

COVID-19 Vaccine – Recombinant Protein, Adjuvanted Novavax (Nuvaxovid) Vaccine Biological Page

Section 7:	Biological Product Information	Standard #: 07.209
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Novavax (Nuvaxovid) COVID-19 Vaccine	
Manufacturer	Novavax, Inc.
Biological Classification	<ul style="list-style-type: none"> SARS-CoV-2 recombinant spike (S) protein adjuvanted with Matrix-M
Indications for Provincially Funded Vaccine	<p>Persons 18 years of age and older</p> <ul style="list-style-type: none"> Novavax vaccine may be offered to individuals 18 years of age and older without contraindications to the vaccine who are contraindicated for mRNA vaccines (e.g. anaphylaxis to PEG) or decline mRNA COVID-19 vaccines. <p>Note:</p> <ul style="list-style-type: none"> A complete series and a booster dose with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.
Preferred Use	N/A
Dose	0.5 mL
Route	IM in the deltoid or vastus lateralis muscle
Schedule	<p>Primary Series 2 doses</p> <ul style="list-style-type: none"> Dose 1: day 0 Dose 2: 8 weeks <p>Recommended spacing between dose 1 and dose 2 is at least 8 weeks</p> <ul style="list-style-type: none"> Data from mRNA and viral vector vaccines shows that extending the interval between the first and second dose by several weeks leads to even higher immune responses and better protection against COVID-19 infection that is also expected to last longer. This is consistent with general principles of vaccinology, and expected to also apply to Novavax vaccine. As such, the very good protection already provided by COVID-19 vaccines may be further improved when the interval between the first and second doses are extended. When choosing to use a longer dose interval, the risk of infection between doses needs to be considered based on the extent of local transmission, and person's risk of exposure to the virus. Individuals can consult with their health care provider if they have questions about when to get the second dose. <p>Notes:</p> <ul style="list-style-type: none"> Minimum spacing between doses is 21 days. A shortened interval between dose 1 and dose 2 (no less than 21 days) may be considered in certain situations: required for travel, work requirement, increased risk for infection based on local transmission and the degree of individual risk of exposure. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series. Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization based on the individual's treatment.

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	<p>Booster Dose Indications</p> <ul style="list-style-type: none"> • A booster dose should be offered to provide stronger protection for those who have waning immune response to vaccines focusing on individuals who are at higher risk for severe COVID-19 outcomes. • A bivalent Omicron-containing mRNA COVID-19 vaccine should be offered as a booster dose to the authorized age groups. • If individuals refuse a bivalent booster, a monovalent mRNA COVID-19 vaccine should be offered. • Individuals who refuse both bivalent and monovalent mRNA vaccines may receive a dose of Novavax as their booster. <p>Individuals 18 years of age and older</p> <p><u>Booster dose</u></p> <ul style="list-style-type: none"> ❖ At least 5 calendar months after the last dose of COVID-19 vaccine received, whether that was the final dose in the primary series or a booster dose (regardless of vaccine type and number of previous booster doses). <p>Note:</p> <ul style="list-style-type: none"> • A shortened interval of at least 3 calendar months between the last dose (or infection) and the bivalent booster may be considered (e.g. for individuals at higher risk for severe outcomes). • A longer interval of at least 5 calendar months leads to a better immune response against COVID-19 that is also expected to last longer, because it allows time for the immune response to mature in breadth and strength. This needs to be considered in situations where individuals request an interval shorter than 5 months. However, individuals should not be turned away if they still choose a shortened interval. • The schedule for a booster dose in individuals with immunocompromising conditions is the same as the schedule for the general population.
Schedule for Individuals with Certain Immunocompromising Conditions	<p>Individuals with certain immunocompromising conditions are preferentially recommended to receive mRNA vaccine because there is currently limited evidence on the use of the Novavax Nuvaxovid in this population, while there is evidence on the safety profile and effectiveness of mRNA COVID-19 vaccines in this population based on real world use with large numbers of individuals. COVID-19 mRNA vaccines should be offered except in the event of contraindication or refusal.</p> <p>Primary series 3 doses</p> <ul style="list-style-type: none"> • Dose 1: day 0 • Dose 2: 28 days after dose 1 • Dose 3: 8 weeks after dose 2 <ul style="list-style-type: none"> • It is recommended that individuals with certain immunocompromising conditions be immunized with a primary series of three doses of an mRNA COVID-19 vaccine. This is to provide stronger protection for those who may have a suboptimal immune response to vaccines. • It is recommended that the interval between dose 1 and dose 2 be 28 days and the interval between dose 2 and dose 3 be 8 weeks. <ul style="list-style-type: none"> ○ The interval between dose 2 and dose 3 is recommended to be 8 weeks because emerging evidence from the general population indicates that a longer interval will likely result in a better immune response and duration of protection. ○ However, there is heterogeneity among those who are moderately to severely immunocompromised, and risks from COVID-19, as well as the likelihood of a reduced response to vaccines, will vary depending on the immunocompromising condition. Thus, a shortened interval no less than 28 days may be considered for those with increased risk of exposure and greater severity of immunodeficiency, based on their clinician's recommendation. • Specific Immunocompromising conditions that make an individual eligible: <ul style="list-style-type: none"> ○ solid organ transplant recipients - pre-transplant and post-transplant

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	<ul style="list-style-type: none"> ○ hematopoietic stem cell transplants recipients - pre-transplant and post-transplant while in immunosuppressed state (post-HSCT individuals are generally considered to be immunocompetent after 3 years as long as they are not on immunosuppressive drugs) ○ individuals with malignant hematologic disorders and non-hematologic malignant solid tumors prior to receiving or receiving active treatment which includes chemotherapy, targeted therapies, and immunotherapy or having received previous COVID-19 vaccines while on active treatment (does not include individuals receiving solely hormonal therapy, radiation therapy or a surgical intervention). ○ individuals on anti-B-cell therapies – including anti-CD19, anti-CD20, anti-CD22 and anti-CD52 monoclonal antibodies (such as rituximab, ocrelizumab, and ofatumumab) ○ individuals with chronic kidney disease on peritoneal dialysis or hemodialysis. ○ Individuals receiving chimeric antigen receptor (CAR)-T-cell therapy. ○ Individuals on: <ul style="list-style-type: none"> ▪ long term high-dose systemic steroid treatment (prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), or ▪ alkylating agents, or ▪ antimetabolites (e.g. methotrexate, azathioprine, mycophenolate), or ▪ tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab, certolizumab, etanercept, golimumab, infliximab), or ▪ other agents that are significantly immunosuppressive at clinicians' discretion ○ HIV-infected individuals without viral suppression, or those with acquired immunodeficiency syndrome (AIDS). ○ Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome). <p>Notes:</p> <ul style="list-style-type: none"> • Documentation of immunocompromising conditions is not required. Individuals who identify themselves as meeting at least one of the criteria above could be offered the 3 dose primary series. • Immunization for immunocompromised individuals should occur at a time when the individual is most likely to mount an immune response. Physician consultation is recommended regarding the timing of immunization based on the individual's treatment. • Hematopoietic stem cell transplant (HSCT) recipients who received COVID-19 vaccine pre-transplant are eligible to restart their COVID-19 vaccine series beginning at least 3 months post-transplant. Consultation with their HSCT physician is not necessary as long as the initial clearance letter has been received to proceed with inactivated vaccines. • CAR-T cell therapy recipients without a prior history of HSCT who received COVID-19 vaccine pre-CAR-T therapy are eligible to restart their COVID-19 vaccine series, beginning at least 3 months post-CAR-T cell therapy. Consultation with their physician is not necessary as long as a clearance letter has been received to proceed with inactivated vaccines. • For HSCT recipients whose post-HSCT vaccine series were interrupted by CAR-T cell therapy, see the following HSCT guidance: <ul style="list-style-type: none"> ○ #08.304 Standard for Immunization of Transplant Candidates and Recipients ○ Immunization of Adult HSCT Transplant Recipients
<p>Interval between previous COVID-19 infection and COVID-19 immunization</p>	<p>For individuals with a history of confirmed COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.</p> <p>Notes:</p> <ul style="list-style-type: none"> • Please see CMOH Order 02-2022 and Order 04-2022 for definition of confirmed COVID-19 infection.

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<ul style="list-style-type: none"> • These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised. • For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days). 		
Infection prior to initiation or completion of a primary COVID-19 immunization series	Individuals without certain immunocompromising conditions AND no history of multisystem inflammation syndrome in children (MIS-C)	8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C	4 to 8 weeks after symptom onset or positive test (if asymptomatic)
	History of MIS-C (regardless of immunocompromised status)	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer
Infection after primary series	Individuals eligible for booster doses	5 months after symptom onset or positive test (if asymptomatic) AND at least 5 months after last dose A shortened interval of at least 3 calendar months may be considered (e.g. for individuals at higher risk for severe outcomes).
Contraindications/ Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Persons under 18 years of age • Known severe hypersensitivity to any component of the vaccine. <ul style="list-style-type: none"> ○ One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medical preparations (e.g. vitamin oils, tablets, anticancer agents) and cosmetics. • Anaphylaxis to previous dose of Novavax COVID-19 vaccine. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations. <p>Precautions:</p> <ul style="list-style-type: none"> • Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. • Administration should be postponed in individuals suffering from acute severe febrile illness. • Refer to Immunocompromised and Auto-Immune Disorders section for specific information on these populations 	

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Myocarditis/ Pericarditis	<ul style="list-style-type: none"> • Myocarditis was identified in two teenage males shortly after receiving a second dose of Novavax COVID-19 vaccine in the clinical trial, however the information currently available is insufficient to determine a causal relationship with the vaccine. Post-market safety surveillance is required to determine whether this is an adverse event of interest associated with Novavax COVID-19 vaccine. • It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis. <ul style="list-style-type: none"> ○ Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA or Novavax vaccines. ○ If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines. • Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of Novavax COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization. • In most circumstances, further doses of Novavax COVID-19 vaccine should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an Novavax COVID-19 vaccine. <ul style="list-style-type: none"> ○ However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician. ○ Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of Novavax COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of Novavax COVID-19 vaccine. • Anyone receiving a Novavax COVID-19 vaccine should be informed of the potential risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. • Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with Novavax COVID-19 vaccine.
Immunocompromised and Auto-Immune Disorders	<ul style="list-style-type: none"> • Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine • The clinical trial excluded participants who were significantly immunocompromised or immunosuppressed. • COVID-19 vaccine can be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder. <ul style="list-style-type: none"> ○ It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions. ○ However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine. <ul style="list-style-type: none"> ▪ Response for immunizers if individual has not consulted with their primary health care provider: “Vaccine studies are not complete on the use of this vaccine in immunocompromised individuals or those with auto-immune disorders. We recommend you speak to your physician regarding the timing of immunization based on your treatment or if you have questions about the immunization, but it is not required to receive the vaccine.” <p>Exceptions:</p>

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	<ul style="list-style-type: none"> ▪ SOT clients require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine. ▪ HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccines. • <u>Additional resources:</u> <ul style="list-style-type: none"> ○ COVID-19 Scientific Advisory Group Rapid Evidence Report.
Pregnancy	<ul style="list-style-type: none"> • The safety and efficacy of Novavax COVID-19 vaccines in pregnant women has not yet been established in clinical trials, however, there is evidence on the safety profile and effectiveness of mRNA COVID-19 vaccines in this population based on real world use with large numbers of individuals. • Novavax vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for the woman and fetus. <ul style="list-style-type: none"> ○ However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of the absence of evidence on the use of a Novavax COVID-19 vaccine in this population and the preference for an mRNA vaccine due to published effectiveness and safety data. ○ Response for immunizers if individual has not consulted with their primary health care provider: “The vaccine studies have not tested whether this vaccine is safe or effective for you. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor.” • <u>Additional resources:</u> <ul style="list-style-type: none"> ○ Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.
Lactation	<ul style="list-style-type: none"> • It is unknown whether Novavax COVID-19 Vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded. • Novavax COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding. <ul style="list-style-type: none"> ○ It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns. ○ However, consultation with a primary health care provider or medical specialist is not required to receive Novavax COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion. ○ Response for immunizers if individual has not consulted with their primary health care provider: “Vaccine studies are not complete on the use of this vaccine in breastfeeding women. If you have questions about the immunization, we recommend you speak to your physician but it is not required to receive the vaccine.”
Other Considerations	<ul style="list-style-type: none"> • Individuals presenting for immunization do not need to be tested for previous COVID-19 infection. • It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals. It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective. • Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. • Individuals with COVID-19-like symptoms, should not go to an immunization venue in order to minimize the risk of COVID-19 transmission and their immunization should be deferred.

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Possible Reactions	<p>Common</p> <ul style="list-style-type: none"> • Pain, tenderness, redness, and swelling at the injection site • Fever, chills • Fatigue • Malaise • Headache, myalgia, arthralgia, • Nausea, vomiting • Pain in extremity <p>Rare:</p> <ul style="list-style-type: none"> • Allergic reactions • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Composition	<p>Each 0.5 mL dose contains:</p> <p>Suspension, (5×10^{10} virus particles), recombinant spike protein</p> <ul style="list-style-type: none"> • Disodium hydrogen phosphate heptahydrate • Hydrochloric acid (for adjustment of pH) • Polysorbate 80 • Sodium chloride • Sodium dihydrogen phosphate monohydrate • Sodium hydroxide (for adjustment of pH) • Water for injection <p>For adjuvant (Matrix-M)</p> <ul style="list-style-type: none"> • Cholesterol • Disodium hydrogen phosphate dihydrate • Phosphatidylcholine (including all-rac-α-Tocopherol) • Potassium chloride • Potassium dihydrogen phosphate • Sodium chloride <p>No preservatives</p>
Blood/Blood Products	Contains no human blood/blood products.
Bovine/Porcine Products	Contains no bovine/porcine products.
Latex	Does not contain latex.
Interchangeability	<ul style="list-style-type: none"> • Currently, no data exists on the interchangeability of COVID-19 vaccines. • There are no data available on the use of the Novavax (Nuvaxovid) COVID-19 vaccine to complete a series initiated with another COVID-19 vaccine.
Administration with Other Products	<ul style="list-style-type: none"> • Novavax COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines). • Currently there is no data on the impact of the COVID-19 vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results. <ul style="list-style-type: none"> ○ In the absence of data, and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test. • However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results.

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	<ul style="list-style-type: none"> • Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses. <ul style="list-style-type: none"> ○ A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type. ○ Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown. ○ There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients. ○ Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who received the monoclonal antibodies or convalescent plasma for their infection. • Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference. <p>Note: Anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma should not be administered concomitantly with COVID-19 vaccines (i.e. administer on different days).</p> <ul style="list-style-type: none"> • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis. • COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including Rhlg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.
Appearance	<ul style="list-style-type: none"> • The solution is colourless to slightly yellow, clear to mildly opalescent, free of particles.
Storage	<ul style="list-style-type: none"> • Unopened vials can be stored in a refrigerator between 2°C to 8°C storage for a maximum of 9 months. • Store in the original carton to protect from light. • Punctured vials (first dose is withdrawn) can be stored between 2°C to +25°C for 6 hours. • After 6 hours, the punctured vial must be discarded. • Do not freeze.
Packaging	<ul style="list-style-type: none"> • 10 doses per vial. • 5 mls of solution in a 10-dose vial (clear glass) with a rubber stopper and a blue plastic flip-off cap. • 10 vials per package.
Preparation/ Reconstitution	<ul style="list-style-type: none"> • No reconstitution is required. • Gently swirl the multidose vial before and in between each dose withdrawal. • Do not shake.
Vaccine Code	COVNVASub
Antigen Code	COVID-19-3
Licensed Use	<ul style="list-style-type: none"> • 18 years of age and older.
Off-License Use	<ul style="list-style-type: none"> • Booster doses/additional doses
Program Notes:	
<ul style="list-style-type: none"> • 2022 February 17: Licensed for use in Canada. • 2022 April 12: Implemented in Alberta. 	

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- 2022 June 6: Updated to include recommendation for immunization post CAR-T cell therapy.
- 2022 July 19: Updated to expand second booster dose eligibility to include all individuals 18 years of age and older; updated recommendations for timing of COVID-19 vaccines and receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prophylaxis of COVID-19.
- 2022 October 31 – Updated booster dose recommendations, updated recommendations on timing of tuberculin skin testing/ interferon gamma release assay and COVID-19 immunization

Related Resources:

- Alberta Health Services Website (2022). COVID-19 Vaccines - Protein Based Information Sheet.

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9. Shimabukuro, T., Kim, S., et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. American Journal of Medicine. (2021 April 21) <https://www.nejm.org/doi/full/10.1056/NEJMoa2104983>