Form 49
[Rule 13.19]

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


| | | |
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| ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT | Ackroyd LLP<br>Barristers and Solicitors<br>1500, 10665 Jasper Avenue<br>Edmonton, Alberta T5J 3S9<br>Attention: Richard C. Secord | Justice Centre for Constitutional Freedoms<br>#253, 7620 Elbow Drive SW<br>Calgary, Alberta T2V 1K2<br>Attention: Eva Chipiuk |


[redacted]

**AFFIDAVIT OF DR. BLAINE ACHEN**
**Sworn on December 7, 2021**

I, Dr. Blaine Achen, of the City of Edmonton, 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 graduated from medical school at the University of Alberta (the "University") in 1999. I completed my residency in Anesthesia in 2004 and began my career at the University as an Assistant Clinical Professor in the Department of Anesthesia and Pain Medicine in 2005 at the University. Until November 18, 2021, when I was immediately terminated from my position, I held the position of Chief of Cardiac Anesthesia at the Mazankowski Alberta Heart Institute of Alberta (the "Hospital"). I have worked for a total of sixteen years in my capacity as both a

general and cardiac anesthesiologist. Attached hereto and marked as **Exhibit "A"** to this my Affidavit is a copy of my Curriculum Vitae.

3. For the past 20 months, essentially from when the state of emergency was first declared in March of 2020 by Dr. Deena Hinshaw (the "Pandemic"), I have been in close contact with Covid-19 positive patients while working on the Cardiovascular Intensive Care Unit ("CVICU") and Operating Rooms at the Hospital. During the Pandemic, I have not been infected by a patient nor infected any patients or staff.

4. As medical practitioners, and especially those working in the operating room, strict protocols for infection, protection, and control are followed to ensure that the operating room is a very sterile environment. These include meticulous hand hygiene, sterile gown, and glove-wearing, appropriate masking (N95 for aerosol-generating medical procedures when infectious agents are suspected). I have been following this practice for the last sixteen years.

5. In late April and early May of 2021, my wife had symptoms of Covid-19 and I isolated myself for two weeks and stayed home. Both my wife and I tested positive for Covid-19 with a PCR test. I returned to work after my two weeks of isolation and have been working since that time, again being in close contact with Covid-19 positive patients.

6. After I recovered from Covid-19 and before AHS announced their vaccination policy, I had a conversation with my superior, Dr. Dominic Cave, regarding an alleged vaccination policy which we understood was being considered by Alberta Health Services ("AHS"). I indicated I would be seeking an exemption to any mandate requiring experimental medical injections, as I already tested positive for Covid-19 and have natural immunity. He indicated that would be reasonable.

7. On September 14, 2021, AHS Policy 1189 - Immunization of Workers for Covid-19 was put in place effective October 31, 2021 (the "Policy"). Attached hereto and marked as **Exhibit "B"** to this my Affidavit is a copy of the Policy.

8. On September 14, 2021, I had my blood drawn for a Covid-19 antibody test performed by the Mayo Clinic Laboratories. On September 24, 2021, I obtained my Covid-19 antibody test results which demonstrated my robust natural immunity six months post-recovery from Covid-19. I surpassed the maximum titration with >250 U/mL antibodies to the Sars-CoV-2 spike

glycoprotein, indicating I have very strong natural immunity. Attached hereto and marked as **Exhibit "C"** to this my Affidavit is a copy of my Covid-19 antibody test result.

***The Policy and My Request for Accommodation***

9. On October 1, 2021, I applied for an exemption to the Policy based on both medical grounds due to natural immunity and religious grounds. Attached hereto and marked as **Exhibit "D"** to this my Affidavit is a copy of my exemption request to AHS.

10. On October 15, 2021, my superior, Dr. Cave, sent an email suggesting all staff not complying with the mandate should request a voluntary unpaid leave of absence ("LOA") from Clinical Duties. This voluntary unpaid LOA was to ensure we did not lose our privileges according to the AHS By-Laws and "going forward this may be very important for resuming practice." Attached hereto and marked as **Exhibit "E"** to this my Affidavit is a copy of the email from Dr. Cave.

11. On October 15, 2021, I also received a response from Dr. David Zygun, Edmonton Zone Medical Director for AHS, denying my request for an exemption pursuant to the Policy. Dr. Zygun's letter included the Recommendation by the AHS Medical and Midwifery Staff Exception Review Panel dated October 13, 2021 ("Exemption Review Panel Report"). Attached hereto and marked as **Exhibit "F"** to this my Affidavit is a copy of the letter from Dr. Zygun and the attached Exemption Review Panel Report.

12. The Exemption Review Panel Report response I received was generic. It did not speak to the issues in the medical evidence and scientific research concerns that I raised. For AHS to ask me, as a medical professional, to inject myself with a hastily tested, novel medical intervention, threaten my job and livelihood, and not specifically respond to my concerns is absolutely unacceptable and unethical.

13. The Exemption Review Panel Report also made no mention of why my religious exemption was denied. I am absolutely opposed to the use of fetal cell lines in the use of any medical experimentation or testing. To demand that I take either a Pfizer or Moderna injection would violate my conscience, religious values, and freedoms. The sanctity of life is deeply rooted in both my Christian heritage and medical practice. For AHS to tell me I cannot work unless I infringe on my conscience and religious values is coercion of the highest order.

14. AHS has not disclosed who the Exemption Review Panel is comprised of and what the qualifications are in making these medical and religious decisions. Furthermore, it is my view that the Exemption Review Panel is an illusion. To date, I have heard of only one individual that was granted an exemption. However, he is still not allowed to work at AHS facilities because of his work, like mine, he can only work in AHS facilities. In other words, he does not, and cannot work outside AHS facilities in Alberta. So while he was granted an exemption, AHS did not accommodate him to continue working. What is the point of an exemption if AHS still prevents you from working and earning a living?

15. Following the receipt of the denial of my exemption request, Dr. Zygun pressed me to make a decision and set up a meeting to discuss the next steps.

16. On October 20, 2021, I had a digital Zoom meeting with Dr. Zygun, and we talked about my options given the denial of my exemption request. At that meeting, I was informed that as of November 1, 2021, I was no longer allowed to work at AHS facilities. I stated I thought the Policy was wrong and not based on the established science of natural immunity and I should be allowed to work as I was completely immunized as evidenced in the scientific literature based on my status of Covid-19 convalescent and positive antibody test. I also set out that AHS had a shortage of anesthesiologists and it would not make operational sense to lay people off or force them to resign with such a demand for anesthesiologists. Following this meeting, Dr. Zygun sent me an email again setting out my options. Attached hereto and marked as **Exhibit "G"** to this my Affidavit is a true copy of that email.

17. On October 22, 2021, AHS announced that the deadline for vaccination pursuant to the Policy was pushed to November 30, 2021. On November 29th, AHS extended the Policy again to December 13, 2021, and introduced rapid testing at certain sites. Attached hereto and marked respectively as **Exhibit "H"** and **"I"** to this my Affidavit are the emails from AHS announcing the extensions.

18. The AHS extensions and changes have caused extreme confusion and problems for myself, AHS staff, and my patients. On November 28, 2021, I had no surgeries booked after December 1, 2021. Following the AHS announcement, I was booked for surgeries until December 13, 2021, in general operating rooms, whereas normally I would be working more complicated cases in the cardiac operating rooms. It is my opinion that this type of last-minute change and scheduling is very dangerous both for AHS staff and patients.

19. On November 2, 2021, my legal counsel, Ms. Eva Chipiuk, from the Justice Centre for Constitutional Freedoms, sent a letter to AHS via Dr. Verna Yiu requesting that she reverse the Covid-19 vaccination requirement or grant accommodation in order to keep working. Attached hereto and marked as **Exhibit "J"** to this my Affidavit is a copy of the letter to AHS.

20. On November 8, 2021, Shalee Kushnerick, Associate General Counsel, Litigation for AHS, acknowledged receipt of Ms. Chipiuk's letter and confirmed that AHS will not make changes to the Policy and is prepared to take action against me to enforce the Policy. Attached hereto and marked as **Exhibit "K"** to this my Affidavit is a copy of the letter from AHS.

21. On November 17, 2021, I received a letter from Dr. Braden Manns, Associate Chief Medical Officer, asking me to meet and again asking me to submit to injection of the Covid-19 vaccine. Attached hereto and marked as **Exhibit "L"** to this my Affidavit is a copy of the letter from Dr. Manns.

22. On November 17, 2021, I also received a letter from Dr. David Zygun, Edmonton Zone Medical Director, informing me that I was terminated effective immediately from my leadership role of Zone Clinical Section Chief, Adult Cardiac Anesthesia. Attached hereto and marked as **Exhibit "M"** to this my Affidavit is a copy of the letter received from Dr. David Zygun.

23. On November 25, 2021, I had another zoom meeting with Dr. Manns where he gave me 4 options, however, he acknowledged in that meeting that none of the options applied to me because of my specific work and given that my work is exclusively performed in operating rooms which are AHS facilities. Dr. Manns also confirmed that the Policy was not an immunity mandate but an immunization mandate. This made no sense to me because if the objective of the Policy is to keep AHS staff and patients safe, the Policy cannot ignore immunity. On November 28, 2021, I followed up with these questions to Dr. Manns. Attached hereto and marked as **Exhibit "N"** to this my Affidavit is my email to Dr. Manns. To date, I have not received a response from Dr. Manns.

24. Furthermore, the Policy, and how AHS is enforcing it, has caused a toxic and harmful work environment. AHS leadership at the Hospital has made inflammatory statements and accusations against unvaccinated individuals. One of the CVICU intensivists told me anyone not vaccinated should pay their own health care costs should they need healthcare for a Covid-19 infection. As medical professionals, this is unethical and against our duty of care. Further, as medical professionals, working in a public health care system, it is irresponsible and immoral

for AHS representatives to make such statements. We don't discriminate against individuals who smoke tobacco, drink alcohol excessively, drink and drive, use recreational drugs, participate in risky sports, yet we treat them all when they come in. Some of the activities are illegal, but as medical professionals, we still treat everyone without hesitation.

25. AHS also prepares regular bulletin updates. I mentioned to Dr. Zygun that this same CVICU intensivist reported to AHS that 30% of double-vaccinated patients were coming into the hospital on or around October 19, 2021. I recalled seeing the bulletins before and since then, I noticed that the AHS bulletins no longer show the percentage of vaccinated patients entering the hospital with Covid-19 infection.

26. AHS is taking action and enforcing measures without disclosing the information it is relying on. There is a lack of transparency that is unacceptable in the setting of the Pandemic where our rights and freedoms are being suspended if we are not vaccinated. Based on my observations, and from reading scientific and medical information, it is clear that the Covid-19 vaccine is not effective at preventing infection or stopping the spread of Covid-19. The percentage of vaccinated patients continues to rise. AHS is arbitrarily and unjustly discriminating against non-vaccinated staff, all while I have naturally acquired immunity that is more enduring and effective than the Covid-19 vaccines.

***My Professional Judgement***

27. As a doctor, I must inform my patient of the benefits and risks of all medication, including possible side effects. With this information, the patient can decide whether or not to accept the treatment. This is called informed consent, which is a basic tenet of medicine. The Covid-19 vaccines remain subject to ongoing clinical trials and the vaccines bear Health Canada warning labels. The risks and adverse impacts should not be taken lightly by AHS or anyone enforcing mandatory vaccination.

28. The AstraZeneca vaccine has a rare, but potentially fatal risk, of developing blood clots attached to its use and was temporarily halted for people under 55 years of age in Canada and multiple European countries. Attached hereto and marked as **Exhibit "O"** to this my Affidavit is a copy of an article from CBC regarding the AstraZeneca vaccine. The mRNA vaccines (Pfizer/Moderna) have a risk of developing myocarditis and pericarditis in young males and the Moderna vaccine is not being recommended for 12-29 year-olds. Attached hereto and marked

as **Exhibit "P"** to this my Affidavit is the AHS document with information on mRNA vaccines whereas on page 2 the serious side effects are set out.

29. The number of Serious Adverse Reactions to these Covid 19 vaccines in <u>just one year</u> eclipses all the adverse reactions of all other vaccines combined over the last 50 plus years. Attached hereto and marked as **Exhibit "Q"** to this my Affidavit is the World Health Organization's website showing the adverse reactions reported from the Covid-19 vaccine. This is not a safe vaccine! Both vaccinated and unvaccinated can spread Covid-19 to others.

30. Many countries around the world are seeing large numbers of double vaccinated people get sick and test positive for Covid 19; "approximately two-thirds of the cases of severe Covid-19 in Israel during the study period occurred in persons who had received two doses of the BNT162b2 vaccine." Attached hereto and marked as **Exhibit "R"** to this my Affidavit is an article from The New England Journal of Medicine called *Waning Immunity after the BNT162b2 Vaccine in Israel*.

31. Given the above, there are significant medical reasons for me personally, and as a qualified medical professional, to have concerns about the risk, safety, and efficacy of these vaccines.

32. The Policy violates a basic tenant of medicine known as informed consent and the Hippocratic medical maxim – "do no harm." The Policy introduces elements of duress, overreach, and coercion since I am being forced to take an experimental medical procedure or face losing my job.

33. The Policy claims to be for the safety and wellbeing of staff and patients; however, to date, no data has been provided by AHS to confirm that the contents of the vaccines themselves meet AHS employee safety standards or that they do not contain concerning levels of toxicity.

34. I refuse to be coerced into taking the Covid-19 vaccination for the reasons stated by Ms. Chipiuk in her letter, and specifically because the Policy is completely unscientific. The literature is compelling and undeniable. These vaccines developed for Covid-19 neither protect you from being infected or from transmitting it to others. The Policy will not keep AHS staff or its patients safe. In fact, there have been numerous outbreaks at the Hospital wards where several fully immunized healthcare workers were infected. Attached hereto and marked as **Exhibit "S"** to this my Affidavit is an AHS document that outlines the outbreaks in AHS facilities.

35. I also have first-hand knowledge of a case where four general surgery residents (fully vaccinated) were all infected and passed it to each other. This information was shared during a zone combined surgery anesthesia meeting.

36. Clearly, the Policy is not, and will not, keep AHS workers or patients safe. Every day I see the number of fully vaccinated patients being admitted to the hospital increase.

37. As of December 7, 2021, the AHS website shows 45.99% of new cases in Alberta are fully vaccinated. Attached hereto and marked as **Exhibit "T"** to this my Affidavit is a screenshot from the AHS website evidencing this. It is incredulous that AHS is willing to fire its personnel who are willing to care for patients. AHS is willing to disrupt the care of patients in Alberta because of a mandatory vaccine policy that ignores the science.

38. The safest AHS worker right now is one who has recovered from a previous Covid-19 infection. Attached hereto and marked as **Exhibit "U"** to this my Affidavit is a report prepared by immunologist Dr. Braym Bridle. My risk of re-infection is exceptionally low, less than 1% in the vast majority of studies. Attached hereto and marked as **Exhibit "V"** to this my Affidavit is an article from the European Journal of Clinical Investigation titled *SARS-CoV-2 re-infection risk in Austria.*

39. I enjoy a much more comprehensive immunity compared to any that a vaccine can offer. Attached hereto and marked as **Exhibit "W"** to this my Affidavit is an Open Letter to the President of Guelph University from Dr. Bridle. I can say this with full confidence as a medical professional, natural immunity is a basic medical principle which AHS is ignoring. Attached hereto and marked as **Exhibit "X"** to this my Affidavit is an article from Harvard Medical School *titled How The Body Reacts to Viruses*. Further, as Alberta's public health provider, there are many things that AHS can promote to its staff and patients like healthy eating, vitamins (especially vitamins D and C), exercise, good hand hygiene, use of nasal antiseptic sprays. All of these measures would help keep staff, patients, and Albertans safe, but AHS has not been promoting or enforcing any of these measures the way the Covid-19 vaccine has been.

40. The Centre for Disease Control and Prevention ("CDC") was compelled to disclose they have no documents demonstrating Covid-19 recovered individuals being infected and transmitting to others. Attached hereto and marked as **Exhibit "Y"** to this my Affidavit is an exchange of letters from the law firm of Siri Glimstad and the CDC.

41. A Freedom of Information and Privacy ("FOIP") request was made to AHS requesting that they disclose what documents they are relying on to discount natural immunity. Unbelievably, AHS responded to the FOIP request stating that there are no documents they have in possession regarding natural immunity that they are relying on. Attached hereto and marked as **Exhibit "Z"** to this my Affidavit is an article regarding a FOIP request to AHS regarding natural immunity.

42. I have demonstrated my antibody levels are high to the Sars-Cov-2 spike protein and could also have my plasma tested for numerous other epitopes of the virus, as Dr. Bridle has done. All the emerging science and medical data are demonstrating that naturally acquired immune staff are the safest staff in AHS facilities. Yet I am being fired because I refuse a vaccine that carries with it the highest serious adverse reaction rate of any vaccine released in the last fifty years. It also poses a more serious risk of experiencing worse side effects to those having been infected with Covid-19. Attached hereto and marked as **Exhibit "AA"** to this my Affidavit are studies on the risks to receiving the Covid-19 vaccine.

43. It is ethically and morally wrong for AHS to force and coerce staff with the Policy knowing the risks of the vaccines and given that naturally immune staff are not at risk of catching or spreading Covid-19. Furthermore, it is reprehensible that AHS used us during the Pandemic, while we risked our lives going to work when we did not know how severe the virus was. In fact, at the start of the Pandemic, I was vocal about ensuring that all staff have proper N-95 masks, but AHS quickly dismissed that suggestion because they said they don't have enough masks for everyone.

44. The risk-benefit analysis is clearly not in my favor or the favor of many Albertans in general. I support, and have always supported, all previous ethical, effective, and safe vaccines. This is not the case with the Covid-19 vaccines.

45. After an extensive review of the scientific research and medical data, and as a medical doctor, I believe that my proven natural immunity is at least 13 times more effective than the Covid-19 vaccination and acts as a protective agent against contracting Covid-19 for at least one year and likely for many years based on numerous studies. Attached hereto and marked respectively as **Exhibit "BB"** and **"CC"** to this my Affidavit is an article from the European Journal of Immunology titled *Persistence of neutralizing antibodies a year after SARS-CoV-2*

*infection in humans* and Nature titled *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls.*

46. The Policy is going against science, my medical understanding, and my natural immunity. In addition, the Policy is infringing on my Charter rights, human rights, and the Nuremberg Code to take an experimental medical procedure. This goes against everything I have learned as a medical professional.

47. AHS is going against clear and established science that natural immunity is more effective than the Covid-19 vaccine. A growing body of compelling evidence demonstrates that natural immunity is superior to vaccine immunity by every measure. It is unscientific and unethical for AHS to coerce or mandate a vaccine on an employee who already enjoys natural immunity as a result of having contracted and recovered from the virus, particularly since recent evidence suggests that the vaccines tend to diminish the protection natural immunity provides.

48. AHS is also going against Alberta's own Covid-19 Restriction Exemption Program which allows for rapid antigen testing. Rapid antigen testing is a clear alternative. Rapid antigen testing is an accurate and immediate method to minimize the risk that a person infected with Covid-19 may spread the SARS-CoV-2 virus to staff and patients. Such a policy is based on the fact that both vaccinated and unvaccinated individuals may contract Covid-19, in which case both vaccinated and unvaccinated individuals can potentially transmit the virus. AHS's most recent amendment to the Policy shows how rapid testing can be used effectively. It is arbitrary and unreasonable for AHS to pick and choose where rapid testing can take place, given the desired effect – keeping AHS staff and patients safe - is the same around the province.

***Irreparable Harm***

49. I started on my journey to become a medical doctor when I had two toddlers and a wife to care for, back in 1992. We have a close-knit family and I continue to support both my married children through their educational endeavors. Now with the economy suffering, I am relied upon to support them again as they have lost jobs and employment opportunities. My aging parents will require care in the very near future and I plan to care for them in my home. AHS' decision to terminate me will impact my ability to help others in my family.

50. The arbitrary, unscientific vaccine mandate policy has caused me a tremendous amount of stress and emotional suffering. My reputation has been tarnished by the termination of my

position of Chief of Adult Cardiac Anesthesia. My career has been halted indefinitely, likely permanently here in Alberta, due to the excessive and harsh treatment by AHS. My only option is to leave Alberta to pursue my professional career (encompassing twelve years of training and sixteen years of clinical staff service) all this while Alberta has an extreme shortage of anesthesiologists.

51. If I am forced to resign under duress, I believe my absence will harm the standard of care received by patients within AHS. A publication by AHS in 2019 identified that anesthesiologists are in demand with a significant shortage expected in the next few years, particularly in the Edmonton area. Attached hereto and marked as **Exhibit "DD"** to this my Affidavit is a report published by AHS outlining the shortages of anesthesiologists in Alberta.

52. Over the last 16 years, I have witnessed a health system that is running over capacity all the time. For over 10 years we have had CVICU bed shortages due to a lack of expansion. It was very common to have to wait before proceeding with our second operation at the Hospital because there was a shortage of CVICU beds following surgery. The Pandemic caused additional stress to an already overburdened system by diverting health care workers from their usual station to another area for the potential influx of new Covid-19 cases. It is my opinion that the overburden is not because of unvaccinated staff or patients, it is the AHS management and oversight to address an already existing problem of bed shortages.

53. Furthermore, AHS' management during the Pandemic cause disruption in the normal activity of health care workers, and the lack of normalcy in the rest of life, has led to burnout and a serious lack of health care personnel to care for the usual number of patients. There are unprecedented numbers of nurses and allied health care workers taking leave of absences for stress, sickness, and simply resigning due to the ongoing fiasco of the Pandemic and AHS' management. Sadly, AHS is willing to further exacerbate this shortage by terminating competent and qualified health care workers like myself with unrivaled immunity to Covid-19.

54. The medical system in Alberta is struggling. The recent treatment of health care workers in this province, in addition to the current AHS policies and management, is driving physicians out of Alberta and will further exacerbate an already dire situation. AHS' last-minute amendments and extensions to the Policy caused confusion and scheduling problems at the Hospital, which have negatively impacted AHS staff and patients. My forced departure will invariably cause additional delays in the operating room and will cause harm to patients in Alberta.

55. It is unreasonable and unethical for AHS not to offer me an exemption or to terminate me when alternative options, such as rapid testing or recognizing natural immunity, are available. By not providing reasonable, safe, and efficient alternatives to preserve workforce capacity and support the healthcare system, AHS is causing irreparable harm to me personally and professionally, and the public health care system in Alberta generally.

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

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

SWORN BEFORE ME at
Edmonton, Alberta, this 7th, day
of December, 2021.

[redacted]

A Commissioner for Oaths
in and for the Province of Alberta

[redacted]

DR. BLAINE ACHEN

**Eva Chipiuk**
**Barrister & Solicitor**

# Exhibit "A"

# Blaine Achen, M.D.

Curriculum Vitae

[redacted]

## Education

| | | | |
|---|---|---|---|
| FRCPC | Dept. of Anesthesia and Pain Medicine | University of Alberta | 1999-2004 |
| MD | Faculty of Medicine and Dentistry | University of Alberta | 1995-1999 |
| B. MSc. | Faculty of Science | University of Alberta | 1993-1995 |
| B. Th | Faculty of Theology | Prairie Bible College | 1982-1986 |

## Experience

| | | | |
|---|---|---|---|
| Assistant Clinical Professor | Dept. of Anesthesia and Pain Medicine | Univ. of Alberta | 2005 - present |
| CV Anesthesia Rotation Coordinator | Dept. of Anesthesia and Pain Medicine | Univ. of Alberta | 2007 - 2017 |
| Anesthesia PGME board member | Dept. of Anesthesia and Pain Medicine | Univ. of Alberta | 2007 - 2017 |
| Mentor/Teacher Chinese anesthesiologists | China, Zhejiang Provincial People's Hospital | | 2014, 2016, 2017 |

## Publications/Presentations

Karkouti K, et al. **Achen BM.** Point-of-Care Hemostatic Testing in Cardiac Surgery. A Stepped-Wedge Clustered Randomized Controlled Trial. Circulation. 2016;134:1152-1162

**Achen BM**, McNamee CJ, Black T, Tracheo-Inominate Artery Fistula. Thoracic Trauma and Critical Care. Kluwer Academic Publishers, 2002.

McNamee CJ, **Achen BM**, Hemoptysis Following Catheter Induced Rupture of the Pulmonary Artery. Thoracic Trauma and Critical Care. Kluwer Academic Publishers, 2002.

Richardson M, Schmidt AM, **Achen BM**, Russell JC, Vasculopathy and Insulin Resistance in the JCR:LA-cp rat. Atherosclerosis 138(1998) 135-146.

**Achen BM,** Cardiovascular Anesthesia in the Elderly. Zhejiang Provincial People's Hospital, China. Anesthesia Conference. 2017

**Achen BM,** Challenges and Complications in Transfusion and Anticoagulation. Alberta Anesthesiology Summit. Red Deer, Nov. 2015.

**Achen BM,** Factor Concentrates in Cardiovascular Surgery: What should we be doing? Combined CV/Surgical/ICU Rounds. Mazankowski Alberta Heart Institute (MAHI) Dec. 14, 2012

**Achen BM**, Bergstrom RJ. Redo Cardiac Surgery – Challenges for the Anesthesiologist. Seminar at Canadian Anesthesiologist Society Annual Meeting, Calgary 2007.

**Achen BM**, Finucane B, Terblanche O. Glottis view comparison: Miller vs. Macintosh Blades. Poster Presentation at the Western Anesthesia Conference (WARC) April 4-6, 2003, Stanford University, California.

## Conference Co-founder and Chair

Western Canada Cardiac Anesthesia Symposium (WCCAS) 2020

Western Canada Cardiac Anesthesia Symposium (WCCAS) 2021

This is Exhibit " A " referred to in the Affidavit of

Dr. Blaine Achen

Sworn before me this 7th day

of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

## Licensure/Certifications

| | |
|---|---|
| National Board of Echocardiography | 2015 - present |
| Fellow of Royal College of Physicians and Surgeons of Canada (FRCPC) | 2004 - present |
| Fellow of Royal College of Physicians and Surgeons of Alberta | 2004 - present |
| LMCC part I | 1999 |
| LMCC part II | 2000 |

## Research Experience

Department of Surgery, 275 Heritage Medical Research Center, University of Alberta.

Preceptor: James Russell

Projects:

1. Performed experiments involving the implantation of diffusion pumps in rats to study the effects of melatonin on cholesterol production and accumulation. 1997
2. Performed experiments involving the implantation of diffusion pumps in rats to study the relationship between hyperinsulinemia and the development of hyperglycemia, hypercholesterolemia and hypertriglyceridemia. 1997

Department of Surgery, 275 Heritage Medical Research Center, University of Alberta.

Preceptor: James Russell

Projects:

1. Performed visual analysis of endothelial cells for the concentration of VCAM-1 and ICAM-1 using a high-resolution computer-controlled camera (EDC 1000H) and software (MOCHA, v1.2 Jandel Scientific). 1996
2. Performed experiments on the carotid arteries of JCR: LA-cp rats to determine endothelial function after vascular ischemia. 1996

## Affiliations/Memberships

| | |
|---|---|
| Society of Cardiovascular Anesthesia | 2005 - present |
| Canadian Medical Association | 2004 – present |
| American Society of Echocardiography | 2006 – present |
| Canadian Medical Protective Association | 1999 – present |

## Extracurricular Experience

| | |
|---|---|
| Chair of Annual Christian Conference for Adults | 2014 – present |
| Administrative lead of Young Adult (age 18-30) teaching in Church | 2013 – 2018 |

# Exhibit "B"

Alberta Health Services

# POLICY



**TITLE**
**IMMUNIZATION OF WORKERS FOR COVID-19**

**SCOPE**
Provincial

**DOCUMENT #**
1189

**APPROVAL AUTHORITY**
Alberta Health Services President and Chief Executive Officer

**INITIAL EFFECTIVE DATE**
September 14, 2021

**SPONSOR**
Workplace Health and Safety

**REVISION EFFECTIVE DATE**
October 22, 2021

**PARENT DOCUMENT TITLE, TYPE, AND NUMBER**
Not applicable

**SCHEDULED REVIEW DATE**
April 22, 2022

**NOTE:** The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

If you have any questions or comments regarding the information in this document, please contact Policy Services at policy@ahs.ca. The Policy Services website is the official source of current approved policies, procedures, directives, standards, protocols, and guidelines. Only the electronic version of this document, as hosted on the Policy Services website or www.ahs.ca, is valid.

## OBJECTIVES

- To set out **worker** immunization requirements for COVID-19 to protect the health and safety of workers, patients, and the communities that Alberta Health Services (AHS) serves.

## PRINCIPLES

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 the AHS Values of Compassion, Accountability, Respect, Excellence, and Safety.

This Policy is in addition to other AHS policy documents supporting worker and patient safety during the COVID-19 pandemic including, but not limited to, the AHS *Use of Masks During COVID-19* Directive, *Attending Work with COVID-19 Symptoms, Positive Test, or Close Contact* Directive, and the *Fit for Work Screening (COVID-19)* Protocol.

This Policy shall be reviewed regularly, and at least every six (6) months, to ensure alignment with public health measures and regulations, and to confirm it adequately covers the health and safety risks that it addresses.

## APPLICABILITY

Compliance with this document is required by 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. Compliance requirements for other contracted service providers, such as continuing care, will be

communicated directly to the contracted service providers. This document does not apply to physicians with Community Appointments.

## ELEMENTS

### 1. Immunization Requirements

1.1 Effective November 30, 2021, all workers must be **fully immunized** against COVID-19.

1.2 A worker on an approved Leave of Absence must be fully immunized prior to returning to work.

1.3 A worker hired after November 30, 2021 must be fully immunized prior to commencing work.

### 2. Proof of Immunization Records

2.1 No later than November 15, 2021, workers shall disclose accurate proof of their immunization status to:

a) AHS or an AHS subsidiary, if the worker is an AHS employee, medical staff, midwifery staff, or volunteer;

b) Covenant Health, if the worker is a Covenant Health employee, medical staff, or volunteer;

c) their educational institution, if the worker is a student or instructor; or

d) their employer, if the worker is a contracted service provider.

2.2 Proof of immunization is being collected to protect the health and safety of workers, patients, and other persons accessing AHS sites and to preserve AHS' workforce capacity to support the health care system.

2.3 Proof of immunization records collected under this Policy shall be securely and confidentially retained, accessed, and used as necessary to determine fit for work status of workers, to manage and administer employment and other working relationships with workers, to address accommodation requests, and to comply with all applicable laws, such as the *Occupational Health and Safety Act* (Alberta) and *Regional Health Authorities Act* (Alberta).

2.4 Proof of immunization records are collected under the authority of Section 33(c) of the *Freedom of Information and Protection of Privacy Act* (Alberta) and shall be used, accessed, and disclosed in accordance with the legislation and the AHS *Collection, Access, Use, and Disclosure of Information* Policy.

## 3. Workplace Accommodation

3.1 Any AHS employee who is unable to be immunized due to a medical reason, or for another protected ground under the *Alberta Human Rights Act*, will be reasonably accommodated, up to the point of undue hardship, in accordance with the AHS *Workplace Accommodation* Policy.

3.2 Employees of AHS subsidiaries, Covenant Health, and applicable contracted service providers, who are unable to be immunized due to a medical reason, or for another protected ground under the *Alberta Human Rights Act,* will be reasonably accommodated, up to the point of undue hardship, in accordance with their applicable workplace accommodation policies.

3.3 Any current AHS employee requesting workplace accommodation shall make a request for the accommodation as soon as reasonably possible, and no later than October 16, 2021, and provide required information in accordance with the AHS *Workplace Accommodation* Policy (or the appropriate accommodation policy of an AHS subsidiary or Covenant Health, if applicable).

3.4 Any current AHS member of the medical or midwifery staff who is not an employee of AHS, an AHS subsidiary, or Covenant Health, and who is unable to be immunized due to a medical reason, may request an exception as soon as reasonably possible and no later than October 16, 2021. A request for an exception shall be made on the *Medical or Midwifery Staff Request for Exception COVID-19 Mandatory Immunization for Workers* form and shall be submitted as directed on the form. The lack of immunization may affect the safe exercise of their Clinical Privileges as described in the *Medical Staff Bylaws* and *Rules* (Rule 3.4.4.2), or may directly impact their ability to practice and patient safety as described in the *Midwifery Staff Bylaws* and *Rules* (Rule 3.3.4), as applicable.

## 4. Non-Compliance

4.1 With respect to students, instructors, and applicable contracted service providers, failure to comply with this Policy shall result in AHS reviewing the applicable contract or other relevant circumstances and initiating further discussions with the applicable educational institution or contracted service provider and, in this respect, AHS reserves all rights it has at law, equity, or pursuant to any applicable agreement to address such non-compliance.

4.2 In all other cases not outlined in Section 4.1 above, except where a workplace accommodation or exception (for medical or midwifery staff) applies, failure to comply with this Policy shall result in:

a) a meeting being held with the worker to discuss their concerns with vaccination against COVID-19 and provide educational materials on the COVID-19 vaccines; and

b) if the worker remains non-compliant with this Policy, the worker being placed on an unpaid leave of absence for the period of time required to

become fully immunized or, in the case of medical or midwifery staff, Immediate Action being taken as set out in Part 6 of the *Medical Staff* Bylaws or *Midwifery Staff* Bylaws.

## DEFINITIONS

**Fully immunized** means a worker:

a) who has 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
b) 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.

**Worker** means AHS, its subsidiaries and Covenant Health employees, members of the medical and midwifery staffs, students and instructors, volunteers, and applicable contracted service providers (including anyone providing services for AHS on behalf of an applicable contracted service provider).

## REFERENCES

- Alberta Health Services Governance Documents:
  - *Attending Work with COVID-19 Symptoms, Positive Test, or Close Contact* Directive (#1188)
  - *Collection, Access, Use, and Disclosure of Information* Policy (#1112)
  - *Fit for Work Screening (COVID-19)* Protocol (#1184-01)
  - *Medical Staff Bylaws* and *Rules*
  - *Midwifery Staff* Bylaws and *Rules*
  - *Use of Masks During COVID-19* Directive (#HCS-267)
  - *Workplace Accommodation* Policy (#1156)
- Alberta Health Services Forms:
  - *Employee Request for Accommodation* Form (#19566)
  - *Got My COVID-19 Immunization* Form
  - *Medical or Midwifery Staff Request for Exception COVID-19 Mandatory Immunization for Workers* Form
- Alberta Health Services Resources:
  - AHS Immunization Information Insite Page
  - AHS Values
- Non-Alberta Health Services Documents:
  - *Alberta Human Rights Act*
  - *Freedom of Information and Protection of Privacy Act* (Alberta)
  - *Occupational Health and Safety Act* (Alberta)
  - *Regional Health Authorities Act* (Alberta)

# Exhibit "C"

This is Exhibit " C " referred to in the Affidavit of

Dr. Blaine Achen

Sworn before me this 7th day

of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

MAYO CLINIC LABORATORIES

1-800-533-1710

**COVSQ**

SARS-CoV-2 Spike Ab, Semi-Quant, S

| Patient ID | Patient Name | | Birth Date | Gender | Age |
|---|---|---|---|---|---|
| [redacted] | Achen, Blaine | | [redacted] | | |
| **Order Number** | **Client Order Number** | **Ordering Physician** | **Report Notes** | | |
| [redacted] | [redacted] | Client | | | |
| **Account Information** | | **Collected** | | | |
| [redacted] | | 14 Sep 2021 09:15 | | | |

## SARS-CoV-2 Spike Ab, Semi-Quant, S

### SARS-CoV-2 Spike Ab, Interp, S

SDL

**Reference Value**
Negative

⚠ Positive

Abn

Antibodies to the SARS-CoV-2 spike glycoprotein detected. These results suggest recent or prior SARS-CoV-2 infection and/or vaccination. No minimum antibody level or threshold has been established to indicate long-term protective immunity against re-infection. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended. Serologic results should not be used to diagnose recent SARS-CoV-2 infection. False-positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

### SARS-CoV-2 Spike Ab, Quant, S

SDL

**Reference Value**
<0.80

⚠ >250 U/mL

High

ADDITIONAL INFORMATION

Testing was performed using the Roche Elecsys Anti-SARS-CoV-2 S Reagent assay from Roche Diagnostics, which has received Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration.

Fact sheets for this Emergency Use Authorization (EUA) assay can be found at the following links:
For Healthcare Providers:
https://www.fda.gov/media/144035/download
For Patients:

# Exhibit "D"

Alberta Health Services

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

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.

This is Exhibit "J" referred to in the Affidavit of Dr. Blaine Achen

Sworn before me this 7th day of December, A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

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

## Part 1. Medical or Midwifery Staff Member Identification

Last Name achen | First Name blaine

Regulatory College
☑ CPSA ☐ ADAC ☐ Podiatry ☐ Midwifery

Registration Number [redacted]

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 I have tested my antibody titer after recovering from Covid 19 and it remains above 250/mL.

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<br>☐ Other *(specify)* _____ |

Were there any adverse reactions after receipt of COVID-19 vaccine?
If yes, please provide details *(e.g. timing of reaction in relation to when vaccine was received, nature of the adverse reaction, any required treatment, etc)* and confirm if the Adverse Event Following Immunization (AEFI) was reported to Public Health *(https://www.albertahealthservices.ca/info/Page16187.aspx)*.
Please provide any AEFI documentation if available.

Is there any additional information that you feel would be pertinent to your patient's request for an exception on medical grounds to AHS' COVID-19 immunization policy?
In May 2021 I contracted Covid 19 and subsequently recovered fully. I have read the literature and note that the vast majority of people who had a serious Covid 19 infection develop long lasting immunity to the virus. I have tested my antibodies at the Mayo Clinic Lab using the Sars-CoV-2 S Reagent assay from Roche Diagnostics. My result was > 250 U/mL. This exceeds the parameters of the test. I have a very high titer and thus immunity to Covid 19. I also have seen the entire virus and thus, no doubt, have produced a catalogue of Antibodies to the virus beyond just the spike protein which is all the vaccine gives you. This level of Ab titer requires no vaccine to boost it and only carries the risk of a potential adverse reaction. The gold standard for immunity to Covid 19 should be Ab titer levels not whether or not you had a shot!

| Primary Care Provider Name | Relevant Alberta Regulatory College |
|---|---|
| I DO NOT currently have | |
| Signature [redacted] | Date *(dd-Mon-yyyy)*<br>01-10-2021 |

Your immunization status information is being collected under the authority of section 33(c) of the Freedom of Information and Protection of Privacy Act (Alberta), and will be used and disclosed as necessary to: (i) manage and administer your working relationship with AHS, Covenant Health, and Alberta Precision Labs, as applicable, including your fitness for work and exception requests, (ii) manage COVID-19 outbreaks, (iii) ensure that there are sufficient healthy staff available to provide health services to Albertans across the province, and (iv) comply with obligations under the Occupational Health and Safety Act (Alberta), the Regional Health Authorities Act (Alberta) and the Public Health Act (Alberta). If you have questions or concerns about the collection, use or disclosure of your information or the completion of this form, please contact an administrator at md.midwife.covidvacc@ahs.ca.

**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.

See attached letter from my Pastor.

| Medical or Midwifery Staff Member Signature | Date *(dd-Mon-yyyy)* |
|---|---|
| | |

fellowship
baptist church

14323 107A Ave NW
Edmonton, AB T5N 1G2
780-454-8733
www.fellowshipedmonton.com

To Whom It May Concern,

My name is Jason Hagen and as the Lead Pastor of Fellowship Baptist Church I'm writing on behalf of Dr. Blaine Achen to confirm that his sincerely held religious beliefs prevent him from receiving a mandatory COVID 19 vaccination.

I can affirm that Dr. Achen is committed to upholding the historical Christian faith which holds the supremacy of the Holy Scriptures and the Lordship of Christ over all of life, teaches the liberty of conscience, the honoring and preserving of human life, and the autonomy of individuals and families.

Therefore, Dr. Achen's application for religious exemption is not a matter of opinion, or philosophy, but a deeply held religious conviction, protected under Canadian law, section 2 of the Canadian Charter of Rights and Freedoms, and the Alberta Human Rights Act.

I appreciate your understanding in this matter,

Rev. Hagen

# Exhibit "E"

This is Exhibit " E " referred to in the Affidavit of Dr. Blaine Achen

Sworn before me this 7th day of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

---------- Forwarded message ---------

From: **Heather Clark M.** [redacted]

Date: Fri, Oct 15, 2021 at 4:23 PM

Subject: Sending on behalf of Dominic Cave

[redacted]

Dear Colleagues,

I recognize that some of you have struggled with the decision around vaccination.

I strongly urge you to get vaccinated if you are not. It is our best option to maintain service and safety.

If however you find yourself unable to comply, or have submitted an exemption request but are unsure whether it will be recognized, please do not wait for Medical Affairs to remove privileges.

I would strongly advise that if you find yourself in that position in the next week or so that you submit a request for Leave from Clinical duties.

https://www.albertahealthservices.ca/assets/info/hp/phys/if-hp-phys-bylaws-ahs-absence-request.pdf

This will make your absence voluntary and means that privileges will not be revoked. Going forward this may be very important for resuming practice as removal of privileges by the organization is something that needs to be declared in future applications.

Let me close by saying how much I appreciate the challenges of this time for everyone, and how much I hope we can find common purpose going forward.

Dominic Cave MBBS FRCPC (Anes, Crit Care) CHE
Interim Zone Clinical Department Head Anesthesia
Edmonton Zone

# Exhibit "F"

Alberta Health Services

Healthy Albertans.
Healthy Communities.
Together.

Canada's Top 100 Employers 2018

This is Exhibit " F " referred to in the Affidavit of
Dr Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

**CONFIDENTIAL**

October 15, 2021

Dr. Blaine Achen
Dept. of Anesthesia
University Hospital
8440 -112 Street NW
Edmonton, AB
T6G 2B7

sent via email: [redacted]

Dear Dr. Achen:

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

I am in receipt of your request for an exception received October 7, 2021 to the Immunization of Workers for COVID-19 Policy (Policy). All exception requests for members of the Medical Staff are reviewed by the Exception Review Panel, which makes a recommendation to me in my role as Zone Medical Director. Please find enclosed with this letter, a copy of the report from the Exception Review Panel.

As set out in the enclosed report, the Exception Review Panel has recommended that your exception request, for both medical and religious reasons, be denied.

**I agree with the recommendation of the Exception Review Panel**. Specifically, in regards to your request for a medical exception, you are not considered fully immunized, as defined in the Policy, if you have not completed a vaccine series in accordance with the Policy. The Policy requires Medical Staff to be fully immunized regardless of whether they have already had COVID-19.

Additionally, while I understand that you have also expressed a religious belief against receiving a Covid-19 vaccine, Alberta Health Services' (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 your request for an exception to the Policy is being denied, in accordance with section 3.4.4.3 of the Medical Staff Rules (Rules) I have determined that further action or investigation is required by my office. In accordance with section 3.4.4.5 of the Rules, my office will proceed to schedule a brief online or telephone meeting with you 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. Additionally or alternatively, I can also arrange a discussion with an AHS physician 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.

I strongly encourage you to take steps to become fully immunized, as required by the Policy. If you are unable to meet the deadline of **October 31, 2021**, to become fully immunized, AHS will take steps in accordance with the non-compliance section of the Policy.

Sincerely,

[redacted]
Edmonton Zone Medical Director
Alberta Health Services

***Attachment:***

1. Exception Review Panel Report

Alberta Health Services

# Edmonton 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:** [redacted]
**College & Registration Number:** [redacted]
**File ID:** [redacted]

**Date:** October 13, 2021

## I. Nature of the Request

On October 7, 2021, Dr. Blaine Achen 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 Medical and Non-Medical Reasons.

## II. Supporting Documentation Provided

On October 7, 2021, Dr. Blaine Achen submitted the following documents in support of the exception request:

a. Antibody titer C19.jpeg
b. Exception letter.pdf
c. Religious exemption.pdf

## III. Recommendation

In considering the request dated October 7, 2021 and the documents provided, the Panel recommends that an exception on the basis of Medical and Non-Medical Reasons not be approved by the Edmonton Zone Medical Director.

## IV. Reasons

The applicant has applied for a **Medical and 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 [redacted], Edmonton Zone Medical Director for decision.

# Exhibit "G"

[redacted]

This is Exhibit " G " referred to in the Affidavit of Dr. Blaine Achen
Sworn before me this 7th day of December A.D. 2021
A Notary Public, A Commissioner for Oaths In and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

[redacted]

**From:** David Zygun [redacted]
**Sent:** October 20, 2021 11:35 AM
**To:** Blaine Achen [redacted]
**Subject:** Meeting follow up

October 20, 2021

Dear Dr Achen,

Thank you for meeting with me this morning in relation to my letter of October 15, 2021.

I appreciated hearing your views on the effect of the policy on AHS staff as well as your interpretation of the literature. I acknowledged that there can be multiple interpretations of the literature but I believe AHS has a robust process through the Scientific Advisory Group that includes both scientific expertise to review the available literature and frontline providers/leaders. This informs AHS policy. I noted that evidence and resultant AHS policies have and will continue to evolve over the pandemic.

We discussed your options given my decision to support the recommendation of the exemption review committee. These included:

1. Resignation of AHS appointment and privileges – this can be accomplished through completion of the attached change appointment form and submitted to your ZCDH and me.

2. Change to community appointment – I indicated this was not relevant to the practice of anesthesiology that requires on site presence.

3. Temporary LOA for 3-6 months – this can be accomplished through completion

of the attached LOA form and submitted to your ZCDH and me

I understand that currently you have made the choice not to be immunized but did offer you the opportunity to meet with AHS physicians to provide further information that may inform your choice to be immunized. You indicated you would consider such meetings for further information and get back to me.

You asked if AHS would remove your privileges on November 1 if you did not take one of the above options. I indicated that you would be provided a notice of detailing the procedures that would be undertaken given you would not be compliant with the policy. The procedures are detailed in the AHS medical staff bylaws and rules that govern the relationship between AHS and our medical staff. This could include enacting immediate action provisions.

We also discussed your plan for your medical leadership position. You indicated you have already spoken to Dr. Cave and have suggested an individual who would be your recommendation to replace you in your role. I will discuss with Dr Cave his plans for November 1.

Please confirm this is an accurate representation of the discussion we had or indicate any additions or changes by October 24, 2021 at 1600hrs.

Best Regards,

Dave

David Zygun
Edmonton Zone Medical Director
Alberta Health Services

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<48B11BA329E64F77B2A790E21281CDA1.png>

# ABSENCE FROM CLINICAL PRACTICE

## Request/Notification Form

*Personal information that you provide on this form is collected under the authority of section 33(c) of* the Freedom of Information and Protection of Privacy Act *and is governed by the* Health Information Act of Alberta. *The information is collected and used for the purposes of identifying and regulating medical staff at Alberta Health Services and for managing the health system (s. 27). The information will only be disclosed to other agencies or for other purposes with the applicant's consent or to a health professional body for the purposes of investigation, discipline, practice review, or inspection of the medical staff member or in accordance with other legislation (s. 37).*

## PRACTITIONER INFORMATION

| Last Name | First Name | Middle Name |
|---|---|---|
| | | |

## *Instructions*

Please refer to section 4.15 "Absence from Clinical Practice in Sites of Clinical Activity" of the *AHS Medical Staff Rules*. Also note that some Zones or Clinical Departments may have additional rules or guidelines regarding absences (i.e. may require approval of the relevant Section Chief(s), etc).

- Complete all sections and submit this form to each applicable Zone Clinical Department. Requests will be reviewed by each Zone separately.
- Absences greater than 42 consecutive days must be approved by all applicable Zone Clinical Department Heads and the Zone Medical Director.

## APPOINTMENT SUMMARY *(submit to each Zone Clinical Department)*

Appointment Category

- ☐ Active
- ☐ Community
- ☐ Probationary (active)
- ☐ Probationary (locum tenens)
- ☐ Locum Tenens
- ☐ Temporary

Appointment End Date *(if applicable)*

| Zone | Department and Section(s) |
|---|---|
| | **PRIMARY:** |

## ABSENCE DETAILS

| Start Date *(of this request)* | Original Start Date *(if extending a leave)* | End Date |
|---|---|---|
| Reason for Leave | Patient Coverage<br>☐ On Call Schedule/Roster *(leaves less than or up to 96 hours, unless otherwise permitted)*<br>☐ Personal On Call Group<br>☐ Transfer Responsibility to:<br>_____<br>_____ | Is there a requirement to maintain access to Patient Information Systems during this Leave?<br>Reason(s):<br>_____<br>_____<br>_____ |

Is there a requirement to provide direct or indirect patient care during this Leave? ☐ Yes ☐ No

*If YES, appropriate licensure and malpractice coverage must be kept current.*

## REQUESTOR *(if not the Practitioner)*

| Requestor Name | Requestor Title - Department | Requestor Phone Number |
|---|---|---|
| | | |

## APPROVAL *(for leaves >42 consecutive days)*

| **ZCDH Signature** | Printed Name<br>Department | Date<br>☐ Accept<br>☐ Deny |
|---|---|---|
| **Zone Medical Director** | Printed Name<br>Comments | Date<br>☐ Accept<br>☐ Deny |

**PLEASE SUBMIT THE COMPLETED FORM TO THE RELEVANT ZONE CLINICAL DEPARTMENT(S) FOR REVIEW**
**Absences greater than 42 consecutive days require formal approval by the Zone Medical Director(s).**

| Duration of Planned Absence | Minimum Notice Required (days) |
|---|---|
| 42 days | 42 days |
| 43 - 60 days | 90 days |
| 61 - 90 days | 120 days |
| 90 - 180 days | 180 days |
| >180 days | Notice Period determined by ZCDH with ZMD approval |

## North Zone Medical Staff Office

| | |
|---|---|
| FORT MCMURRAY<br>7 Hospital Street<br>Fort McMurray, AB T9H 1P2<br>Fax: 780-788-1744 | GRANDE PRARIE<br>10409 – 98 Street<br>Grande Prairie, AB T8V 2E8<br>Fax: 780-538-7277 |

## Edmonton Zone Medical Staff Office

| | |
|---|---|
| Medical Affairs, Edmonton Zone<br>5th Floor Seventh Street Plaza<br>10030-107 Street<br>Edmonton, AB T5J 3E4 | Edm.MedicalAffairs@ahs.ca<br>Fax: 780-735-0756<br>Toll-Free Fax: 1-855-776-3810 |

## Central Zone Medical Staff Office

| | |
|---|---|
| Medical Affairs, Central Zone<br>43 Michener Bend<br>P.O. Bag 5030<br>Red Deer, Alberta<br>T4N 6R2<br><br>Fax: 403-309-2809 | **Jennifer Liber**<br>Appointing & Privileging Specialist<br>Phone: 403-309-2886<br>Fax: 403-309-2809<br>Email: jennifer.liber@albertahealthservices.ca<br><br>**Tanya Burley**<br>Appointing & Privileging Specialist -Locum Support<br>Phone: 403-357-5187<br>Fax: 403-309-2809<br>Email:<br>tanya.burley@albertahealthservices.ca |

## Calgary Zone Medical Staff Office

| | |
|---|---|
| Medical Affairs, Calgary Zone<br>5th Floor, 10301 Southport Lane SW<br>Calgary, AB T2W 1S7 | CAL.MedicalStaffOffice@ahs.ca<br>Fax: 403-476-8792 |

## South Zone Medical Staff Office

| | |
|---|---|
| **LETHBRIDGE**<br>Chinook Regional Hospital<br>960 – 19 Street South<br>Lethbridge, AB T1J 1W5<br>Phone: 403-388-6135/403-388-6552<br>Fax: 403-388-6708<br>Medical.AffairsCRH@ahs.ca | **MEDICINE HAT**<br>Medicine Hat Regional Hospital<br>666 – 5th Street<br>Medicine Hat, AB T1A 4H6<br>Phone: 403-529-8024/403-528-8124<br>Fax: 403-529-8998<br>Medical.AffairsMHRH@ahs.ca |

**Please Note:** Requests may need to be submitted separately to each office as well as Covenant Health (medicalaffairs@covenanthealth.ca) and the Faculty of Medicine (University of Alberta or University of Calgary).

# CHANGE REQUEST
# Medical Staff Appointment and Clinical Privileges

***Edmonton Zone***

## PERSONAL INFORMATION AND OVERVIEW

| Last Name | First Name | Middle Name |
|---|---|---|
| | | |

| Anticipated/Required Change Date | Comments/Additional Instructions |
|---|---|
| | |

## *Instructions*

1. Complete the first two pages.
   a. "Change to Primary Zone of Appointment" – identify transfers between zones.
   b. "Request for Privileges" – identify where changes to Clinical Privileges are requested.
   c. "Current Appointment Profile" – identify the Current Appointment Category and all current Appointments.
   d. "Requested Appointment Category" – identify the new/required Appointment Category and list all required Appointments.
2. Attach all required supporting documents (e.g. certificates, supporting documentation, etc.).
3. Circulate the form for signature (may include separate written consent of the Practitioner) and submit to Medical Affairs.

Note: - If the Practitioner is new to the Zone (appointed in another Zone), please also submit a Contact Information Change Form.
- If the Requested Changes affect another Zone, please make sure a separate form is submitted for that other Zone.

## ☐ CHANGE TO PRIMARY ZONE OF APPOINTMENT

| *Current Primary Zone:* | *Change Primary Zone to (only check ONE):* |
|---|---|
| ☐ North | North ☐ |
| ☐ **Edmonton** | Edmonton ☐ |
| ☐ Central | Central ☐ |
| ☐ Calgary | Calgary ☐ |
| ☐ South | South ☐ |

## ☐ REQUEST FOR PRIVILEGES

| *Current Privileges in the Following Zone(s):* | *Change(s) Requested:* | | |
|---|---|---|---|
| | | **ADD** | **DELETE** |
| ☐ North | | | |
| ☐ **Edmonton** | **Edmonton** | ☐ | ☐ |
| ☐ Central | | | |
| ☐ Calgary | | | |
| ☐ South | | | |

## CURRENT APPOINTMENT PROFILE

Current Appointment Category:

- ☐ Active
- ☐ Community
- ☐ Locum Tenens
- ☐ Probationary (active)
- ☐ Probationary (locum)
- ☐ Temporary

| # | Current Zone(s) | Current Department(s) |
|---|---|---|
| 1 | | **PRIMARY:** |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |

| Appointment End Date *(if applicable)* | |
|---|---|
| Long Service Date* *(if known)* | Original Health Entity* |

***The Long Service Date and Original Health Entity (e.g. Capital Health Region) are important if the Practitioner is transferring their Primary Appointment from another Zone.***

The personal information collected by this form is collected under the authority of section 33(c) of the Freedom of Information and Protection of Privacy Act of Alberta. Detailed information about how your information will be used is available at https://www.albertahealthservices.ca/medstaff/Page16933.aspx. If you have any questions about the collection of your personal information please contact Edmonton Zone Medical Affairs at MedicalAffairs.EdmontonZone-PhysicianResources@ahs.ca

## REQUESTED APPOINTMENT PROFILE

New Appointment Category:

- ☐ Active
- ☐ Community
- ☐ Locum Tenens
- ☐ Probationary (active)
- ☐ Probationary (locum)
- ☐ Temporary

New End Date *(if applicable)*

| # | Requested Zone(s) | Requested Department(s) |
|---|---|---|
| 1 | | **PRIMARY:** |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |

If a request to change Medical Staff Appointment Category from Probationary to Active or Locum Tenens:

*Date of Performance Assessment:* DD/MMM/YY

☐ Leave of Absence *Planned Duration:* to

*Approval must be obtained by the relevant Primary ZCDH and the Edmonton ZMD.*

End Medical Staff Appointment(s)

☐ Resignation ☐ Retirement ☐ Other (describe):

***Note: A change from the Community or Locum Tenens Staff category to Active or Probationary may require an Impact Analysis to be completed by the Zone Clinical Department.***

## ☐ CHANGE TO SITES OF CLINICAL ACTIVITY

*For changes to specific clinical privileges, please use the separate clinical privilege request form provided with this document by your Zone Medical Affairs Office.

### Sites of Clinical Activity

A - HOSPITAL SERVICE

| Site | Add | Remove | Change Prime Site to | Non-admitting | Admitting | OR Access |
|---|---|---|---|---|---|---|
| Alberta Hospital (AHE) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Cross Cancer Institute (CCI) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Devon General Hospital (DGH) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Edmonton General Hospital (EGH)* | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Fort Saskatchewan Health Centre (FSHC) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Glenrose Rehabilitation Hospital (GRH) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Grey Nuns Community Hospital (GNCH)* | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Leduc Community Hospital (LCH) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Misericordia Community Hospital (MCH)* | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Royal Alexandra Hospital (RAH) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Strathcona Community Hospital (STCH) | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Stollery Children's Hospital | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Sturgeon Community Hospital (SCH) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| University of Alberta Hospital (UAH)/Mazankowski Heart Institute | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Westview Health Centre (WHC) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Villa Caritas (VC)* | ☐ | ☐ | ☐ | ☐ | ☐ | |

***This is a Covenant Health Facility and, as such, approval of a grant of clinical privileges at this facility rests with Covenant Health.**

B - OUTPATIENT CLINICS AND SERVICES IN HOSPITAL AND OTHER FACILITIES

| Site | Add | Site | Add |
|---|---|---|---|
| Addictions Clinics (ARC, ODP, HTC) | ☐ | Northeast Community Health Centre (NECHC) | ☐ |
| Birth Control Clinic (BCC) | ☐ | Provincial Corrections Services (FSCC, EYOC, ERC) | ☐ |
| East Edmonton Community Health Centre (EECHC) | ☐ | UAH Kaye Edmonton Clinic | ☐ |
| Edmonton Mental Health Clinics (EMHC) | ☐ | Other: | ☐ |
| Forensic Assessment & Community Services (FACS) | ☐ | Other: | ☐ |

C - CONTINUING CARE FACILITIES

| Site | Remove | Add | Non-admitting | Admitting |
|---|---|---|---|---|
| Allen Gray (AG) | ☐ | ☐ | ☐ | ☐ |
| Benevolence Care Centre (BECC) | ☐ | ☐ | ☐ | ☐ |
| Capital Care Dickensfield (CCD) | ☐ | ☐ | ☐ | ☐ |
| Capital Care Grandview (CCG) | ☐ | ☐ | ☐ | ☐ |
| Capital Care Kipnes Centre (CCK) | ☐ | ☐ | ☐ | ☐ |
| Capital Care Lynwood (CCL) | ☐ | ☐ | ☐ | ☐ |
| Capital Care Norwood (CCN) | ☐ | ☐ | ☐ | ☐ |
| Capital Care Strathcona Care (CCS) | ☐ | ☐ | ☐ | ☐ |
| Citadel Continuing Care Centre (CCC) | ☐ | ☐ | ☐ | ☐ |
| Devon Long Term Care (DLTC) | ☐ | ☐ | ☐ | ☐ |
| Devonshire Care Centre (DCC) | ☐ | ☐ | ☐ | ☐ |
| Edmonton Chinatown Care Centre (ECCC) | ☐ | ☐ | ☐ | ☐ |
| Edmonton General Care Centre (EGCC) | ☐ | ☐ | ☐ | ☐ |
| Extendicare Eaux Claires (EEC) | ☐ | ☐ | ☐ | ☐ |
| Extendicare Leduc (EL) | ☐ | ☐ | ☐ | ☐ |
| Extendicare Holyrood (EH) | ☐ | ☐ | ☐ | ☐ |
| George Hennig Place (GHP) | ☐ | ☐ | ☐ | ☐ |
| Good Samaritan Zetter Centre (GSZC) | ☐ | ☐ | ☐ | ☐ |
| Good Samaritan Millwoods Centre (GSMC) | ☐ | ☐ | ☐ | ☐ |
| Good Samaritan Southgate (GSS) | ☐ | ☐ | ☐ | ☐ |
| Good Samaritan Stony Plainn (GSSP) | ☐ | ☐ | ☐ | ☐ |
| Hardisty Nursing Home (HNH) | ☐ | ☐ | ☐ | ☐ |
| Jasper Place Continuing Care Centre (JPCC) | ☐ | ☐ | ☐ | ☐ |
| Jubilee Lodge Nursing Home (JLNH) | ☐ | ☐ | ☐ | ☐ |
| Kensington Village (KV) | ☐ | ☐ | ☐ | ☐ |
| Laurier House Lynwood (LHL) | ☐ | ☐ | ☐ | ☐ |
| Laurier House Strathcona (LHS) | ☐ | ☐ | ☐ | ☐ |
| McConnell Place North (MPN) | ☐ | ☐ | ☐ | ☐ |
| McConnell Place West (MPW) | ☐ | ☐ | ☐ | ☐ |
| Miller Crossing Continuing Care (MCCC) | ☐ | ☐ | ☐ | ☐ |
| Millwoods Shepherd's Care (MSC) | ☐ | ☐ | ☐ | ☐ |
| Rivercrest Lodge Care Centre (RLCC) | ☐ | ☐ | ☐ | ☐ |
| Salem Manor Nursing Home (SMNH) | ☐ | ☐ | ☐ | ☐ |
| Sherwood Park Care Centre (SPCC) | ☐ | ☐ | ☐ | ☐ |
| South Terrace Continuing Care Centre (STCC) | ☐ | ☐ | ☐ | ☐ |
| Strathcona Alzheimer's Care (SAC) | ☐ | ☐ | ☐ | ☐ |
| St. Joseph's Auxilliary Hospital (SJAH) | ☐ | ☐ | ☐ | ☐ |
| St. Michael's Long Term Care Centre (SMLTC) | ☐ | ☐ | ☐ | ☐ |
| Touchmark Care Centre (TCC) | ☐ | ☐ | ☐ | ☐ |
| Venta Care Centre (VCC) | ☐ | ☐ | ☐ | ☐ |
| Westview Continuing Care (WCC) | ☐ | ☐ | ☐ | ☐ |
| Youville Home (YH) | ☐ | ☐ | ☐ | ☐ |
| OTHER: | ☐ | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ | ☐ |

APPLICANT NAME:

## DISCLOSURE

Do you have any pending investigations regarding your professional status or qualifications, including but not limited to licensure, disciplinary actions, professional sanctions or the imposition of any monitoring requirements?

☐ **Yes** ☐ **No**

If "Yes" please describe:

In this application for a change in my Appointment or Delineation of Privileges under the Alberta Health Services Medical Staff Bylaws, I hereby declare the above information is correct and in accordance with my practice requirements. I fully understand that any significant misstatement or omission from this application may constitute cause for denial of my application or cause for summary dismissal from the Alberta Health Services (AHS) Medical Staff.

**SIGNATURE**: _____ Date: _____

## EDMONTON ZONE APPROVALS

| | | | |
|---|---|---|---|
| **Primary ZCDH Signature** | Printed Name | Date | ☐ Recommend<br>☐ Do not recommend |
| | Department | | |
| **Supplementary ZCDH Signature** | Printed Name | Date | ☐ Recommend<br>☐ Do not recommend |
| | Department | | |
| **Supplementary ZCDH Signature** | Printed Name | Date | ☐ Recommend<br>☐ Do not recommend |
| | Department | | |
| **Edmonton ZMD Signature** | Printed Name | Date | ☐ Recommend<br>☐ Do not recommend |
| | Comments | | |
| **Edmonton ZARC Chair Signature** | Printed Name | Date | ☐ Recomend<br>☐ Do not recommend |
| | Comments | | |

| PLEASE SUBMIT THIS FORM TO | | |
|---|---|---|
| Ashley Turlione<br>Tel: 780 735-0758<br>Fax: 780-735-0756<br>Ashley.Turlione@albertahealthservices.ca<br><br>Emergency Medicine<br>Family Medicine<br>Oncology | Deborah Day<br>Tel: 780 735-0979<br>Toll Free Fax: 1-855-776-3811<br>Deborah.Day@albertahealthservices.ca<br><br>Adult Critical Care<br>Anesthesia<br>Surgery<br>Women's Health | Patti Lawrence<br>Tel: 780 735-0759<br>Toll Free Fax: 1-855-776-3810<br>Patti.Lawrence@albertahealthservices.ca<br><br>Child Health<br>Diagnostic Imaging |
| Kellie Machell<br>Tel: 780-735-0710<br>Fax: 1-855-776-3812<br>Kellie.Machell@albertahealthservices.ca<br><br>Addiction & Mental Health<br>Cardiac Sciences<br>Clinical Neurosciences<br>Medicine | | |
| Mailing Address: 5th Floor, Seventh Street Plaza, North Tower, 10030 – 107 Street, Edmonton, AB T5J 3E4 | | |

# Exhibit "H"

[redacted]

This is Exhibit " H " referred to in the Affidavit of
Dr. Blaine Acher
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

**From:** AHS CEO [redacted]
**Sent:** Friday, October 22, 2021 11:24 AM
**To:** AHS.All [redacted]
**Subject:** Immunization of Workers for COVID-19 Policy Deadline Extended

Graphical user interface, text□ □ Description automatically generated

# *Immunization of Workers for COVID-19 Policy Deadline Extended*

**Dear staff, physicians and volunteers**

AHS is pleased to announce that 94 per cent of AHS full-time and part-time employees, 94 per cent of AHS physicians and more than 97 per cent of ICU staff have submitted proof of having being fully immunized. We are grateful to all who have already submitted their proof of immunization and continue to go above and beyond to keep each other and our patients safe.

We appreciate the pressures our teams face in this fourth wave, especially those

on the frontlines, and we want to provide every opportunity for our workers, including our contracted service and continuing care providers, to submit their proof of immunization.

We are extending the deadline to comply with the Immunization of Workers for COVID-19 Policy until Nov. 30, 2021. This extension applies to all AHS, Alberta Precision Laboratories (APL), Carewest, CapitalCare and Covenant Health employees, medical and midwifery staff, students, volunteers and contracted healthcare providers. The deadline to submit your Got My COVID-19 Immunization Form has been extended to Nov. 15, 2021.

This is not a situation where we have low immunization rates among healthcare workers – we know that most healthcare workers are immunized. We want to ensure as many staff as possible have the opportunity to be immunized and provide full proof of immunization. We stand by this policy, and it will be fully implemented. We must continue to protect staff and patients from COVID-19.

Here's what you need to know:

- Individuals must receive their second dose of a two-dose vaccine — or the first dose of a single dose vaccine — no later than **Nov. 15** to be considered fully immunized by **Nov. 30.**
- Workers will need to provide proof of immunization no later than **Nov. 15** by submitting the Got My COVID-19 Immunization Form after their final dose.
- Those workers who are not fully immunized, will be placed on an unpaid leave of absence until they can provide proof of immunization, except where a workplace accommodation is approved.

To date, AHS has received about 1,400 requests for accommodation on medical or religious grounds, with 875 submitting the required paperwork.

Those requiring a medical, religious, or other form of accommodation had until Oct. 16, 2021 to submit their request. AHS continues to process and validate accommodation requests submitted. Should the need for an accommodation arise in the future, AHS will review those requests as per our accommodation policy.

This policy strengthens the work AHS has done throughout the pandemic to keep our hospitals and healthcare facilities safe, including mandatory use of

Personal Protective Equipment, daily fit for work screening for all healthcare staff, visitor restrictions, Infection Prevention and Control measures, and ongoing staff education.

We would like to thank those staff members who have already submitted their proof of immunization and strongly urge those who haven't to do so as soon as possible.

We encourage staff who remain unimmunized to address any concerns they may have with their leader or healthcare provider and get their immunization as soon as possible. COVID-19 immunization appointments can be booked through ahs.ca/vaccine. Appointments can also be booked through the Government of Alberta's new Alberta Vaccine Booking System.

We must work together to maintain a work environment that promotes worker safety and well-being. There are many supports and resources on Insite. You can also find additional information in the staff FAQ. Contact AHSVaccineTaskForce@ahs.ca if you have further questions.

Thank you for your ongoing support and dedication.

Sincerely,

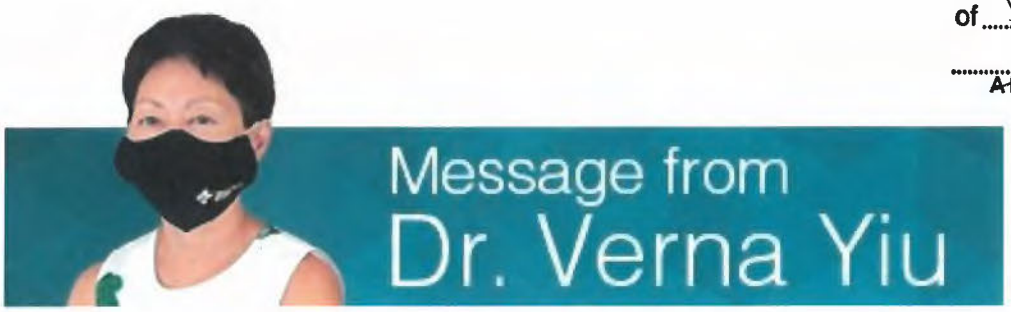
**Dr. Verna Yiu**

AHS President and CEO

# Exhibit "I"

**From:** CMO [redacted]
**Sent:** November 29, 2021 4:22 PM
**Subject:** Immunization of Workers for COVID-19 Policy - Targeted Testing Introduced

This is Exhibit " I " referred to in the Affidavit of
Dr. Blaine Acher
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor




# *Immunization of Workers for COVID-19 Policy - Targeted Testing Introduced*

**Dear staff, physicians and volunteers,**

At the direction of the Government, AHS will temporarily introduce frequent, targeted COVID-19 testing as part of our *Immunization of Workers for COVID-19 Policy*. Only work locations at significant risk of service disruptions due to staffing shortages resulting from employees who are not fully immunized will be part of the testing program, which will be reviewed by the end of March 2022.

We've had an overwhelmingly positive response to the policy. As of Nov. 29, 2021, 96 per cent of AHS full-time and part-time employees, 99 per cent of AHS physicians and 99 per cent of ICU staff have submitted proof of being fully immunized. We're extremely grateful to all employees and physicians who are now fully immunized.

To ensure uninterrupted patient care, eligible employees who are not fully immunized at a limited number of work locations will be able to provide proof of negative COVID-19 tests starting Dec. 13, 2021. The immunization policy deadline will also be adjusted to Dec. 13 to accommodate the introduction of targeted testing.

Currently, we anticipate about 260 employees will be eligible for this temporary testing option, across approximately 16 work locations provincially. This represents about 0.2 per cent of staff, at about three per cent of AHS sites. We anticipate this number will decrease as we continue to implement additional mitigation strategies to ensure any service disruptions are limited.

Eligible employees at affected locations who are not fully immunized and choose the testing option will be required to provide proof of a negative (Health Canada approved) COVID-19 test that has been completed no more than 48 hours before each of their working shifts. A positive rapid test will require the individual to be off

work until results of a follow-up PCR test are available. If an employee has multiple shifts in a week, this may mean multiple tests will be required. Testing costs and coordination will be the responsibility of the employee.

If an eligible employee who is not fully immunized at an affected work location opts not to provide regular proof of a negative COVID-19 test, they will be placed on an unpaid leave of absence. Except for where an accommodation has been granted, employees at all other locations who remain not fully immunized by Dec. 13, 2021 will also be placed on an unpaid leave of absence.

AHS stands by our immunization policy, which was implemented to protect patients and healthcare workers. Patient care has always been the focus of the mandatory immunization policy – AHS must do all it can to ensure patients, particularly those who are more vulnerable or immuno-compromised, are protected while in our care.

Healthcare workers have an ethical and professional responsibility to protect others. Immunization is a tool to assist in meeting this standard. We continue to recommend COVID-19 immunization to all of our employees and physicians as part of our overall approach to protect patients and one another.

The Leader FAQ and Staff FAQ will be updated as more information is available. Staff and leaders at affected work locations will also be provided with more information in the coming days. We appreciate your patience.

Please talk to your leader if you have any questions or contact AHSVaccineTaskForce@ahs.ca.

Thank you for your ongoing support and dedication.

Sincerely,

**Dr. Verna Yiu**
AHS President and CEO

# Exhibit "J"

# Justice Centre
for Constitutional Freedoms

This is Exhibit " J " referred to in the Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
In and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

November 2, 2021

Via Email : [redacted]

Alberta Health Services
Seventh Street Plaza
14th Floor, North Tower
10030 – 107 Street N.W.
Edmonton, Alberta T5J 3E4

**ATTENTION: Alberta Health Services President and Chief Executive Officer**

Dear Dr. Yiu,

**Re: AHS Vaccination Policy**
**Dr. Blaine Achen**

---

We write on behalf of Dr. Blaine Achen, Chief of Cardiac Anesthesia at the Mazankowski Alberta Heart Institute, concerning the actions taken by Alberta Health Services ("AHS") regarding the AHS Policy of September 14, 2021, entitled *Immunization of Workers for COVID 19* (the "Policy"), requiring all physicians, staff and contracted providers to be fully immunized by October 31, 2021[1] and without notice extended the deadline to November 30, 2021.[2]

On October 1, 2021, Dr. Achen submitted AHS Form 21871(2021-09) *Medical or Midwifery Staff Request for Exemption*[3] requesting an exemption on the basis of natural immunity and religious grounds, and claimed protection under the *Alberta Human Rights Act*, RSA 2000, c A-25.5.[4] On October 15, 2021, Dr. Achen's request was denied by Dr. David Zygun, Edmonton Zone Medical Director, on the recommendation of the Exemption Review Panel, which simply confirmed the Policy by referencing its definition of "Fully Immunized."[5] On October 21, 2021, Dr. Zygun followed up via email to a telephone call

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[1] https://extranet.ahsnet.ca/teams/policydocuments/1/clp-ahs-immunization-workers-1189.pdf - Document # 1189 – Immunization of Workers for Covid 19.

[2] AHS extends mandatory COVID-19 immunization deadline | Alberta Health Services.

[3] Document # 2187 – Medical or Midwifery Staff Request for Exception COVID-19 Mandatory Immunization for Workers.

[4] Discrimination re employment practices:
7(1) No employer shall
(a) refuse to employ or refuse to continue to employ any person, or
(b) discriminate against any person with regard to employment or any term or condition of employment, because of the race, religious beliefs, colour, gender, gender identity, gender expression, physical disability, mental disability, age, ancestry, place of origin, marital status, source of income, family status or sexual orientation of that person or of any other person.

[5] October 15, 2021 Letter from David Zygun to Dr. Achen
Fully immunized means a worker:
a) who has 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
b) 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.

during which he outlined the options for Dr. Achen moving forward, effectively calling for his resignation or, in the alternative, restricting his position and privileges. Either option constitutes wrongful dismissal.[6]

The Policy is clear: get vaccinated or *get lost*. The College of Physicians and Surgeons of Alberta ("CPSA") has also been exercising immense pressure on doctors to comply. Medical professionals are not even permitted to question their own medical interventions and the efficacy of the vaccine or the Policy, let alone talk about the risks associated with documented side effects. The Policy has created a hostile and toxic work environment, and a dangerous healthcare environment for patients – that is, the public. By its Policy and actions, AHS is unjustifiably stigmatizing those workers who have chosen not to get the Covid-19 vaccine.

This letter addresses several concerns arising from AHS' actions and the Policy. Dr. Achen demands that the Policy be immediately revoked, or alternatively, that he be exempted from the Policy for the following reasons:

The Policy is Unscientific and Unethical

The definition of "Fully Immunized" in the Policy does not recognize enhanced immunity, established by settled science, possessed by individuals who have recovered from Covid-19. Dr. Achen has fully recovered from Covid-19, has been tested for antibodies by the Mayo Clinic Lab, and has provided scientific evidence of robust natural immunity.[7]

The science on the effectiveness of natural immunity after infection with Covid-19 has been researched and proven. A National Institutes of Health (the "NIH") publication, dated January 26, 2021, stated:

> The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection.[8]

Another recent article in *Clinical Infectious Diseases* (published Oct. 5, 2021) by Jie Zhang, et al. demonstrated further evidence of a robust and long-lasting immunity in Covid-19 convalescents stating: "SARS-CoV-2 specific cellular and humoral immunities are durable at least until one year after disease onset."[9] The World Health Organization also confirms this understanding, stating: "Current evidence points to most individuals developing strong protective immune responses following natural infection with SARSCoV-2."[10]

In a letter addressed to the Center for Disease Control ("CDC") dated May 28, 2021, a number of medical experts urged it to lift of restrictions on the naturally immune to the same extent such restrictions have been lifted on the vaccinated:

> First, in contrast to having had COVID-19, there is no proof that the COVID-19 vaccines prevent infection or transmission. The applications for emergency use authorization

[6] Email from Dr. David Zygun to Dr. Achen, October 20, 2021, 11:35 AM, Subject: meeting follow up.
[7] Mayo Clinic Laboratories – SARS-coV-2 Spike Ab, Semi-Quant, S – Order Number ML07502784.
[8] https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19.
[9] https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561.
[10] See "Conclusions" https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1.

> ("EUA") for all currently authorized COVID-19 vaccines were based on data which supports that these products may reduce certain symptoms of COVID-19 for some individuals, but the FDA's EUAs made clear that there is no evidence the COVID-19 vaccines can prevent recipients from becoming infected with and transmitting the virus. As the FDA explains, at the time of the EUA approval, the data was "not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 [i.e., the virus that causes COVID-19] from person to person." Similarly, the FDA Briefing Documents for the COVID-19 vaccines supporting the grant of an EUA list the following as still unknown: "effectiveness against asymptomatic infection," and "effectiveness against transmission of SARS-CoV-2." Nonetheless, your recommendations lift restrictions on individuals that have been vaccinated, despite the lack of proof that these products prevent infection and transmission, but do not lift restrictions on those that have had COVID-19 despite clear proof that having had the virus prevents them from becoming reinfected and transmitting the virus.[11]

A growing body of compelling evidence demonstrates that natural immunity is superior to vaccine immunity by every measure. It is unscientific and unethical for AHS to coerce or mandate a vaccine on an employee who already enjoys natural immunity as a result of having contracted and recovered from the virus, particularly since recent evidence suggests that the vaccines tend to diminish the protection natural immunity provides.[12] Furthermore, as far back as October 2020, it was known that "COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated."[13]

This well-established scientific evidence was completely disregarded by the Exemptions Review Panel. We demand that you provide the scientific evidence upon which the Policy is based and the rationale for refusing to provide Dr. Achen an exemption, given the above.

<u>The Policy contradicts other AHS polices</u>

According to the Government of Alberta website:

> Health-care workers are strongly encouraged to get immunized. AHS reported the number of AHS health-care workers vaccinated against influenza in 2020-21 was 66%, compared to 67% in 2019-20.
>
> Alberta has a voluntary immunization policy for health-care workers. The focus is on education, promotion, and making it easy for health-care workers to get immunized.[14]

In 2018-2019 Alberta recorded 179 cases per 100,000 for influenza, and in 2017-2018, 215 per 100,000,[15] yet AHS did not implement a mandatory vaccination program for employee and patient safety and wellbeing. The discrepancy between vaccination polices for influenza and COVID-19 are unfounded and

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[11] See Appendix A, Exhibit A: Reply-to-CDC-Re-Natural-Immunity-v-Vaccine-Immunity.pdf (icandecide.org) at p. 4.
[12] Sivan Gazit, et al., Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections medRxiv (August 25, 2021) https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1; https://www.israelnationalnews.com/News/News.aspx/309762; Yair Goldberg, et al., Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel, medRxiv (April 24, 2021) https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.
[13] See "Results of the study": Cardozo, T. and Veazey, R. (2021), Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease. Int J Clin Pract, 75: e13795. https://doi.org/10.1111/ijcp.13795.
[14] See "About Influenza": https://www.alberta.ca/influenza-the-flu.aspx. Influenza – the flu | Alberta.ca.
[15] See Table 1: health-influenza-summary-report-2018-2019.pdf. (alberta.ca) at p. 3.

are particularly troubling when influenza has been ranked among the top 10 leading causes of death in Canada for the last 20 years.[16]

Furthermore, what is startling and very concerning is the actual rate of hospitalization and death rates when comparing influenza and Covid-19. In 2014-2015 Alberta recorded its highest rate of hospitalization case rates at 39.9/100 cases and death rates at 2.3/100 cases.[17] If we compare the total hospitalization and death rates from Covid-19 from start to present - which is well over 1 year of data – Alberta has recorded in total hospitalization case rates at 4.4/100 cases and death rates at 1.0/100 cases for Covid-19.[18] According to government data, in one year influenza was more than twice as deadly as total Covid-19 deaths, yet AHS did not impose a mandatory influenza vaccine policy at that time.

The Policy is Baseless

The electronic version of the Policy, as hosted on AHS Policy Services website[19] (which claims to be the only "valid" document) is shrouded with the following disclaimer (the "Disclaimer"):

> This work is licensed under a Creative Commons Attribution-Non-commercial-Share Alike 4.0 International license. The licence does not apply to AHS trademarks, logos or content for which Alberta Health Services is not the copyright owner. This material is intended for general information only and is provided on an "as is", "where is" basis. **Although reasonable efforts were made to confirm the accuracy of the information, Alberta Health Services does not make any representation or warranty, express, implied or statutory, as to the accuracy, reliability, completeness, applicability or fitness for a particular purpose of such information. This material is not a substitute for the advice of a qualified health professional. Alberta Health Services expressly disclaims all liability for the use of these materials, and for any claims, actions, demands or suits arising from such use.** [Emphasis added]

The Disclaimer is an affront to AHS' Values of Compassion, Accountability, Respect, Excellence and Safety. It renders the Policy an unscientific proclamation of medical authority avoiding all responsibility.

AHS has declared it will not, "represent or warrant, express, implied or statutory, as to the accuracy, reliability, completeness, applicability or fitness for a particular purpose of such information," while making mandatory an experimental inoculation, with threat of unemployment. As a result, the Policy itself is an incongruity and does not support what it stands for.

Given that all material in the Policy is "not a substitute for the advice of a qualified health professional," Dr. Achen has taken the following steps:

1. Sought the advice of a qualified health professional;
2. Assessed his own professional knowledge, including of breakthrough Covid-19 cases (to note: anesthesiologists give more intravenous drugs than all other types of physicians combined and are the only physicians with expert knowledge of potent drugs and how they affect the body);
3. Weighed the potential outcomes of taking the injection against the risk of contracting Covid-19 again; and
4. Came to the personal decision not to receive the Covid-19 vaccines.

[16] Leading causes of death, total population, by age group (statcan.gc.ca).
[17] See Table 3 at page 14 Seasonal Influenza in Alberta: 2019-2020 Season.
[18] See Table 16 COVID-19 Alberta statistics | alberta.ca.
[19] https://extranet.ahsnet.ca/teams/policydocuments/1/clp-ahs-immunization-workers-1189.pdf.

His sincerely held religious beliefs also prevent him from receiving the Covid-19 vaccines.

To further threaten and coerce Dr. Achen violates the fundamental tenet of medicine known as informed consent, and the Hippocratic medical maxim – "do no harm."

Unproven and Unfounded Claims

Many effective medicines carry risks and have side effects which may occur in some patients. This is why a doctor should inform his or her patient of the benefits and risks of a medication, including possible side effects. With this information, the patient can decide whether or not to accept the treatment. This is called informed consent, which is a basic tenet of medicine.

The Covid-19 vaccines remain subject to ongoing clinical trials;[20] the vaccines bear Health Canada warning labels;[21] and the vaccinated and unvaccinated are both able to spread Covid-19 to others.[22] In short, there are significant reasons for individuals to have concerns about the safety and efficacy of these vaccines, and to make their own informed decisions not to receive them.

Statements in the Policy like, "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," cannot be relied upon as accurate science, as expressly stated in AHS's disclaimer. If AHS wishes to maintain this position, we ask that AHS provide the scientific evidence to support the claim that immunization is the **most** effective means to prevent the spread of Covid-19 **and** to preserve workforce capacity **and** to protect those accessing AHS sites. The failure of AHS to provide support for its purportedly scientific positions is causing substantial reputational harm to AHS and will lead to a loss of confidence in its future endeavours, even those unrelated to Coavid-19.

The Policy claims to be for the safety and wellbeing of staff and patients; however, to date, no data has been provided by AHS to confirm that the contents of the vaccines themselves meet AHS employee safety standards or that they do not contain concerning levels of toxicity.

According to the Vaccine Adverse Event Reporting System ("VAERS"), the adverse events reporting database operated by the Food and Drug Administration ("FDA") and the CDC, Covid-19 vaccines have resulted in 9,010 reported deaths in the United States during a period of only eight months.[23] In addition, VAERS reports that the vaccines are associated with 10,333 life-threatening events, 10,124 permanent disability events, 42,353 hospitalizations, 324 hospitalization prolongations, and 82,081 emergency room visits. Reported adverse events associated with the Covid-19 vaccines total 635,842.[24] These figures represent Covid vaccine-related adverse events (including death) over the past <11 months and exceed all adverse events (including death) figures, for all other vaccines combined, over the past 14 years.

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[20] See estimated completion study date, July 30, 2023: Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California - Full Text View - ClinicalTrials.gov.
[21] See "Key Messages": https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75479a-eng.php.
[22] Novel Coronavirus (COVID-19) Frequently Asked Questions (albertahealthservices.ca) at paras. 54 and 181.
[23] https://wonder.cdc.gov/vaers.html.
[24] https://openvaers.com/covid-data.

A 2011 study in which Pilgrim Health Care and Harvard University collaborated,[25] and a 2021 study published in the *Journal of the American Medical Association,*[26] find that actual adverse events occur at approximately 100 times the rate VAERS reports indicate, placing estimated total adverse events within the US at over 63.5 million. Applying the 2011 and 2021 studies, the Covid-19 vaccines may have resulted in over 1 million life threatening events, over 1 million cases of some variety of permanent disability, 4.2 million hospitalizations, over 30,000 prolonged hospital stays, 8.2 million emergency room visits, and 1 million deaths.

Does AHS accept liability for any harm to employees negatively affected by the injections?

Wrongful Dismissal

On October 20, 2021, Dr. Zygun stated:

> We discussed your options given my decision to support the recommendation of the exemption review committee. These included:
>
> 1. Resignation of AHS appointment and privileges – this can be accomplished through completion of the attached change appointment form and submitted to your ZCDH and me.
> 2. Change to community appointment – I indicated this was not relevant to the practice of anesthesiology that requires on site presence.
> 3. Temporary LOA for 3-6 months – this can be accomplished through completion of the attached LOA form and submitted to your ZCDH and me."[27]

Via the Policy and actions taken by AHS, AHS has unilaterally changed the terms of employment, threatening to revoke employment and privileges, thus pressuring its employees to take a leave of absence of quit. Constructive dismissal is prohibited under Canadian and provincial employment laws. Constructive dismissal qualifies an employee for the same damages he or she would have received in an outright termination.

Upon acceptance of their offers of employment with the AHS, employees did not agree to any condition of employment involving injections, let alone subjection to an inoculation which bears a Health Canada warning and is linked to the death and injury of untold recipients, and which is still undergoing clinical trials. The effect of the Policy is causing severe hardship and irreparable harm which cannot be undone. It is alleged that some or all of them may be compelled to take the vaccine against their will because they cannot in their personal and family circumstances take the risk of being left destitute by the Policy they are seeking to challenge.

Finally, employers are legally obligated to respect the autonomy and dignity of their employees, and the confidentially of their medical information;[28] they are obliged not to use medical knowledge to violate the human rights and civil liberties of their employees, even under threat from government authority. Via the Policy, AHS has in fact violated its duties and obligations as a responsible and competent employer.

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[25] Harvard Pilgrim Health Care, Inc. Electronic Support for Public Health-Vaccine Adverse Event Reporting System (ESP:VAERS), online: https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system.

[26] Blumenthal KG, Robinson LB, Camargo CA, et al. Acute Allergic Reactions to mRNA COVID-19 Vaccines. JAMA. 2021;325(15):1562–1565. doi:10.1001/jama.2021.3976.

[27] October 20, 2021 Email from Dr. Zygun

[28] Personal employee information | Alberta.ca.

Nuremberg Code

Following the horrors of the Holocaust and the Nuremberg Military Tribunals, where horrendous practices of "doctors" were brought to light, the Nuremberg Code, established in 1947, placed limitations upon human experimentation. Paragraph 1 of the Nuremberg Code states:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

The AHS vaccine mandate introduces elements of duress, overreach and coercion since employees will be obliged to take experimental shots or face losing their jobs. Even the FDA's Pfizer factsheet for healthcare providers indicates deference to the principle of informed consent, for it states: "The recipient or their caregiver has the option to accept or refuse (Pfizer-BioNTech) vaccine."[29]

Criminal Assault

Forcing a medical intervention on AHS employees under threat of loss of livelihood is a clear violation of the *Criminal Code of Canada* (the "*CCC*")[30] which states in part:

> 265(1) A person commits an assault when
> (a) Without consent of another person he applies force intentionally to the person directly or indirectly...
>
> 265(3) For the purposes of this Section, **no consent** is obtained where the complainant submits or does not resist by reason of...
> (d) The exercise of authority. [emphasis added]

Forcing employees under threat of loss of livelihood is a violation of the *CCC*. Every member of the AHS who supports the Policy supports the criminal assault of his or her fellow medical professionals.

Violation of the *Charter*

The Policy is unconstitutional as it unjustifiably violates sections 2, 7 and 8 of the *Canadian Charter of Rights and Freedoms*[31] (the "*Charter*"), which protects the right to a religious exemption based on the

[29] Healthcare Providers for 12 years of age and older, gray cap (no dilution) (fda.gov) at page 12.
[30] *Criminal Code* R.S.C., 1985, c. C-46 at sections 265(1) and 265(3).
[31] *The Constitution Act*, 1982, Schedule B to the *Canada Act* 1982 (UK), 1982, c 11.

guarantee of "freedom of conscience" and "freedom of religion," and the right to informed consent based on the guarantee of "right to life, liberty and security of the person" and the "right to be secure against unreasonable search and seizure." The Policy also discriminates against an identifiable and increasingly marginalized group, the Covid "unvaccinated", contrary to section 15 of the *Charter*.

Harm Outweighs the Benefit

The medical system in Alberta is struggling. Alberta already has a shortage of anesthesiologists. In 2019, Edmonton was identified by AHS as the most gravely affected.[32] Every day that Dr. Achen does not work, a surgical room is cancelled. Dr. Achen's forced departure jeopardizes the viability of many necessary and life-saving surgical procedures, which will not be performed and will cause longer, unnecessary, and possibly fatal, wait times for patients.

The recent treatment of health care workers in this province, in addition to the current AHS policies, are driving physicians out of Alberta and will further exacerbate an already dire situation. The forced departure of Dr. Achen will cause harm to patients in Alberta and will cause a further strain on an already struggling medical system in Alberta as a whole.

In order for the Policy to be justified in the public interest, the Policy must be necessary to achieve the intended health purposes and the effectiveness in meeting the goals should be evidence-based. Moreover, the Policy must be proportionate to the purpose and ought to have an expiry date.

Terminating or suspending medical professionals during a health crisis ought to be exercised with extreme caution and in cases of negligent behaviour or willful wrongdoing which is not the case here. Employees are being faulted and threatened for simply maintaining and expressing their personal and professional beliefs. AHS itself has put a greater burden on the public health system in Alberta and AHS workers themselves.[33]

With respect to the Covid-19 vaccine itself, it is impossible to ignore the serious injection-related health risks have come to light[34] and that Covid-19 cases continue to flourish among areas with high vaccination rates such as Alberta itself.[35] It is time to publicly acknowledge that the Covid-19 vaccine is not, and cannot, be relied upon as the only answer in response to a constantly evolving SARS-CoV-2 virus.

No Alternatives Provided

AHS has not offered any alternative options, and it is our position that AHS has not taken requests for exemptions seriously.

Rapid antigen testing is a clear alternative. Rapid antigen testing is an accurate and immediate method to minimize the risk that a person infected with Covid-19 may spread the SARS-CoV-2 virus to staff and patient. The first paragraph of the Policy states the purpose "is to protect the health and safety of our workers, patients and the public, and to preserve workforce capacity to support the healthcare system."[36] By not providing reasonable, safe, and efficient alternatives to its employees in order to preserve workforce capacity and support the healthcare system, AHS is in fact going against its stated purpose.

---

[32] 2019/20 Physician Workforce Forecast & Report (albertahealthservices.ca) at pp. 9 – 10.
[33] So far, over 26,000 healthcare workers face discipline or firing for being unvaccinated | True North (tnc.news).
[34] *Supra* note 23.
[35] Covid-19 Breakthrough Infections in Vaccinated Health Care Workers | NEJM.
[36] COVID19 Vaccine Immunization Policy FAQs For Staff (albertahealthservices.ca) at p. 2.

Furthermore, we are aware that many health care facilities engaged in the care of vulnerable people are enacting testing policies whereby both vaccinated and unvaccinated individuals are regularly tested for Covid-19. Such a policy is based on the fact that both vaccinated and unvaccinated individuals may contract Covid-19, in which case both vaccinated and unvaccinated individuals can potentially transmit the virus.

As you know, or ought to know, the vaccines do not prevent Covid-19 infection, nor do they prevent the spread of Covid-19; vaccinated and unvaccinated alike contract Covid-19 and spread it to others. Consistent with these facts, the vaccines are marketed as useful only for reducing the severity of Covid-19 symptoms.

The draconian actions taken by AHS to enforce its Policy as well as the Policy itself are not in line with its claims of promoting safety and wellbeing. Which state in part:

> **A Safe, Healthy and Inclusive Workplace**
> Provide work environments that protect and support physical health, mental wellbeing and a sense of belonging for all.
>
> A safe workplace is essential for diversity and inclusion. We will become diverse and inclusive by ensuring all of us—employees, volunteers, physicians, midwives, patients and family members—feel safe, welcome and valued regardless of race, religious beliefs, colour, gender, gender identity, gender expression, physical disability, mental disability, age, ancestry, place of origin, marital status, source of income, family status, sexual orientation, education or diversity of perspective.[37]

Conclusion

On September 27, 2021, the Australian Fair Work Commission delivered a landmark decision concerning the legality and moral propriety of vaccine mandates and stated as follows:

> [181] Blanket rules, such as mandating vaccinations for everyone across a whole profession or industry regardless of the actual risk, fail the tests of proportionality, necessity and reasonableness. It is more than the absolute minimum necessary to combat the crisis and cannot be justified on health grounds. It is a lazy and fundamentally flawed approach to risk management and should be soundly rejected by courts when challenged.
>
> [182] All Australians should vigorously oppose the introduction of a system of medical apartheid and segregation in Australia. It is an abhorrent concept and is morally and ethically wrong, and the antithesis of our democratic way of life and everything we value.[38]

Dr. Achen has been working for 16 years and is well regarded by his colleagues and patients, and he has never been disciplined or reprimanded by AHS or the College of Physician and Surgeons of Alberta. He remains committed to his role, and is willing and able to continue working, serving the medical needs of the people of Alberta. The Policy is causing undue hardship and irreparable harm to Dr. Achen. His personal beliefs are being attacked and his professional credibility has been undermined.

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[37] https://www.albertahealthservices.ca/assets/about/msd/ahs-msd-ahs-people-strategy.pdf at pp 15 and 19.
[38] Jennifer Kimber v. Sapphire Coast Community Aged Care Ltd., [2021] FWCFB 6015.

Relieving Dr. Achen of his services will unnecessarily cancel needed surgeries, exacerbating patient's pain and suffering and further adding unnecessary strain on an overburdened medical staff. As a result, the Policy is causing undue hardship and irreparable harm to an already struggling public health system, which will be further exacerbated with the loss of much needed medical staff.

For the reasons stated, there is no rational or legal basis for mandating Covid-19 vaccinations as a condition of employment with AHS. The Policy violates provincial, federal and international human rights statutes, agreements and conventions. The Policy is morally and ethically wrong and not founded on well-established science.

This is notice to AHS that if Dr. Achen does not receive accommodation by November 5, 2021, or if AHS should proceed to act upon its threat of suspension without pay or termination, the following actions may be taken without further notice:

1. Commencement of legal action against AHS, including a request for injunctive relief against AHS to prevent irreparable harm to individuals serving in Alberta's medical field and to the Alberta public in need of medical care;

2. Human rights claims alleging violation of *Alberta Human Rights Act*; and/or

3. Labour rights claims filed, alleging violation of applicable provincial and federal legislation.

We expect AHS shall govern itself accordingly. In the interim, we look forward to hearing from you or your legal counsel.

Yours truly,

[redacted]

Eva Chipiuk
Justice Centre for Constitutional Freedoms
Counsel for Dr. Blaine Achen

Cc. David Zygun, Edmonton Zone Medical Director, Alberta Health Services
Cc. Jason Copping, Minister of Health responsible for AHS
Cc. Councillors, College of Physicians and Surgeons of Alberta

# Exhibit "K"

Healthy Albertans.
Healthy Communities.
**Together.**

November 8, 2021

*Via Email:* [redacted]

Justice Centre for Constitutional Freedoms
253-7620 Elbow Drive SW
Calgary, AB T2V 1K2

Attention: Eva Chipiuk

Dear Ms. Chipiuk:

**RE: Dr. Blaine Achen**

I have been provided with a copy of your letter dated November 2, 2021. Please confirm whether you are representing Dr. Achen as a member of the Medical Staff or in his role as Zone Clinical Section Chief, Cardiac Anesthesia.

Your letter contains many inaccuracies, questionable legal argument, and a plethora of misinformation, and as such, AHS disagrees with the claims and assertions contained therein. You are advised that AHS will not be changing the Immunization of Workers for COVID-19 Policy (Policy) at this time, and is prepared to take further action against Dr. Achen to enforce the Policy in the event he remains non-compliant, including restricting his clinical activities.

Please note, members of the Medical Staff are not employees of AHS.

Yours truly,
**Alberta Health Services**

Shalee Kushnerick
Associate General Counsel, Litigation

This is Exhibit " K " referred to in the Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

Alberta Health Services

Legal & Privacy, Litigation
Suite 500, North Tower, Seventh Street Plaza
10030 - 107 Street, Edmonton, AB T5J 3E4
Tel: 780-735-1271 Fax: 780-735-1400
Shalee.Kushnerick@ahs.ca

# Exhibit "L"

Alberta Health Services

November 17, 2021

**Confidential**

This is Exhibit " L " referred to in the Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

Dr. Blaine Achen
CPSA 013745
8440-112 ST NW
ANESTHESIA DEPT
UNIVERSITY HOSPITAL
Edmonton, AB T6G 2B7

Sent via email to [redacted]

Dear Dr. Achen:

**Re: Part 6 Process – Alberta Health Services Medical Staff Bylaws**

I write in relation to the correspondence from the Zone Medical Director, Edmonton Zone, to you, dated November 16, 2021 (the "Concern"). As per section 3.4.4.7 of the Alberta Health Services ("AHS") Medical Staff Rules, I am performing the functions otherwise assigned to the Zone Medical Director in accordance with the AHS Medical Staff Bylaws.

I am requesting to meet with you so that we could discuss the Concern and, more specifically, whether you will be fully immunized against COVID-19 by November 30, 2021, as required by the Immunization of Workers for COVID-19 Policy and, if not, whether you:

- intend to become fully immunized and:
  - if so, whether you would take a temporary leave of absence if you would not be fully immunized by November 30, 2021; and
  - if not, whether you would take a leave of absence for an undefined time period;
- would be interested in changing your AHS Appointment to a Community Appointment, which Appointment category is not captured by the Policy; and/or
- would be interested in submitting a Change Request to end your AHS Appointment and Clinical Privileges.

Please contact Debra Ramstead [redacted] as soon as possible to confirm whether you can meet via Zoom on ***November 23*** at ***0830*** to discuss. Please be advised that, if I do not hear from you in this regard, then I will proceed to take an Immediate Action to restrict or suspend your AHS medical staff appointment and clinical privileges pursuant to s 6.7 of the AHS Medical Staff Bylaws, effective 12:01 a.m. on December 1, 2021.

Regards,

Braden Manns, MD, MSc
Associate Chief Medical Officer
Strategic Clinical Networks™
Alberta Health Services

# Exhibit "M"

Alberta Health Services

Confidential

This is Exhibit "M" referred to in the Affidavit of Dr. Blaine Achen
Sworn before me this 7th day of December A.D. 2021
A Notary Public, A Commissioner for Oaths in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

November 17, 2021

Dr. Blaine Achen
Dept. of Anesthesia
University Hospital
8440-112 Street NW
Edmonton, AB
T6G 2B7

Sent via Email: [redacted]

Dear Dr. Achen:

**Re: Notice of Termination of Medical Administrative Services Agreement**

I am writing in reference to the Medical Administrative Services Agreement ("Agreement") between yourself and Alberta Health Services ("AHS") in your leadership role of Zone Clinical Section Chief, Adult Cardiac Anesthesia.

This letter will serve as notice that this Agreement is terminated effective immediately in accordance with section 7.1(c). In lieu of advance notice, AHS will pay to you a lump sum in the gross amount of $6,321.10. This amount is equal to the Fees (as defined in the Agreement) for ninety (90) days and will be sent via direct deposit.

I would like to take this opportunity to thank you for your service as a medical leader to AHS.

If you have any questions about this matter, please feel free to contact me at [redacted]

Sincerely,

David Zygun, MD MSc. FRCPC
Edmonton Zone Medical Director
Alberta Health Services

# Exhibit "N"

This is Exhibit " N " referred to in the Affidavit of Dr. Blaine Achen

Sworn before me this 7th day of December A.D.

A Notary Public, A Commissioner for Oaths In and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

**From:** Blaine Achen [redacted]
**Sent:** November 28, 2021 4:50 PM
**To:** Braden Manns [redacted]
**Cc:** Blaine Achen [redacted]; Debra Ramstead [redacted]; Blaine Achen [redacted]
**Subject:** Re: Next steps

Hi Dr. Manns,
Thank you for the zoom meeting on November 25 at 10:00 am.
In response to that meeting I have a few followup questions.

1. You mentioned a few times about me being a contractor as opposed to an employee of AHS or Alberta. Can you explain to me who in the whole province I can work for as an anesthesiologist if not under AHS. If AHS has a monopoly on the whole province for anesthesiologists, how can you say that I am a contractor when I have no one else in the whole province to contract with?
2. You mentioned also that this is an Immunization Policy not an Immunity Policy? What does that mean? To me this sounds like you want me to comply with policy where I need to get a vaccine whether or not it provides immunity. The Objective of the Policy says: To set out worker immunization requirements for COVID-19 to protect the health and safety of workers, patients, and the communities that Alberta Health Services (AHS) serves. Can you explain to me how an Immunization Policy (as you describe it) meets the objectives of the Policy for health and safety of staff and workers when it does not have anything to do with Immunity (as you said).
3. Have you considered the negative impact on me as a competent and respected member of the medical community and what a loss that is to Alberta and how you are impacting me personally and professionally? I can say first hand this will very negatively impact my patients and the health care system in Alberta. There is a critical shortage of qualified anesthesiologists in Alberta. AHS will not be able to replace me in the short term, and possibly not in the long term. Are you aware of the detrimental impact terminating me is having on my patients and my staff?
4. As a medical doctor, AHS has stripped me of my medical discretion. How is this in line with anything that we learn as doctors and the oaths that we take regarding informed consent and disclosure of risks and patient autonomy?

I have provided proof of my actual immunity to you with a record of my Ab level to the Sars-Cov-2 spike protein which remains exceptionally high, the medical literature supports my position and numerous jurisdictions around North America and Europe have recognized natural immunity following Covid 19 infection. I and healthcare workers like me remain the safest workers in the hospital. Your own data demonstrates this with the double vaxxed becoming infected and

transmitting the virus.

I am here to serve patients in need of both Cardiac and General anesthesia. There is no medical reason for me not to continue providing care that will stand up to any objective scrutiny of the literature.

In regards to the options, none of the so-called options you outline are in any way acceptable to me.

Regards,
Blaine Achen

On Thu, Nov 25, 2021 at 11:14 AM Braden Manns [redacted] wrote:

Dear Dr Achen:

thanks for meeting with me today.

I wanted to remind you of the options, and next steps.

The options you have are:

- if you intend to become fully immunized, then you could take a temporary leave of absence until you have been fully immunized (14 days after the last dose of the vaccine series you choose).
- if you do not intend to become fully immunized, then the options are:
    - you could take a leave of absence for an undefined time period; If you become in compliance with the vaccine policy, you could be reinstated.
    - you could change your AHS Appointment to a Community Appointment, which Appointment category is not captured by the Policy; However, as we discussed, if you do this, you would NOT be able to work in your current position as an Anesthetist. The definition of a Community Staff Appointment can be found at section 3.1.13 of the Medical Staff Bylaws.
    - OR you could submit a Change Request to end your AHS Appointment and Clinical Privileges. Again, if you do this, you would NOT be able to work in your current position.

- Finally, as we discussed, if none of these options are acceptable to you, then before Dec 1st, an Immediate action will be taken to suspend your appointment / privileges.

Please let me know by Nov 28th, 2021 what your decision is. If you choose a voluntary Leave of absence or wish to change your privileges category, then we will send you the paperwork to complete.

Sincerely,
Braden

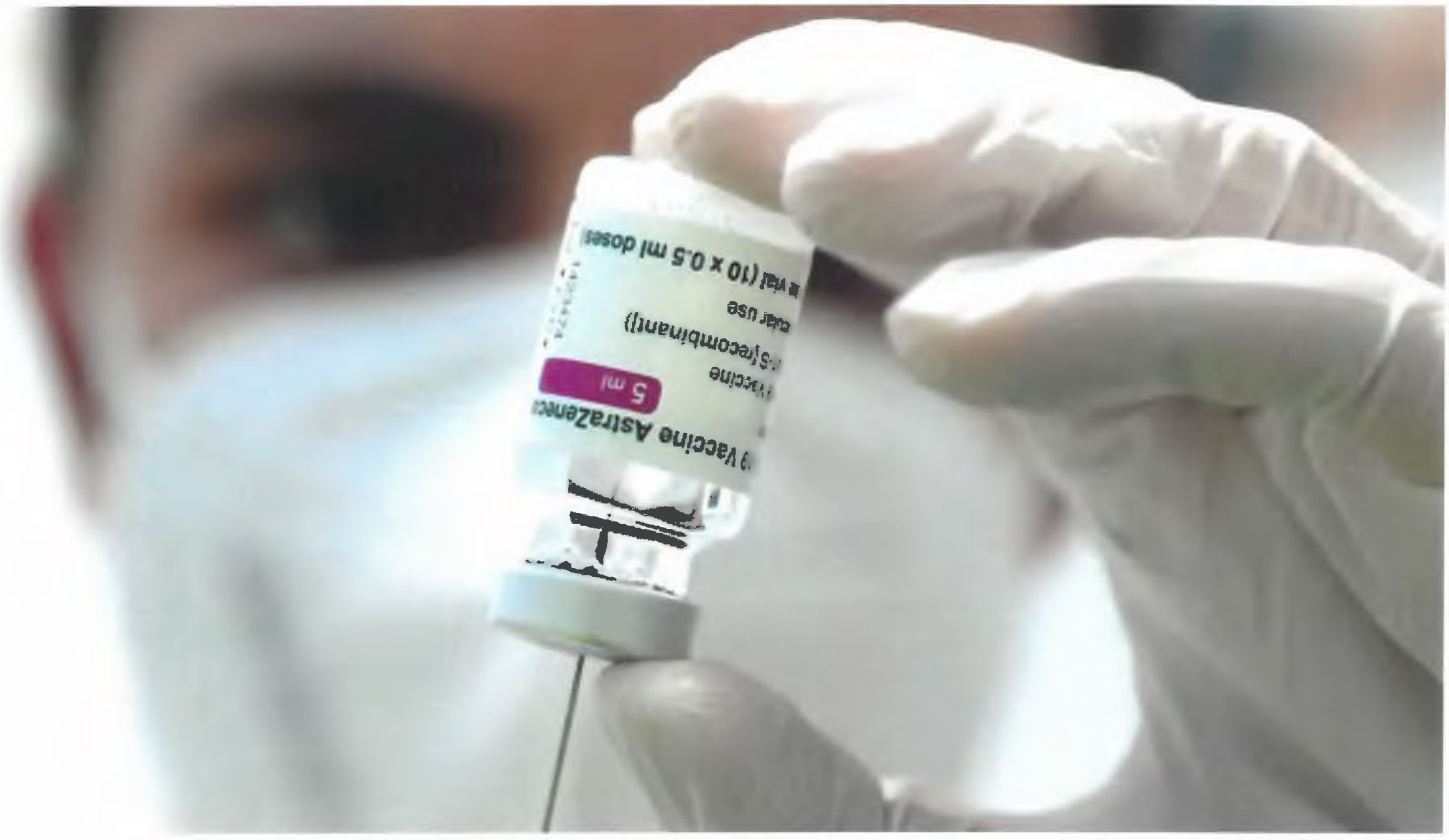
# Exhibit "O"

Politics

# Suspend AstraZeneca use for people under 55, vaccine committee recommends

The updated guidelines come following reports of rare blood clots

David Cochrane, John Paul Tasker · CBC News · Posted: Mar 29, 2021 1:04 PM ET | Last Updated: March 29




Prince Edward Island announced Monday that it is suspending its AstraZeneca-Oxford vaccine program, which was geared to 18-29-year-olds, pending 'further information' from Health Canada. (Matthias Schrader/The Associated Press)

comments

Canada's National Advisory Committee on Immunization (NACI) is recommending provinces pause the use of the AstraZeneca-Oxford COVID-19 vaccine on those under the age of 55 because of safety concerns — guidance most provinces said today that they would follow.

The change comes following reports out of Europe of very rare instances of blood clots in some immunized patients — notably among younger women.

But 300,000 of these shots have been administered in Canada already, with no reports of blood clots here, officials said. The blood clotting problem also has not been reported in people who have received mRNA vaccines like the Pfizer and Moderna products.

Speaking to reporters Monday, Dr. Shelley Deeks, the vice-chair of NACI, said that with "substantial uncertainty" around cases of vaccine-induced thrombocytopenia (VIPIT) in people with low platelets, the committee is recommending the suspension of shots in all people under 55 as a "precautionary measure."

Based on early research out of Europe, VIPIT seems to be rare, occurring in anywhere from 1 in every 125,000 to 1 in 1 million people.

- **No evidence to suggest AstraZeneca's COVID-19 vaccine causing adverse events: Tam**
- **Why Canada is suspending use of AstraZeneca vaccine in people under 55**
- **P.E.I. suspends AstraZeneca vaccine program**

The European Union's drug watchdog, the European Medicines Agency, has said it could not definitively rule out a link between the vaccine and rare types of blood clots associated with thrombocytopenia.

Specifically, it pointed to 18 cases of an extremely rare type of blood clot called cerebral venous sinus thrombosis (CVST), a condition that is much more common in women than men. Most of the cases occurred within 14 days of receiving the AstraZeneca shot, and the majority were in women under the age of 55.

Dr. Howard Njoo, Canada's deputy chief public health officer, said people who develop stroke-like medical symptoms after receiving the AstraZeneca vaccine — shortness of breath, chest pain, leg swelling, abdominal pain, sudden onset of headaches or blurred vision — should immediately seek medical attention. There is no risk for people who have not developed such symptoms 20 days post-vaccination.

Asked why the shot is still recommended for people over the age of 55 given the many unknowns, Dr. Caroline Quach-Thanh, the chair of NACI, said the early data indicate that the rare blood clots are most common in younger people.

She said older Canadians should take whatever vaccine they can get because contracting COVID-19 poses a much greater health risk to them than the outside chance of developing this sort of blood clot.

"If you look at this overall, it's a vaccine that prevents complications and deaths. We're trying to contrast the risks and benefits," she said.

***WATCH: Vaccine committee recommends a pause on use of AstraZeneca vaccine among those under 55***

Dr. Supriya Sharma, Health Canada's chief medical adviser, discusses NACI's recommendation to pause the use of AstraZeneca's COVID-19 vaccine on those under the age of 55. 1:34

Quach-Thanh conceded the barrage of bad headlines about AstraZeneca could increase vaccine hesitancy but said that with the pandemic running "rampant," seniors should get a shot that greatly reduces their risk of COVID-19-related death and hospitalization.

"This vaccine has had all the ups and downs — its looks like a roller coaster," she said, citing the changing guidelines on AstraZeneca.

Asked if he still has confidence in the safety of this product, Marc Berthiaume, the director of the bureau of medical science at Health Canada, said reports of rare, adverse health events are always possible when millions of people are treated with a vaccine.

"This vaccine remains relevant," he said.

"This is something that is very rare and we need to continue to monitor it," said Dr. Supriya Sharma, Health Canada's chief medical adviser, adding this is a sign that Canada has a robust monitoring system.

"It's reasonable to pause for a period of time while this continues to be evaluated," she said. "I fully understand this can be confusing."

> "... the benefits of using our vaccine to protect people from this deadly virus significantly outweigh the risks across all adult age groups."
>
> *- AstraZeneca Canada*

The policy shift comes as Canada is expected to receive 1.5 million doses of this product from the U.S. on Tuesday. The product has not yet been approved for use in the American marketplace.

The AstraZeneca shot has not been widely used in people under the age of 55 in this country.

Some jurisdictions, such as B.C. and P.E.I., have been using some of their supply to immunize young people who work in public-facing sectors like grocery and convenience stores. In New

Brunswick, the shot was made available to first responders and some teachers last week.

Meanwhile, Health Canada — which approved the vaccine for use in Canada in February — said its regulators would be adding "additional terms and conditions on the authorizations" for AstraZeneca and a biologically identical version of the drug manufactured by the Serum Institute of India, which has been branded Covishield.

The manufacturers will be required to conduct a "detailed assessment of the benefits and risks of the vaccine by age and sex in the Canadian context," information that could lead to "additional regulatory actions."

"This information will support the ongoing evaluation of these rare blood clotting events, and allow Health Canada to determine if there are specific groups of people who may be at higher risk," the department said in a press release.

## Benefits outweigh risks: AstraZeneca

AstraZeneca issued a statement this evening saying that it respects the decision by NACI and noting that Health Canada's guidance on the vaccine has not changed since last week.

"Regulatory authorities in the U.K., European Union, the World Health Organization and Health Canada have concluded that the benefits of using our vaccine to protect people from this deadly virus significantly outweigh the risks across all adult age groups," said AstraZeneca spokesperson Carlo Mastrangelo in the statement.

The statement went on to say that tens of millions of people around the world have now taken the AstraZeneca vaccine and "real-world evidence demonstrates its effectiveness."

"Patient safety remains the company's highest priority. We continue to work closely with Health Canada to share and submit safety data as it becomes available to ensure the appropriate use of our vaccine," Mastrangelo said.

## 'We just won't use it, simple as that': Ford

Speaking to reporters in Niagara Falls, Ont., Ontario Premier Doug Ford said today that the province would follow NACI's guidance and reserve the current supply of AstraZeneca for those

in the older cohort.

"I won't hesitate to cancel that in half a heartbeat. If it's going to put anyone in harm, we just won't use it, simple as that," he said, adding he didn't want to "roll the dice" by using AstraZeneca on a group that may have an outsized chance of developing complications.

"The guidance from the federal government is that it is safe for people over 55," Ford said. "I'm talking about younger people taking it, 35 years of age and in that range, that's where the problem is."

Dr. Joss Reimer, the medical lead on Manitoba's vaccine implementation task force, said that the province also would pause its deployment of the vaccine among people under 55 because of a "very rare subtype, one specific type of blood clot."

She said that while there have been no complications reported in Canada, "out of an abundance of caution" Manitoba will restrict the shot to people 55 to 64, for now.

"This is a pause while we wait for more information to better understand what's happened in Europe. This is an important and evidence-based change," she said.

***Watch: Vaccine committee chair addresses AstraZeneca COVID-19 vaccine hesitancy:***

Dr. Caroline Quach-Thanh, chair of the National Advisory Committee on Immunization, responds to questions about Canadians being hesitant to receive the AstraZeneca COVID-19 vaccine. 1:27

Reimer said it's "probably" fine to use the vaccine on all groups — but she's not comfortable with just "probably" and wants to wait to see more data from Europe.

This is just the latest issue the company has faced over the last three months.

Earlier this year, a number of European countries halted vaccinations in response to questions about the AstraZeneca product's efficacy in people over the age of 65, only to restart them after new evidence emerged.

After Health Canada approved the shot for all adults, NACI recommended the product be used only on people under the age of 65, citing a dearth of clinical trial data on the vaccine's effectiveness in older people.

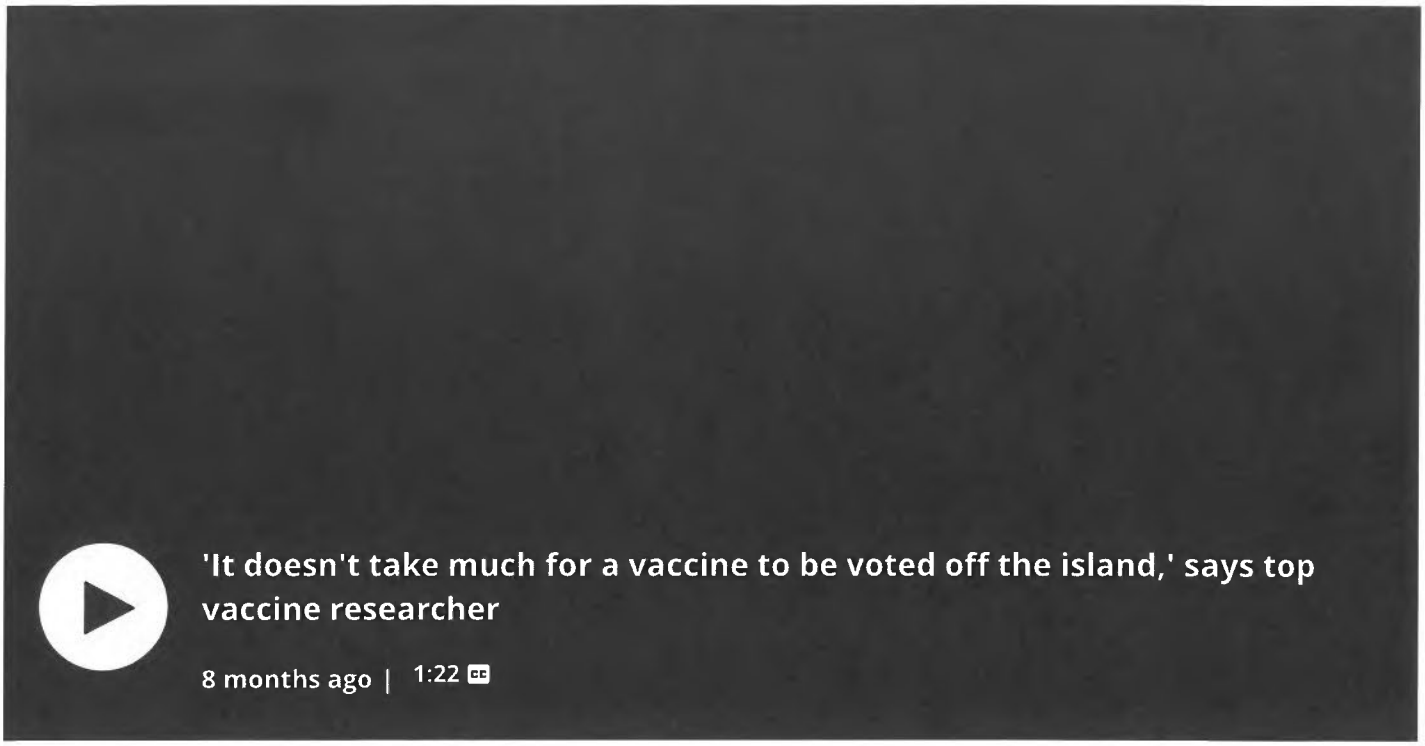

- THE LATEST **Coronavirus: What's happening in Canada and around the world on March 29**
- SECOND OPINION **Canada monitoring guidance on AstraZeneca-Oxford vaccine amid potential link to blood clots**


NACI changed course earlier this month after reviewing three "real-world studies," saying the two-dose viral vector vaccine can and should be used on seniors.

Last week, the U.S. Data and Safety Monitoring Board (DSMB), which keeps an eye on clinical trials, found "outdated information" may have been reported by the company when it released data on U.S. trials.

Dr. Anthony Fauci, U.S. President Joe Biden's chief medical adviser and the head of the NIAID, said the monitoring board was surprised by the the better-than-expected efficacy results published by AstraZeneca.

***WATCH | 'It doesn't take much for a vaccine to be voted off the island,' says top vaccine researcher***




Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine, says the vaccine ecosystem is fragile and the messaging around the AstraZeneca vaccine could cause the public to lose confidence in it even if it's safe and effective. 1:22

# Exhibit "P"

# COVID-19 vaccines - mRNA

## Immunization protects you from disease. Get protected, get immunized.

- **Vaccines make your immune system stronger. They build antibodies to help prevent diseases.**
- **Immunization is safe. It is much safer to get immunized than to get this disease.**

## What are COVID-19 vaccines?

COVID-19 vaccines protect against the SARS-CoV-2 virus (also known as COVID-19). The virus causes an infection in the lungs and airways and is a type of respiratory illness. Go to ahs.ca/covid to learn more about COVID-19.

There are 2 types of COVID-19 vaccines approved for use in Canada:

- **mRNA vaccines:** The Pfizer-BioNTech (Comirnaty) and Moderna (SpikeVax) vaccines are mRNA vaccines.
- **Viral vector-based vaccines:** The AstraZeneca (Vaxzevria)/ COVISHIELD and Janssen (Johnson & Johnson) vaccines are viral vector-based vaccines. For information about the viral vector-based vaccines, read the vaccine information sheet on ImmunizeAlberta.ca.

To learn about how COVID-19 mRNA vaccines work visit canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/type-mrna.

## Who should get an mRNA COVID-19 vaccine?

You should get an mRNA COVID-19 vaccine if you are age 5 years or older. Everyone is at risk of COVID-19. COVID-19 vaccines are free.

### What if my child is getting a COVID-19 vaccine?

Children under age 18 years need a parent or guardian to give consent for them to get a COVID-19 vaccine. If a parent or guardian cannot be at the appointment, they can give consent in writing using the consent form at ahs.ca/VaccineUnder18. In some cases, children under age 18 years may be able to give their own consent.

## How well do COVID-19 vaccines work?

If you are healthy and get all the doses you need, COVID-19 vaccines give you very good protection against COVID-19 infection.

Two doses of the mRNA vaccines give more protection than 2 doses of the AstraZeneca/COVISHIELD vaccine or 1 dose of the Janssen vaccine.

All the vaccines work very well to lower your risk of getting seriously ill and of needing to be in the hospital.

Even if you have had a COVID-19 vaccine, it is still important to follow public health measures to prevent the virus from spreading. Go to ahs.ca/covid for the most up-to-date information.

## How many doses of mRNA COVID-19 vaccine do I need?

You need at least 2 doses of an mRNA COVID-19 vaccine to be considered fully immunized. These doses are called your primary series.

Some people may need more doses. See the following information and visit alberta.ca/covid19-vaccine to learn more.

### Third doses

For some people, 2 doses may not give enough protection. You may need a third dose to complete your primary series if you are age 12 years or older and you have a health problem that weakens your immune system. For example:

- You have had or will have an organ or stem cell transplant.
- You have kidney disease and need dialysis.
- You have acquired immunodeficiency syndrome (AIDS).
- You take certain medicines that weaken your immune system.

### Booster doses

After your primary series, you can get an extra (booster) dose for more protection if you are age 18 years or older and it has been 6 months or more since your last dose. It is especially important to get a booster dose if you are at a high risk of severe disease, for example, if you have certain health conditions (ask your healthcare provider for more information) or you are age 40 years or older.

You can book an appointment for your booster dose as soon as appointments become available for your age group. Certain people can book now. Go to alberta.ca/covid19-vaccine to find out when you can get your booster dose.

### Doses for travel

If you are travelling outside of Canada and you have had only viral vector-based vaccines or different vaccines for your first 2 doses, you may be able to get additional doses. This is only if your destination requires you to have a certain COVID-19 vaccine series.

## Can I get an mRNA COVID-19 vaccine if I am pregnant or breastfeeding?

Yes, you can get an mRNA COVID-19 vaccine if you are pregnant or breastfeeding. Research shows that mRNA vaccines are the safest type of COVID-19 vaccines to get during pregnancy.

When you are pregnant, you have a higher risk of getting very sick from COVID-19. Getting a COVID-19 vaccine when you are pregnant lowers your risk of getting seriously ill from the virus.

If you are pregnant or breastfeeding and have questions about getting a COVID-19 vaccine, talk to your healthcare provider.

## Where can I get a COVID-19 vaccine?

Go to ahs.ca/covidvaccine to find out where and when you can get a COVID-19 vaccine.

## Are there side effects from mRNA COVID-19 vaccines?

There can be side effects from mRNA COVID-19 vaccines, but they tend to be mild and go away in a few days. Side effects may include:

- redness, swelling, or feeling sore where you had the needle
- feeling tired or have a headache
- a fever or chills
- body aches or sore joints
- feeling sick to your stomach (nausea), vomiting (throwing up), or loose stool (diarrhea)
- swollen lymph nodes
- a reduced sense of touch or a feeling of numbness
- feeling dizzy
- a rash or hives

You may be more likely to have these side effects if you have another vaccine at the same time as a COVID-19 vaccine.

Current information shows that there is similar risk of side effects after a first, second, or additional dose of COVID-19 vaccine. Research continues to find out more about the risk of side effects after additional doses.

It is important to stay at the clinic for 15 minutes after your vaccine. Some people may have a rare but serious allergic reaction called anaphylaxis. If anaphylaxis happens, you will get medicine to treat the symptoms.

It is rare to have a serious side effect. Call Health Link at 811 to report any serious or unusual side effects.

## What rare events have been reported after getting an mRNA COVID-19 vaccine?

There have been very rare reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) within 7 days of getting either the Pfizer-BioNTech or the Moderna vaccine.

The inflammation can cause shortness of breath, chest pain or pressure, or a very fast or abnormal heart rate. Get medical help **right away** if you have any of these symptoms.

These rare events were reported mostly after the second dose and in young adults and adolescents. They were also reported more commonly in males. Most cases were mild and got better with treatment. Research is still being done to find out more about the risk of these events after a third dose or a booster dose.

The Moderna vaccine may have a higher risk of these events than the Pfizer-BioNTech vaccine, especially for those age 12 to 29 years getting their primary series. Because the Moderna vaccine was only recently approved for use in 12 to 17 year olds, there is more to learn about these risks for this age group after getting the Moderna vaccine.

It is best for those age 12 to 29 years to get the Pfizer-BioNTech vaccine for their primary series. It has a lower risk of myocarditis and pericarditis in that age group.

In clinical trials with the Pfizer-BioNTech vaccine, there were no reports of myocarditis or pericarditis in children age 5 to 11 years. But because this vaccine was only recently approved for use in this age group, there is still more to learn about these risks.

Talk to your healthcare provider, if you have ever had myocarditis or pericarditis and you have questions about COVID-19 vaccines. It is not yet known if having a history of these health problems puts you at higher risk for these rare events after a COVID-19 vaccine.

Your risk of getting seriously ill from COVID-19 is much higher than your risk of having a rare event after these vaccines.

Go to COVID-19 vaccine – Frequently Asked Questions on ahs.ca/topics/Page17389.aspx for more information.

## How can I manage side effects?

- To help with soreness and swelling, put a cool, wet cloth over the area where you had the needle.
- There is medicine to help with a fever or pain. Check with your doctor or pharmacist if you are not sure what medicine or dose to take. Follow the directions on the package.
- Children under the age of 18 years should **not** take aspirin because it can cause serious health problems.
- Some people with health problems, such as a weak immune system, must call their doctor if they get a fever. If you have been told to do this, call your doctor even if you think the fever is from the vaccine.

## What vaccine will I get for my primary series?

Here are the recommended vaccines by age group:

- Age 5 to 11 years: You will get the Pfizer-BioNTech mRNA vaccine.
- Age 12 to 17 years: You can get either the Pfizer-BioNTech or Moderna mRNA vaccine.
- Age 18 years and older: You can get either the Pfizer-BioNTech or Moderna mRNA vaccine. If you cannot get or do not want an mRNA vaccine, you can get a viral vector-based vaccine.

If you are age 12 to 29 years, it is best to get the Pfizer-BioNTech vaccine. This vaccine has a lower risk of myocarditis and pericarditis for this age group.

Usually you get the same vaccine for all your doses.

If you got an mRNA vaccine for your first dose, you can get a different mRNA vaccine if your first-dose vaccine is not available or you prefer a different mRNA vaccine.

If you got the AstraZeneca/COVISHIELD vaccine for your first dose, you can choose the same vaccine or an mRNA vaccine for your next dose.

Whichever vaccine you get to complete your primary series protects you against COVID-19.

Go to ahs.ca/seconddose for more information.

## What vaccine will I get for my booster or additional dose?

You will get an mRNA vaccine for any booster or additional doses. If you cannot get or do not want an mRNA vaccine, you can get the AstraZeneca/COVISHIELD vaccine.

The Pfizer-BioNTech and Moderna vaccines are licensed for booster doses for people age 18 years or older who get their booster dose no sooner than 6 months after they have completed their primary series. In other cases, the vaccine is not licensed for more than 2 doses. But vaccine experts support this in certain situations. This is called "off-label use."

Getting more than 2 doses of a COVID-19 vaccine is off-label use if:

- You are age 5 to 17 years.
- You get a dose sooner than 6 months after you have completed your primary series.
- You get the AstraZeneca/COVISHIELD vaccine as a third dose, booster dose, or additional dose.

Talk to your healthcare provider about which vaccine you can get and when you should have your doses.

## What if I had or am getting another type of vaccine?

If you are age 12 years or older, you can get any vaccine at the same time as, any time before, or any time after a COVID-19 vaccine.

Children under age 12 years should wait at least 14 days after getting a COVID-19 vaccine before getting another vaccine. If they got another vaccine first, they should wait 14 days before getting a COVID-19 vaccine. This helps you watch for any side effects from the COVID-19 vaccine. However, if your child needs another vaccine on the same day or within 14 days before or after the COVID-19 vaccine, there are no safety concerns. Both vaccines will still work to protect your child. This may happen if your child is due to have a routine school immunization within 14 days of having the COVID-19 vaccine. Talk to your healthcare provider if you have questions about your child's vaccine schedule.

## Who should not get an mRNA COVID-19 vaccine?

You may not be able to get an mRNA COVID-19 vaccine if you:

- have an allergy to any part of the vaccine
- had a severe (serious) or unusual side effect after this vaccine or one like it
- are under age 5 years

Check with your doctor or a public health nurse before you get an mRNA COVID-19 vaccine.

Be sure to talk to your doctor **before** you get an mRNA COVID-19 vaccine, if you:

- have a weak immune system (because of a medicine you take or a health problem)
- have an autoimmune disorder (like rheumatoid arthritis or lupus)
- have had a stem cell or organ transplant
- have a history of myocarditis or pericarditis after receiving a dose of COVID-19 vaccine
- have been treated for a COVID-19 infection in the last 90 days
- are under age 12 years and have a history of multisystem inflammatory syndrome (MIS-C)

Always tell your healthcare provider if you have allergies or if you have had a side effect from a vaccine in the past.

## For More Information

Call Health Link at **811**

Go to MyHealth.Alberta.ca

Go to ImmunizeAlberta.ca

Go to ahs.ca/covidvaccine

# Exhibit "Q"

VigiAccess™ Uppsala Monitoring Centre | WHO Collaborating Centre for International Drug Monitoring (https://who-umc.org) FAQ

Covid-19 vaccine Search

**Covid-19 vaccine** contains the active ingredient(s): **Covid-19 vaccine**.
Result is presented for the active ingredient(s).
Total number of records retrieved: **2678485**.

This is Exhibit "Q" referred to in the Affidavit of

Sworn before me this 7th day of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

## Distribution

▼Adverse drug reactions (ADRs)

Blood and lymphatic system disorders (111053)
Cardiac disorders (146239)
Congenital, familial and genetic disorders (1587)
Ear and labyrinth disorders (88579)
Endocrine disorders (4297)
Eye disorders (98035)
Gastrointestinal disorders (531195)
General disorders and administration site conditions (1605373)
Hepatobiliary disorders (5710)
Immune system disorders (42771)
Infections and infestations (210131)
Injury, poisoning and procedural complications (143258)
Investigations (379990)
Metabolism and nutrition disorders (59461)
Musculoskeletal and connective tissue disorders (758266)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (4552)
Nervous system disorders (1126264)
Pregnancy, puerperium and perinatal conditions (6660)
Product issues (4073)
Psychiatric disorders (125497)
Renal and urinary disorders (22360)
Reproductive system and breast disorders (123789)
Respiratory, thoracic and mediastinal disorders (285827)
Skin and subcutaneous tissue disorders (360530)
Social circumstances (19488)
Surgical and medical procedures (32206)
Vascular disorders (142635)

▼Geographical distribution

| Continent | Count | Percentage |
|---|---|---|
| Africa | 75007 | 3 |
| Americas | 1010807 | 38 |
| Asia | 182555 | 7 |
| Europe | 1314084 | 49 |
| Oceania | 96032 | 4 |

## Age group distribution

| Age group | Count | Percentage |
|---|---|---|
| 0 - 27 days | 402 | 0 |
| 28 days to 23 months | 1562 | 0 |
| 2 - 11 years | 3075 | 0 |
| 12 - 17 years | 46153 | 2 |
| 18 - 44 years | 1060594 | 40 |
| 45 - 64 years | 816958 | 31 |
| 65 - 74 years | 250742 | 9 |
| ≥ 75 years | 169908 | 6 |
| Unknown | 329091 | 12 |

## Patient sex distribution

| Sex | Count | Percentage |
|---|---|---|
| Female | 1829723 | 68 |
| Male | 815481 | 30 |
| Unknown | 33281 | 1 |

## ADR reports per year

# Exhibit "R"

The NEW ENGLAND JOURNAL of MEDICINE



ORIGINAL ARTICLE

# Waning Immunity after the BNT162b2 Vaccine in Israel

Yair Goldberg, Ph.D., Micha Mandel, Ph.D., Yinon M. Bar-On, M.Sc., Omri Bodenheimer, M.Sc., Laurence Freedman, Ph.D., Eric J. Haas, M.D., Ron Milo, Ph.D., Sharon Alroy-Preis, M.D., Nachman Ash, M.D., and Amit Huppert, Ph.D.

## ABSTRACT

### BACKGROUND

In December 2020, Israel began a mass vaccination campaign against coronavirus disease 2019 (Covid-19) by administering the BNT162b2 vaccine, which led to a sharp curtailing of the outbreak. After a period with almost no cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, a resurgent Covid-19 outbreak began in mid-June 2021. Possible reasons for the resurgence were reduced vaccine effectiveness against the delta (B.1.617.2) variant and waning immunity. The extent of waning immunity of the vaccine against the delta variant in Israel is unclear.

### METHODS

We used data on confirmed infection and severe disease collected from an Israeli national database for the period of July 11 to 31, 2021, for all Israeli residents who had been fully vaccinated before June 2021. We used a Poisson regression model to compare rates of confirmed SARS-CoV-2 infection and severe Covid-19 among persons vaccinated during different time periods, with stratification according to age group and with adjustment for possible confounding factors.

### RESULTS

Among persons 60 years of age or older, the rate of infection in the July 11–31 period was higher among persons who became fully vaccinated in January 2021 (when they were first eligible) than among those fully vaccinated 2 months later, in March (rate ratio, 1.6; 95% confidence interval [CI], 1.3 to 2.0). Among persons 40 to 59 years of age, the rate ratio for infection among those fully vaccinated in February (when they were first eligible), as compared with 2 months later, in April, was 1.7 (95% CI, 1.4 to 2.1). Among persons 16 to 39 years of age, the rate ratio for infection among those fully vaccinated in March (when they were first eligible), as compared with 2 months later, in May, was 1.6 (95% CI, 1.3 to 2.0). The rate ratio for severe disease among persons fully vaccinated in the month when they were first eligible, as compared with those fully vaccinated in March, was 1.8 (95% CI, 1.1 to 2.9) among persons 60 years of age or older and 2.2 (95% CI, 0.6 to 7.7) among those 40 to 59 years of age; owing to small numbers, the rate ratio could not be calculated among persons 16 to 39 years of age.

### CONCLUSIONS

These findings indicate that immunity against the delta variant of SARS-CoV-2 waned in all age groups a few months after receipt of the second dose of vaccine.

From Technion–Israel Institute of Technology, Haifa (Y.G.), the Hebrew University of Jerusalem (M.M.), and the Israeli Ministry of Health (O.B., E.J.H., S.A.-P., N.A.), Jerusalem, the Weizmann Institute of Science, Rehovot (Y.M.B.-O., R.M.), the Gertner Institute for Epidemiology and Health Policy Research, Sheba Medical Center Tel Hashomer, Ramat Gan (L.F., A.H.), Tel Aviv University, Tel Aviv (A.H.), and Ben Gurion University, Beersheva (E.J.H.) — all in Israel. Dr. Goldberg can be contacted at yairgo@technion.ac.il or at the Faculty of Industrial Engineering and Management, Technion–Israel Institute of Technology, Haifa 3200003, Israel.

Drs. Goldberg and Mandel and Drs. Alroy-Preis, Ash, and Huppert contributed equally to this article.

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A KEY TO THE CONTAINMENT OF THE coronavirus disease 2019 (Covid-19) pandemic is mass vaccination of the population. However, the success of this policy is challenged by breakthrough infection and disease in fully vaccinated persons. One potential cause of breakthrough infection is the emergence of new variants of concern[1] that escape immunity, thus reducing the effectiveness of the vaccine. Several studies investigating the effectiveness of the BNT162b2 vaccine (Pfizer–BioNTech) against the beta (B.1.351)[2,3] and delta (B.1.617.2)[4-6] variants showed only modest rates of breakthrough infection and disease, whereas other studies showed higher rates.[7,8]

A second potential cause of breakthrough infection is waning of the immunity conferred by the vaccine. Mass vaccination with the BNT162b2 vaccine began in December 2020, and little is known about waning immunity over time. A recent study on longer-term follow-up of the participants in the phase 2–3 randomized trial of the BNT162b2 vaccine[9] showed a reduction in vaccine efficacy from 96% (in the period of 7 days to <2 months after receipt of the second dose) to 84% (in the period of 4 months to approximately 7 months after receipt of the second dose), which indicated a decrease in protection by a factor of four (i.e., [100−84]÷[100−96]). Preliminary reports of waning effectiveness of the same vaccine have come from a health maintenance organization in Israel[10] and from the United States,[11] and a decrease in vaccine-induced neutralization titers during the first 6 months after receipt of the second dose of vaccine has been reported.[12]

Israel conducted a very successful vaccination campaign using the BNT162b2 vaccine.[13-15] Starting in December 2020, more than half the adult population received two doses of vaccine within 3 months. The vaccination campaign, together with social measures, led to a sharp curtailing of the outbreak. By May 2021, infection rates had decreased to a few dozen cases daily, most of which were in unvaccinated persons or in persons returning from abroad. However, the number of polymerase-chain-reaction (PCR) tests that were positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) started to rise exponentially in June 2021, with a substantial number of infections being reported in vaccinated persons (Fig. 1). This rise in community transmission was followed by a concomitant increase in the numbers of severe cases and deaths, in both the vaccinated and unvaccinated populations. Genetic analysis showed that as of June 2021, more than 98% of the positive cases in Israel were attributed to the delta variant.[16] In this study, we estimated the role of waning immunity in the observed breakthrough against the delta variant.

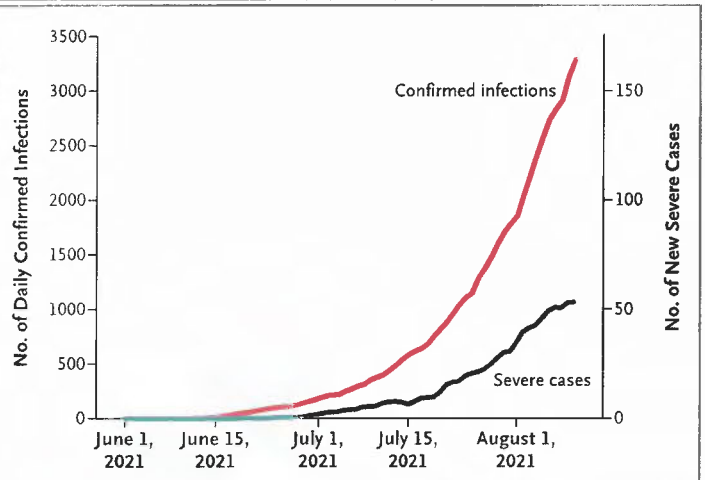


**Figure 1. Daily Confirmed SARS-CoV-2 Infections and New Cases of Severe Covid-19 among Fully Vaccinated Persons in Israel, June through Early August 2021.**

The graph shows increases in the numbers of daily severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections and new cases of severe coronavirus disease 2019 (Covid-19), on different scales, during the delta variant wave among persons who had received two doses of vaccine.

## METHODS

### DATA SOURCE

Data on all residents of Israel who had been fully vaccinated before June 1, 2021, and who had not been infected before the study period were extracted from the Israeli Ministry of Health database on September 2, 2021. We defined fully vaccinated persons as those for whom 7 days or more had passed since receipt of the second dose of the BNT162b2 vaccine. We used the Ministry of Health official database that contains all information regarding Covid-19 (see Supplementary Methods 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). We extracted from the database information on all documented SARS-CoV-2 infections (i.e., positive result on PCR assay) and on the severity of the disease after infection. We focused on infections that had been documented

in the period from July 11 through 31, 2021 (study period), removing from the data all confirmed cases that had been documented before that period. The start date was selected as a time when the virus had already spread throughout the entire country and across population sectors. The end date was just after Israel had initiated a campaign regarding the use of a booster vaccine (third dose). The study period happened to coincide with the school summer vacation.

We omitted from all the analyses children and adolescents younger than 16 years of age (most of whom were unvaccinated or had been recently vaccinated). Only persons 40 years of age or older were included in the analysis of severe disease because severe disease was rare in the younger population. Severe disease was defined as a resting respiratory rate of more than 30 breaths per minute, oxygen saturation of less than 94% while the person was breathing ambient air, or a ratio of the partial pressure of arterial oxygen to the fraction of inspired oxygen of less than 300.[14] Persons who died from Covid-19 during the follow-up period were included in the study and categorized as having had severe disease.

During the study period, approximately 10% of the detected infections were in residents of Israel returning from abroad. Most residents who traveled abroad had been vaccinated and were exposed to different populations, so their risk of infection differed from that in the rest of the study population. We therefore removed from the analysis all residents who had returned from abroad in July.

### VACCINATION SCHEDULE

The official vaccination regimen in Israel involved the administration of the second dose 3 weeks after the first dose. All residents 60 years of age or older were eligible for vaccination starting on December 20, 2020, thus becoming fully vaccinated starting in mid-January 2021. At that time, younger persons were eligible for vaccination only if they belonged to designated groups (e.g., health care workers and severely immunocompromised adults). The eligibility age was reduced to 55 years on January 12, 2021, and to 40 years on January 19, 2021. On February 4, 2021, all persons 16 years of age or older became eligible for vaccination. Thus, if they did not belong to a designated group, persons 40 to 59 years of age received the second dose starting in mid-February, and those 16 to 39 years of age received the second dose starting in the beginning of March. On the basis of these dates, we defined our periods of interest in half months starting from January 16; vaccination periods for individual persons were determined according to the time that they had become fully vaccinated (i.e., 1 week after receipt of the second dose). All the analyses were stratified according to vaccination period and to age group (16 to 39 years, 40 to 59 years, and ≥60 years).

### STATISTICAL ANALYSIS

The association between the rate of confirmed infections and the period of vaccination provides a measure of waning immunity. Without waning of immunity, one would expect to see no differences in infection rates among persons vaccinated at different times. To examine the effect of waning immunity during the period when the delta variant was predominant, we compared the rate of confirmed infections (per 1000 persons) during the study period (July 11 to 31, 2021) among persons who became fully vaccinated during various periods. The 95% confidence intervals for the rates were calculated by multiplying the standard confidence intervals for proportions by 1000. A similar analysis was performed to compare the association between the rate of severe Covid-19 and the vaccination period, but for this outcome we used periods of entire months because there were fewer cases of severe disease.

To account for possible confounders, we fitted Poisson regressions. The outcome variable was the number of documented SARS-CoV-2 infections or cases of severe Covid-19 during the study period. The period of vaccination, which was defined as 7 days after receipt of the second dose of the Covid-19 vaccine, was the primary exposure of interest. The models compared the rates per 1000 persons between different vaccination periods, in which the reference period for each age group was set according to the time at which all persons in that group first became eligible for vaccination. A differential effect of the vaccination period for each age group was allowed by the inclusion of an interaction term between age and vaccination period. Additional potential confounders were added as covariates, as described below, and the natural logarithm of the number of persons was added as an offset. For each vaccination period and age group, an

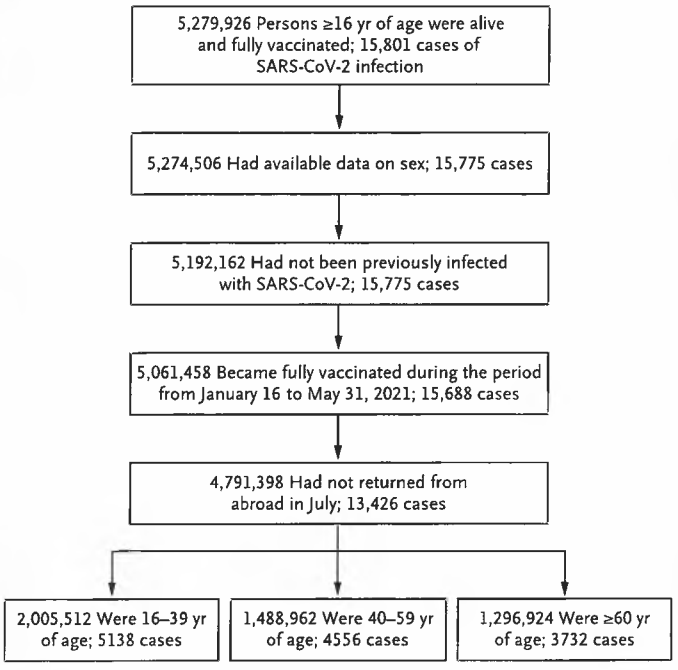


**Figure 2. Study Population.**

The population included persons who were fully vaccinated before June 1, 2021, were not abroad during July 2021, and had no documented SARS-CoV-2 infection according to polymerase-chain-reaction assay before July 11, 2021.

adjusted rate was calculated as the expected number of weekly events per 100,000 persons if all the persons in that age group had been vaccinated in that period. All the analyses were performed with the use of the glm function in the R statistical software package.[17]

In addition to age and sex, the regression analysis included as covariates the following confounders. First, because the event rates were rising rapidly during the study period (Fig. 1), we included the week in which the event was recorded. Second, although PCR testing is free in Israel for all residents, compliance with PCR-testing recommendations is variable and is a possible source of detection bias. To partially account for this, we stratified persons according to the number of PCR tests that had been performed during the period of March 1 to November 31, 2020, which was before the initiation of the vaccination campaign. We defined three levels of use: zero, one, and two or more PCR tests. Finally, the three major population groups in Israel (general Jewish, Arab, and ultra-Orthodox Jewish) have varying risk factors for infection. The proportion of vaccinated persons, as well as the level of exposure to the virus, differed among these groups.[18] Although we restricted the study to dates when the virus was found throughout the country, we included population sector as a covariate to control for any residual confounding effect.

We conducted several secondary analyses to test the robustness of the results, including calculation of the rate of confirmed infection in a finer, 10-year age grouping and an analysis restricted to the general Jewish population (in which the delta outbreak began), which comprises the majority of persons in Israel. In addition, a model including a measure of socioeconomic status as a covariate was fitted to the data, because this was an important risk factor in a previous study.[18] Since socioeconomic status was unknown for 5% of the persons in our study and the missingness of the data seemed to be informative, and also owing to concern regarding nondifferential misclassification (persons with unknown socioeconomic status may have had different rates of vaccination, infection, and severe disease), we did not include socioeconomic status in the main analysis. Finally, we compared the association between the number of PCR tests that had been conducted before the vaccination campaign (i.e., before December 2020) with the number that were conducted during the study period in order to evaluate the possible magnitude of detection bias in our analysis. A good correlation between past behavior regarding PCR testing and behavior during the study period would provide reassurance that the inclusion of past behavior as a covariate in the model would control, at least in part, for detection bias.

## RESULTS

### STUDY POPULATION

Among 5,279,926 fully vaccinated adults, we retained data on 4,791,398 persons for the main analysis (Fig. 2). Among these persons, 13,426 had a positive PCR test (confirmed SARS-CoV-2 infection) and 403 had severe Covid-19. Table 1 provides the number of events according to vaccination period, and Table S1 in the Supplementary Appendix provides a more detailed summary according to vaccination period and age group. Table 1 shows the characteristics of the study population according to vaccination period; Ta-

**Table 1. Demographic and Clinical Characteristics of the Study Population According to Vaccination Period.***

| Variable | Vaccination Period | | | | | | |
|---|---|---|---|---|---|---|---|
| | Jan. 16–31 (N=1,076,708) | Feb. 1–15 (N=972,835) | Feb. 16–28 (N=747,788) | March 1–15 (N=819,040) | March 16–31 (N=749,422) | April 1–30 (N=325,201) | May 1–31 (N=100,404) |
| No. of positive SARS-CoV-2 PCR tests | 3779 | 3182 | 2259 | 2146 | 1459 | 459 | 142 |
| No. of cases of severe Covid-19 | 251 | 108 | 16 | 17 | 5 | 5 | 1 |
| Male sex — no. (%) | 518,196 (48) | 459,251 (47) | 380,135 (51) | 410,371 (50) | 358,398 (48) | 153,619 (47) | 46,352 (46) |
| Age group — no. (%) | | | | | | | |
| 16–39 yr | 125,977 (12) | 195,961 (20) | 352,722 (47) | 549,090 (67) | 496,779 (66) | 217,731 (67) | 67,252 (67) |
| 40–59 yr | 243,741 (23) | 418,282 (43) | 328,038 (44) | 208,064 (25) | 190,326 (25) | 78,281 (24) | 22,230 (22) |
| ≥60 yr | 706,990 (66) | 358,592 (37) | 67,028 (9) | 61,886 (8) | 62,317 (8) | 29,189 (9) | 10,922 (11) |
| No. of previous SARS-CoV-2 PCR tests — no. (%)† | | | | | | | |
| 0 | 700,766 (65) | 655,201 (67) | 502,035 (67) | 564,855 (69) | 536,943 (72) | 240,548 (74) | 75,696 (75) |
| 1 | 204,238 (19) | 197,137 (20) | 163,752 (22) | 172,576 (21) | 144,087 (19) | 56,873 (17) | 16,320 (16) |
| ≥2 | 171,704 (16) | 120,497 (12) | 82,001 (11) | 81,609 (10) | 68,392 (9) | 27,780 (9) | 8,388 (8) |
| Population sector — no. (%)‡ | | | | | | | |
| General Jewish | 970,782 (90) | 826,783 (85) | 617,113 (83) | 656,786 (80) | 506,554 (68) | 201,850 (62) | 72,292 (72) |
| Arab | 62,003 (6) | 107,704 (11) | 90,289 (12) | 115,399 (14) | 198,375 (26) | 102,798 (32) | 20,740 (21) |
| Ultra-Orthodox Jewish | 43,923 (4) | 38,348 (4) | 40,386 (5) | 46,855 (6) | 44,493 (6) | 20,553 (6) | 7,372 (7) |

* The numbers of persons in the column heads represent the numbers of persons who were fully vaccinated during that period. Positivity on the polymerase-chain-reaction (PCR) assay for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; i.e., confirmed infection) and cases of severe coronavirus disease 2019 (Covid-19) were assessed in the study period of July 11 to 31, 2021. Percentages may not total 100 because of rounding.

† Shown are the numbers of PCR tests that had been performed during the period of March 1 to November 31, 2020, which was before the initiation of the vaccination campaign.

‡ Population sector was determined on the basis of the area of residency, with the use of classifications provided by the Israeli Bureau of Statistics.

bles S2 through S4 show these data for each of the three age groups.

Because of the risk-based vaccination policy in Israel, persons who were vaccinated in January were older than those who were vaccinated later. In addition, the lower risk of Covid-19–related complications among younger persons may have caused a belief that vaccination was not urgent or even necessary, which also affected the age distribution of vaccination over the months.[19] The distribution of the number of previous PCR tests changed slightly between the periods, with 65% of the persons who became fully vaccinated in the second half of January having had no previous tests, as compared with 75% of those fully vaccinated in May. The number of tests seemed to be inversely correlated with age. A considerable difference was noted in the time of vaccination among the main population sectors: Arabs and ultra-Orthodox Jewish persons received vaccines later than did persons in the general Jewish population. Age and cultural differences contribute to these disparities.[18] (These differences in risk factors were adjusted for by their inclusion as covariates in the Poisson regression analysis.)

#### DESCRIPTIVE ANALYSIS

The rate of confirmed SARS-CoV-2 infection showed a clear increase as a function of time from vaccination. Among persons 60 years of age or older who were fully vaccinated in the second half of January, the rate was 3.3 confirmed infections per 1000 persons during the study period, as compared with 2.2 confirmed infections per 1000 persons who became fully vaccinated in the second half of February and 1.7 confirmed infections per 1000 persons fully vaccinated in the second half of March (Fig. 3A). Similar results were observed in the other age groups and when the analysis was categorized according to age in decades (Figs. 3A and S1). However, primarily health care workers and severely immunocompromised adults became fully vaccinated during the first three vaccination periods (January 16 to February 28) in the 16–39-year-old group and during the first two vaccination periods (January 16 to February 15) in the 40–59-year-old group; thus, the results for those vaccination periods in these age groups may be biased owing to selective samples and should be interpreted with caution.

A similar pattern was observed in the analysis of severe Covid-19 in the group of persons 60 years of age or older (Fig. 3B). In this analysis, vaccination periods were defined as January, February, March, and the combined April–May period because of the small numbers of severe cases in each age group. The rate of severe Covid-19 among persons 60 years of age or older who were fully vaccinated in January was 0.34 cases per 1000 persons over the study period and decreased to 0.26 cases per 1000 persons among those who were fully vaccinated in February, 0.15 cases per 1000 persons fully vaccinated in March, and 0.12 cases per 1000 persons fully vaccinated in the April–May period. The numbers of severe cases in the younger age groups were too small for conclusions to be drawn.

#### REGRESSION ANALYSIS

Tables 2 and 3 present the results of the regression analyses regarding confirmed SARS-CoV-2 infection and severe Covid-19, respectively; the complete set of estimated coefficients is provided in Tables S5 and S6. For each age group, the numbers in the tables show the ratios between the estimated rates in the first period when the persons in that group were eligible to become fully vaccinated (i.e., the second half of January for persons ≥60 years of age, the second half of February for those 40 to 59 years of age, and the first half of March for those 16 to 39 years of age) and the estimated rates in the other periods. The tables also include the adjusted rates for each vaccination period. In the group of persons 60 years of age or older, the rate of confirmed infection among those vaccinated in the second half of January was 1.1 times as high as the rate among those vaccinated in the first half of February. The rate ratio increased to 1.6 and 2.2 when comparing January vaccinees with those who were vaccinated in March and in April, respectively. The same phenomenon, of an increasing rate of confirmed infection with increased time since vaccination, was observed in all age groups.

Fewer cases of severe Covid-19 were noted in persons younger than 60 years of age, especially in the group of persons 16 to 39 years of age (Table S1), so the model could be fitted only to the groups of persons 40 to 59 years of age and those 60 years of age or older and only for the vaccination months of January through March.

The confidence intervals were wide; however, the results suggest a monotonic increase in the rate of severe disease as time since vaccination increased.

The analysis was repeated with socioeconomic status as an additional covariate, with the use of four categories (0 to 3 [indicating low socioeconomic level], 4 to 6 [indicating medium socioeconomic level], 7 to 10 [indicating high socioeconomic level], and unknown) and yielded similar results with only slightly smaller rate ratios (Table S8). Similar results were obtained when the analysis was restricted to the general Jewish population (Table S9).

## DISCUSSION

The centralized health care system in Israel succeeded in vaccinating most of the Israeli population relatively early and in a short time.[13-15] This population is, therefore, useful for studying the effects of the BNT162b2 vaccine on the spread of SARS-CoV-2 infection and severity of Covid-19, as well as for studying the waning of vaccine protection over time. The appearance and rapid predominance of the delta variant in June 2021 resulted in a dramatic increase in the number of new SARS-CoV-2 infections among fully vaccinated persons, which aroused concern regarding

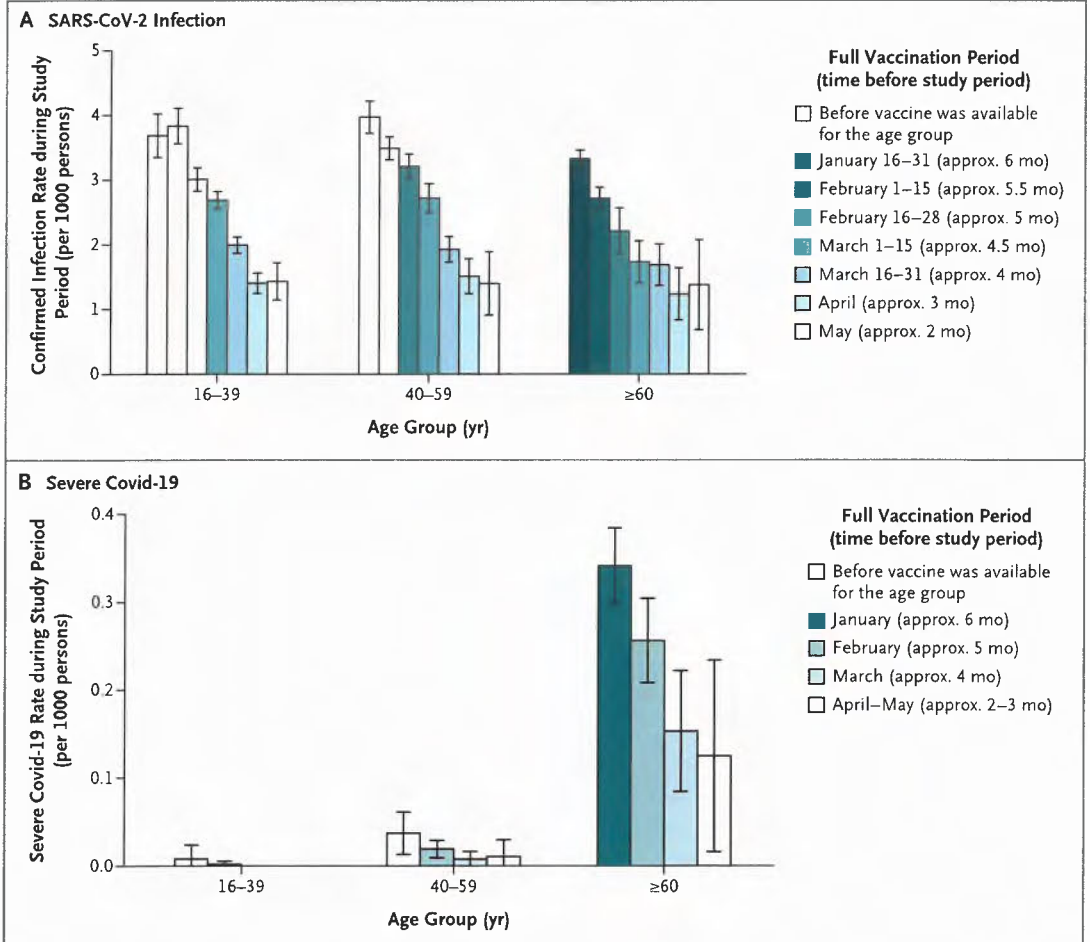


**Figure 3. Rates of Documented SARS-CoV-2 Infection and Severe Covid-19, July 11 to 31, 2021.**

Shown are the rates of documented infection per 1000 persons (Panel A) and rates of severe Covid-19 per 1000 persons (Panel B), according to period of second dose of Covid-19 vaccine and age group. In the analyses in the age groups younger than 60 years, white bars represent periods during which vaccination was restricted to only designated groups (e.g., health care workers and severely immunocompromised adults). I bars represent 95% confidence intervals, which are not adjusted for multiplicity. In Panel A, white bars represent half a month; in Panel B, white bars represent a month.

**Table 2. Rate Ratios of Confirmed SARS-CoV-2 Infection According to Age Group and Vaccination Period.***

| Age Group | Vaccination Period | | | | | | |
|---|---|---|---|---|---|---|---|
| | Jan. 16–31 | Feb. 1–15 | Feb. 16–28 | March 1–15 | March 16–31 | April 1–30 | May 1–31 |
| 16–39 Yr | | | | | | | |
| Rate ratio of reference vs. period (95% CI) | 0.8 (0.7–0.9) | 0.7 (0.7–0.8) | 0.9 (0.8–1.0) | Reference | 1.2 (1.1–1.3) | 1.5 (1.4–1.8) | 1.6 (1.3–2.0) |
| Adjusted rate — no. of events/wk/100,000 persons | 108.7 | 117.9 | 93.4 | 85.7 | 72.7 | 55.4 | 52.1 |
| 40–59 Yr | | | | | | | |
| Rate ratio of reference vs. period (95% CI) | 0.9 (0.8–1.0) | 1.0 (0.9–1.0) | Reference | 1.1 (1.0–1.2) | 1.4 (1.3–1.6) | 1.7 (1.4–2.1) | 2.1 (1.4–3.0) |
| Adjusted rate — no. of events/wk/100,000 persons | 117.2 | 110.7 | 106.0 | 95.9 | 75.0 | 61.3 | 51.2 |
| ≥60 Yr | | | | | | | |
| Rate ratio of reference vs. period (95% CI) | Reference | 1.1 (1.1–1.2) | 1.3 (1.1–1.5) | 1.6 (1.4–2.0) | 1.6 (1.3–2.0) | 2.2 (1.6–3.1) | 2.2 (1.3–3.6) |
| Adjusted rate — no. of events/wk/100,000 persons | 105.7 | 92.4 | 82.3 | 64.3 | 65.2 | 47.9 | 49.1 |

* Analyses were adjusted for week of infection, number of previous PCR tests (0, 1, or ≥2), population sector, and sex. Shown are rate ratios for confirmed SARS-CoV-2 infection during the period of July 11 through 31, 2021 (study period), as a function of time since full vaccination. We defined fully vaccinated persons as those for whom 7 days or more had passed since receipt of the second dose of the BNT162b2 vaccine. The comparison was between the estimated rate among persons who became fully vaccinated during the first vaccination period in which their age group was eligible (reference; i.e., January 16 to 31 for persons ≥60 years of age, February 16 to 28 for persons 40 to 59 years of age, and March 1 to 15 for persons 16 to 39 years of age) and the estimated rate among persons who became fully vaccinated in another vaccination period. For example, among persons 60 years of age or older, the rate of confirmed SARS-CoV-2 infection during the July 11–31 period among those vaccinated in January (105.7 events per week per 100,000 persons) was divided by the rate among those vaccinated in the second half of March (65.2 events per week per 100,000), yielding a rate ratio of 1.6. The 95% confidence intervals are not adjusted for multiplicity.

**Table 3. Rate Ratios of Severe Covid-19 According to Age Group and Vaccination Period.***

| Age Group | Vaccination Period | | |
|---|---|---|---|
| | January | February | March |
| 40–59 Yr | | | |
| Rate ratio of reference vs. period (95% CI) | 0.6 (0.3–1.4) | Reference | 2.2 (0.6–7.7) |
| Adjusted rate — no. of events/wk/100,000 persons | 1.0 | 0.6 | 0.3 |
| ≥60 Yr | | | |
| Rate ratio of reference vs. period (95% CI) | Reference | 1.2 (1.0–1.5) | 1.8 (1.1–2.9) |
| Adjusted rate — no. of events/wk/100,000 persons | 10.7 | 9.0 | 5.9 |

* For severe Covid-19, estimates are provided for the whole months of January, February, and March. Estimates are not provided for the youngest age group (16 to 39 years of age) and for the latest vaccination periods (April and May) because of very low case numbers. Analyses were adjusted for week of infection, number of previous PCR tests (0, 1, or ≥2), population sector, and sex. Shown are rate ratios during the period of July 11 through 31, 2021, as a function of time since full vaccination. The numbers in each age group are the ratios between the estimated rates in the first period when persons in that group were eligible to receive vaccination and the estimated rates in the other periods. The 95% confidence intervals are not adjusted for multiplicity.

decreased efficacy of the vaccine over time (Fig. 1).

A comparison of the rate of confirmed infection among persons vaccinated at different times revealed a clear increase in the rate as the time from vaccination increased in all age groups, with and without correction for measured confounding factors (Fig. 3A and Table 2). The rate of confirmed infection among persons 60 years of age or older who became fully vaccinated in the second half of January was 1.6 times as high as that among persons in the same age group who became fully vaccinated in March. The data show a similar increase in rate with increasing time since vaccination in the other age groups. The rate of severe Covid-19 cases also increased as a function of time from vaccination. Serologic studies in Israel have shown a correlated time-dependent reduction in neutralization titers,[12,20] which might be the biologic mechanism governing the observed waning immunity, and thus support the finding in this population-based research.

In contrast to early findings from the United Kingdom,[5] approximately two thirds of the cases of severe Covid-19 in Israel during the study period occurred in persons who had received two doses of the BNT162b2 vaccine. Two major differences exist between the studies. First, the current analysis used data from July 2021, a time when, for most of the Israeli population, at least 5 months had passed since receipt of their second dose of vaccine. The U.K. data were collected during the period of April through June 2021, with a much shorter time from vaccination to infection. Second, Israel has followed the original Pfizer–BioNTech protocol of administering the second dose 3 weeks (21 days) after the initial injection in most recipients, whereas the time between doses in the United Kingdom has typically been longer.[6]

A comparison of vaccinated persons with unvaccinated persons is of interest in order to predict the future burden on the health system. We therefore obtained data on the entire Israeli population from the Israeli Central Bureau of Statistics and calculated the number of unvaccinated persons indirectly. Moreover, unvaccinated persons might differ from the vaccinated population in important characteristics that could result in biased estimates. Nevertheless, we estimated the effectiveness of the vaccine against confirmed SARS-CoV-2 infection (see Supplementary Analysis 1). Vaccinated persons were found to be protected even after 6 months, as compared with unvaccinated persons. However, vaccine effectiveness was considerably lower than it had been closer to the vaccination date. Our findings are in line with findings from the randomized trial of the BNT162b2 vaccine, which showed a reduction in vaccine efficacy against symptomatic infection from 96% in the first 2 months after vaccination to 84% at 4 to 7 months after vaccination, when averaged over all age groups combined.[9]

Observational studies are subject to confound-

ing bias and detection bias. We examined these biases by using different sensitivity analyses (see Supplementary Analysis 2) and obtained similar results. Nevertheless, some sources of bias might remain; for instance, any effects that were due to differences in coexisting conditions between the vaccination periods could not be controlled for, because coexisting conditions are not recorded in the national database.

We did not separate the contribution of vaccine breakthrough due to waning immunity from the contribution due to the change in the dominant variant from alpha (B.1.1.7) to delta. Our analysis showed only the clear effect of waning vaccine-induced immunity against the delta variant. In addition, we were not able to quantify the extent of waning in the months immediately after vaccination (when the prevalence was extremely low in Israel).

Understanding the extent of waning immunity is critical for policy making, especially regarding vaccination strategies. The results presented here provided an epidemiologic basis for the decision by the Israeli Ministry of Health on July 30, 2021, to approve the administration of a booster (third dose) of Covid-19 vaccine to persons who had been vaccinated at least 5 months previously. The findings also suggest the need to follow the effects of waning immunity closely and to inform policymakers worldwide who are facing decisions regarding the administration of booster vaccinations.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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# Exhibit "S"

# Acute Care Outbreaks in Alberta

## novel coronavirus (COVID-19)

**Last Updated: November 25, 2021**

There are currently COVID-19 outbreaks at these AHS and Covenant Health acute care facilities.

North Zone

- Queen Elizabeth II Hospital (Grande Prairie)
- Slave Lake Healthcare Centre

Edmonton Zone

- Royal Alexandra Hospital
- University of Alberta Hospital

Central Zone

- Daysland Health Centre
- Olds Hospital and Care Centre
- Ponoka Hospital and Care Centre
- Red Deer Regional Hospital Centre
- Vermillion Health Centre

Calgary Zone

- Alberta Children's Hospital

This is Exhibit " S " referred to in the Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

# North Zone

## Queen Elizabeth II Hospital

- An outbreak was declared on a unit at the Queen Elizabeth II Hospital on Nov. 2, 2021. To date, eight individuals associated to this outbreak have tested positive for COVID-19.

## Slave Lake Healthcare Centre

- An outbreak was declared on the acute care unit at Slave Lake Healthcare Centre on Nov. 9, 2021. To date, two individuals associated to this outbreak have tested positive for COVID-19.

# Acute Care Outbreaks in Alberta

novel coronavirus (COVID-19)

## Edmonton Zone

### Royal Alexandra Hospital (RAH)

An outbreak was declared on one unit on November 5, 2021.

- Four patients have tested positive for COVID-19.

### University of Alberta Hospital (UAH)

An outbreak was declared on one unit on November 15, 2021.

- Two patients have tested positive for COVID-19.

## Central Zone

### Daysland Health Centre

- An outbreak was declared in acute care on November 11. To date, two individuals have tested positive.

### Olds Hospital and Care Centre

- An outbreak was declared in acute care on November 24. To date, two individuals have tested positive.

### Ponoka Hospital and Care Centre

- An outbreak was declared in acute care at the Ponoka Hospital and Care Centre on October 8, 2021. To date, 11 individuals have tested positive for COVID-19.

### Red Deer Regional Hospital Centre

There are two units currently on outbreak at Red Deer Regional Hospital Centre.

- An outbreak was declared November 17, 2021 on once acute care inpatient unit. To date, eight individuals have tested positive for COVID-19.
- An outbreak was declared November 7, 2021 on one acute care inpatient unit. To date, 11 individuals have tested positive for COVID-19.

# Acute Care Outbreaks in Alberta

novel coronavirus (COVID-19)

## Two Hills Health Centre

This outbreak was declared over November 25, 2021.

## Vermillion Health Centre

- An outbreak was declared November 7, 2021 on one acute care inpatient unit. To date, three individuals have tested positive for COVID-19.

# Calgary Zone

## Alberta Children's Hospital (ACH)

An outbreak was declared on one unit on November 12, 2021.

- Three healthcare workers have tested positive for COVID-19.

## Outbreak Protocols

Outbreak control measures have been implemented on each of the affected units. Any patient with symptoms, or who has tested positive for COVID-19, is isolated and treated in designated rooms.

All at-risk patients on each unit have been tested. Contact tracing for patients and healthcare workers potentially exposed to these individuals is ongoing.

All AHS facilities follow rigorous Infection Prevention and Control standards and practices. All healthcare workers are asked to self-assess for COVID-19 symptoms and exposure risk using a screening tool before reporting to a site for their shift, and our frontline teams are practicing continuous masking and diligent hand hygiene practices while at work.

Designated family/support persons and visitors entering AHS facilities are instructed to follow all appropriate measures. Visitation restrictions are in place to minimize risk of transmission to and from outside of the hospital.

If you are feeling unwell, please do not visit friends and loved ones in hospital at this time.

# Acute Care Outbreaks in Alberta

## novel coronavirus (COVID-19)

For visitation information and restrictions at our AHS healthcare facilities please see the Family Support & Visitation page.

**Note:** As of Apr. 22, all healthcare worker COVID-19 cases still under investigation, or where the source of infection is inconclusive or indeterminate, will be counted as part of an acute care outbreak case count.

Thus, as cases are under investigation, numbers may fluctuate as cases are resolved.

# Exhibit "T"

This is Exhibit " T " referred to in the
Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alb

Eva Chipiuk
Barrister & Solicitor



- **67.4%** of COVID-19 deaths (1,167/1,732) since Jan 1, 2021 were unvaccinated or diagnosed within two weeks from the first dose immunization date

Table 3. COVID-19 case outcomes in Alberta by vaccine status. Counts are provided for new, active cases, and those currently identified as being hospitalized.

| Outcome | Vaccine status | Count (n) | Percent (%) |
|---|---|---|---|
| New cases | Complete | 86 | 45.99 |
| New cases | Partial | 7 | 3.74 |
| New cases | Unvaccinated | 94 | 50.27 |
| Active cases | Complete | 1,825 | 41.72 |
| Active cases | Partial | 141 | 3.22 |
| Active cases | Unvaccinated | 2,408 | 55.05 |
| Currently hospitalized | Complete | 122 | 33.33 |
| Currently hospitalized | Partial | 15 | 4.10 |
| Currently hospitalized | Unvaccinated | 229 | 62.57 |

*Note:*
Vaccine status category is based on protection. Doses administered within 14 days prior to a person's COVID-19 diagnosis are not considered protective; as a result, partial or complete vaccination categories only include those identified as cases over 14 days past their first or second immunization date.

# Exhibit "U"

This is Exhibit " U " referred to in the Affidavit of

Dr. Blaine Achen

Sworn before me this 7th day of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

April 24, 2021

Dr. Byram W. Bridle, PhD

# Table of Contents



| **List of Abbreviations** | |
|---|---|
| COVID-19 | coronavirus disease that emerged in 2019 |
| Ct | cycle threshold |
| IFR | infection fatality rate |
| PCR | polymerase chain reaction |
| SARS-CoV-2 | severe acute respiratory syndrome-coronavirus-2 |
| VOCs | variants of concern |

## 1. The Problem

Severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) can cause atypical pneumonia, known as 'coronavirus disease that was identified in 2019' (COVID-19) in a subset of individuals. For most people, COVID-19 causes, at most, mild or moderate illness. For some, SARS-CoV-2 is not even a pathogen since

it does not cause disease in them. However, for two well-defined demographics, COVID-19 can be potentially severe and even lethal. This includes individuals who are immunocompromised and the elderly, especially if co-morbidities exist. Shortly after the COVID-19 pandemic was declared in Canada, caution was exercised through the declaration of emergency orders and implementation of a what was supposed to be a short-term lockdown to allow time to: (a) assess the severity of the situation, and (b) slow the first wave of cases of COVID-19 so hospitals would not get overwhelmed. This was to be a temporary measure to 'flatten the curve', which referred to a stabilization in the daily reported cases of COVID-19 when plotted on a graph. Then, we would learn to live with the virus, like we have with the man other respiratory pathogens to which we were exposed. However, more than one year later, we have experienced cyclic emergency lockdown orders on a background of constant isolation, physical distancing, and masking measures. The overall response to the declared pandemic has not altered despite overwhelming scientific data that show the risk of severe and lethal disease is almost entirely limited to two well-defined demographics. Rather than taking a balanced approach, in which economic, physical and human resources could be focused on protecting the most vulnerable, governments have opted for a very long-term 'one-size-fits-all' approach that has had dramatic consequences for the minority of high-risk individuals as well as low-risk people, who are in the majority. What follows is a discussion some of the data that highlight where COVID-19 policies have been flawed and/or have caused harm, which, in some cases, has been irreparable.

## 2. Dr. Byram W. Bridle's Credentials and Role in the COVID-19 'Pandemic'

Dr. Bridle is an Associate Professor of Viral Immunology in the Department of Pathobiology at the University of Guelph. His academic appointment as an independent researcher and faculty member began in January 2012. He received a MSc and PhD in immunology and completed a post-doctoral fellowship in viral immunology. His research program focuses on the development of vaccines to prevent infectious diseases and treat cancers, as well as studying host immune responses to viruses. He teaches in several courses at the undergraduate and graduate level on the topics of immunology, virology, and cancer biology. He is also involved in training Canada's next generation of multidisciplinary researchers. With respect to COVID-19, Dr. Bridle received funding from the Ontario government (COVID-19 Rapid Research Fund, Ministry of Colleges and Universities) and federal government (Pandemic Response Challenge Program, National Research Council of Canada) to develop vaccines against COVID-19. He also holds numerous grants in support of his cancer research and basic viral immunology research programs. Since the beginning of the COVID-9 pandemic he has been actively involved in disseminating fact-based, balanced scientific information to the public and policy makers to assist people with making fully informed decisions. Additional qualifications can be found in his curriculum vitae.

## 3. SARS-CoV-2 is Not a Problem of Pandemic Proportions

Infection fatality rate (IFR) is a way to assess how dangerous a pathogen is. It is calculated based on the number of people that die from among the total number that were infected. Early in the declared COVID-19 pandemic, it was estimated that the IFR for SARS-CoV-2 was ~10-fold higher than for a serious outbreak of an influenza virus, or ~1%. Indeed the IFR for a bad 'flu' season can be as high as ~0.1%[1].

It is important to note that calculating an accurate IFR requires having accurate data for the denominator in the equation, which is the total number of people that have been infected. Exacerbated be a lack of testing for evidence of seroconversion (*i.e.* when pathogen-specific antibodies are present in an individual, which indicates they were infected) against SARS-CoV-2, it has been impossible to ascertain how many Canadians have been infected. However, as data have accumulated globally, the total number of infections that have occurred keeps getting re-adjusted to higher numbers. As a result, the IFR for SARS-CoV-2 has been steadily declining. Remarkably, as the data regarding total infections has become more accurate, the IFR for SARS-CoV-2 has dropped to only ~0.15%[2]. It is also possible that this IFR will drop even further as the extent of unnoticed infections is further elucidated. Indeed, a recent study found that proportion of people in British Columbia that had been exposed to SARS-CoV-2 is likely substantially higher than previously appreciated[3].

Conclusion: The IFR for SARS-CoV-2 was vastly overestimated at the beginning of the declared pandemic. It is now approaching the range of a serious influenza outbreak, but with severity of disease limited to a more restricted demographic (*i.e.* unlike influenza viruses, SARS-CoV-2 is not particularly dangerous to the very young).

### 4. Asymptomatic Transmission of SARS-CoV-2 is Negligible

The definition of an asymptomatic individual is a person who is known to be infected with a microorganism but fails to develop disease. Indeed, we are all 'asymptomatic carriers' in the sense that we harbor vast numbers of bacteria and viruses in our bodies. However, these normal microbiomes usually do not cause us any disease, unless we become immunosuppressed or 'safe' microbes get transferred to anatomical locations where they can potentiate disease (*e.g.* fecal to oral transfer of some strains of Escherichia coli). So, in the context of SARS-CoV-2, an asymptomatic carrier would be defined as an individual that is infected with the virus but fails to develop COVID-19.

Viral culture studies suggest that pre-symptomatic individuals can potentially shed infectious SARS-CoV-2 one to two days before the onset of symptoms and continue to be infectious up to seven days thereafter[4]. However, a study of the prevalence of SARS-CoV-2 in ~10 million people in Wuhan, China found no evidence of asymptomatic transmission[5]. In the United Kingdom, the 'Scientific Advisory Group for Emergencies' recommended that "Prioritising rapid testing of symptomatic people is likely to have a greater impact on identifying positive cases and reducing transmission than frequent testing of asymptomatic people in an outbreak area"[6]. Consequently, they have asked their government to change their testing policy by moving away from asymptomatic testing.

The World Health Organization notes that "Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information"[7].

On its own, a positive result on a polymerase chain reaction (PCR) test to detect SARS-CoV-2 is insufficient to diagnose COVID-19. In addition to the potential for false positive tests, true positive results can also be obtained from genomes of SARS-CoV-2 particles that are no longer infectious. An example of the latter would be an individual who has mounted a successful immune response and may have remnant

viral particles of partially degraded viral genetic material inside relatively long-lived phagocytic cells that have killed the virus. Indeed, following clearance of SARS-CoV-2 from the body, full and/or partial genomes of SARS-CoV-2 can remain for many days, even weeks. One key reason for this is that some phagocytic cells, which are a component of the innate immune system, can be long-lived. The three primary phagocytic cells in the body are neutrophils, macrophages, and dendritic cells. Neutrophils are the 'first responders' of the immune system. They rapidly infiltrate sites of SARS-CoV-2 infection and begin to phagocytose (*i.e.* consume or internalize) SARS-Cov-2 particles. The neutrophils, which are short-lived, then recruit macrophages and dendritic cells to the site of infection. Note that dendritic cells also reside at strategic sites of infection where they can immediately begin to phagocytose SARS-CoV-2. The macrophages and dendritic cells are much larger than neutrophils and can phagocytose relatively large quantities of the virus and can be relatively long-lived. One of the reasons for this is because these two cell types are critical for activating T cells and B cells, which are the key effectors against viral infections. Phagocytosis of SARS-CoV-2 is a mechanism to kill and remove the virus from the body and to activate other immunological effector cells. As such, these can be a source of SARS-CoV-2 genomes that could be amplified by a RT-PCR test. However, these genomes would not have the potential to cause COVID-19. Persistence of whole or partial genomes that are not associated with infectious particles is well-documented for a variety of other viruses, including measles[8], Middle East respiratory syndrome-coronavirus[9], and other coronaviruses[10].

Too often, a positive PCR test for the presence of SARS-CoV-2 is being used, on its own, to define positive cases of COVID-19. However, the presence of a portion of the viral genome in an individual, on its own, does not necessarily equate with disease (*i.e.* COVID-19). To be declared COVID-19, the infection would also have to be associated with expected signs and/or symptoms. The latter is known as a clinical diagnosis and would be based on evaluation by a physician, in conjunction with the test results. A gold-standard test for infectivity of a virus is a cell-based functional assay that determines the potential to cause cell death. However, such an assay is not in routine use in Canada. The absence of a test of the infection-potential of a virus further confounds any meaningful interpretation of positive results in asymptomatic people. Drawing conclusions based solely on the results of laboratory tests, would take the diagnosis of diseases would be taken out of the hands of physicians and placed into the hands of technicians employed by testing laboratories.

Positive PCR tests for SARS-CoV-2 in asymptomatic people are often based on high cycle threshold (Ct) values, which, in and of themselves, raise the question of whether these individuals harbor infectious viral particles. The low prevalence of positive PCR tests in asymptomatic people often does not differ much from the false positive rate. These issues combined with the absence of a functional cell-based assay to prove infectivity renders results of asymptomatic testing nearly impossible to interpret accurately. Indeed, the World Health Organization, agreeing with many health professionals around the world, has emphasized that spreading of SARS-CoV-2 by asymptomatic individuals is rare and an emphasis should be placed, therefore, on testing people with signs or symptoms of illness, not those who are apparently healthy[11]. Of particular concern in the context of the high cycle numbers being used by labs in Alberta (*i.e.* up to 35 cycles being defined as 'positive' by Alberta Health Services[12]), is the fact that several studies have been conducted to determine the highest Ct value at which SARS-CoV-2 could be successfully cultured in cells. The results were 25[13], 22-27[14], 30[15]. This suggests that tests with Ct values above 22-30 are almost certainly not indicative of the presence of replication-competent SARS-CoV-2. The conclusion is that it is erroneous to declare samples with high Ct values, especially those above 30, as being positive

for infectious SARS-CoV-2. It was even concluded in a study by La Scola B, *et al.*, that patients testing 'positive' with Ct values above 33 could likely be discharged from hospitals[16]. This means that an unknown number of positive cases reported in Alberta were likely not true positives, especially if individuals were asymptomatic. This is further supported by evidence that asymptomatic people have detectable SARS-CoV-2-specific memory T cells after exposure to the virus, which would be inconsistent with a risk of them spreading the virus to others[17].

Importantly, false positive test results, which have a greater risk of happening among asymptomatic people, have been shown to have numerous negative consequences in terms of physical and mental health, and causes financial losses[18].

Conclusion: Testing of asymptomatic people for the presence of portions of the SARS-CoV-2 genome does not make medical nor economic sense. Positive test results cannot be interpreted in a clinically meaningful way. Also, there is no substantial evidence to suggest that people who are asymptomatic represent a substantial risk of causing COVID-19-related hospitalizations or deaths in others.

### 5. Individuals Who Had COVID-19 Cannot Re-Transmit the Virus

When people get infected with a respiratory pathogen, their immune system detects the virus as something that is dangerous and worth responding to. Rapid innate immune responses provide early effector mechanisms to being clearing the virus from the body. The innate arm of the immune system will also induce an adaptive immune response. The primary effectors against viruses in the adaptive arm of the immune system are cytotoxic T cells that can kill virally infected cells to prevent them from serving as a 'virus-production factory', and B cells, which can produce antibodies to neutralize the virus and prevent it from entering cells. The most notable characteristic of the adaptive immune response is that it results in the generation of immunological memory. This allows a host to respond much more rapidly and to a much greater magnitude when re-exposed to the same pathogen. The result is that the virus gets cleared so rapidly that there is usually no disease.

Note that some non-immunologists have erroneously concluded that memory conferred by natural infection with SARS-CoV-2 is not long-lasting. However, this has been based on assessments that show declining concentrations of virus-specific antibodies. The antibodies are produced by B cells. The antibodies are merely proteins in circulation with limited half-lives. They will be cleared from circulation over time. The relevant measure of memory is detection of memory B and T cells. A memory B cells can rapidly initiate the production of massive quantities of antibodies upon re-exposure to the pathogen.

Several published studies have shown that the immune response against SARS-CoV-2 infections is robust, effective, broadly targets multiple components of the virus and confers memory that lasts at least as long this aspect has been able to be studied within the context of a novel pandemic[19, 20, 21, 22, 23, 24].

Conclusion: The scientific evidence demonstrates that immune responses following infection with SARS-CoV-2 are protective and long-lasting. There is no evidence that people who previously tested positive for SARS-CoV-2 represent a substantial risk of causing COVID-19-related hospitalizations or deaths in others.

## 6. SARS-CoV-2 Variants of Concern

Many viruses mutate over time. This includes coronaviruses. Indeed, these viruses have an error-prone mechanism of copying their genome. This provides a strategy to adapt to novel environmental pressures. Of concern for SARS-CoV-2 is the potential for randomly generated mutants to sufficiently alter the structure of their spike protein to be able to evade the narrowly conferred spike protein-specific immunity conferred by all of the first-generation COVID-19 vaccines while maintaining the ability to infect cells. Since the beginning of the pandemic, large numbers of mutant viruses have been identified. However, three core lineages of the variants are of current concern[25]: 1. B.1.1.7, also known as the UK variant[26], 2. B.1.351, also known as the South African variant[26], 3. P.1, the Brazilian variant[27]. SARS-CoV-2 from the B1.351 lineage can largely bypass the immunity conferred by AstraZeneca's COVID-19 vaccine. However, the Pfizer and Moderna vaccines remain effective against all three lineages for the VOCs.

Some of the VOCs seem to be associated with more efficient spreading between people. This is likely due, at least in part, to the increased affinity of their spike protein for the ACE2 molecule that SARS-CoV-2 uses to enter cells. However, there is no evidence that the current VOCs are associated with a higher incidence of severe or fatal COVID-19.

Importantly, naturally acquired immunity against SARS-CoV-2 has been shown to be both long-lasting and protective. Notably, this type of immunity would be expected to be particularly protective against emerging VOCs because it is very broad, meaning that it targets multiple components of SARS-CoV-2, with both T cells and antibodies induced as effector mechanisms. Indeed, evidence of the breadth of naturally acquired immunity has recently been published[3]. In contrast, current vaccine-induced immunity targets a single protein, with a strong bias towards antibody-mediated responses. Notably, the B.1.1.7, B.1.351, and P.1 variants of SARS-CoV-2 are of concern because of their altered spike proteins, particularly in the 'receptor binding domain' (*i.e.* the portion that binds to the ACE2 molecule on host cells), which is the primary target of neutralizing antibodies. So, although there is evidence of some monoclonal antibodies failing to recognize the spike protein in some VOCs and some convalescent sera (*i.e.* sources of antibodies) being less able to neutralize the VOCs, T cells can effectively recognize conserved regions of the spike protein as well as other viral proteins.

Since SARS-CoV-2 has shown such a propensity to mutate, it is reasonable to expect this virus will become endemic. Indeed, should a variant emerge that can completely bypass the spike-specific immunity conferred by the current vaccines, additional immunizations will be required with re-designed vaccines, especially for those without naturally acquired broad-based immunity.

Conclusion: The goal in Canada should not be to get everyone vaccinated per se. Instead, the goal should be to get as many Canadians immune to SARS-CoV-2 as possible. There are two ways to achieve this: 1. Vaccination, 2. Natural acquisition of immunity. The great news is that Canada might be closer to the natural acquisition of herd immunity than what was previously appreciated[3], likely due, in large part, to the ongoing spread of the virus after the implementation of ineffective masking and misguided physical distancing policies that failed to account for the physics behind aerosol-mediated transmission of SARS-CoV-2. Like many other viruses, including other coronaviruses and influenza viruses, SARS-CoV-2 will likely become endemic, meaning that we may encounter new versions of the virus on a regular and long-term basis. As such, it is imperative that we learn to live with SARS-CoV-2 rather than attempting to hide from it; just like we have done with the other respiratory pathogens that we have accepted as a trade-off for living our lives outside the confines of lockdowns.

## 7. Masking Lacks Rationale in the Context of SARS-CoV-2 Spreading via Aerosols

It is now widely recognized that SARS-CoV-2 is effectively spread via aerosols coming from the respiratory system[28, 29, 30, 31, 32]. A pulmonary (*i.e.* lung-derived) aerosol is a suspension of fine water droplets suspended in exhaled air. Many people who wear glasses will be familiar with these aerosols. Indeed, when a person exhales onto the lenses of their glasses to polish them with a cloth, the liquid being deposited is due to the condensation of the lung-derived aerosol. Also, these aerosols can be readily visualized when exhaling into cold air, which causes the fine droplets to condense (*i.e.* drop out of the gaseous phase). Indeed, this condensation effect of cold air minimizes the distance that respiratory aerosols can travel since the condensed water droplets are relatively large. However, in warm air these aerosols are invisible and can potentially travel long distances depending on the rate of ambient air flow. The masks in common use among Canadians (*e.g.* surgical and cloth masks) lack standardization, users are not required to undergo fit-testing, and even if these were done, they would still lack the ability to prevent the spread of aerosols. Low-cost masks do not seal properly around the face, with leaks commonly occurring around the nose and at the joints of the jaw. Due to simple physics in which air will follow the path of least resistance, most exhaled and inhaled air will leave and enter via these gaps in the masks. This is further exacerbated by anything that increases these gaps. An example would include a beard, which would separate the mask from the chin, thereby replacing the mask material with a coarse-haired filter with massive pore sizes relative to the size of a virus. Anyone who wears glasses and a mask can attest to the venting issue around the nose, as it often causes the lenses to fog. It seems illogical to force a person's pulmonary exhaust to flow over their eyes, since this is a known route of infection for SARS-CoV-2 and could, therefore, potentiate spreading of the infection in an individual. It was shown that ocular tissues express entry receptors for SARS-CoV-2 and conjunctivitis is common among people diagnosed with COVID-19, sometimes even preceding the onset of signs and symptoms of respiratory distress[33]. As such the eyes could potentially serve as both a portal of entry and a source of person-to-person transmission.

Air venting past the ears, which is the other common location of leakage with low-cost masks, means that aerosols are generally directed behind a person. However, public health policies usually recommend that people turn away from other individuals if they must pass within proximity. If anything, this simply increases the chance of someone being exposed to pulmonary aerosols with a higher flow rate. The principles of distributing pulmonary aerosols over the eyes and behind a person also holds true for face shields. This highlights how poorly thought out masking policies are. Even if low-cost masks were properly sealed around the neck and face, SARS-CoV-2-laden aerosols and still readily pass through the relatively large pore sizes of the filtering material. Indeed, a study published in 2019 found that the low-cost masks had pore sizes ranging from 80 to 500 µm in diameter[34]. Water droplets that come from the lungs are defined as 'large droplets', 'small droplets' or 'droplet nuclei' and range in size from >60 µm, 10-60 µm, and <10 µm in diameter, respectively[35]. Coughs and sneezes will discharge droplets of all sizes. However, regular breathing and talking primarily discharges small droplets and droplet nuclei. Notably, SARS-CoV-2 has a diameter of only ~1 µm. This means that virus-laden droplets in pulmonary aerosols will have a maximum diameter of ~62 µm, with the vast majority being much smaller (remember that the pores in low-cost masks are ≥80 µm. As such, low-cost masks fail to stop the spread of SARS-CoV-2. One of the biggest challenges in relaying the science is the 'invisibility' of the microbial world. To place this into a context that is easier to picture, this would be akin to thinking that a person is locked inside a house when

the walls have huge gaping holes (*i.e.* the leakage points were there proper seals are lacking) and the front door is open (*i.e.* representing the pore size of a mask). The reality of this scenario is that the person is free to come and go as they wish.

Also, aerosols from the lungs can travel beyond two meters and the directionality will be dictated by air currents[36]. Although the viral load that a person would be exposed to from aerosols would decrease with distance, the long-range potential of aerosols highlights the arbitrariness of 2-meter physical distancing policies. Further, buildings with poor ventilation, which encompasses most buildings in Canada, facilitate the build-up of aerosols over time, which further confounds the value of two-meter distancing[37]. Finally, for the vast majority of people it is not possible to wear masks for prolonged periods of time without touching it with their fingers. For example, jaw movements associated with talking, yawning, *etc.*, causes low-cost masks to slide off the nose. Handling of masks that are dampened with aerosols promotes contamination of the fingers and anything they touch thereafter. In addition to spreading via aerosols, the other major route of transmission is via contaminated hands of infected individuals[38], which is potentiated by masking. As such, removing masking mandates and promoting traditional hand washing would be a more logical approach to reducing the spread of SARS-CoV-2.

A recent review of masking data generated during the pandemic concluded there are numerous other harms associated with masking and that it is not effective in preventing transmission of SARS-CoV-2[39]. Here are the precise conclusions from this study: "*The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression.*"

Demonstration of inadequate sealing of low-cost masks around the face are shown in figures 3 and 4. The relative size of SARS-CoV-2-laden water particles and pores of low-cost masks is shown inf figure 5. Figure 6 shows how readily aerosols can pass through masks, even when having to pass through five three-ply surgical masks. Figure 7 shows the personal protective equipment required to safely work with containment level-3 pathogens such as SARS-CoV-2.

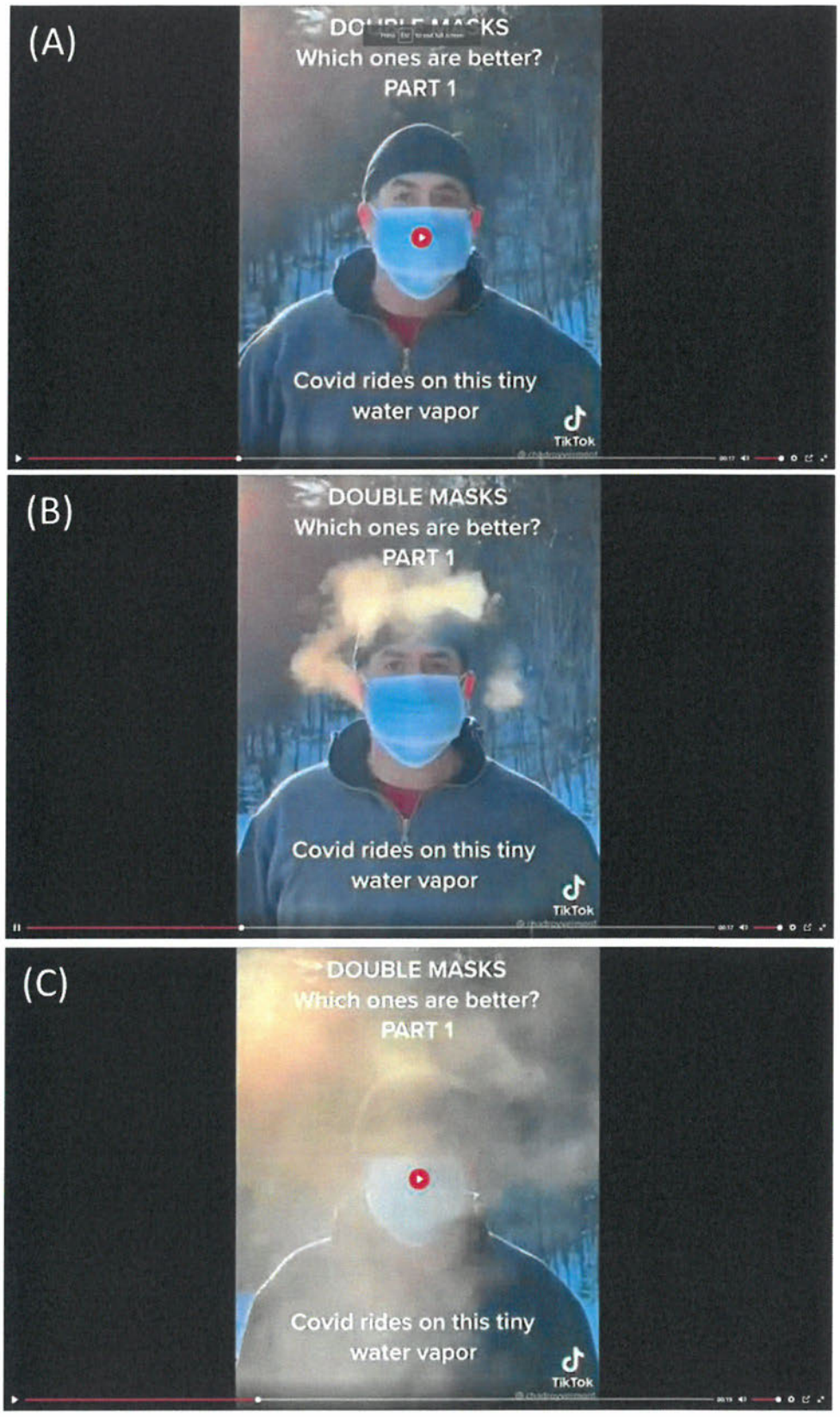


**Figure 3: The leakiness of low-cost masks.**
These are screen shots taken from a video showing cold-mediated condensation of a pulmonary aerosol when exhaling while wearing two three-layer surgical masks that had the metal bar pinched over the nose. (A) at the end of the inhalation. (B) During exhalation aerosol exiting the lungs is condensing in the cold air. (C) At the end of the exhalation, the profound amount of aerosol released from the mask after a single exhalation is evident.

(A)

(B)

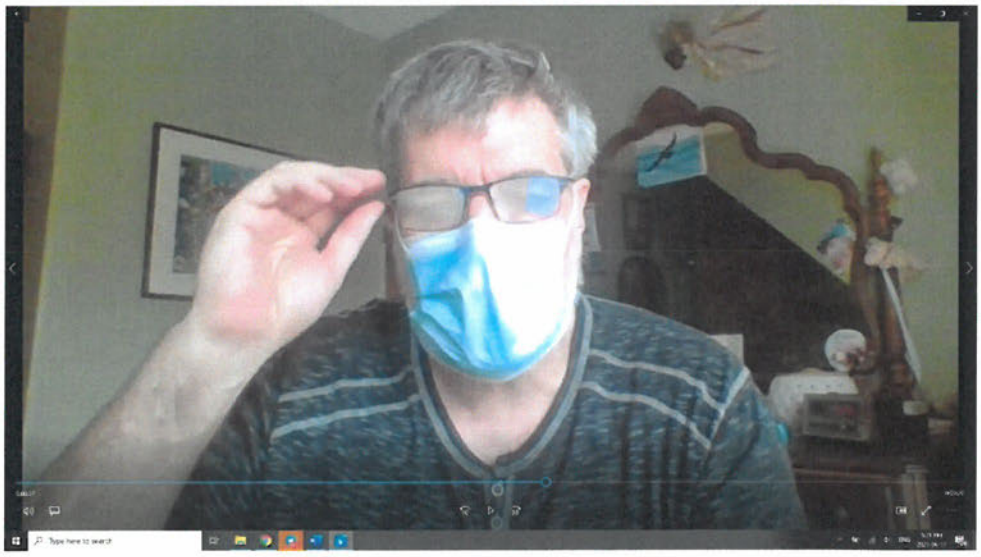

**Figure 4: The leakiness of low-cost masks.**

These are screen shots taken from a video showing fogging of eyeglasses when wearing a three-layer surgical mask. (A) While inhaling, the metal bar over the nose is pinched to maximize the 'seal'. (B) During exhalation aerosol exiting the lungs is condensing on the lenses of the glasses, causing them to fog.

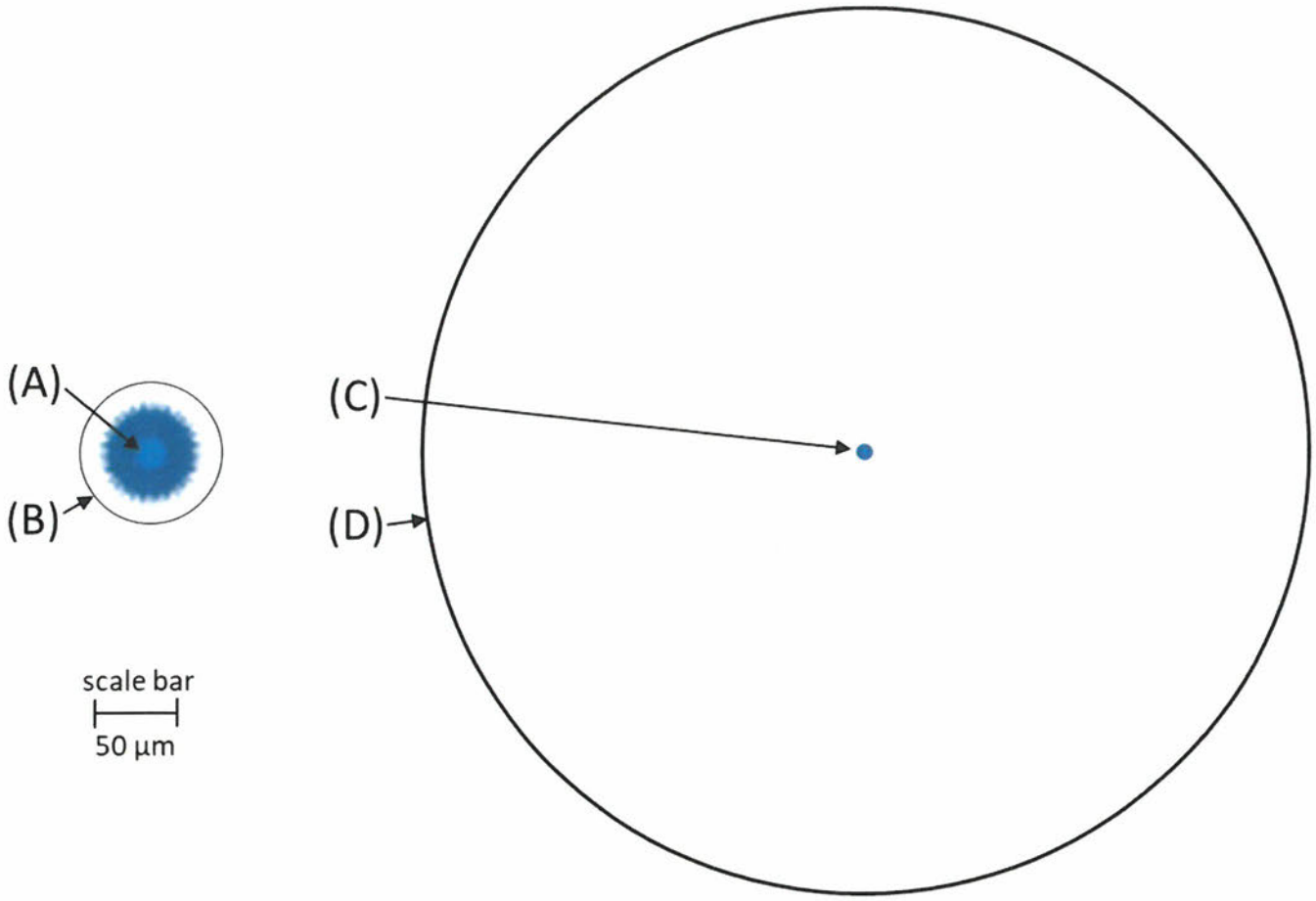


**Figure 5: The relative size of SARS-CoV-2-laden water particles and pores of low-cost masks.** SARS-CoV-2 particles have a diameter of ~1 µm. Water droplets in air exhaled from the lungs can be classified into three sizes. Large droplets are >60 µm, small droplets are 10-60 µm in diameter, and droplet nuclei are >10 µm in diameter. Individuals who are not coughing or sneezing will exhale an aerosol that consists almost entirely of droplet nuclei and small droplets. (A) The largest of the small droplets that are laden with SARS-CoV-2 will have a diameter of ~62 µm. (B) The smallest pore size of a low-cost mask is ~80 µm. (C) The largest of the droplet nuclei that are laden with SARS-CoV-2 will have a diameter of ~12 µm. (D) The largest pore size of a low-cost mask is ~500 µm.
= virus-laden droplet = pore in a low-cost mask

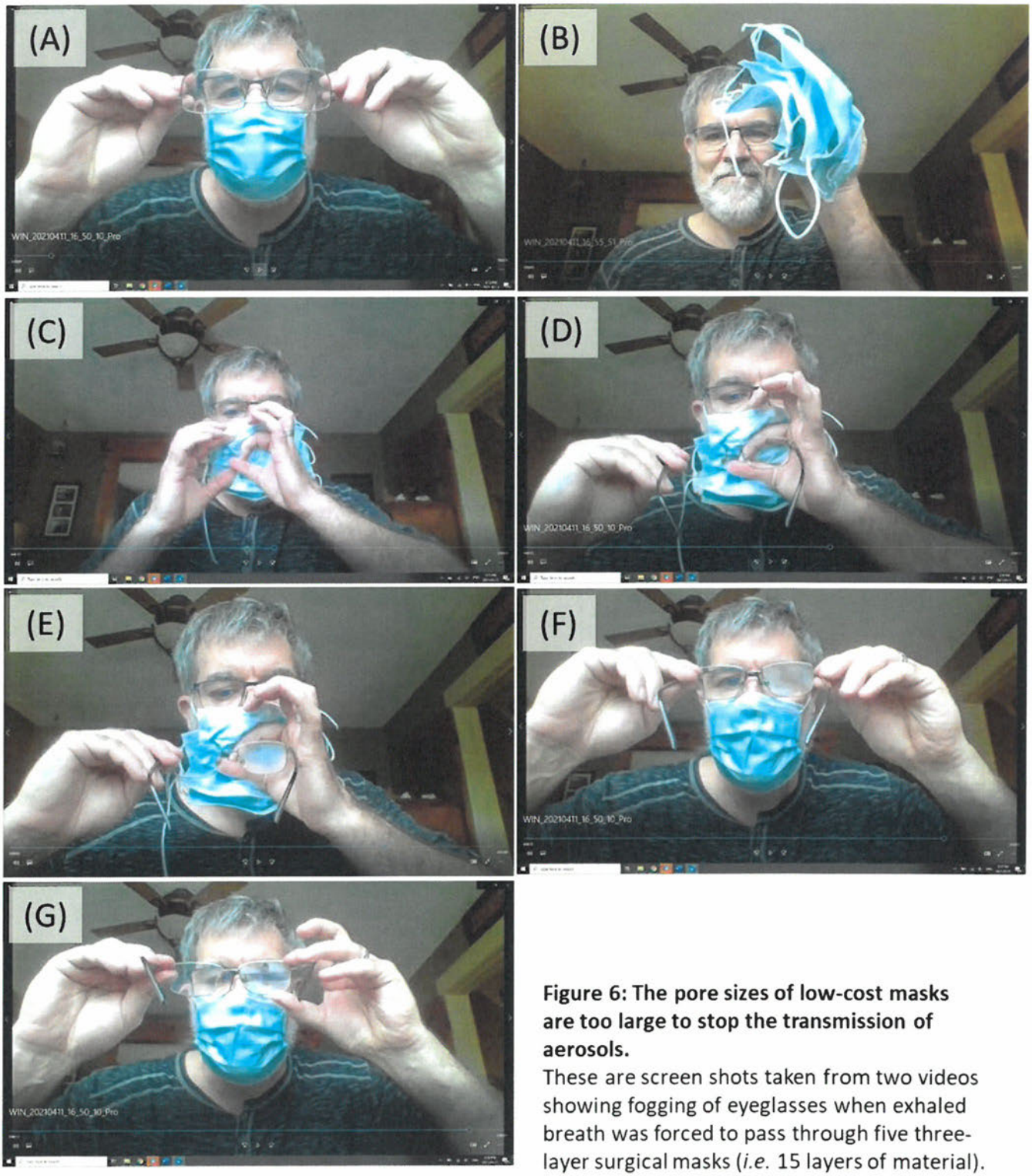


**Figure 6: The pore sizes of low-cost masks are too large to stop the transmission of aerosols.**

These are screen shots taken from two videos showing fogging of eyeglasses when exhaled breath was forced to pass through five three-layer surgical masks (*i.e.* 15 layers of material). (A) This image shows the clarity of the eyeglasses when no fogging is present. (B) Five surgical masks were placed sequentially over the mouth. (C) A ring was made with the finger and thumb to apply pressure around the lips and seal the mask so the only place exhaled air could exhaust was through the five three-ply surgical masks. (D) Beginning to exhale through the five masks. (E) Near the end of exhalation. (F) Post-exhalation evidence of fogging is present on the lens of the eyeglasses to the right of the image. (G) So much aerosol had condensed on the lens of the eyeglasses that a cross pattern could be drawn in the liquid.


**Figure 7: Personal protective equipment required to safely work with containment level-3 pathogens such as SARS-CoV-2.**

SARS-CoV-2 is defined as what is known as a 'containment level-3 pathogen' by the Public Health Agency of Canada. The personal protective equipment that they require scientists to use to ensure safe handling of SARS-CoV-2 typically includes the following: 1. Handling of SARS-CoV-2 can only be done inside a certified containment level-3 facility. 2. Anything containing SARS-CoV-2 can only be opened inside a biological safety cabinet, which is designed to provide a barrier between the virus and the scientist. 3. The scientist must wear a full body suit, including shoe covers and gloves. A head covering with a clear face shield and that seals around the neck and face must be worn. The head covering is connected by a tube that is attached to a pump that delivers filtered air into the head covering, thereby maintaining positive pressure (*i.e.* ambient air cannot flow into the head covering). Personal protective equipment that is known to prevent the wearer from being infected with a containment level-3 pathogen, such as SARS-CoV-2, is shown in figure 7.

A person wearing a low-cost mask would not be allowed to enter a containment level-3 facility due to a profound lack of protection. There is, therefore, a large discrepancy between what truly protects an individual from SARS-CoV-2 and the public health messaging surrounding cloth and surgical masks, which falsely implies a substantial amount of protection.

There are other notable harms associated with long-term masking. Although the pores sizes of low-cost masks are too large to efficiently stop the spread of SARS-CoV-2-laden aerosols, bacteria are much larger, as are dust and other environmental particles. Long-term prevention of exposure to the microbial world and natural environment in children has been associated with an increased incidence of allergies, asthma and autoimmune diseases based on an immunological principle known as the 'hygiene hypothesis'[40, 41]. Another potential harm of wearing masks is the psychological effect it has on adherence to public health protocols. The false sense of security that a mask confers causes many people to become less aware of or less concerned with the practice physical distancing. Additional problems include things like blunting social cues by preventing reading of facial body language, muffling speech (a particular concern for individuals with pre-existing speech disorders), preventing lip-reading, and exposure to hypoxia (low oxygen levels) due to slowing of gas exchange, especially when active[39].

Conclusion: Once one realizes that SARS-CoV-2 can pass through low-cost masks and travel >2 meters and sometimes much further on 'droplet nuclei' in pulmonary aerosols, it becomes readily apparent that the policies of mask-wearing and two-meter physical distancing are not adequately protective against the spread of SARS-CoV-2. If low-cost masking combined with only two-meter physical distancing does little to prevent the spread of SARS-CoV-2, it would be expected that a relatively high proportion of Canadians would have naturally acquired immunity to the virus over the past year. Indeed, this is precisely what was found in a recently published study that showed that the majority of apparently healthy adults in British Columbia have evidence of naturally acquired immunity[3]. Therefore, low-cost masking to protect against transmission of SARS-CoV-2 is futile. At the very least, liberal mask exemptions should be more commonplace.

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# Exhibit "V"

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ORIGINAL ARTICLE

# SARS-CoV-2 re-infection risk in Austria

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Correction added on 26 February 2021, after first online publication: Author spelling is corrected to John PA Ioannidis



## Abstract

**Background:** A key question concerning coronavirus disease 2019 (COVID-19) is how effective and long lasting immunity against this disease is in individuals who were previously infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). We aimed to evaluate the risk of SARS-CoV-2 re-infections in the general population in Austria.

**Methods:** This is a retrospective observational study using national SARS-CoV-2 infection data from the Austrian epidemiological reporting system. As the primary outcome, we aim to compare the odds of SARS-CoV-2 re-infections of COVID-19 survivors of the first wave (February to April 30, 2020) versus the odds of first infections in the remainder general population by tracking polymerase chain reaction (PCR)-confirmed infections of both groups during the second wave from September 1 to November 30, 2020. Re-infection counts are tentative, since it cannot be excluded that the positive PCR in the first and/or second wave might have been a false positive.

**Results:** We recorded 40 tentative re-infections in 14 840 COVID-19 survivors of the first wave (0.27%) and 253 581 infections in 8 885 640 individuals of the remaining general population (2.85%) translating into an odds ratio (95% confidence interval) of 0.09 (0.07 to 0.13).

**Conclusions:** We observed a relatively low re-infection rate of SARS-CoV-2 in Austria. Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies. Further well-designed research on this issue is urgently needed for improving evidence-based decisions on public health measures and vaccination strategies.

KEYWORDS

COVID-19, epidemiology, PCR, re-infection, Risk, SARS-CoV-2

Stefan Pilz and Ali Chakeri contributed equally as first authors to this manuscript

## 1 | INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic is a major public health crisis.[1,2] A key question concerning measures against COVID-19 is the strength and durability of immunity against this disease in individuals previously infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[3-10] Vaccination strategies, considerations regarding herd immunity, and overall simulations for the pandemic depend on the efficacy and the time course of immunity against COVID-19.[5]

Data on immune responses to COVID-19 are limited by knowledge gaps regarding their dynamics over time and their clinical significance with reference to protection against re-infections.[3-10] There is evidence for re-infections from numerous case reports, but it is occasionally challenging to differentiate true re-infections from prolonged viral shedding that may last for up to about 4 months.[5,11,12] Notably, a study of 12 541 healthcare workers in the UK recently found major protection against re-infection for those who had anti-SARS-CoV-2 antibodies determined by anti-spike and anti-nucleocapsid assays versus those who did not.[13] After a follow-up of up to 31 weeks, they calculated a rate ratio of 0.11 (95% confidence interval (CI): 0.03 to 0.44; $P = .002$) for re-infections in seropositive healthcare workers versus first infections in healthcare workers with negative antibody status.[13] Similarly, another recent study among healthcare workers from the UK reported no re-infection case in 1038 individuals with evidence of previous SARS-CoV-2 infection based on PCR tests and/or antibody status.[10] While these studies suggest a high protection against SARS-CoV-2 re-infections in healthcare workers, the risk of re-infections in the general population remains uncertain.

Austria was hit very early in this pandemic with a first wave occurring from 22 February to 30 April 2020 (all further dates refer to the year 2020). Data on the re-infection rate during the second wave from September 1 to November 30 can therefore provide, as a rough estimate, evidence on the immunity against SARS-CoV-2 over more than half a year.[14,15] Therefore, we investigated data from the Austrian epidemiological reporting system (ERS) provided by the Austrian Agency for Health and Food Safety (AGES).[15] As the primary outcome, we compared the odds for SARS-CoV-2 re-infections in COVID-19 survivors versus first infections in the remainder general population during the second infection wave. In addition, we also evaluate data on hospitalization status during both infection waves and on COVID-19 deaths during the second wave, in order to obtain measures of disease severity.

**Key messages**

- In this study in the whole general population in Austria with a follow-up of over half a year, those individuals with a previous SARS-CoV-2 infection had a significant reduction by 91% for the odds of a re-infection versus the odds of a first infection in the remainder general population.
- Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies.

## 2 | METHODS

Data for this study were derived from the Austrian ERS that is tracking SARS-CoV-2 infection data in Austria, including among others data on hospitalization status and COVID-19 deaths.[15] Ethical approval for this study was obtained from the ethics committee at the Medical University of Graz, Graz, Austria.

Patients who had a positive polymerase chain reaction (PCR) test during both, the first and second infection wave are referred to here as patients with 'tentative re-infections'. We use the term 'tentative' re-infection because a certain number of these cases might reflect false-positive results in the testing during the first and/or second wave. This is based on the consideration that the specificity (with 95% confidence region) of PCR tests (nucleic acid amplification tests) for SARS-CoV-2 is less than 100%, with 98.1% (95.9 to 99.2%) according to a recent meta-analysis.[16]

The group size of 'COVID-19 survivors' was calculated as all individuals who had a positive PCR test result for SARS-CoV-2 minus all reported COVID-19 deaths from February 22 to April 30. The control group ('general population group') are the remainder Austrian residents that we calculated as the reported Austrian population on January 1 with 8 901 064 individuals (the closest approximation for the population size) minus all patients tested SARS-CoV-2 positive during the first wave.[17] In Austria, population changes from year to year are usually significantly less than 1%.[17] The observation period for tracking SARS-CoV-2 infections was from September 1 to November 30 (the pre-specified date for our analyses), corresponding to what we term the second wave. Automated matching of records in the first and second wave to detect tentative re-infections was done by using IDs consisting of the first two initials of the first name, the first three initials of the surname and the date of birth (eg ST.PIL.15.12.1979). All entries with the identical ID were then carefully and manually checked including data such as full names and laboratory dates to evaluate whether the criteria for a re-infection were met.

We did not primarily track tentative re-infections of COVID-19 survivors from May to August as it may be unclear whether positive SARS-CoV-2 tests represented re-infection or persistent infection when considering long-term

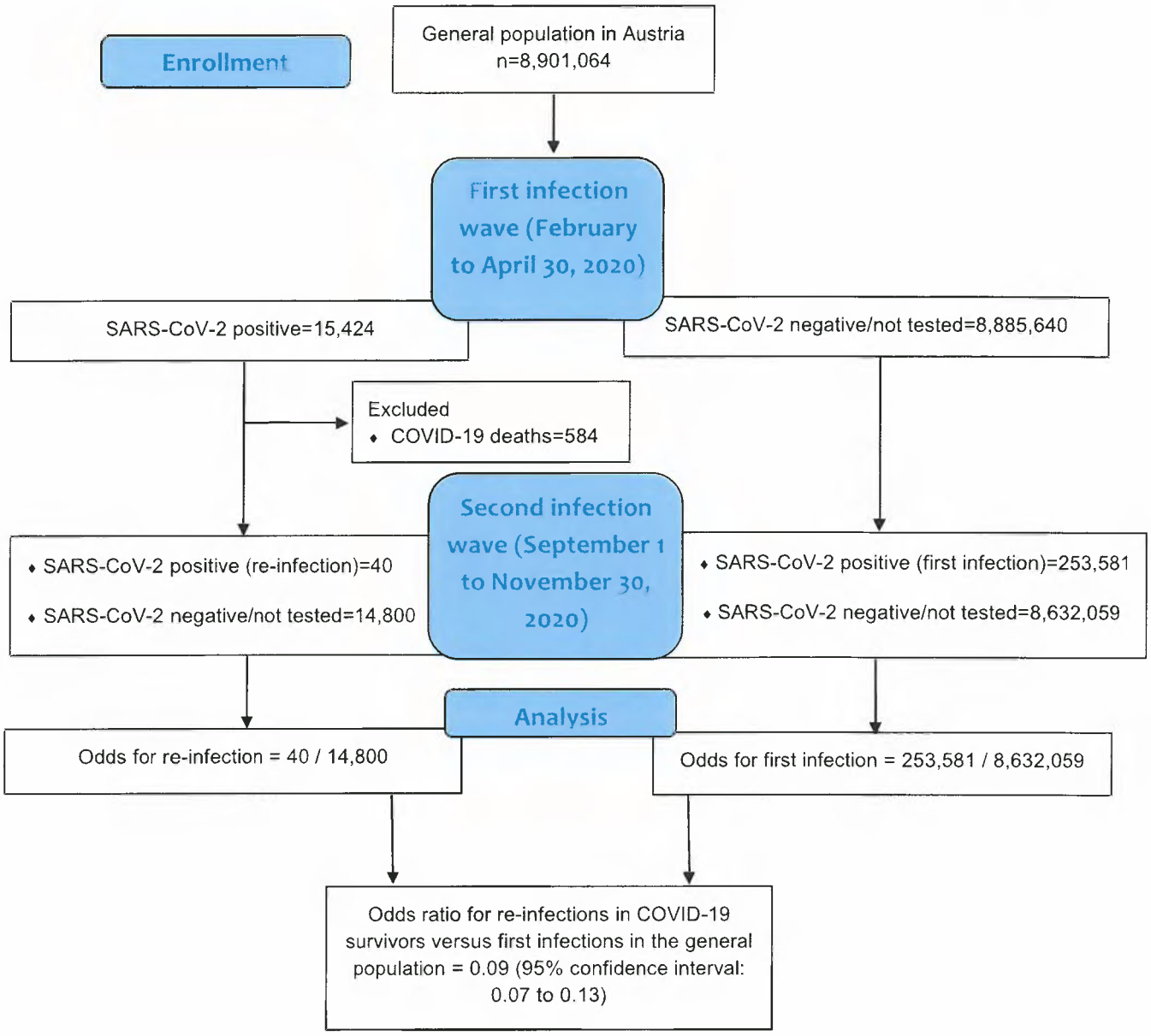


**FIGURE 1** Analysis plan for calculating the odds ratio for re-infections versus first infections with SARS-CoV-2 in the general population in Austria

viral shedding for up to about 4 months.[5-7] This 4 month interval was also the main consideration to separate the time frame for the two waves. Of note, there were only relatively few documented SARS-CoV-2 cases (<0.15% of the Austrian population) from May to August.[15]

Regardless of the main reason for hospitalization, any hospitalized patient who was tested SARS-CoV-2 positive was classified as hospitalized in the ERS. All persons who were tested SARS-CoV-2 positive and died for whatever reason within 28 days after the last positive test were classified as COVID-19 deaths.

As our primary outcome analysis, we calculated the odds ratio (OR) (with 95% confidence interval [CI]) of SARS-CoV-2 re-infections in the COVID-19 survivor group versus first infections in the general population group. Statistical analyses were performed by using SPSS Version 25.0 (IBM SPSS Inc, Chicago, IL, USA).

## 3 | RESULTS

From 15 424 patients with SARS-CoV-2 positive tests in the first wave, 584 were recorded as COVID-19 deaths, so that our COVID-19 survivor group consists of 14 840 patients (see Figure 1 for our analysis plan). Excluding the COVID-19 survivor group, the number of individuals of the general population group resulted in 8 885 640 individuals.

During the observation period from September 1 to November 30, we recorded 40 tentative re-infections in the COVID-19 survivor group (0.27%), and 253 581 new infections

**TABLE 1** Characteristics of 40 patients with re-infection

| Gender | Age at first infection(years) | Time between infections (days) | Hospitalization | |
|---|---|---|---|---|
| | | | First wave | Second wave |
| Female | 84 | 148 | Yes | No |
| Female | 53 | 223 | No | No |
| Female | 54 | 183 | No | No |
| Male | 34 | 215 | Yes | No |
| Female | 31 | 200 | Unknown | Unknown |
| Female | 25 | 206 | No | No |
| Male | 89 | 196 | No | No |
| Female | 39 | 175 | No | No |
| Male | 52 | 222 | No | Unknown |
| Male | 22 | 251 | No | Unknown |
| Female | 84 | 148 | Yes | Yes |
| Male | 79 | 238 | Yes | Unknown |
| Female | 23 | 236 | No | Unknown |
| Female | 55 | 214 | No | No |
| Female | 37 | 203 | No | No |
| Female | 23 | 222 | No | No |
| Male | 15 | 235 | No | No |
| Female | 76 | 219 | Yes | Yes |
| Male | 52 | 206 | No | No |
| Female | 72 | 172 | No | No |
| Male | 24 | 207 | No | No |
| Female | 51 | 221 | No | No |
| Male | 19 | 210 | No | No |
| Female | 43 | 246 | No | No |
| Male | 61 | 246 | No | Unknown |
| Male | 25 | 221 | Yes | Yes |
| Male | 47 | 232 | No | No |
| Female | 34 | 222 | No | Yes |
| Female | 31 | 231 | No | No |
| Female | 30 | 213 | No | No |
| Female | 54 | 173 | Yes | Yes |
| Male | 27 | 203 | No | No |
| Female | 23 | 172 | No | No |
| Female | 40 | 214 | No | Unknown |
| Male | 25 | 221 | No | No |
| Female | 93 | 237 | Yes | Unknown |
| Female | 26 | 227 | No | No |
| Female | 41 | 226 | No | No |
| Female | 48 | 216 | No | No |
| Male | 27 | 243 | No | No |

in the general population group (2.85%). The OR (with 95% CI) for infections in the COVID-19 survivor group versus the general population group was 0.09 (95% CI, 0.07 to 0.13).

Characteristics of the 40 re-infection cases are tabulated in Table 1. Of the patients with tentative re-infections, 62.5% were women and the median age (with 25th to 75th

percentile; minimum–maximum) at the first infection was 39.8 (25.9 to 54.5; 15.4 - 93.8) years. The mean (± standard deviation) time from the first to the tentative re-infection was 212 ± 25 days. Of the 40 tentative re-infections, 4, 12 and 24 were documented in September, October and November, respectively (among 18 106, 61 384 and 174 131 total infections, respectively).

Hospitalization status in numbers of patients coded as yes, no and unknown was 8, 31 and 1 for the first infection and 5, 27 and 8 for the tentative re-infection, respectively. Four patients were hospitalized during both infection waves. Unknown hospitalization data during the second wave are probably mainly due to a delay in hospitalization data entry into the ERS.

With follow-up on mortality available until December 23, only one 72-year-old woman died two days after her tentative re-infection diagnosis. She was not hospitalized and according to her medical records her cause of death ('acute vascular occlusion of an extremity with rhabdomyolysis') was not causally attributed to COVID-19.

## 4 | DISCUSSION

We documented a relatively low re-infection risk for SARS-CoV-2 in the general population of Austria by using data from the ERS. Patients with re-infections covered both genders, a wide age range and included also patients who were hospitalized during both infections.

Our study is, to the best of our knowledge, the first systematic investigation of tentative re-infection risk with SARS-CoV-2 in a large national population. Several case reports on SARS-CoV-2 re-infections in the general population indicate that there is at least some risk of re-infection, but they did not provide quantification of re-infection risk that requires a standardized comparison to the 'background' infection risk in the general population.[3-5] While data on immune responses to previous SARS-CoV-2 infections exist, they can only be regarded a proxy for a previous infection and the associated clinical protection against re-infections, thus requiring studies like ours to address the question to what extent patients who experienced PCR confirmed SARS-CoV-2 infections are protected against re-infections.[3-5] Importantly, the study by Lumley et al in 12 541 healthcare workers documented protection against re-infection for those who had anti-SARS-CoV-2 antibodies with a rate ratio (0.11) very similar to what we observed.[13] While the investigation by Lumley et al was restricted to a specific population of predominantly healthy adult healthcare workers 65 years of age or younger, and was based on only two re-infections in seropositive individuals, our study extends this knowledge by data from a much larger population based survey using solely PCR-confirmed SARS-CoV-2 infection cases.[13] Importantly, a recent study using SARS-CoV-2 PCR and antibody test data from 66 001 patients from a laboratory in south-west London documented 8 patients with evidence of re-infections, and calculated a relative risk of re-infections versus first infections of 0.0578 (95% CI: 0.0288 to 0.1160)[18] which is also compatible with our estimate.

Our data do not include detailed clinical characteristics of the patients with tentative re-infections but it is noteworthy that these patients covered both genders with a wide age range and included also several hospitalized patients. These data are of interest since previous studies indicate a high correlation between neutralizing antibodies against SARS-CoV-2 and COVID-19 severity. This in turn suggests that those patients with more severe infections may develop a stronger protective humoral immune response against SARS-CoV-2 compared to those with less severe infections. This hypothesis is, however, not strongly supported by our findings as several patients with tentative re-infections were already hospitalized during their first infection.[8] Regarding duration of acquired immunity against SARS-CoV-2 re-infections, we provide data with a median follow-up time of about 7 months. Importantly, there was no clear sign of decreasing protection against re-infections in descriptive analyses of monthly stratified re-infection cases.

In view of ongoing discussions on vaccination approaches regarding SARS-CoV-2, our data suggest that the protection against SARS-CoV-2 after natural infection is roughly similar to the highest estimates of SARS-CoV-2 vaccine efficacies among vaccines that have been authorized to-date, although a direct comparison cannot be made due to differences in study designs and study populations.[19,20] Nevertheless, we believe that based on our findings, waving urgent recommendations to undergo SARS-Cov-2-vaccination for persons with PCR-documented previous COVID-19 infection seems prudent as long as any shortage of vaccines is present.

Our findings on a significant protection against SARS-CoV-2 re-infections, provide also evidence for the rapid evolution of the pandemic towards 'herd immunity', in particular because of a huge underreporting of SARS-CoV-2 cases.[21,22] Therefore, the relatively high prevalence of individuals who were already infected with SARS-CoV-2 along with the currently rapidly increasing number of vaccinated individuals may work in concert towards an ensuring 'herd immunity' that will hopefully bend this pandemic within the near future.[2,23,24] This may already be the case in some countries such as India, where seroprevalence rose rapidly from 0.7% in May to 7% in August and 60% in November in national surveys.[25-27] Accordingly, the epidemic wave in India (both for documented cases and for COVID-19 deaths) has largely abated by February 2021. It must, however, be noted that the concept of herd immunity has recently been challenged by resurgence of COVID-19 in Manaus, Brazil, a region in which seroprevalence data

suggested that about 76% of the population had been infected with SARS-CoV-2 by October 2020.[28] It is unknown whether there was an error with over-estimation of the first wave seroprevalence, or the resurgence can be explained by the advent of a new strain (P1) that has a high propensity for re-infection. Careful monitoring for new strains and for their ability to evade existing natural immune responses and vaccine-induced immunity is needed.

Our findings are limited due to lack of detailed clinical characteristics, the observational nature of our study design, and the strong dependence on the data quality of the ERS. The 40 tentative re-infections have quite similar demographics to the totality of COVID-19 documented cases in Austria, but data are limited for meaningful formal comparisons.[9] Data on hospitalizations are very sparse and hospitalization data during the second wave are missing for some participants, probably, due to a delay in reporting such data. Infections in the first wave are likely to have been far more common than the documented ones, so some of the general population controls may actually represent people already infected in the first wave. Moreover, the relative risk of re-infection may be over-estimated, if re-infection cases are artefacts of PCR false positives in either wave; and underestimated if people who were infected in the first wave were less likely to be tested in the second wave compared with other people having the same symptoms. In this context, Lumley et al reported that seropositive healthcare workers attended asymptomatic screening less often than seronegative healthcare workers with a rate ratio of 0.76 (95% CI: 0.73 to 0.80), a finding that is similar compared to another study from the UK.[10,13] Another limitation of our work is that we did not have access to viral sequencing data to compare first and re-infections, and it is not known how well our findings generalize to the re-infection risk concerning different genetic variants of SARS-CoV-2. Finally, we have to stress that our main findings are only a rough estimate of SARS-CoV-2 re-infection risk, requiring urgent confirmation in other populations and study settings.

In conclusion, we observed a relatively low tentative re-infection rate of SARS-CoV-2 in Austria that suggests a similar protection against SARS-CoV-2 infection compared to vaccine efficacies.[5,19,20] These data may be useful for decisions on public health measures and vaccination strategies to fight the COVID-19 pandemic.[2,19,20,23,24] Further studies are urgently needed to improve our knowledge on SARS-CoV-2 re-infection risk and its predisposing factors and clinical significance.

## ACKNOWLEDGMENT

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## CONFLICTS OF INTEREST

The authors report no conflicts of interest.

## AUTHOR CONTRIBUTIONS

All authors have substantially contributed to the design, performance, analysis and reporting of the work. AC, LR and FA contributed to data collection. SP and JPAI analysed the data and wrote the manuscript.

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# Exhibit "W"

# AN OPEN LETTER TO THE PRESIDENT OF THE UNIVERSITY OF GUELPH

This is Exhibit " W " referred to in the
Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

Friday September 17, 2021

University of Guelph
50 Stone Rd. E.
Guelph, ON,
N1E 2G1

Dear Dr. Charlotte A.B. Yates, President and Vice-Chancellor,

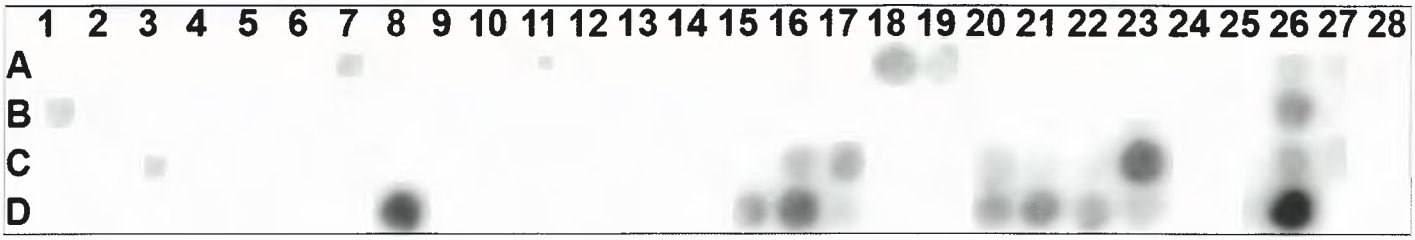
I will forewarn you that this is a lengthy letter. However, it only represents a fraction of the information that I would like to be able to share with you. I have found it necessary to write this so you can fully understand my perspective. With my life and that of my family, many friends and treasured colleagues being destroyed under your watch, I figure the least you can do is read and consider this very carefully. It is incredible to note that many, if not most, of my on-campus detractors have judged me without reading any of my scientific arguments or talking to me about them.

## The COVID-19 Vaccine Mandate at the University of Guelph

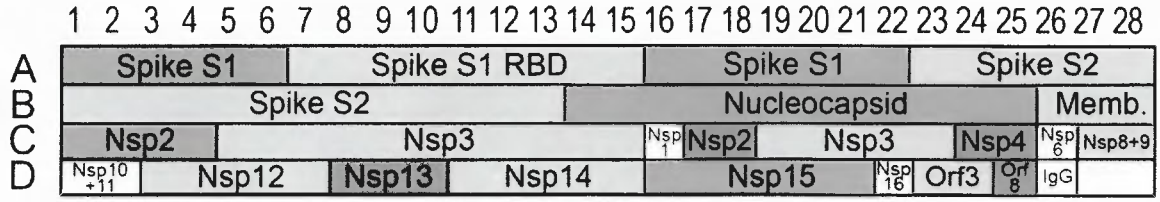
You issued a mandate that everyone within the University of Guelph community must receive a COVID-19 vaccine. I have spent most of my lifetime learning to be a very deep and critical thinker and to follow the weight of scientific evidence. I am a well-recognized expert in vaccinology. As per my extensive funding, research, publication, and teaching records, I am a vaccine lover and an innovator in this field. I promote highly effective vaccines that have undergone extensive, rigorous, and proper safety testing as the most efficient type of medicines that exist. Vaccines that meet these criteria have prevented a vast amount of mortality and morbidities around the world. However, **I could not be in stronger disagreement with you forcing the current COVID-19 vaccines upon everyone** who is part of our campus community. I respect the challenges that a university president faces when trying to manage a large and dynamic academic institution. However, your roots are as a scholar. As a publicly funded institution of advanced learning, it is incumbent on us to demonstrate an ability to view the world around us in a constructively critical fashion such that we can improve the lives of others. We should be able to do this free of political or financial pressures and without bias or prejudice or fear of censorship and harassment. As a viral immunologist that has been working on the front lines of the scientific and medical community throughout the duration of the declared COVID-19 pandemic, I feel compelled to speak on behalf of the many who will not, due to extreme fear of retribution. We now live in a time when it is common practice for people to demand and expect to receive confidential medical information from others. I will not be coerced into disclosing my private medical information. However, for the sake of highlighting some of the absurdities of COVID-19 vaccine mandates I choose, of my own free will, to freely disclose some of my medical information here...

## Those with Naturally Acquired Immunity Don't Need to be Vaccinated and are at Greater Risk of Harm if Vaccinated

I participated in a clinical trial that has been running for approximately 1.5 years. The purpose is to develop a very sensitive and comprehensive test of immunity against SARS-CoV-2; in large part to inform the development of better COVID-19 vaccines (https://insight.jci.org/articles/view/146316 ). My personal results prove that I have naturally acquired immunity against SARS-CoV-2. With this test, spots indicate a positive result for antibodies against a particular part of the virus. Darker spots correlate with more antibodies. Antibody responses correlate with the induction of memory B cells. Antibodies will wane over time, but B cells can survive for many years and rapidly produce massive quantities of antibodies upon re-exposure to a pathogen. On the following page are my results, along with a map of which part of the virus each spot represents...




Peptide Identification on CCJ SARS-CoV-2 SPOT peptide arrays




The dark spot at position D26 is the positive control and indicates that the assay worked. My results demonstrate that I have broad immunity against multiple components of SARS-CoV-2, including the spike protein. Importantly, spot B26 shows that I have antibodies against the membrane protein. This protein is not highly conserved across coronaviruses. As such, it provides evidence that I was infected with SARS-CoV-2. Note that I was sick only once since the pandemic was declared. It was a moderately severe respiratory infection that took ~four weeks to recover from. The SARS-CoV-2 PCR test was negative, despite being run at an unreasonably high number of cycles. This suggests that I was one of the many for whom SARS-CoV-2 has proven to be of low pathogenicity or not even a pathogen (*i.e.* no associated disease). There is a plethora of scientific literature demonstrating that naturally acquired immunity against SARS-CoV-2 is likely superior to that conferred by vaccination only. Indeed, it is much broader, which means that emerging variants of SARS-CoV-2 will have more difficulty evading it as compared to the very narrow immunity conferred by the vaccines. Importantly, the duration of immunity (*i.e.* how long a person is protected) has proven to be far longer than that generated by the current vaccines. The duration of immunity for the mRNA-based COVID-19 vaccines appears to be a horrifically short ~4.5 months. I actually wrote a lay article back in February 2021 to explain why a vaccine of this nature would fail to be able to achieve global herd immunity on its own (https://theconversation.com/5-factors-that-could-dictate-the-success-or-failure-of-the-covid-19-vaccine-rollout-152856). This is why places like Canada, the USA, and Israel have found it necessary to roll out third doses. And now there is talk (and a commitment in Israel) to roll out fourth doses (yes, that's four doses within one year). The World Health Organization recognized the value of natural immunity quite some time ago. Unfortunately, in Canada and at the University of Guelph, we have failed to recognize that the immune system works as it was designed to. Its ability to respond is not limited solely to vaccines. Here are some references to support this: https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1; https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiab295/6293992; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7803150/. As someone who develops vaccines, I can tell you that it is difficult to make a vaccine that will perform as poorly as the current COVID-19 vaccines. Indeed, most vaccines given in childhood never require a booster shot later in life. The take-home message here is that people like me, who have naturally acquired immunity, do not need to be vaccinated. Nor is it needed to protect those around the person who already has immunity. Worse, research from three independent groups has now demonstrated that those with naturally acquired immunity experience more severe side-effects from COVID-19 vaccines than those who were immunologically naïve prior to vaccination (https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00194-2/fulltext; https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1; https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1). In other words, **for those with natural immunity, vaccination is not only unnecessary, but it would put them at enhanced risk of harm. Knowing this, nobody should ever mandate COVID-19 vaccination**. Instead, it would be in the best interest of helping everyone make the most informed health decisions for themselves to make voluntary testing for immunity available.

**Testing for Naturally Acquired Immunity was a Viable Option but was Ignored**

You and the provost met with me and two other colleagues back in March 2021 and we presented the opportunity for the University of Guelph to show leadership and offer testing for immunity to our campus community in support of a safe return to in-person teaching and learning. You embraced this idea with enthusiasm and promised to move forward with it. This did not materialize so one of my colleagues contacted you. Once again, you agreed it was an excellent idea and that you would move forward with it. Nothing happened. So, my two colleagues and I met with one of our vice-presidents in May 2021. They also thought that making an antibody test available was an excellent idea and promised to work on getting it implemented on campus. Nothing materialized. They were contacted again by one of my colleagues. There was no response. There is no excuse for forcing vaccines on people, especially after having been given the opportunity to implement testing for immunity and refusing to do so.

The University of Guelph won't pay for me to receive a booster vaccine against rabies unless I can demonstrate that my antibodies are below what has been deemed to be a protective titer. This is because it would not be appropriate to give me a vaccine that is not without risk if I don't need it. Also, the university does not want to pay the ~$850 cost of the vaccination regimen unless I absolutely need it. In short, you will not allow me to receive that booster vaccine without first evaluating me on an annual basis for evidence of immunity (or lack thereof). So why was this principle rejected for the SARS-CoV-2 vaccines, for which there is vastly less reliable safety data available, and none for the long-term? Canada should have been acquiring data about immunity starting a long time ago. It is a particularly poor precedent for a university to reject the concept of acquiring data that could inform safer and more effective COVID-19 policies. Immunity testing would even benefit vaccinated individuals. It is well known that responses to vaccines in outbred populations follows a normal curve and includes individuals that are non-responders (*i.e.* they are left without immunity and are, therefore, unprotected following vaccination) and low-responders (insufficient protection). In fact, this concept has been the focus of an internationally recognized research program on our campus that has brought many accolades and awards to our institution.

You have banned me from campus for at least the next year. I can show proof of immunity against SARS-CoV-2 but you will not allow me to enter buildings. But someone else can show a receipt saying that someone saw two needles go into their arm and you will allow them to enter. You actually have no idea if that person has immunity. There have even been reported cases of people accidentally or even intentionally (*e.g.* a case in Germany) being administered saline instead of the vaccine. **Does it make sense to ban someone who is immune from campus but allow people who are presumed, but not confirmed, to be immune?** This is a scenario that you have created. As a fellow academic, **I am requesting that you provide me with a strong scientific rationale why you are allowing thousands with an unconfirmed immunity status onto our campus, but you are banning people like me who are known to have immunity**. Further, **please explain how you feel it is ethical to force COVID-19 vaccines on people who are uncomfortable with being coerced when you do not know their immunity status**. Despite attempts to halt the spread of SARS-CoV-2 via masking and physical distancing, the reality is that the virus has not complied with these attempts to barricade it. Indeed, it has infected many people across Canada, many of whom may not have even realized it because it is not a dangerous pathogen for them. From the perspective of a medical risk-benefit analysis, this is a no-brainer. A medical procedure that adds no value but carries known and still-to-be-defined risks should never be mandated!

**The University Back-Tracked on Advice from its Own Legal Counsel**

I, along with two colleagues, attended a meeting with one of our vice-presidents in May 2021. In that meeting the legal advice that was provided to the University of Guelph was disclosed. We were told this included making COVID-19 vaccines voluntary, that nobody on campus should be made to feel coerced into being vaccinated, and that nobody should feel pressured to disclose their vaccination status. On this basis, I was to serve as one of the on-campus faculty contacts for anyone who experienced any of these issues. **Did Canada's laws change during the summer in a way that rendered this legal advice no longer valid?** Now I am having to spend an inordinate amount of time trying to help the many people whose lives have imploded due to the university's vaccine mandate.

**I am a Scientist Who is Knowledgeable and Values Integrity Despite What So-Called 'Fact Checkers' Have Claimed**

There are many on our campus who repeatedly put my name out to the public with claims that I disseminate misinformation. Not one of these individuals has ever given me the courtesy of a conversation prior to publicly attacking me. None of them will engage me in public discussions of the science to allow people to judge the legitimacy, or lack thereof, of what I am saying. Censorship on our campus has become as prevalent as it is off-campus. My detractors, rather than showing a deep understanding of the science underlying COVID-19 vaccines, continually refer to the so-called 'fact checks' that have been posted about me. Let me tell you some things about the so-called 'fact checkers'. Firstly, they give scientists and physicians of integrity unreasonably short periods of time to respond to their requests for answers. For example, as I write this letter, I have 13,902 unread messages in my inbox and my voice mail is at maximum capacity. I have yet to see a 'fact check' request prior to its expiry, which remarkably, is often within mere hours of an e-mail being sent. This is an unreasonable expectation from a busy professional. Also, many 'fact checkers' lack sufficient expertise. In some cases, 'fact checker' sites have had to rely on postdoctoral trainees in other countries to write responses.

Most of the harassment against me began after 'fact checkers' cherry-picked one short radio interview that I gave to a lay audience. Some have accused me of only giving half the story in that interview. They were most kind; I was only able to reveal ~0.5% of the story. It is unfair to critique a tiny portion of one's arguments that were presented off-the-cuff to a lay audience with no opportunity for me to respond in real-time. For your information, **I have rebutted every single one of the 'fact checks' that I am aware of** in various public interviews. Let me give you one example that some of our colleagues on our campus have repeatedly misused while harassing me in social media...

One of the many issues that I have raised with the vaccines is that should a reasonable concentration of the free spike protein get into systemic circulation, it could potentially harm the endothelial cells lining our blood vessels. I cited this study: https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.121.318902. The authors were contacted, and they claimed I had misinterpreted the study. They said that spike-specific antibodies would mop up any spike proteins in the blood, thereby protecting the blood vessels. They argued that this demonstrated that vaccinating people against the spike protein is a good thing. However, the authors are not immunologists and they failed to recognize the limitations of their own study in drawing these kinds of conclusions. Specifically, they did not recognize that in a naïve individual receiving a mRNA-based COVID-19 vaccine, there are no antibodies; either pre-existing in the host, or in the vaccine formulation. In fact, it will take many days for the antibody response to be induced and for titers to begin reaching substantial concentrations. This leaves a large window of time in which any free spike proteins could exert their biological functions/harm in the body before there are any antibodies to neutralize them. Worse, most of the spike proteins should be expressed by our own cells. In that case, the antibodies will target and kill them in a form of autoimmunity. The authors of the paper forgot that their model was in the context of natural infection, where vaccination would precede exposure to SARS-CoV-2. In that case, I agree that there would be pre-existing antibodies that could neutralize spike proteins of viral origin entering the circulation. This was perceived to be one of the 'strongest' arguments used by others to try to discredit me. The reality is that it is completely incorrect and represents an embarrassing misinterpretation by the authors of the original paper and the many 'fact-checkers' that believed them without question.

**Criminal Harassment**

You have allowed colleagues to harass me endlessly for many consecutive months. They have lied about me, called me many names, and have even accused me of being responsible for deaths. I submitted a harassment claim and your administrators ruled that it did not meet the bar of civil harassment. In stark contrast, I have been contacted by members of off-campus policing agencies who have told me that it exceeds the minimum bar of criminal harassment. I am sorry, but a faculty member can only take so much bullying and see such a lack of adherence to scientific and bioethical principles before it becomes necessary to speak up. Under your watch, you have allowed my life to be ruined by turning a blind eye to on-campus bullying, ignoring our campus principles of promoting mental

well-being and a workplace in which I can feel safe. In addition to this you have banned me from the campus because I have robust, broadly protective, and long-lasting immunity against SARS-CoV-2 but lack a piece of paper suggesting that it was obtained via two injections. Did you see this front page of one of Canada's major newspapers?...


...remarkably, the on-campus COVID-19 policies you are promoting fuel this kind of pure hatred from people, most of whom have not confirmed their own immunity status, against someone like me who is immune to SARS-CoV-2!!! **Does that make any sense?** My workplace has become a poisoned environment where the bullying, harassment, and hatred against me have been incessant. Are you ever going to put an end to the childish and irrational behaviours being demonstrated by our colleagues? I have received thousands of emails from around the world that indicate the university should be embarrassed and ashamed to allow such childish behaviour from faculty members to go unchecked in front of the public. I have invested a decade of my life into the University of Guelph. I have conducted myself professionally and worked to an exceptionally high standard. I have consistently received excellent ratings for my research, teaching, and service. I have received rave reviews from students for my teaching. I have received prestigious research and teaching awards. I have brought funding to our campus from agencies that had never partnered with the University of Guelph in our institution's history. I have brought in ~$1 million-worth of equipment to improve our infrastructure, etc., etc. I am a man of integrity and a devoted public servant. I want to make Canada a better place for my family and for my fellow Canadians. We are a public institution. My salary is covered by taxpayers. This declared pandemic involves science that is in my 'wheelhouse'. Since the beginning, I have made myself available to answer questions coming from the public in a fashion that is unbiased and based solidly on the ever-exploding scientific literature. My approach has not changed. Has some of it contradicted the very narrow public health narrative carried by mainstream media? Yes. Does that make it wrong? No. I will stand by my track record. When Health Canada authorized the use of AstraZeneca's vaccine I, along with two colleagues, wrote an open letter requesting that this vaccine not be used, in part on the grounds that it was being investigated for a link to potentially fatal blood clots in many European countries. I was accused at that time by so-called 'fact checkers' of providing misinformation. Less than two months later, Canada suspended the AstraZeneca vaccination program because it was deemed to be too unsafe as a result of causing blood clots that cost the unnecessary loss of lives of Canadians. More recently, I was heavily criticized for raising concerns in a short radio interview about a potential link between the Pfizer BioNTech COVID-19 vaccine and heart inflammation in young people, especially males. This is now a well-recognized problem that has been officially listed as a potential side-effect of the mRNA COVID-19 vaccines. It was also the subject of a recent Public Health Ontario Enhanced Epidemiological Summary Report highlighting the increased risk of myocarditis and pericarditis to young males following COVID-19 mRNA vaccination. As such, I have a proven track record of accurately identifying concerns about the COVID-19 vaccines.

## A Lack of Safety Data in Pregnant Females as Another Example of Why Vaccines Should Not be Mandated

I would like to give another disconcerting safety-related example of why a COVID-19 vaccine mandate could be dangerous. We have pregnant individuals or those who would like to become pregnant on campus. There was a highly publicized study in the prestigious *New England Journal of Medicine* that formed the foundation of declaring COVID-19 vaccines safe in pregnant females (https://www.nejm.org/doi/full/10.1056/nejmoa2104983). The authors of this study declared that there was no risk of increased miscarriage to vaccinated females. This study resulted in

many policies being instituted to promote vaccination of this demographic, for which the bar for safety should be set extremely high. Did you know that this apparent confirmation of safety had to be rescinded recently because the authors performed an obvious mathematical error? I witnessed several of my colleagues from Canada and other countries bravely push for a review of this paper under withering negative pressures. Once the editor finally agreed to do so, the authors had no choice but to admit that made a mathematical error. Most of the world does not realize this. This admission of using an inappropriate mathematical formula can be found here: https://www.nejm.org/doi/full/10.1056/NEJMx210016. This means that **the major rationale for declaring COVID-19 vaccines safe in pregnant females is gone! How can someone force a COVID-19 vaccine on a pregnant female when there are insufficient safety data available to justify it?**

**Advocating for the Vulnerable and Those Fearful of Retribution**

My concern is not primarily for myself. I am using my case to highlight how wrong your vaccine mandate is. I am more concerned for the more vulnerable on our campus. I hold tenure, and if ever there was a time when this was important, it is now. However, I have had to bear witness to numerous horrible situations for students and staff members. Students have been physically escorted off our campus, sometimes being removed from their residence, sometimes with their parents also being escorted off. Staff members have been escorted off campus and immediately sent home on indefinite leaves without pay, leaving them unable to adequately care for their families. In many of these situations it seemed like the interactions intentionally occurred in very public settings with it being made clear to all onlookers that the person or people were not vaccinated. Parents have been denied attending meetings with their children who are entering the first year of a program. They recognize that adult learners would normally not have their parents accompany them, but we are living in unusual times with excessive and unfair (arguably illegal?) pressures being applied and these parents are entitled to advocate and defend the best interests of their sons and daughters. Many students have deferred a year in the desperate hope that our campus community will not be so draconian next year. Others fought hard to earn their way into very competitive programs and are not being guaranteed re-entry next year. Many faculty members refused to offer on-line learning options for those who did not wish to be vaccinated. On the flip-side, there are also faculty members, like many students and staff, who are completely demoralized. This includes some who were happily vaccinated but are upset by the draconian measures of your COVID-19 policies and/or will be unwilling to receive future booster shots. I can tell you many stories of students and staff members who couldn't resist the pressure to get vaccinated because they were losing vast amounts of sleep and experiencing incredible anxiety and were on the verge of mental and/or physical breakdowns. In some of these cases, they were crying uncontrollably before, during, and after their vaccination, which they only agreed to under great duress. This does not represent informed consent! I have had several members of our campus community contact me with concerns that they may have suffered vaccine-induced injuries ranging from blood clots to chest pain to vision problems to unexpected and unusual vaginal bleeding. Can I prove these were due to the vaccine? No. But can anyone prove they were not? No. And it is notable that these are common events reported in adverse event reporting systems around the world. In all cases, the attending physicians refused to report these events, even though it is supposed to be a current legal requirement to do so. These people obediently got vaccinated and were then abandoned when they became cases that did not help sell the current public health messaging.

**A World Where Everyone is Vaccinated Looks Nothing Like Normal**

The two-week lockdown that was supposed to lead into learning to live with SARS-CoV-2 has turned into the most mismanaged crisis in the history of our current generations. I ask you to look around with a very critical eye. You just reported that 99% of the campus community is vaccinated. Congratulations, you have far exceeded the stated standard for what is apparently the new goal of 'herd vaccination'. I cannot use the typical term 'herd immunity' here because immunity is not being recognized as legitimate; only inferred immunity based on receiving two needles counts. We were told that achieving herd immunity by vaccination alone was the solution to this declared pandemic. This has been achieved on our campus in spades. I sat in on our town hall meetings with our local medical officer of health who confidently told us that the risk of breakthrough infections in the vaccinated was almost zero. Why, then are people so petrified of the unvaccinated. Look at vaccines for travellers going to exotic locations.

These are vaccines of some quality. Travellers take these vaccines, and not only do they not avoid the prospective pathogen, but they happily travel to the location where it is endemic (*i.e.* they enthusiastically enter the danger zone because they are protected). So, what does our campus look like with almost every person vaccinated? Everyone must remain masked and physically distanced. There is no gathering or loitering allowed in stairwells or any open spaces in buildings or outside. People are still being told which doors to enter and exit, when they can do so, where to stand in line, when to move. Incredibly, time restrictions are even being implemented in some eating areas because some students were deemed to be "snacking too long" with their masks off and, therefore, putting others at risk of death. In short, the on-campus COVID-19 policies are even more draconian than they were last year, but everyone is vaccinated. It doesn't seem like the vaccines are working very well when a fully vaccinated campus cannot ease up on restrictions. But, of course, we already know how poorly these vaccines are performing. Based on fundamental immunological principles, parenteral administration of these vaccines provides robust enough systemic antibody responses to allow these antibodies to spill over into the lower respiratory tract, which is a common point at which pathogens can enter systemic circulation due to the proximity of blood vessels to facilitate gas exchange. However, they do not provide adequate protection to the upper respiratory tract, like natural infection does, or like an intranasal or aerosolized vaccine likely would. As such, people whose immunity has been conferred by a vaccine only are often protected from the most severe forms of COVID-19 due to protection in the lower lungs, but they are also susceptible to proliferation of the virus in the upper airways, which causes them to shed equivalent quantities of SARS-CoV-2 as those who completely lack immunity. Dampened disease with equal shedding equals a phenotype that approaches that of a classic super-spreader; something that we erroneously labeled healthy children as until the overwhelming scientific evidence, which matches our historical understanding, clarified that this was not the case. I have been in meetings where faculty have demanded to know who the unvaccinated students will be in their classes so they can make them sit at the back of the classroom! I can't believe that some of my colleagues are thinking of resorting to the type of segregation policies that heroes like Viola Desmond, Rosa Parks, Martin Luther King Jr., Carrie M. Best, and Lulu Anderson fought so hard against so many years ago.

**The Exemption Fiasco**

With respect to exemptions for COVID-19 vaccines, the University of Guelph provided a number based on creed or religion but then, remarkably, rescinded these. These previously exempt individuals were required to resubmit applications using a more onerous form; many that had been honoured previously were rejected upon re-submission. Many have been rejected since. Based on the reports I have received from many people these rejections of exemption requests were typically not accompanied by explanations. Nor have many been told, despite asking, who it is that sits on the committee making decisions about these exemptions. I would never be allowed to assign marks to students anonymously, nor without being able to justify them. Yet there seems to be a lack of transparency with exemptions and many of these decisions are destroying people's lives; the outcomes are not trivial. Could you please disclose the names of the people serving on the University of Guelph's committee that reviews exemptions? Also, could this committee please provide to applicants, retroactively, comments to justify their decisions? I have even heard it said in recent meetings that a lot of people are happy to hear that exemptions, including some medical exemptions are being denied. Why are our faculty celebrating refusals of medical exemptions for students?

**A Lack of Consultation with the Experts on Vaccines**

You have stated on numerous occasions that your COVID-19 policies have only been implemented after extensive consultation with local and regional experts. Interestingly, however, you have refused, for some unknown reason, to consult with any of the senior non-administrative immunologists on your campus. I would like to remind you that vaccinology is a sub-discipline of immunology. Notably, all three of us have offered repeatedly to serve on COVID-19 advisory committees, both on-campus and for our local public health unit, which also lacks advanced training in immunology and virology. The three of us have stayed on top of the cutting-edge scientific findings relevant to COVID-19 and meeting regularly with many national and international collaborative groups of scientists and physicians to debate and discuss what we are learning. I think it is notable that the senior non-administrative

immunologists unanimously agree that COVID-19 vaccines should not be mandated for our campus based on extensive, legitimate scientific and safety reasons.

**Mandating COVID-19 Vaccines is Criminal**

I am no legal expert but have consulted with many lawyers who have told me that these vaccine mandates break many existing laws. Here is one example copied from the Criminal Code of Canada:

***Extortion***

- ***346 (1)*** *Every one commits extortion who, without reasonable justification or excuse and with intent to obtain anything, by* ***threats****, accusations, menaces or violence* ***induces or attempts to induce any person****, whether or not he is the person threatened, accused or menaced or to whom violence is shown,* ***to do anything or cause anything to be done****.*

In your case, you are demanding that members of our academic community submit to receiving a COVID-19 vaccine against their will (a medical procedure that may very well be unnecessary and carry enhanced risk of harm) or face banishment from the campus. Again, I am not an expert in this area, but I am confident there will be lawyers willing to test this in court. Those responsible for issuing vaccine mandates will need to decide how confident they are that they will not lose these legal battles.

**Integrity of Teaching**

In this new world where followers of scientific data are vilified, I also worry about my ability to teach with integrity. Unbelievably, the Minister of Health of Canada, Patty Hajdu, told Canadians that vitamin D being a critical and necessary component of the immune system in its ability to clear intracellular pathogens like SARS-CoV-2 is fake news! Do you now that I have taught all my students about the importance of vitamin D (often in the historical context of how it was discovered as being critical for positive outcomes in patients with tuberculosis that were quarantined in sanatoriums). I also teach the concept of herd immunity, with vaccination being a valuable tool to achieve this. I do not teach the concept of 'herd vaccination' while promoting ignorance of natural immunity. There are other basic immunological principles that I teach that have either not been recognized during the pandemic as legitimate scientific principles or they have been altogether contradicted by public health and/or government officials. Will I still be allowed to teach immunology according to the decades of scientific information that I have built my course upon? Or will I be disciplined for teaching immunological facts? There are many attempts to regulate what I can and cannot say these days, so these are serious questions.

**Instilling Fear of a Minority Group Breeds Hatred**

We live in an era where issues of equity, diversity, and inclusion are supposed to be at the forefront of all discussions at academic institutions. However, you are openly discriminating against and excluding a subset of our community that happens to be highly enriched with people engendered with critical thinking; a quality that we are supposed to be nurturing and promoting. With COVID-19 mandates, an environment has been created on our university campus that promotes hatred, bullying, segregation, and fear of a minority group whose only wrongdoing has been to maintain critical thinking and decision-making that is based on facts and common sense. I have yet to meet an anti-vaxxer on our campus. Everyone I know of is simply against the mismanagement of exceptionally poor-quality COVID-19 vaccines. History tells us that instilling fear of a minority group never ends well. This scenario must be rectified immediately if our campus is ever to return to a safe and secure working and learning environment for all.

## Committing to Abolishing the COVID-19 Vaccine Mandate

President Yates, **the favour of a reply is requested**. Not the kind that defers to public health officials, or a committee, or anyone else. Instead, a reply with the scientific rigour expected from a scholarly colleague rebutting each of my comments and addressing each question. Surely, you know the science underpinning COVID-19 vaccines inside and out by now. I strongly suspect that nobody would made a decision that disrupts an entire community and destroys the lives of some of its members without a fully developed rationale that can point to the weight of the peer-reviewed scientific literature to back it up. If it would be easier, I would be happy to have an open and respectful, but public and blunt moderated conversation about your vaccine mandate in front of our campus community; much like in the spirit of old-fashioned, healthy scientific debates. You can have your scientific and medical advisors attend and I will invite an equal number. I am not saying this to be challenging. I honestly think it would be a great way to educate our campus community and expose them to the full spectrum of the science. And, if I am as wrong as my 'fact checkers' say, I would love for them to demonstrate this for my own sake as much as anyone else's. So far, despite hundreds of invitations, not one person has done this in a scenario where I can respond in real-time. You need to understand; all I want is my life back and to be able to recognize my country again. I want to see the lives of the students, staff, and other faculty members that I have seen destroyed be restored again. I want to be able to return to my workplace and not be fearful of being hated or exposed to social, mental, and physical bullying. Instead, I want to be able to turn my talents and full attention back to being an academic public servant who can design better ways to treat diseases and help train Canada's next generation of scientific and medical leaders. I simply cannot know all that I have shared in this letter and have suffered as much as I have and be silent about it. My great uncles and family members before them served heroically in the World Wars to ensure Canada would remain a great and free democracy. I think they would be horrified by what they see in Canada today. Indeed, many of my friends who immigrated from Communist countries or countries run by dictatorships are sharing fears about the direction our country is heading; it is reminding them of what they fled from. Further, mandating COVID-19 sets a scary precedent. Did you know that multiplex tests for both SARS-CoV-2 and influenza viruses are on the horizon, along with dual-purpose vaccines that will use the same mRNA-based technology to simultaneously target SARS-CoV-2 and influenza viruses (https://www.ctvnews.ca/health/coronavirus/moderna-developing-single-dose-covid-19-flu-combo-vaccine-1.5578445). Rhetorically, will the University of Guelph consider masking, distancing, and/or mandating vaccines for influenza in the future? **Please rescind your COVID-19 vaccine mandate immediately**. **It is doing more harm than good**. **Unbelievably, among many other problems, it is even discriminating against those who can prove they are immune to SARS-CoV-2!**

## Mandating COVID-19 Vaccines Creates Absurd Situations

In closing, and to highlight the absurdity of mandating COVID-19 vaccines...
President Yates, I have proven to you that I am immune to SARS-CoV-2, but you have banned me from the campus and ruined my life because I don't have a piece of paper saying that someone saw two needles go into my shoulder. You have a piece of paper that says that someone saw two needles go into your shoulder, but you have not proven that you are immune to SARS-CoV-2. However, you are allowed on campus and your life can proceed uninterrupted. **How is that fair?**

Respectfully and in the mutual interest of the health and well-being of **all** members of our community,

Byram W Bridle

Dr. Byram W. Bridle, PhD
Associate Professor of Viral Immunology
Department of Pathobiology
University of Guelph

# Exhibit "X"

# How The Body Reacts To Viruses

Learn with Harvard Medical School faculty about how the body fights disease.

We live in a microbial world, which means that we constantly encounter microorganisms that could harm our health. The human immune system continuously defends us against these threats to our survival. Understanding how immunity works is important for making sense of the news around the risk, spread, and treatment of diseases like COVID-19 (also known as coronavirus disease).

In this curated selection of videos and interactive materials from HMX Immunology courses, you'll learn about the processes that enable our immune system to respond to microbial threats.

**Please note:** *HMX online courses in immunology are primarily designed for those working in areas related to health care and the immune system, including diagnostics and treatments. Given the current situation, we've decided to make relevant material available to all. We understand that not everyone may have the appropriate background, and*

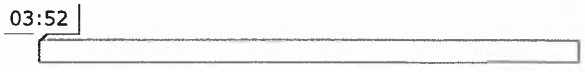
This is Exhibit " X " referred to in the Affidavit of
Dr. Blaine Achen
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

*we encourage you to use other resources as needed to understand any unfamiliar terms and get the most from this material.*

# Topics

## An Immune System for our Microbial World

In this video, you will see a high-level overview of the immune system at work in the context of daily life. What is seen here equally applies to transmission and the body's reaction to a coronavirus. The immune system mounts a response against pathogens as they infect an individual and replicate. The response includes both an immediate innate response and a slower adaptive response, which are explained in greater detail in the following sequence. This video features HMX Fundamentals Immunology faculty member Andrew Lichtman of Harvard Medical School.




## Introduction to the Innate Immune Response

The innate immune response forms the first line of defense against invading pathogens. Innate immunity includes barriers and a variety of cells and molecules that are part of the

rapid response to threats to our health. In this interactive you will be introduced to the various aspects of the innate immune response and the ways in which they work together to prevent and control infection. While the immune system protects us from many pathogens, the inflammation that occurs as part of the immune response can also damage our own tissues and impair the function of our organs when pathogens stimulate a very strong response.

HMX

## Innate Immune Responses to Microbes

Now that you understand the basics of how the innate immune response works, you're ready to look at an example. In this interactive, you will learn how the innate immune response acts against an invading pathogen. Innate immunity can help protect us from a variety of pathogens, including the coronavirus that causes COVID-19, though the specifics and the efficacy of the response can differ depending on the type of pathogen.

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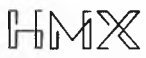
## Introduction to B Cells and Antibodies

While the innate immune response is able to prevent or control some infections, it is limited in the ways in which it can react. The adaptive immune response, which includes both B cell-based humoral immunity and T cell-based cellular immunity, reacts much more specifically and powerfully to invading pathogens. B cells produce antibodies that help to control microbial invasion in a variety of ways, as described in this interactive.




## B Cell Responses to Bacteria

With your new knowledge about antibodies, you are ready to see an example of the B cell response in action. In this interactive, the reaction of B cells to an invading pathogen is shown, including how the antibody response arises and how it is able to control the infection. While the response to a bacterial protein is shown, the steps necessary to act against viruses such as the coronavirus that causes COVID-19 are very similar. Antibody responses are the main way in which vaccines protect us from infection by a variety of viruses, and the absence of protective antibodies contributes to the rapid spread

of new viruses in previously unexposed and unvaccinated populations.

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## What Do T Cells See?

The antibodies produced by B cells form part of the adaptive immune response and can recognize almost any molecule that might invade the body. In addition, there is a second branch to the adaptive immune system called cellular immunity. T cells form the basis of cellular immunity and can very specifically kill cells that have been infected by viruses. This video compares the two branches of the adaptive immune response, with a particular emphasis on the antiviral effects of T cells. This video features HMX Fundamentals Immunology faculty member Shiv Pillai of Harvard Medical School.

## Introduction to the T Cell Response

T cells form the second branch of the adaptive immune response. Unlike B cells, the receptors on T cells are only able to recognize protein fragments displayed on specific cell surface molecules. In this interactive, you will learn about the different types of T cells, including cytotoxic T cells that kill infected cells and helper T cells that increase the activation of other immune cells.

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## T Cell Responses to Viral Infections

While the innate immune and B cell responses are effective against a wide variety of pathogens, T cells can respond very specifically to intracellular pathogens, such as viruses. In this interactive, you will walk through an example of a T cell response to a viral invasion, as would occur in the case of COVID-19.

HMX

Looking for a more in-depth online learning experience? Our foundational immunology course covers key concepts in the field. If you'd like to understand the latest developments in protecting against viral infections, consider our advanced course on vaccines and viral immunology.

HMX Fundamentals Immunology instructors Andrew Lichtman and Shiv Pillai have also shared their thoughts about the importance of understanding immunology and what the science tells us about reducing transmission of SARS-CoV-2.

Looking for more information specific to the coronavirus? Please see the Coronavirus Resource Center from Harvard Health Publishing.

# Exhibit "Y"

This is Exhibit " Y " referred to in the Affidavit of Dr. Bhinder Achen

Sworn before me this 7th day of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

**FREEDOM OF INFORMATION ACT REQUEST**

**VIA ONLINE PORTAL**

September 2, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

*Re: COVID-19 Reinfection and Transmission (IR# 0552)*

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

> **Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of its mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through its website, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents

in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN of course reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

*/s/ Gabrielle G. Palmer*
Gabrielle G. Palmer, Esq.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 05, 2021

***SENT VIA EMAIL***

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
[redacted]

***2nd Letter Subject: Final Response Letter***

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 02, 2021, Freedom of Information Act (FOIA) request on September 02, 2021, seeking:

> "Documents reflecting any documented case of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected."

A search of our records failed to reveal any documents pertaining to your request. The CDC Emergency Operations Center (EOC) conveyed that this information is not collected.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by February 03, 2022.

Sincerely,

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

This is Exhibit " " referred to in the Affidavit of

.....

Sworn before me this .....day

of .....A.D.....

.....

A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta

#21-02152-FOIA

# Exhibit "Z"

This is Exhibit " 2 " referred to in the Affidavit of
D. Blaine Archer
Sworn before me this 7th day
of December A.D. 2021
A Notary Public, A Commissioner for Oaths
in and for the Province of Alberta
Eva Chipiuk
Barrister & Solicitor

OPINION

# SELICK: AHS says it has no documents for its policy of disregarding natural immunity

The firefighters believe once they've recovered from COVID-19, they've got broad and long-lasting immunity — possibly even s imparted by the vaccine.



Published 1 week ago on November 29, 2021
By **Karen Selick**


SELICK: AHS says it has no documents for its policy of disregarding natural immunity

Freedom of Information (FOI) requests have long been a useful tool for journalists, lawyers, and ordinary citizens to gain access to documents the government might prefer them not to see.

Sometimes, however, there is even greater value in finding out the government doesn't have a single document in its possession to back up what it's doing.

A case in point is the recent FOI request sent to Alberta Health Services by lawyer Derek From. From is counsel for several Alberta firefighters and paramedics who wish to decline, for various reasons, mandatory COVID-19 vaccination. Their application challenging the constitutionality

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of Alberta Health Services (AHS) policy will be filed in the Court of Queen's Bench



Some of the firefighters have already acquired natural immunity to COVID-19 by virtue of having been sick with the illness and then recovering from it. However, the AHS document entitled *Immunization of Workers for COVID-19 Policy 1189*, makes no reference whatsoever to individuals with this medical history. Like everyone else, they are required to be "fully vaccinated" by November 30 or lose their jobs.

The firefighters believe once they've recovered from COVID-19, they've got broad and long-lasting immunity — possibly even superior to that imparted by the vaccine. They're therefore extremely unlikely to get COVID-19 again for a long time, and consequently wouldn't be able to spread it to anyone else. They argue they've never seen any evidence indicating an unvaccinated person who has recovered from COVID-19 can actually spread the virus.

Therefore, they wanted to know exactly what evidence AHS relied upon when preparing its policy. AHS seemed to presume people with natural immunity could pose a danger to others, but did it have any facts to back up that presumption?

Lawyer From submitted a Freedom of Information request on November 21 asking for "all records of the scientific evidence that AHS relied upon in the development of the policy."

The answer came back within a few days: after conducting a comprehensive search, AHS could find no such records in its possession.

There must be thousands of Albertans by now who are in the same position as the firefighters, having recovered from COVID-19. AHS has never even investigated whether there's any need for them to be vaccinated. It appears to be oblivious to their condition, their concerns and their wellbeing.

What's worse is emerging evidence shows people who've developed natural immunity are more likely than other people to experience adverse reactions to vaccination, just as vaccinated individuals are more likely to experience adverse reactions after two doses than after one. The AHS policy of mandatory vaccination therefore puts those with natural immunity at greater risk than the rest of the population, when they are in fact the people who pose the least threat to others.

It must be apparent to AHS executives that their policy arguably infringes on the constitutional rights of individuals to life, liberty and security of the person under Sec. 7 of the Charter of Rights and Freedoms. They must know they will be called upon eventually to justify their policy under Sec. 1 of the Charter — in other words, to show the policy is "demonstrably justified in a free and democratic society."

But their cupboard is bare. They don't possess a single document showing the necessity of vaccinating people who have natural immunity, if their response to the Freedom of Information request can be believed.

In other words, the policy is a huge bluff on the part of AHS — a despicable pantomime acted out for some unknown purpose, that will wreak havoc on the lives of thousands of Albertans as they scramble to replace their jobs and income, and simultaneously to bring their constitutional challenges before the courts. AHS displays shocking arrogance in continuing to inflict such burdens on the province's residents when it must know that the policy will likely, eventually, be found unconstitutional.

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Left Coast on **Committee sl spending plans**

**Art Betke** on **MAKICHUK: TI only a matter of time**

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SHAR

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Western Standard

The AHS is headed up by Chief Executive Officer Dr. Verna Yiu, who reports to a board, which



In my view, they are failing on several counts.

Fire them all.

***Karen Selick is a columnist for the Western Standard***

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# Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination.

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## Key Points

***Question:*** Does previous COVID-19 infection or 'Long-COVID' increase the frequency of Adverse Events (AEs) following first dose of BNT162b2/Pfizer vaccination?

***Findings***: In a survey-based observational study, healthcare workers in the United Kingdom reported AEs experienced after their first dose of BNT162b2/Pfizer vaccine. Prior COVID-19 infection, but not Long-COVID, were associated with increased risk of self-reported AEs including lymphadenopathy post-vaccination. Duration since COVID-19 infection did not affect severity of AEs.

***Meaning:*** Our study can inform education and understanding of AEs associated with COVID-19 vaccination and help to combat vaccine hesitancy.

**Abstract**

***Importance***: Understanding Adverse Events (AEs) associated with SARS-CoV-2 vaccination has public health implications, especially with regards to vaccine hesitancy.

***Objective***: To establish whether individuals with prior history of COVID-19 were more likely to experience AEs after BNT162b2/Pfizer vaccination, than those without previous COVID-19, and whether COVID-19-vaccination interval influenced AE severity.

***Design***: An observational study explored AEs after vaccination. Participants were invited to complete an electronic survey, capturing self-reported COVID-19 symptoms, PCR/antibody results, and AEs following first dose of BNT162b2/Pfizer vaccine. In a subset where PCR/antibody results could be verified, a sensitivity analysis was conducted.

***Setting:*** Three North-East England hospital Trusts in the United Kingdom.

***Participants***: Healthcare workers formed an opportunistic sample – 265 of 974 reported prior positive SARS-CoV-2 PCR and/or antibody.

***Exposure:*** All participants had received their first dose of BNT162b2/Pfizer vaccine.

***Main Outcomes and Measures:*** Nature, severity, duration, and onset of self-reported AEs (reported via a modified version of the FDA Toxicity Grading Scale for vaccine-associated AEs), was compared between those with and without a prior history of COVID-19, using 2-way ANCOVA and logistic regression. Effects of age, gender, illness-vaccine interval, and ongoing symptoms ('Long-COVID') on AEs, were also explored.

***Results:*** Of 974 respondents (81% female, mean age 48), 265 (27%) reported previous COVID-19 infection. Within this group (symptoms median 8.9 months pre-vaccination), 30 (11%) complained of Long-COVID. The proportion reporting one moderate/severe symptom was higher in the previous COVID-19 group (56% v 47%, OR=1.5 [95%CI, 1.1–2.0], p=.009), with fever, fatigue, myalgia-arthralgia and lymphadenopathy significantly more common. There was no significant relationship between illness-vaccine interval and symptom composite score ($r_s$=0.09, p=.44). Long-COVID was not associated with worse AEs in

comparison to the group without previous COVID-19. In the smaller sensitivity analysis cohort (412 people) similar findings were obtained although only myalgia and arthralgia remained significant.

***Conclusions and Relevance***: Prior COVID-19 infection but not ongoing Long-COVID symptoms were associated with an increase in the risk of self-reported adverse events following BNT162b2/Pfizer vaccination. COVID-19 illness-vaccination interval did not significantly influence AEs. This data can support education around vaccine-associated AEs and, through improved understanding, help to combat vaccine hesitancy.

## Introduction

The BNT162b2/Pfizer and mRNA-1273/Moderna COVID-19 vaccines[1,2] were recently approved for use in the UK, with the former widely used amongst priority groups. While safety profiles were deemed acceptable (following phase 3 trials), participants with previous COVID-19 infection were excluded. Recent evidence suggests mRNA vaccines may cause more Adverse Events (AEs) in those with a history of COVID-19.[3-5] A small study found that AEs reported after the first dose of mRNA vaccine in seropositive individuals, were greater than in those with no prior COVID-19.[3] The 'ZOE COVID-19 Symptom Study' also observed similar outcomes via a self-reporting app.[4] Most recently in a larger study, 532 out of 2002 participants with prior COVID-19 reported increased (mostly systemic) AEs after either an mRNA or vector-based (AZD1222/AstraZeneca) vaccine.[5]

These preliminary studies suggest a need for further investigation into the effect of prior COVID-19 history on vaccine-related AEs. Consideration of whether time between previous infection and vaccination administration or the presence of 'Long-COVID'[6-8] can predict AEs, is also warranted. This information is important, as it could assist in identifying individuals who are more likely to experience side effects to COVID-19 vaccines. Furthermore, there are public health implications with regards to vaccine hesitancy, which is somewhat driven by fear of AEs.[9-11] As part of a longitudinal observational study of COVID-19 in healthcare workers in North-East England, we evaluated AEs following first doses of BNT162b2/Pfizer vaccine, with particular reference to previous COVID-19 and Long-COVID.

## Method

National Health Service (NHS) workers (employed by 3 North-East Trusts in the UK) completed an electronic survey on AEs following COVID-19 vaccination. The survey captured self-reported COVID-19 symptoms, PCR/antibody results, and AEs following the first dose. The FDA Toxicity Grading Scale[12] (with simplified language) was modified allowing participants to self-report AEs for severity (mild/moderate/severe/very severe),

duration (≤24 hours/>24 hours) and onset (≤24 hours/>24 hours); lymphadenopathy was included as an additional symptom.

A composite score for symptom nature and severity was calculated, to provide an overall estimate of AE-related morbidity, for the former by adding number of moderate/severe symptoms, and the latter by multiplying this by symptom duration. Individual and composite AE scores were compared between those with and without a prior history of COVID-19, as indicated by self-reported prior positive antibody and/or PCR result. Long-COVID was defined as symptoms persisting >2 months to vaccination. Effects of age, gender and time between past infection to vaccination were also considered.

Respondents who had permitted laboratory results to be accessed (SARS-CoV-2 PCR and antibody), formed a subgroup for sensitivity analysis. Statistical analysis was carried out using JASP v0.14.1.0. Composite scores were compared using 2-way ANCOVA. Multivariable logistic regressions were performed to identify the relationship between COVID-19 status and the presence of moderate/severe symptoms in each category, and the Bonferroni correction applied to the resulting significance and confidence intervals. The study was approved by Cambridge East Research Ethics Committee.

## Results

Of 974 healthcare workers (aged 19-72-years) responding to the survey and providing complete data for analysis, 265 (27%) participants (84% female, mean age 48.9) reported a prior positive PCR and/or antibody result, and 709 (80% female, mean age 47.0) had no COVID-19 history. Within the previous COVID-19 group (symptoms median 8.9 months

before vaccination), 30 (83% female, mean age 48.8) complained of Long-COVID (median duration 9.3 months, range 2.8–10.4).

Figure 1A shows frequencies of each symptom by COVID-19 status. The proportion of participants reporting at least one moderate-to-severe symptom was higher in the previous COVID-19 group (56% v 47%, OR=1.5 [95%CI, 1.1–2.0], p=.009). Symptom onset was mostly within 24 hours (75%) with no onset >48 hours. Number and total duration of reported symptoms was greater in women (1.24 (1.67) v 0.84 (1.46) symptoms, d=0.25 [0.09–0.42], p=.002; 2.10 (2.99) v 1.39 (2.54) symptom-days, d=0.22 [0.09–0.42], p=.001) and significantly decreased with age (symptoms: $r_s$=-0.25, p<.001; symptom-days: $r_s$=-0.24, p<.001). After controlling for age and sex, higher symptom number (1.61 (2.26) v 0.89 (2.02) symptoms, d=0.34 [0.20-0.49], p<.001) and severity (2.7 (6.65) v 1.5 (2.21) symptom-days, d=0.41 [0.27-0.55], p<.001) were significantly associated with reporting previous COVID-19.

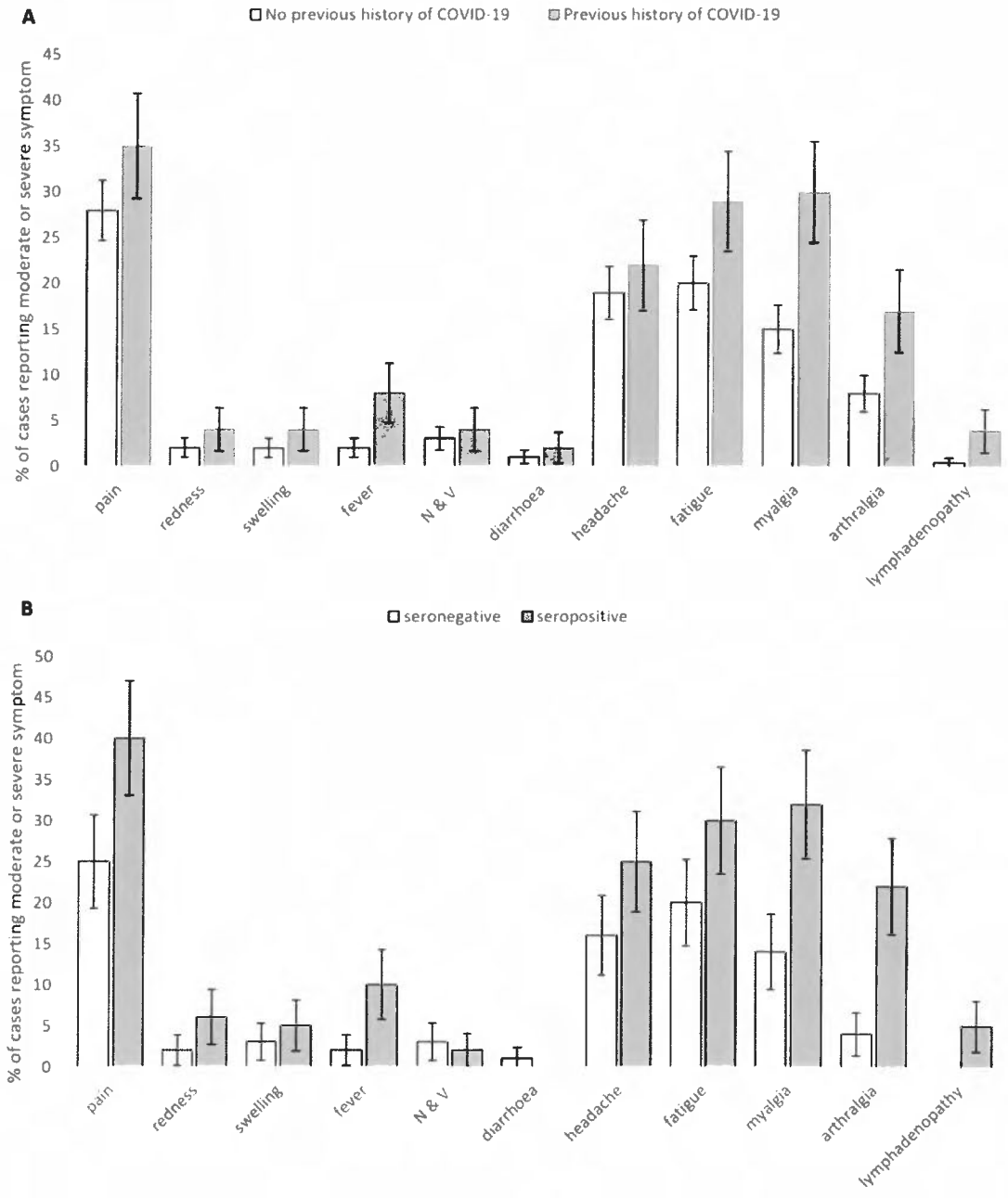


**Figure 1**. ***Moderate and Severe Symptoms by COVID-19 Status***: Percentage of cases reporting moderate or severe symptoms (95% CI) in those with and without a history of COVID-19. N & V: nausea and vomiting. Upper panel (A): entire cohort; lower panel (B): sensitivity analysis subset

Logistic regressions (Table 1) controlling for age and sex showed five systemic symptoms were significantly associated with previous COVID-19 status: fever, fatigue, myalgia, arthralgia and lymphadenopathy. Arthralgia was regularly co-reported with myalgia (87 cases) but rarely alone and was not independently associated (OR 1.4 [95%CI 0.86–2.37], p=0.49) with COVID-19 exposure once myalgia was controlled for. Neither local nor gastrointestinal symptoms were significantly associated with previous COVID-19 history.

| | **Whole cohort** | | **Sensitivity Analysis Subset** | |
|---|---|---|---|---|
| | Odds Ratio (95% C.I.) | p | Odds Ratio (95% C.I.) | p |
| Fever | 2.87 (1.10 – 7.51) | .044 | 5.68 (0.69 – 46.65) | .32 |
| Fatigue | 1.78 (1.12 – 2.84) | .011 | 2.17 (0.85– 5.54) | .31 |
| Myalgia | 2.34 (1.44 – 3.88) | <.001 | 3.18 (1.16 – 8.69) | .02 |
| Arthralgia | 2.25 (1.23 – 4.12) | .004 | 7.06 (2.05 – 36.91) | .01 |
| Lymphadenopathy | 5.18 (1.19 – 22.63) | .033 | **** | **** |
| Local Pain | 1.55 (0.99 – 2.40) | .09 | 2.28 (0.96 – 5.43) | .11 |
| Local Redness | 2.93 (0.84 – 10.20) | .24 | 3.92 (0.43 – 35.79) | >.99 |
| Local Swelling | 2.0 (0.64 – 6.27) | .14 | 2.1 (0.29 – 15.33) | >.99 |
| N & V | 1.47 (0.48 – 4.42) | >.99 | 0.72 (0.05 – 8.81) | >.99 |
| Diarrhoea | 2.35 (0.30 – 18.25) | >.99 | **** | **** |
| Headache | 1.31 (0.80 – 2.15) | >.99 | 1.78 (0.65 – 4.83) | >.99 |

**** No model could be calculated due to absence of cases in this cohort. In all cases age and gender were included in the null model as nuisance variables. Adjusted P values and adjusted confidence intervals corrected (Bonferroni) for 11 outcomes in each case.

**Table 1.** ***Results of Logistic Regression Analyses***: Logistic regressions showing those symptoms significantly predicted by previous history of COVID-19 after controlling for differences in age and gender and with p values and confidence intervals corrected (Bonferroni) for multiple comparisons.

Symptom number and duration was not significantly higher in those with Long-COVID after accounting for gender and age effects and no individual symptom was significantly associated with this condition. Importantly, among those with prior COVID-19, there was no significant relationship between illness-vaccine time interval and either composite score ($r_s$=0.09 p=.44 for symptoms; $r_s$=0.10, p=.42 for symptom–days) nor any difference in mean time interval based on presence of any of the symptoms (all p>0.05).

For the sensitivity analysis, 412 participants had verified PCR/antibody results. Of this subgroup, 228 (55%) were PCR/antibody negative (80% female, mean (SD) age 47.0 [11.1]) and 184 (45%) PCR or antibody positive (91% female, mean (SD) age 47.3 [11.5]). Nine (5%) complained of Long-COVID (range 2.8–10.4 months). The pattern of results was broadly replicated in this subgroup analysis (Figure 1B), with more previous-COVID-19 individuals reporting at least one moderate symptom (63% v 43%, OR=2.2 [1.2–4.0], p=.006) and previous-COVID-19 being associated with higher symptom number (1.81 (3.09) v 0.85 (4.12) symptoms, d=0.25 [0.05–0.44] p=.012) and severity (3.0 (8.3) v 1.5 (5.6) symptom days d=0.2 [95% CI 0.02–0.41], p=.0350). Only myalgia and arthralgia remain as significant outcomes once multiple comparisons were controlled for though pattern of outcomes remains similar.

## Discussion

This study of healthcare workers demonstrated that prior COVID-19 infection, but not Long-COVID, is associated with increased risk of AEs including lymphadenopathy following BNT162b2/Pfizer vaccination, although there was no relationship with duration since COVID-19 illness. Women and younger individuals were also more likely to experience vaccine-related AEs. Our findings add to other reports supporting wider understanding of AEs following COVID-19 vaccination.[3-5] Importantly, given the hesitancy surrounding COVID-19

vaccination,[9-11] our findings may help inform those with previous COVID-19, including Long-COVID, of increased susceptibility to certain AEs. Our study also adds weight to the question of whether a second dose of mRNA vaccine is necessary in those with previous COVID-19, assuming effective immunity is established after the first dose.[3,14] This is relevant, given that another study has suggested worse AEs following the second dose.[5]

Our study has several limitations. Firstly, some non-responder bias[13] is likely, with 27% of participants reporting previous COVID-19. This is slightly higher than in UK healthcare workers.[15] Nevertheless, the sample was broadly representative of UK healthcare employees and likely generalizable. Secondly, information on AEs was gathered via self-reported questionnaires, and hence subjective. Thirdly, PCR and antibody results were self-reported. We addressed this via a sensitivity analysis on a subset of participants with laboratory data available, which mostly confirmed the findings in the entire sample. Finally, the numbers with Long-COVID were relative small for comparison.

In conclusion, this large study shows an association of previous COVID-19 with increased AEs and will help those with previous COVID-19 infection understand better what to expect following vaccination.

## Author Contributions

DRC/CK/RKR conceived the study and DRC is chief investigator of CHOIS. RKR acted as site principal investigator. DRC/RKR/CW contributed to the study protocol, design, and data collection. JR/RKR/DRC did the statistical analysis. RKR/JR/DRC prepared the manuscript. All authors critically reviewed and approved the final version.

## Declarations of Interest

No conflicts of interest.

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**Brief report**

# Self-reported real-world safety and reactogenicity of COVID-19 vaccines:

# An international vaccine-recipient survey.

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MG, AU, SA, LP, DP

**Authors contribution:** Study conception: NDB and MG, Study design: AGM, MG, SA, RB, AU, NDB. Distribution of the survey: All authors. Data analysis: AGM, NDB. Manuscript drafting: AGM, NDB. Critical revision: All authors. Approval of the final manuscript: All authors.

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**Abstract**

**Background:** The safety of COVID-19 vaccines has been demonstrated in selected populations in recent studies, but more data in specific groups is needed to inform vaccine choice and health policy.

**Objectives:** An international, online survey was conducted to compare the safety, tolerability and reactogenicity of available COVID-19 vaccines in different recipient groups.

**Methods:** This survey was launched in February 2021, for 11 days. Recipients of a first COVID-19 vaccine dose ≥7 days prior to survey completion were eligible. The incidence and severity of vaccination side effects were assessed.

**Results:** Survey was completed by 2,002 respondents, of whom 26.6% had prior COVID-19 infection (68.8% laboratory confirmed). Prior COVID-19 infection was associated with increased risk of any side effect (risk ratio 1.08, 95% confidence intervals [1.05-1.11]), fever (2.24 [1.86-2.70]), breathlessness (2.05 [1.28-3.29]), flu-like illness (1.78 [1.51-2.10]), fatigue (1.34 [1.20-1.49]) and local reactions (1.10 [1.06-1.15]). It was also associated with increased risk of severe side effects, leading to hospital care (1.56 [1.14-2.12]).

While mRNA vaccines were associated with a higher incidence of any side effect (1.06 [1.01-1.11]) compared to viral vector-based vaccines, these were generally milder ($p<0.001$), mostly local reactions. Importantly, mRNA vaccine-recipients reported considerably lower incidence of systemic reactions (RR<0.6) including anaphylaxis, swelling, flu-like illness, breathlessness and fatigue, and of side effects requiring hospital care (0.42 [0.31-0.58]).

**Conclusion:** For the first time, our study links prior COVID-19 illness with increased incidence of vaccination side effects and demonstrates that mRNA vaccines cause milder, less frequent systemic side effects, but more local reactions.

**Key messages:**

- People with prior COVID-19 illness appear to experience significantly increased incidence and severity of side effects after receiving the COVID-19 vaccine.
- In this first head-to-head comparison of the safety and reactogenicity of different types of vaccines, it was demonstrated that mRNA vaccines cause milder, less frequent systemic side effects, compared to viral vector vaccines, but more local reactions.

**Tweetable Summary:** A survey of >2000 COVID-19 vaccine-recipients links prior COVID-19 illness with increased incidence of vaccination side effects; mRNA vaccines cause milder, less frequent systemic side effects, but more local reactions.

**Keywords:** Coronavirus disease 2019, COVID-19, COVID-19 vaccine, safety, adverse events

## Introduction

Coronavirus Disease 2019 (COVID-19) rapidly became a leading cause of death, short and long-term morbidity among people over the age of 45[1,2], posing an unprecedented burden to healthcare systems, with worldwide economic consequences and prolonged lockdowns[3]. Vaccines currently being rolled out are anticipated to significantly modify these trends. While their effectiveness and safety have been proven in recent studies[4,5,6], data in specific groups remains lacking. Generally, people with a previous history of COVID-19, in whom vaccination is currently advised[7], were excluded from the clinical trials[4,5,6]. Whilst it is accepted that prior infection with COVID-19 induces natural immunity potentially lasting for at least six months[8], yet it is unknown if previous infection may be associated with more vaccination side effects. Moreover, the safety and reactogenicity of the different types of vaccines (mRNA or viral vector-based) have not been compared head-to-head. This anonymized international online survey was conducted to compare the safety profiles of available COVID-19 vaccines and evaluate their side effects in different groups of vaccine recipients.

## Methods

This online survey, developed in plain English language and piloted by experts and lay people, captured basic epidemiological data, details on COVID-19 exposure, vaccination history, the incidence and severity (table e1) of the respective side effects. More specifically, we have enquired about the following symptoms: Localized reactions (pain, swelling, tenderness, redness, itching or other), fever, skin rash, shortness of breath, tingling in the mouth, face, body / extremities, swelling in the face or mouth, generalized swelling, anaphylaxis (severe allergic reaction with face swelling and breathlessness), tiredness or fatigue, flu-like illness, or any other side effects. It was launched via Google Forms on 3rd February 2021, for 11 days, and was shared within the investigators' institutions, through professional contacts and social media. The only inclusion criterion was the receipt of the first dose of any COVID-19 vaccine at least 7 days prior to survey completion.

The main objectives were to evaluate differences in the incidence and severity of vaccination side effects among (i) people with versus without previously reported COVID-19 infection and (ii) those who received different vaccine types. Moreover, we explored differences in self-reported side effects between the first and second vaccine dose, among different ethnicities and among those with different preconceptions towards the vaccine. Finally, we explored the impact of the interval between COVID-19 exposure and vaccination and the incidence of side effects.

For our main analysis, a positive COVID-19 history was considered in cases of (a) a self-reported history of symptoms consistent with COVID-19 disease, provided that COVID-19 was not excluded by a negative PCR test, (b) a positive COVID-19 PCR test, or (c) a positive COVID-19 antigen test. In a sensitivity analysis, COVID-19 infection was only considered valid if it was confirmed by PCR or antigen testing, while patients with uncertain exposure (clinical history not confirmed by laboratory testing) were excluded.

Between-group differences were assessed using chi-squared and Mann-Whitney U tests for dichotomous and continuous variables, respectively, after Shapiro-Wilk test excluded normal distribution of the latter. Between group differences in the incidence of side effects are presented as risk ratios (RR) with the respective 95% confidence intervals (CI). Predictors of the incidence and severity of side effects were evaluated in univariate, followed by multivariate binomial logistic regression and cumulative link models for ordinal data, respectively. Age, gender, ethnicity, vaccine type, prophylactic analgesia or other medication use prior to vaccination, vaccine preconceptions, and prior COVID-19 exposure were evaluated as potential confounding factors. Unless otherwise specified, the analyses were based on side effect profiles from the first dose of the vaccine.

Ethics approval was not necessary for this anonymized survey.

**Results**

Within 11 days, this international online survey was completed by 2,002 participants (table e2, figure e1), mostly health professionals of a working age (median: 45, IQR: 35-50 years). 532 (26.6%) had history of previous COVID-19 infection, of whom 366 (68.8%) were confirmed by PCR (n=273) and/or antigen testing (n=162). COVID-19 infection preceded the first vaccination dose by a median of 87 [IQR: 47-223] days. The majority of respondents were Caucasians (88.3%), mostly from the UK (78.6%) and Greece (16.6%). As anticipated, prior history of COVID-19 infection was more prevalent among frontline workers, health professionals and people from the UK, where a very high incidence of COVID-19 was documented[9]. Moreover, recipients of a viral vector-based vaccine (mainly the AstraZeneca vaccine) were relatively older (figure e2, $p<0.001$) and were mostly based in the UK (89.7%, compared to 76.4% of those that received viral mRNA vaccines, $p<0.001$). Finally, doctors were more likely to have received mRNA based vaccine compared to the other groups ($p<0.001$).

Prior COVID-19 infection was associated with a 8% increase in the risk of having any side effects after the first vaccine dose (RR 1.08, 95% CI [1.05-1.11], table 1, figure 1). We also observed significantly increased risk of self-reported fever (2.24 [1.86-2.70]), breathlessness (2.05 [1.28-3.29]), flu-like illness (1.78 [1.51-2.10]), fatigue (1.34 [1.2-1.49]), local reactions (1.10 [1.06-1.15]) and "other" side effects (1.46 [1.16-1.82]). Among those experiencing side effects, prior COVID-19 infection was associated with increased severity of any side effect, local side effects, or fatigue ($p<0.001$). More importantly, prior COVID-19 infection was associated with the risk of experiencing a severe side effect, requiring hospital care (1.56 [1.14-2.12]). These observations remained significant in multivariate analyses and our sensitivity analysis (table e3). A similar increase in the risk of any side effects following the second dose in those with prior COVID-19 infection was also noted (1.08 [1.05-1.11]), although the lack of significant associations with specific side effects may result from the limited sample included in this analysis.

Furthermore, significant differences were observed between the side effect profiles of mRNA versus viral vector vaccines (predominantly Pfizer versus AstraZeneca, table 2, figure 2). Overall, recipients

of mRNA vaccines reported a higher incidence of any self-reported side effects (1.06 [1.01-1.11]), which however were of significantly milder severity, compared to those who received viral vector vaccines. While mRNA vaccines were associated with an increased incidence of reported local reactions (1.29 [1.19-1.40]), they were associated with considerably lower incidence of self-reported systemic side effects including anaphylaxis (0.19 [0.04-0.62]), fever (0.28 [0.24-0.34]), swelling in the face or mouth (0.29 [0.10-0.80]) or generalized swelling (0.29 [0.15-0.56]), flu-like illness (0.34 [0.29-0.40]), breathlessness (0.43 [0.26-0.70]), fatigue (0.56 [0.51-0.62]) or other side effects (0.67 [0.52-0.86]). These observations were corroborated by multivariate analyses. Most importantly, mRNA vaccines were associated with a significantly lower incidence of severe side effects (requiring hospital care, RR 0.42 [0.31-0.58]).

In general, the second dose of the vaccine was associated with higher incidence of side effects (table 3). More specifically, respondents reported experiencing more frequently any side effects (1.04 [1.01-1.07]), skin rash (2.25 [1.4-3.62]), fever (1.72 [1.46-2.02]), flu-like illness (1.67 [1.45-1.91]), and fatigue (1.40 [1.28-1.53]). In addition, multivariate regression demonstrated that participants who had side effects after the first vaccine dose, were at significantly higher risk of having the same side effects after the second dose. Among those experiencing side effects, the severity did not significantly differ between the two doses. However, the likelihood of having a severe side effect, requiring hospital care was significantly decreased (0.58 [0.38-0.88]).

Stratification by ethnicity revealed that white participants reported lower incidence of fever (0.62 [0.48-0.79]) and flu-like illness (0.78 [0.62-0.97]), compared to the remaining participants (table e4). Finally, those reporting pre-vaccination concern about the safety of the vaccine, reported more often tingling (2.23 [1.45-3.42]), breathlessness (1.73 [1.00-2.98]), and fatigue (1.17 [1.03-1.34], table e5).

Multivariate analyses also revealed a strong, negative association between age and the self-reporting of any side effect, local reactions, fever, flu-like illness, rash, tingling, generalized swelling and fatigue ($p<0.01$). Finally, a history of allergy was associated with an increased incidence of self-reported

breathlessness and rash (p<0.01). However, as described in the previous paragraphs and tables, most of the associations observed in univariate analyses remained significant in multivariate analyses accounting for these and other potential confounding factors.

## Discussion

People with prior COVID-19 exposure were largely excluded from the vaccine trials[4,5,6] and, as a result, the safety and reactogenicity of the vaccines in this population have not been previously fully evaluated. For the first time, this study demonstrates a significant association between prior COVID-19 infection and a significantly higher incidence and severity of self-reported side effects after vaccination for COVID-19. Consistently, compared to the first dose of the vaccine, we found an increased incidence and severity of self-reported side effects after the second dose, when recipients had been previously exposed to viral antigen. In view of the rapidly accumulating data demonstrating that COVID-19 survivors generally have adequate natural immunity for at least 6 months, it may be appropriate to re-evaluate the recommendation for immediate vaccination of this group.

Moreover, this is the first head-to-head real-world comparison of the self-reported safety of viral vector versus mRNA vaccines, with the latter associated with a 58% decreased incidence of self-reported severe side effects, requiring hospital care. While more recipients of mRNA vaccines reported at least one (any) side effect, the difference was predominantly driven by the frequent local reactions, while the incidence of each of the systemic side effects evaluated, which are more burdensome to the recipients, was significantly reduced. Recipients of the viral vector-based vaccines were relatively older. However, differences in the incidence of adverse events were confirmed in multivariate analyses accounting for the age of the respondents as a covariate. Moreover, given that older people reported side effects less frequently, potential bias due to age difference would be expected to favour viral vector-based vaccines. These findings may have an impact on vaccine choice, and health policies.

The main strengths of our study include a large study population that better reflects real-life compared to the populations studied in the clinical trials, the availability of adequate details about the participants and the vaccines' safety profiles, and very limited missing data. Potential respondents bias is the main limitation of any survey and since this survey was shared though social media, we were not able to estimate the non-response rate. However, respondents bias is more likely to affect the absolute incidence of side effects, that we did not evaluate here, rather than the relative incidence and severity across different groups of people. Potential recall bias should also be mentioned, although all participants had been vaccinated within 10 weeks prior to completing the survey. As noted, most respondents were from the UK and Greece due to the ability of the investigators to establish contacts quickly to publicise this survey. The UK has also been successful in rolling out COVID-19 vaccines quickly leading to more of those invited being eligible to participate. It is not surprising that Pfizer vaccine was the most delivered vaccine as it was the first vaccine to be licensed within the UK, with more individuals receiving it in total when the survey was circulated.

In conclusion, this extensive survey of over 2,000 recipients of the COVID-19 vaccines links previous COVID-19 illness with increased incidence of vaccination side effects. It also demonstrates that mRNA vaccines cause milder, less frequent systemic side effects, but more local reactions. These findings will need to be validated in clinical studies, preferably randomized controlled trials, including patients from multiple groups.

## Figures and Tables Legends

**Figure 1:** Incidence and severity of self-reported side effects after the first dose of the COVID-19 vaccine among participants who had or did not have known prior COVID-19 infection. Risk ratios less than 1 favours those that did not have prior COVID-19 infection.

**Figure 2:** Incidence and severity of side effects after the first dose of an (1) mRNA or (2) viral vector vaccine. Risk ratios less than 1 favours the mRNA vaccines.

**Table 1:** Differences in the incidence and severity of side effects after the first dose of the COVID-19 vaccine among participants who had, or did not have prior COVID-19 infection.

**Table 2:** Differences in the incidence and severity of side effects among people who received an mRNA or a viral vector vaccine.

**Table 3:** Differences in the incidence and severity of side effects after the second or the first dose of the vaccine.

**Figure 1:** Incidence and severity of self-reported side effects after the first dose of the COVID-19 vaccine among participants who had or did not have known prior COVID-19 infection. Risk ratios less than 1 favours those that did not have prior COVID-19 infection.

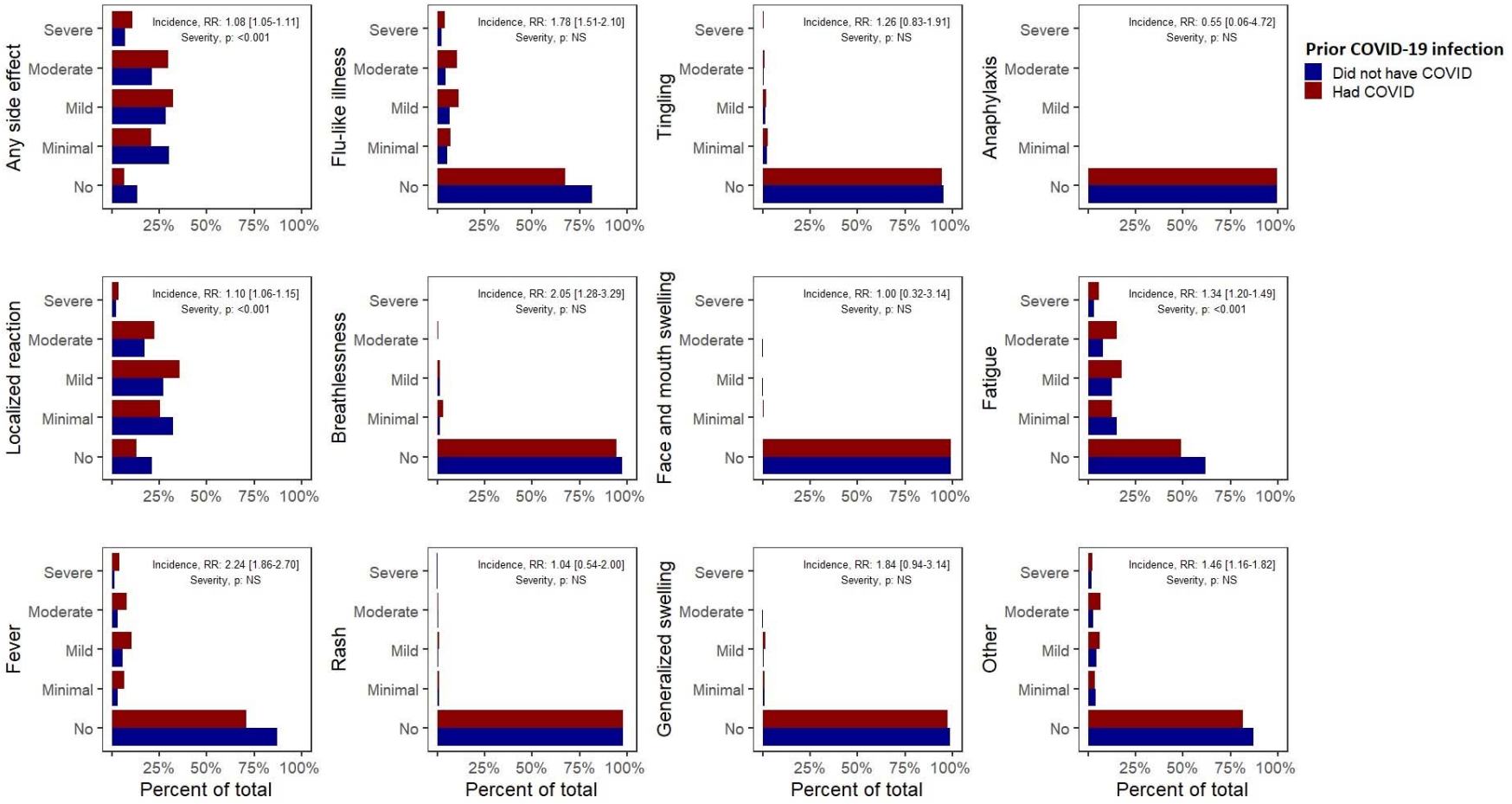

**Figure 2:** Incidence and severity of side effects after the first dose of an (1) mRNA or (2) viral vector vaccine. Risk ratios less than 1 favours the mRNA vaccines.

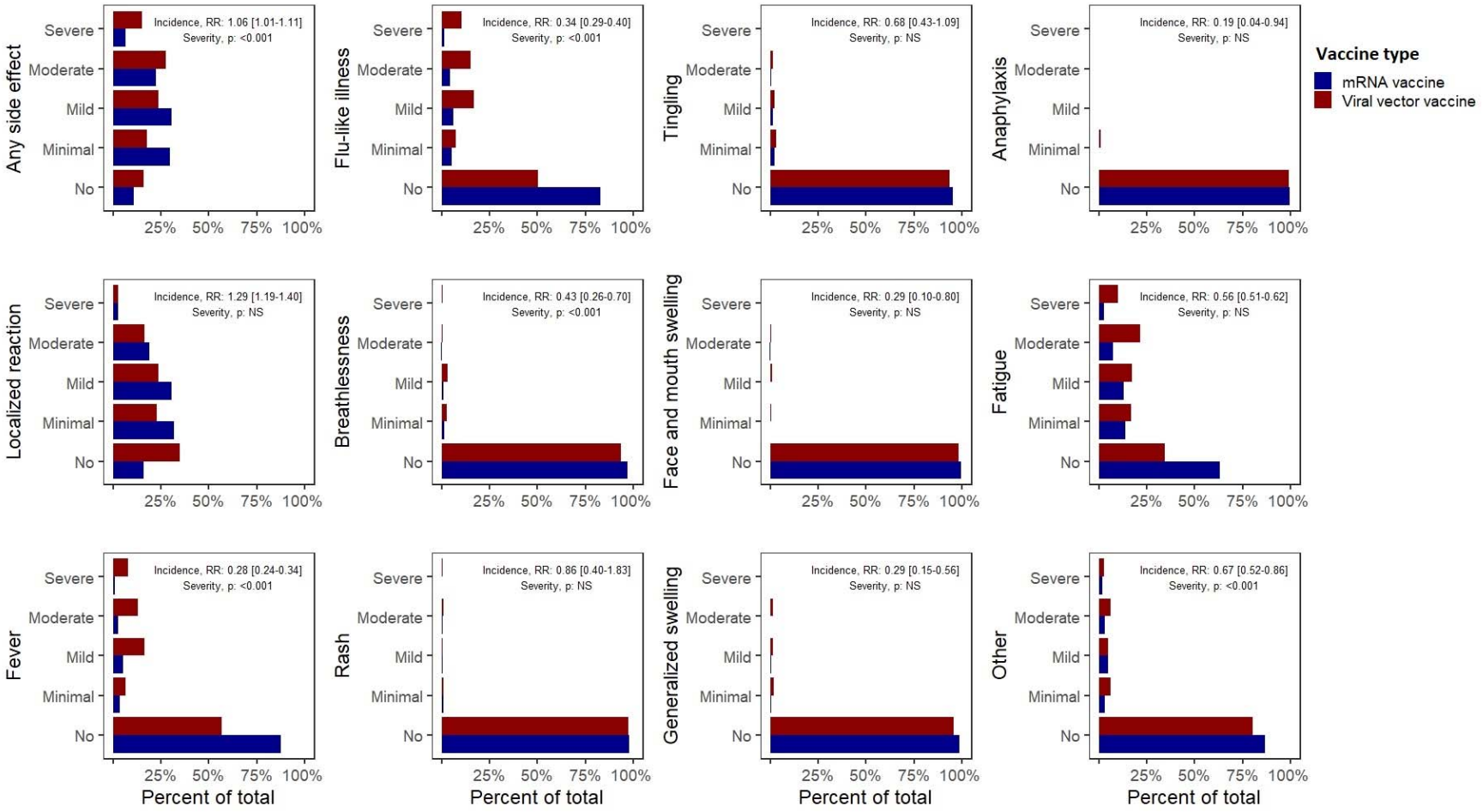

**Table 1:** Differences in the incidence and severity of side effects after the first dose of the COVID-19 vaccine among participants who had, or did not have prior COVID-19 infection.

| Side effect | Incidence of side effects: Risk ratio [95% CI] | Incidence of side effects: Multivariate logistic regression, coefficient (p-value) | Severity of side effects: Univariate cummulative risk models (p-value) | Severity of side effects: Multivariate cummulative risk models (p-value) |
|---|---|---|---|---|
| Any side effect | 1.08 [1.05-1.11] | 0.575 (0.004) | <0.001 | <0.001 |
| Localized reaction | 1.10 [1.06-1.15] | 0.45 (0.003) | <0.001 | 0.003 |
| Fever | 2.24 [1.86-2.70] | 0.876 (<0.001) | NS | NS |
| Flu-like illness | 1.78 [1.51-2.10] | 0.658 (<0.001) | NS | NS |
| Shortness of breath | 2.05 [1.28-3.29] | 0.651 (0.011) | NS | NS |
| Skin rash | 1.04 [0.54-2.00] | NS | NS | NS |
| Tingling | 1.26 [0.83-1.91] | NS | NS | NS |
| Swelling | 1.00 [0.32-3.14] | NS | NS | NS |
| Generalized Swelling | 1.84 [0.94-3.60] | NS | NS | NS |
| Anaphylaxis | 0.55 [0.06-4.72] | NS | NS | NS |
| Fatigue or Tiredness | 1.34 [1.2-1.49] | 0.418 (<0.001) | <0.001 | <0.001 |
| Other | 1.46 [1.16-1.82] | 0.349 (0.013) | NS | NS |

Worse outcomes associated with prior COVID-19 infection

**Table 2:** Differences in the incidence and severity of side effects among people who received an mRNA or a viral vector vaccine.

| Side effect | Incidence of side effects: Risk ratio [95% CI] | Incidence of side effects: Multivariate logistic regression, coefficient (p-value) | Severity of side effects: Univariate cummulative risk models (p-value) | Severity of side effects: Multivariate cummulative risk models (p-value) |
|---|---|---|---|---|
| Any side effect | 1.06 [1.01-1.11] | NS | <0.001 | <0.001 |
| Localized reaction | 1.29 [1.19-1.40] | 0.892 (<0.001) | NS | NS |
| Fever | 0.28 [0.24-0.34] | -1.993 (<0.001) | <0.001 | NS |
| Flu-like illness | 0.34 [0.29-0.40] | -1.795 (<0.001) | <0.001 | NS |
| Shortness of breath | 0.43 [0.26-0.70] | -0.853 (0.002) | NS | NS |
| Skin rash | 0.86 [0.40-1.83] | NS | NS | NS |
| Tingling | 0.68 [0.43-1.09] | NS | NS | NS |
| Swelling | 0.29 [0.10-0.80] | -1.326 (0.015) | NS | NS |
| Generalized Swelling | 0.29 [0.15-0.56] | -1.423 (<0.001) | NS | NS |
| Anaphylaxis | 0.19 [0.04-0.94] | -1.890 (0.024) | NS | NS |
| Fatigue or Tiredness | 0.56 [0.51-0.62] | -1.331 (<0.001) | <0.001 | NS |
| Other | 0.67 [0.52-0.86] | -0.471 (0.004) | NS | NS |

| |
|---|
| mRNA vaccines superiority |
| Viral vector vaccines superiority |

**Table 3:** Differences in the incidence and severity of side effects after the second or the first dose of the vaccine.

| Side effect | Incidence of side effects: Risk ratio [95% CI] | Incidence of side effects: Multivariate logistic regression, coefficient (p-value) | Severity of side effects: Univariate cummulative risk models (p-value) | Severity of side effects: Multivariate cummulative risk models (p-value) |
|---|---|---|---|---|
| Any side effect | 1.04 [1.01-1.07] | NS | NS | NS |
| Localized reaction | 0.98 [0.94-1.03] | 2.469 (<0.001) | NS | NS |
| Fever | 1.72 [1.46-2.02] | 1.3 (<0.001) | NS | NS |
| Flu-like illness | 1.67 [1.45-1.91] | 0.979 (0.001) | NS | NS |
| Shortness of breath | 0.95 [0.57-1.61] | 4.491 (<0.001) | NS | NS |
| Skin rash | 2.25 [1.4-3.62] | 4.297 (<0.001) | 0.05 | NS |
| Tingling | 1.31 [0.89-1.92] | 3.096 (<0.001) | NS | NS |
| Swelling | 2.03 [0.87-4.77] | NS | NS | NS |
| Generalized Swelling | 1.2 [0.61-2.34] | 4.925 (<0.001) | NS | NS |
| Anaphylaxis | 2.54 [0.72-8.98] | 4.747 (0.012) | NS | NS |
| Fatigue or Tiredness | 1.4 [1.28-1.53] | 0.868 (<0.001) | NS | NS |
| Other | 1.05 [0.83-1.32] | 2.104 (<0.001) | NS | NS |

Worse outcomes after the second COVID-19 vaccine dose

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# Self-reported real-world safety and reactogenicity of COVID-19 vaccines:

# An international vaccine-recipient survey.

Alexander G. Mathioudakis, Murad Ghrew, Andrew Ustianowski, Shazaad Ahmad, Ray Borrow, Lida P. Papavasileiou, Dimitrios Petrakis, Nawar Diar Bakerly

## ONLINE APPENDIX

**Table e1:** Definitions of side effects severity.

| Severity | Definition |
|---|---|
| **Minimal** | Negligible impact |
| **Mild** | No treatment needed |
| **Moderate** | Needed treatment or advice from healthcare professional outside the hospital |
| **Severe** | Needed hospital care |

**Table e2:** Baseline characteristics of study participants. Continuous variables as presented as medians [IQR] and categorical as n (%). Between group differences were anticipated and explained by the incidence of COVID-19 in different subgroups. Characteristically, higher incidence of prior COVID-19 infection was observed among frontline workers, health professionals and among British people (a very high incidence of COVID-19 was documented in the UK).

| Characteristics | Participants with prior COVID-19 infection (n=532) | Participants with no known prior COVID-19 infection (n=1,470) | Missing data | Between group differences (P-value) |
|---|---|---|---|---|
| **Gender (Female)** | 393 | 1,051 | 0.7% | NS |
| **Weight (kg)** | 75 [64-88] | 74 [64-85] | 4.0% | NS |
| **Height (cm)** | 168 [163-173] | 168 [162-175] | 2.2% | NS |
| **Country** | | | 0.6% | <0.001 |
| Europe | | | | |
| UK | 472 (88.7%) | 1,100 (74.8%) | | |
| Greece | 38 (7.1%) | 294 (20%) | | |
| Other European countries | 10 (1.9%) | 30 (2.0%) | | |
| Americas | 5 (0.9%) | 17 (1.2%) | | |
| Asia | 5 (0.9%) | 17 (1.2%) | | |
| Africa | 0 (0%) | 1 (0.1%) | | |
| **Ethnicity** | | | 1.8% | NS |
| White | 464 (87.2%) | 1,303 (88.6%) | | |
| Asian | 35 (6.6%) | 63 (4.3%) | | |
| Arab | 21 (3.9%) | 45 (3.1%) | | |
| Other | 7 (1.3%) | 28 (1.9%) | | |
| **Role** | | | 3.2% | <0.001 |
| Doctor | 140 (26.3%) | 486 (33.1%) | | |
| Nurse | 125 (23.5%) | 188 (12.8%) | | |
| Other health professional | 161 (30.3%) | 382 (26.0%) | | |
| Not a health professional | 105 (19.7%) | 401 (27.8%) | | |
| **Frontline workers** | 372 (69.9%) | 795 (54.1%) | 0.6% | <0.001 |
| **COVID-19 prior to vaccination** | | | 0% | |
| Laboratory confirmed exposure | 366 (68.8%) | NA | | |
| Consistent symptoms, not tested | 166 (31.2%) | NA | | |
| No known exposure | NA | 1,470 (100%) | | |

| | | | | |
|---|---|---|---|---|
| **Vaccine type** | | | 0.5% | NS |
| Pfizer | 443 (83.3%) | 1,230 (83.7%) | | |
| Oxford – AstraZeneca | 80 (15.0%) | 202 (13.7%) | | |
| Other | 4 (0.8%) | 20 (1.4%) | | |
| Unknown | 2 (0.4%) | 3 (0.2%) | | |
| **Vaccine preconception** | | | 0.8% | NS |
| Positive | 343 (64.5%) | 1,027 (69.9%) | | |
| Neutral | 76 (14.3%) | 174 (11.8%) | | |
| Negative | 110 (20.7%) | 259 (17.6%) | | |
| **Second vaccine dose received** | 114 (21.4%) | 411 (28.0%) | 0% | 0.004 |
| **Past Medical History** | | | 7.7% | |
| Chronic Cardiac Disease | 9 (1.7%) | 25 (1.7%) | | NS |
| Chronic Respiratory Disease | 74 (13.9%) | 171 (11.6%) | | NS |
| Chronic Kidney Disease | 4 (0.8%) | 9 (0.6%) | | NS |
| Chronic Liver Disease | 1 (0.2%) | 6 (0.4%) | | NS |
| Chronic Neurological Disease | 8 (1.5%) | 17 (1.2%) | | NS |
| Active cancer | 1 (0.2%) | 9 (0.6%) | | NS |
| Asplenia | 1 (0.2%) | 4 (0.3%) | | NS |
| Allergy | 56 (10.5%) | 134 (9.1%) | | NS |
| Diabetes | 17 (3.2%) | 49 (3.3%) | | NS |
| Hay fever, eczema | 114 (21.4%) | 251 (17.1%) | | 0.04 |
| Immunosuppression | 14 (2.6%) | 49 (33.3%) | | NS |
| Transplantation history | 0 (0%) | 0 (0%) | | NS |
| None | 282 (53.0%) | 825 (56.1%) | | NS |

** Participants with prior COVID-19 exposure were younger compared to those without prior exposure.*

**Table e3:** Differences in the incidence and severity of side effects after the first dose of the COVID-19 vaccine among participants who had or did not have prior self-reported COVID-19 infection. Sensitivity analysis only including participants with prior COVID-19 infection confirmed with a

consistent PCR or antibody test (n=366) versus those without any suspicion of prior COVID-19 infection (n=1,470).

| Side effect | Incidence of side effects: Risk ratio [95% CI] | Incidence of side effects: Multivariate logistic regression, coefficient (p-value) | Severity of side effects: Univariate cummulative risk models (p-value) | Severity of side effects: Multivariate cummulative risk models (p-value) |
|---|---|---|---|---|
| Any side effect | 1.09 [1.05-1.12] | 0.581 (0.015) | <0.001 | 0.004 |
| Localized reaction | 1.11 [1.06-1.16] | 0.411 (0.019) | 0.002 | NS |
| Fever | 2.45 [2.01-3] | 0.902 (<0.001) | NS | NS |
| Flu-like illness | 1.92 [1.61-2.29] | 0.691 (<0.001) | NS | NS |
| Shortness of breath | 2.06 [1.22-3.49] | 0.564 (0.043) | NS | NS |
| Skin rash | 1.38 [0.7-2.71] | NS | NS | NS |
| Tingling | 1.22 [0.75-1.98] | NS | NS | NS |
| Swelling | 0.73 [0.16-3.28] | NS | NS | NS |
| Generalized Swelling | 1.72 [0.8-3.73] | NS | NS | NS |
| Anaphylaxis | 0.8 [0.09-6.85] | NS | NS | NS |
| Fatigue or Tiredness | 1.39 [1.24-1.56] | 0.459 (<0.001) | <0.001 | 0.002 |
| Other | 1.45 [1.12-1.87] | 0.288 (0.069) | NS | NS |

Worse outcomes associated with prior COVID-19 infection

**Table e4:** Differences in the incidence and severity of side effects among different ethnicities (white or other).

| Side effect | Incidence of side effects: Risk ratio [95% CI] | Incidence of side effects: Multivariate logistic regression, coefficient (p-value) | Severity of side effects: Univariate cummulative risk models (p-value) | Severity of side effects: Multivariate cummulative risk models (p-value) |
|---|---|---|---|---|
| Any side effect | 1.05 [0.99-1.11] | NS | NS | NS |
| Localized reaction | 1.04 [0.97-1.12] | NS | NS | NS |
| Fever | 0.62 [0.48-0.79] | -0.546 (0.003) | NS | NS |
| Flu-like illness | 0.78 [0.62-0.97] | NS | NS | NS |
| Shortness of breath | 1.16 [0.54-2.5] | NS | NS | NS |
| Skin rash | 0.7 [0.32-1.56] | NS | NS | NS |
| Tingling | 1.69 [0.79-3.61] | NS | NS | NS |

| | | | | |
|---|---|---|---|---|
| Swelling | 0.86 [0.2-3.81] | NS | NS | NS |
| Generalized Swelling | 0.64 [0.27-1.53] | NS | NS | NS |
| Anaphylaxis | 0.66 [0.08-5.67] | NS | NS | NS |
| Fatigue or Tiredness | 0.88 [0.76-1.02] | NS | NS | NS |
| Other | 1.38 [0.94-2.03] | 0.446 (0.049) | NS | NS |

Worse outcomes: Non-white ethnicity

Worse outcomes: White ethnicity

**Table e5:** Differences in the incidence and severity of side effects among people with different preconception toward the vaccine prior to vaccination, those who were keen to receive the vaccine versus those who were concerned about receiving the vaccine.

| Side effect | Incidence of side effects: Risk ratio [95% CI] | Incidence of side effects: Multivariate logistic regression, coefficient (p-value) | Severity of side effects: Univariate cummulative risk models (p-value) | Severity of side effects: Multivariate cummulative risk models (p-value) |
|---|---|---|---|---|
| Any side effect | 1.01 [0.97-1.06] | NS | <0.001 | 0.025 |
| Localized reaction | 0.99 [0.93-1.05] | NS | 0.002 | NS |
| Fever | 1.19 [0.93-1.53] | NS | 0.009 | NS |
| Flu-like illness | 1.07 [0.86-1.34] | NS | <0.001 | NS |
| Shortness of breath | 1.73 [1.00-2.98] | -0.085 (0.03) | NS | NS |
| Skin rash | 1.25 [0.59-2.65] | NS | NS | NS |
| Tingling | 2.23 [1.45-3.42] | -0.114 (0.001) | NS | NS |
| Swelling | 0.4 [0.05-3.03] | NS | NS | NS |
| Generalized Swelling | 0.72 [0.26-2.04] | NS | NS | NS |
| Anaphylaxis | NA | NS | NS | NS |
| Fatigue or Tiredness | 1.17 [1.03-1.34] | NS | 0.009 | NS |
| Other | 1.26 [0.96-1.66] | -0.043 (0.045) | NS | NS |

Worse outcomes: Concerned

**Figure e1:** Age of the participants, stratified by whether they had or did not have a previous COVID-19 infection.

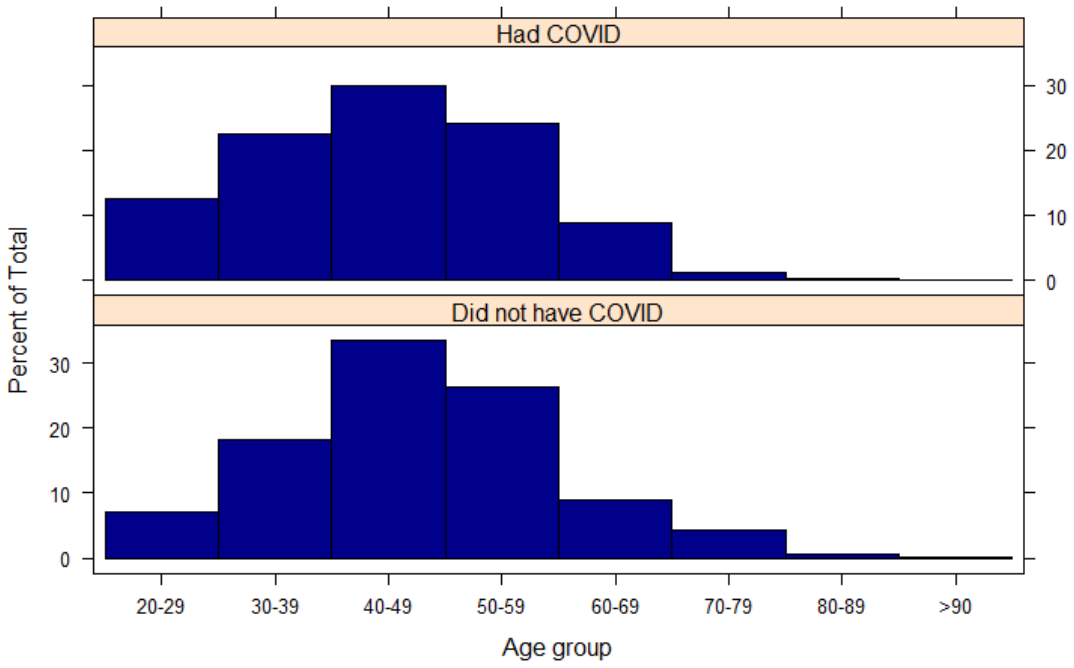
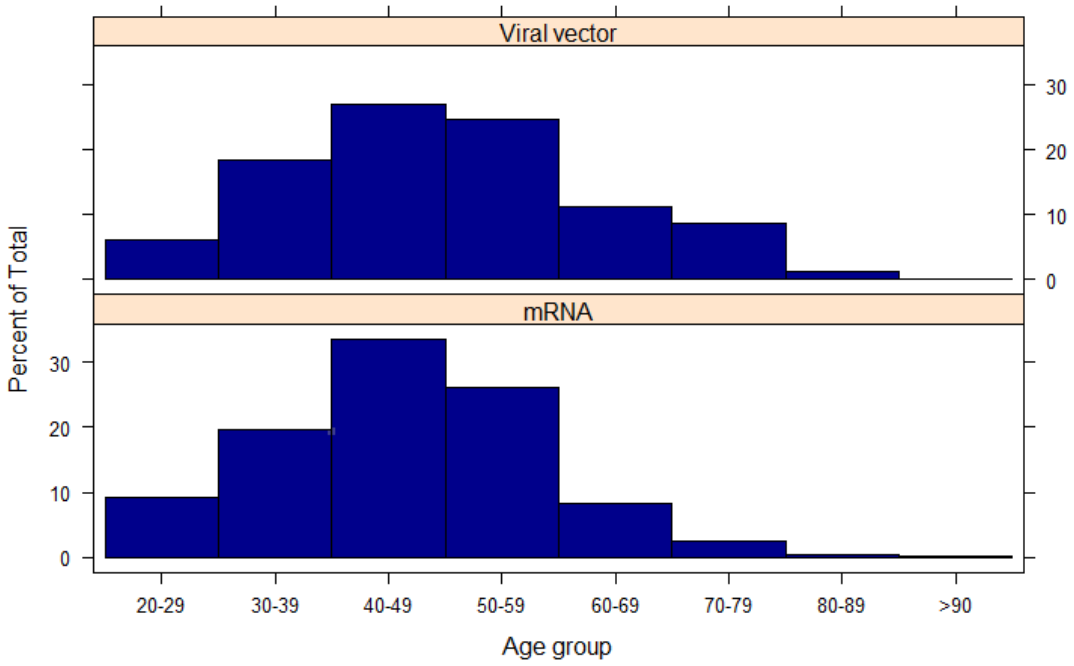
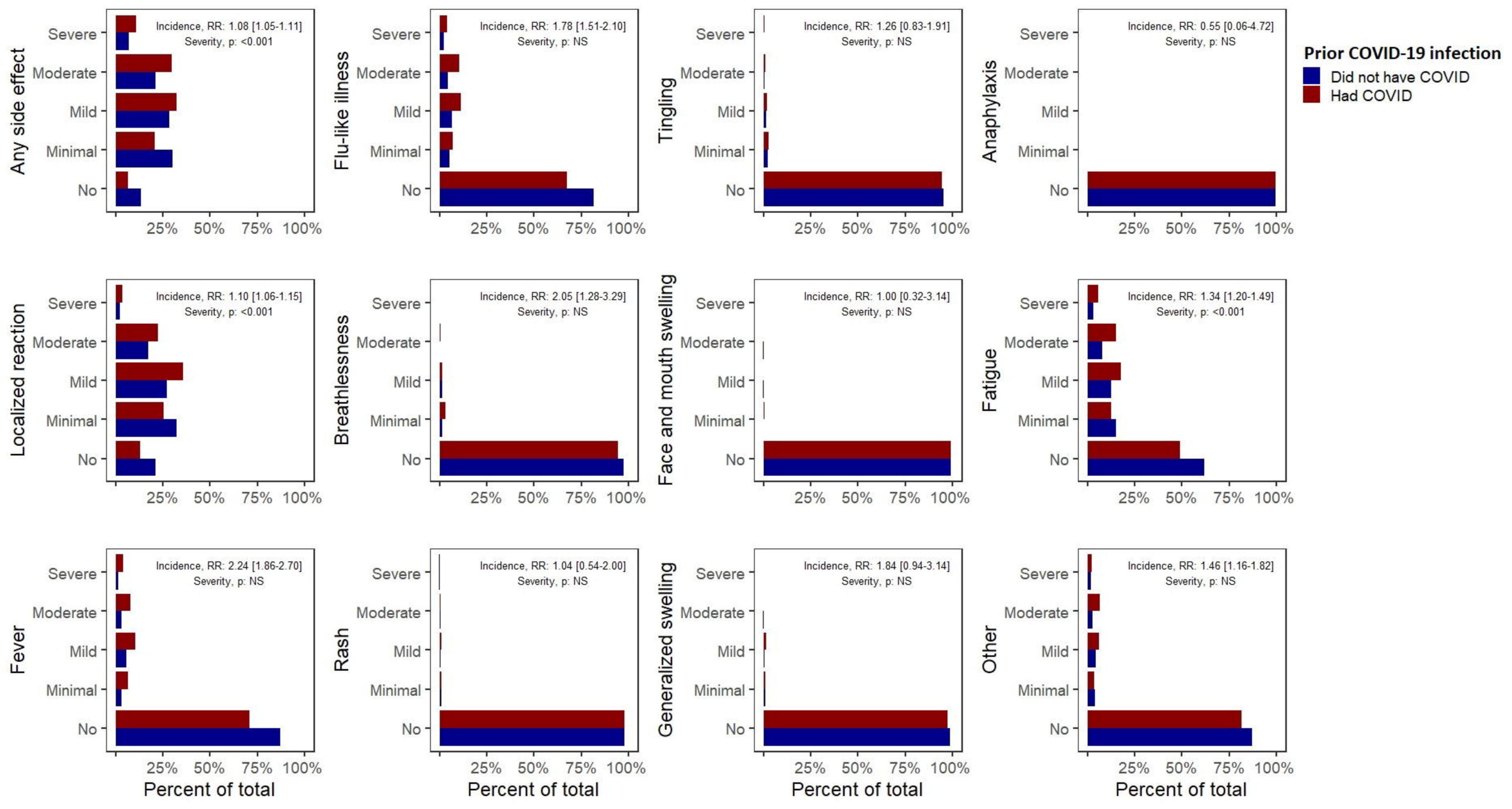
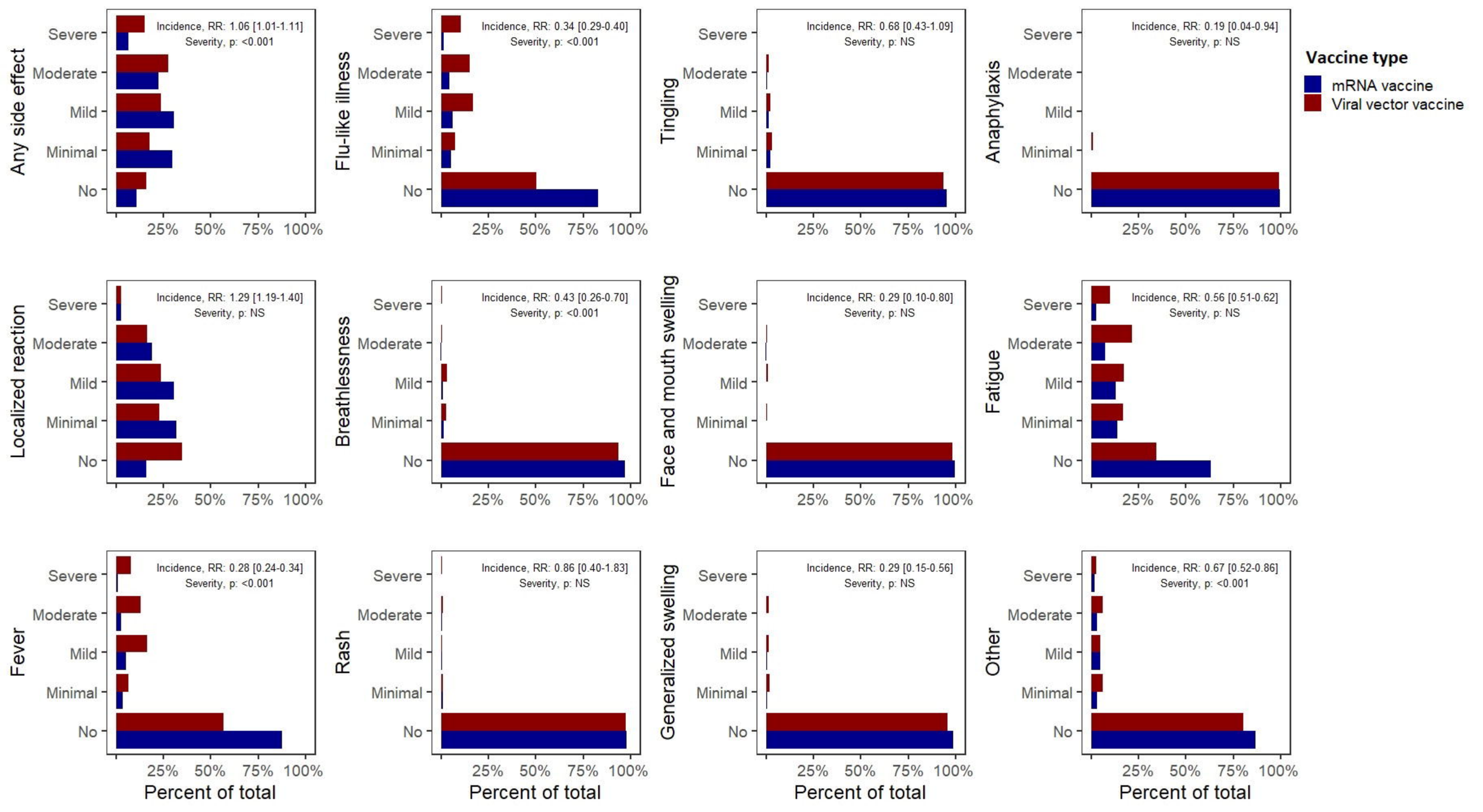



**Figure e2:** Age of the participants, stratified by the type of vaccine they received




Any side effect
Incidence, RR: 1.08 [1.05-1.11]
Severity, p: <0.001
Flu-like illness
Incidence, RR: 1.78 [1.51-2.10]
Severity, p: NS
Tingling
Incidence, RR: 1.26 [0.83-1.91]
Severity, p: NS
Anaphylaxis
Incidence, RR: 0.55 [0.06-4.72]
Severity, p: NS
Localized reaction
Incidence, RR: 1.10 [1.06-1.15]
Severity, p: <0.001
Breathlessness
Incidence, RR: 2.05 [1.28-3.29]
Severity, p: NS
Face and mouth swelling
Incidence, RR: 1.00 [0.32-3.14]
Severity, p: NS
Fatigue
Incidence, RR: 1.34 [1.20-1.49]
Severity, p: <0.001
Fever
Incidence, RR: 2.24 [1.86-2.70]
Severity, p: NS
Rash
Incidence, RR: 1.04 [0.54-2.00]
Severity, p: NS
Generalized swelling
Incidence, RR: 1.84 [0.94-3.14]
Severity, p: NS
Other
Incidence, RR: 1.46 [1.16-1.82]
Severity, p: NS
Severe
Moderate
Mild
Minimal
No
25%
50%
75%
100%
Percent of total
Prior COVID-19 infection
Did not have COVID
Had COVID


Any side effect
Incidence, RR: 1.06 [1.01-1.11]
Severity, p: <0.001
Flu-like illness
Incidence, RR: 0.34 [0.29-0.40]
Severity, p: <0.001
Tingling
Incidence, RR: 0.68 [0.43-1.09]
Severity, p: NS
Anaphylaxis
Incidence, RR: 0.19 [0.04-0.94]
Severity, p: NS
Localized reaction
Incidence, RR: 1.29 [1.19-1.40]
Severity, p: NS
Breathlessness
Incidence, RR: 0.43 [0.26-0.70]
Severity, p: <0.001
Face and mouth swelling
Incidence, RR: 0.29 [0.10-0.80]
Severity, p: NS
Fatigue
Incidence, RR: 0.56 [0.51-0.62]
Severity, p: NS
Fever
Incidence, RR: 0.28 [0.24-0.34]
Severity, p: <0.001
Rash
Incidence, RR: 0.86 [0.40-1.83]
Severity, p: NS
Generalized swelling
Incidence, RR: 0.29 [0.15-0.56]
Severity, p: NS
Other
Incidence, RR: 0.67 [0.52-0.86]
Severity, p: <0.001
Severe
Moderate
Mild
Minimal
No
25%
50%
75%
100%
Percent of total
Vaccine type
mRNA vaccine
Viral vector vaccine

# Exhibit "BB"

European Journal of Immunology

Immunity to infection

Clinical

Research Article

# Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans

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**Most subjects develop antibodies to SARS-CoV-2 following infection. In order to estimate the duration of immunity induced by SARS-CoV-2 it is important to understand for how long antibodies persist after infection in humans. Here, we assessed the persistence of serum antibodies following WT SARS-CoV-2 infection at 8 and 13 months after diagnosis in 367 individuals. The SARS-CoV-2 spike IgG (S-IgG) and nucleoprotein IgG (N-IgG) concentrations and the proportion of subjects with neutralizing antibodies (NAb) were assessed. Moreover, the NAb titers among a smaller subset of participants ($n = 78$) against a WT virus (B) and variants of concern (VOCs): Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.617.2) were determined. We found that NAb against the WT virus persisted in 89% and S-IgG in 97% of subjects for at least 13 months after infection. Only 36% had N-IgG by 13 months. The mean S-IgG concentrations declined from 8 to 13 months by less than one third; N-IgG concentrations declined by two-thirds. Subjects with severe infection had markedly higher IgG and NAb levels and are expected to remain seropositive for longer. Significantly lower NAb titers against the variants compared to the WT virus, especially after a mild disease, suggests reduced protection against VOCs.**

**Keywords:** IgG antibodies · neutralizing antibodies · SARS-CoV-2 · seroprevalence · variants of concern

Additional supporting information may be found online in the Supporting Information section at the end of the article.

## Introduction

Infection with Severe acute respiratory coronavirus 2 (SARS-CoV-2) induces antibodies in most subjects to viral nucleoprotein (N) and spike (S) glycoprotein (1). Neutralizing antibodies (NAb) against SARS-CoV-2 target the receptor-binding domain (RBD) of the S protein and sterically interfere with the binding of the viral S protein and the host's angiotensin-converting enzyme 2 (2, 3). NAb levels are highly predictive of protection against infection and clinical disease (4) and detectable NAb have been reported to persist in most subjects at least 6 to 12 months after infection (5–13). Previous findings suggest that neutralizing activity against the SARS-CoV-2 is mediated particularly by IgG1 and IgA antibodies (14, 15). However, as the concentration of anti-SARS-CoV-2 IgA antibodies has been shown to decline rapidly following

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[#]Both authors contributed equally to this work.

**Table 1.** Demographics and clinical characteristics of study participants in the study cohorts at 8 and 13 months after infection

| | 8 months participants | 13 months participants | Study Cohort | Sub Cohort |
|---|---|---|---|---|
| **N** | | | | |
| **8 months** | 1292 | N/A | 367 | N/A |
| **13 months** | N/A | 995 | 367 | 78 |
| **Gender** | | | | |
| **Male n (%)** | 520 (40%) | 386 (39%) | 159 (43%) | 40 (51%) |
| **Female n (%)** | 772 (60%) | 609 (61%) | 208 (57%) | 38 (49%) |
| **Age at diagnosis (median, range)** | | | | |
| **<60y** | 45.1 (17.3-59.9) | 47.5(17.6-59.9) | 45.9 (17.7-59.9) | 51.6 (19.0-59.7) |
| **>60y** | 65.1 (60.0-94.3) | 65.4 (60.0-95.6) | 63.3 (60.0-79.0) | 63.0 (60.0-81.3) |
| **All** | 50.0 (17.3-94.3) | 52.5 (17.6-95.6) | 48.8 (17.7-79.0) | 59.4 (19.0-81.3) |
| **Time (mo) after diagnosis at sampling** | | | | |
| **8 months** | 7.6 (5.9-9.9) | N/A | 7.6 (6.1-9.7) | N/A |
| **13 months** | N/A | 12.7 (11.7-14.3) | 12.7 (11.9-14.0) | 13.0 (12.2-13.6) |
| **Disease severity** | | | | |
| **Severe** | 190 (15%) | 149 (15%) | 47 (13%) | 39 (50%) |
| **Mild** | 1102 (85%) | 846 (85%) | 320 (87%) | 39 (50%) |

infection (16–18), long-term neutralization is thus driven by IgG antibodies to the spike protein (16).

SARS-CoV-2 is constantly mutating yet most changes have little or no impact on its virulence (19). However, some changes are causing concerns regarding disease severity, viral transmissibility, and potential escape from natural and vaccine-induced immunity (20). The World Health Organization (WHO) in collaboration with an international network of experts has characterized the variants of concern (VOC) (https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/). Reduced NAb levels as compared to the WT virus have been shown against VOCs, especially against the Beta variant, both after vaccination (13, 21–23) and 9 (13) and 12 months (12) after infection. A similar reduction in NAb titers has also been reported against the Delta variant from convalescent sera collected 3–12 months post symptoms or after vaccination (24, 25).

Previous infection with SARS-CoV-2 has shown to induce effective immunity and protection against reinfections in most individuals (26, 27). In animal studies, a protective antibody titer against SARS-CoV-2 infection has been suggested to be low (28, 29). Higher IgG antibody levels against SARS-CoV-2 among health care workers within three months after vaccination were found to be associated with lower infectivity (30). However, a protective threshold for humans is still under debate and subject to the standardization of serological methods. The accumulating research data on the persistence of antibodies after natural infection, and NAbs in particular, will provide important insight into estimating for how long antibodies induced by Coronavirus disease 2019 (COVID-19) vaccination can be expected to persist and provide protection against emerging SARS-CoV-2 variants. In this study, we investigated the antibody persistence up to 14 months after natural SARS-CoV-2 infection and assessed the potential cross-protection by comparing the NAb levels of WT virus (B lineage) to three VOC strains Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.617.2).

## Results

### Persistence and kinetics of SARS-CoV-2 antibodies

We first assessed the persistence of NAb and serum IgG antibodies specific to SARS-CoV-2 Spike full length (SFL)-IgG, RBD-IgG, and N-IgG at 8 months following SARS-CoV-2 infection. We found that 89% (1148/1292) of the subjects had NAb against the WT virus, 96% (1240/1292) had antibodies to SFL and RBD (S-IgG) and 66% (846/1292) had N-IgG. We further assessed the persistence of NAb and IgG antibodies a year after SARS-CoV-2 infection by randomly selecting 367 of 652 subjects who had not received a SARS-CoV-2 vaccination of the 995 subjects who participated at both time points (Fig. 1). Participant demographics and clinical characteristics for the selected cohort were similar to the overall cohort (Table 1). NAb, S-IgG, and N-IgG antibodies were detected in 91%, 98%, and 67% of subjects in the selected cohort at 8 months after infection, respectively (Table 2). One year after infection the proportion of positive samples was still high for NAb and S-IgG (89% (326/367) and 97% (356/367)), respectively, but had decreased to 36% (132/367) for N-IgG. The mean IgG concentrations decreased significantly ($p < 0.001$) for SFL-IgG, RBD-IgG, and N-IgG from 8 months (3.2, 2.3, 1.2 binding antibody unit concentrations (BAU)/ml) to 13 months (2.3, 1.7, 0.44 BAU/ml, respectively) after infection. The decrease in mean IgG concentration was more notable (-63%) for N-IgG compared to SFL-IgG (-28%) or RBD-IgG (-26%) (Fig. 2).

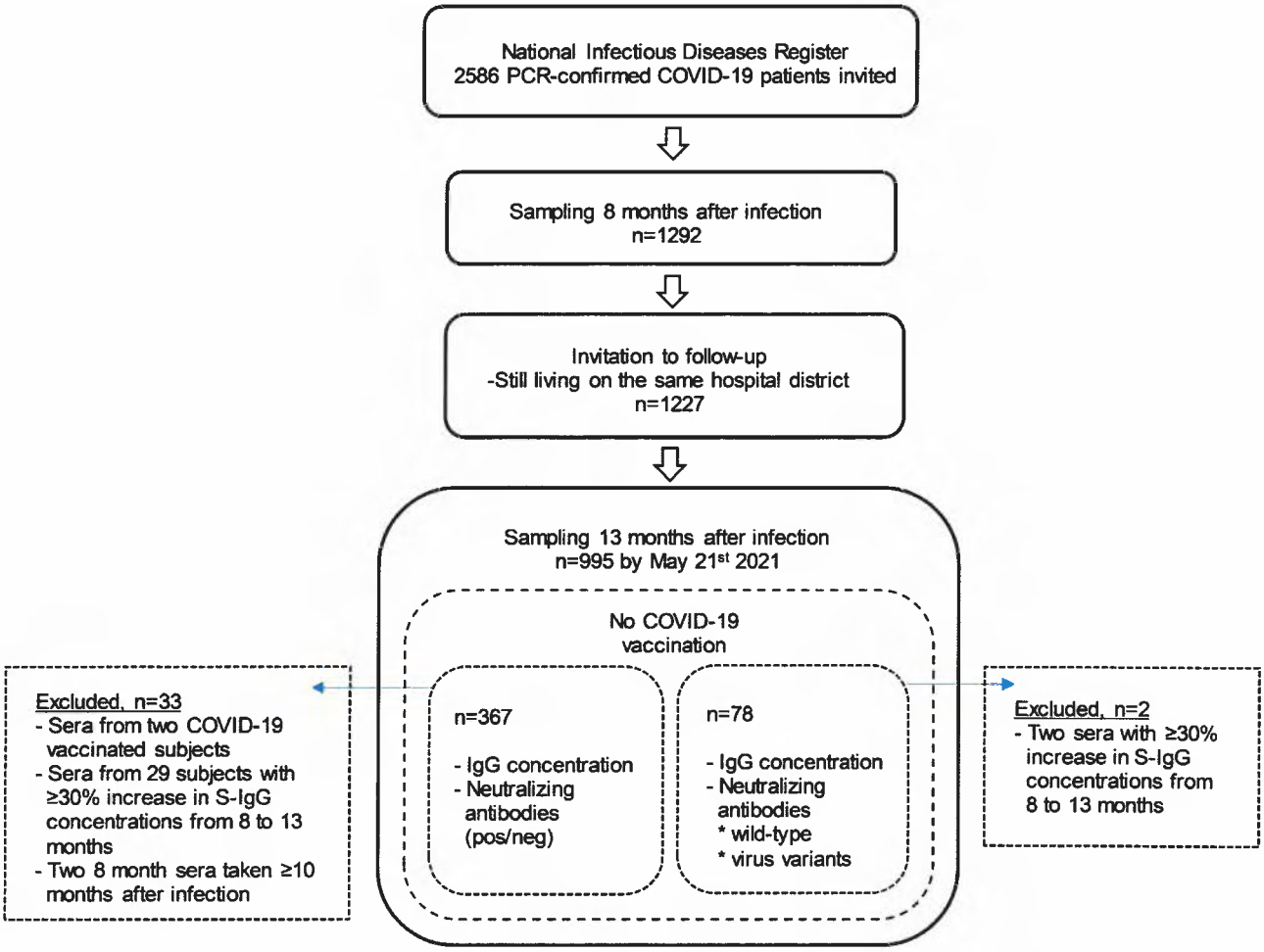


**Figure 1.** The study flow chart showing the selection of serum samples of the study participants for the determination of antibody concentration and neutralizing antibodies 8 and 13 months after infection.

## Effect of disease severity, age, and gender on SARS-CoV-2 antibodies

We observed higher mean N-IgG, SFL-IgG, and IgG-RBD concentrations in subjects who had recovered from severe disease than in those with mild disease 8 months after infection ($p < 0.001$; Fig. 3). The difference was 2.0- to 7.4-fold, depending on the age group, and persisted for at least 13 months after infection (Fig. 3, Table 3). The proportion of seropositive subjects remained high for S-IgG and NAb (100%) and relatively high for N-IgG (67%)

**Table 2.** Number and proportion of positive samples for spike protein IgG (S-IgG) and neutralizing antibodies (NAb) by disease severity, age and gender of the participants 8 and 13 months after infection, n=367

| | | | S-IgG positive n/n (%) | | | | NAb positive (wt) n/n (%) | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Disease severity | Age (years) | Gender | 8 months | | 13 months | | 8 months | | 13 months | |
| **Severe** | ≥60 | M | 16/16 | (100) | 16/16 | (100) | 16/16 | (100) | 16/16 | (100) |
| | | F | 18/18 | (100) | 18/18 | (100) | 17/18 | (94) | 18/18 | (100) |
| | <60 | M | 6/6 | (100) | 6/6 | (100) | 6/6 | (100) | 6/6 | (100) |
| | | F | 7/7 | (100) | 7/7 | (100) | 7/7 | (100) | 7/7 | (100) |
| **Mild** | ≥60 | M | 120/122 | (98) | 117/122 | (96) | 105/122 | (86) | 99/118 | (84) |
| | | F | 166/171 | (97) | 165/171 | (97) | 159/171 | (93) | 151/171 | (88) |
| | <60 | M | 15/15 | (100) | 15/15 | (100) | 15/15 | (100) | 14/15 | (93) |
| | | F | 12/12 | (100) | 12/12 | (100) | 10/12 | (83) | 12/12 | (100) |

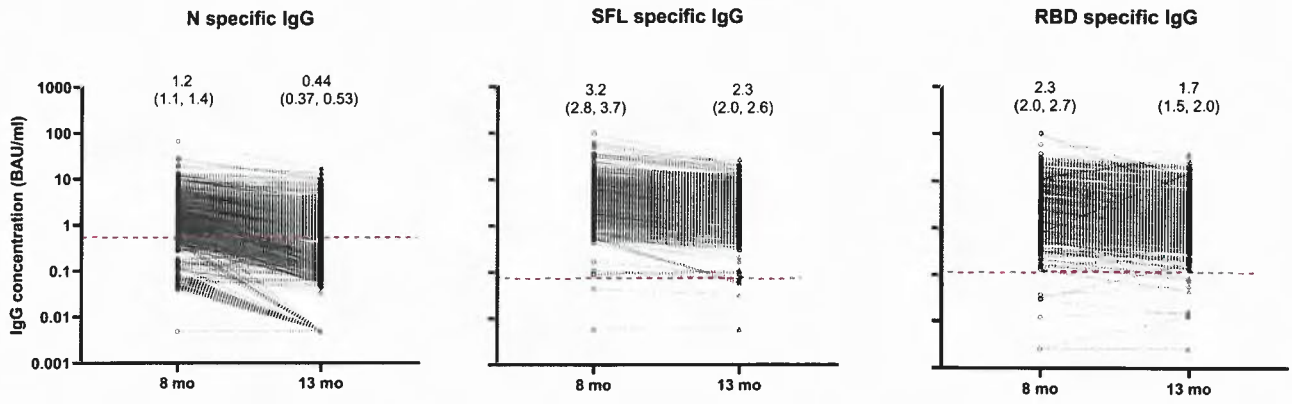


**Figure 2.** Nucleoprotein (N), and spike protein (SFL, RBD) specific IgG concentrations (BAU/ml) with geometric mean concentrations (95% CI) at 8 and 13 months after infection, $n = 367$ subjects. FMIA specific cut-off for seropositivity is indicated by a dashed red line. Each sample was tested as technical duplicates in each experiment and the experimental precision was confirmed by two control samples in each independent experiment.

a year after severe infection, compared to 97%, 87%, and 32%, respectively, of those with a milder infection. A higher proportion (33%) of subjects in the elderly age group (≥60 years of age) had been hospitalized compared to the younger age groups (13% of 40 to 59 years and 6% of those 17 to 39 years of age). Elderly subjects (≥60 years of age) with mild infection had similar levels of S-IgG antibodies (Table 3) and an equally high proportion of them had NAb compared to younger subjects with mild infection. N-IgG concentrations were, however, higher among ≥60-year old subjects than in subjects <60 years of age with a mild disease at 8 and 13 months after infection ($p < 0.01$). We could not demonstrate any difference in N-, SFL-, or RBD-IgG concentrations between males and females at 8 or 13 months after infection.

## Comparison of NAb titers between a WT virus and three VOCs

A smaller age- and gender-matched subset of participants ($n = 78$) of 13-month samples was randomly selected for NAb titration due to the laborious live-virus microneutralization test (MNT). The samples were re-analyzed against a WT virus isolated in Finland during 2020 and three VOCs (Alpha, Beta, and Delta) isolated in Finland during 2021. The samples to be included in the NAb titration were selected based on a seropositive result (NAb titer ≥6) in the screening test.

Within the whole cohort (n = 78), NAb titers were significantly lower for all VOCs ($p < 0.0001$, Kruskal-Wallis test) compared to WT virus. This decrease in geometric mean titers (GMT) was more notable for the Beta (-77%) and Delta (-69%) variants than for the Alpha variant (-42%) (Table 4). NAb titers for all VOCs correlated well with WT virus titers, yet a more pronounced correlation was seen for the Alpha and Delta variants and lower for the Beta variant (Supporting information Fig. 1).

For both WT virus and the Alpha variant, the proportion of seropositive individuals with severe disease remained high 13 months after infection (Fig. 4, Supporting information Table 1). Lower titers against the Alpha variant compared to the WT virus were seen in mild disease groups with an increasing proportion of low positive (borderline) or negative subjects. The greatest

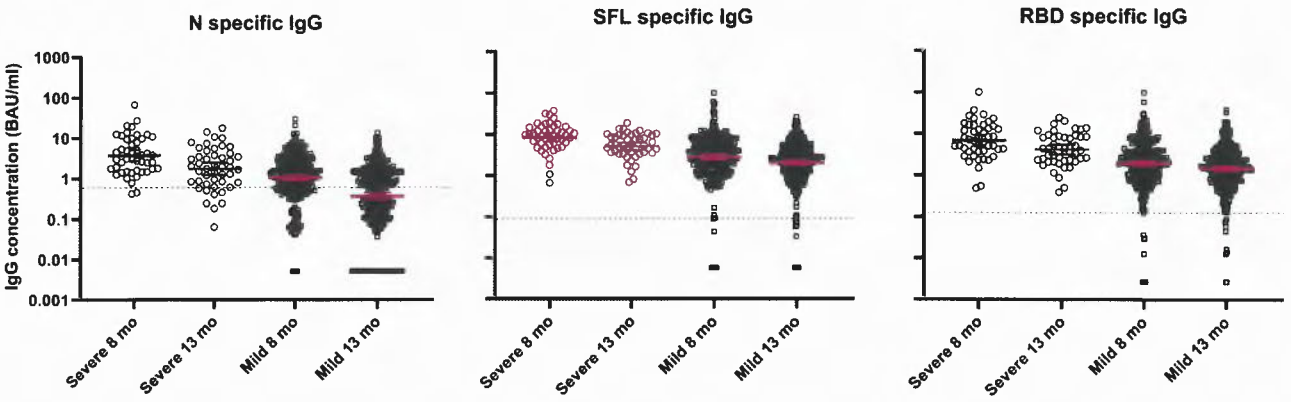


**Figure 3.** Distribution and the geometric mean of IgG concentrations (BAU/ml and 95% CIs) for nucleoprotein (N specific IgG), and spike protein (SFL and RBD specific IgG) in subjects 8 and 13 months after severe ($n = 47$ subjects) or mild ($n = 320$ subjects) infection. FMIA specific cut-off for seropositivity is indicated by a dashed red line. Each sample was tested as technical duplicates in each experiment and the experimental precision was confirmed by two control samples in each independent experiment.

**Table 3.** Geometric mean IgG concentrations, GMC [95% CI], expressed as BAU/ml for nucleoprotein (N), spike proteins (SFL and RBD) at 8 and 13 months after COVID-19 infection per age group and disease severity. Significantly higher (Kruskal-Wallis test, $p<0.05$) IgG concentrations in subjects with severe as compared to mild disease within age groups are shown in bold

| Disease | Age (years)n | N-IgGGMC [95% CI] | | RBD-IgGGMC [95% CI] | | SFL-IgGGMC [95% CI] | |
|---|---|---|---|---|---|---|---|
| | | 8 months | 13 months | 8 months | 13 months | 8 months | 13 months |
| **Mild** | **17-39** | 0.71 | 0.23 | 1.7 | 1.5 | 2.5 | 2.0 |
| | n=101 | [0.40–1.0] | [0.0061–0.46] | [0.87–2.5] | [0.85–2.1] | [1.1–4.0] | [1.4–2.6] |
| | **40-59** | 1.2 | 0.41 | 2.0 | 1.5 | 2.8 | 1.9 |
| | n=192 | [0.74–1.6] | [0.18–0.64] | [0.68–3.4] | [0.83–2.1] | [1.4–4.1] | [1.4–2.5] |
| | **≥60** | 2.1 | 0.81 | 3.0 | 1.9 | 4.0 | 2.6 |
| | n=27 | [0.32–3.9] | [-0.29 –1.9] | [1.1–4.8] | [-0.70–4.5] | [1.9–6.1] | [1.1–4.2] |
| **Severe** | **17-39** | 2.9 | **1.7** | 8.4 | 4.6 | 6.9 | 5.1 |
| | n=6 | [-1.9–7.7] | **[-0.33–3.7]** | [-33–50] | [0.19–9.0] | [0.35–14] | [0.82–9.4] |
| | **40-59** | **3.9** | **1.8** | **6.2** | **4.0** | **7.6** | **4.7** |
| | n=28 | **[-0.96–8.7]** | **[0.29–3.2]** | **[3.5–8.8]** | **[1.8–6.2]** | **[5.2–10]** | **[3.2–6.3]** |
| | **≥60** | 4.1 | 1.8 | 8.4 | 4.5 | **11.4** | 6.4 |
| | n=13 | [-1.4 –9.5] | [-0.91–4.5] | [1.4–15] | [0.89–8.1] | **[5.2–18]** | [4.1–8.7] |

decrease of NAb titers was seen between the WT virus and the Beta variant with markedly lower GMTs and seropositivity with several borderline titers also in groups of severe disease. NAb titers and seropositivity for the Delta variant were also markedly lower compared to WT virus. The Delta GMT values were placed between the GMTs of the Alpha and Beta variants, yet the seropositivity of severe disease groups was relatively well preserved (≥80%) compared to that of the Beta variant (65%).

**Table 4.** Geometric mean IgG concentrations, GMC [95% CI] expressed as BAU/ml for nucleoprotein (N) and spike proteins (SFL and RBD) and geometric mean titers, GMT [95% CI] of neutralizing antibodies (NAb) against wild-type (wt) virus and three variants of concern Alpha (B.1.1.7), Beta (B.1.351) and Delta (B.1.617.2) 13 months after infection (n=78)

| | | | | IgG concentration (BAU/ml) | | | MNT titer | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Disease severity | Age | Gender | n | N-IgG | S-IgG (RBD) | S-IgG (SFL) | NAb wt | NAb Alpha | NAb Beta | NAb Delta |
| **Severe** | <60y | M+F | 22 | 1.5 [0.88-2.7] | 3.9 [2.5-6.1] | 4.7 [3.0-7.2] | 27 [17-41] | 21 [14-34] | 8.1 [5.0-13] | 10 [7.1-15] |
| | | M | 12 | 2.0 [0.99-4.0] | 4.7 [2.4-9.0] | 5.5 [2.9-10.4] | 29 [16-55] | 26 [14-49] | 9.2 [4.6-19] | 14 [8.1-23] |
| | | F | 10 | 1.1 [0.45-2.9] | 3.2 [1.8-5.7] | 3.8 [2.1-6.8] | 24 [12-47] | 17 [8.5-32] | 6.8 [3.6-13] | 7.7 [4.5-13] |
| | ≥60y | M+F | 17 | 1.6 [0.98-2.5] | 5.1 [3.0-8.7] | 7.6 [4.8-12] | 52 [39-71] | 30 [20-44] | 8.0 [5.1-13] | 15 [10-22] |
| | | M | 8 | 0.89 [0.60-1.3] | 4.2 [2.2-8.0] | 5.8 [3.6-9.2] | 39 [27-57] | 28 [18-42] | 9.2 [4.8-18] | 13 [8.5-21] |
| | | F | 9 | 2.6 [1.3-5.0] | 6.1 [2.6-14] | 9.7 [4.6-21] | 68 [45-100] | 32 [16-61] | 7.0 [3.6-14] | 16 [8.6-31] |
| **Mild** | <60y | M+F | 22 | 0.41 [0.22-0.75] | 1.6 [1.3-2.1] | 2.3 [1.9-2.9] | 15 [12-20] | 8.0 [5.4-12] | 3.6 [2.7-4.8] | 4.0 [2.8-5.7] |
| | | M | 12 | 0.36 [0.14-0.93] | 1.3 [0.89-1.8] | 1.8 [1.4-2.4] | 12 [9.5-16] | 5.1 [3.1-8.4] | 2.9 [2.1-4.1] | 2.9 [2.0-4.0] |
| | | F | 10 | 0.47 [0.22-1.0] | 2.2 [1.6-3.0] | 3.1 [2.3-4.0] | 20 [14-30] | 13 [8.3-22] | 4.6 [2.9-7.3] | 6.0 [3.4-11] |
| | ≥60y | M+F | 17 | 0.50 [0.26-1.1] | 1.8 [1.0-3.1] | 2.1 [1.3-3.4] | 19 [11-31] | 8.5 [4.8-15] | 4.2 [2.8-6.5] | 5.6 [3.5-8.8] |
| | | M | 8 | 0.94 [0.42-2.1] | 1.5 [0.72-3.2] | 1.5 [0.82-2.8] | 12 [6.1-23] | 4.6 [2.2-9.7] | 2.9 [1.8-4.6] | 4.1 [2.2-7.6] |
| | | F | 9 | 0.28 [0.081-0.98] | 2.1 [0.91-4.7] | 2.9 [1.5-5.7] | 28 [14-55] | 15 [7.1-30] | 6.0 [3.2-11] | 7.4 [3.8-14] |

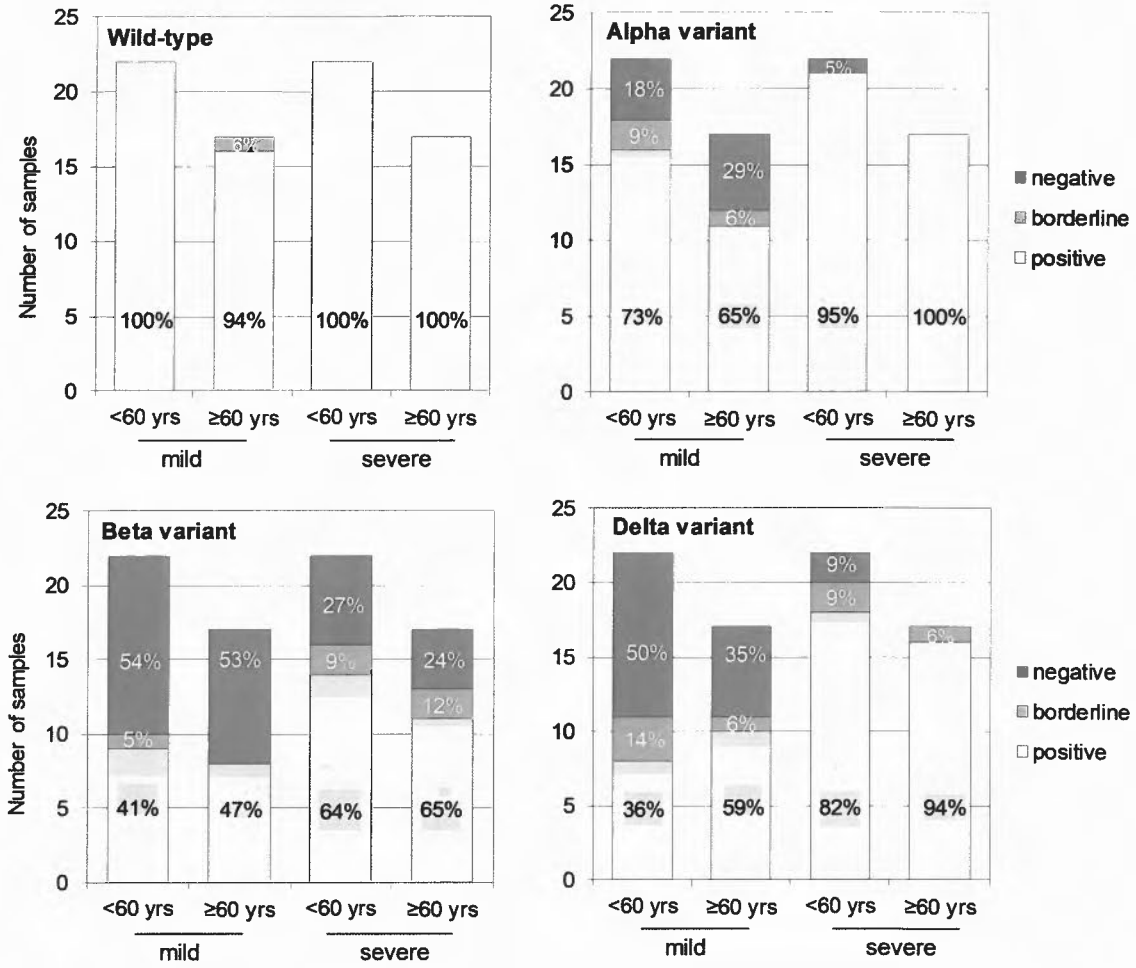


**Figure 4.** The proportion of subjects positive, low positive (borderline), and negative for neutralizing antibodies 13 months after infection against four SARS-CoV-2 virus strains ($n$ = 78 subjects): The WT virus (B), the Alpha variant (B.1.1.7), the Beta variant (B.1.351), and the Delta variant (B.1.617.2). Each sample was tested as technical duplicates in each experiment and the experimental precision was confirmed by two control samples in each independent experiment.

For all viruses, the subjects who recovered from the severe disease had overall 2.1 to 3.0-fold higher NAb titers compared to those with mild disease ($p < 0.01$). The same finding was seen with all IgG concentrations. The difference in IgG concentrations between severe and mild disease was prominent in both sexes in the large study cohort ($n = 367$). However, in the small cohort ($n = 78$) only males with a mild disease had markedly lower NAb titers and S-IgG concentrations compared to those recovered from severe disease ($p < 0.05$; Supporting information Table 2). The difference was not statistically significant for females although the trend was similar.

NAb titers against WT virus were higher in the elderly group (≥60 years) compared to <60 years old ($p = 0.045$) whereas NAb titers for VOCs did not differ significantly between age groups (Supporting information Table 3). We detected a strong and statistically significant correlation ($p < 0.0001$) between NAb titers and S-IgG antibody concentrations indicating an overall parallel trend between severe and mild disease antibody levels (Fig. 5).

## Discussion

Studies of individuals who have recovered from SARS-CoV-2 infection are crucial in determining for how long antibodies persist after infection and whether these antibodies protect against re-infection. We showed that S-IgG antibodies and, most importantly, NAbs persist in most subjects for at least a year following SARS-CoV-2 infection. The concentration of N-IgG, on the contrary, declined among a large proportion of subjects. In accordance with previous observations (6, 8, 31), subjects with severe infection had higher N-IgG, S-IgG concentrations, and NAb titers than subjects with mild infection and are expected to remain seropositive for a longer time.

Previous studies show that most patients recovering from COVID-19 have detectable antibody responses peaking at approximately one month after infection (7, 8, 32). Antibody levels to N and S protein antigens decline during the first few months with differences in isotype and antigen specificity of the antibody (7). The decay rate has been shown to slow down thereafter (12).

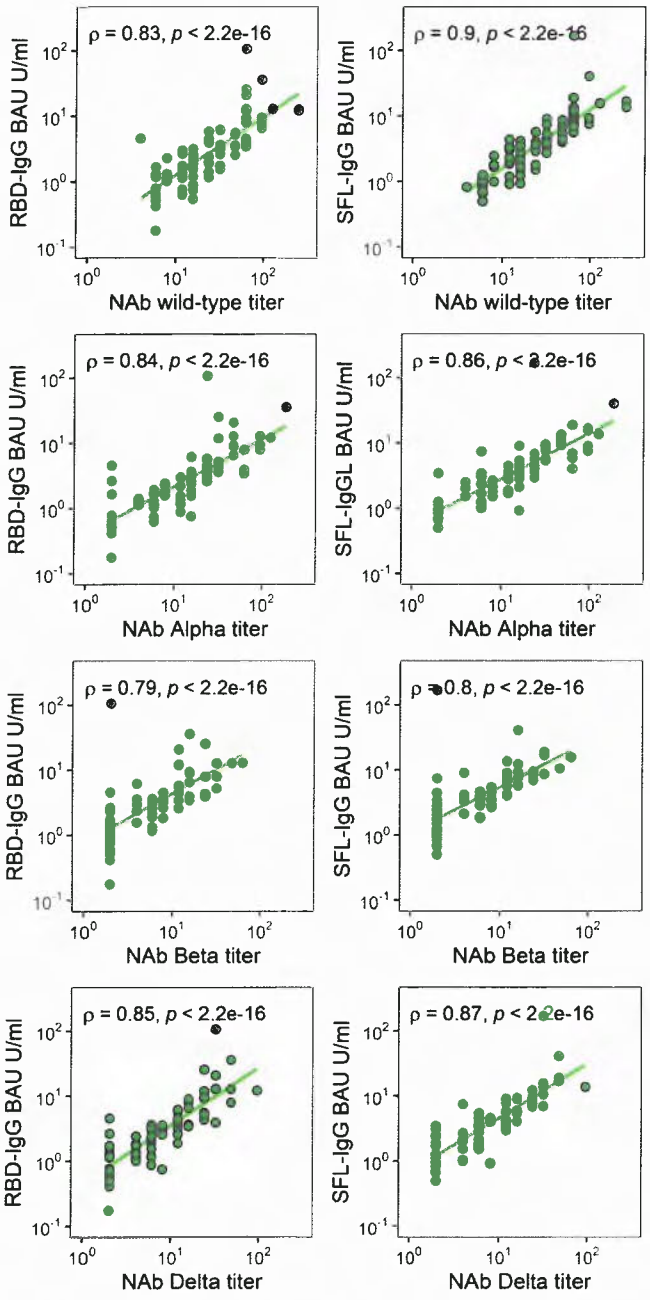


**Figure 5.** Spearman correlation ($\rho$) and significance ($p$) between S-IgG antibody concentrations and neutralizing antibody (NAb) titers against the WT virus (B) and the variants of concern: Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.617.2). One point may represent multiple samples (n = 78 subjects). Each sample was tested as technical duplicates in each experiment and the experimental precision was confirmed by two control samples in each independent experiment.

The relatively rapid early decline in S-IgG antibodies followed by slower decay indicates a transition of serum antibodies from being produced by short-lived plasmablasts to a more persistent population of long-lived plasma cells generated later in the immune response (33). Consistently, NAbs and T cell immunity have been reported to persist at least 6 to 12 months after infection (6-8, 11–13, 34). Our data are consistent with previous data suggesting that, even though NAb titers decline with time, NAbs persist in most subjects, at least up to 13 months.

We observed that a markedly lower proportion of subjects had N-IgG than S-IgG antibodies at 8 months after infection. Thereafter the concentration of N-IgG antibodies declined to a level that was not distinguishable from unspecific, cross-reactive antibodies among a large proportion of subjects 13 months after infection. SARS-CoV-2 N is produced abundantly during infection and since it is not a component in present vaccines or vaccine candidates it could potentially serve as a measure of past infection. However, our results clearly show that the sensitivity of our N-IgG-based antibody assay is inversely proportional to the time after infection. In agreement with our findings, the more rapid decay of N-IgG after SARS-CoV and SARS-CoV-2 infection has also been reported in other studies (32, 35, 36). The loss of sensitivity of SARS-CoV-2 N based antibody assays over time likely results not only from the decay of the antibodies, but from the difficulty of differentiating very low concentrations of SARS-CoV-2-specific antibodies from cross-reactive N antibodies induced by past infections with common cold human coronaviruses that share highly conserved regions (37).

Even though NAbs persist relatively long in most subjects, neutralization efficiency against the Alpha (B.1.1.7), Beta (B.1.351), and Delta (B.1.617.2) variants was decreased compared to the WT virus. This was emphasized in subjects who had recovered from mild disease representing the majority of COVID-19 cases (1). Indeed, mild symptomatic or asymptomatic individuals may develop no or only low levels of NAbs that may wane relatively quickly after infection (38).

In line with earlier observations 9 (13) and 12 months after infection (12), we found that NAb levels against the Alpha variant were only slightly reduced, while NAb levels against the Beta variant were considerably declined compared to the WT virus. The Beta variants have been shown to evade antibody responses induced upon infection as well as vaccination (21-23, 39, 40). Although the NAb levels were declined against the Beta variant, we observed that over 60% of hospitalized subjects were seropositive a year after infection, indicating long-lived cross-neutralization capacity induced by severe disease.

We detected substantially declined NAb titers against the Delta variant in subjects with mild disease, similar to what has been previously reported after vaccination or up to 12 months after SARS-CoV-2 infection (24, 25, 41–43). However, we observed that over 80% of the subjects who had recovered from a severe disease were seropositive against the Delta variant. This is in line with one study reporting only modestly reduced (88%) NAb levels against the Delta variant 2–4 weeks after second vaccine dose (44). Our results support the previous findings that the emerging variant Delta partially but significantly escapes NAbs (24, 25).

One previous study reported lower seropositivity rates one year after mild SARS-CoV-2-infection compared to our results; 58% were positive for S1-IgG and 85% for S-IgG measured with enzyme immunoassay and 58% had NAb (11). Direct comparison of the IgG concentrations and NAb titers between studies may not be possible since the age groups, viruses, as well as the serological

tests, differed. Neutralizing antibody tests have not been standardized and among other things, the starting dilutions of serum samples may vary between assays. The microneutralization assay used in this study utilized live virus and the starting dilution of 1:4 further enhances the sensitivity of the assay in detecting low levels of NAbs.

In our study population, we could not see a gender effect in hospitalized individuals, as previously reported (6, 31). However, hospitalized subjects ≥60 years tended to have slightly higher IgG and NAb levels compared to hospitalized subjects <60 years suggesting more severe infection in the elderly age group. Although there was no overall difference between the genders, especially males with mild disease had markedly lower NAb titers for all viruses compared to individuals who recovered from severe disease.

There is a major research effort to produce effective SARS-CoV-2 vaccines. The long-term persistence of immunity after vaccination is, however, largely unknown. Evidence from convalescent sera from individuals who have recovered from infection may help determine for how long immunity persists, and whether antibodies might protect against re-infection. Previous data shows that, when measured as IgG antibodies against S protein or RBD and NAb, immune response after two doses of SARS-CoV-2 vaccine is similar to that observed in convalescent sera from COVID-19 patients (45–48). Evidence of persistence of immunity after infection will help in predicting the persistence of immunity after SARS-CoV-2 vaccination.

We recognize certain limitations in our study. Due to high SARS-CoV-2 vaccine coverage in the older age groups (≥60 years of age) at the time of our study, only 11% of the participants were ≥60 years of age, the age group with the highest disease incidence and morbidity. Our results may not necessarily apply to all age groups. The number of subjects selected for the NAb titer comparison was limited but the study subjects were matched by disease severity, age, and gender, and randomly selected from the participants.

Previous studies have indicated that the presence of antibodies to SARS-CoV-2 was associated with a significantly reduced risk of SARS-CoV-2 reinfection among healthcare workers for up to 7 months after infection (27, 49). We observed that S-IgG antibodies and NAbs persist at least a year after infection in most individuals. This strongly suggests that protection against re-infection is long-lived, although antibody-mediated immunity may not persist equally well among elderly subjects. A previous study found that patients >60 years had fewer memory B cells secreting total IgG and RBD-specific IgG than patients <60 years old 9 months after infection (9). We observed that IgG concentrations declined from 8 to 13 months more substantially in subjects ≥60 years compared to younger age groups. A similar more rapid decline in NAb concentrations was observed among the elderly compared to younger subjects who were followed up to 6 months following vaccination (50). The results of our study support previous findings indicating that protection against infection mediated by NAbs may be impaired against the VOCs, especially after a mild disease. While in the absence of NAbs reinfection is possible, cellular immunity is not similarly affected by mutations in the RBD site (22) and is likely to provide long-term protection against severe disease.

## Materials and methods

### Study design and participants

In October 2020, 2586 subjects ≥18 years of age, native language Finnish or Swedish, living within five selected hospital districts in Finland and with a PCR-confirmed COVID-19 diagnosis between February 29 and April 30, 2020 were identified in the National Infectious Disease Register and invited to participate in the follow-up study. Subjects within institutional care were excluded. Informed consent was obtained from all study subjects before sample collection. A total of 1292 (50%) subjects (median age 50.0, range 17.3-94.3) with PCR-confirmed COVID-19 participated and donated a blood sample for determination of SARS-CoV-2 specific serum antibodies 5.9 to 9.9 months (median 7.6 months) after infection. All those previously enrolled and still living in the same hospital district ($n$ = 1227) were invited to a follow-up visit and blood sampling a year after the COVID-19 diagnosis in March-April 2021. By May 21, 2021, altogether 995 participants (median age 52.5, range 17.6-95.6 years) had participated at 12.7 months (median, range 11.7 to 14.3 months) after the diagnosis of PCR-confirmed COVID-19. Demographics, clinical characteristics, and SARS-CoV-2 vaccination history of the participants were collected from the National Infectious Disease Register, the Care Register for Health Care, the Register of Primary Health Care Visits, and the National Vaccination Registry and are summarized in Table 1. The disease severity was defined as severe or mild. Severe infection was defined as an individual with laboratory-confirmed COVID-19 and who required hospital treatment. Mild infection was defined as an individual with laboratory-confirmed COVID-19 without hospital treatment. Since late December 2020 SARS-CoV-2 vaccinations have been offered according to the national recommendations in Finland.

### Sample processing and selection of samples

Sera were separated by centrifugation, aliquoted, and stored at -20°C or below. For assessment of NAbs, sera were heat-inactivated (56°C for 30 min) and then stored at -20°C or below.

For assessment of persistence of serum antibodies 8 months following PCR-confirmed COVID-19 diagnosis, all samples taken ≤10 months after diagnosis ($n$ = 1292) were selected for assessment of SARS-CoV-2 IgG antibody concentration and NAbs (positive/borderline/negative). For assessment of antibody persistence 13 months after infection, 400 of 995 sera were randomly selected for determination of SARS-CoV-2 IgG antibody concentration and NAbs. Selection criteria were: 8-month sample available,

PCR-confirmed COVID-19 diagnosis, no documentation of SARS-CoV-2 vaccination in the Register of Primary Health Care Visits by June 10th 2021. Further, samples of subjects with ≥30% increase in IgG antibody concentration to both SARS-CoV-2 S gp antigens (full-length spike protein (SFL) and RBD) between 8- and 13-month blood sampling (n = 29) were excluded from the analysis. An additional four samples were excluded due to the late discovery of these samples not meeting selection criteria. Of the four samples, two were excluded due to vaccination and two due to samples taken >10 months after infection. Consequently, 367 sera were selected.

For comparison of NAb titers against a WT virus and VOCs (Alpha, Beta, and Delta), 80/536 13-month sera screened to NAb (titer ≥6 against WT virus) were randomly selected as mentioned above. Later observed ≥30% increase in IgG antibody concentration between 8- and 13-month samples excluded two of 80 samples, leaving total sample size to 78. SARS-CoV-2 IgG antibody concentration was measured from this cohort to ensure its comparability to the other 367 sera selected.

### SARS-CoV-2 MNT

A cytopathic effect-based MNT was performed as previously described (51, 52). Briefly, heat-inactivated serum samples were 2-fold serially diluted starting from 1:4 in Eagle's MEM supplemented with penicillin, streptomycin, and 2% of heat-inactivated fetal bovine serum. At the biosafety level 3 laboratory, pre-titrated virus was added to obtain 100× tissue culture infectious dose 50% per well following incubation for 1 h at +37°C, 5% $CO_2$. African green monkey kidney epithelial (VeroE6) cells were added and the 96-well tissue culture plates were incubated at +37°C, 5% $CO_2$ for 4 days. Wells were fixed with 30% formaldehyde and stained with crystal violet. Results were expressed as MNT titers corresponding to the reciprocal of the serum dilution that inhibited 50% of SARS-CoV-2 infection observed by the cytopathic effect of inoculated cells. MNT titer ≥6 was considered positive, borderline when 4, and negative when <4. Borderline values were further confirmed with biological repeats. For titer comparison, a titer of 192 was measured for the WHO International Standard (NIBSC 20/136 (53)) using the WT virus Fin1-20.

### SARS-CoV-2 viruses selected for MNT

All samples were screened with WT virus Fin1-20 (B lineage): hCoV-19/Finland/1/2020 (GISAID accession ID EPI_ISL_407079; GenBank accession ID MZ934691) for NAb positivity. Fin1-20 was the first SARS-CoV-2 strain detected in Finland in January 2020. Virus isolation and propagation were performed in Vero E6 cells (51). A smaller subset of samples was analyzed also with VOCs isolated in Finland during January 2021: Fin34-21, Fin32-21, and May 2021: Fin37-21, which stand for the Alpha, Beta, and Delta variant, respectively. Alpha variant (B.1.1.7) Fin34-21 indicates the isolate hCoV-19/Finland/THL-202102301/2021 (EPI_ISL_2590786; MZ944886). Spike region of the isolate hCoV-19/Finland/THL-202101018/2021 (Fin32-21) showed typical Beta variant (B.1.351) amino acid changes (EPI_ISL_3471851; MZ944846). The Delta variant (B.1.617.2) Fin37-21 indicates hCoV-19/Finland/THL-202117309/2021 (EPI_ISL_2557176; MZ945494). All variant viruses were isolated and propagated (passages 1–2) in VeroE6-TMPRSS2-H10 cells (54) and further propagated in Vero E6 cells (passage 3) for MNT.

### SARS-CoV-2 fluorescent multiplex immunoassay

The SARS-CoV-2 fluorescent multiplex immunoassay (FMIA) has been previously described in detail by Ekström et al. (52) and Solastie et al. (55). Briefly, diluted sera, reference, and controls were mixed with microspheres conjugated with SARS-CoV-2 N and SFL and RBD of the spike protein. IgG antibodies were detected by R-Phycoerythrin-conjugated secondary antibody and median fluorescence intensity was measured with MAGPIX system (Luminex) and BAU (U/ml) were interpolated from 5-parameter logistic curves with xPONENT (v. 4.2, Luminex) created by 7-point serial fourfold diluted reference sera calibrated against WHO International Standard (NIBSC code 20/136; (53)). When the median fluorescence intensity of a sample was below the linear range of the reference, the sample was assigned an antibody concentration half of the limit of detection (0.0094, 0.012, and 0.0057 BAU/ml for N-, SFL-, and RBD-IgG). A sample was considered positive for SARS-CoV-2 S-IgG when SFL and RBD specific antibody concentrations were ≥0.089 and ≥0.13 BAU/ml, respectively. A sample was considered positive for N-IgG when N-IgG concentration was ≥0.58 BAU/ml. The cut-offs for seropositivity were determined during clinical validation of the FMIA and yielded both sensitivity and specificity of 100% for SFL- and RBD-IgG and 98.6% and 100% for N-IgG for samples taken 13 to 150 days post-onset of symptoms, respectively (52, 55).

### Statistical methods

We calculated the geometric mean concentrations (GMC) and GMTs with 95% confidence intervals (CI) for IgG and NAb levels, respectively. We assessed the statistical differences in antibody levels between groups using the Kruskal-Wallis test with Bonferroni correction. Differences in mean IgG concentrations between 8 and 13 months after infection were compared using Student's paired *t*-test and log-transformed data. The statistical significance level of difference was set to $p<0.05$. We used Spearman correlation in the correlation analyses. MNT titers <4 were assigned a titer value of 2. Samples with IgG concentrations below the limit of detection were assigned an antibody concentration equal to half of the limit of detection. Statistical analyses were performed using SPSS v27 and R (v4.0.4) with Rstudio (v1.4.1106).

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Ethics approval and patient consent statement: The study protocol was approved by the ethical committee of the Hospital District of Helsinki and Uusimaa and registered under the study protocol HUS/1137/2020. Informed consent was obtained from all study subjects before sample collection.

Author contributions: M.M., N.E., and A.H. designed the experiments. M.M., A.A.P., and H.N. contributed to the study design. C.V. and A.S. developed and performed the FMIA tests. A.H. developed and performed the microneutralization tests. P.Ö. coordinated the virus isolations. A.H., N.E., and A.S. analyzed the data. E.I. and N.E coordinated the participant recruitment, sample collection, and sample processing. A.H., N.E., and M.M. wrote the manuscript and all co-authors contributed to the edition of the text.

Conflict of interest: Finnish Institute for Health and Welfare has received research funding for unrelated studies from GlaxoSmithKline Vaccines (N.E., C.V., A.A.P. and M.M. as investigators), Pfizer (A.A.P.), and Sanofi Pasteur (A.A.P.). The other authors report no potential conflicts of interest.

Data availability statement: The data that support the findings of this study are available from the corresponding author upon reasonable request. The complete data are not publicly available due to privacy or ethical restrictions.

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*Abbreviations:* **BAU:** binding antibody unit concentration · **COVID-19:** Coronavirus Disease 2019 · **FMIA:** fluorescent multiplex immunoassay · **GMC:** geometric mean concentration · **GMT:** geometric mean titer · **MNT:** microneutralization test · **NAb:** neutralizing antibody · **N:** nucleoprotein · **PCR:** polymerase chain reaction · **RBD:** receptor-binding domain · **SARS-CoV-2:** Severe acute respiratory syndrome coronavirus 2 · **S:** spike protein · **SFL:** spike full length · **VOC:** variants of concern

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# Exhibit "CC"

Article

# SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls

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Memory T cells induced by previous pathogens can shape susceptibility to, and the clinical severity of, subsequent infections[1]. Little is known about the presence in humans of pre-existing memory T cells that have the potential to recognize severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Here we studied T cell responses against the structural (nucleocapsid (N) protein) and non-structural (NSP7 and NSP13 of *ORF1*) regions of SARS-CoV-2 in individuals convalescing from coronavirus disease 2019 (COVID-19) ($n = 36$). In all of these individuals, we found CD4 and CD8 T cells that recognized multiple regions of the N protein. Next, we showed that patients ($n = 23$) who recovered from SARS (the disease associated with SARS-CoV infection) possess long-lasting memory T cells that are reactive to the N protein of SARS-CoV 17 years after the outbreak of SARS in 2003; these T cells displayed robust cross-reactivity to the N protein of SARS-CoV-2. We also detected SARS-CoV-2-specific T cells in individuals with no history of SARS, COVID-19 or contact with individuals who had SARS and/or COVID-19 ($n = 37$). SARS-CoV-2-specific T cells in uninfected donors exhibited a different pattern of immunodominance, and frequently targeted NSP7 and NSP13 as well as the N protein. Epitope characterization of NSP7-specific T cells showed the recognition of protein fragments that are conserved among animal betacoronaviruses but have low homology to 'common cold' human-associated coronaviruses. Thus, infection with betacoronaviruses induces multi-specific and long-lasting T cell immunity against the structural N protein. Understanding how pre-existing N- and ORF1-specific T cells that are present in the general population affect the susceptibility to and pathogenesis of SARS-CoV-2 infection is important for the management of the current COVID-19 pandemic.

SARS-CoV-2 is the cause of COVID-19[2]. This disease has been declared a pandemic by the World Health Organization (WHO), and is having severe effects on both individual lives and economies around the world. Infection with SARS-CoV-2 is characterized by a broad spectrum of clinical syndromes, which range from asymptomatic disease or mild influenza-like symptoms to severe pneumonia and acute respiratory distress syndrome[3].

It is common to observe the ability of a single virus to cause widely differing pathological manifestations in humans. This is often due to multiple contributing factors including the size of the viral inoculum, the genetic background of patients and the presence of concomitant pathological conditions. Moreover, an established adaptive immunity towards closely related viruses[4] or other microorganisms[5] can reduce susceptibility[6] or enhance disease severity[7].

SARS-CoV-2 belongs to the *Coronaviridae*, a family of large RNA viruses that infect many animal species. Six other coronaviruses are known to infect humans. Four of them are endemically transmitted[8] and cause the common cold (OC43, HKU1, 229E and NL63), while SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV) have caused epidemics of severe pneumonia[9]. All of these coronaviruses trigger antibody and T cell responses in infected patients: however, antibody levels appear to wane faster than T cells. SARS-CoV-specific antibodies dropped below the limit of detection within 2 to 3 years[10], whereas SARS-CoV-specific memory T cells have been detected even 11 years after SARS[11]. As the sequences of selected structural and non-structural proteins are highly conserved among different coronaviruses (for example, NSP7 and NSP13 are 100% and 99% identical, respectively, between SARS-CoV-2, SARS-CoV and the bat-associated bat-SL-CoVZXC21[12]), we investigated whether cross-reactive SARS-CoV-2-specific T cells are present in individuals who resolved SARS-CoV, and compared the responses with those present in individuals who recovered from SARS-CoV-2 infection. We also

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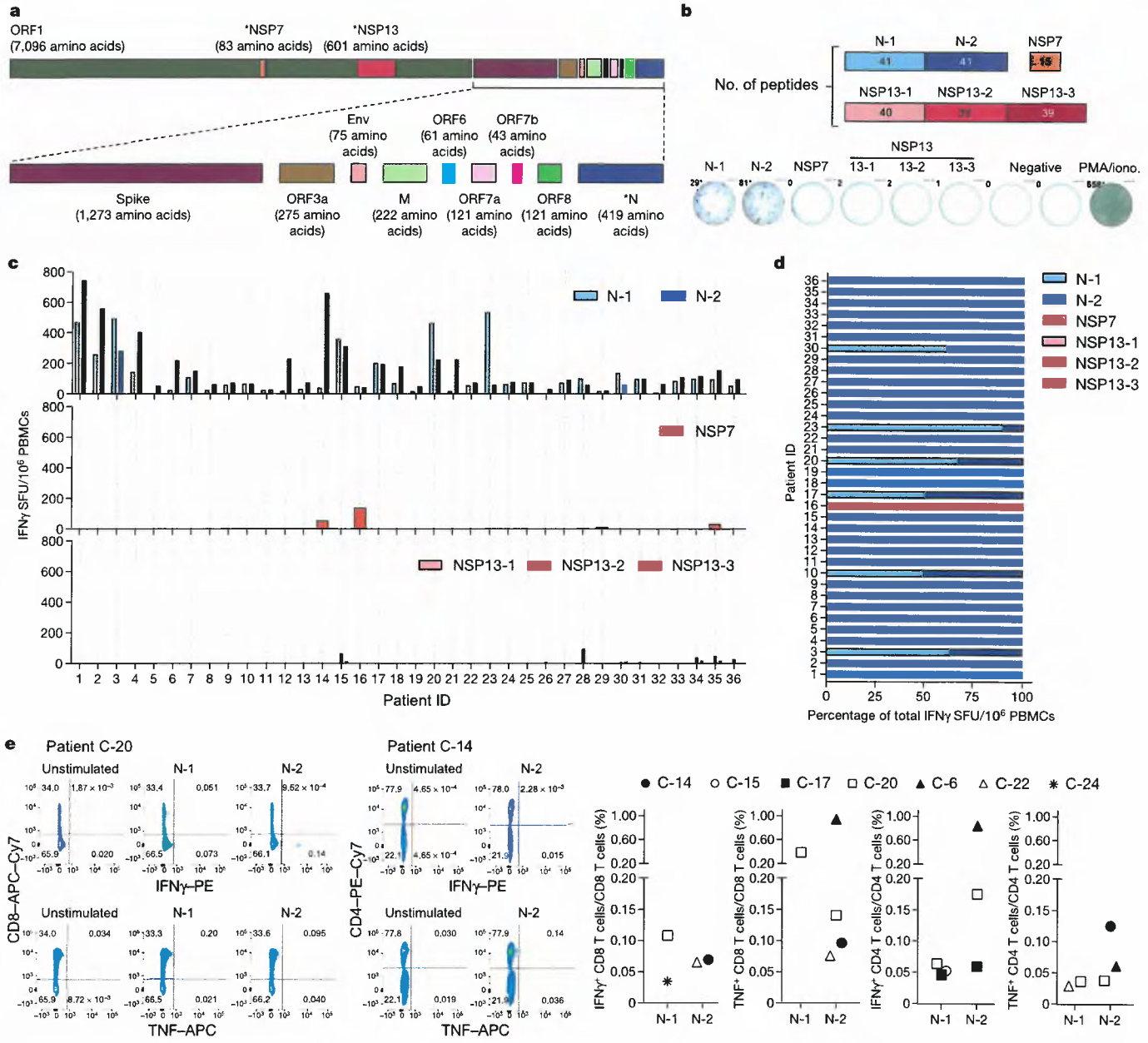


**Fig. 1 | SARS-CoV-2-specific responses in patients recovered from COVID-19. a**, SARS-CoV-2 proteome organization; analysed proteins are marked by an asterisk. **b**, The 15-mer peptides, which overlapped by 10 amino acids, comprising the N protein, NSP7 and NSP13 were split into 6 pools covering the N protein (N-1, N-2), NSP7 and NSP13 (NSP13-1, NSP13-2, NSP13-3). **c**, PBMCs of patients who recovered from COVID-19 ($n = 36$) were stimulated with the peptide pools or with phorbol 12-myristate 13-acetate (PMA) and ionomycin (iono) as a positive control. The frequency of spot-forming units (SFU) of IFNγ-secreting cells is shown. **d**, The composition of the SARS-CoV-2 response in each individual is shown as a percentage of the total detected response. N-1, light blue; N-2, dark blue; NSP7, orange; NSP13-1, light red; NSP13-2, red; NSP13-3, dark red. **e**, PBMCs were stimulated with the peptide pools covering the N protein (N-1, N-2) for 5 h and analysed by intracellular cytokine staining. Dot plots show examples of patients (2 out of 7) that had CD4 and/or CD8 T cells that produced IFNγ and/or TNF in response to stimulation with N-1 and/or N-2 peptides. The percentage of SARS-CoV-2 N-peptide-reactive CD4 and CD8 T cells in $n = 7$ individuals are shown (unstimulated controls were subtracted for each response).

studied these T cells in individuals with no history of SARS or COVID-19 or of contact with patients with SARS-CoV-2. Collectively these individuals are hereafter referred to as individuals who were not exposed to SARS-CoV and SARS-CoV-2 (unexposed donors).

## SARS-CoV-2-specific T cells in patients with COVID-19

SARS-CoV-2-specific T cells have just started to be characterized for patients with COVID-19[13,14] and their potential protective role has been inferred from studies of patients who recovered from SARS[15] and MERS[16]. To study SARS-CoV-2-specific T cells associated with viral clearance, we collected peripheral blood from 36 individuals after recovery from mild to severe COVID-19 (demographic, clinical and virological information is included in Extended Data Table 1) and studied the T cell response against selected structural (N) and non-structural proteins (NSP7 and NSP13 of ORF1) of the large SARS-CoV-2 proteome (Fig. 1a). We selected the N protein as it is one of the more-abundant structural proteins produced[17] and has a high degree of homology between different betacoronaviruses[18] (Extended Data Fig. 1).

NSP7 and NSP13 were selected for their complete homology between SARS-CoV, SARS-CoV-2 and other animal coronaviruses that belong to the betacoronavirus genus[12] (Extended Data Fig. 2), and because

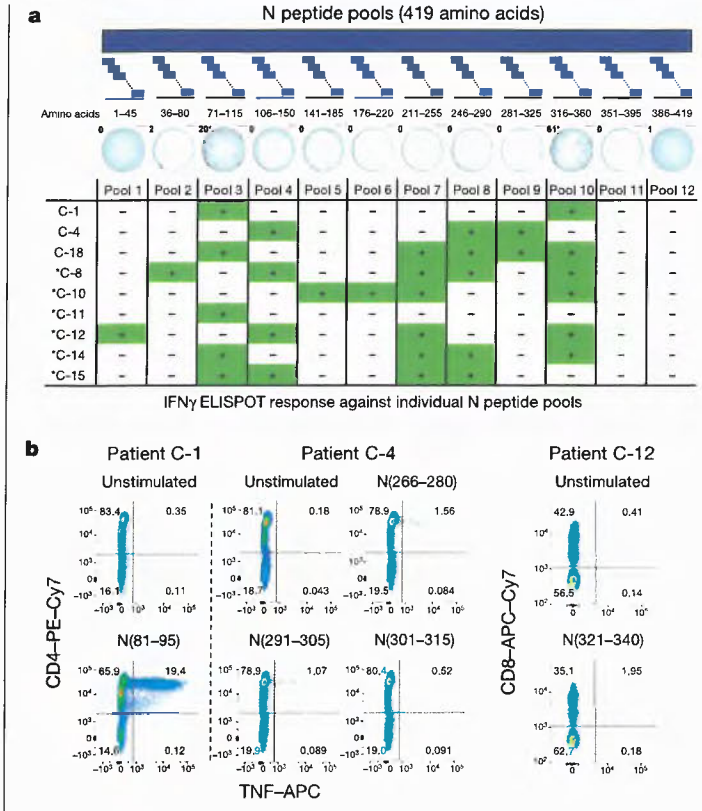


**Fig. 2 | SARS-CoV-2-specific T cells in COVID-19 convalescent individuals target multiple regions of the N protein. a**, PBMCs of 9 individuals who recovered from COVID-19 were stimulated with 12 different pools of 7–8 N peptides. The table shows IFNγ ELISpot responses against the individual N peptide pools. The asterisk denotes responses detected after in vitro expansion. **b**, After in vitro cell expansion, a peptide pool matrix strategy was used. T cells that reacted to distinct peptides were identified by IFNγ ELISpot and confirmed by ICS. Representative dot plots of 3 out of 7 patients are shown.

they are representative of the ORF1a/b polyprotein that encodes the replicase–transcriptase complex[19]. This polyprotein is the first to be translated after infection with coronavirus and is essential for the subsequent transcription of the genomic and sub-genomic RNA species that encode the structural proteins[19]. We synthesized 216 15-mer peptides that overlapped by 10 amino acids and that covered the whole length of NSP7 (83 amino acids), NSP13 (601 amino acids) and N (422 amino acids) and split these peptides into five pools of approximately 40 peptides each (N-1, N-2, NSP13-1, NSP13-2 and NSP13-3) and a single pool of 15 peptides that spanned NSP7 (Fig. 1b). This unbiased method with overlapping peptides was used instead of bioinformatics selection of peptides, as the performance of such algorithms is often sub-optimal in Asian populations[20].

Peripheral blood mononuclear cells (PBMCs) of 36 patients who recovered from COVID-19 were stimulated for 18 h with the different peptide pools and virus-specific responses were analysed by interferon-γ (IFNγ) ELISpot assay. In all individuals tested (36 out of 36), we detected IFNγ spots after stimulation with the pools of synthetic peptides that covered the N protein (Fig. 1c, d). In nearly all individuals, N-specific responses could be identified against multiple regions of the protein: 34 out of 36 individuals showed reactivity against the region that comprised amino acids 1–215 (N-1) and 36 out of 36 individuals showed reactivity against the region comprising amino acids 206–419 (N-2). By contrast, responses to NSP7 and NSP13 peptide pools were detected at very low levels in 12 out of 36 COVID-19-convalescent individuals tested.

Direct ex vivo intracellular cytokine staining (ICS) was performed to confirm and define the N-specific IFNγ ELISpot response. Owing to their relative low frequency, N-specific T cells were more difficult to visualize by ICS than by ELISpot; however, a clear population of CD4 and/or CD8 T cells that produced IFNγ and/or TNF was detectable in seven out of nine analysed individuals (Fig. 1e and Extended Data Figs. 3, 4). Moreover, despite the small sample size, we could compare the frequency of SARS-CoV-2-specific IFNγ spots with the presence of virus-neutralizing antibodies, the duration of infection and disease severity and found no correlations (Extended Data Fig. 5). To confirm and further delineate the multi-specificity of the N-specific responses detected ex vivo in patients who recovered from COVID-19, we mapped the precise regions of the N protein that is able to activate IFNγ responses in nine individuals. We organized the 82 overlapping peptides that covered the entire N protein into small peptide pools (of 7–8 peptides) that were used to stimulate PBMCs either directly ex vivo or after an in vitro expansion protocol that has previously been used for patients with hepatitis B virus[21] or SARS[22]. A schematic representation of the peptide pools is shown in Fig. 2a. We found that 8 out of 9 patients who recovered from COVID-19 had PBMCs that recognized multiple regions of the N protein of SARS-CoV-2 (Fig. 2a). Notably, we then defined single peptides that were able to activate T cells in seven patients. Using a peptide matrix strategy[22], we first deconvolved the individual peptides that were responsible for the detected response by IFNγ ELISpot. Subsequently, we confirmed the identity of the single peptides by testing—using ICS—the ability of the peptides to activate

**Table 1 | SARS-CoV-2-specific T cell epitopes**

| Participants | T cell phenotype | Protein (amino acid residues) | SARS-CoV-2 amino acid sequence | SARS-CoV amino acid sequence |
|---|---|---|---|---|
| C-1 | CD4 | N (81–95) | DDQIGYYRRATRRIR | DDQIGYYRRATRRVR |
| | CD8 | N (321–340) | G**MEVTPSGTWL**TYTGAIKLD | G**MEVTPSGTWL**TYHGAIKLD |
| C-4 | CD4 | N (266–280) | KAYNVTQAFGRRGPE | KQYNVTQAFGRRGPE |
| | CD4 | N (291–305) | LIRQGTDYKHWPQIA | LIRQGTDYKHWPQIA |
| | CD4 | N (301–315) | WPQIAQFAPSASAFF | WPQIAQFAPSASAFF |
| C-8 | CD4 | N (51–65) | SWFTALTQHGKEDLK | SWFTALTQHGKEELR |
| | CD4 | N (101–120) | **MKDLSPRWYFYYLG**TGPEAG | **MKELSPRWYFYYLG**TGPEAS |
| C-10 | CD4 and CD8 | N (321–340) | G**MEVTPSGTWL**TYTGAIKLD | G**MEVTPSGTWL**TYHGAIKLD |
| C-12 | CD8 | N (321–340) | G**MEVTPSGTWL**TYTGAIKLD | G**MEVTPSGTWL**TYHGAIKLD |
| C-15 | CD4 | N (101–120) | **MKDLSPRWYFYYLG**TGPEAG | **MKELSPRWYFYYLG**TGPEAS |
| C-16 | CD4 | NSP7 (21–35) | RVESSSKLWAQCVQL | RVESSSKLWAQCVQL |

T cells that react with distinct peptides were identified by IFNγ ELISpot and confirmed by ICS. Previously described T cell epitopes for SARS-CoV are highlighted in bold; non-conserved amino acid residues between SARS-CoV and SARS-CoV-2 are underlined.

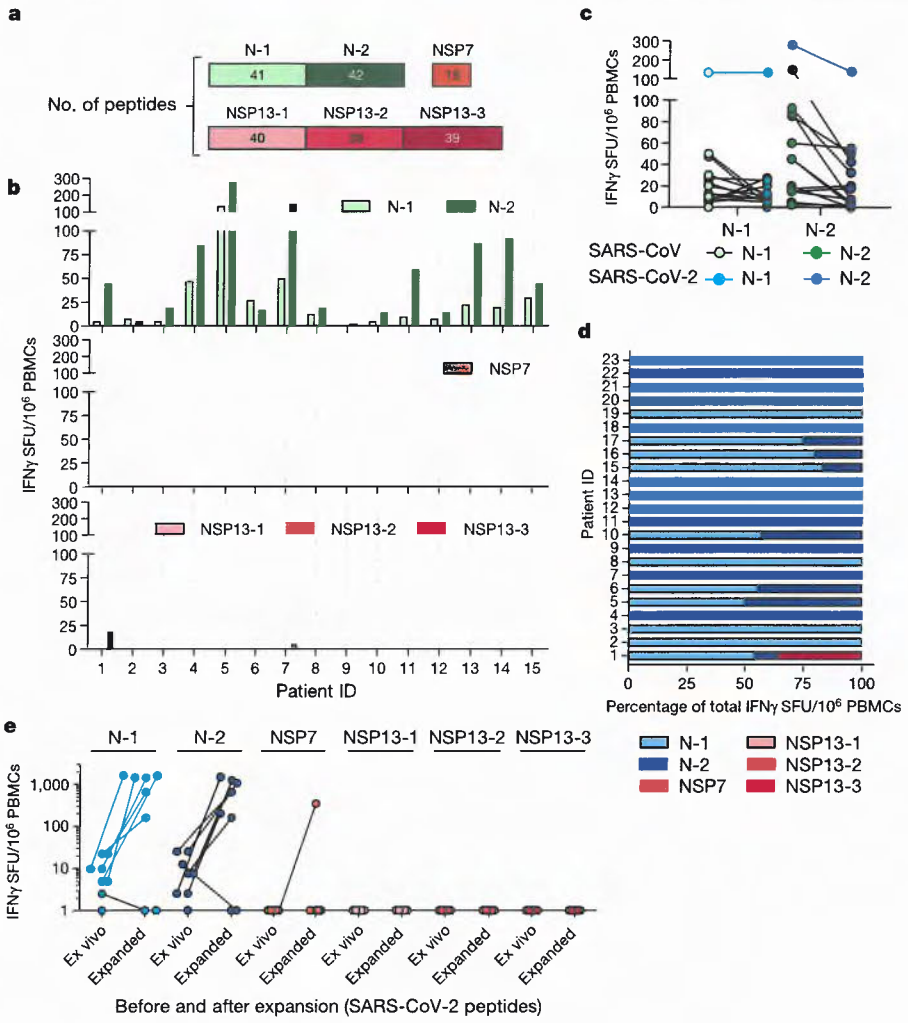


**Fig. 3 | SARS-CoV-2 cross-reactive responses are present in patients who recovered from SARS.** **a**, PBMCs isolated from 15 individuals who recovered from SARS 17 years ago were stimulated with SARS-CoV N, NSP7 and NSP13 peptide pools. **b**, Spot-forming units of IFNγ-secreting cells after overnight stimulation with the indicated peptide pools. **c**, PBMCs of 15 individuals who recovered from SARS were stimulated in parallel with peptide pools covering the N proteins of SARS-CoV and SARS-CoV-2, and the frequency of IFNγ-producing cells is shown. **d**, The composition of the SARS-CoV-2 response in each individual who recovered from SARS ($n = 23$) is shown as a percentage of the total detected response. N-1, light blue; N-2, dark blue; NSP7, orange; NSP13-1, light red; NSP13-2, red; NSP13-3, dark red. **e**, PBMCs of 8 individuals who recovered from SARS were stimulated with all peptides covering N, NSP7 and NSP13 of SARS-CoV-2 to detect cross-reactive responses. The numbers of cells that are reactive to the different peptide pools directly ex vivo and after in vitro expansion are shown.

CD4 or CD8 T cells (Table 1 and Fig. 2b). Table 1 summarizes the different T cell epitopes that were defined by both ELISpot and ICS for seven individuals who recovered from COVID-19. Notably, we observed that COVID-19-convalescent individuals developed T cells that were specific to regions that were also targeted by T cells from individuals who recovered from SARS. For example, the region of amino acids 101–120 of the N protein, which is a previously described CD4 T cell epitope in SARS-CoV-exposed individuals[11,22], also stimulated CD4 T cells in two COVID-19-convalescent individuals. Similarly, the region of amino acids 321–340 of the N protein contained epitopes that triggered CD4 and CD8 T cells in patients who recovered from either COVID-19 or from SARS[22]. The finding that patients who recovered from COVID-19 and SARS can mount T cell responses against shared viral determinants suggests that previous SARS-CoV infection can induce T cells that are able to cross-react against SARS-CoV-2.

## SARS-CoV-2-specific T cells in patients with SARS

For the management of the current pandemic and for vaccine development against SARS-CoV-2, it is important to understand whether acquired immunity will be long-lasting. We have previously demonstrated that patients who recovered from SARS have T cells that are specific to epitopes within different SARS-CoV proteins that persist for 11 years after infection[11]. Here, we collected PBMCs 17 years after SARS-CoV infection and tested whether they still contained cells that were reactive against SARS-CoV and whether these had cross-reactive potential against SARS-CoV-2 peptides. PBMCs from individuals who had resolved a SARS-CoV infection ($n = 15$) were stimulated directly ex vivo with peptide pools that covered the N protein of SARS-CoV (N-1 and N-2), NSP7 and NSP13 (Fig. 3a). This revealed that 17 years after infection, IFNγ responses to SARS-CoV peptides were still present and were almost exclusively focused on the N protein rather than the NSP peptide pools (Fig. 3b). Subsequently, we tested whether the N peptides of SARS-CoV-2 (amino acid identity, 94%) induced IFNγ responses in PBMCs from individuals who resolved a SARS-CoV infection. Indeed, PBMCs from all 23 individuals tested reacted to N peptides from SARS-CoV-2 (Fig. 3c, d). To test whether these low-frequency responses in individuals who had recovered from SARS could expand after encountering the N protein of SARS-CoV-2, the quantity of IFNγ-producing cells that responded to the N, NSP7 and NSP13 proteins of SARS-CoV-2 was analysed after 10 days of cell culture in the presence of the relevant peptides. Seven out of eight individuals tested showed clear, robust expansion of N-reactive cells (Fig. 3e) and ICS confirmed that individuals who recovered from SARS had SARS-CoV N-reactive CD4 and CD8 memory T cells[11] (Extended Data Fig. 6). In contrast to the response to the N peptides, we could not detect any cells that reacted to the peptide pools that covered NSP13 and only cells from one out of eight individuals reacted to NSP7 (Fig. 3e).

Thus, SARS-CoV-2 N-specific T cells are part of the T cell repertoire of individuals with a history of SARS-CoV infection and these T cells are able to robustly expand after encountering N peptides of SARS-CoV-2. These findings demonstrate that virus-specific T cells induced by infection with betacoronaviruses are long-lasting, supporting the notion that patients with COVID-19 will develop long-term T cell immunity. Our findings also raise the possibility that long-lasting T cells generated

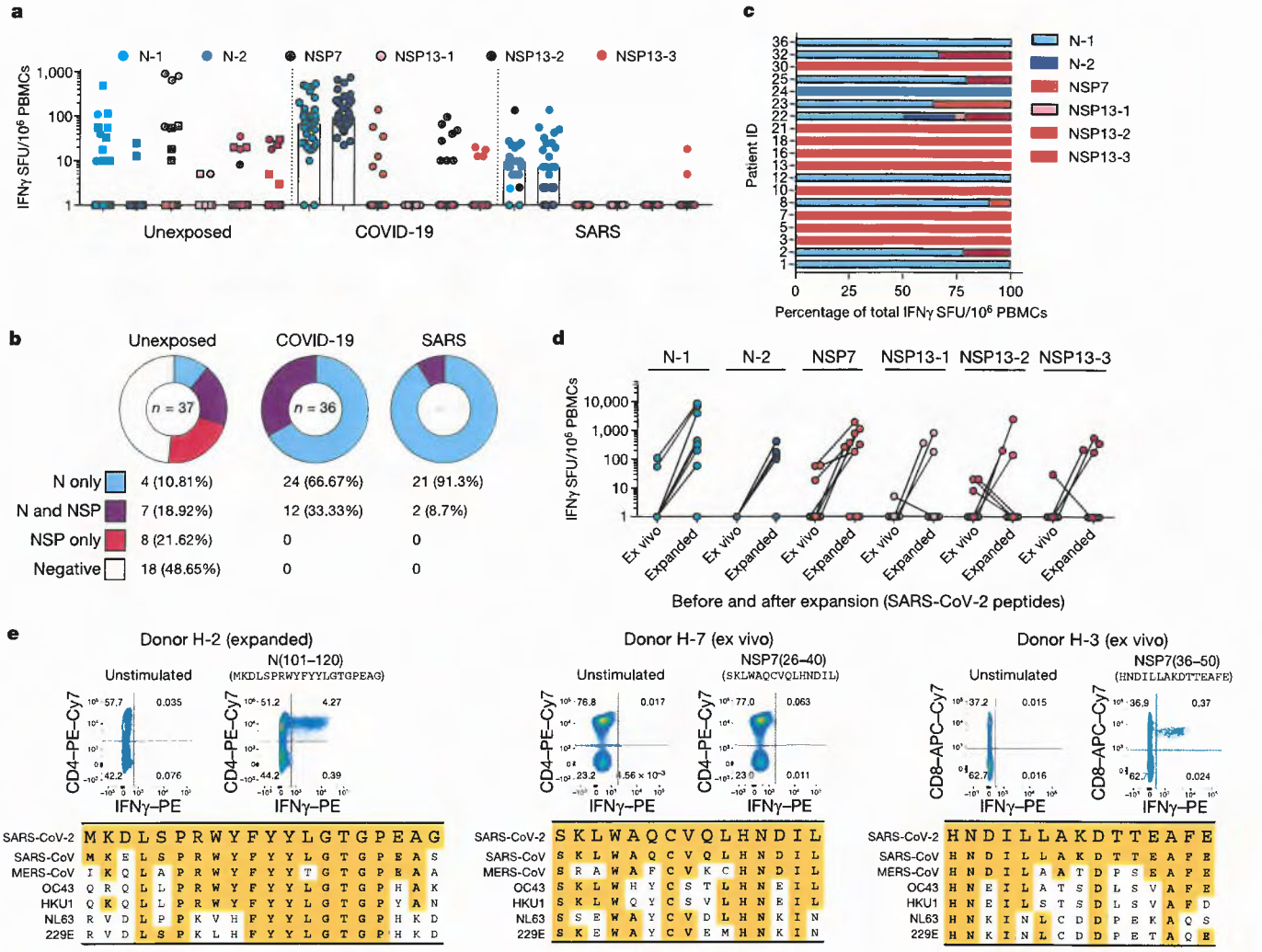


**Fig. 4 | Immunodominance of SARS-CoV-2 responses in patients who recovered from COVID-19 and SARS, and in unexposed individuals.** **a**, PBMCs of individuals who were not exposed to SARS-CoV and SARS-CoV-2 ($n = 37$), recovered from SARS ($n = 23$) or COVID-19 ($n = 36$) were stimulated with peptide pools covering N (N-1, N-2), NSP7 and NSP13 (NSP13-1, NSP13-2, NSP13-3) of SARS-CoV-2 and analysed by ELISpot. The frequency of peptide-reactive cells is shown for each donor (dots or squares) and the bars represent the median frequency. Squares denote PBMC samples collected before July 2019. **b**, The percentage of individuals with N-specific, NSP7 and NSP13-specific responses, or N-, NSP7- and NSP13-specific responses in cohort. **c**, The composition of the SARS-CoV-2 response in each responding unexposed donor ($n = 19$) is shown as a percentage of the total detected response. N-1, light blue; N-2, dark blue; NSP7, orange; NSP13-1, light red; NSP13-2, red; NSP13-3, dark red. **d**, Frequency of SARS-CoV-2-reactive cells in 11 unexposed donors to the indicated peptide pools directly ex vivo and after a 10-day expansion. **e**, A peptide pool matrix strategy was used for three individuals who were not exposed to SARS-CoV and SARS-CoV-2. The identified T cell epitopes were confirmed by ICS, and the sequences were aligned to the corresponding sequence of all coronaviruses known to infect humans.

after infection with related viruses may be able to protect against, or modify the pathology caused by, infection with SARS-CoV-2.

## SARS-CoV-2-specific T cells in unexposed donors

To explore this possibility, we tested N-, NSP7- and NSP13-peptide-reactive IFNγ responses in 37 donors who were not exposed to SARS-CoV and SARS-CoV-2. Donors were either sampled before July 2019 ($n = 26$) or were serologically negative for both SARS-CoV-2 neutralizing antibodies and SARS-CoV-2 N antibodies[23] ($n = 11$). Different coronaviruses known to cause common colds in humans such as OC43, HKU1, NL63 and 229E present different degrees of amino acid homology with SARS-CoV-2 (Extended Data Fig. 1 and 2) and recent data have shown the presence of SARS-CoV-2 cross-reactive CD4 T cells (mainly specific to the spike protein) in donors who were not exposed to SARS-CoV-2[14]. Notably, we detected SARS-CoV-2-specific IFNγ responses in 19 out of 37 unexposed donors (Fig. 4a, b). The cumulative proportion of all studied individuals who responded to peptides covering the N protein and the ORF1-encoded NSP7 and NSP13 proteins is shown in Fig. 4b. Unexposed donors showed a distinct pattern of reactivity; whereas individuals who recovered from COVID-19 and SARS reacted preferentially to N peptide pools (66% of individuals who recovered from COVID-19 and 91% of individuals who recovered from SARS responded to only the N peptide pools), the unexposed group showed a mixed response to the N protein or to NSP7 and NSP13 (Fig. 4a–c). In addition, whereas NSP peptides stimulated a dominant response in only 1 out of 59 individuals who had resolved COVID-19 or SARS, these peptides triggered dominant reactivity in 9 out of 19 unexposed donors with SARS-CoV-2-reactive cells (Fig. 4c and Extended Data Fig. 7). These SARS-CoV-2-reactive cells from unexposed donors had the capacity to expand after stimulation with SARS-CoV-2-specific peptides (Fig. 4d). We next delineated the SARS-CoV-2-specific response detected in unexposed donors in more detail. Characterization of the N-specific response in one donor (H-2) identified CD4 T cells that were reactive to an epitope within the region

of amino acids 101–120 of the N protein. This epitope was also detected in patients who recovered from COVID-19 and SARS[8,22] (Fig. 2b). This region has a high degree of homology to the sequences of the N protein of MERS-CoV, OC43 and HKU1 (Fig. 4e). In the same donor, we analysed PBMCs collected at multiple time points, demonstrating the persistence of the response to the 101–120 amino acid region of the N protein over 1 year (Extended Data Fig. 8a). In three other donors who were not exposed to SARS-CoV or SARS-CoV-2, we identified CD4 T cells specific to the region of amino acids 26–40 of NSP7 (SKLWAQCVQLHNDIL; donor H-7) and CD8 T cells specific to an epitope comprising the region of amino acids 36–50 of NSP7 (HNDILLAKDTTEAFE; H-3, H-21; Fig. 4e, Extended Data Fig. 8b).

These latter two T cell specificities were of particular interest as the homology between the two protein regions of SARS-CoV, SARS-CoV-2 and other common cold coronaviruses (OC43, HKU1 NL63 and 229E) was minimal (Fig. 4e), especially for the CD8 T cell epitope. Indeed, the low-homology peptides that covered the sequences of the common cold coronaviruses failed to stimulate PBMCs from individuals with T cells responsive to amino acids 36–50 of NSP7 (Extended Data Fig. 8c). Even though we cannot exclude that some SARS-CoV-2-reactive T cells might be naive or induced by completely unrelated pathogens[5], this finding suggests that unknown coronaviruses, possibly of animal origin, might induce cross-reactive SARS-CoV-2 T cells in the general population.

We further characterized the NSP7-specific CD4 and CD8 T cells that were present in the three unexposed individuals. The reactive T cells expanded efficiently in vitro and mainly produced either both IFNγ and TNF (CD8 T cells) or only IFNγ (CD4 T cells) (Extended Data Fig. 9a). We also determined that the CD8 T cells that were specific to amino acids 36–50 of NSP7 were HLA-B35-restricted and had an effector memory/terminal differentiated phenotype ($CCR7^{-}CD45RA^{+/-}$) (Extended Data Fig. 9b, c).

## Conclusions

It is unclear why NSP7- and NSP13-specific T cells are detected and often dominant in unexposed donors, while representing a minor population in individuals who have recovered from SARS or COVID-19. It is, however, consistent with the findings of a previous study[11], in which ORF1-specific T cells were preferentially detected in some donors who were not exposed to SARS-CoV-2 whereas T cells from individuals who had recovered from COVID-19 preferentially recognized structural proteins. Induction of virus-specific T cells in individuals who were exposed but uninfected has been demonstrated in other viral infections[24–26]. Theoretically, individuals exposed to coronaviruses might just prime ORF1-specific T cells, as the ORF1-encoded proteins are produced first in coronavirus-infected cells and are necessary for the formation of the viral replicase–transcriptase complex that is essential for the subsequent transcription of the viral genome, which then leads to the expression of various RNA species[18]. Therefore, ORF1-specific T cells could hypothetically abort viral production by lysing SARS-CoV-2-infected cells before the formation of mature virions. By contrast, in patients with COVID-19 and SARS, the N protein—which is abundantly produced in cells that secrete mature virions[17]—would be expected to preferentially boost N-specific T cells.

Notably, the ORF1 region contains domains that are highly conserved among many different coronaviruses[9]. The distribution of these viruses in different animal species might result in periodic human contact that induces ORF1-specific T cells with cross-reactive abilities against SARS-CoV-2. Understanding the distribution, frequency and protective capacity of pre-existing structural or non-structural protein-associated SARS-CoV-2 cross-reactive T cells could be important for the explanation of some of the differences in infection rates or pathology observed during this pandemic. T cells that are specific to viral proteins are protective in animal models of airway infections[27,28], but the possible effects of pre-existing N- and/or ORF1-specific T cells onthe differential modulation of SARS-CoV-2 infection will have to be carefully evaluated.

## Online content

Any methods, additional references, Nature Research reporting summaries, source data, extended data, supplementary information, acknowledgements, peer review information; details of author contributions and competing interests; and statements of data and code availability are available at https://doi.org/10.1038/s41586-020-2550-z.


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## Methods

### Data reporting

No statistical methods were used to predetermine sample size. The experiments were not randomized and the investigators were not blinded to allocation during experiments and outcome assessment.

### Ethics statement

All donors provided written consent. The study was conducted in accordance with the Declaration of Helsinki and approved by the NUS Institutional Review Board (H-20-006) and the SingHealth Centralised Institutional Review Board (reference CIRB/F/2018/2387).

### Human samples

Donors were recruited based on their clinical history of SARS-CoV or SARS-CoV-2 infection. Blood samples of patients who recovered from COVID-19 ($n = 36$) were obtained 2–28 days after PCR negativity and of patients who recovered from SARS ($n = 23$) 17 years after infection. Samples from healthy donors were either collected before June 2019 for studies of T cell function in viral diseases ($n = 26$), or in March–April 2020. All healthy donor samples tested negative for RBD-neutralizing antibodies and negative in an ELISA for N IgG ($n = 11$)[19].

### PBMC isolation

PBMCs were isolated by density-gradient centrifugation using Ficoll–Paque. Isolated PBMCs were either studied directly or cryopreserved and stored in liquid nitrogen until use in the assays.

### Peptide pools

We synthesized 15-mer peptides that overlapped by 10 amino acids and spanned the entire protein sequence of the N, NSP7 and NSP13 proteins of SARS-CoV-2, as well as the N protein of SARS-CoV (GL Biochem Shanghai; see Supplementary Tables 1, 2). To stimulate PBMCs, the peptides were divided into 5 pools of about 40 peptides covering N (N-1, N-2) and NSP13 (NSP13-1, NSP13-2, NSP13-3) and one pool of 15 peptides covering NSP7. For single-peptide identification, peptides were organized in a matrix of 12 numeric and 7 alphabetical pools for N, and 4 numeric and 4 alphabetical pools for NSP7.

### ELISpot assay

ELISpot plates (Millipore) were coated with human IFNγ antibody (1-D1K, Mabtech; 5 μg/ml) overnight at 4 °C. Then, 400,000 PBMCs were seeded per well and stimulated for 18 h with pools of SARS-CoV or SARS-CoV-2 peptides (2 μg/ml). For stimulation with peptide matrix pools or single peptides, a concentration of 5 μg/ml was used. Subsequently, the plates were developed with human biotinylated IFNγ detection antibody (7-B6-1, Mabtech; 1:2,000), followed by incubation with streptavidin-AP (Mabtech) and KPL BCIP/NBT Phosphatase Substrate (SeraCare). Spot forming units (SFU) were quantified with ImmunoSpot. To quantify positive peptide-specific responses, 2× mean spots of the unstimulated wells were subtracted from the peptide-stimulated wells, and the results expressed as SFU/$10^6$ PBMCs. We excluded the results if negative control wells had >30 SFU/$10^6$ PBMCs or positive control wells (phorbol 12-myristate 13-acetate/ionomycin) were negative.

### Flow cytometry

PBMCs or expanded T cell lines were stimulated for 5 h at 37 °C with or without SARS-CoV or SARS-CoV-2 peptide pools (2 μg/ml) in the presence of 10 μg/ml brefeldin A (Sigma-Aldrich). Cells were stained with the yellow LIVE/DEAD fixable dead cell stain kit (Invitrogen) and anti-CD3 (clone SK7; 3:50), anti-CD4 (clone SK3; 3:50) and anti-CD8 (clone SK1; 3:50) antibodies. For analysis of the T cell differentiation status, cells were additionally stained with anti-CCR7 (clone 150503; 1:10) and anti-CD45RA (clone HI100; 1:10) antibodies. Cells were subsequently fixed and permeabilized using the Cytofix/Cytoperm kit (BD Biosciences-Pharmingen) and stained with anti-IFNγ (clone 25723, R&D Systems; 1:25) and anti-TNF (clone MAb11; 1:25) antibodies and analysed on a BD-LSR II FACS Scan. Data were analysed by FlowJo (Tree Star). Antibodies were purchased from BD Biosciences-Pharmingen unless otherwise stated.

### Expanded T cell lines

T cell lines were generated as follows: 20% of PBMCs were pulsed with 10 μg/ml of the overlapping SARS-CoV-2 peptides (all pools combined) or single peptides for 1 h at 37 °C, washed and cocultured with the remaining cells in AIM-V medium (Gibco; Thermo Fisher Scientific) supplemented with 2% AB human serum (Gibco; Thermo Fisher Scientific). T cell lines were cultured for 10 days in the presence of 20 U/ml of recombinant IL-2 (R&D Systems).

### HLA-restriction assay

The HLA type of healthy donor H-3 was determined and different Epstein–Barr virus (EBV)-transformed B cells lines with one common allele each were selected for presentation of peptide NSP7(36–50) (see below). B cells were pulsed with 10 μg/ml of the peptide for 1 h at 37 °C, washed three times and cocultured with the expanded T cell line at a ratio of 1:1 in the presence of 10 μg/ml brefeldin A (Sigma-Aldrich). Non-pulsed B cell lines served as a negative control for the detection of potential allogeneic responses and autologous peptide-pulsed cells served as a positive control. The HLA class I haplotype of the different B cell lines: CM780, A*24:02, A*33:03, B*58:01, B*55:02, Cw*07:02, Cw*03:02; WGP48, A*02:07, A*11:01, B*15:25, B*46:01, Cw*01:02, Cw*04:03; NP378, A*11:01, A*33:03, B*51:51, B*35:03, Cw*07:02, Cw*14:02; NgaBH, A*02:01, A*33:03, B*58:01, B*13:01, Cw*03:02.

### Sequence alignment

Reference protein sequences for ORF1ab (accession numbers: QHD43415.1, NP_828849.2, YP_009047202.1, YP_009555238.1, YP_173236.1, YP_003766.2 and NP_073549.1) and the N protein (accession numbers: YP_009724397.2, AAP33707.1, YP_009047211.1, YP_009555245.1, YP_173242.1, YP_003771.1 and NP_073556.1) were downloaded from the NCBI database (https://www.ncbi.nlm.nih.gov/protein/). Sequences were aligned using the MUSCLE algorithm with default parameters and percentage identity was calculated in Geneious Prime 2020.1.2 (https://www.geneious.com). Alignment figures were made in Snapgene 5.1 (GSL Biotech).

### Surrogate virus neutralization assay

A surrogate virus-neutralization test was used. Specifically, this test measures the quantity of anti-spike antibodies that block protein–protein interactions between the receptor-binding domain of the spike protein and the human ACE2 receptor using an ELISA-based assay[29].

### Statistical analyses

All statistical analyses were performed in Prism (GraphPad Software); details are provided in the figure legends.

### Reporting summary

Further information on research design is available in the Nature Research Reporting Summary linked to this paper.

## Data availability

Reference protein sequences for ORF1ab (accession numbers: QHD43415.1, NP_828849.2, YP_009047202.1, YP_009555238.1, YP_173236.1, YP_003766.2 and NP_073549.1) and the N protein (accession numbers: YP_009724397.2, AAP33707.1, YP_009047211.1, YP_009555245.1, YP_173242.1, YP_003771.1 and NP_073556.1) were downloaded from the NCBI database (https://www.ncbi.nlm.nih.gov/

protein/). All data are available in the Article or the Supplementary Information. Source data are provided with this paper.

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**Author contributions** N.L.B. and A.T.T. designed all experiments and analysed all of the data, prepared the figures and edited the paper; K.K., C.Y.L.T., M.H., A.C., M.L. and N.T. performed ELISpots and intracellular cytokine staining, and generated short-term T cell lines; M.H.Y.C. and M.L. performed viral sequence homology and analysed data; W.N.C. and L.-F.W. carried out antibody testing; M.I-C.C., E.E.O., S.K., P.A.T., J.G.-H.L. and Y.-J.T. selected and recruited patients and analysed clinical data; Y.-J.T. provided funding and designed the study; AB designed and coordinated the study, provided funding, analysed the data and wrote the paper.

**Competing interests** A.B. is a cofounder of Lion TCR, a biotechnology company that develops T cell receptors for the treatment of virus-related diseases and cancers. All other authors have no competing interests related to the study.

**Additional information**

**Supplementary information** is available for this paper at https://doi.org/10.1038/s41586-020-2550-z.

**Correspondence and requests for materials** should be addressed to A.B.

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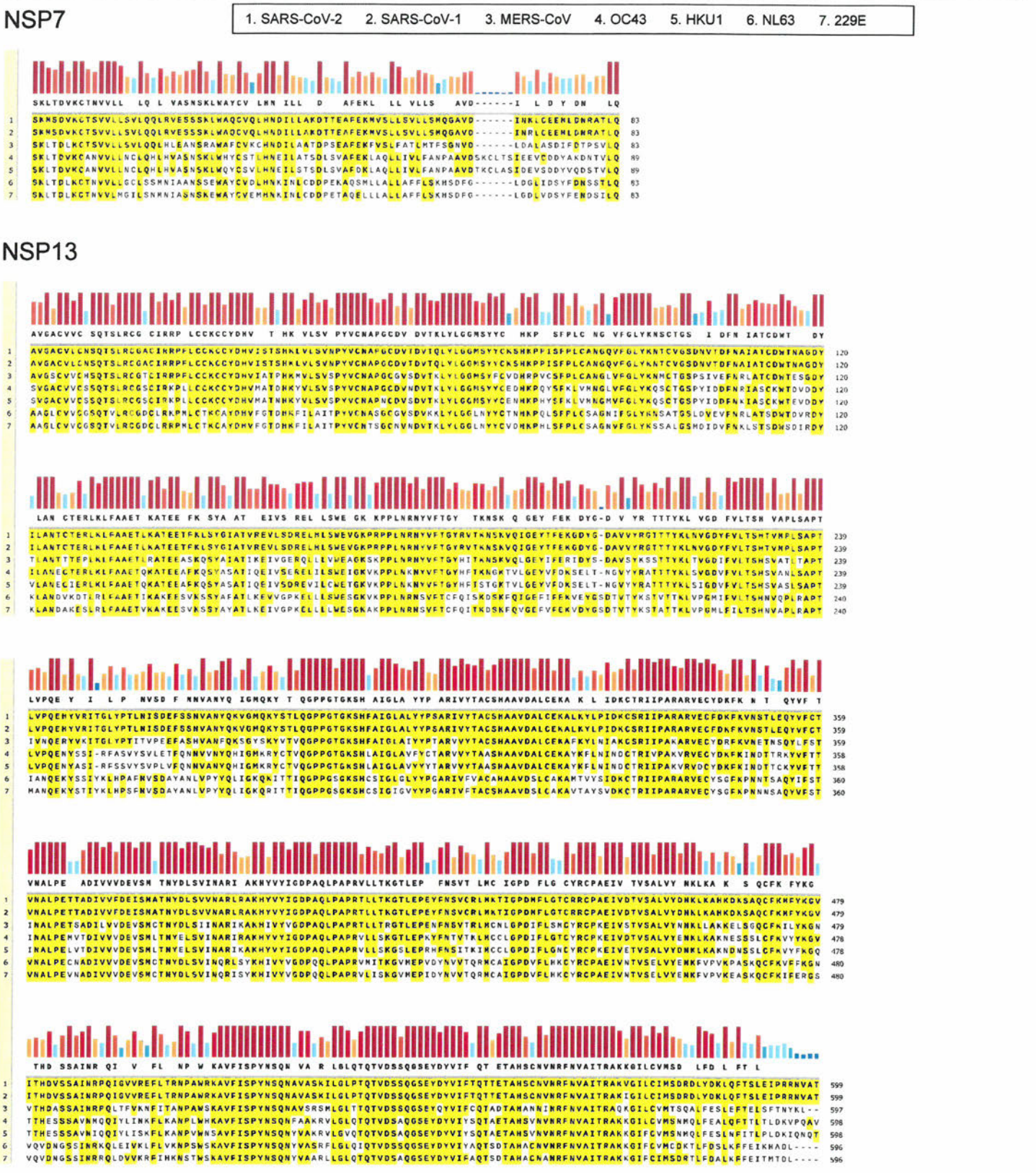
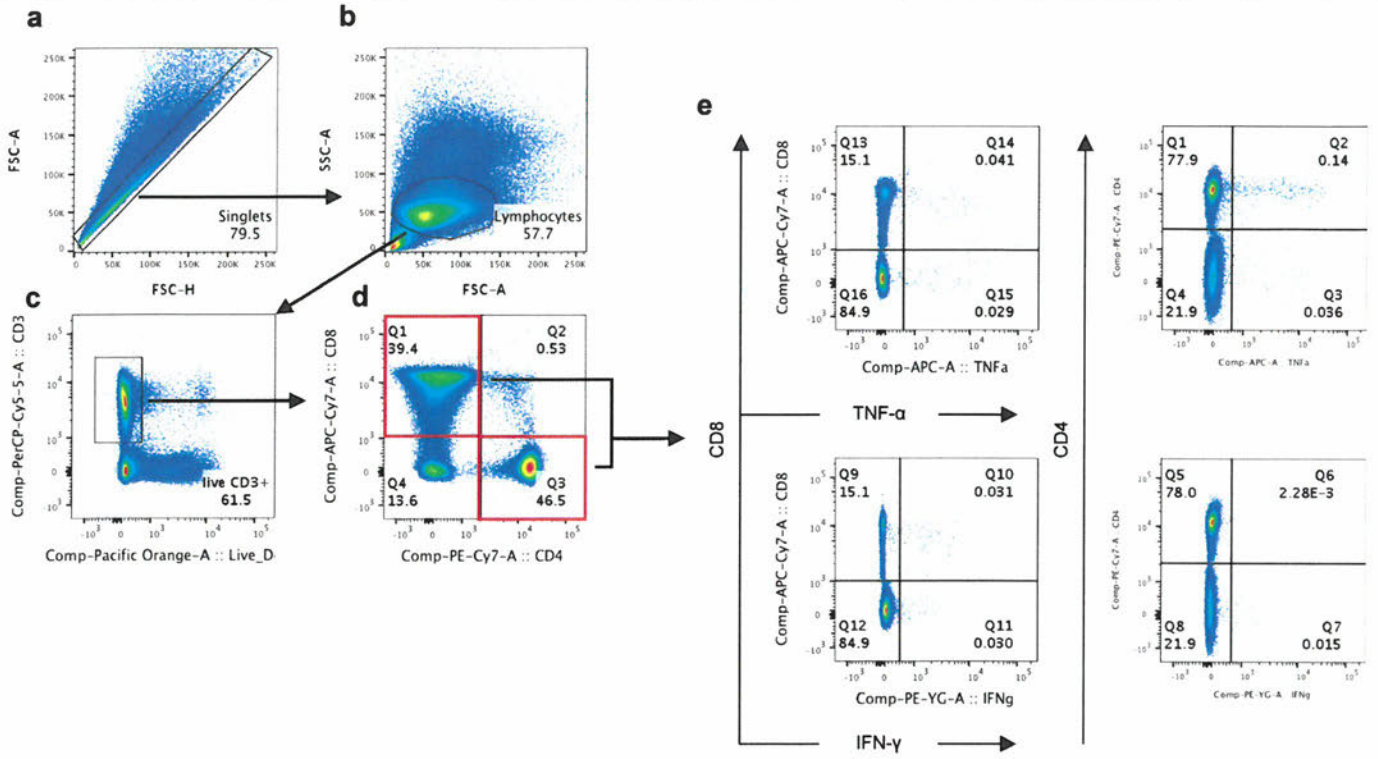
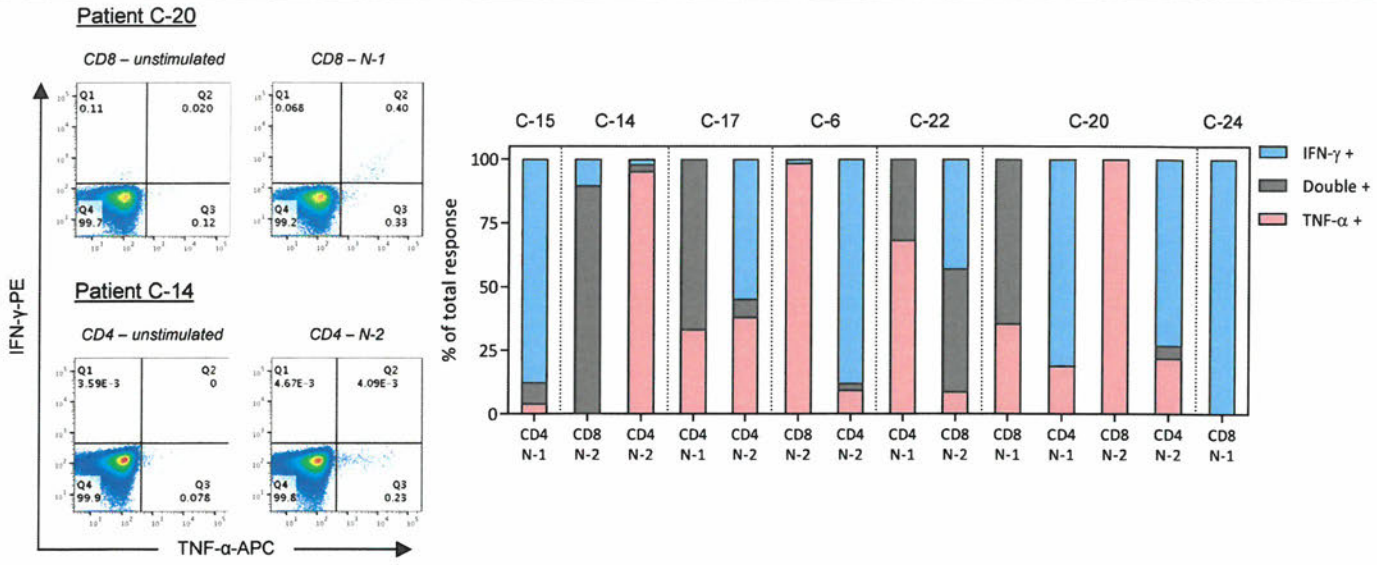
**Extended Data Fig. 1 | Sequence alignment of the N protein from all types of human coronaviruses.** Amino acid sequences for the N protein were downloaded from the NCBI database and aligned using the MUSCLE algorithm. Conserved residues are highlighted in yellow and the degree of conservation is indicated by the coloured bars above.



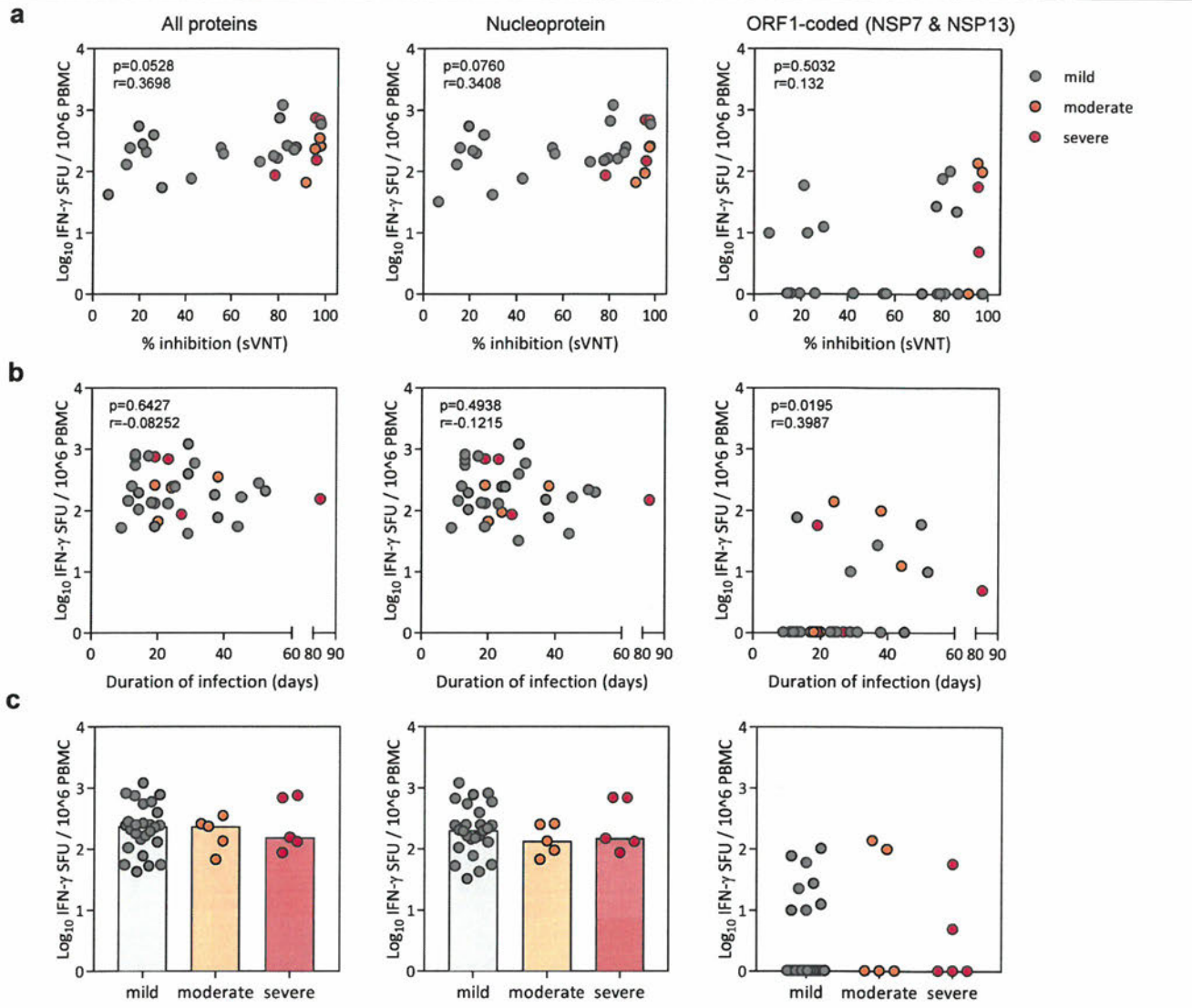

**Extended Data Fig. 2 | Sequence alignment of the ORF1-encoded non-structural proteins NSP7 and NSP13 from all types of human coronaviruses.** Protein sequences for ORF1ab were downloaded from the NCBI database and aligned using the MUSCLE algorithm. The alignment for NSP7 and NSP13 is shown.



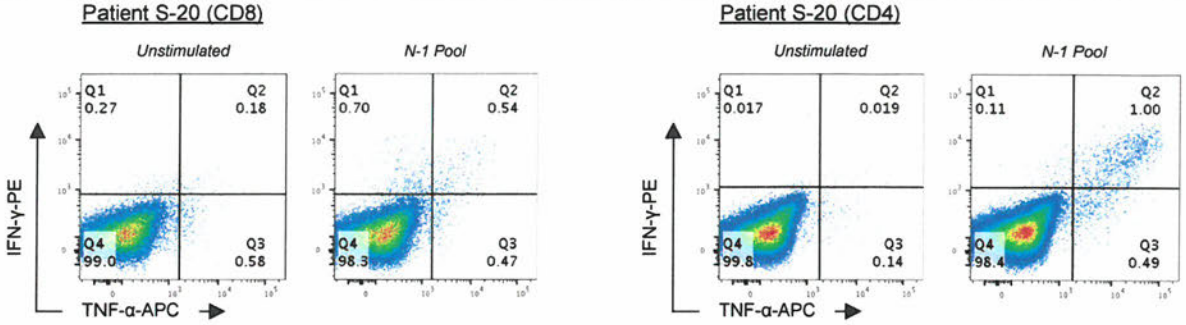

**Extended Data Fig. 3 | Flow cytometry gating strategy.** **a**, Forward scatter area (FSC-A) versus forward scatter height (FSC-H) density plot for doublet exclusion. **b**, Forward and side scatter (SSC-A) density plots to identify the lymphocyte population. **c**, Live T cells were gated based on CD3 expression and a live/dead discrimination dye. **d**, **e**, Only single expressing CD8 and CD4 T cells were Boolean gated (**d**) and used for IFNγ and/or TNF analysis (**e**).



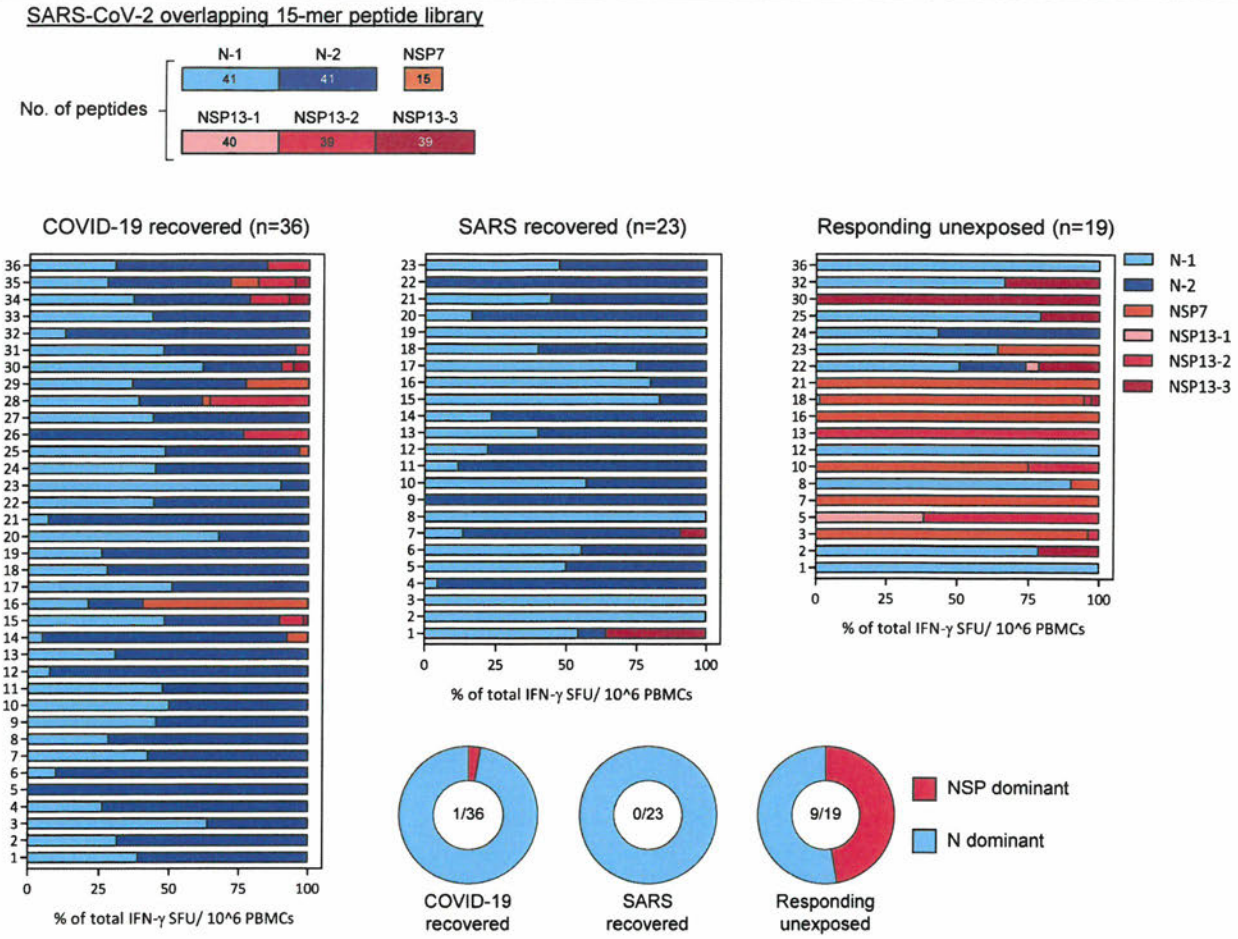

**Extended Data Fig. 4 | IFNγ and TNF production profile of SARS-CoV-2-specific T cells of patients who recovered from COVID-19.** PBMCs from patients recovered from COVID-19 ($n = 7$) were stimulated with the peptide pools covering N (NP-1, NP-2) for 5 h and analysed by intracellular cytokine staining for IFNγ and TNF. Dot plots show examples of patients with CD8 (top) or CD4 (bottom) T cells that produced IFNγ and/or TNF in response to stimulation with N-1 or N-2 peptide pools. The bars show the respective single and double cytokine producing T cells as a proportion of the total detected response after stimulation with the corresponding N peptide pools in each patient who recovered from COVID-19.



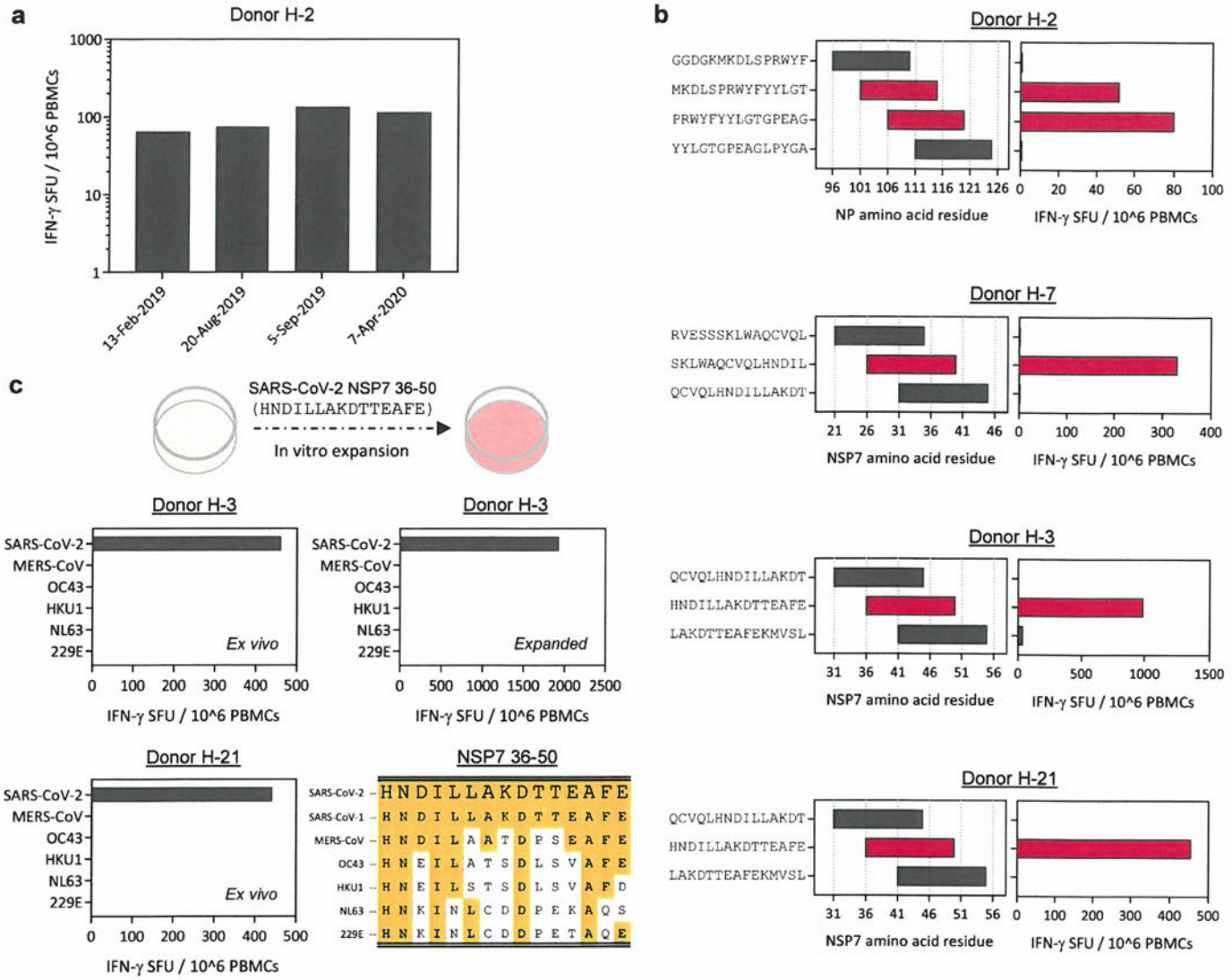

**Extended Data Fig. 5 | Correlation analysis of SARS-CoV-2-specific IFNγ responses with the presence of virus-neutralizing antibodies, duration of infection and disease severity. a**, **b**, The magnitude of SARS-CoV-2-specific responses, as quantified by IFNγ ELISpot, against all (N, NSP7 and NSP13) SARS-CoV-2 proteins tested (left), N (middle) or NSP7 and NSP13 (right) was correlated with the level of virus-neutralizing antibodies assayed using a surrogate virus neutralization assay (**a**; $n = 28$) and the duration of SARS-CoV-2 PCR positivity (**b**; $n = 34$). The respective $P$ values (two-tailed) and correlation coefficients (Spearman correlation) are indicated. Patients who present with mild (grey), moderate (orange) or severe (red) disease are indicated. **c**, Magnitude of SARS-CoV-2-specific responses stratified by mild ($n = 26$), moderate ($n = 5$) and severe ($n = 5$) disease. The bars represent the median magnitude of the response. Mild disease, with or without chest radiograph changes, not requiring oxygen supplement. Moderate disease, oxygen supplement less than 50%. Severe disease, oxygen supplement 50% or more or high-flow oxygen or intubation.



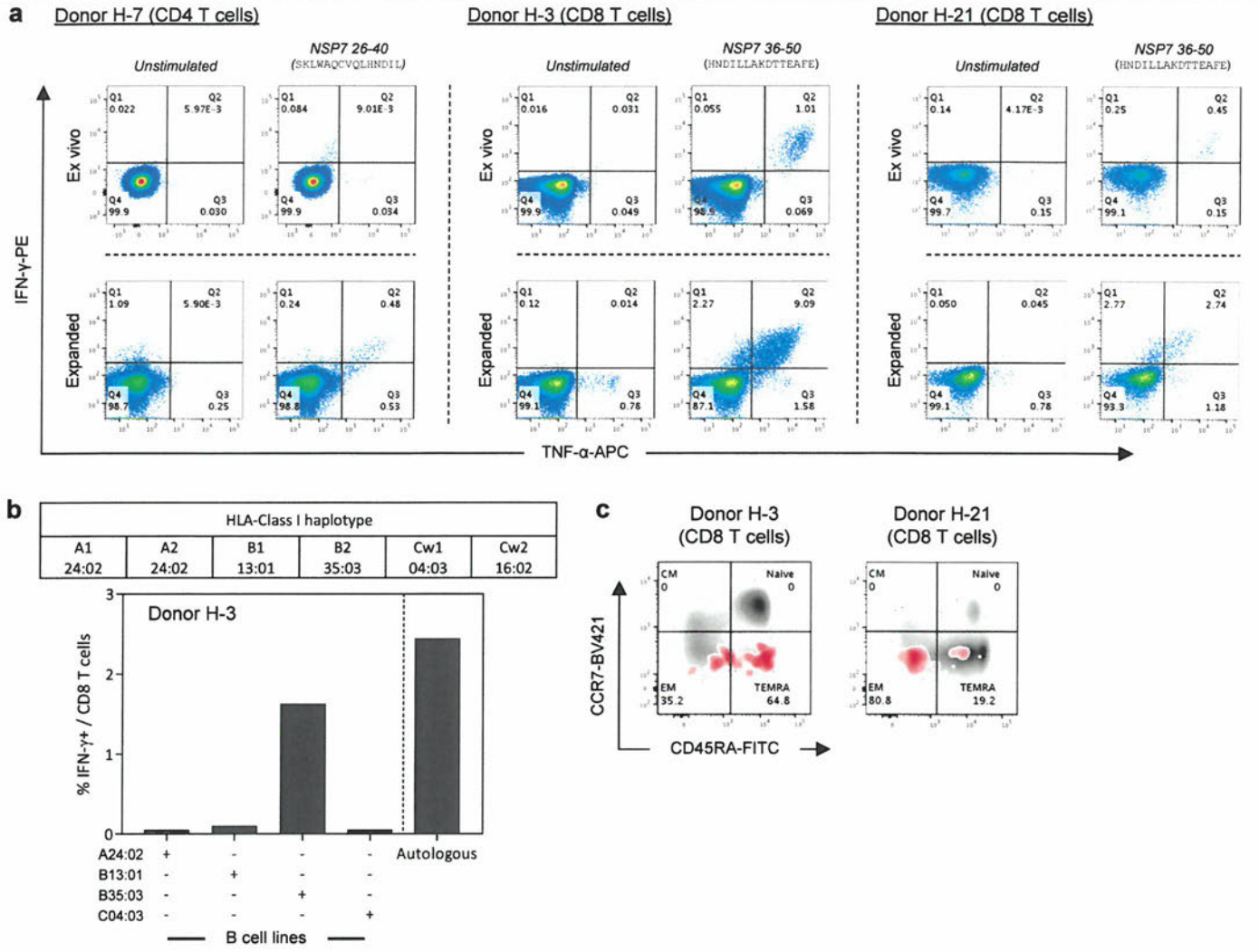

**Extended Data Fig. 6 | Analysis of SARS-CoV N response.** PBMCs of patient S-20 were expanded for 10 days and the frequency of T cells specific for the N-1 peptide pool were analysed by intracellular cytokine staining for IFNγ and TNF. Dot plots show CD8 and CD4 T cells that produced IFNγ and/or TNF in response to stimulation with the N-1 peptide pool.




**Extended Data Fig. 7 | Dominance of SARS-CoV-2 N, NSP7 and NSP13 responses in donors who recovered from COVID-19 or SARS as well as in unexposed individuals.** PBMCs from the respective individuals were stimulated with SARS-CoV-2 peptide pools as described in Fig. 1. The composition of the SARS-CoV-2 response is shown as a percentage of the total detected response in each group. N-1, light blue; N-2, dark blue; NSP7, orange; NSP13-1, light red; NSP13-2, red; NSP13-3, dark red. The proportion of individuals with NSP-dominant responses are illustrated in the pie charts.




**Extended Data Fig. 8 | Identification of SARS-CoV-2 epitopes in donors who were not exposed to SARS-CoV and SARS-CoV-2. a**, Longitudinal analysis of the SARS-CoV-2 N(101–120) response in individual H-2. PBMCs collected at the stated time points were stimulated with peptides spanning amino acids 101–120 of the N protein and assayed by IFNγ ELISpot. The frequencies of IFNγ SFU are shown. **b**, PBMCs were stimulated with the single peptides identified by the peptide matrix in parallel with the neighbouring peptides and assayed by IFNγ ELISpot. The amino acid residues are shown on the left; the frequency of IFNγ SFU on the right. Activating peptides are indicated in red and neighbouring peptides in black. **c**, PBMCs from individuals H-3 and H-21 were stimulated with the NSP7 peptide comprising amino acids 36–50 from SARS-CoV-2, MERS-CoV, OC43, HKU1, NL63 and 229E and analysed ex vivo by IFNγ ELISpot. A NSP7 (36–50) T cell line expanded from individual H-3 was also tested with the corresponding peptides of other coronaviruses by IFNγ ELISpot. Amino acid sequences of the various peptides are shown in the table. Conserved amino acids are highlighted in yellow.




**Extended Data Fig. 9 | Characterization of SARS-CoV-2 NSP7-specific T cell responses in three individuals who were not exposed to SARS-CoV and SARS-CoV-2. a**, Dot plots show the frequency of IFNγ- and/or TNF-producing CD8 or CD4 T cells specific to the SARS-CoV-2 peptides directly ex vivo and after a 10-day expansion in three unexposed donors. **b**, The HLA class I haplotype of individual H-3 is shown in the table. HLA restriction of the NSP7(36–50)-specific T cells from this individual was deduced by co-culturing the T cells with NSP7(36–50)-peptide-pulsed EBV-transformed B cell lines that share the indicated HLA class I molecule (+). Activation of the NSP7(36–50)-specific T cells by autologous cells was achieved by the direct addition of the peptide and used as the positive control. **c**, The memory phenotype of CD8 T cells specific for NSP7(36–50) in individuals H-3 and H-21 were analysed ex vivo and shown in the dot plots. The frequencies of naive, effector memory, central memory and terminally differentiated NSP7(36–50)-specific CD8 T cells (red) are shown and density plots were overlaid on the total CD8 T cells (grey).

**Extended Data Table 1 | Donor characteristics**

| | COVID-19 recovered | SARS recovered | SARS-CoV-1/2 unexposed |
|---|---|---|---|
| Number | 36 | 23 | 37 |
| Median age in years (range) | 42 (27-78) | 49 (21-67) | 39 (28-63) |
| Gender | | | |
| Male | 72% (26/36) | 26% (6/23) | 62% (23/37) |
| Female | 28% (10/36) | 74% (17/23) | 38% (14/37) |
| Residence | | | |
| Singapore | 100% | 100% | 100% |
| Ethnicity | | | |
| Chinese | 38.9% (14/36) | 43.5% (10/23) | 62.2% (23/37) |
| Caucasian | 27.8% (10/36) | 0% (0/23) | 16.2% (6/37) |
| Indian | 25.0% (9/36) | 21.7% (5/23) | 8.1% (3/37) |
| Bangladeshi | 5.6% (2/36) | 0% (0/23) | 0% (0/37) |
| Japanese | 2.8% (1/36) | 0% (0/23) | 0% (0/37) |
| Malay | 0% (0/36) | 30.4% (7/23) | 13.5% (5/37) |
| Ceylonese | 0% (0/36) | 4.3% (1/23) | 0% (0/37) |
| *Disease Severity | | | |
| Mild | 72.2% (26/36) | 73.9% (17/23) | N/A |
| Moderate | 13.9% (5/36) | 13% (3/23) | N/A |
| Severe | 13.9% (5/36) | 13% (3/23) | N/A |
| Critical | 0% (0/24) | 0 | N/A |
| Virological parameters | | | |
| SARS-CoV-1 PCR positive | N/A | 100% | N/A |
| SARS-CoV-2 PCR positivity | 100% | N/A | N/A |
| [23]SARS-CoV-2 NP Ig positivity | 100% | 100% | 0% |
| [23]SARS-CoV-2 RBD Ig positivity | 100% | 0% | 0% |
| Time since PCR negativity | 2-28 days | 17 years | N/A |

*Disease severity is defined as follows. Mild, with or without chest radiograph changes; not requiring oxygen supplement. Moderate, oxygen supplement less than 50%. Severe, oxygen supplement 50% or more or high-flow oxygen or intubation.

nature research

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Last updated by author(s): Jul 3, 2020

# Reporting Summary

Nature Research wishes to improve the reproducibility of the work that we publish. This form provides structure for consistency and transparency in reporting. For further information on Nature Research policies, see our Editorial Policies and the Editorial Policy Checklist.

## Statistics

For all statistical analyses, confirm that the following items are present in the figure legend, table legend, main text, or Methods section.

| n/a | Confirmed | |
|---|---|---|
| ☐ | ☒ | The exact sample size (*n*) for each experimental group/condition, given as a discrete number and unit of measurement |
| ☐ | ☒ | A statement on whether measurements were taken from distinct samples or whether the same sample was measured repeatedly |
| ☐ | ☒ | The statistical test(s) used AND whether they are one- or two-sided<br>*Only common tests should be described solely by name; describe more complex techniques in the Methods section.* |
| ☒ | ☐ | A description of all covariates tested |
| ☒ | ☐ | A description of any assumptions or corrections, such as tests of normality and adjustment for multiple comparisons |
| ☒ | ☐ | A full description of the statistical parameters including central tendency (e.g. means) or other basic estimates (e.g. regression coefficient) AND variation (e.g. standard deviation) or associated estimates of uncertainty (e.g. confidence intervals) |
| ☐ | ☒ | For null hypothesis testing, the test statistic (e.g. *F*, *t*, *r*) with confidence intervals, effect sizes, degrees of freedom and *P* value noted<br>*Give P values as exact values whenever suitable.* |
| ☒ | ☐ | For Bayesian analysis, information on the choice of priors and Markov chain Monte Carlo settings |
| ☒ | ☐ | For hierarchical and complex designs, identification of the appropriate level for tests and full reporting of outcomes |
| ☒ | ☐ | Estimates of effect sizes (e.g. Cohen's *d*, Pearson's *r*), indicating how they were calculated |

*Our web collection on statistics for biologists contains articles on many of the points above.*

## Software and code

Policy information about availability of computer code

| | |
|---|---|
| Data collection | No software was used for data collection. |
| Data analysis | Graphpad Prism 7; Flowjo Version 10.6.2; ImmunoSpot 7.0.26.0<br>Viral sequences were aligned using the MUSCLE algorithm (3.8.425) with default parameters and percentage identity was calculated in Geneious Prime 2020.1.2 (https://www.geneious.com). Alignment figures were made in Snapgene 5.1 (GSL Biotech). |

For manuscripts utilizing custom algorithms or software that are central to the research but not yet described n published literature, software must be made available to editors and reviewers. We strongly encourage code deposition in a community repository (e.g. GitHub). See the Nature Research guidelines for submitting code & software for further information.

## Data

Policy information about availability of data

All manuscripts must include a data availability statement. This statement should provide the following information, where applicable:

- Accession codes, unique identifiers, or web links for publicly available datasets
- A list of figures that have associated raw data
- A description of any restrictions on data availability

Coronavirus reference protein sequences for ORF1ab and Nucleocapsid Protein were downloaded from the NCBI database. All other data are included n this manuscript.

# Field-specific reporting

Please select the one below that is the best fit for your research. If you are not sure, read the appropriate sections before making your selection.

☒ Life sciences ☐ Behavioural & social sciences ☐ Ecological, evolutionary & environmental sciences

For a reference copy of the document with all sections, see nature.com/documents/nr-reporting-summary-flat.pdf

# Life sciences study design

All studies must disclose on these points even when the disclosure is negative.

| | |
|---|---|
| Sample size | Aim of the study was to characterize SARS-CoV-2-specific T cells in patients who recovered from SARS 17 years ago. 23 of those individuals gave informed consent and were available to donate blood samples. Therefore similar numbers of COVID-19 convalescents and non-infected controls were selected. |
| Data exclusions | No data points were excluded. |
| Replication | We evaluated the SARS-CoV-2 specific T cell responses in 36 COVID-19 convalescents, in 23 SARS-recovered, and in 37 uninfected donors. |
| Randomization | No randomization was used in this study, since we are comparing 3 different well defined cohorts: COVID-19 convalescents, SARS recovered patients and SARS-CoV-1/2 non-exposed individuals. |
| Blinding | Blinding was not done for this study. The groups were defined by their infection history and studied by the investigators using standard protocols. |

# Reporting for specific materials, systems and methods

We require information from authors about some types of materials, experimental systems and methods used in many studies. Here, indicate whether each material, system or method listed is relevant to your study. If you are not sure if a list item applies to your research, read the appropriate section before selecting a response.

## Materials & experimental systems

| n/a | Involved in the study |
|---|---|
| ☐ | ☒ Antibodies |
| ☒ | ☐ Eukaryotic cell lines |
| ☒ | ☐ Palaeontology and archaeology |
| ☒ | ☐ Animals and other organisms |
| ☐ | ☒ Human research participants |
| ☒ | ☐ Clinical data |
| ☒ | ☐ Dual use research of concern |

## Methods

| n/a | Involved in the study |
|---|---|
| ☒ | ☐ ChIP-seq |
| ☐ | ☒ Flow cytometry |
| ☒ | ☐ MRI-based neuroimaging |

## Antibodies

| | |
|---|---|
| Antibodies used | ELISpot: IFN-γ coating antibody (clone: 1-D1K, MabTech, Cat. Nr. 3420-3-1000); biotinylated IFN-γ detection antibody (clone: 7-B6-1, MabTech, Cat. Nr: 3420-6-1000)<br>Flow cytometry: anti-human CD3-PerCP-cy5.5 (BD Pharmingen, clone: SK7, Cat. Nr: 340949); anti-human CD4-PECy7 (BD Pharmingen, clone: SK3, Cat. Nr: 557852); anti-human CD8-APC-Cy7 (BD Pharmingen, clone: SK1, Cat. Nr: 557834); anti-human TNFa-APC (BD Pharmingen, clone: MAb11, Cat. Nr: 554514); anti-human IFNg-PE (R&D Systems, clone: 25273, Cat. Nr: IC285P); anti-human CCR7-BV421 (BD Pharmingen, clone: 150503, Cat. Nr: 562555); anti-human CD45RA-FITC (BD Pharmingen, clone: HI100, Cat. Nr: 555488) |
| Validation | All antibodies were obtained from commercial vendors and we based specificity on descriptions and information provided in corresponding Data Sheets available and provided by the Manufacturers. |

## Human research participants

Policy information about studies involving human research participants

| | |
|---|---|
| Population characteristics | The characteristics of the human research participants are described in Extended Data Table 1 of the manuscript. |
| Recruitment | All donors were recruited based on the infection history. COVID-19 convalescents were previously PCR positive for SARS-CoV-2; SARS-recovered donors were tested PCR positive 17 years ago for SARS-CoV. Written informed consent was obtained from all subjects. All donors were recruited and resident n Singapore, were of mixed ethnicity and age. |
| Ethics oversight | Written informed consent was obtained from all subjects. The study was conducted in accordance with the Declaration of Helsinki and approved by the NUS institutional review board (H-20-006); SingHealth Centralised Institutional Review Board (reference CIRB/F/2018/2387) |

Note that full information on the approval of the study protocol must also be provided in the manuscript.

## Flow Cytometry

### Plots

Confirm that:

[x] The axis labels state the marker and fluorochrome used (e.g. CD4-FITC).

[x] The axis scales are clearly visible. Include numbers along axes only for bottom left plot of group (a 'group' is an analysis of identical markers).

[x] All plots are contour plots with outliers or pseudocolor plots.

[x] A numerical value for number of cells or percentage (with statistics) is provided.

### Methodology

| | |
|---|---|
| Sample preparation | PBMC and T cell lines were prepared and stained according to standard protocols |
| Instrument | BD-LSR FACS Scan |
| Software | Flowjo Version 10.6.2 |
| Cell population abundance | N/A. No sorting was performed. |
| Gating strategy | Gating strategy: live cells (yellow LIVE/DEAD positive cells were excluded); singlets (SSC-H/SSC-A); Lymphocytes (FSC-A/SSCA); CD3+ (CD-3-PerPC-Cy5.5/CD8-APC-Cy7); CD4+ and CD8+ (CD4--PECy7/CD8-APC-Cy7); IFNg+ and TNFa+ gates were based on the unstimulated control sample. |

[x] Tick this box to confirm that a figure exemplifying the gating strategy is provided in the Supplementary Information.

# Exhibit "DD"

Alberta Health Services

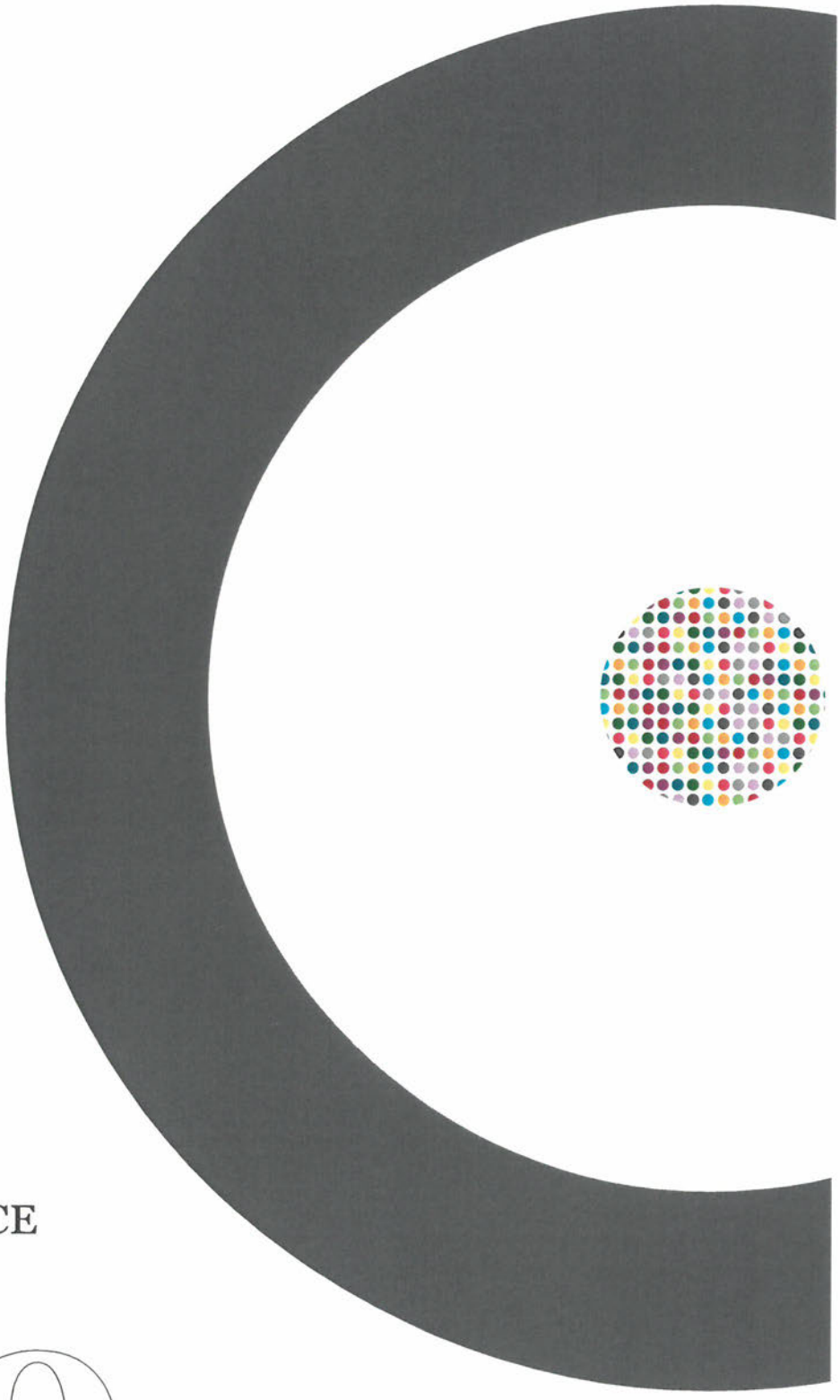
This is Exhibit " DD " referred to in the Affidavit of

Dr. Blaine Acher

Sworn before me this 7th day of December A.D. 2021

A Notary Public, A Commissioner for Oaths in and for the Province of Alberta

Eva Chipiuk
Barrister & Solicitor





# PHYSICIAN WORKFORCE FORECAST & REPORT

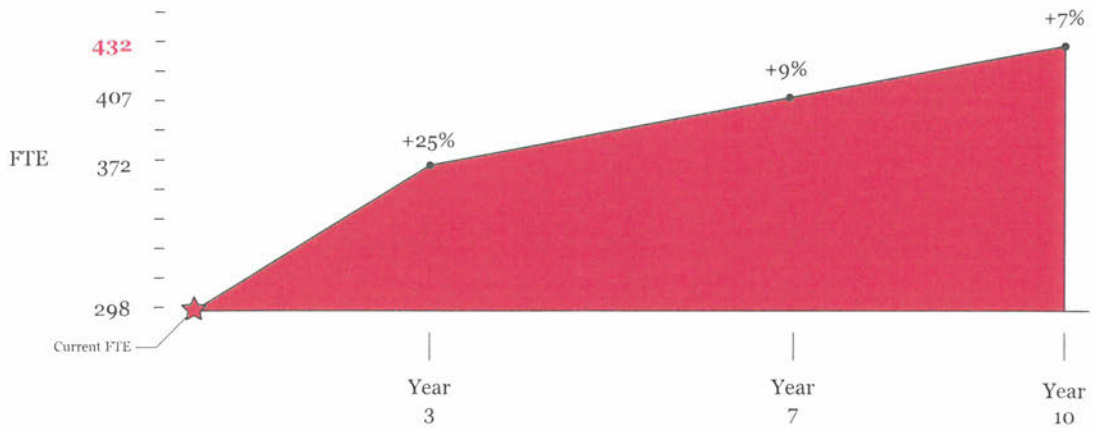
# 2019

Alberta Health Services

# Anesthesiology.

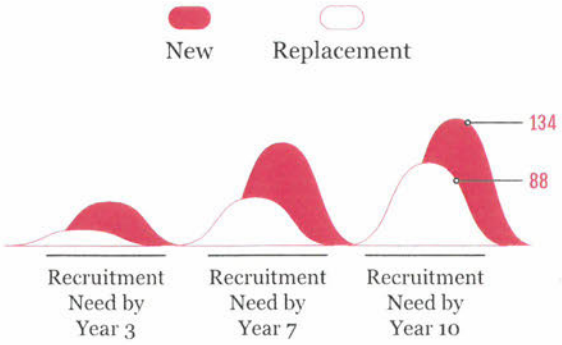
## Numbers

### 10-year Net New Forecast




| Total Net New FTE Increase (#) | 134 | Overall Net New FTE Increase (%) | 46% |
|---|---|---|---|

### Total Recruitment Need




| Total 10-year Recruitment Need (new & replacement) | 222 |
|---|---|

### Zone 10-year Recruitment Need

| | |
|---|---|
| North | 17 |
| Edmonton | 102 |
| Central | 8 |
| Calgary | 80 |
| South | 15 |

*Includes both new and replacement FTE*

### Notes

*Net New FTE Growth*

Over the next 10 years, the total needed FTE for Anesthesiology will rise from 298 to 432. A large increase from current FTE will come in year 3 (25%).

*Replacement FTE*

It is anticipated that 88 FTE will also need to be replaced due to physicians leaving the workforce through retirement, movement away from Alberta, etc.

*Recruitment Need*

In order to meet the projected forecast of 432 FTE, AHS would need to recruit 222 FTE - 134 net new and 88 replacement.

This would require an average recruitment need per year of about 22 FTE.

*Zone Need*

Edmonton is the Zone with the overall highest recruitment need at 102 net new and replacement FTE over 10 years.

# Anesthesiology.

## Analysis

### 10-Year Forecast Outcome

The forecast projects an overall increase to the current Anesthesiology workforce of roughly 46% after a decade (from 298 FTE to 435 FTE).

### 3-Year Forecast Outcome

Within the next 3 years, Anesthesiology shows a high recruitment need (both net new and replacement) for around 93 FTE. This will present short-term challenges.

***"The main drivers for Anesthesiology FTE increase are a growing and aging Alberta population. While there are significant challenges with rural recruitment of Anesthesiologists, the Zone with the highest risk for recruitment is Edmonton."***

### Calgary

Calgary Zone has based recruitment of staff on the availability of OR rooms, inpatient beds, and clinical space. As there is no anticipated changes to these resources expected in Calgary over the coming years, recruitment of net new physicians will be uncommon.
The need for anesthesiologists over the next 3 years is primarily based on replacement due to anticipated retirement and/or relocation out of Calgary Zone. and the FTE within Anesthesiology should remain static.
However, the gowing and anticipated need for access to surgery amongst the Calgary Zone population does still predict new new increases over the long-term forcast.

### Edmonton

This year, after an aggressive year of recruitment, the forecast shows an even greater need for the Department of Anesthesia. Edmonton has been operating with a shortage of anesthesiologists over the past several years.
In the spring of 2018, the Edmonton Zone Department of Anesthesia set a goal to recruit 25 new anesthetists over a 2 year period. The 2018 forecast showed a need of 30.5 FTE in year 1 of the 10 year forecast. That target was accomplished, with 15 anesthetists starting in the 2018/2019 fiscal year, and 13 set to start in the 2019/2020 fiscal year. With these successful recruitments over the past 12 months, existing physicians can begin to reduce their FTE to a more ideal/manageable level.
The 2019 forecast shows a need of approximately 44 FTE in year 1. Going forward, the goal will again be to recruit 25 anesthetists in a 2 year period (approximately 13 per year) until there is a well-staffed situation.

### North

New facilities and upgrades to existing facilities will require an increase in anesthesiology FTE within the North Zone. Net new FTE increases will be required to match capacity of additional operating theatre developed at the QEII Regional Hospital in Grande Prairie. Additional net new FTE will also be required to increase surgical capacity, reduce patient waitlist times, and prepare for transition to new Grande Prairie Regional Hospital expected to open in 2020.