

Consent for immunization

Information for Health Care Providers

In Yukon, the [Care Consent Act](#) applies to people of all ages. That means anyone can consent to their own health care as long as they are capable of understanding and appreciating the consequences of that decision (s.6 (4) CCA). If a minor presents **with or without** parent/representative consent, it is **your professional responsibility as a health care provider** to assess their ability to consent and inform them about their right to provide consent on their own behalf despite the consent or refusal to consent by the parents.

As a health care provider, you determine the capability of the individual **throughout the appointment**, which includes cognitive functioning, hearing and language barriers. If at any point you feel that the client could not be deemed capable of consenting, you can pause and suggest that the parent/guardian be involved in the decision (e.g., “This can be a lot to take in. We need to have your parent/guardian involved in the decision”).

How does consent work?

Any person under the age of 19 who is capable of providing informed consent to their own health care has the authority to give, refuse, or revoke consent for their own immunizations. They can also determine who can access their immunization records.

Consent is based on capacity, not age, but adolescents do have varying levels of capability. A minor is considered capable of providing informed consent to their own health care if they demonstrate the ability to understand the benefits of vaccination, the risks of not getting a vaccine, and other standard information.

IT IS YOUR PROFESSIONAL RESPONSIBILITY TO ASSESS THEIR ABILITY TO CONSENT AND INFORM THEM ABOUT THEIR RIGHT TO PROVIDE CONSENT ON THEIR OWN BEHALF.

A CONSENT IS EFFECTIVE FOR THE LENGTH OF THE SERIES CONSENTED TO, UNLESS REVOKED.

A REFUSAL TO CONSENT IS EFFECTIVE UNTIL REVOKED.

Additional Resources

- [Yukon Immunization Manual: Section 2 – Informed Consent](#)
- [BCCDC Mature Minor Informed Consent Video](#)



How to obtain informed consent for COVID-19 vaccines for 12-17 year olds

This script is for Immunizers to follow when a minor presents at an Immunization Clinic requesting a COVID-19 vaccine without a parent/guardian. There are 7 steps to take to assess if a minor can provide informed consent to immunization:

1. **Determine authority** – Introduce yourself and determine if the client is interested in immunization.

- “Hello, my name is [name]. I am a [professional designation] and I will be giving you some information about the COVID-19 vaccine and asking you some questions. Before we begin, do you have any questions? Feel free to ask me questions at any time during our conversation.”
- “Did you discuss getting the COVID-19 vaccine with your parent or guardian? If yes, what did they say?” If no, encourage client to talk with a parent or guardian about their wishes and their decision.
- “For us to get consent to give you the COVID vaccine, I’ll need to go over a few things with you. Is that ok?”

NOTE: It is the professional’s responsibility to inform the minor of their right to provide consent on their own behalf.

2. **Determine capability** by communicating with the client in a way they can understand and that considers any barriers.

- Assess language, communication methods, hearing, cognitive abilities
- Use clinical judgement. If the minor does not appear to be able to provide informed consent, consider phoning the parent or guardian for verbal consent so the minor is not denied an immunization opportunity.

3. **Provide standard information** on the vaccine by reviewing the [COVID-19 mRNA Info Sheet](#).

- “I am going to review a few pieces of information about the COVID-19 vaccine so you are fully aware of what to expect. Feel free to ask any questions.”
- **Vaccine process**
 - “The vaccine is injected into the muscle in your upper arm and you will need a second injection in about 3 weeks to be fully protected.”
- **Vaccine protection against illness**
 - “The vaccine is 100% effective at preventing people your age from getting sick with COVID-19. It also almost completely protects you from being hospitalized or dying from COVID-19, even though that is rare for people your age.”
- **Benefits on a personal and community level**
 - “Vaccination is the best way to protect you and others. Getting vaccinated also lowers the risk of spreading COVID-19. By getting the vaccine, you are helping protect everyone around you.”
- **Eligibility**
 - “The COVID-19 vaccine is available for your age group. We recommend that you get it even if you have had COVID-19 because you may not be immune to the virus and could get



○ **Common side effects**

- “You cannot get COVID-19 from the vaccine but you may have a reaction. Common reactions include soreness, redness, swelling and itchiness where the vaccine was given. Other reactions may include tiredness, headache, fever, chills, muscle soreness, swollen lymph nodes under the armpit, nausea, and vomiting. These are mild and should only last 1 or 2 days.”

○ **Risks of not getting immunized**

- “Without getting vaccinated, you will be at risk for getting sick from the COVID-19 virus. Even if you don’t get very sick, you are also at risk of spreading it to others in who may get very sick or die.”

○ **Small but important risk of anaphylaxis**

- “Very rarely, people can have a severe allergic reaction to the vaccine. This only happens in about 1 in 100,000 people. This is why you will need to wait for 15 minutes after the vaccine – to make sure you don’t have any reactions. If you do, we can treat you right away. If you have a severe allergic reaction after leaving, call 9-1-1 right away.”

○ **Screen for contraindications**

- “Do you have any allergies?”

4. **Confirm understanding** of standard information

- Assess non-verbal cues
- Clarify reasons for silence or refusal to engage in discussion if present
- Ask questions to confirm understanding if uncertain
- “Before we go ahead, I need to make sure you understand what we discussed. Is that ok?”
Ask questions such as:
 - What are some common side effects to the COVID-19 vaccine?
 - What are some benefits to the COVID-19 vaccine?
 - Why do we have people wait for 15 minutes after vaccination?
 - How many doses of the COVID-19 vaccine are required?

5. **Provide opportunity to ask questions**

- Ask, “Do you have any questions?”

6. **Confirm consent**

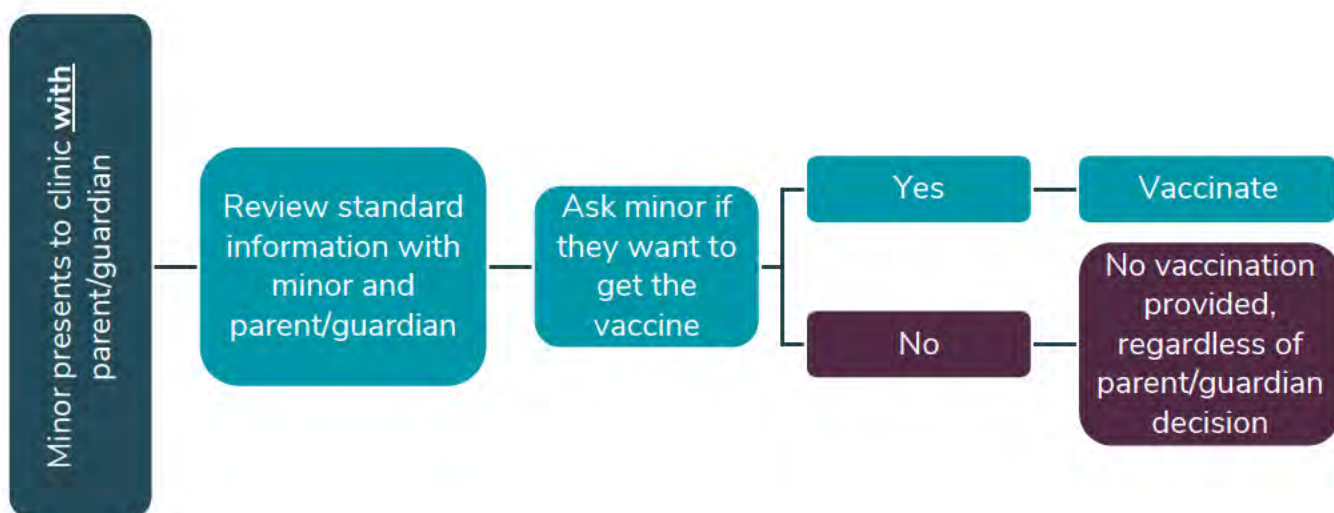
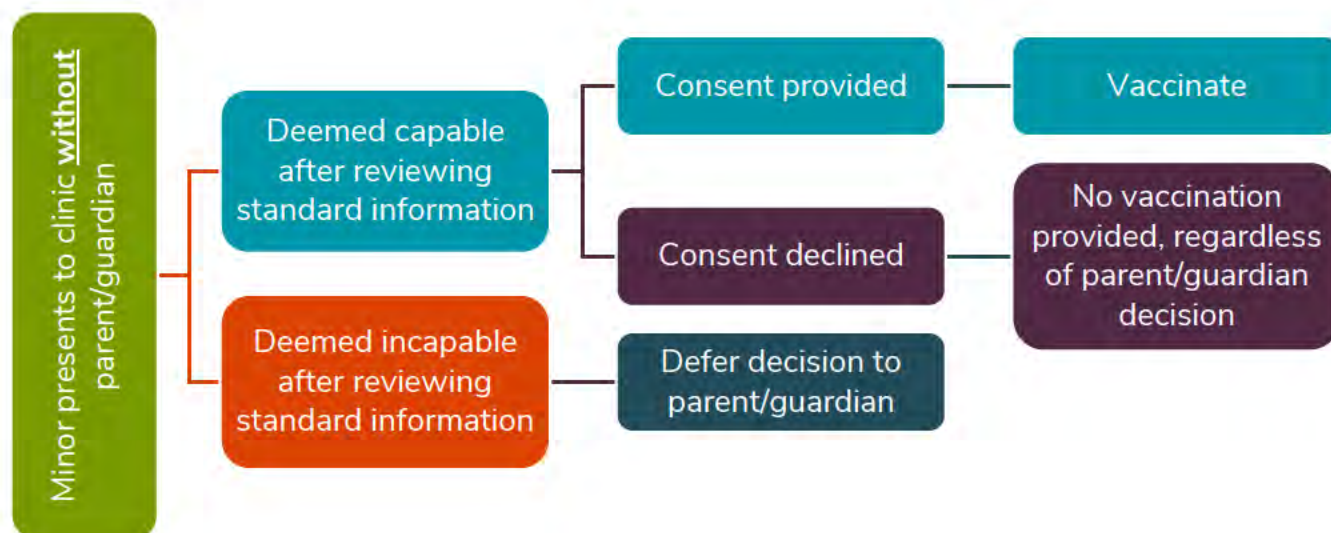
- Ask, “Are you ready to get your vaccine?”

7. **Document** consent or refusal in Panorama.

- When a minor consents to immunization, document this in the comments box in Panorama when you **record consent**
 - Clearly identify if consent was given by the minor and include a statement of the assessment of capacity (e.g., “The client is able to appreciate and understand the consequences of their decision”).



APPENDIX A: MINOR CAPABILITY ASSESSMENT GENERAL PROCESS FLOW



APPENDIX B: CHECKLIST FOR OBTAINING MINOR CONSENT FOR VACCINATION

In Yukon, the [Care Consent Act](#) applies to people of all ages. That means anyone can consent to their own health care as long as they are capable of understanding and appreciating the consequences of that decision (s.6 (4) CCA). If a minor presents with or without parent/representative consent, it is **your professional responsibility as a health care provider** to assess their ability to consent and inform them about their right to provide consent on their own behalf despite the consent or refusal to consent by the parents.

<input checked="" type="checkbox"/>	DETERMINE AUTHORITY	<input checked="" type="checkbox"/> Determine authority – Introduce yourself and determine if the client is interested in immunization.
<input checked="" type="checkbox"/>	ASSESS CAPABILITY	<input checked="" type="checkbox"/> Assess: language, communication methods, hearing, cognitive abilities <input checked="" type="checkbox"/> Use clinical judgement <ul style="list-style-type: none"> • If child does not appear to be able to provide informed minor consent, consider phoning parent/guardian for verbal consent so child is not denied an immunization opportunity
<input checked="" type="checkbox"/>	PROVIDE STANDARD INFORMATION	<input checked="" type="checkbox"/> Consent is obtained for a vaccine series <input checked="" type="checkbox"/> Provide time for review of COVID-19 mRNA vaccine information sheet <ul style="list-style-type: none"> • Review: <ul style="list-style-type: none"> ○ Vaccine protects against COVID-19 illness ○ Benefits, personal and community ○ Risk if unvaccinated ○ Common side effects ○ Small but important risk of anaphylaxis ○ Screen for contraindications (anaphylaxis to previous dose of COVID-19 vaccine or any components in vaccine)
<input checked="" type="checkbox"/>	CONFIRM UNDERSTANDING	<input checked="" type="checkbox"/> Assess non-verbal cues <input checked="" type="checkbox"/> Clarify reasons for silence or refusal to engage in discussion if present <input checked="" type="checkbox"/> Ask questions to confirm understanding if uncertain
<input checked="" type="checkbox"/>	PROVIDE OPPORTUNITY TO ASK QUESTIONS	<input checked="" type="checkbox"/> Ask “do you have any questions?”
<input checked="" type="checkbox"/>	CONFIRM CONSENT	<input checked="" type="checkbox"/> Ask, “are you ready to proceed?”
<input checked="" type="checkbox"/>	DOCUMENT CONSENT	<input checked="" type="checkbox"/> Document consent or refusal in Panorama. <ul style="list-style-type: none"> ○ If minor consents to immunization, document this in the comments box in Panorama when you record consent ○ Clearly identify if consent was given by the minor and include a statement on the assessment of capacity





COVID-19 Vaccine FAQ's for Health Care Providers

November 2021



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Background

Updated as of November 9, 2021

This FAQ document includes information on COVID-19 vaccines and answers common questions about the vaccines that are currently in use in Yukon.

These FAQs are for your own information, but more importantly are designed to help you counsel patients appropriately about vaccines, to address vaccine hesitancy, to ensure that patients have their questions answered, and to inform their consent to receiving the vaccine.

The most trusted source of vaccine information is a patient's health care provider.

COVID-19 vaccine information is evolving, and as such, this FAQ document will be updated as new information becomes available.

COVID-19 disease

1. What is the epidemiology of COVID-19?

For the most up-to-date data on COVID-19 cases, go to:

- Global: <https://health-infobase.canada.ca/covid-19/international/>
- National: <https://health-infobase.canada.ca/covid-19/>
- Yukon: <https://yukon.ca/en/health-and-wellness/covid-19-information/case-counts-covid-19>

2. Why is COVID-19 vaccination important?

Preventative measures such as physical distancing, frequent handwashing, and wearing a mask help to reduce the risk of exposure and transmission of SARS-CoV-2, but these measures alone are not enough. The combination of COVID-19 vaccination and following [prevention measures](#) will provide the best protection against COVID-19.

Ending this pandemic requires all the tools we have available including, most importantly, vaccination. Safe and effective vaccines will reduce the transmission of the virus that causes COVID-19 and associated illnesses and deaths. Over time, widespread immunization will allow Yukoners to live with fewer restrictions.

COVID-19 vaccination protects the person being vaccinated and also the people around them, including those unable to be vaccinated. The level of COVID-19 vaccination coverage required to reach herd immunity will vary based on vaccine effectiveness. For an R_0 of 2.5 to 3.5 (the average number of people who become directly infected by someone with COVID-19), approximately 60-72% of the population would need to be immunized to block the continued transmission of SARS-CoV-2.

3. How do I know if someone has an expected vaccine response or if they should be tested for COVID-19?

While some of the side effects of the vaccine are similar to symptoms of COVID-19 infection, it is important not to assume that symptoms are due to the vaccine. For example, cough or other respiratory symptoms are not side effects of the vaccine and are more likely to be due to a respiratory infection like COVID-19. Symptoms that are multiple and last longer than a few days also could be due to COVID-19. The routine [testing recommendations](#) for COVID-19 (July 15, 2020) should be applied in the immediate post-immunization period and to people who are fully immunized against COVID-19.

It is particularly important to test people who present with any of the following symptoms regardless of COVID-19 immunization history: cough, fever/chills, shortness of breath, difficulty breathing, or loss of taste or smell. Regardless of vaccination status, there should be a low threshold for testing anyone who is a contact of a COVID-19 case or returned from out-of-Yukon travel in the 14 days prior, and testing is recommended as soon as possible.

Vaccine development and safety

4. What is NACI (National Advisory Committee on Immunization)?

The National Advisory Committee on Immunization (NACI) is a national advisory committee of experts in the fields of pediatrics, infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmaco-economics, social science and public

health. NACI has been providing guidance on the use of vaccines currently or newly approved for use in Canada to the Government of Canada since 1964. The Committee reports to the Vice-President of the Infectious Disease Prevention and Control Branch, and works with staff of the Centre for Immunization and Respiratory Infectious Diseases of the Public Health Agency of Canada to provide ongoing and timely medical, scientific and public health advice.

NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted. NACI knowledge syntheses, analyses and recommendations on vaccine use in Canada are included in published literature reviews, statements and updates.

5. [How do we know that the COVID-19 vaccines are safe and effective if they were developed so quickly?](#)

The efforts to find a vaccine for COVID-19 have been on a scale that has never been seen before. With so many resources put towards it, these vaccines were developed in record time. Factors that allowed the COVID-19 vaccine to progress quickly include advances in vaccine technology, government funding and purchase commitments, international collaboration to develop the vaccine, rapid recruitment of participants for clinical trials, and streamlined vaccine approval processes by the national drug regulatory organizations, including Health Canada. While the need to deliver the vaccine quickly was important, no steps in Canada's rigorous approval process were missed. Instead, with more resources came faster results

As with all vaccines and treatments, Health Canada reviews all evidence and scientific data before deciding whether to authorize a product for use in Canada. They will only authorize the vaccine when the evidence shows that:

- The vaccine is safe, effective and of good quality; and,
- The benefits outweigh the known and potential risks.

For example, Health Canada's approval of the Pfizer-BioNTech vaccine was based on ensuring that the vaccine itself, laboratory studies and three phases of double-blinded randomized clinical trials showed safety, immunogenicity (ability to generate an immune response) and efficacy (ability to prevent COVID-19 disease) in animals, and in adolescents and adults 16 years of age and older. Approximately 44,000 individuals randomized (1:1) to receive either the vaccine or placebo participated in phases 2 and 3 of the clinical trials. This population has been considered sufficient to approve vaccines based on safety and efficacy.

Health Canada also has processes in place that allow for sharing of information with other countries' regulatory bodies including the US Food and Drug Administration and the European Medicines Agency.

Once approved, vaccine safety and effectiveness are continuously monitored to detect rare, serious, or unexpected side effects.

6. [What is the approval process for COVID-19 vaccines in Canada?](#)

The Biologic and Radiopharmaceutical Drugs Directorate (BRDD) is part of Health Canada and supervises all pieces of vaccine production and quality control. When the manufacturer collects enough scientific and clinical evidence of the safety, efficacy, and quality of a vaccine, they file a complete package of information and submit it to BRDD for market authorization. The submission includes data from scientific studies and information about the manufacturing process, including the facility and method. BRDD then reviews the submission to determine if the benefits of a vaccine outweigh any potential risks. BRDD also reviews the procedures for safety monitoring by the manufacturer and any plans to minimize identified risks. BRDD may also visit the manufacturing site to evaluate the process' quality and make sure the manufacturer is completing the necessary quality controls for the vaccine.

The review process was able to be expedited for COVID-19 vaccines because of administrative changes to the process, including the allowance of submission of data when available rather than waiting until the entire data package is complete prior to

submission. In addition, Canada and many countries have allowed for a shorter period of follow-up of people enrolled in the phase 3 clinical trials. Clinical trials will continue to accrue cases and safety information for up to two years following immunization and the results of these studies will provide additional information about issues such as duration of protection. For non-pandemic vaccines, the follow-up period is typically over one year.

More Health Canada information can be found at: [Vaccines and Treatments for COVID-19: Progress](#) and [Interim order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#).

7. How do we reassure the public that COVID-19 vaccines are safe and effective?

In order to have an effective conversation about COVID-19 vaccines, the conversation must come from a place of compassion and understanding. As mentioned earlier, the most trusted source of vaccine information is a patient's health care provider. Be transparent about the latest information, reassure that there is a robust vaccine safety system in Canada, and emphasize the role vaccines play in the protection of the recipient and people around them. Your willingness to listen to the patients' concerns will be critical in developing trust in you and your recommendations. If the patient has concerns or questions, this doesn't always mean they won't accept a COVID-19 vaccine. Sometimes patients simply want your answers to their questions. Once you've responded to their questions, ensure them that you are open to continuing the conversation. Direct them towards trusted sources of information, like the [federal](#) or [Yukon](#) government websites. Continue the conversation about COVID-19 vaccination during future visits.

8. How will the safety of the COVID-19 vaccines be monitored in Canada?

Local, territorial/provincial, and national surveillance systems are used to carefully monitor any adverse events following immunization and detect any vaccine safety concerns. Once a vaccine is approved, its safety is continuously monitored as long as it is being used. In most places, health care providers are legally obliged to report all

serious and unexpected adverse events following immunization to the medical health officer. Every serious or concerning event is then reported to Yukon Immunization Program. These reports are reviewed at Yukon Immunization Program and also sent to the Public Health Agency of Canada system called the Canadian Adverse Events Following Immunization System (CAEFISS), as are reports from all provinces and territories. Additional monitoring for adverse events is being done through a system called CANVAS (Canadian National Vaccine Safety Network) through which recipients of the vaccine can enroll to self-report adverse events following receipt of the vaccine.

At the international level, the World Health Organization's International Drug Monitoring Program collects reports from over 75 countries and uses these data to monitor for any vaccine safety concerns. In addition, all vaccine manufacturers are required to report serious adverse events of which they become aware, in Canada or internationally, to Health Canada. For COVID-19 vaccines, manufacturers are expected to implement enhanced monitoring.

More information about Canada's vaccine safety surveillance system can be found in the [Canadian Immunization Guide: Vaccine safety and pharmacovigilance](#).

9. How do health care providers report an adverse event following COVID-19 immunization?

Vaccine providers should refer to the [Yukon Immunization Manual – Section 13 – Adverse Events Following Immunization](#) for criteria on reporting adverse events following immunization (AEFI), and report AEFIs by entering them into Panorama. If the provider does not have access to Panorama then notify the Yukon Immunization Program by fax to 867-393-4357.

10. What is VITT (Vaccine-Induced Immune Thrombotic Thrombocytopenia)? Are there any concerns about safety issues with the COVID-19 vaccines?

There have been no confirmed cases of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) with the Pfizer-BioNTech or Moderna COVID-19 vaccines.