, where the SARS-CoV-2 variant of concern B.1.351 (or beta) was predominant, a vaccine efficacy of 100% (95% CI, 53.5 to 100) was observed.

CONCLUSIONS

Through 6 months of follow-up and despite a gradual decline in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing Covid-19. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Dormitzer can be contacted at philip.dormitzer@pfizer.com or at Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965.

*A list of the investigators in the C4591001 Clinical Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

This article was published on September 15, 2021, at NEJM.org.

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DOI: 10.1056/NEJMoa2110345

CME at NEJM.org

A Quick Take is available at NEJM.org

The coronavirus disease 2019 (COVID-19) pandemic continues, with recent estimates of more than 187 million cases diagnosed and more than 4 million deaths.[1] Vaccines are currently available by means of full approval, conditional marketing approval, and emergency use authorization pathways.[2-5] BNT162b2 is a lipid nanoparticle–formulated,[6] nucleoside-modified RNA[7] encoding the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) full-length spike glycoprotein in a prefusion stabilized conformation.[8] To date, more than 1 billion doses of BNT162b2 have been distributed.

We previously reported safety and efficacy data obtained through a median of 2 months of postimmunization follow-up from a global phase 1–2–3 trial of BNT162b2 involving persons 16 years of age or older. Vaccine efficacy against Covid-19 was 95%. BNT162b2 had a favorable safety profile in diverse populations.[9] These data formed the basis for BNT162b2 emergency or conditional authorizations globally.[10] Safety, efficacy, and immunogenicity data from participants 12 to 15 years of age in this trial have been reported.[11] Here, we report safety and efficacy findings from a prespecified analysis of the phase 2–3 portion of the trial through approximately 6 months of follow-up. These additional data contributed to the full approval of BNT162b2 in the United States.

Methods

Objectives, Participants, and Oversight

This randomized, placebo-controlled, observer-blinded, phase 1–2–3 trial assessed the safety, efficacy, and immunogenicity of the BNT162b2 vaccine in adolescents and adults. The current report of the findings from the phase 2–3 portion of the trial focuses on safety assessments among participants 16 years of age or older and prespecified assessments of vaccine efficacy among participants 12 years of age or older through 6 months of follow-up after immunization. Because the enrollment of participants 12 to 15 years of age began on October 15, 2020, 6-month postimmunization data are currently unavailable for this age cohort. Shorter-duration safety, immunogenicity, and efficacy data for participants 12 to 15 years of age are reported separately[11]; however, data for this cohort are included in the analyses of vaccine efficacy in the overall population (all participants ≥12 years of age) reported here.

Participants who were healthy or had stable chronic medical conditions were eligible. An active immunocompromising condition or recent immunosuppressive therapy was an exclusion criterion. Participants with a history of Covid-19 were excluded, although evidence of current or previous SARS-CoV-2 infection on laboratory testing of trial-obtained samples was not an exclusion criterion. Trial-related responsibilities and ethical conduct are summarized in the Supplementary Appendix, available with the full text of this article at NEJM.org. The protocol contains additional details of the trial and is available at NEJM.org. The first draft of the manuscript was written by the fourth author. The authors had the opportunity to review the data included in this article and confirm the accuracy of the data presented through the specified data cutoff date. The authors vouch for the accuracy and completeness of the data and for the fidelity of the trial to the protocol.

Procedures

The participants were randomly assigned in a 1:1 ratio to receive two 30-μg intramuscular injections, 21 days apart, of BNT162b2 (0.3 ml volume per dose) or saline placebo. Randomization was performed with an interactive Web-based system. Starting in December 2020, after BNT162b2 became available under emergency or conditional use authorizations, participants 16 years of age or older who became eligible for Covid-19 vaccination according to national or local recommendations were given the option to learn their trial assignment. Those who had been randomly assigned to receive placebo were offered BNT162b2. After unblinding of the group assignments, participants were followed in an open-label trial period.

Safety

Safety end points included solicited, prespecified local reactions, systemic events, and antipyretic or pain medication use during the first 7 days after receipt of each vaccine or placebo dose, which were recorded in an electronic diary; unsolicited adverse events after receipt of the first dose through 1 month after the second dose; and serious adverse events after receipt of the first dose through 1 and 6 months after the second dose

was received. Safety data are presented for the blinded follow-up and open-label periods.

EFFICACY

BNT162b2 efficacy against laboratory-confirmed Covid-19 with an onset of 7 days or more after the second dose was assessed and summarized descriptively in participants without serologic or virologic evidence of SARS-CoV-2 infection within 7 days after the second dose and in participants with or without evidence of previous infection. Efficacy against severe Covid-19 was also assessed. Lineages of SARS-CoV-2 detected in midturbinate specimens are reported here for Covid-19 cases that occurred 7 days or more after the second dose in South African participants without evidence of previous infection. Methods for determining SARS-CoV-2 lineages and case definitions for confirmed and severe cases of Covid-19 are summarized in the Supplementary Appendix.

STATISTICAL ANALYSIS

The analysis populations are summarized in Table S1 in the Supplementary Appendix. Safety analyses included participants 16 years of age or older without known human immunodeficiency virus (HIV) infection who provided informed consent and received at least one BNT162b2 or placebo dose. The results of the safety analyses, which are descriptive and not based on formal hypothesis testing, are presented as counts, percentages, and associated Clopper–Pearson 95% confidence intervals for adverse events, according to terms in the *Medical Dictionary for Regulatory Activities*, version 23.1, and reactogenicity events for each trial group. Safety data that were reported up to March 13, 2021, are summarized here. The 95% confidence intervals in this report were not adjusted for multiplicity.

The analysis of vaccine efficacy during the blinded period of the trial included all participants 12 years of age or older without known HIV infection who received at least one BNT162b2 or placebo dose. Vaccine efficacy was calculated as $100 \times (1-\text{IRR})$, where IRR (incidence rate ratio) is the ratio of the rate (number per 1000 person-years of follow-up) of confirmed cases of Covid-19 in the BNT162b2 group to the corresponding rate in the placebo group. Descriptive analyses of vaccine efficacy were performed and associated 95% confidence intervals were calculated with the use of the Clopper–Pearson method, with adjustment for surveillance time, which accounts for potential differential follow-up between the two trial groups. As described in the statistical analysis plan, available with the protocol, hypothesis-testing analyses were performed with the use of a Bayesian approach, and the descriptive analyses presented here were performed with a frequentist approach for clarity of communication. Because the percentage of participants who reported symptoms but were missing a valid polymerase-chain-reaction test result was small and slightly higher in the placebo group, data for these participants were not imputed in the analysis.

The previously reported primary efficacy objective was achieved on the basis of an analysis of 170 accrued cases of Covid-19 that could be evaluated (data cutoff date, November 14, 2020).[9] The current report provides updated efficacy analyses that were performed with data from cases that had accrued up to March 13, 2021.

RESULTS

PARTICIPANTS

Between July 27, 2020, and October 29, 2020, a total of 45,441 participants 16 years of age or older underwent screening, and 44,165 underwent randomization at 152 sites (130 sites in the United States, 1 site in Argentina, 2 sites in Brazil, 4 sites in South Africa, 6 sites in Germany, and 9 sites in Turkey) in the phase 2–3 portion of the trial. Of these participants, 44,060 received at least one dose of BNT162b2 (22,030 participants) or placebo (22,030), and 98% (21,759 in the BNT162b2 group and 21,650 in the placebo group) received the second dose (Fig. 1). During the blinded period of the trial, 51% of the participants in each group had 4 to less than 6 months of follow-up after the second dose; 8% of the participants in the BNT162b2 group and 6% of those in the placebo group had 6 months of follow-up or more after the second dose. During the combined blinded and open-label periods, 55% of the participants in the BNT162b2 group had 6 months of follow-up or more after the second dose. A total of 49% of the participants were female, 82% were White, 10% were Black, and 26% were Hispanic or Latinx; the median age was 51 years. A total of 34% of the participants had a body-mass index (the weight in kilograms divided by the square of the height in meters) of

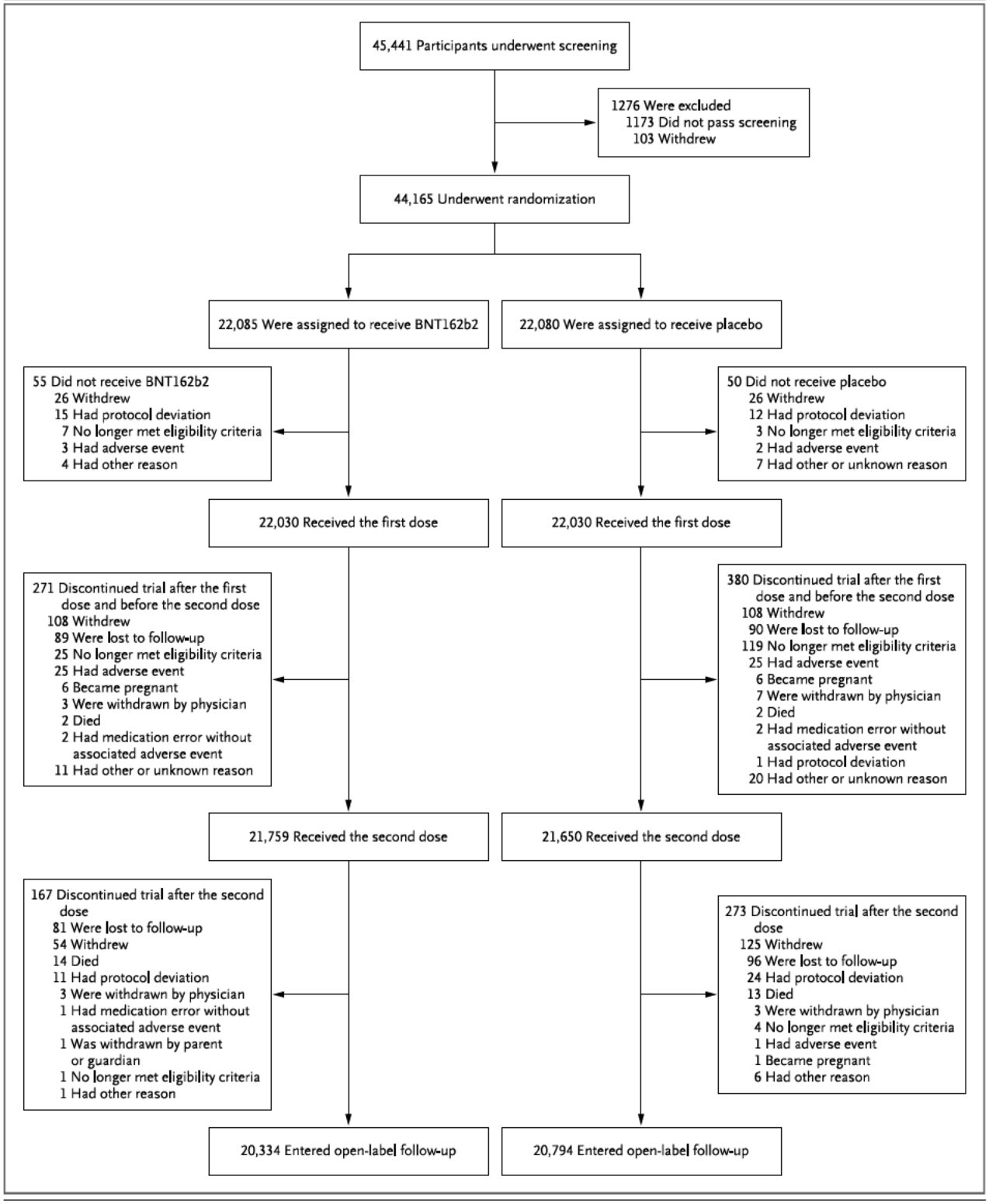


Figure 1 (facing page). **Screening, Randomization, and Follow-up.**

The diagram represents all enrolled participants 16 years of age or older through the data cutoff date (March 13, 2021). The diagram includes two deaths that occurred after the second dose in human immunodeficiency virus (HIV)–infected participants (one in the BNT162b2 group and one in the placebo group; these deaths were not reported in the Results section of this article because the analysis of HIV-infected participants is being conducted separately). Information on the screening, randomization, and follow-up of the participants 12 to 15 years of age has been reported previously.[11]

30.0 or more, 21% had at least one underlying medical condition, and 3% had baseline evidence of a previous or current SARS-CoV-2 infection (Table 1 and Table S2).

Between October 15, 2020, and January 12, 2021, a total of 2306 participants 12 to 15 years of age underwent screening, and 2264 underwent randomization at 29 U.S. sites. Of these participants, 2260 received at least one dose of BNT162b2 (1131 participants) or placebo (1129), and 99% (1124 in the BNT162b2 group and 1117 in the placebo group) received the second dose.[11] Among participants who received at least one dose of BNT162b2 or placebo, 58% had at least 2 months of follow-up after the second dose, 49% were female, 86% were White, 5% were Black, and 12% were Hispanic or Latinx. Full details of the demographic characteristics of the participants have been reported previously.[11]

SAFETY

Reactogenicity

The subgroup that was evaluated for reactogenicity in the current report, in which reactions were reported in an electronic diary, included 9839 participants 16 years of age or older. In this subgroup, 8183 participants had been included in the previous analysis, and 1656 were enrolled after the data cutoff for that analysis.[9] The reactogenicity profile of BNT162b2 in this expanded subgroup did not differ substantially from that described previously.[9] This subgroup included 364 participants who had evidence of previous SARS-CoV-2 infection, 9426 who did not have evidence, and 49 who lacked the data needed to determine previous infection status.

More participants in the BNT162b2 group than in the placebo group reported local reactions, the most common of which was mild-to-moderate pain at the injection site (Fig. S1A). Local reactions were reported with similar frequency among the participants with or without evidence of previous SARS-CoV-2 infection, and the reactions were of similar severity. No local reactions of grade 4 (according to the guidelines of the Center for Biologics Evaluation and Research[12]) were reported.

More participants in the BNT162b2 group than in the placebo group reported systemic events, the most common of which was fatigue (Fig. S1B). Systemic events were mostly mild to moderate in severity, but there were occasional severe events. Systemic reactogenicity was similar among those with or without evidence of previous SARS-CoV-2 infection, although BNT162b2 recipients with evidence of previous infection reported systemic events more often after receipt of the first dose, and those without evidence reported systemic events more often after receipt of the second dose. For example, 12% of recipients with evidence of previous SARS-CoV-2 infection and 3% of those without evidence reported fever after receipt of the first dose; 8% of those with evidence of previous infection and 15% of those without evidence reported fever after the second dose. The highest temperature reported was a transient fever of higher than 40.0°C on day 2 after the second dose in a BNT162b2 recipient without evidence of previous infection.

Adverse Events

Analyses of adverse events during the blinded period included 43,847 participants 16 years of age or older (Table S3). Reactogenicity events among the participants who were not in the reactogenicity subgroup were reported as adverse events, which resulted in imbalances between the BNT162b2 group and the placebo group with respect to adverse events (30% vs. 14%), related adverse events (24% vs. 6%), and severe adverse events (1.2% vs. 0.7%). New adverse events attributable to BNT162b2 that were not previously

Table 1. **Demographic Characteristics of the Participants at Baseline.***

Characteristic	BNT162b2 (N=22,026)	Placebo (N=22,021)	Total (N=44,047)
Sex — no. (%)			
Male	11,322 (51.4)	11,098 (50.4)	22,420 (50.9)
Female	10,704 (48.6)	10,923 (49.6)	21,627 (49.1)
Race or ethnic group — no. (%)†			
White	18,056 (82.0)	18,064 (82.0)	36,120 (82.0)
Black or African American	2,098 (9.5)	2,118 (9.6)	4,216 (9.6)
Asian	952 (4.3)	942 (4.3)	1,894 (4.3)
American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Native Hawaiian or other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Multiracial	550 (2.5)	533 (2.4)	1,083 (2.5)
Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Ethnicity†			
Hispanic or Latinx	5,704 (25.9)	5,695 (25.9)	11,399 (25.9)
Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Country — no. (%)			
Argentina	2,883 (13.1)	2,881 (13.1)	5,764 (13.1)
Brazil	1,452 (6.6)	1,448 (6.6)	2,900 (6.6)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
United States	16,792 (76.2)	16,794 (76.3)	33,586 (76.3)
Age group at vaccination — no. (%)			
16–55 yr	13,069 (59.3)	13,095 (59.5)	26,164 (59.4)
>55 yr	8,957 (40.7)	8,926 (40.5)	17,883 (40.6)
Age at vaccination — yr			
Median	51.0	51.0	51.0
Range	16–89	16–91	16–91
SARS-CoV-2 status — no. (%)‡			
Positive	689 (3.1)	716 (3.3)	1,405 (3.2)
Negative	21,185 (96.2)	21,180 (96.2)	42,365 (96.2)
Missing data	152 (0.7)	125 (0.6)	277 (0.6)
Body-mass index — no. (%)§			
≥30.0: obese	7,543 (34.2)	7,629 (34.6)	15,172 (34.4)
Missing data	7 (<1)	6 (<1)	13 (<1)

* Data are summarized for participants 16 years of age or older in the safety population. The demographic characteristics of participants 12 to 15 years of age were reported previously.[11] Percentages may not total 100 because of rounding. SARS-CoV-2 denotes severe acute respiratory syndrome coronavirus 2.

† Race and ethnicity were reported by the participants. The categories shown are those that were used to collect the data.

‡ Positive status was defined as a positive N-binding antibody result or a positive nucleic acid amplification test (NAAT) result at visit 1 or medical history of coronavirus disease 2019 (Covid-19). Negative status was defined as a negative N-binding antibody result or a negative NAAT result at visit 1 and no medical history of Covid-19.

§ The body-mass index is the weight in kilograms divided by the square of the height in meters.

Table 2. Vaccine Efficacy against Covid-19 from 7 Days after Receipt of the Second Dose during the Blinded, Placebo-Controlled Follow-up Period.*

Efficacy End Point	BNT162b2			Placebo			Vaccine Efficacy (95% CI)‡
	No. of Cases	Surveillance Time†	No. at Risk	No. of Cases	Surveillance Time†	No. at Risk	
		1000 person-yr			*1000 person-yr*		*percent*
		(N=20,998)			**(N=21,096)**		
First occurrence of Covid-19 from 7 days after receipt of the second dose among participants without evidence of previous infection	77	6.247	20,712	850	6.003	20,713	91.3 (89.0–93.2)
		(N=22,166)			**(N=22,320)**		
First occurrence of Covid-19 from 7 days after receipt of the second dose among participants with or without evidence of previous infection	81	6.509	21,642	873	6.274	21,689	91.1 (88.8–93.0)

* This analysis included participants who had no serologic or virologic evidence (within 7 days after receipt of the second dose) of previous SARS-CoV-2 infection (i.e., negative N-binding antibody [serum] test at visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at visits 1 and 2) and had a negative NAAT at any unscheduled visit up to 7 days after receipt of the second dose.

† The surveillance time is the total time (in 1000 person-years) at risk for the given end point across all participants within each group. The time period for the accrual of Covid-19 cases was from 7 days after the second dose to the end of the surveillance period.

‡ Vaccine efficacy was calculated as 100×(1−IRR), where IRR (incidence rate ratio) is the ratio of the rate (number per 1000 person-years of follow-up) of confirmed cases of Covid-19 in the BNT162b2 group to the corresponding rate in the placebo group. The 95% confidence interval for vaccine efficacy was derived with the use of the Clopper–Pearson method, with adjustment for surveillance time.

identified in earlier reports included decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Few participants had serious adverse events or adverse events that led to trial withdrawal. No new serious adverse events were considered by the investigators to be related to BNT162b2 after the data cutoff date of the previous report.[9]

During the combined blinded and open-label periods, cumulative safety data during follow-up were available through 6 months after the second dose for 12,006 participants who were originally randomly assigned to the BNT162b2 group. No new safety signals relative to the previous report were observed during the longer follow-up period in the current report, which included open-label observation of the original BNT162b2 recipients and placebo recipients who received BNT162b2 after unblinding.[9]

During the blinded, placebo-controlled period, 15 participants in the BNT162b2 group and 14 in the placebo group died; during the open-label period, 3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died. None of these deaths were considered to be related to BNT162b2 by the investigators. Causes of death were balanced between BNT162b2 and placebo groups (Table S4).

Safety monitoring will continue according to the protocol for 2 years after the second dose for participants who originally received BNT162b2 and for 18 months after the second BNT162b2 dose for placebo recipients who received BNT162b2 after unblinding.

EFFICACY

Among 42,094 participants 12 years of age or older who could be evaluated and had no evidence of previous SARS-CoV-2 infection, Covid-19 with an onset of 7 days or more after the second dose was observed in 77 vaccine recipients and in 850 placebo recipients up to the data cutoff date (March 13, 2021), corresponding to a vaccine efficacy of 91.3% (95% confidence interval [CI], 89.0 to 93.2) (Table 2). Among 44,486 participants

with or without evidence of previous infection who could be evaluated, cases of Covid-19 were observed in 81 vaccine recipients and in 873 placebo recipients, corresponding to a vaccine efficacy of 91.1% (95% CI, 88.8 to 93.0).

Among the participants with evidence of previous SARS-CoV-2 infection based on a positive baseline N-binding antibody test, Covid-19 was observed in 2 vaccine recipients after the first dose and in 7 placebo recipients. Among the participants with evidence of previous SARS-CoV-2 infection based on a positive nucleic acid amplification test at baseline, cases of Covid-19 were observed in 10 vaccine recipients and in 9 placebo recipients (Table S5). Covid-19 was less common among the placebo recipients with positive N-binding antibodies at trial entry (7 of 542 participants, for an incidence of 1.3%) than among those without evidence of infection at trial entry (1015 of 21,521, for an incidence of 4.7%); these findings indicate that previous infection conferred approximately 72.6% protection.

Among the participants with or without evidence of previous infection, cases of Covid-19 were observed in 46 vaccine recipients and in 110 placebo recipients from receipt of the first dose up to receipt of the second dose, corresponding to a vaccine efficacy of 58.4% (95% CI, 40.8 to 71.2) (Fig. 2). During the interval from the approximate start of observed protection at 11 days after receipt of the first dose up to receipt of the second dose, vaccine efficacy increased to 91.7% (95% CI, 79.6 to 97.4). From its peak after the second dose, observed vaccine efficacy declined. From 7 days to less than 2 months after the second dose, vaccine efficacy was 96.2% (95% CI, 93.3 to 98.1); from 2 months to less than 4 months after the second dose, vaccine efficacy was 90.1% (95% CI, 86.6 to 92.9); and from 4 months after the second dose to the data cutoff date, vaccine efficacy was 83.7% (95% CI, 74.7 to 89.9).

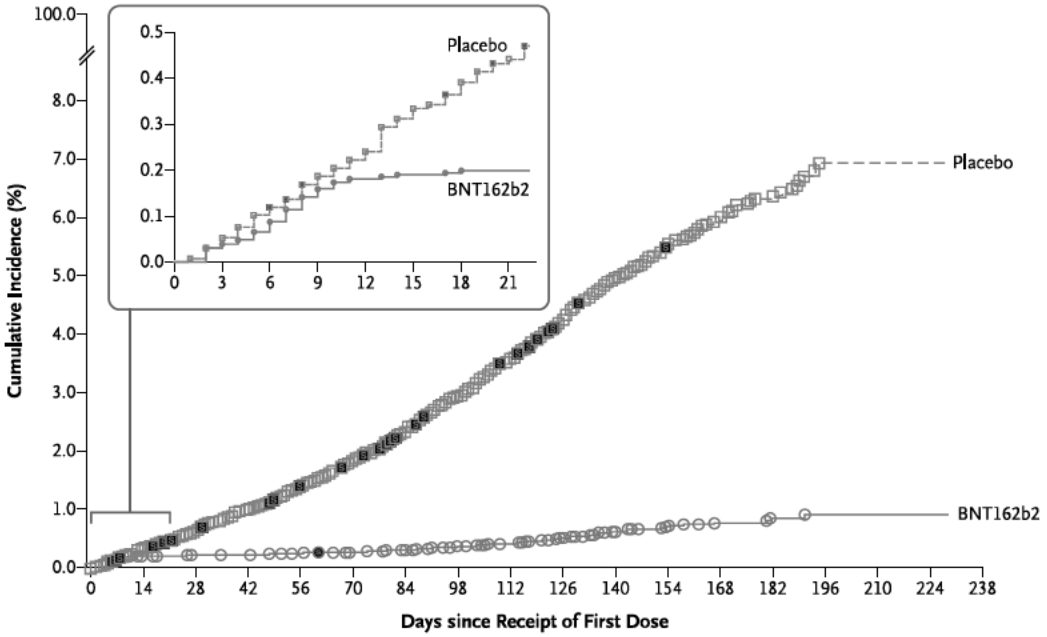
Severe Covid-19, as defined by the Food and Drug Administration,[13] with an onset after receipt of the first dose occurred in 31 participants, of whom 30 were placebo recipients; this finding corresponds with a vaccine efficacy of 96.7% (95% CI, 80.3 to 99.9) against severe Covid-19 (Fig. 2 and Table S6). Although the trial was not powered to definitively assess efficacy according to subgroup, supplemental analyses indicated that vaccine efficacy after the second dose in subgroups defined according to age, sex, race, ethnic group, presence or absence of coexisting medical conditions, and country was generally consistent with that observed in the overall population (Table 3 and Table S7).

Given the concern about the SARS-CoV-2 B.1.351 (or beta) variant, which appears to be neutralized less efficiently by BNT162b2-immune sera than many other lineages,[14] whole-viral-genome sequencing was performed on midturbinate samples from Covid-19 cases observed in South Africa, where this lineage was prevalent. Nine cases of Covid-19 were observed in South African participants without evidence of previous SARS-CoV-2 infection, all of whom were placebo recipients; this finding corresponds with a vaccine efficacy of 100% (95% CI, 53.5 to 100) (Table 3). Midturbinate specimens from 8 of 9 cases contained sufficient viral RNA for whole-genome sequencing. All viral genomes were the beta variant (Global Initiative on Sharing All Influenza Data accession codes are provided in the Supplementary Appendix).

DISCUSSION

In this update to the preliminary safety and efficacy report of two 30-μg doses, at 21 days apart, of BNT162b2, 91.1% vaccine efficacy against Covid-19 was observed from 7 days to 6 months after the second dose in participants 12 years of age or older. Vaccine efficacy against severe disease with an onset after receipt of the first dose was approximately 97%. This finding, combined with the totality of available evidence, including real-world effectiveness data,[15-18] alleviates theoretical concerns over potential enhancement of vaccine-mediated disease.[19]

The benefit of BNT162b2 immunization started approximately 11 days after receipt of the first dose, with 91.7% vaccine efficacy from 11 days after receipt of the first dose up to receipt of the second dose. The trial cannot provide information on persistence of protection after a single dose, because 99% of the participants received the second dose as scheduled during the blinded trial period. A recent trial showed that although nonneutralizing viral antigen–binding antibody levels rise between the first and second BNT162b2 dose, serum neutralizing titers are low or undetectable during this interval.[20] Early protection against Covid-19 without strong serum neutral-



Efficacy End Point	BNT162b2 (N=23,040)			Placebo (N=23,037)			Vaccine Efficacy
	No. of cases	Surveillance time	No. at risk	No. of cases	Surveillance time	No. at risk	
		1000 person-yr			*1000 person-yr*		*% (95% CI)*
Overall: first occurrence of Covid-19 after receipt of first dose	131	8.412	22,505	1034	8.124	22,434	87.8 (85.3 to 89.9)
After receipt of first dose up to receipt of second dose	46	1.339	22,505	110	1.331	22,434	58.4 (40.8 to 71.2)
<11 Days after receipt of first dose	41	0.677	22,505	50	0.675	22,434	18.2 (−26.1 to 47.3)
≥11 Days after receipt of first dose up to receipt of second dose	5	0.662	22,399	60	0.656	22,369	91.7 (79.6 to 97.4)
After receipt of second dose to <7 days after	3	0.424	22,163	35	0.422	22,057	91.5 (72.9 to 98.3)
≥7 Days after receipt of second dose	82	6.649	22,132	889	6.371	22,001	91.2 (88.9 to 93.0)
≥7 Days after receipt of second dose to <2 mo after	12	2.923	22,132	312	2.884	22,001	96.2 (93.3 to 98.1)
≥2 Mo after receipt of second dose to <4 mo after	46	2.696	20,814	449	2.593	20,344	90.1 (86.6 to 92.9)
≥4 Mo after receipt of second dose	24	1.030	12,670	128	0.895	11,802	83.7 (74.7 to 89.9)

Figure 2. Efficacy of BNT162b2 against Covid-19 after Receipt of the First Dose (Blinded Follow-up Period).

The top of the figure shows the cumulative incidence curves for the first occurrence of coronavirus disease 2019 (Covid-19) after receipt of the first dose (efficacy analysis population of participants ≥12 years of age who could be evaluated). Each symbol represents Covid-19 cases starting on a given day, and filled symbols represent severe Covid-19 cases. Because of overlapping dates, some symbols represent more than one case. The inset shows the same data on an enlarged y axis through 21 days. The bottom of the figure shows the time intervals for the first occurrence of Covid-19 in the efficacy analysis population, as well as the surveillance time, which is given as the total time (in 1000 person-years) at risk for the given end point across all participants within each group. The time period for the accrual of Covid-19 cases was from after receipt of the first dose to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval. Vaccine efficacy was calculated as 100×(1−IRR), where IRR (incidence rate ratio) is the ratio of the rate (number per 1000 person-years of follow-up) of confirmed cases of Covid-19 in the BNT162b2 group to the corresponding rate in the placebo group. The 95% confidence interval for vaccine efficacy was derived with the use of the Clopper–Pearson method, with adjustment for surveillance time.

ization indicates that neutralizing titers alone do not appear to explain early BNT162b2-mediated protection from Covid-19. Other immune mechanisms (e.g., innate immune responses, CD4+ or CD8+ T-cell responses, B-cell memory responses, and antibody-dependent cytotoxicity) may contribute to protection.[21-26]

Efficacy peaked at 96.2% during the interval from 7 days to less than 2 months after the second dose and declined gradually to 83.7% from

Table 3. Vaccine Efficacy against Covid-19 up to 7 Days after Receipt of the Second Dose among Participants without Evidence of Infection.*

First Occurrence of Covid-19 after Receipt of the First Dose	BNT162b2 (N=20,998)			Placebo (N=21,096)			Vaccine Efficacy (95% CI)‡
	No. of Cases	Surveillance Time†	No. at Risk	No. of Cases	Surveillance Time†	No. at Risk	
		1000 person-yr			*1000 person-yr*		*percent*
Overall population	77	6.247	20,712	850	6.003	20,713	91.3 (89.0 to 93.2)
Age group — yr							
16 or 17	0	0.061	342	10	0.057	331	100 (58.2 to 100)
16 to 55	52	3.593	11,517	568	3.439	11,533	91.2 (88.3 to 93.5)
≥55	25	2.499	8,194	266	2.417	8,208	90.9 (86.3 to 94.2)
≥65	7	1.233	4,192	124	1.202	4,226	94.5 (88.3 to 97.8)
≥75	1	0.239	842	26	0.237	847	96.2 (76.9 to 99.9)
Sex							
Male	42	3.246	10,637	399	3.047	10,433	90.1 (86.4 to 93.0)
Female	35	3.001	10,075	451	2.956	10,280	92.4 (89.2 to 94.7)
Race or ethnic group§							
White	67	5.208	17,186	747	5.026	17,256	91.3 (88.9 to 93.4)
Black or African American	4	0.545	1,737	48	0.527	1,737	91.9 (78.0 to 97.9)
Asian	3	0.260	946	23	0.248	934	87.6 (58.9 to 97.6)
American Indian or Alaska Native	0	0.041	186	3	0.037	176	100 (–119.0 to 100)
Native Hawaiian or other Pacific Islander	0	0.015	54	1	0.008	30	100 (–1961.2 to 100)
Multiracial	3	0.151	518	22	0.128	476	88.5 (61.6 to 97.8)
Not reported	0	0.026	85	6	0.030	104	100 (2.8 to 100)
Ethnicity§							
Hispanic or Latinx	29	1.786	5,161	241	1.711	5,120	88.5 (83.0 to 92.4)
Non-Hispanic and non-Latinx	47	4.429	15,449	609	4.259	15,484	92.6 (90.0 to 94.6)
Not reported	1	0.032	102	0	0.033	109	NA
Country							
Argentina	15	1.012	2,600	108	0.986	2,586	86.5 (76.7 to 92.7)
Brazil	12	0.406	1,311	80	0.374	1,293	86.2 (74.5 to 93.1)
Germany	0	0.047	236	1	0.048	242	100 (–3874.2 to 100)
South Africa	0	0.080	291	9	0.074	276	100 (53.5 to 100)
Turkey	0	0.027	228	5	0.025	222	100 (–0.1 to 100)
United States	50	4.674	16,046	647	4.497	16,046	92.6 (90.1 to 94.5)

* This analysis of vaccine efficacy during the blinded, placebo-controlled follow-up period included all participants who had undergone randomization and were 12 years of age or older without baseline evidence of previous infection who had undergone randomization. NA denotes not applicable.

† Surveillance time is the total time (in 1000 person-years) at risk for the given end point across all participants within each group. The time period for the accrual of Covid-19 cases was from 7 days after the second dose to the end of the surveillance period.

‡ Vaccine efficacy was calculated as 100×(1−IRR). The 95% confidence interval for vaccine efficacy was derived with the use of the Clopper–Pearson method, with adjustment for surveillance time.

§ Race and ethnicity were reported by the participants. The categories shown are those that were used to collect the data.

4 months after the second dose to the data cutoff date — an average decline of approximately 6% every 2 months. Ongoing follow-up is needed to understand persistence of the vaccine effect over time, the need for booster dosing, and timing of such a dose. Most participants who initially received placebo have now been immunized with BNT162b2, ending the placebo-controlled period of the trial. Nevertheless, ongoing observation of participants through 2 years in this trial, together with real-world effectiveness data,[15-18] will determine whether a booster is likely to be beneficial after a longer interval. Booster trials to evaluate safety and immunogenicity of BNT162b2 are under way to prepare for this possibility.

From 7 days after the second dose, 86 to 100% efficacy was observed across diverse demographic profiles, including age, sex, race or ethnic group, and factors that increase the risk of Covid-19, such as high body-mass index and other coexisting medical conditions. BNT162b2 was also highly efficacious in various geographic regions including North America, Europe, South Africa, and Latin America. Although vaccine efficacy was slightly lower in Latin American countries, BNT162b2 had a high efficacy of approximately 86% in Argentina and Brazil. Circulation of SARS-CoV-2 variants — some of which are associated with more rapid transmission and potentially greater pathogenicity[27] — has raised concerns that such variants could evade vaccine-mediated protection. Our studies of in vitro neutralization of a variety of SARS-CoV-2 variants have, to date, showed that all tested BNT162b2-immune sera neutralize all tested variants.[14,28-32] The beta variant, which has shown the greatest reduction in neutralization and was the dominant strain in South Africa during the reported observation period, is still neutralized at serum titers higher than those observed at the onset of protection against Covid-19 after the first vaccine dose.[9,14,20] We found that BNT162b2 had an observed efficacy of 100% (95% CI, 53.5 to 100) against Covid-19 in South Africa (9 cases occurred in the placebo recipients and 0 cases in the BNT162b2 recipients), and 8 of 9 cases for which sequence information could be obtained involved the beta variant of SARS-CoV-2.

Safety data are now available for approximately 44,000 participants 16 years of age or older; 12,006 participants have at least 6 months of safety follow-up data after a second BNT162b2 dose. The safety profile observed at a median of 2 months after immunization was confirmed through 6 months after immunization in the current analysis. No cases of myocarditis were noted.

Before immunization, 3% of the participants 16 years of age or older had evidence of SARS-CoV-2 infection. Although this group had a slightly higher incidence of systemic reactogenicity events after receipt of the first dose than those without evidence of previous infection, the group had a slightly lower incidence of reactogenicity events after the second dose than those without previous infection. Thus, there was minimal observed difference in the overall reactogenicity profile on the basis of infection status at baseline. Nine cases of Covid-19 were observed among participants with previous serologically defined natural infection: two cases were observed among the vaccine recipients and seven among the placebo recipients. These data support the current practice of immunizing without screening for evidence of previous infection.

This report has several limitations. Duration of protection and safety data that could be collected in a blinded, placebo-controlled manner were limited by the ethical and practical need to immunize eligible initial placebo recipients under emergency use authorization and according to the recommendations of public health authorities. The data presented here do not address whether vaccination prevents asymptomatic infection; however, evaluation of that question is ongoing in this trial, and real-world data suggest that BNT162b2 prevents asymptomatic infection.[33,34] Preliminary analyses of breakthrough cases have not yet identified a correlate of protection, since vaccine protection rates remain high. This report does not address vaccine efficacy and safety in pregnant women and in children younger than 12 years of age. Studies evaluating BNT162b2 in these populations are ongoing.

The data in this report show that BNT162b2 prevents Covid-19 effectively for up to 6 months after the second dose across diverse populations, despite the emergence of SARS-CoV-2 variants, including the beta variant, and the vaccine continues to show a favorable safety profile.

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APPENDIX

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Exhibit "F"

Strategies to help patients understand risks

John Paling

Explaining risks to patients in an effective way is an essential part of ensuring that consent is "informed." A consultant in risk communication discusses the strategies that can help doctors to communicate risks clearly, and thereby also build closer relationships with their patients

Effective risk communication is the basis for informed patient consent for medical treatment, yet until recently doctors have lagged behind other professionals in learning this skill. In other industries where risks have to be conveyed to the public (such as chemical, nuclear, water, and food industries) usually only a few people carry out this task on behalf of their organisations and they are specially trained. In contrast, in health care (where the risks are usually far higher and more uncertain and complex) almost every doctor who interacts with patients has to communicate information on risk, yet few have any training.

Specific strategies can help to remedy this deficiency and improve patients' understanding of risks. Doctors can now choose from a "toolbox" of simple, practical, time efficient techniques that benefit the widest possible variety of patients.

Methods

I have taught risk communication in risk prone professions outside medicine for over a decade.[1] More recently, I have adapted my materials to respond to the needs of doctors and genetic counsellors.[2] I continually review both the literature about risk communication and web based discussion groups, and this practice has informed this article.

I suggest here a set of strategies that doctors can use immediately to become more effective in helping patients to understand risks. Using visual aids also helps to foster good doctor-patient partnerships. The suggestions that follow are not a recipe of essential steps but rather a toolbox of techniques which, depending on the circumstances, can help to improve doctors' ability to communicate risk effectively.

The challenges for doctors

Communicating risk is not simple. Many different dimensions and inherent uncertainties need to be taken into account. Recent findings on the perception of risks and benefits from a psychological perspective further complicate the task. For example, Lloyd and colleagues have suggested that patients just extract the gist of any information—not the detail—to make decisions.[3]

Furthermore, most patients' assessment of risks is primarily determined not by facts but by emotions.[4] Thus, although most doctors can readily provide a competent account of the biomedical data relating to a particular risk, this alone is likely to be sterile. If the patient's feelings skew an understanding of the facts, then his or her ability to make objective decisions about clinical management will be impaired.

For this reason, the most powerful precursor for effective risk communication is for the doctor to strive

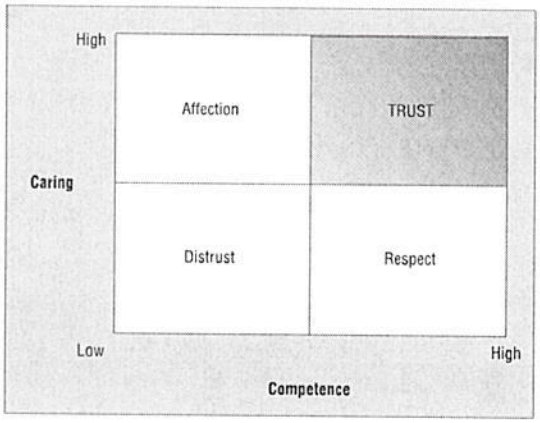

Fig 1 Competence and caring in relation to building trust. Adapted from Spence[6]

to display both competence and a caring approach.[5] The doctor should therefore wish to discuss risks in a context that would enable the patient to have the best chance of understanding those risks (fig 1).[6]

Trade-offs of risks and benefits

It is prudent to remind patients that virtually all treatments are inevitably associated with some risk of possible harm. This not only reflects the truth but also helps to counteract the tendency of some patients to expect totally risk-free medicine. It also enables the doctor to

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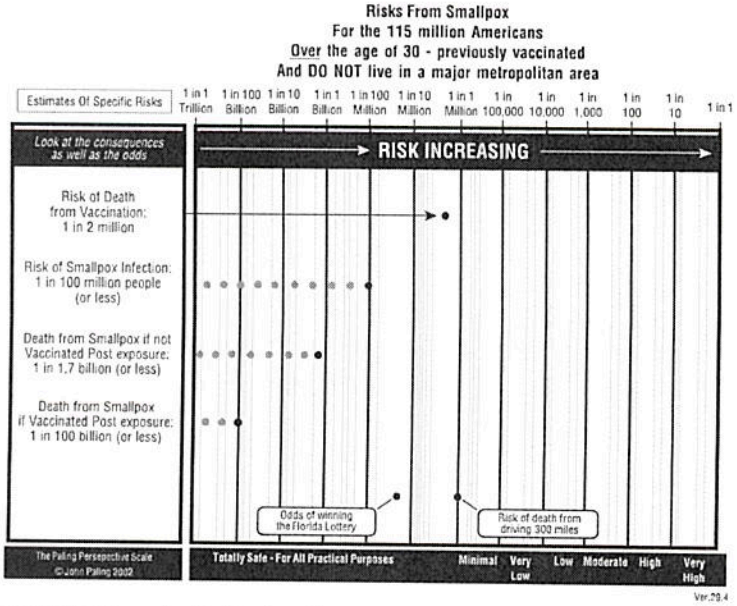


Fig 2 Paling Perspective Scale© —for giving perspective to risks of low order of probability.[16] From research report by Small P et al[17]

reassure the patient that all medical staff will do their best for the patient whatever treatment is chosen.

How to communicate the numbers

As well as empathising with the emotions of the patient, doctors are responsible for quoting estimates for the possible outcomes on the basis of previous cases. Often they do this by simply describing a possible treatment then telling the patient about the most likely associated risks on the basis of some unspecified population. Several simple techniques, however, can improve the way you communicate numbers.

Avoid using descriptive terms only

Avoid explaining risks in purely descriptive terms (such as "low risk"). Instead, elaborate by providing estimated numbers. Abundant evidence exists that descriptive terms reflect the speaker's perspective, with the patient often understanding the risks to be of a totally different order of magnitude.[7]

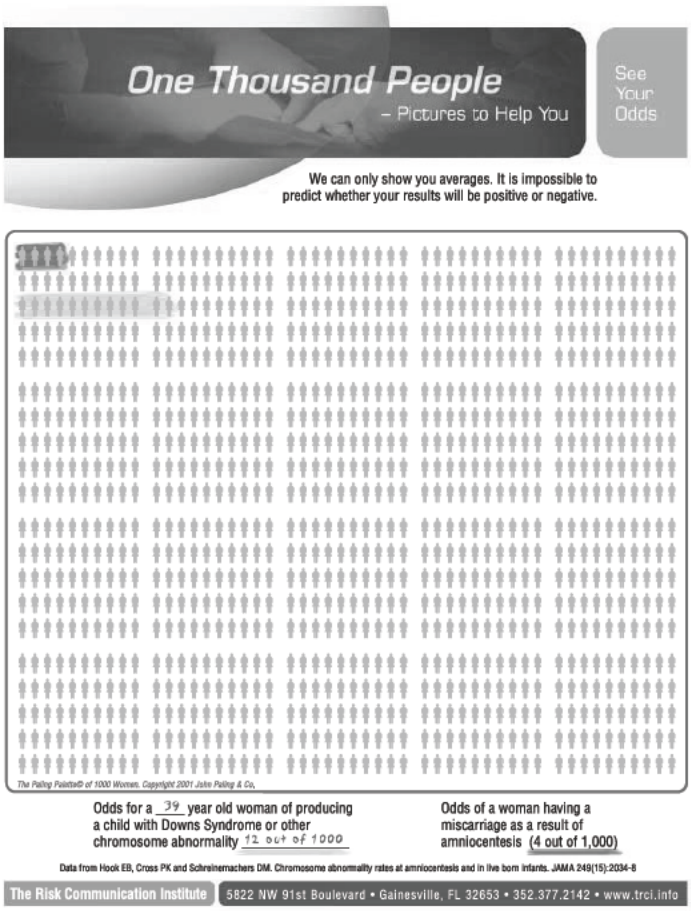


Fig 3 Paling Palette© —for displaying most medical risks with a probability of higher than 1 in 1000.[16] The doctor or genetic counsellor fills in the relevant data while sitting beside the patient. This format shows the estimates of positive and negative outcomes simultaneously and presents unambiguous visual representations of the probabilities. The patient may take a printout home for further consideration, or the form may be signed by the patient and a copy kept on file

Use standardised vocabulary

Discuss with colleagues at a local and national level the use of a standardised vocabulary of descriptive words that consistently relate to approximate levels of probability so that miscommunication is reduced.[8] The European Union's suggestions for a standardised vocabulary ("very common," "common," "uncommon," "rare," and "very rare"), however, do not communicate risk effectively: patients' interpretations of these terms do not seem to correlate with the probabilities that they were intended to convey. Different countries also probably bring different shades of meaning to various descriptions.[9]

Use consistent denominator

Express the odds of possible outcomes with a consistent denominator—for example, 40 out of 1000 and 5 out of 1000, rather than 1 in 25 and 1 in 200. If different denominators are used, many patients mistake which is the greater risk.[10] Some may think that 1 in 200 is a bigger risk than 1 in 25, presumably because the number is larger. Using a common denominator is just as accurate and communicates just as well to people of all educational levels.

Offer positive and negative outcomes

Never present only the negative perspective (or "frame"). Ideally offer outcomes in both positive and negative forms—for example, chances of survival and of death, or chance of side effects and of remaining free of side effects. A choice expressed as offering a "97 out of 100 chance of being cured" is psychologically more acceptable than a "3 out of 100 chance of dying." In situations where the patient's attitude is especially important in the healing process, reinforce the placebo effect by presenting the odds in a positive manner.[11] However, honesty (including presenting outcomes in both positive and negative forms) is more likely to foster mature and resilient doctor-patient partnerships.

Use absolute numbers

Whenever possible, use absolute numbers—not relative risks. Patients can easily misinterpret statements such as "three times as many people were cured with approach A as with approach B."[12] These issues are described further in the accompanying paper by Gigerenzer and Edwards (pp 741-4).[13]

Use visual aids for probabilities

Use appropriate visual aids to help patients from all backgrounds to understand your explanations.[14] Even in developed countries substantial numbers of patients have poor numeracy or literacy skills and are likely to have difficulty understanding the meaning of the numbers that doctors wish to share. For these people, visual aids can help by showing the numbers in perspective. The pie chart (pioneered by Florence Nightingale[15]) is a prime example of a simple yet effective visual aid, helpful to people at all academic levels.

I have developed several tools for helping to explain the risks of different orders of likelihood (figs 2-4).

Ensure that consent is "informed"

For many patients, truly "informed" consent (or indeed "dissent") is difficult to achieve without visual aids. Professionals in communications do not consider information and data to be the same. Information is considered to be data (facts) presented in a context that allows them to be meaningful to the listener. Unless

probability data are expressed in some meaningful context, a case could be made that, for less educated patients, so called informed consent or dissent is often not informed at all. Good visual aids can help the viewer to see the risk numbers in context, thus providing information and not just data.

Use visual aids to build partnership

When simple visual communication tools are shared between doctor and patient, they offer an opportunity to deepen the bond between them. The closer the doctor-patient partnership, the more likely the patient is to be satisfied. Malpractice claims are also less likely; when primary care physicians with no malpractice claims against them were compared with those who had been the subject of such claims, distinct differences were found in style of communication. Statements about what to expect, enabling discussion to take place, and taking time to explore the human dimensions were all seen as teachable behaviours associated with fewer malpractice claims.[18]

Strategies to discuss and elicit responses

Recent meta-analyses have highlighted the fact that women doctors in general are better than men at encouraging patients to talk more freely.[19] This does not mean that men are irretrievably impeded by their gender from gaining high scores in eliciting responses from patients. Indeed, in gynaecology, where there is usually a strong preference among patients for women doctors, the men were at least equal to (and often better than) the women in all aspects of their conversational style. Thus adjustments of conversational style seem to be possible with motivation and training.

Summary points

- The way doctors communicate risk can affect a patient's perception of risks
- Supplement verbal explanations with numerical data
- Use absolute numbers; do not use relative risks or percentage improvements
- State the odds from a positive and negative perspective and use a consistent denominator
- Use visual aids wherever possible, to maximise understanding
- Use of simple visual aids can also improve the doctor-patient relationship
- Make sure the patient's informed consent is based on information—not just data

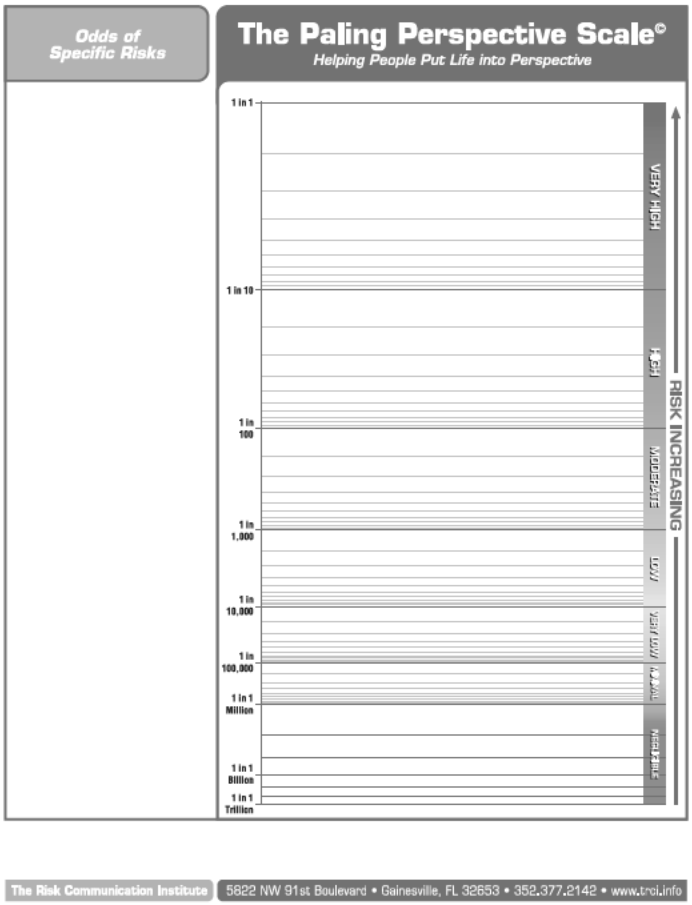


Fig 4 Revised Paling Perspective Scale© —for displaying risks covering widely different orders of magnitude[16]

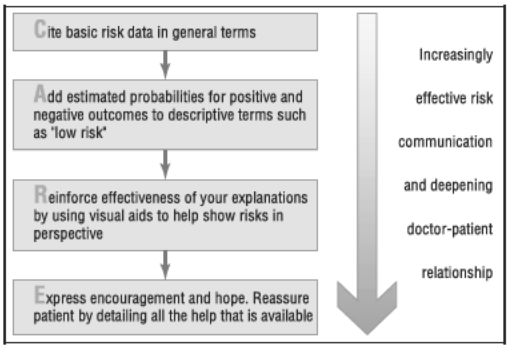
Future of risk communication in health care

Effective risk communication can improve the quality of health care in all countries and all disciplines. Three important developments are needed in this area.

Firstly, doctors need more training in communicating risk to patients.[20] The motivation for this may be stimulated by the potential for improving doctor-patient partnerships (and in some countries, such as the United States, for lowering the risk of malpractice suits).

Secondly, more research is needed on how different strategies, particularly use of visual aids, help patients to understand risk. Similar studies have already assessed analogous visual tools such as the Wong-Baker FACES pain rating scale—widely used to help patients communicate their level of pain.[21]

Thirdly, research should assess further how differences in culture, age, and gender affect patients' perception of risks. Few studies have examined how different groups respond to risks of any kind, and no studies seem to have investigated which approaches are the most effective for communicating medical risks to different populations. Since the time of Aristotle it has been recognised that there are different "possible ways of persuading people about any subject,"[22] and this is probably the case with different cultures. Given



Making risk communication more effective

the many diverse circumstances in which medicine is practised throughout the world, it is important always to be empathetic to the individual situation of each patient. By adopting a set of simple and practical strategies, doctors should be better able to convey information on risk to their patients.

Competing interest: JP earns his living from teaching about and consulting on risk communication with doctors and genetic counsellors.

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From cardiac anaesthetist to humanist officiant

My interest in non-religious funerals dates back to the death of my father. I was working abroad when he died; by the time I returned, things were cut and dried, and the funeral director had already engaged a local minister. The resulting service seemed a travesty, not only because we weren't a religious family, but also because the ceremony itself seemed in no way to recognise my father as an individual. There was scarcely any mention of his achievements, his love of his family, his principles, or the things he believed in, such as social justice. My mother and I left the crematorium feeling short changed.

My mother told me later that she did not want a religious funeral when she died. And so I approached the British Humanist Association and obtained their booklet *Funerals without God.* Eventually I became accredited to conduct humanist funerals, an activity that has become an important part of my life since I retired from my NHS post as a cardiac anaesthetist.

Humanists are atheists who believe it is possible to have morality without religion. Religion is rejected on the grounds that there simply isn't enough evidence for belief in a caring, loving God who created the universe and who answers our prayers. Thus the humanist takes an "evidence based" or scientific view of the world, as opposed to a belief based one.

After conducting a few funerals, it struck me that there was a similarity between visiting bereaved families in order to gather information to use in a ceremony and visiting cardiac surgery patients and their families at the bedside preoperatively. This is not primarily because the cardiac surgery patient knows there is some risk of not surviving, but rather because there is an immense need for trust. The patient and family are usually very pleased to have a consultant visit at the bedside, especially if he or she gives the impression of having time to stay and answer a few questions. They will already have seen the surgeon, but that could have been months ago. They often pin their faith on this new visitor, in whom they very much need to have confidence. This new doctor, they want to believe, will look after dad. It feels much the same making a visit before a funeral. I often, especially in close knit families, feel the family reaching out to me, relying on me, implying "we trust you totally to do the right thing for dad." And just as an anaesthetist takes a pride in delivering a patient in good condition to the recovery ward, as a humanist officiant, I take a great pride giving the bereaved family the help and support they need at a difficult time to mourn their loved one.

Since I don't conduct religious ceremonies, I have no control group with which to compare, but I have a feeling that non-religious funerals are often requested by truly remarkable people, who have led unusually full lives, sometimes exemplary ones. They have often been close to their families and are dreadfully missed. They are often noted for their willingness to help others, and have been active in educating their children to be rounded individuals. They are inventors and innovators. One man at whose funeral I officiated, an engineer by profession, had noted haematuria during a long distance flight he made in his 70s. On returning home, he made a microscope slide of a drop of urine, thought he saw some abnormal cells, and showed them to his doctor. The patient was right: he had diagnosed his own bladder cancer.

Roger Fletcher *retired anaesthetist*

Exhibit "G"

Read The CDC Disclaimer

VAERS COVID Vaccine Adverse Event Reports

Reports from the Vaccine Adverse Events Reporting System. Our default data reflects all VAERS data including the "nondomestic" reports.

All VAERS COVID Reports | US/Territories/Unknown

927,738 Reports
Through November 26, 2021

This is **Exhibit "G"** referred to in the Affidavit of Tyler May sworn (or affirmed) before me at Muswinb, Alberta, this 3th day of December, 2021.

A Commissioner/Notary Public in and for the Province of Alberta

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

19,532
DEATHS

99,943
HOSPITALIZATIONS

102,602
URGENT CARE

145,286

DOCTOR OFFICE VISITS

8,301

ANAPHYLAXIS

11,636

BELL'S PALSY

3,148

Miscarriages

9,746

Heart Attacks

15,424

Myocarditis/Pericarditis

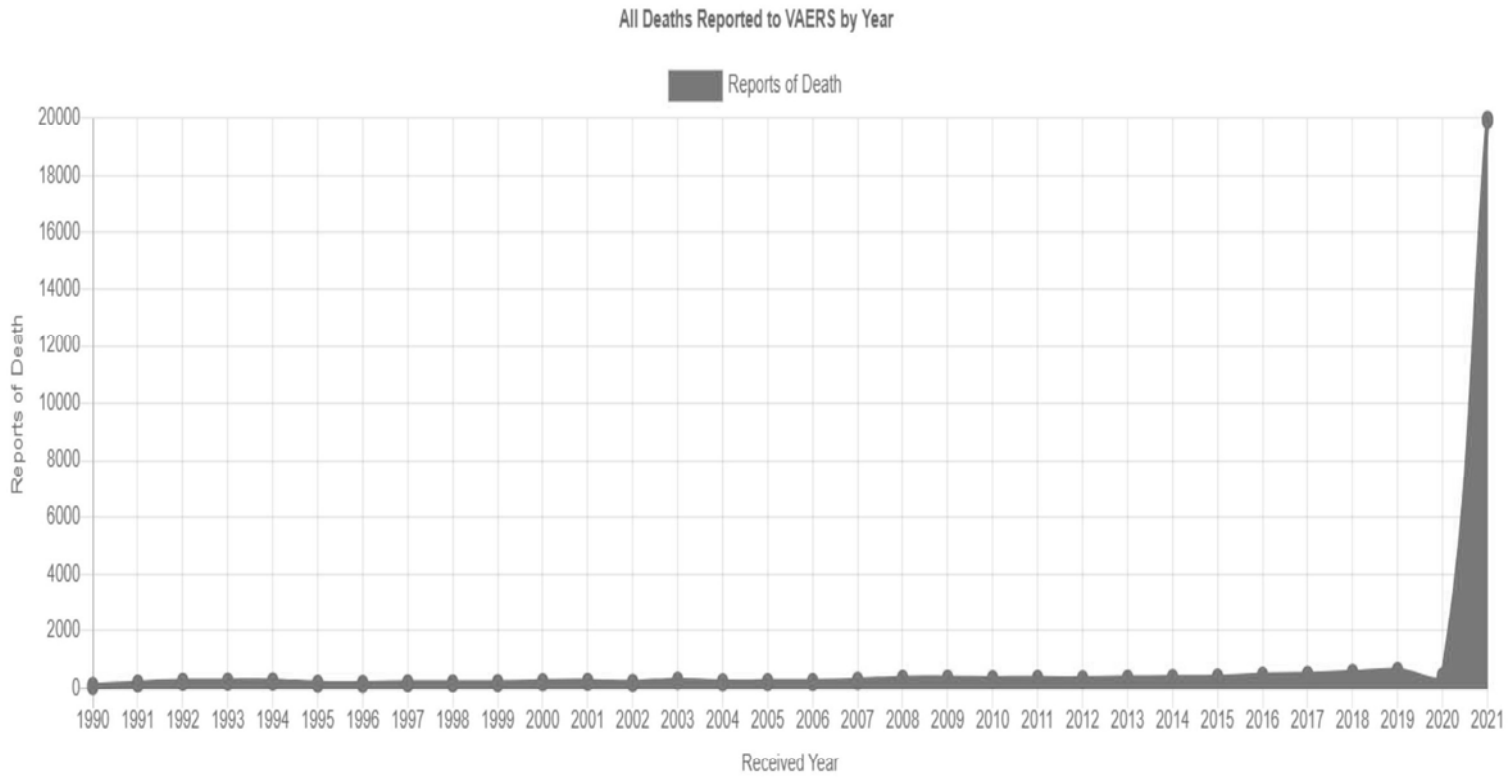
31,652
Permanently Disabled

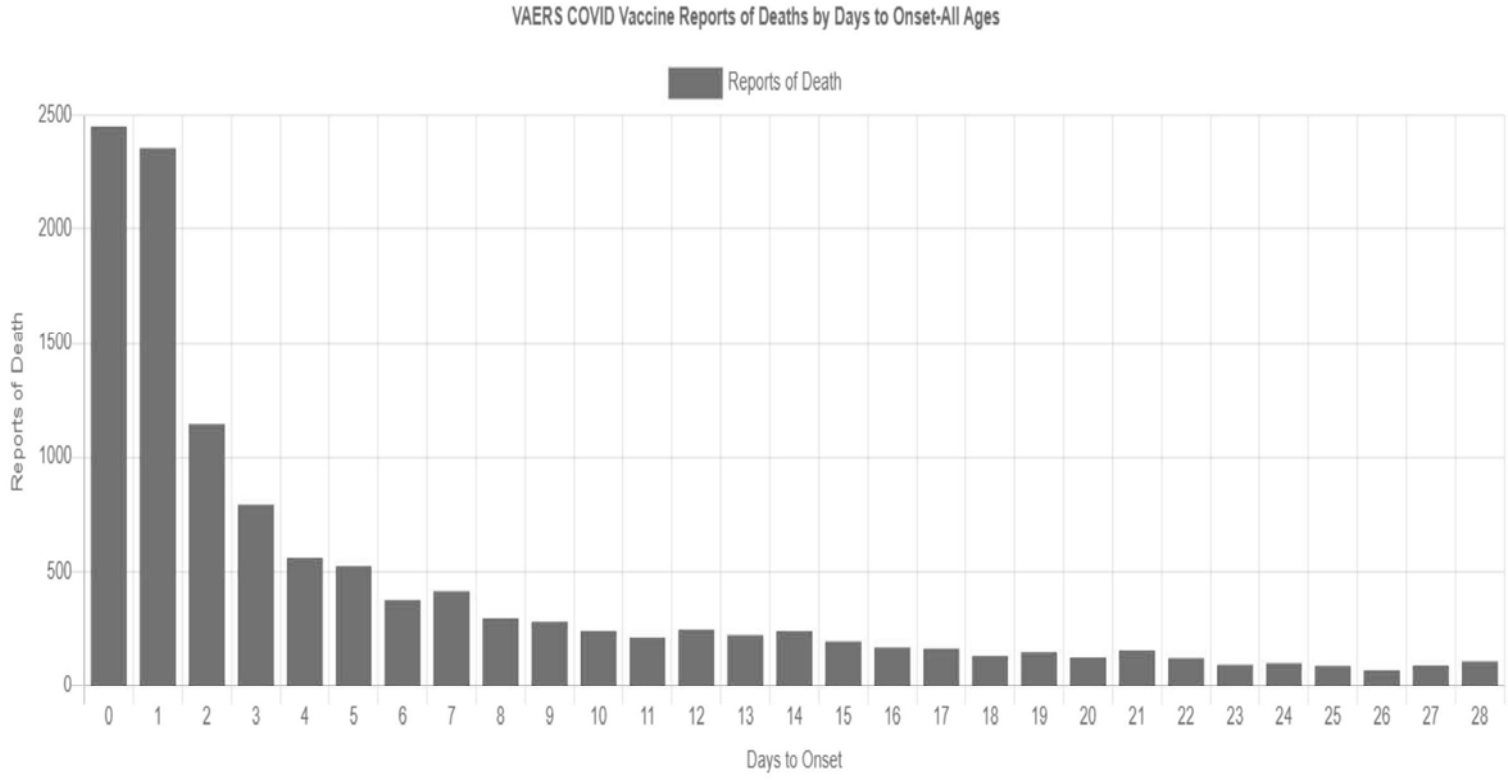
4,602
Thrombocytopenia/
Low Platelet

21,932
Life Threatening

34,481
Severe Allergic Reaction

10,787
Shingles





Questions? Comments? Bugs?

info@openvaers.com

Due to the high volume of inquiries, please be patient with response times.

Exhibit "H"

This is **Exhibit "H"** referred to in the
Affidavit of Tyler May
sworn (or affirmed) before me at
Manning, Alberta, this
8th day of December, 2021.

A Commissioner/Notary Public in and for
the Province of Alberta

DAVIN D. MAY
BARRISTER & SOLICITOR
NOTARY

Increased risk of infection with SARS-CoV-2 Beta, Gamma, and Delta variant compared to Alpha variant in vaccinated individuals

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Anniek A.N. Tanja, Rob Schuurman, Annemarie M.J. Wensing, L. Marije Hofstra (UMC Utrecht)
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Abstract

The extent to which severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) variants of concern (VOC) break through infection- or vaccine-induced immunity is not well understood. Here, we analyze 28,578 sequenced SARS-CoV-2 samples from individuals with known immune status obtained through national community testing in the Netherlands from March to August 2021. We find evidence for an increased risk of infection by the Beta (B.1.351), Gamma (P.1), or Delta (B.1.617.2) variants compared to the Alpha (B.1.1.7) variant after vaccination. No clear differences were found between vaccines. However, the effect was larger in the first 14-59 days after complete vaccination compared to 60 days and longer. In contrast to vaccine-induced immunity, no increased risk for reinfection with Beta, Gamma or Delta variants relative to Alpha variant was found in individuals with infection-induced immunity.

Introduction

Since the worldwide spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) the virus has been slowly but steadily evolving. Although many nucleotide mutations are synonymous, multiple amino acid substitutions in functional domains of the spike protein are observed, some of which with likely impact on transmissibility, disease severity and pre-existing immunity[1].

SARS-CoV-2 constellations of mutations under strong suspicion of a negative impact on virus epidemiology, virulence or effectiveness of social and public health measures (including diagnostics, vaccines, therapeutics) are designated Variant-of-Concern (VOC)[2]. As of 1 September 2021, four VOCs have been defined by the ECDC and WHO: Alpha (B.1.1.7, first detected in September 2020 in the United Kingdom), Beta (B.1.351, first detected in May 2020 in South Africa), Gamma (P.1, first detected in November 2020 in Brazil) and Delta (B.1.617.2, first detected in October 2020 in India)[2].

All four VOCs contain amino acid substitutions in the receptor binding domain (RBD) and N-terminal domain (NTD) of the Spike protein, which are known to be the main target of neutralizing antibodies. Several studies have shown decreased sensitivity of VOCs for convalescent and post-vaccination sera *in vitro*, with little to no reduction in sensitivity for the Alpha variant, the highest reduction in sensitivity for Beta and to a lesser extent for Gamma and Delta[3–6].

These observations and the rapid global spread of first Alpha and later Delta sparked fear for SARS-CoV-2 escape from pre-existing immunity and selection of these variants in vaccinated and previously infected individuals. There are indications that the vaccine effectiveness (VE), especially against SARS-CoV-2 infection or mild COVID-19, is lower for the Beta, Gamma and Delta variant[7]. Less is known about the association between the observed VOCs and reinfection. Although an ecological study from the UK did not find an increase in the reinfection rate for the Alpha variant relative to pre-existing variants in the last quarter of 2020[8], it needs to be determined if increased risk exists of reinfection by the Beta, Gamma, or Delta variants compared to the Alpha variant.

In January 2021, the COVID-19 vaccination program was rolled out in the Netherlands, first prioritizing health care workers, nursing home residents and the elderly. Current approved vaccines are either based on mRNA (Comirnaty, Spikevax) or on an Adeno-based vector system (Janssen COVID-19 vaccine, Vaxzevria) and are aimed to elicit a spike protein targeted humoral immune response that prevents virus entry and replication[9,10]. As of July 2021, all persons of 12 years and older have been offered COVID-19 vaccination. As of November 2021, 84% of all adults were fully vaccinated and 88% received at least one dose[11]. In the vaccination program in the Netherlands, Comirnaty (BNT162b2, BioNTech/Pfizer) has been used most often and has been offered to all age groups (76.0% of all administered doses). Spikevax (mRNA-1273, Moderna) has been mostly used in long term care facilities, health care workers, high medical risk groups and later also in the general

88 population below 60 years (8.5% of all administered doses). Vaxzevria (ChAdOx1, AstraZeneca) has
89 been used most in health care workers and the 60-65 years age group (12.1% of all administered
90 doses). Janssen COVID-19 vaccine (Ad26.COV2.S, Janssen) has been used most in the 50-59 years age
91 group and young adults (3.4% of all administered doses)[12]. Vaccination has proven to be highly
92 effective against COVID-19, especially against hospitalization and death and reduces the secondary
93 attack rate within households[7,13–17].

94

95 Next to vaccination, infection with SARS-CoV-2 elicits a protective immune response though
96 reinfections do occur. Studies comparing infection rates in the first and second surge of the SARS-
97 CoV-2 pandemic between people who tested RT-PCR or antigen negative and positive in Denmark,
98 Austria and Italy reported protection against repeat infection of 81%, 91% and 94%, respectively[18–20].
99 A prospective cohort study among health care workers in the UK found a 84% lower risk of infection
100 after a previous infection[21].

101

102 In the Netherlands, randomly selected SARS-CoV-2 RT-PCR positive specimens are sequenced to
103 continuously monitor changes in the virus[22]. The Alpha variant started to increase rapidly from
104 January 2021, and quickly became the dominant strain in the Netherlands. From June 2021, the
105 Delta variant increased rapidly and caused nearly all infections from August 2021 onwards. In this
106 study we aimed to investigate whether vaccine- or infection-induced immunity protects less well
107 against infection by specific variants. Therefore, we compared the variant distribution of SARS-CoV-2
108 positive individuals who were either unvaccinated, vaccinated or had a previous infection using
109 national epidemiological and molecular surveillance data from March up to August 2021.

110

111 ***Methods***

Data

Persons testing positive for SARS-CoV-2 either by community testing or in a hospital are notified by Public Health Services (PHS) to the national surveillance database. Community testing is available through the PHS. Testing is encouraged in case of experiencing COVID-19-like symptoms, contact with a positive case, returning from another country, or upon a positive self-test. Data relevant for source and contact tracing and for surveillance is collected in the national surveillance database through a telephone interview, including data on vaccination status (i.e. number of doses, type of vaccine, and date of vaccination).

The Dutch national SARS-CoV-2 molecular surveillance program sequences whole virus genomes of randomly selected SARS-CoV-2 positive specimens from both community testing (via PHS) and hospitals, using a proper nationwide geographical distribution. In the current analysis, only samples with information on vaccination status and information on previous infection can be used. This information is collected in the national surveillance database and linked to sequence data using a sample identifier supplied during community testing. Sequences from hospital samples (5,893 out of the total 42,662 (13.8%) sequences of the SARS-CoV-2 genomic surveillance samples) and 7,464 of the 36,769 sequenced community samples were excluded as these could not be linked to the national surveillance database for required meta-data. In addition to randomly selected specimens, additional community testing specimens were requested for partially or fully vaccinated individuals as well as for cases with known prior laboratory-confirmed infection. This was done on a 3-weekly basis. This additional sampling resulted in an additional 1,516 cases to be included in the study and allowed for a detailed investigation of infecting variants after vaccination or reinfection. In the current analyses, cases with a sampling date between March 1 and August 31, 2021, were included.

RT-PCR amplification and Nanopore sequencing

The majority of isolates were sequenced according to the following representative sequence method (minimal 85.3%), additional detailed protocols are available upon request. Total nucleic acid from combined nasopharyngeal and oropharyngeal swab was extracted using MagNApure 96 (MP96) with total nucleic acid kit small volume (Roche). Total nucleic acid was eluted in 50 µl Tris EDTA buffer. SARS-CoV-2 specific RT-PCR amplification and sequencing was performed using the Nanopore protocol based on the ARTIC v3 amplicon sequencing protocol[23]. Several modifications to the protocol were made for optimization: 1) The total volume of the cDNA reaction is 12µl with a volume of 0.4µl Superscript IV instead of 0.6µl. 2) primer concentrations and primer sequence were adjusted for several amplicons to optimized amplicon yield and to match novel variants. Updated primer sequences are available upon request. 3) No distinction was made on the basis of Cp value, PCR was performed using 47 cycles. After the combination of PCR reactions A and B, the samples were quantified with the Qubit, samples with a concentration >35ng/µl were diluted to 6ng/µl in water. 5 µl of diluted PCR mix was used in the end-prep reaction. This end-prep is incubated for 15 min at 20°C and 15 min at 65°C. Barcoding was performed using the NEBNext Ultra II Ligation Module (E7595). In short, 1.3 µl end-prepped DNA was added to 2.5µl water, 6µl NEBNext Ultra II Ligation Master Mix, 0.2µl NEBNext Ligation Enhancer and 2 µl Native barcode SQK-LSK109 (EXP-NBD196). The Barcoding was incubated for 30 min at 20°C and 20 min at 65°C. Barcoded fragments were washed with twice with 870 µl short fragment buffer (SFB), once with 150 µl ethanol and eluted in 74 µl after 4 minute incubation with the beads. Adapter ligation was perfomed using NEBNext Quick Ligation Module (NEB) in a total volume 50 µl using 25 µl of AMPure XP beads. After washing with 125 µl short fragment buffer (SFB), the pellet was resuspended in 15.5 µl elution buffer. Finally, 45ng of library preparation was loaded on a flowcell (Nanopore) and sequencing was performed on a R9.4.1 flow cell multiplexing 48 up to 96 samples per sequence run for a run-time of 30 hours on a GridION (Nanopore).

GridION data was analyzed to get consensus genomes, with the SARS2seq pipeline and additional manual curation[24]. These genomes were analyzed with Pangolin (version 3.1.11) and NextClade (version 1.3.0) to get a final variant call[25,26].

Vaccination and previous infection status

Vaccination status is determined relative to the date used for statistics (DUFS). For symptomatic cases, this is the date of symptom onset or, if missing, the date of a positive test result minus 2 days. For asymptomatic cases, the DUFS is the date of positive test result. Fully vaccinated is defined as having received two doses of Comirnaty, Spikevax or Vaxzevria at least 14 days before DUFS or one dose of Janssen COVID-19 vaccine at least 28 days before DUFS. Partly vaccinated is defined as having received one dose of Comirnaty, Spikevax or Vaxzevria at least 14 days before DUFS, or two doses of Comirnaty, Spikevax or Vaxzevria less than 14 days before DUFS. A case is defined as recently vaccinated after one dose of Comirnaty, Spikevax or Vaxzevria 0-13 days or Janssen COVID-19 vaccine 0-27 days before DUFS. Individuals with a subsequent positive RT-PCR or antigen test result with an interval of at least 8 weeks after a previous positive test, including a period without symptoms, were defined as reinfections. This is either reported in the notification by the PHS or identified using record linkage by date of birth, sex, and 6-digit postal code.

Statistical analyses

We compared the proportion of the four VOCs (Alpha, Beta, Gamma and Delta variant) between four immune status groups: 1) unvaccinated cases without a known previous infection (naïve), 2) partly vaccinated cases without a known previous infection, 3) fully vaccinated cases without a known previous infection, 4) unvaccinated cases with a previous infection. In a secondary analysis, fully vaccinated cases were further stratified by time between infection and last vaccination (<60

185 days versus >=60 days). Cases who were recently vaccinated, irrespective of their previous infection
186 status, were excluded from the analyses, due to a possible incomplete immune response. Since the
187 number of vaccinated cases with a previous infection was small (*n* = 111) this group was excluded.

188

189 The association between immune status and the Beta, Gamma and Delta variant was assessed using
190 logistic regression. Immune status (group 2: partly vaccinated, group 3: fully vaccinated and group 4:
191 previous infection versus group 1: naïve) was included in the model as the independent variable and
192 Beta, Gamma or Delta vs Alpha as the dependent variable. We estimated odds ratios (ORs) with 95%
193 confidence interval (CI) for any vaccine type and separately for Comirnaty, Spikevax, Vaxzevria and
194 Janssen COVID-19 vaccine. An additional analysis was performed on the time since vaccination,
195 stratifying the fully vaccinated by 14-59 and more than 60 days between complete vaccination and
196 DUFS. As calendar time is both related to vaccination uptake and prevalence of a certain variant, i.e.
197 a confounder, we included a natural cubic spline (5 knots) for calendar week of sample date in all
198 regression models. In addition, all analyses were also adjusted for 10-year age group (40-49 years as
199 reference) and sex.

200

201 ***Results***

202 From 1 March to 31 August 2021, a total of 661,658 SARS-CoV-2 positive cases were notified to the
203 national surveillance database (Table 1). Of these, 38,261 (5.8%) cases were partly vaccinated,
204 25,933 (3.9%) were fully vaccinated and 10,565 (1.6%) had a known previous infection
205 (Supplementary Figure 1). Of (partly) vaccinated cases, most received Comirnaty (65.0%), followed
206 by Vaxzevria (19.3%), Janssen COVID-19 vaccine (9.8%) and Spikevax (5.9%). We included data of
207 29,305 samples that were sequenced through the national SARS-CoV-2 surveillance program (Table
208 1). In addition, 1,516 additional samples were sequenced to increase insight in variants present in
209 infections after vaccination and reinfections were included.

Up to June 2021, 94.4% (14,068 of 14,903) of infections were caused by the Alpha variant, with a small proportion caused by the Beta (1.3%) and Gamma (1.3%) variant. The proportion of Delta increased from 0.9% (42 of 4874) in May to 98.7% (4561 of 4620) in August 2021. This pattern was observed over different immune statuses (Figure 1). In total, 17,890 (58.0%) Alpha, 209 (0.7%) Beta, 250 (0.8%) Gamma, 11,937 (38.7%) Delta and 535 (1.7%) other variant sequences were observed.

Logistic regression analysis showed that full vaccination was significantly associated with infection with the Beta, Gamma or Delta variant compared to the Alpha variant (adjusted OR: 3.1 (95% CI: 1.3-7.3); 2.3 (95% CI: 1.2-4.4); 1.9 (95% CI: 1.4-2.5); respectively; Figure 2). The association for partial vaccination was less strong and not significant for Beta and Gamma, but still significant for Delta when compared to Alpha (adjusted OR: 1.6 (95% CI: 1.2-2.0); Figure 2). We did not find a significant association between previous infection and the Beta, Gamma or Delta variant over Alpha (adjusted OR: 1.4 (95% CI 0.5-3.7); 0.3 (95%CI 0.0-1.9; 1.0 (95%CI 0.6-1.5), respectively; Figure 2). The Delta variant was significantly associated with younger age groups, which highlights the importance of adjustment for age group (Supplementary Figure 3). When only including data from the genomic surveillance (excluding data from additional sampling of vaccinated and reinfected cases), similar odds ratios were found, although not significant anymore for Beta and Gamma due to less power (data not shown).

When stratified by vaccine type, the association between full vaccination and infection with the Delta variant was significant for Comirnaty and Janssen COVID-19 vaccine, but not for Spikevax and Vaxzevria (Table 2). The association between partial vaccination and the Delta variant was significant for Comirnaty and Vaxzevria but not Spikevax. In addition, we stratified the fully vaccinated by time since vaccination. The association for individuals with less time (14-59 days) between onset and last

dose was higher (OR: 2.3 (95%CI 1.6-3.4)) compared to individuals with 60 days and more (OR: 1.4 (95%CI 1.0-2.1)) for the Delta variant. A similar trend was observed for Beta variant and Gamma variant, although with wide confidence intervals (Table 2).

Discussion

Using national epidemiological and whole genome sequencing surveillance data from March to August 2021 in the Netherlands, our analysis provides evidence for an increased risk of infection by the Beta, Gamma, or Delta variants compared to the Alpha variant after full vaccination, regardless of the vaccine used. This indicates lower vaccine effectiveness against infection with the Beta, Gamma and Delta variant compared to the Alpha variant. No clear differences between vaccine type were observed as confidence intervals largely overlap. Interestingly, we did not find a significant difference between susceptibility to any of the investigated VOCs among individuals with immunity due to a previous infection compared to naïve individuals. Also when stratified by time between infections no differences are observed (data not shown). Of note is that these analyses do not aim to determine the probability of getting infected after vaccination or previous infection, but rather calculate the likelihood of getting infected with specific VOCs.

The association with vaccination status was higher for Beta and Gamma (OR of 3.1 and 2.3, respectively) than for Delta (OR of 1.9), although confidence intervals for Beta and Gamma were wide because of low numbers. This is in line with literature showing lower vaccine effectiveness estimates against infection for Beta and Gamma compared to Delta[7]. An OR for Delta of 1.9 implicates a reduction of vaccine effectiveness from 90% to 80%, which has been shown in the UK[3,27]. Current literature still shows high vaccine effectiveness of 90-95% against severe COVID-19 for the Delta variant[7,17], which is reassuring. However, note that with very high vaccine effectiveness, a difference of a factor 1.5-2.0 between two variants could go unnoticed, as it would only mean a decrease of effectiveness of 95 to 92%.

Spike binding and neutralization have been shown to be substantially reduced against Beta, Gamma, and Delta with the largest reduction in neutralization against Beta[4–6], which is consistent with our results. This observation did not differ for infection- or vaccine-induced immunity, although convalescent sera from mild infections showed lower levels of neutralization potency to VOCs compared to hospitalized cases and vaccinated individuals[4]. However, in Alpha and Beta a reduction was not observed for T-cell-mediated immunity[28].

We observed a larger effect of vaccination in the first 14-59 days after vaccination (i.e. OR 2.3 (95%CI 1.6-3.5) for Delta) compared to 60 days and longer (i.e. OR 1.4 (95%CI 1.0-2.1) for Delta), suggesting that the difference in VE between Delta and Alpha variant reduces over time since vaccination, possibly due to waning immunity. A recent large cohort study describes an effect of waning and a small effect of the circulating variant (i.e. Delta vs non-Delta) on the VE against SARS-CoV-2 infection[29]. They find a non-delta VE of 97% and a delta VE of 93% one month after vaccination, which means a ratio of 2.3 between non-delta VE and delta VE. Four to five months post vaccination, VE estimates of 67% and 53% for non-delta and delta were observed respectively, a ratio of 1.4. This very well corresponds with our results. Given the broad and sometimes overlapping confidence intervals of these data, however, the differences need to be interpreted with caution.

We found no association between previous infection and a new infection with Beta, Gamma or Delta versus Alpha, suggesting that there is a no difference in immunity between Alpha and Beta, Gamma or Delta after previous infection, in contrast to vaccine-induced immunity. It is not yet clear whether previous infection or vaccination induces better protection against infection. However, primary infection comes with a risk of hospitalization or death, especially in older persons or individuals with underlying conditions. Even if infection-induced immunity protects better against reinfection with

novel variants, vaccination is preferred over infection to protect individuals against severe disease as the cumulative risk from two infections should be taken into account.

Some limitations of our study need to be addressed. Asymptomatic or mild cases with low viral load are less likely to be identified and only detectable infections can be sequenced and included. In addition, sequencing is more successful in samples with low to medium Ct values (high to medium viral load). If infection with Beta, Gamma or Delta leads to lower Ct values than Alpha and Ct values are higher for infections after vaccination[30–32], this could have led to an overestimation of the studied association. Another limitation is that prior infections could go undetected, especially if occurred during the first wave when there was no mass scale testing capacity. This could lead to an underestimation of cases with a previous infection, as we do not directly measure pre-existing infection-induced immunity.

In conclusion, our results confirm a lower vaccine effectiveness against infection for the Delta variant, and similarly the Beta and Gamma variant, compared to Alpha. This effect was largest early after complete vaccination. These findings are informative for considerations on vaccine updates, future vaccination and pandemic control strategies.

Acknowledgements

The authors would like to thank all personnel at the 25 Public Health Services for data collection in the national surveillance database and all laboratories for providing specimens for sequence analyses.

Code availability

Code for sequencing data processing is publicly available at github.com/RIVM-bioinformatics/SARS2seq. Scripts for statistical analysis, figures, and tables can be found at github.com/Stijn-A/xxxxx.[upon publication]

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Figures and Tables

Figure 1 *Variants found in SARS-CoV-2 positive samples of individuals with naïve (unvaccinated and no known previous infection), vaccine-induced, or infection-induced immune status. Number of naïve, partly vaccinated, fully vaccinated, and reinfected documented SARS-CoV-2 positive individuals by variant from March 1 to August 31, 2021 (upper panel) and proportion of the respective groups (lower panel).*

Figure 2 *Odds ratios of the logistic regression models for the association between immune status and VOC (Beta, Gamma or Delta over the Alpha variant) adjusted for week of sampling, sex and 10-year age group. Error bars correspond to the 95% confidence intervals.*

Table 1 *Characteristics of notified SARS-CoV-2 positive cases overall and for which variant information was available, 1 March to 31 August 2021, the Netherlands*

	Notifications	**Variant information from genomic surveillance**	**Variant information from additional sampling**
Total	661,658	29,305	1,516
Immune status			
Naïve	487,063 (73.6%)	20,804 (71.0%)	NA
Recently vaccinated	47,565 (7.2%)	2,140 (7.3%)	18 (1.2%)
Partly vaccinated	38,261 (5.8%)	2,016 (6.9%)	707 (46.6%)
Fully vaccinated	25,933 (3.9%)	1,791 (6.1%)	516 (34.0%)
Previous infection	10,565 (1.6%)	284 (1.0%)	191 (12.6%)
Vaccinated and previous infection	2,065 (0.3%)	62 (0.2%)	49(3.2%)
Unknown	50,206 (7.6%)	2,208 (7.5%)	35 (2.3%)
Age group			
0-9	42,666 (6.4%)	1,818 (6.2%)	4(0.3%)
10-19	125,782 (19.0%)	5,869 (20.0%)	111 (7.3%)
20-29	157,896 (23.9%)	7,018 (23.9%)	283 (18.7%)
30-39	92,400 (14.0%)	4,162 (14.2%)	187 (12.3%)

40-49	85,492 (12.9%)	3,851 (13.1%)	222 (14.6%)
50-59	87,112 (13.2%)	3,652 (12.5%)	265 (17.5%)
60-69	44,226 (6.7%)	1,828 (6.2%)	251 (16.6%)
70-79	21,074 (3.2%)	848 (2.9%)	86 (5.7%)
80+	5,010 (0.8%)	259 (0.9%)	107 (7.1%)
Sex			
Male	330,247 (49.9%)	14,437 (49.3%)	629 (41.5%)
Female	331411 (50.1%)	14,868 (50.7%)	692 (58.5%)
Symptoms			
Yes	556,214 (84.1%)	25,478 (86.9%)	1355 (89.4%)
No	66,593 (10.1%)	2,248 (7.7%)	121 (8.0%)
Unknown	38,851 (5.9%)	1,579 (5.4%)	40 (2.6%)
Month (sampling date)			
March	149,103 (22.5%)	5,408 (18.5%)	177 (11.7%)
April	171,534 (25.9%)	4,621 (15.8%)	335 (22.1%)
May	114,536 (17.3%)	4,874 (16.6%)	137 (9.1%)
June	24,904 (3.8%)	3,162 (10.8%)	97 (6.4%)
July	146,978 (22.2%)	6,620 (22.6%	438 (28.9%)
August	54,603 (8.3%)	4,620 (15.8%)	331(21.8%)

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411 ***Table 2*** *Odds ratios (ORs) and 95% confidence intervals (CIs) for the association between immune*
412 *status and VOC (Beta, Gamma or Delta over the Alpha variant) by vaccine type and days between*
413 *onset and last dose, both adjusted for week of sampling, sex and 10-year age group.*

	Beta	**Gamma**	**Delta**
	OR (95% CI)	**OR (95% CI)**	**OR (95% CI)**
Naïve	Reference	Reference	Reference
Partly vaccinated			
Comirnaty	1.1 (0.3-3.7)	1.9 (1.0-3.7)	1.8 (1.4-2.3)
Spikevax	n/a	2.5 (0.6-10.4)	1.1 (0.6-2.0)
Vaxzevria	2.1 (1.0-4.1)	1.0 (0.5-2.0)	2.1 (1.3-3.5)
Fully vaccinated			
Comirnaty	3.2 (1.4-7.7)	2.2 (1.0-4.7)	2.2 (1.4-3.3)
Spikevax	n/a	n/a	1.3 (0.4-4.3)
Vaxzevria	n/a	2.8 (0.7-12.3)	1.4 (0.9-2.3)
Janssen	n/a	4.4 (0.6-34.5)	2.2 (1.2-4.2)
Naïve	Reference	Reference	Reference
Fully vaccinated			
14-60 days	3.7 (1.4-9.5)	3.0 (1.3-7.1)	2.3 (1.6-3.4)
>60 days	1.7 (0.2-12.8)	1.7 (0.6-4.6)	1.4 (1.0-2.1)

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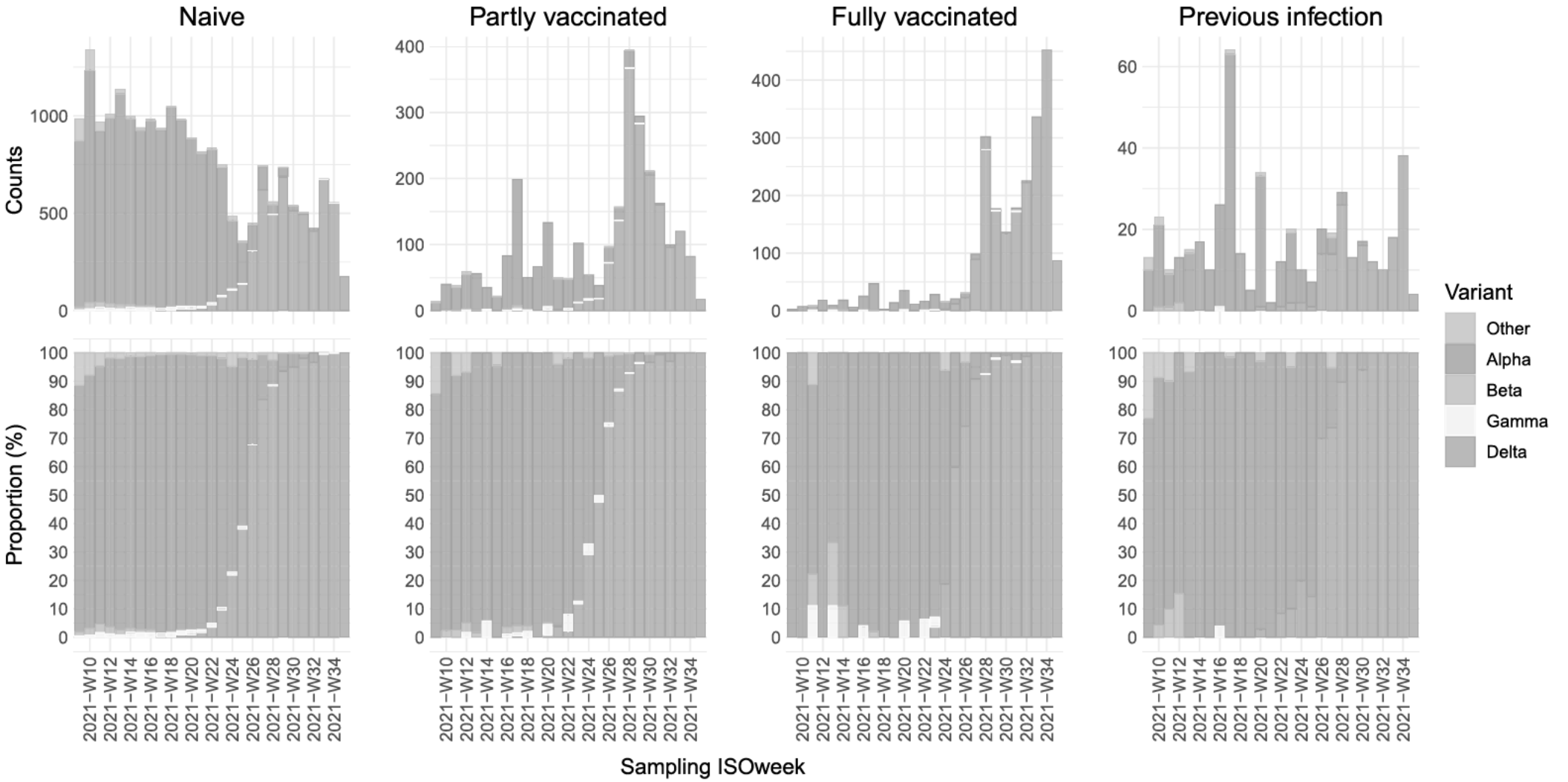
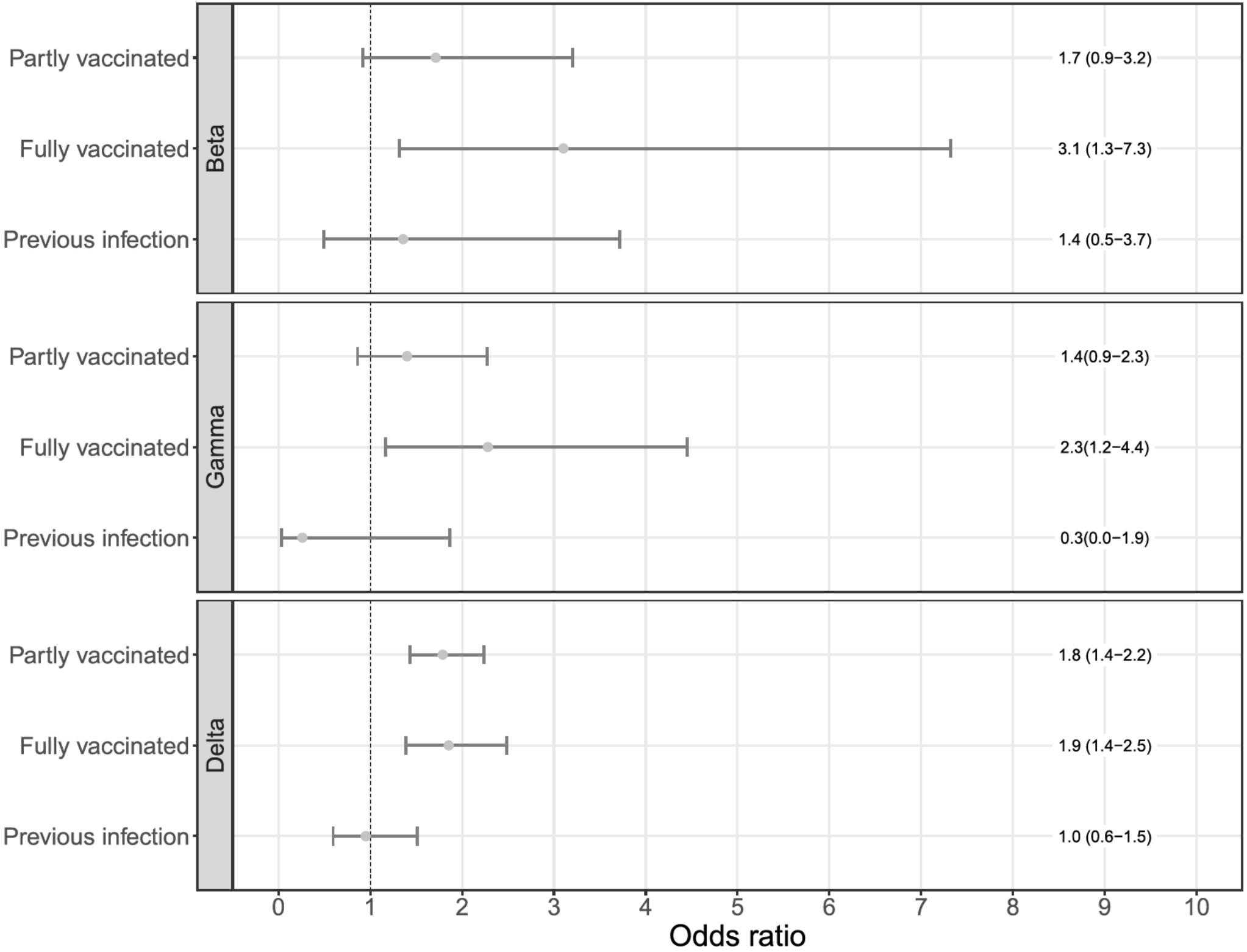

Naive
Partly vaccinated
Fully vaccinated
Previous infection
Counts
Proportion (%)
Sampling ISOweek
Variant
Other
Alpha
Beta
Gamma
Delta


Beta
Partly vaccinated
Fully vaccinated
Previous infection
1.7 (0.9–3.2)
3.1 (1.3–7.3)
1.4 (0.5–3.7)
Gamma
Partly vaccinated
Fully vaccinated
Previous infection
1.4(0.9–2.3)
2.3(1.2–4.4)
0.3(0.0–1.9)
Delta
Partly vaccinated
Fully vaccinated
Previous infection
1.8 (1.4–2.2)
1.9 (1.4–2.5)
1.0 (0.6–1.5)
0
1
2
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Odds ratio

Exhibit "I"

FEE Stories

Harvard Epidemiologist Says the Case for COVID Vaccine Passports Was Just Demolished

New research found that natural immunity offers exponentially more protection than COVID-19 vaccines.

Monday, August 30, 2021

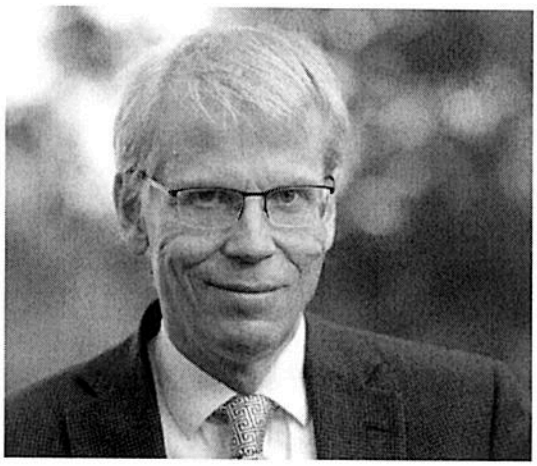

Photo by Thérèse Soukar, CC BY-SA 4.0 , via Wikimedia Commons

Jon Miltimore

Politics Vaccine Passport Vaccines Natural Immunity COVID-19 Freedom of Movement CDC Israel

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A newly published medical study found that infection from COVID-19 confers considerably longer-lasting and stronger protection against the Delta variant of the virus than vaccines.

"The natural immune protection that develops after a SARS-CoV-2 infection offers considerably more of a shield against the Delta variant of the pandemic coronavirus than two doses of the Pfizer-BioNTech vaccine, according to a large Israeli study that some scientists wish came with a

'Don't try this at home' label," *Science* reported Thursday. "The newly released data show people who once had a SARS-CoV-2 infection were much less likely than vaccinated people to get Delta, develop symptoms from it, or become hospitalized with serious COVID-19."

Put another way, vaccinated individuals were 27 times more likely to get a symptomatic COVID infection than those with natural immunity from COVID.

A Death Blow to Vaccine Passports?

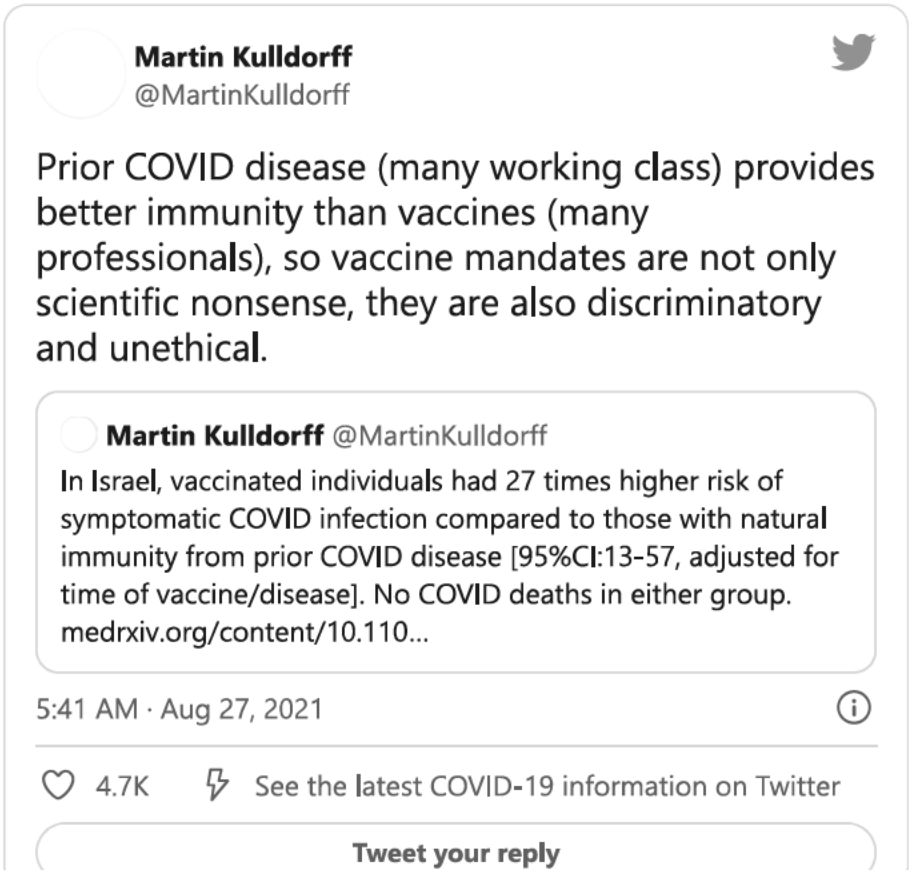
The findings come as many governments around the world are demanding citizens acquire "vaccine passports" to travel. New York City, France, and the Canadian provinces of Quebec and British Columbia are among those who have recently embraced vaccine passports.

Meanwhile, Australia has floated the idea of making higher vaccination rates a condition of lifting its lockdown in jurisdictions, while President Joe Biden is considering making interstate travel unlawful for people who have not been vaccinated for COVID-19.

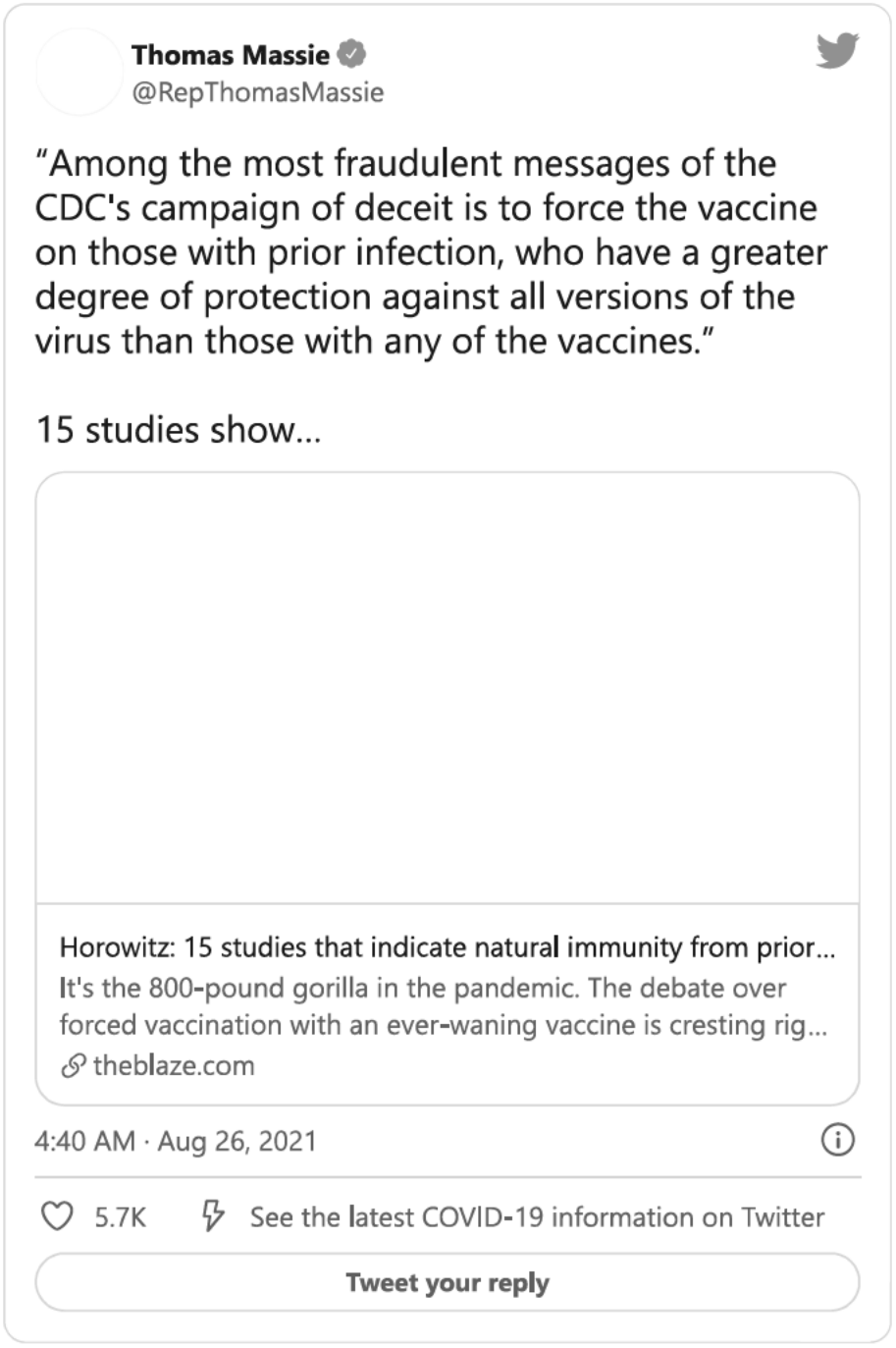
Vaccine passports are morally dubious for many reasons, not the least of which is that freedom of movement is a basic human right. However, vaccine passports become even more senseless in light of the new findings out of Israel and revelations from the CDC, some say.

Harvard Medical School professor Martin Kulldorff said research showing that natural immunity offers exponentially more protection than vaccines means vaccine passports are both unscientific and discriminatory, since they disproportionately affect working class individuals.

"Prior COVID disease (many working class) provides better immunity than vaccines (many professionals), so vaccine mandates are not only scientific nonsense, they are also discriminatory and unethical," Kulldorff, a biostatistician and epidemiologist, observed on Twitter.



Nor is the study out of Israel a one-off. Media reports show that no fewer than 15 academic studies have found that natural immunity offers immense protection from COVID-19.



Moreover, CDC research shows that vaccinated individuals still get infected with COVID-19 and carry just as much of the virus in their throat and nasal passage as unvaccinated individuals

“High viral loads suggest an increased risk of transmission and raised concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus,” CDC Rochelle Director Walensky noted following a Cape Cod outbreak that included mostly vaccinated individuals.

These data suggest that vaccinated individuals are still spreading the virus much like unvaccinated individuals.

The Bottom Line

Vaccine passports would be immoral and a massive government overreach even in the absence of these findings. There is simply no historical parallel for governments attempting to restrict the movements of healthy people over a respiratory virus in this manner.

Yet the justification for vaccine passports becomes not just wrong but absurd in light of these new revelations.

People who have had COVID already have significantly more protection from the virus than people who’ve been vaccinated. Meanwhile, people who’ve not had COVID and choose to not get vaccinated may or may not be making an unwise decision. But if they are, they are principally putting only themselves at risk.

Join us in preserving the principles of economic freedom and individual liberty for the rising generation

Support FEE's Mission

Jon Miltimore

Jonathan Miltimore is the Managing Editor of FEE.org. His writing/reporting has been the subject of articles in TIME magazine, The Wall Street Journal, CNN, Forbes, Fox News, and the Star Tribune.
Bylines: Newsweek, The Washington Times, MSN.com, The Washington Examiner, The Daily Caller, The Federalist, the Epoch Times.

Exhibit "J"

This is **Exhibit "J"** referred to in the
Affidavit of Tyler May
sworn (or affirmed) before me at
Mundare, Alberta, this
8 th day of December, 2021.

A Commissioner/Notary Public in and
for the Province of Alberta

DAVID D. MAY
BARRISTER & SOLICITOR
NOTARY

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Correspondence/Letter to the Editor

Higher incidence of reported adverse events following immunisation (AEFI) after first dose of COVID-19 vaccine among previously infected health care workers

Dear Editor,

Coronavirus disease 2019 (COVID-19) has affected the world in an unprecedent manner. Countries across the globe are making efforts to vaccinate their vulnerable population against this disease. Development of COVID-19 vaccines and processes for their mandatory regulatory approval have been fast-tracked keeping in view of urgent requirement of these vaccines to contain the pandemic.[1] India has given emergency approval and rolled out two vaccines—ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD) and whole-virion inactivated SARS-CoV-2 vaccine BBV152 (COVAXIN) for vaccination of its health care workers and frontline workers.[2] At present, data on adverse events after immunisation (AEFI) following COVID-19 vaccination are limited.[3] Hence, we carried out this study to determine incidence and risk factors of systemic AEFI reported following first dose of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant).

This study was conducted among Armed Forces Medical Services healthcare workers (HCW) deployed in Northern India, who took first dose of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) voluntarily in 14 vaccination centres in January–February 2021. Data regarding their age, COVID-19 infection in the past and other comorbidities was also obtained through a structured questionnaire before vaccination. These health workers were given 0.5 ml of vaccine intramuscularly in deltoid region and observed for 30 min in vaccination centres. Thereafter, these vaccine recipients were asked to report to officer in charge vaccination centre in case they develop AEFI symptoms, as per COVID-19 vaccination operational guidelines.[3] Data obtained from all vaccination centres was collated and summarised by mean, standard deviation and proportions. Incidence proportion and relative risk of any AEFI with 95% confidence interval (CI) were calculated by log binomial regression. Variables with p-value < 0.1 in bivariable analysis were included for multivariable regression to estimate adjusted relative risk. We also carried out sensitivity analysis by excluding one vaccination site at a time from the analysis to assess the robustness of association of risk factors with AEFI. R software ver 3.6.1 was used for statistical analysis. Informed consent was taken from the study participants and the study was approved by the institutional ethics committee.

A total of 1634 HCW were given first dose of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant). Their mean (SD) age was 32.04 (7.84) years and only 68 (4.16%) out of them were females. Study participants consisted of 106 (6.5%) doctors, 734 (44.9%) paramedical staff and 794 (48.6%) administrative and support staff. About 105 vaccine recipients reported at least one AEFI symptoms following COVID-19 vaccination (incidence proportion 6.4%, 95% CI: 5.3%, 7.7%). All AEFI reported were minor which were managed by tablet paracetamol and subsided after 1–2 days. Fever (65, 3.98%) was the most commonly reported AEFI followed by myalgia (54, 3.30%) (Fig. 1). About 48 (2.94%) study participants reported 2 or more AEFI, most common being fever with myalgia (19, 1.16%) and fever with headache (18, 1.10%). No severe or serious AEFI was reported among vaccine recipients. Incidence of systemic AEFI reported in our study is lesser than reported in phase 1/2 clinical trial of this vaccine[4], as we have used passive surveillance to monitor AEFI as per Government of India's policy on COVID-19 vaccine AEFI surveillance[3] as compared with active surveillance used in clinical trials. In our study, incidence of reported AEFI was higher among female HCW, doctors, younger HCW and those who had previous COVID-19 infection (Table 1). Pre-existing comorbidities were not found to be associated with AEFI. We observed that after adjusting for other variables, previous COVID-19 infection (aRR = 2.40, 95% CI: 1.48, 3.91) and female sex (aRR = 2.24, 95% CI: 1.22, 4.09) were significant independent risk factors for any systemic AEFI reported after COVID-19 vaccination. In sensitivity analysis also, previous COVID-19 infection and female sex were found to be consistently associated with reported AEFI.

Most of these AEFI symptoms reported were related to vaccine reactogenicity, which is mediated by pyrogenic cytokines such as interleukin-1 (IL-1), IL-6, prostaglandin-E2 and tumour necrosis factor–alpha (TNF-α), released due to activation of immune response on vaccination. Some vaccines are known to cause increased postvaccination titres in those with evidence of prior infection as well as more systemic reactions after repeat doses

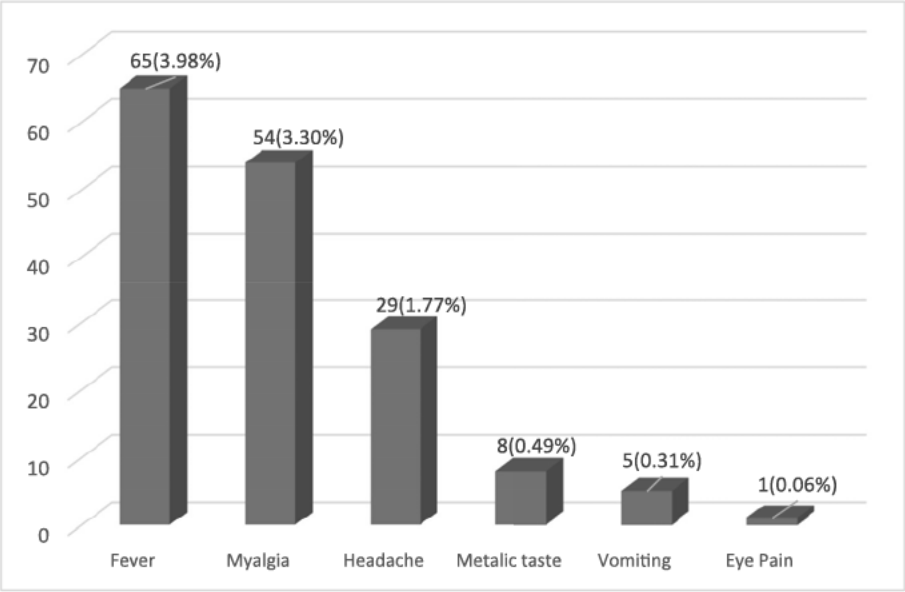

Fig. 1 – Systemic AEFI reported after first dose of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant).

due to induction of pre-existing immunity.[5] In our study also, incidence of AEFI reported among those with previous COVID-19 infection was higher than other health workers even after adjusting for their sex, age and profession. Higher incidence of AEFI after first dose of vaccine among previously infected COVID-19 cases has also been reported in a study by Krammer et al[6] (mRNA vaccines) as well as from ZOE COVID Symptom Study[7] being conducted in the United Kingdom (mRNA and ChAdOx1 nCoV-19 vaccine). Studies on mRNA vaccines by Saadat et al[8] and Krammer F et al[6] have brought out that the antibody titers in COVID-19 recovered vaccinees is 10–20 times higher than other vaccine recipients, which can be responsible for higher incidence of AEFI in this group of individuals.

We observed higher incidence of reported AEFI among female and younger age group vaccine recipients. These findings are consistent with the results of study by CDC in USA[9] (mRNA vaccines) and Jayadevan et al[10] in India (ChAdOx1 nCoV- 19 vaccine and BBV152/COVAXIN), which have also reported that women are more likely to report AEFI after COVID-19 vaccination. Studies done on AEFI of other vaccines[5,11,12] had also documented higher rate of AEFI among females. The difference can be due to genetic factors as well as due to hormones which are known to influence cytokine levels and immune response to vaccination. It has been reported that women tend to produce higher neutralizing titres after vaccination as compared with men.[12] Similarly, studies have found that young people are more likely to report AEFI due to higher immune response.[10,12] Older people are known to have lower levels of CRP, IL-10 and IL-6 after vaccination, which can explain lesser systemic adverse events in them.[5] In view of these findings, we recommend that further studies on immune response and AEFI after COVID-19 vaccination may be carried out in these high-risk groups.

Table 1 – Risk factors of reported AEFI after COVID-19 vaccination.

Risk Factors	Total Number	No. Reporting AEFI (%)	Relative Risk (95% CI)	p value	Adjusted Relative Risk (95% CI)	p Value
Previous COVID-19 infection						
No	1529	88 (05.8%)	Ref	<0.001	Ref	<0.001
Yes	105	17 (16.2%)	2.81 (1.74, 4.55)		2.40 (1.48, 3.91)	
Sex						
Male	1566	92 (05.9%)	Ref	<0.001	Ref	0.009
Female	68	13 (19.1%)	3.25 (1.92, 5.52)		2.24 (1.22,4.09)	
Type of HCW						
Paramedical & Support staff	1528	90 (05.9%)	Ref	<0.001	Ref	0.072
Doctors	106	15 (14.2%)	2.40 (1.44, 4.00)		1.70 (0.95, 3.02)	
Co-morbidities						
No	1601	104 (06.5%)	Ref	0.441		
Yes	33	1 (03.0%)	0.47 (0.06, 3.24)			
Age (per year)			0.98 (0.95, 1.00)	0.075	0.98 (0.95, 1.00)	0.104

Disclosure of competing interest

The authors have none to declare.

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