Medical Directive: Authority to Provide mRNA COVID-19 Immunizations by Band Employed Registered Nurses and Registered Practical Nurses and ISC FNIHB Surge Nurses Working in First Nations Communities in Ontario Region

Medical Directive: CD-IMM-COVID19-002
Activation Date: 07 APRIL 2022
Review Due by: 07 APRIL 2023

Sponsoring Person(s)

- James Brooks, MD, FRCPC, Director, Health Protection Unit
- Shari Glenn, NP (PHC), Director, Primary Health Care

Implementation of this Directive by Band employed staff/communities transferred for health service delivery including immunization programming is OPTIONAL. Band/First Nation Community-employed nursing staff must operate under the direction of an attending Physician or Nurse Practitioner, however, this does not imply FNIHB and can be through the local Public Health Unit or other prescriber working in a designated community.

Where a Community chooses to implement FNIHB's directive, they have the responsibility to assure that staff meet the mandatory education and practice competencies as outlined by FNIHB's directive in order for it to be valid.

NOTE: As there are several COVID-19 vaccines available, providers must be knowledgeable about each vaccine through the manufacturer product monographs as well as current Ontario Ministry of Health guidance documents, including age, eligibility and contraindications.

Delegated Procedure/Order

- The safe and effective administration of mRNA COVID-19 vaccines to individuals living/working in First Nations communities in Ontario Region, in accordance with the manufacturer product monographs, FNIHB Ontario Region (OR) Immunization Protocol (which includes the current Canadian Immunization Guide and Regional Policies), the Ontario Ministry of Health COVID-19 Immunization guidelines and directives, and The College of Nurses of Ontario's (CNO) Nursing Standards and Guidelines.
- If readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage), the same mRNA COVID-19 vaccine product should be offered for any subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.
- The management of post-immunization anaphylaxis in a non-hospital setting in accordance with the current Canadian Immunization Guide https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html

Informed Consent

Registered Nurses (RN) and Registered Practical Nurses (RPN) will obtain informed consent as per the College of Nurses of Ontario: Practice Guidelines on Consent with additional support from the FNIHB-Ontario Region Immunization Protocol https://www.onehealth.ca/on/Public-Health-Unit/Communicable-Disease-Unit/About-Immunization/Immunization-Protocol

Recipient Clients/Patients

- Individuals, families or groups living/working on First Nations reserves, and those who meet eligibility requirements for vaccines currently offered in Ontario as outlined by the Product Monograph and the Ontario Ministry of Health guidelines: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/covid19_vaccine.aspx

- Vaccination post COVID-19 infection: There is emerging evidence indicating that a longer interval between COVID-19 infection and vaccination is associated with improved antibody responses to COVID-19 vaccines. A previous COVID-19 infection is defined as a COVID-19 case confirmed by a molecular (e.g., PCR) or rapid antigen test, or symptomatic AND a household contact of a confirmed COVID-19 case. Individuals may receive a COVID-19 vaccine after having completed their isolation and the recommended interval (post infection) has been reached. An individual is still permitted to receive vaccine at the current minimum intervals in the vaccine schedule with informed consent. If an individual meets this definition of infection, it is prudent to inform them of the suggested interval to receive vaccine post infection and document that specific informed consent was provided if the vaccine is administered at a shorter interval than recommended. See Appendix A for specific intervals following infection.

- Age: The following is only a brief statement (please see the Ontario Ministry of Health for complete information)
    - Pediatric Comirnaty (Pfizer-BioNTech) COVID-19 vaccine for individuals 5 to 11 years of age. Please note: NACI and Ontario Guidance state that it is prudent to wait for a period of at least 14 days BEFORE or AFTER the administration of another vaccine before administering the pediatric COVID-19 vaccine. However, it is acceptable to shorten this interval or administer both vaccines at the same time if the circumstances necessitate it.
    - Comirnaty (Pfizer-BioNTech) COVID-19 vaccine for individuals 12 years of age and older~~,~~
    - SpikeVax (Moderna) COVID-19 vaccine is currently authorized for individuals 12 years of age and older; however, the National Advisory Committee on Immunization (NACI) and Ontario Ministry of Health have issued a preferential recommendation for the use of Comirnaty (Pfizer-BioNTech) COVID-19 vaccine for individuals 12-29.

Immunocompromised Individuals:

- Moderately to severely immunocompromised individuals (including children aged 5-11) and those receiving dialysis are eligible for a 3-dose primary series. The Ontario Ministry of Health recommended interval is **at least 2 months (56 days) between the first and second dose and between the second and third dose.** As per NACI, the minimum interval can be as short as 28 days; however, an interval longer than the minimum 28 days between doses is likely to result in a better immune response. Exact timing should be decided with the treating provider in order to optimize the immune response from the vaccine series minimize delays in management of the individual's underlying condition. Please see Ontario Ministry of Health guidance document, *COVID-19 Vaccine Third Dose and Booster Recommendations,* *https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_third_dose_recommendations.pdf* or most current. Individuals may present with a letter from their primary care provider indicating they are eligible, or they may present with a prescription, which can include the label on a pill bottle, for any immunosuppressant medication listed in Appendix A: List of Immunosuppressive Medications in Ontario Ministry of Health the guidance document, *COVID-19 Vaccine Third Dose and Booster Recommendations* (linked above). A small number of immunocompromised individuals will not be taking these medications. For these individuals, a letter or prescription for a third dose from their physician is required (and can also be used for fourth dose eligibility). For patients receiving dialysis it is common for them to already have either a letter or some other form of documentation.
    - Moderately to severely immunocompromised children ages 5-11 are eligible for a 3-dose primary series only, the pediatric Comirnaty (Pfizer-BioNTech) vaccine may be given. Indirect data from adult populations (18 and older) suggests Spikevax (Moderna) (100 mcg) may result in a higher vaccine effectiveness after a 2-dose primary series compared to Comirnaty (Pfizer-BioNTech) (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients. Given this potential benefit, administration of the Spikevax (Moderna) (50 mcg or 0.25 mL dose) vaccine as a 3-dose primary series may be considered for some immunocompromised individuals 6 to 11 years of age, as outlined in the product monograph.
    - Moderately to severely immunocompromised individuals 12 to 29 years of age are preferentially recommended to receive Comirnaty (Pfizer-BioNTech) (30 mcg) but may receive Spikevax (Moderna) (100 mcg) based on clinical discretion. For individuals 30 years of age and older, the fourth dose should be a full dose of either SpikeVax (Moderna) (100 mcg) COVID-19 vaccine or Comirnaty (Pfizer-BioNTech) (30mcg) COVID-19 vaccine. Data suggest that Spikevax (Moderna) COVID-19 vaccine may provide a more robust humoral and cellular immune response.
    - Moderately to severely immunocompromised individuals 12 years of age and older, including those on dialysis, are eligible for a fourth dose after completion of their 3-dose primary series. This also includes individuals 12 years of age and older who were receiving active treatment necessitating a 3-dose primary series even if not currently receiving active treatment. The minimum interval between the third and fourth dose is 3 months (84 days). **Individuals 12-17 years of age are recommended to receive their fourth dose at an interval of at least 6 months (168 days) following the third dose, or at an interval recommended by their provider**. The same preferential recommendations for vaccine products apply to the fourth dose.

Primary Series:

- Interval between doses in primary series: please see the tables below for guidance on recommended intervals between dose 1 and 2 for those 12 years of age and older and for children 5 to 11 years of age. NACI, the Ontario Ministry of Health and this Medical Directive strongly advocate for an 8-week interval as the "best" individual immunological response is obtained.

- **If an individual or parent/guardian requests an interval shorter than 8 weeks but is consistent with the product monograph of the vaccine used for the individual's first dose, informed consent should be provided and include that longer dose intervals, compared with the authorized 21 or 28 day interval, improves the immune response and is associated with greater vaccine effectiveness that may last longer and that data suggests an extended interval between the first and second dose may reduce the risk of myocarditis/pericarditis following the second dose of an mRNA COVID-19 vaccine. The client's request to use the shorter interval and informed consent should be documented in the client's chart/COVax (if applicable in community).**

First and Second Dose Interval for 12 years and older:

	Minimum Interval (as per original Manufacturer Clinical Study) and permitted per Ontario Guidance	HC Authorized Interval and permitted per Ontario Guidance	NACI "Optimal Interval" and per Ontario Guidance "Recommended Interval"	FNIHB Ontario Region Medical Directive suggested interval
Comirnaty (Pfizer-BioNTech)	19 days	21 days	8 weeks	8 weeks
SpikeVax (Moderna) (For 1st and 2nd dose: Full dose (100 mcg))	21 days	28 days	8 weeks	8 weeks

First and Second Dose Interval for 5 to 11 year olds:

	Minimum Interval (as per original Manufacturer Clinical Study) and permitted per Ontario Guidance	HC Authorized Interval and permitted per Ontario Guidance	NACI and Ontario Guidance "Recommended Interval"	FNIHB Ontario Region Medical Directive suggested interval
Pediatric Comirnaty (Pfizer-BioNTech)	19 days	21 days	8 weeks	8 weeks

Third (Booster) Doses:

- All individuals 12 years of age and older are eligible to receive a third (booster) dose. Depending on the age of the recipient (**see preferential recommendations for vaccine products above**), either SpikeVax (Moderna) COVID-19 vaccine or Comirnaty (Pfizer-BioNTech) COVID-19 vaccine may be used as a third (booster) dose. See below for additional information specific to population, age and dosing.

- Third (booster) doses should be offered to the following populations at a **minimum interval of three months (84 days) or longer between their second and third (booster) dose**. **For individuals 12-17 years of age, it is recommended that they receive their third (booster) dose at an interval of at least 6 months (168 days) between their second and third (booster) dose**. This interval may be associated with a lower risk of myocarditis with or without pericarditis. With informed consent, individuals 12-17 years of age may receive a third (booster) dose at a minimum of 3 months (84 days) after completion of a primary COVID-19 vaccine series.
    - Individuals aged 12 to 29 years of age should receive Comirnaty (Pfizer-BioNTech) (30 mcg) COVID-19 vaccine as their third (booster) dose.
    - Individuals less than 70 years of age if offering SpikeVax (Moderna) COVID-19 vaccine as a third (booster), a half dose (50 mcg) is recommended. For this same age group, if offering Comirnaty (Pfizer-BioNTech) COVID-19 vaccine for a third (booster) dose, the full dose (30 mcg – as before) is recommended. Vulnerable older adults living in congregate settings should receive the full dose (irrespective of age).
    - Individuals 70 years of age and older are recommended to receive a full dose of either SpikeVax (Moderna) (100 mcg) or Comirnaty (Pfizer-BioNTech) (30mcg) COVID-19 vaccine. Data suggest that Spikevax (Moderna) COVID-19 vaccine may provide a more robust humoral and cellular immune response.

Fourth (Booster) Doses:

- Residents of Elder Care Lodges and older adults living in congregate settings providing assisted living and health services are eligible to receive a fourth dose at a minimum interval of three months (84 days) between their third and fourth dose.
    - The fourth dose should be a full dose of either SpikeVax (Moderna) (100 mcg) or Comirnaty (Pfizer-BioNTech) (30mcg) COVID-19 vaccine. Data suggest that Spikevax (Moderna) COVID-19 vaccine may provide a more robust humoral and cellular immune response. Some residents may receive shorter intervals than the recommended three months (84 days) due to operational considerations when boosting entire facilities.

- First Nations, Inuit and Métis individuals and their non-Indigenous household members who are 18 years of age and older are eligible to receive a fourth (booster) dose. Depending on the age of the recipient (**see preferential recommendations for vaccine products above**), either SpikeVax (Moderna) COVID-19 vaccine or Comirnaty (Pfizer-BioNTech) COVID-19 vaccine may be used as a fourth (booster) dose. The recommended interval is 5 months (140 days) following the third (booster) dose. A minimum interval of 3 months (84 days) following their third (booster) dose is permitted with informed consent.
    - First Nations, Inuit and Métis individuals must be 18 years of age by birth date to be eligible.
    - For the broader Ontario population, all individuals who are 59 turning 60 years old this year are eligible.

- Adults less than 70 years of age, if offering SpikeVax (Moderna) COVID-19 vaccine as a fourth (booster), a half dose (50 mcg) is recommended. For this same age group, if offering Comirnaty (Pfizer-BioNTech) COVID-19 vaccine for a fourth (booster) dose, the full dose (30 mcg – as before) is recommended. Please remember the preferential use of the Pfizer vaccine for the 12-29 age group (understanding that in this context it is applicable to the 18-29 age group)
- Individuals 70 years of age and older are recommended to receive a full dose of either SpikeVax (Moderna) (100 mcg) or Comirnaty (Pfizer-BioNTech) (30mcg) COVID-19 vaccine. Data suggest that Spikevax (Moderna) COVID-19 vaccine may provide a more robust humoral and cellular immune response.

In conclusion:

- This Medical Directive contains information about different considerations when administering COVID-19 vaccines, such as age eligibility, preferential vaccine selection, vaccine formulation, place of residence (ie congregate living), dosing interval (both recommended and minimum), intervals post infection and medical conditions (ie immunocompromised). We are grateful to WAHA for developing and sharing the attached flow-chart (Appendix B) which IS endorsed by the ISC-ON PHU to facilitate decision making for vaccine administration.

Authorized Implementers

This medical directive may be implemented by Band employed RNs and RPNs, and ISC FNIHB Surge nurses working in First Nations communities in Ontario Region who:

- Are in good standing with the CNO, with no suspensions
- Have successfully completed the FNIHB-Ontario Region COVID-19 vaccine(s) mandatory education session(s) specific to the vaccinations being given, including the process for reporting of Adverse Events Following Immunization (AEFI)
- Have not completed the entire FNIHB OR General Immunization certification process (modules, exam, skills demonstration) and are therefore not covered under the FNIHB OR General Immunization Directive for all vaccines under the Publicly Funded Immunization Schedule for Ontario (PFISO)

All RNs/RPNs using this directive must:

- Be knowledgeable about the available and supplied COVID-19 vaccine(s) indications, dosage, administration, contraindications, storage and handling
- Be able to apply their knowledge, judgment and skills in safely administering the COVID-19 vaccine(s) as per the Ontario Ministry of Health guidelines for vaccine use in Ontario
- Remain up-to-date on changes to the COVID-19 vaccine(s) information as updated by the PHAC, the Ontario Ministry of Health, and the FNIHB-Ontario Region
- Remain up-to-date on changes to the FNIHB-Ontario Region Immunization Protocol including the current Canadian Immunization Guide and approved regional policies
- Be knowledgeable and remain up-to-date on the recognition and treatment of Early Vaccine Reactions Including Anaphylaxis found in the Canadian Immunization Guide: Part 2 - Vaccine Safety, available at: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html

- Be currently certified in cardiopulmonary resuscitation (CPR)
- Have immediate access to an up-to date and complete anaphylaxis kit

Guidelines for Implementing the Procedure/Order

Implementation of this medical directive require:

- Upon receipt of vaccine from the local Public Health Unit, highlight in yellow and circle in red ink the date and time indicating the expiry of the vaccine shipment's viability. The vaccine should not be administered after this indicated date and time.
- The vaccine fridge must be monitored twice daily and the results recorded. Any deviations in temperature outside of the acceptable 2 to 8 degrees Celsius will be immediately reported to the Nurse-In-Charge, Nurse Manager, and applicable vaccine supplier/provincial Public Health Unit. The vaccine will not be administered until guidance is received from the Public Health Unit.
- Before preparing and administering vaccine, the expiry date and time of the vaccine must be confirmed by two providers (e.g., two registered nurses, one registered nurse and one paramedic, or two paramedics). The expiry date and time of the unique shipment as well as the expiry date and lot number on the individual vials must be confirmed. Unpunctured vials can remain between 2 and 8 degrees Celsius up to 31 days for the Adult formulation of Comirnaty (Pfizer-BioNTech) COVID-19 vaccine, 30 days for SpikeVax (Moderna) COVID-19 vaccine and 10 weeks for the Pediatric formulation of Comirnaty (Pfizer-BioNTech) vaccine.
- Ensure the date and time of first puncture are recorded on the vial. Two providers must ensure the date and time and therefore the viability of the vaccine prior to administering from the first puncture is 6 hours for the Adult formulation of Comirnaty (Pfizer-BioNTech) COVID-19 vaccine, 24 hours for SpikeVax (Moderna) COVID-19 vaccine and 12 hours for the Pediatric formulation of Comirnaty (Pfizer-BioNTech) COVID-19 vaccine.
- SpikeVax (Moderna) COVID-19 vaccine can only be punctured up to 20 times. If using a 15 dose vial of SpikeVax (Moderna), ensure you are documenting number of punctures. When 20 punctures is reached, record/document the remaining vaccine in the vial as wastage and discard according to policy.
- Discuss with the recipient or parent/guardian, the benefits and risks of receiving or not receiving the COVID-19 vaccine, and answer questions in order to obtain free and prior informed consent.
- Assess and document allergies and contraindications related to immunization for the vaccine
- Document the intervention and treatment of any Adverse Event Following Immunization (AEFI) according to band policy, the FNIHB-Ontario Region Immunization Protocol, and provincial requirements

Contraindications to the Implementation of this Directive

This medical directive cannot be implemented in the following cases:

- When a client/patient has a contraindication to the vaccine or any component.
- When a client/patient is living in provincially and/or privately funded Health Care facility, for example, Long-Term Care (LTC) facilities, where care is managed and delivered under another physician's where care is managed and delivered under another physician's supervision; immunizations in those facilities would be provided under the authority of the supervising physician and would not be covered by this medical directive.

Documentation and Communication Guidelines

Documentation and communication must be in compliance with the requirements outlined by the CNO current Nursing Practice Standards on Documentation and the FNIHB-Ontario Region Immunization Protocol, and any additional Provincial documentation related to the specific product(s)

Quality Assurance and Review Process

- Competencies for safe and effective administration of the Publicly Funded Immunization Schedules for Ontario are provided in the FNIHB-Ontario Region Immunization Orientation and Competency Certification as well as in the FNIHB-Ontario Region Nursing Policy and Practice Manual
- Ongoing immunization competency support is provided via ongoing education sessions, access to updated information at https://www.onehealth.ca/on/ and access to a FNIHB Ontario CD Unit Practice Advisor-Public Health (CD Nurse), CD Unit Practice Consultant-Public Health (Immunization), and FNIHB Nurse Practice Consultant (NPC) as necessary
- This medical directive will be reviewed every year or earlier if needed and revised as required

Approving Physician(s)/Authorizer(s)

James Brooks, MD, FRCPC, Director, Health Protection Unit

Signature:_____ Date: April 19, 2022

Administrative Approval(s)

Shari Glenn, NP (PHC), Director, Primary Health Care

Signature:_____ Date: April 19, 2022

Appendix A : Suggested COVID-19 vaccination intervals following COVID-19 Infection

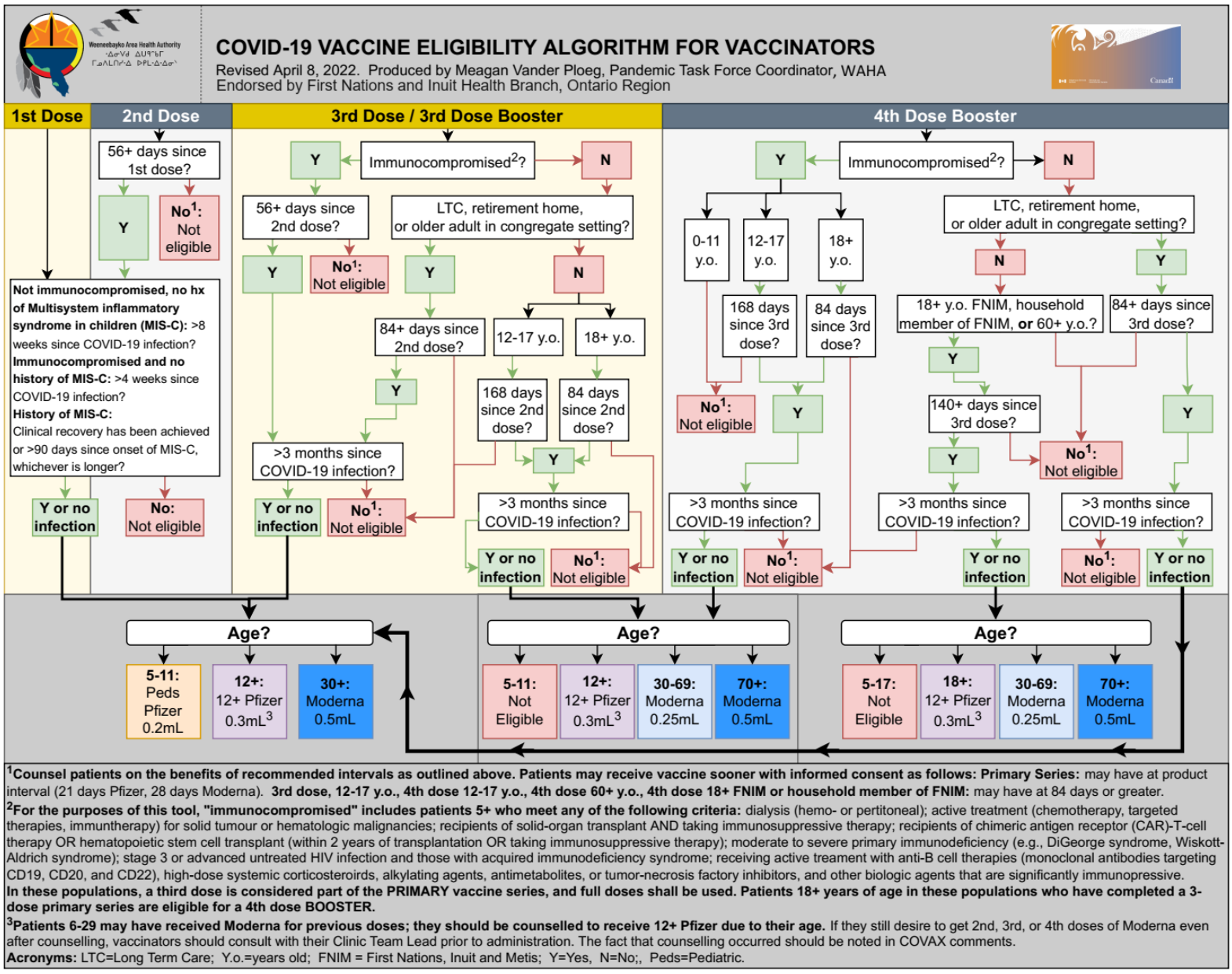
Infection timing relative to COVID-19 vaccination	Population	Suggested interval between infection* and vaccination
Infection prior to completion or initiation of primary vaccination series	Individuals 5 years of age and older who are not considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	Receive the vaccine 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 5 years of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C	Receive the vaccine dose 4 to 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 5 years of age and older with a previous history of MIS-C (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥ 90 days since the onset of MIS-C, whichever is longer
Infection after primary series but before third (booster) dose	Individuals 12 years of age and older currently eligible for a third (booster) dose	3 months after symptom onset or positive test (if asymptomatic) **AND** provided they meet current recommended/minimum intervals between the primary series and third (booster) dose
Infection after third (booster) dose but before fourth (booster) dose	First Nations, Inuit and Métis and their non-Indigenous household members 18 years of age and older, and individuals 60 years and older in the general Ontario population	3 months after symptom onset or positive test (if asymptomatic) **AND** provided they meet current recommended/minimum intervals between third and fourth (booster) doses

* A previous infection with SARS-CoV-2 is defined as :

- Confirmed by molecular (e.g., PCR) or rapid antigen test; or
- Symptomatic AND a household contact of a confirmed COVID-19 case

The information on timing of vaccination post infection is provided from the Ontario Ministry of Health COVID-19 Vaccine Administration guidance document, see page 14-15; Ontario Ministry of Health : COVID-19 Vaccine Administration

Appendix B : COVID-19 Vaccine Eligibility Algorithm for Vaccinators



[1]**Counsel patients on the benefits of recommended intervals as outlined above. Patients may receive vaccine sooner with informed consent as follows: Primary Series:** may have at product interval (21 days Pfizer, 28 days Moderna). **3rd dose, 12-17 y.o., 4th dose 12-17 y.o., 4th dose 60+ y.o., 4th dose 18+ FNIM or household member of FNIM:** may have at 84 days or greater.

[2]**For the purposes of this tool, "immunocompromised" includes patients 5+ who meet any of the following criteria:** dialysis (hemo- or pertitoneal); active treatment (chemotherapy, targeted therapies, immuntherapy) for solid tumour or hematologic malignancies; recipients of solid-organ transplant AND taking immunosuppressive therapy; recipients of chimeric antigen receptor (CAR)-T-cell therapy OR hematopoietic stem cell transplant (within 2 years of transplantation OR taking immunosuppressive therapy); moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome); stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome; receiving active treament with anti-B cell therapies (monoclonal antibodies targeting CD19, CD20, and CD22), high-dose systemic corticosteroirds, alkylating agents, antimetabolites, or tumor-necrosis factory inhibitors, and other biologic agents that are significantly immunopressive.
In these populations, a third dose is considered part of the PRIMARY vaccine series, and full doses shall be used. Patients 18+ years of age in these populations who have completed a 3-dose primary series are eligible for a 4th dose BOOSTER.

[3]**Patients 6-29 may have received Moderna for previous doses; they should be counselled to receive 12+ Pfizer due to their age.** If they still desire to get 2nd, 3rd, or 4th doses of Moderna even after counselling, vaccinators should consult with their Clinic Team Lead prior to administration. The fact that counselling occurred should be noted in COVAX comments.
Acronyms: LTC=Long Term Care; Y.o.=years old; FNIM = First Nations, Inuit and Metis; Y=Yes, N=No;, Peds=Pediatric.