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Posted Date: 5 August 2024

doi: 10.20944/preprints202408.0311.v1

Keywords: COVID-19 vaccine safety; immune mediated inflammatory diseases; serious adverse events



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Article

How Safe are COVID-19 Vaccines in Immune-Mediated Inflammatory Diseases? The SUCCEED Study

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Abstract: We were tasked by Canada's COVID-19 Immunity Task Force to describe severe adverse events (SAE) associated with emergency department (ED) visits and/or hospitalizations in immune-mediated inflammatory diseases (IMID). At 8 Canadian centres, data were collected from adults with rheumatoid arthritis (RA), axial spondyloarthritis (AxS), systemic lupus (SLE), psoriatic arthritis (PsA) and inflammatory bowel disease (IBD). We administered questionnaires, analyzing SAEs experienced within 31 days following SARS-CoV-2 vaccination. About two-thirds (63%) of 1556 participants were female; mean age was 52.5 years. BNT162b2 (Pfizer) vaccine was the most common, with mRNA-1273 (Moderna) being second. Forty-nine percent of participants had IBD, 27.4% RA, 14.3% PsA, 5.3% SpA, and 4% SLE. Twelve SAEs leading to ED visit or hospitalization were self-reported, occurring in 11 participants. SAEs included 6 ED visits (including one Bell's Palsy 31 days after first vaccination) and 6 hospitalizations (including one Guillain-Barré syndrome 15 days after the first vaccination). Two SAEs involved pericarditis, one in SLE (considered a serious disease flare) and one in RA. Thus, in the 31 days after SARS-CoV-2 vaccination in IMID, though several serious AEs occurred, these were relatively few. As SARS-CoV2 continues to be a common cause of death, our findings may help optimize vaccination acceptance.

Keywords: COVID-19 vaccine safety; immune mediated inflammatory diseases; serious adverse events.

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is now endemic and remains a global concern. Vaccines are effective in reducing severe SARS-CoV-2 infection and deaths in the general population [1–3]. However, the original vaccine safety trials largely excluded immunocompromised individuals who have increased risk of a serious SARS-CoV-2 infection [1,2].

Immune mediated inflammatory diseases (IMIDs) such as rheumatoid arthritis (RA), inflammatory bowel disease (IBD), axial spondyloarthritis (AxS), psoriasis/psoriatic arthritis (PsOPsA), systemic lupus erythematosus (SLE) and other conditions affect up to 10% of North Americans [4–6]. Many individuals with IMID take immune suppressing medications, placing them at higher risk for COVID-19 related death, critical care need, and hospital admissions [7]. Information on safety helps in decision-making regarding vaccination against SARS-CoV-2 in IMID [8]. SARS-CoV2 continues to be a common cause of death in the general population, and providing robust, detailed data on severe adverse events may help optimize vaccination acceptance by people with IMID.

The SURveillance of responses to COVID-19 vaCcines in systEmic immunE mediated inflammatory Diseases (SUCCEED) project was launched in 2021 to capture information on vaccine safety and effectiveness as part of Canada's COVID Immunity Task Force initiative (CITF, created by the government of Canada in 2020) to inform the National Advisory Committee on Immunization (NACI) and the Public Health Agency of Canada (PHAC) regarding Canada's vaccine strategies in IMID. One of the primary objectives of this study was to describe vaccine safety, particularly severe adverse events (SAE) defined as events associated with emergency department (ED) visits and/or hospitalizations.

Methods

Consenting adults with RA, IBD, AxS, PsO/PsA, and SLE were recruited from clinical centres in Vancouver, Calgary, Winnipeg, Montreal, Quebec City, Sherbrooke, Toronto, and Hamilton. Initial recruitment (in all centres except Vancouver, Montreal and Sherbrooke) began early in 2021, a few months after Canada began vaccinating against SARS-CoV-2 (mostly with mRNA formulations) and ended in March 2023. Patients were recruited by research staff during in-person patient visits at each clinical investigator's centre. Treating physicians could also obtain permission from patients (during a telehealth or in-person visit) for the research coordinator to contact them via email or telephone to explain the study and consent patients.

Recruitment at most centres targeted the assessment timepoints of pre-dose 1 and 2 (for mRNA formulations, which were anticipated to be the vast majority), at 2-4 weeks and then 3 and 6 months later. CITF funding was rolled out April 2021 and as it became clear that patients would be receiving 3rd and subsequent boosters, we amended our protocol to include those time points. We anticipated the vast majority (about 90% of our target of approximately 2000) of subjects would be on a disease-modifying agent and/or biologic and/or systemic corticosteroid, though this was not a criterion, and we anticipated that about 10% of our IMID participants might be on minimal (e.g., hydroxychloroquine or topical agents) or no IMID therapy. Exclusion criteria were individuals who had not been vaccinated for COVID for a duration longer than 6 months prior to recruitment and/or the unvaccinated (unless they planned to be vaccinated shortly).

Participants provided baseline and follow-up questionnaires (paper or electronic) on past COVID-19 infections (including dates and treatments), COVID-19 vaccinations (including dates and type) and clinical history (type of IMID, date of diagnosis, medications). Post-enrolment, participants were asked to contact the research team if they received additional vaccine doses, developed a COVID-19 infection or had a vaccine related adverse event. Participants were also contacted at 3, 6, and 12 months to update information on medications and confirm whether or not they had had additional COVID-19 infection, vaccinations, or adverse event, up to end of study. The questionnaire included a separate form where participants self-reported any adverse events that they believed was related to the vaccine.

Baseline information was recorded on demographic characteristics (age, sex, race/ethnicity), clinical factors (type of IMID, disease duration, drugs) and COVID vaccination (dates and types of vaccine). Follow-up questionnaires at 3-to-6-month intervals were completed by participants to update their clinical history (i.e., disease activity, drugs, COVID testing), health care use (physician visits, emergency room visits, and hospitalizations, including reasons for each) and COVID vaccination history (type, date).

To describe patient demographics, age and disease duration at study entry, we used means and standard deviations. Other characteristics were described in terms of frequency (N, percent). The number of ED visits and hospitalizations occurring within 31 days of vaccine administration were described (separately), following each vaccination dose, focusing specifically on severe adverse events. Adverse events post vaccination are typically monitored and reported within 28-31 days in many vaccination studies [1,2] and NACI recommended a 19-28 day timeframe between the 2 COVID-19 vaccine doses. Therefore, the 31-day timeframe was chosen to include the events happening within a month post vaccination as events within this period have a higher likelihood of being attributable to the effect of the vaccine, and correctly remembered by participants. The Adverse Events Following Immunization (AEFI) form was used to collect AE, as well as define SAE. Severe adverse events were defined as vaccine related AE that either led to ED visit or a hospitalization [9]. Among all events, it was determined how many were due to a severe IMID flare and how many were events that may have represented a non-flare severe vaccine side effect (e.g., Bell’s Palsy, cardiac events, etc.). This allowed us to report a) the number of severe disease flares requiring ED visit or hospitalization within 31 days post-vaccination and b) the number of ED visits or hospitalizations due to severe vaccine adverse events.

A virtual meeting was held with people with lived experience of rheumatic disease, where results were presented to them. Their feedback was collected regarding key takeaways and whether the results align with their experiences. These comments were incorporated into the paper discussion. People with lived experience had also been involved in the initial grant-writing, planning and conducting the study, and interpretation of preliminary results at every step of the study.

Results

Demographic and clinical characteristics of the study sample are presented in Table 1. About two-thirds (63%) of 1556 participants were female; mean age was 52.5 years. BNT162b2 (Pfizer) vaccine accounted for 75% of first/second doses, 67.8% of third doses, 63.3% of fourth doses and 62% of fifth doses. mRNA-1273 (Moderna) was the second most common vaccine. Forty-nine percent of participants had IBD, 27.4% had RA, 14.3% had PsO/PsA, 5.3% had AxS, and 4% had SLE.

Table 1. Baseline participant characteristics/demographics.

Characteristic	Total N = 1556 (%)
Age, N (%)	
60+ years	533 (34.3)
≤ 60 years	1014 (65.2)
Not specified	9 (0.6)
Mean age, (SD)	52.5 (15.7)
Sex, N (%)	
Male	569 (36.6)
Female	978 (62.9)
Not specified	9 (0.6)
White Race/ethnicity, N (%)	1343 (86.3)
Mean disease duration (SD) (years)	17.1 (13.4)
Current smoker, N (%)	78 (5.1)
Disease, N (%)	
Rheumatoid arthritis	426 (27.4)
Psoriasis/Psoriatic arthritis	223 (14.3)

Systemic lupus erythematosus	62 (4.0)
Inflammatory bowel disease	763 (49.0)
Axial spondylarthritis	82 (5.3)
Current prednisone use, N (%)	308 (19.8)
Current biologic use, N (%)	
Current anti-TNF	551 (35.4)
Current rituximab	17 (1.1)
Current abatacept	39 (2.5)
Current Vedolizumab	100 (6.4)
Current Ustekinumab	170 (10.9)
Current other biologic	46 (3.0)
No biologic	496 (31.9)
Non-biologic drug use, N (%)	
Current jak-inhibitor	86 (5.5)
Current methotrexate	439 (28.2)
Current hydroxychloroquine	234 (15.0)
Current azathioprine	90 (5.8)
Current leflunomide	56 (3.6)
Current sulfasalazine	89 (5.7)
Current other	8 (0.5)
Number vaccines, N (%)	
One dose	43 (2.8)
Two doses	223 (14.3)
Three doses	675 (43.4)
Four doses	531 (34.1)
Five doses	84 (5.4)
Vaccine Type, n (%)	
BNT-162b2 monovalent	1018 (65.4)
mRNA1273 monovalent	223 (14.3)
Mixed BNT-162b2/ mRNA1273	262 (16.8)
Non-mRNA vaccine ^a	53 (3.4)

^a These patients are those who received a single dose of either ChAdOx1 nCoV-19 or Ad26.COV2.S or those who received two doses of ChAdOx1 nCoV-19.

There were 12 (0.77%; 95% CI: 0.34%, 1.2%) self-reported SAEs leading to ED visit or hospitalization, occurring in 11 participants; one participant reported 2 SAEs (pericarditis due to a potential SLE flare and labyrinthitis). There were 6 adverse events requiring ED visits. These included one case of Bell's Palsy (31 days after the first vaccine dose), one serious allergic reaction of hives and a severe rash (within 24 hours after the first vaccine dose), one episode of labyrinthitis (27 days after the 3rd vaccine dose), one case of severe menstrual bleeding (4 days after the 2nd vaccine dose) and one case of pericarditis (24 days after the 3rd vaccine dose). This pericarditis event may have represented a case of a disease flare in a person with SLE given the concomitant new presence of other SLE symptoms. This SLE participant also reported a second event which was labyrinthitis, this occurred 3 days following diagnosis of pericarditis. The remaining 6th event was a case of pericarditis which was not specifically labelled by the individual (who had RA) as vaccine-related and occurred 21 days after the 2nd vaccine dose. With the exception of the above potential disease flare in SLE participant, no other disease flares requiring ED visit/hospitalization within 31 days of vaccination were recorded.

Table 2. Severe, self-reported vaccine-related adverse events and severe disease flare within 31 days of each COVID-19 vaccine dose.

	Dose 1	Dose 2	Dose 3	Dose 4	Dose 5
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	N=1556	N=1506	N=1278	N=597	N=50
Requiring emergency department, ED visit only (no admissions)					
Neurologic events ^a	1	0	0	0	0
Thrombosis	0	0	0	0	0
Pericarditis	0	1	0	0	0
Disease flare ^b	0	0	1	0	0
Other ^c	1	1	1	0	0
Total	2	2	2	0	0
Requiring Hospitalization (+/-ED)					
Neurologic events ^a	1	0	0	0	0
Thrombosis	0	0	0	0	0
Disease flare	0	0	0	0	0
Other ^d	0	1	3	1	0
Total	1	1	3	1	0

^aNeurologic includes: Bell's Palsy (1), Guillain-Barre syndrome (1). ^bDisease flare occurred in 1 SLE patient post dose 3. ^cOther reasons for ED visits include: severe allergic reaction (1), labyrinthitis (1), and severe menstrual bleeding (1). ^dOther for hospitalization include: diverticulosis (1), idiopathic thrombocytopenia purpura (1), transient multifactorial renal failure (1), atrial fibrillation (1), and migraine aura (1).

There were 6 hospitalizations (unrelated to the above non-hospitalized ED visits) which occurred within 31 days following a COVID-19 vaccination and all were labeled by the participant as a vaccine adverse event: these included one case of Guillain-Barre syndrome (15 days after the first vaccine dose), idiopathic thrombocytopenic purpura (within 31 days after second vaccine dose), one episode of atrial fibrillation (in an elderly RA patient with known prior heart disease, 21 days after the third vaccine dose), one episode of transient multifactorial renal failure, possibly triggered by diarrhea (9 days after the third vaccine dose), one new-onset migraine with aura (one day after the 4th vaccine dose), and one diverticulosis flare in a patient who presented to the hospital multiple times for recurrent diverticulosis (1 day after the 3rd vaccine dose). There were two other hospitalizations within 31 days of a COVID-19 vaccine which were not specifically labelled by the participant as vaccine-related; these included one case of shingles (27 days after the 4th vaccine dose) and one episode of epiploic appendagitis (torsion of an outpouching of peritoneal fat) 24 days after the 3rd vaccine dose.

Among the 12 self-reported vaccine-related SAEs, 7 were experienced by participants <65 years old. Three events occurred after the first vaccine dose, 3 after the second dose, 5 after the third dose, and 1 after the fourth dose. No deaths occurred in the 31 days after vaccination.

Discussion

In this large, longitudinal study, IMID participants reported the frequency of SAE post COVID-19 vaccination. In summary, the number of serious adverse events in our study was relatively low, which is reassuring to policymakers, clinicians, and most importantly, people with IMID. We noted presumed to be part of an SLE flare). Myocarditis, cardiogenic shock, myocardial infarction, or arterial/venous thrombosis have all been reported in the general population after vaccination with mRNA COVID vaccines and other products as well [1,10,11]. Our participants did not identify any ED visits or within 31 days of vaccination, that were related to these events. Our results are consistent with what has been reported in the literature in IMID [12–14].

Our findings from this study were presented and discussed with people with lived experience of rheumatic diseases. They pointed out that in 2021, many people with IMID had to reconcile the need for a vaccine that could potentially prevent infection (and possibly, hospital stays or even death), with the knowledge that there were very few early studies of adverse events after COVID vaccination, and none in people with auto-immune diseases. People with IMID with jobs requiring

reporting physically to work (e.g., in health care or other fields) would have had the extra pressure of needing to be vaccinated early in 2021 because of the increased risk of contracting COVID-19, despite some uncertainty regarding safety in IMID. Since 2021, we now have accumulated data on adverse events after COVID vaccination in IMID [12–14]. Of note, more recent variants (e.g., Omicron) have tended to cause somewhat less severe COVID-19 disease. A potential result may be that even in the face of PHAC/NACI recommendations to receive booster doses, some people with IMID may hesitate to get additional boosters beyond their 3rd vaccine dose (which currently represents the ‘primary series’ in immunocompromised individuals).

Undoubtedly, a potential concern is that adverse events, including flares, may have been under-reported if individuals were comfortable self-managing their flares or if individuals were averse to presenting to the ED. This could be due to concerns regarding wait time or exposure to COVID infection, particularly in 2021–2022 when many individuals may not yet have had COVID infection and feared putting themselves at risk from sick COVID patients in the ED. Another reason is that individuals with chronic conditions often prefer to present to their family physicians or rheumatologists who know them well, rather than to the ED given their past health care interactions. Among the flares that did occur, some of these may have been due to individuals delaying their immunosuppressive medications for 1–2 weeks prior to getting a vaccine and/or not taking it for 1–2 weeks afterwards. We could not document this with our study design.

Naturally, there may be remaining concerns about long-term data on the effects (positive or negative) of multiple COVID vaccinations in IMID, regarding disease control or comorbidity. People with IMID may have specific factors (e.g., past, concurrent, or family history of cardiac disease, demyelinating disorders, thrombosis) that made them hesitant to be vaccinated in the past and/or may contribute to their hesitancy regarding future vaccination (e.g., in the setting of recommendations for booster vaccinations every 6–12 months). In addition, most North Americans have had one or more COVID infections, and some people may feel their antibody titres are high enough. Some people may also believe that since they have recovered from COVID without sequelae, they would recover again. On the other hand, considering that people with IMID have an increased risk for hospitalization and intensive care unit stays for infection in general, some individuals with IMID may welcome regular boosters. This may also arise if they have a high risk of COVID infection due to living with young children or exposure to grandchildren, or if they have family members who are also immunocompromised.

In terms of vaccine type and related adverse events, people with an IMID may very well have made vaccine type choices due to evolving knowledge (across 2021) regarding specific adverse event associations in subgroup populations. Some of the adverse events include myocarditis in young men with mRNA vaccines [15], or thrombosis in people receiving early COVID vaccine formulations [16] (which could be particularly of concern for IMID individuals with baseline risk factors for thrombosis, such as anti-phospholipid and related antibodies and/or past thrombosis).

One major strength of our study includes our large sample of IMID participants with data gathered across eight Canadian sites who are likely representative of the general IMID population. As well as involving people with lived experience in the planning and execution of our research, our study was novel in that we asked a group of people with lived experience to help us interpret the results, which allowed their voices to be heard. This is extremely important, since our ultimate goal is that the study results would help optimize uptake of COVID-19 vaccine, in an era where SARS-CoV-2 continues to circulate, at the same time that social ‘vaccine fatigue’ or safety concerns may prevent people with IMID from continuing to get boosters.

Our study has some potential limitations. Firstly, although the study was launched only a few months after COVID-19 vaccinations were approved in Canada, many participants were only recruited after their second or subsequent vaccine doses, thus potentially subject to recall bias as we had asked them to report on their initial vaccines at enrolment. Moreover, individuals who experienced a SAE following the initial vaccine doses may have been hesitant to proceed with subsequent doses. Additionally, we relied on participants self-reporting of their SAE, which we confirmed only by contacting each site’s study directors, however, we did not consult subjects’ health

records to verify this information. Lastly, our sample we analyzed data from participants who received the monovalent vaccines which had no specificity for Omicron variants.

In conclusion, within the 31 days after SARS-CoV-2 vaccination in IMID, there were relatively few serious AEs, and no deaths. Our findings could provide reassurance to those with IMID regarding the safety of COVID-19 vaccines, increasing vaccine acceptance and uptake.

Author Contributions: Conceptualization OT, GK, PRF, CAH, VC, ML, AAZ, GB, IC, DL, LL, DP, JL, SB; data collection, OT, GGK, PF, CAH, ML, GB, NB, CD, LKW, DP, LW, LL, DP, JL; Formal analysis OT, LL, SB; methodology OT, GK, PRF, CAH, VC, ML, AAZ, GB, IC, DL, LL, DP, JL, SB; Validation NL, LP, DR, NB, CD, LKW, DP, LW; original draft preparation, All authors; manuscript revision, all authors. All authors have read and agreed to the published version of the manuscript.

Funding: This project was supported by funding from the Public Health Agency of Canada, through the Vaccine Surveillance Reference group and the COVID-19 Immunity Task Force. The views expressed here do not necessarily represent the views of the Public Health Agency of Canada. Dr. Fortin holds a Canada Research Chair on Systemic Autoimmune Rheumatic Diseases. Dr. Vinod Chandran is supported by a clinician scientist salary award from the Department of Medicine, University of Toronto.

Institutional Review Board Statement: The study was approved by the ethics board of the research institute of the McGill University Health Center (MP-37-2022-7763) and all participating centers.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data is contained within the article. The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Acknowledgments: This research was made possible by funding from the PHAC, via the Vaccine Surveillance Reference Group and the CITF. The opinions presented here are solely those of the authors and do not reflect the official stance of the PHAC. We extend our gratitude to all research team members for their excellent collaboration, their dedication and their efforts on this project, and to the patients who participated in the study.

Conflicts of Interest: The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results. Dr. Boire has received honoraria (none relevant to this work) for speaking or consultancy from Abbvie, BMS, Lilly, Novartis, Pfizer, Samsung BioEpi, Viartis; multi-centric research grants (none relevant to this work) from Janssen and Pfizer; unrestricted grant support (none relevant to this work) for local initiatives from BMS, Lilly and Pfizer. Dr. Chandran has received research grants from AbbVie and has received honoraria for advisory board and consultations from AbbVie, Amgen, BMS, Eli Lilly, Fresenius Kabi, Janssen, Novartis and UCB. His spouse is an employee of AstraZeneca. Dr. Fortin participated in advisory boards for Moderna in 2023- not related to this work. Dr. Hitchon participated in advisory boards for Astra-Zeneca (not related to this work) and has received research grants (unrelated to this work) for multi-centric research and from Pfizer (unrelated to this work).

References

1. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med* 2020;383:2603-15.
2. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med* 2021;384:403-16.
3. Krammer F. SARS-CoV-2 vaccines in development. *Nature* 2020;586:516-27.
4. Eder L, Widdifield J, Rosen CF, et al. Trends in the Prevalence and Incidence of Psoriasis and Psoriatic Arthritis in Ontario, Canada: A Population-Based Study. *Arthritis Care Res (Hoboken)* 2019;71:1084-91.
5. Ng SC, Shi HY, Hamidi N, et al. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies. *Lancet* 2017;390:2769-78.
6. Widdifield J, Paterson JM, Bernatsky S, et al. The epidemiology of rheumatoid arthritis in Ontario, Canada. *Arthritis Rheumatol* 2014;66:786-93.
7. MacKenna B, Kennedy NA, Mehrkar A, et al. Risk of severe COVID-19 outcomes associated with immune-mediated inflammatory diseases and immune-modifying therapies: a nationwide cohort study in the OpenSAFELY platform. *Lancet Rheumatol* 2022;4:e490-e506.
8. Markovinović A, Quan J, Herauf M, et al. Adverse Events and Serological Responses After SARS-CoV-2 Vaccination in Individuals with Inflammatory Bowel Disease. *Am J Gastroenterol*. 2023 Sep 1;118(9):1693-1697.

9. Vaccine Vigilance Working Group & PHAC. Reporting Adverse Events Following Immunization (AEFI) in Canada: User guide to completion and submission of the AEFI reports. Government of Canada 2023.
10. Yasmin F, Najeeb H, Naeem U, et al. Adverse events following COVID-19 mRNA vaccines: A systematic review of cardiovascular complication, thrombosis, and thrombocytopenia. *Immun Inflamm Dis* 2023;11:e807.
11. Fraiman J, Erviti J, Jones M, et al. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. *Vaccine* 2022;40:5798-805.
12. Bartels LE, Ammitzboll C, Andersen JB, et al. Local and systemic reactogenicity of COVID-19 vaccine BNT162b2 in patients with systemic lupus erythematosus and rheumatoid arthritis. *Rheumatol Int* 2021;41:1925-31.
13. Naveen R, Parodis I, Joshi M, et al. COVID-19 vaccination in autoimmune diseases (COVAD) study: vaccine safety and tolerance in rheumatoid arthritis. *Rheumatology (Oxford)* 2023;62:2366-76.
14. Botwin GJ, Li D, Figueiredo J, et al. Adverse Events After SARS-CoV-2 mRNA Vaccination Among Patients With Inflammatory Bowel Disease. *Am J Gastroenterol* 2021;116:1746-51.
15. Knudsen B, Prasad V. COVID-19 vaccine induced myocarditis in young males: A systematic review. *Eur J Clin Invest* 2023;53:e13947.
16. d'Almeida S, Markovic S, Hermann P, et al. Thromboembolism after Astra Zeneca COVID-19 vaccine: Not always PF4- antibody mediated. *Human Vaccines & Immunotherapeutics* 2023;19.

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