



IMMUNIZATION COMMUNICATION TOOL 2021

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immunization has saved
more lives than any other
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BC Centre for Disease Control
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We gratefully acknowledge that the BC Centre for Disease Control main office is located on the unceded, ancestral, and occupied traditional lands of the xʷməθkʷəy̕əm (Musqueam), Səl̓ílwətaʔ (Tsleil-Waututh), and Skwxwú7mesh (Squamish) Nations.

The Immunization Communication Tool (ICT) for health care providers is a project of the Professional Education Working Group, a subcommittee of the British Columbia Immunization Committee. The first Immunization Communication Tool was created in 2008 and updated in 2014.

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Introduction

The Immunization Communication Tool (ICT) is a project of the Professional Education Working Group, a subcommittee of the British Columbia Immunization Committee, and the British Columbia Centre for Disease Control (BCCDC) Communicable Diseases and Immunization Service team.

The purpose of the ICT is to support health care providers with the information and tools needed to communicate effectively about vaccines and address vaccine hesitancy.

The ICT was first created in 2008 and updated in 2014. This 2021 edition of the tool has a new format and new content. When revising the tool, special consideration was given to the most recent literature recommendations for addressing vaccine hesitancy.

Section 1: Vaccine hesitancy

- This section provides information on the vaccine acceptance continuum and a new framework for discussing vaccines and addressing vaccine hesitancy.

Section 2: Answering common questions about vaccines and immunization

- This section has key messages for the public, additional information for health care providers, graphics, and motivational interviewing examples.

Appendices

- This section provides additional information on motivational interviewing, resources with immunization stories, and information on reducing immunization injection pain.

An online version of the 2021 Immunization Communication Tool is available on the BCCDC website.

Section 1: Vaccine hesitancy

What is vaccine hesitancy?

The Strategic Advisory Group of Experts (SAGE) at the World Health Organization (WHO) defines vaccine hesitancy as a “delay in acceptance or refusal of vaccination despite the availability of vaccination services.” They further define vaccine hesitancy as being “complex and context specific, varying across time, place and vaccines” and “influenced by factors such as complacency, convenience and confidence.”¹

Most (an estimated >90%) of Canadian parents ensure their children receive all routine vaccines.² However, health care providers will encounter vaccine-hesitant individuals as well as those that refuse vaccines altogether. A recent Canadian study showed 19% of parents consider themselves vaccine-hesitant and 3% refuse all vaccines for their children.³

Vaccine behaviors and beliefs can be seen as falling along a continuum ranging from full acceptance to outright refusal of all vaccines, with vaccine-hesitant individuals being the group in the middle. These individuals may accept some vaccines but refuse others, delay vaccines, or accept or refuse all vaccines but be unsure in doing so.¹

Vaccine hesitancy continuum

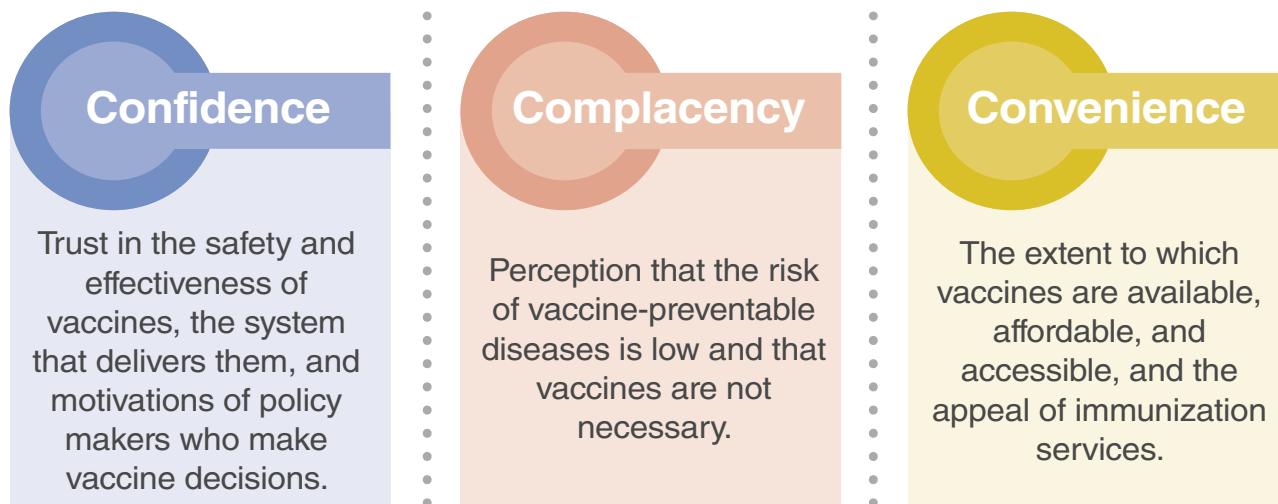


Source: Strategic Advisory Group of Experts on Immunization. World Health Organization. Report of the SAGE Working Group on Vaccine Hesitancy. Geneva, Switz: World Health Organization; 2014.

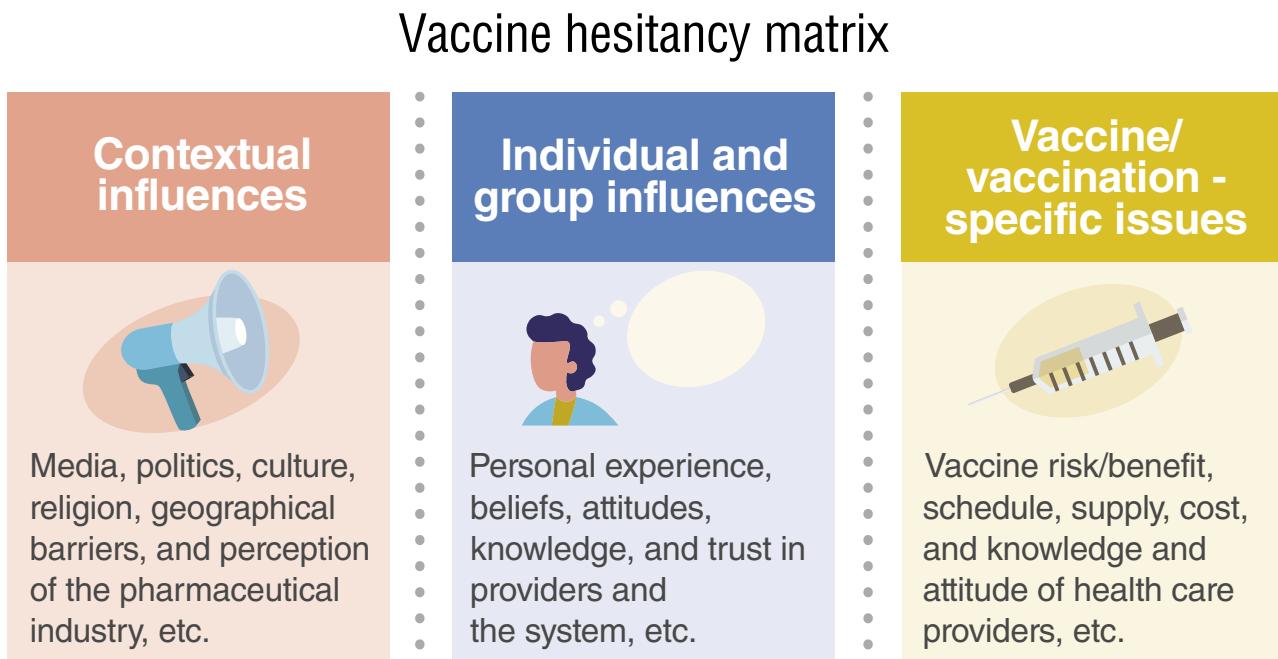
What are the causes of vaccine hesitancy?

Vaccine hesitancy is complex, with no single cause and many factors at play. To help capture and categorize the causes of vaccine hesitancy, the SAGE working group chose two models: an easy-to-grasp model that outlines the three key factors associated with vaccine hesitancy—complacency, convenience, and confidence (the 3Cs)—and a more comprehensive vaccine hesitancy matrix that better captures the complexity of the contextual influences, individual and group influences, and vaccine-specific issues.¹

The 3Cs model



Source: Strategic Advisory Group of Experts on Immunization. World Health Organization. Report of the SAGE Working Group on Vaccine Hesitancy. Geneva, Switz: World Health Organization; 2014.



Source: Strategic Advisory Group of Experts on Immunization. World Health Organization. Report of the SAGE Working Group on Vaccine Hesitancy. Geneva, Switz: World Health Organization; 2014.

Evidence-based strategies for addressing vaccine hesitancy

Vaccine hesitancy is complex, and there is no single best strategy that can address it in all situations.¹ There are, however, many evidence-based strategies for addressing vaccine hesitancy that have been recommended in the current literature. A number of these strategies are highlighted below.

Understand that health care providers play a key role in a person's decision to vaccinate

The strength of a health care provider's recommendation can greatly influence a person's decision to vaccinate their child or get vaccinated themselves.^{4 5 6} Studies have shown that while Canadian parents often consult friends, family, and the internet for information on vaccines, they consider health care providers to be their most trusted source for this information.³ Further, parents who planned to delay or refuse vaccines frequently cite accurate information and reassurance provided by their health care provider as the main reasons they changed their minds.^{4 7}

Build trust

Trust in a health care provider is key in supporting vaccine acceptance.⁸ Culturally safe care is essential to building trust and every immunization encounter should be approached with this as a foundation. Cultural safety results in an environment free of racism and discrimination, where people feel safe.⁹ Achieving a culturally safe care outcome involves the health care provider being able to practice cultural humility and self-reflection and embrace continuous learning.¹⁰ More



information and resources on [culturally safe care](#) can be found on the BC Centre for Disease Control website. To further build and maintain trust, health care providers need to be confident in their knowledge regarding vaccines and be able to deliver vaccine information in a caring and compassionate manner.¹¹

Start early

Prenatal visits are a great time to start having discussions about vaccines. Evidence shows that parents who delayed or refused vaccines were more likely to start thinking about vaccines before the birth of their child.¹² Further, a randomized controlled trial showed that parents who received prenatal education about vaccines were more likely to follow the routine childhood immunization schedule.¹³

Use a presumptive statement

Using a presumptive statement (for example, “Henry is due for his 4-month vaccines. We will give them to him before you leave today.”) has been found to be more effective in increasing vaccine uptake than using a participatory ask (for example, “How do you feel about Henry getting his 4-month vaccines today?”).¹⁴ When using a presumptive statement, concerns must still be addressed in a non-judgmental, compassionate, and caring manner.¹¹

Use motivational interviewing techniques to understand a person’s vaccine concerns

Motivational interviewing (MI) is a “collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person’s own reasons for change within an atmosphere of acceptance and compassion.”¹⁵

MI has been shown to be effective in addressing vaccine hesitancy.^{16 17} A recent Canadian randomized controlled trial showed that vaccine discussions using MI on maternity wards increased the intention to vaccinate by 20%.¹⁸

MI is complex and it is recognized that many health care providers will not have received formal MI training. It is also recognized that a full MI approach (which can take multiple hours or visits) may not be feasible in the context of a routine immunization appointment. In these cases, a “mini” MI approach is encouraged. Mini MI involves using all the components of MI, but not to the same depth or level of detail as would be used in a full MI approach. Examples of MI are included throughout this tool. Refer to appendix A for more information on MI and vaccine hesitancy.

Keep messages short and simple

Research has shown that for parents who are already vaccine hesitant, messaging that too strongly advocates vaccination can be counterproductive¹⁹ and providing too much information can actually increase hesitancy.²⁰

Present both the risks and benefits of vaccines fairly and accurately

Studies in other countries have found presenting both the benefits and risks of vaccines to be a promising approach for increasing vaccine acceptance.^{21 22} Describe the benefits and risks in an understandable way using simple vocabulary and avoiding medical jargon.

How you frame your message is key.^{23 24} Frame data clearly and positively. For example, saying a vaccine is “99% safe” is more effective than saying “only 1% of people experience side effects.”¹¹ It can also be helpful to emphasize that many diseases can have serious complications that cannot be corrected.¹¹ If vaccine safety is a concern, it can be helpful to discuss the high standards of Canada’s vaccine safety system.²⁵ Refer to the “Vaccine testing, approval, and monitoring” section of this tool for more information on Canada’s vaccine safety system.

Address pain head-on

Studies have shown that fear of needles or pain related to immunization can cause people to be vaccine-hesitant or to refuse vaccines altogether.²⁶ Research has shown that parents are more comfortable with their baby’s vaccinations when pain is controlled.²⁷ It’s important to address pain head-on and provide evidence-based strategies for reducing immunization injection pain. Refer to appendix C for more information on reducing immunization injection pain.

Focus on the protection of the child and the community

Remind parents that choosing not to vaccinate puts their child at risk and others too, including those most vulnerable. Be sure to emphasize the importance of protecting each other. Stories from parents of children who cannot be immunized (for example, children with cancer) can be powerful and can help parents connect to the importance of vaccination.¹¹

Remind parents that community immunity does not guarantee personal protection

Remind parents that for protection from community immunity (herd immunity) to work, vaccination levels for some diseases need to be very high—much higher than they are in some communities. For example, measles requires an immunization rate of at least 95% to achieve community immunity.²⁸ Also, remind parents that protection through community immunity does not exist for some diseases (for example, tetanus).

Use visual aids

About 60% of adults in Canada are unable to obtain, understand, and act upon health information and services to make appropriate health decisions on their own.²⁹ Visual aids such as images, infographics, and graphs can help people (especially those with low numeracy skills) understand complex information. Examples of visual aids are included throughout this tool.

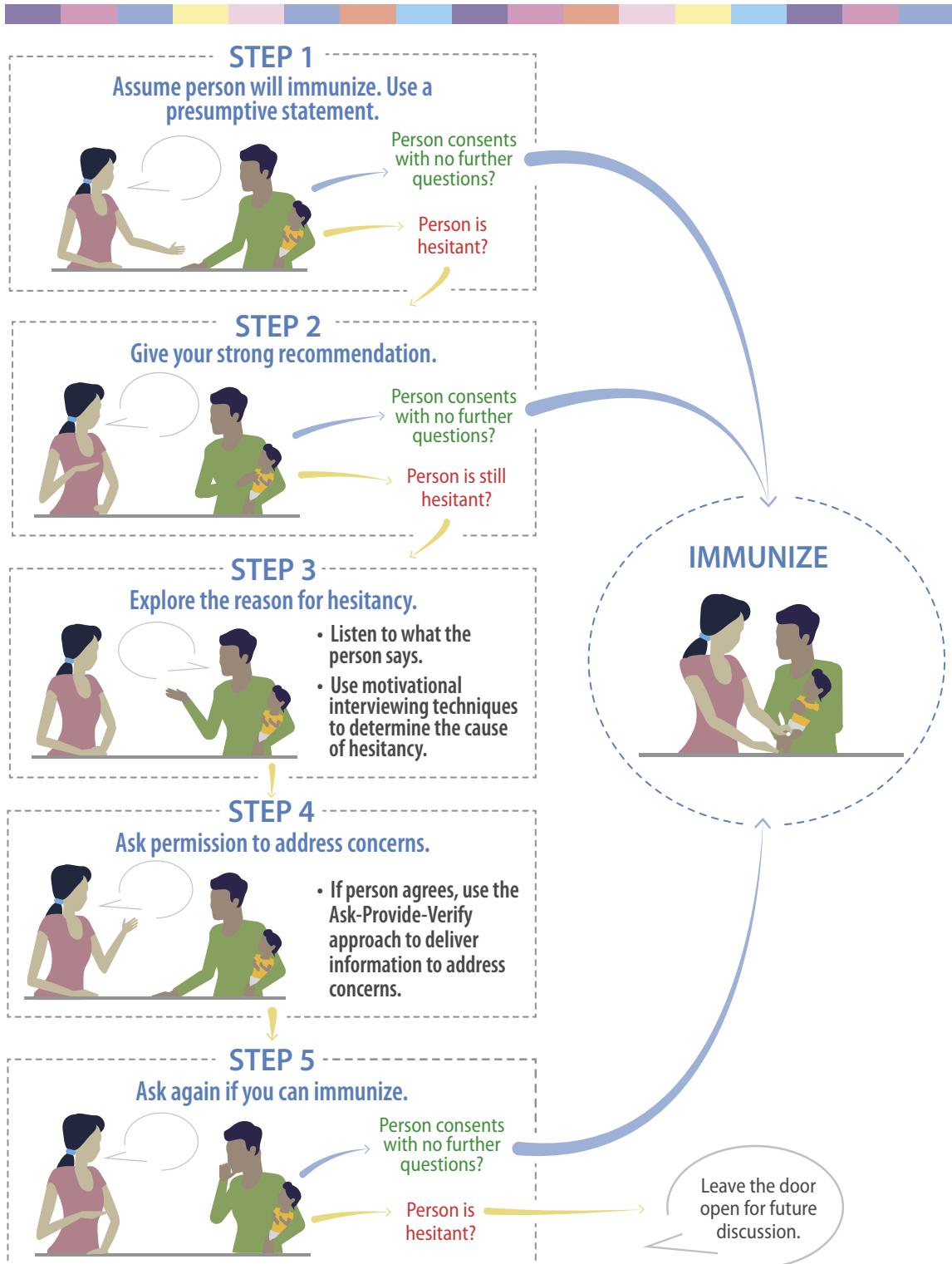
Tell stories

As a health care provider, sharing your story about why you chose to vaccinate or sharing a story about a vaccine-preventable disease strengthens your vaccine recommendation. Many people will not remember statistics, but they will remember a compelling story about the devastating effects of a vaccine-preventable disease. Stories help personalize information and make it more relevant.^{30 31} If you don't have stories of your own, refer to appendix B for a list of websites where you can find real stories from other health care providers and members of the public.

Summary

In summary, working with vaccine-hesitant individuals takes knowledge, skill, and practice. The evidence-based strategies discussed above can help guide and support you. Further, using a consistent and structured approach when discussing vaccines is recommended. On the following page, you will find a recommended 5-step approach to discussing vaccines and addressing vaccine hesitancy. This approach has been adapted from the “Moving to Acceptance: How to address vaccine hesitancy in your busy practice” course with permission from the Canadian Paediatric Society.

A 5-step approach to discussing vaccines and addressing vaccine hesitancy



A 5-step approach to discussing vaccines and addressing vaccine hesitancy

continued

Step 1 - Assume the person will immunize. Use a presumptive statement.

A presumptive statement has been found to be more effective in increasing vaccine uptake than a participatory ask.¹⁴

Example of a presumptive statement:

- *"Your son is due for his 4-month vaccines. We will give him these vaccines before you leave today."*

Example of a participatory ask:

- *"What would you like to do about your son's 4-month vaccines?"*

Presumptive statement = more effective

Participatory ask = less effective

If the person consents with no further questions, immunize. It's important not to plant a reason for hesitancy in someone who already supports vaccines. If the person is hesitant or unsure, move to Step 2.

Step 2 - Give your strong recommendation.

Studies show that parents consistently rank health care providers as their most trusted source of vaccine information and that the strength of the recommendation from the health care provider can influence a person's decision to vaccinate. Your strong recommendation is crucial for vaccine acceptance. Clearly state your recommendation and, if appropriate,^{3 4 5 6} add supporting statements.

Example:

- *"I strongly recommend your child gets these vaccines today. These vaccines are very important to protect your child against serious diseases."*

If the person consents with no further questions, immunize. If the person is hesitant or unsure, move to Step 3.

Step 3 - Explore the reason for hesitancy.

Listen to what the person says and use motivational interviewing (MI) techniques to understand their concerns. MI is a collaborative, goal-oriented style of communication with particular attention to the language of change. Its aim is to strengthen a person's own motivation and commitment to their goals by eliciting

and exploring their own reasons for change within an atmosphere of acceptance and compassion.¹⁵

OARS (open-ended questions, affirmations, reflections, and summaries) is one of the foundational skills used in MI. Examples using OARS to understand a person's specific vaccine concerns are included throughout this tool.

Refer to appendix A for more information on MI and the use of "mini" MI in the context of an immunization appointment.

Step 4 - Ask permission to address concerns.

After listening to the person's concerns, ask permission to address their concerns. If the person agrees, it is important to properly deliver information to address their concerns. One way to do this is to use the Ask-Provide-Verify approach. In this approach, the health care provider will ask the person what they know about the specific reason for hesitancy, provide information to address the issue, and then verify that the information has been understood. After providing information and verifying understanding, it can be helpful to summarize key messages.

Examples using the Ask-Provide-Verify approach when delivering information to address a person's concerns are included throughout this tool.

Step 5 - Ask again if you can immunize.

Ask the person again if you can immunize.

Example:

- *"I hope I was able to address your concerns regarding the safety of vaccines. I really want to ensure your daughter is protected against these diseases. Can I provide the immunizations now?"*

If the person consents, it is important to immunize at the same visit. If they are still hesitant, it is important to leave the door open for future discussion.

Example:

- *"I know you have your child's best interests at heart. If you ever want to discuss this further, please call me."*

Adapted from "Moving to Acceptance: How to address vaccine hesitancy in your busy practice" with permission from the Canadian Paediatric Society.

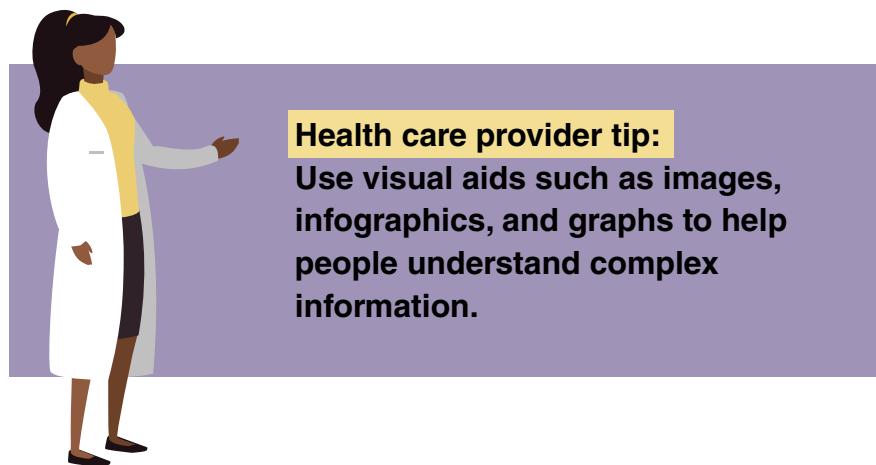
Section 2: Answering common questions about vaccines and immunization

When health care providers use a presumptive statement and give their strong recommendation, many people will consent to vaccination. However, some people will be hesitant and will have questions about vaccines. It's important that health care providers can confidently answer their questions.

This section contains information to assist health care providers in answering some of the most common questions about vaccines. Included for the different question topics are:

- **Key messages for the public** that are written in plain language.
- **More information for health care providers** that can be used when responding to complex questions or for the provider's own learning.
- **Graphics** that providers can use to help explain more complex information.
- **Motivational Interviewing (MI) examples** that use MI skills: open-ended questions, affirmations, reflections, and summaries (OARS), and Ask-Provide-Verify. Refer to Appendix A for more information on MI.
- **Health care provider tips** for addressing vaccine hesitancy.

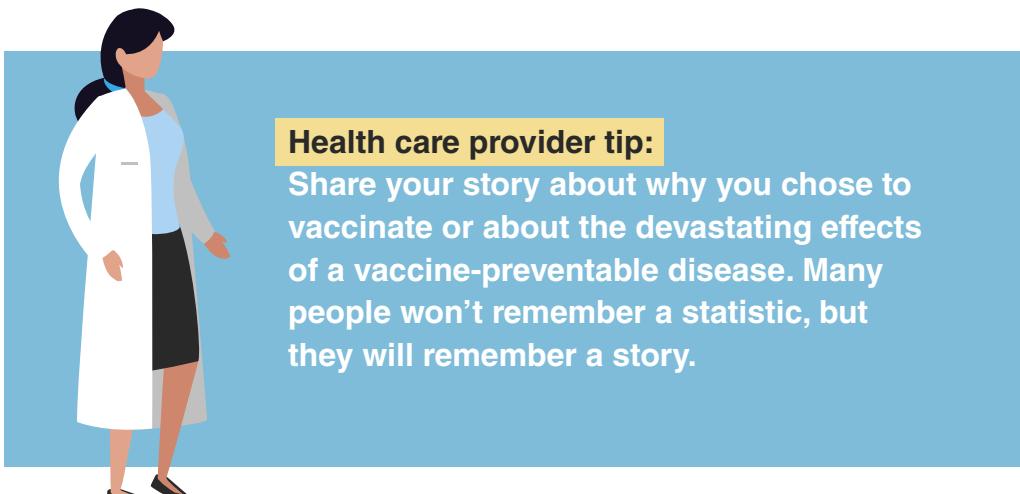
The information in this section is to be used within the “5-Step Approach to Discussing Vaccines and Addressing Vaccine Hesitancy,” particularly Step 4, when delivering information to address vaccine concerns.



1. Why we need vaccines and if vaccines work

Key messages for the public

- Vaccines work. They are the most effective way to protect against vaccine-preventable diseases.³²
- Vaccines prevent diseases that can cause serious illness, long-term disability, and death.
- The World Health Organization estimates that every year, vaccines prevent more than two million deaths worldwide.³³
- Before vaccines, many Canadians died or suffered complications from diseases that we can now prevent.³²
- Thanks to vaccines, many vaccine-preventable diseases are now rare in Canada. However, the viruses and bacteria that cause these diseases still exist. If vaccination rates drop, these diseases will come back. We have seen this happen in other countries, resulting in many preventable hospitalizations and deaths.
- Many other serious vaccine-preventable diseases (such as diphtheria and measles) are still common in other parts of the world and can be imported to Canada through international travel. Until these diseases are eliminated worldwide, we need to keep vaccinating against them.
- When your child gets vaccinated, it doesn't just protect them; it also helps to protect your whole community, including those who can't get vaccinated. This type of protection is called community immunity (also known as herd immunity).³²
- Vaccines help prevent antibiotic use and antibiotic resistance.³⁴



Vaccines Work: Decrease in disease following vaccine introduction

	Cases before	Decrease in cases	Cases after
Diphtheria	8,142	>99%	3
Measles	53,584	>99%	151
Mumps	36,101	98%	565
Pertussis	17,777	84%	2,769
Polio	2,545	100%	0
Rubella	14,974	>99%	1

Cases before: Average number of disease cases reported yearly in Canada during the five years before routine vaccine use, or the closest possible five years where stable reporting was occurring.

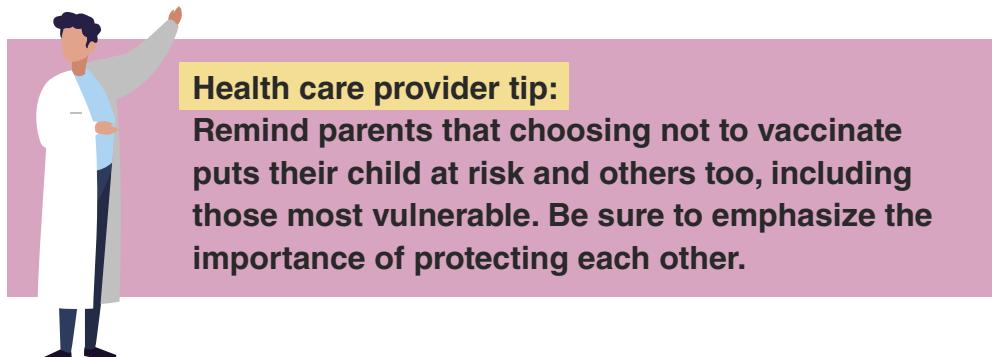
Cases after: Average number of disease cases reported yearly in Canada from 2013 to 2017.

Source: Canada.ca [Internet]. Ottawa (ON): Public Health Agency of Canada. Large data extract – Notifiable diseases on-line; 2021 Jan 14 [cited 2021 Mar 4]. Available from: <https://diseases.canada.ca/notifiable/charts?c=ppd>

More information for health care providers

Vaccines prevent serious diseases and save lives

- Vaccines prevent diseases that can cause serious illness, long-term health problems, and death. For example:
 - Chickenpox (varicella) infection can cause pneumonia.
 - Polio infection can cause permanent paralysis.
 - Measles infection can cause encephalitis (swelling of the brain).
 - Mumps infection can cause deafness.
 - *Haemophilus influenzae* type b (Hib) infection can cause brain damage and death.
- Before vaccines were available, many Canadians suffered or died from diseases like polio, diphtheria, and Hib, all of which we can now prevent.³⁶ For example:
 - In the early 1900s, before the polio vaccine was introduced, thousands of Canadians were paralyzed or died from polio. Thanks to vaccination, we have been polio free for the last 20 years.³⁷
 - Before the introduction of the *Haemophilus influenzae* type b (Hib) vaccine in 1988, Hib was the most common cause of bacterial meningitis (a serious and life-threatening infection) among children younger than five years of age in Canada. Every year about 1500 cases of Hib meningitis occurred in Canada in children under the age of five. Since the vaccine, Hib infections have almost disappeared in Canada.³⁸
- Vaccines have improved the lives of every Canadian. Some examples:
 - Before the tetanus vaccine was available, the fear of tetanus (lockjaw) hovered over every cut and puncture wound. Older adults will easily recall the vigor with which every childhood scrape was disinfected to protect against lockjaw. Today, cases of tetanus in Canada are extremely rare, occurring only in unvaccinated people.
 - At the height of the polio epidemic in the 1950s, families and friends spent their summers in fear of paralytic polio.



Health care provider tip:
Remind parents that choosing not to vaccinate puts their child at risk and others too, including those most vulnerable. Be sure to emphasize the importance of protecting each other.

- While vaccines are highly effective in preventing disease, no vaccine is 100% effective.
- Most routine childhood vaccines are effective for 85% to 95% of recipients.³⁹
- For reasons related to both the individual (e.g., age and health status) and the vaccine (e.g., type of vaccine and the duration of immunity provided by that vaccine), not all people will be fully protected after vaccination.³⁷
- Because no vaccine is 100% effective, a small percentage of vaccinated people may get sick when disease is spreading in their community. However, a much larger percentage of unvaccinated people would generally get sick.³² An example:
 - In 2011, Canada experienced a large measles outbreak with more than 700 cases, largely in Quebec. Where immunization status was known, approximately 80% of people who contracted measles were not adequately immunized for their age.⁵⁷
 - In rare cases when those who have developed only partial immunity after vaccination are infected with the disease, vaccination helps prevent severe illness and serious outcomes, including death.⁴⁰
 - High vaccination coverage in a population helps protect those who develop only partial immunity (refer to information on community immunity below).

When vaccination rates drop, outbreaks and epidemics occur

- Many of the diseases that vaccines prevent are now rarely seen in Canada, mostly because of vaccine programs. But the viruses and bacteria that cause these diseases are still present in Canada or other countries, and we still see some of these diseases such as pertussis (whooping cough) and mumps in small numbers in Canada.
- Many other serious vaccine-preventable diseases (like measles, diphtheria, and polio) are still common in other parts of the world and can be imported to Canada through international travel.
- These diseases can spread quickly if vaccination rates drop, resulting in outbreaks and epidemics of disease and lives lost. We have seen this happen in other countries. For example:
 - In the 1970s, anti-vaccination groups spurred the cessation of pertussis vaccine programs in eight countries. As a result, pertussis rates in these countries rose ten to a hundred times higher than neighbouring countries that did not cease their vaccine programs.⁴¹ The UK saw 10,000 cases of pertussis and 36 deaths in 1978.⁴² Japan saw 13,000 cases of pertussis and 113 deaths between 1976–1979.⁴³
 - During the 1990s, over 140,000 cases of diphtheria and 4,000 deaths were reported in the Commonwealth of Independent States (former Soviet Union) following a decline in immunization rates.³²
 - Because of low immunization coverage in certain countries, or in pockets of countries, multiple regions worldwide experienced large measles outbreaks in 2018, causing many

deaths.⁴⁴ For example, in a December article, WHO addressed the global resurgence of measles, stating failure to vaccinate people as the root cause of the outbreaks. In 2018, measles cases rose to a near ten-year peak with close to 10 million cases and over 140,000 deaths globally.⁴⁵

- Measles outbreaks have also occurred in BC. Some examples of notable outbreaks include:
 - The 2010 outbreak during the Winter Olympic Games in Vancouver, caused by measles importations by visitors. Of the 80 cases, 75% were either unimmunized or had an unknown immunization history.⁴⁶
 - The 2014 outbreak in the Fraser Valley, presumed to be caused by an unvaccinated person contracting measles while travelling to the Netherlands (where an outbreak was occurring) and returning home infected. A total of 343 cases were reported in this outbreak, with almost all cases occurring within a community known to refuse vaccination.⁴⁷
 - The 2019 outbreak in Vancouver related to travellers acquiring measles while visiting Asia and the US (where large measles outbreaks were occurring at the time). More than 30 cases were reported, including spread in local schools.⁴⁸
- Until these diseases are eliminated worldwide, we need to keep vaccinating against them. We are so close to eliminating polio worldwide; however, until polio is eliminated everywhere, we can't stop vaccinating or it will come back.



It's just like a boat that has a slow leak. The water is the disease and a bucket for bailing is the vaccine.

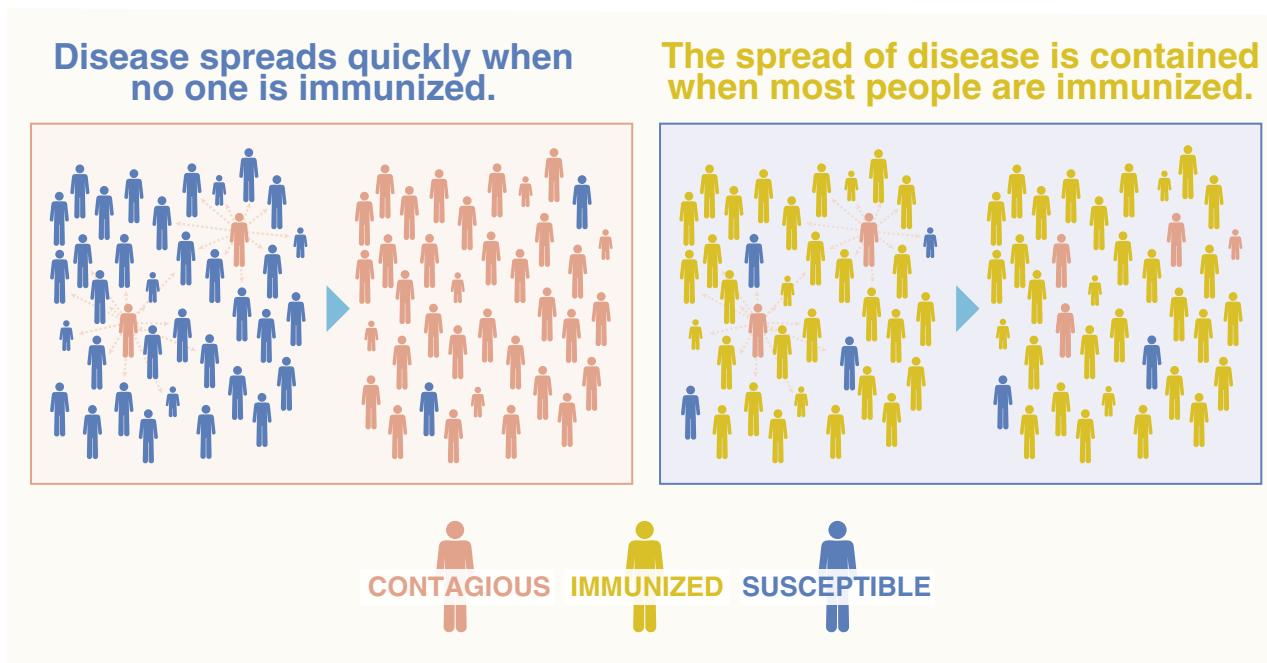
Before we started bailing out the water (vaccinating), the boat was filled with water (disease). We have been bailing fast and hard, and now the boat is almost dry. We could say, "Good. The boat is dry now, so we can throw away the bucket (stop vaccinating) and relax." However, the leak hasn't stopped (the diseases are still present).

Before long, we'd notice water (disease) seeping in, and soon it might be back up to the same level as when we started. Unless we can stop the leak (eliminate the disease), it is important to keep bailing (vaccinating).³⁵

Community Immunity (Herd Immunity)

- The more people in a community who are vaccinated, the harder it is for a disease to spread and the chance of an outbreak greatly decreases. This type of protection is known as community (or herd) immunity.³²
- Immunization rates need to be high for community immunity to work. Depending on several factors, vaccination levels must reach 75% or greater to achieve community immunity.⁴⁹

How community immunity works



- Community immunity protects the most vulnerable among us, including infants who are too young to be fully vaccinated and people who cannot get certain vaccines for medical reasons, such as a child receiving treatment for cancer.³²
- Community immunity does not guarantee protection for unvaccinated individuals.
 - Vaccination rates need to be high for community immunity to work. For example, measles requires an immunization rate of at least 95% to achieve community immunity.²⁸
 - It may not be possible to avoid exposure to a vaccine-preventable disease. For example, an unvaccinated person can catch measles if they spend any length of time in a room where a person infected with measles has been, up to two hours after the infected person has left the room.
 - Community immunity does not protect against all vaccine-preventable diseases. For example, tetanus bacteria can be found in dirt, dust, and soil and does not spread from person to person. Any unimmunized person is at risk of getting tetanus as they are not protected by community immunity.

Vaccines protect future generations

- Just like we are no longer at risk of smallpox thanks to vaccines, in the future we may be able to wipe out other diseases like polio and measles.

Vaccines help reduce antibiotic use and antibiotic resistance

- Ensuring children receive all the recommended vaccines for bacterial and viral illnesses can help reduce the need for antibiotics and thus help reduce antibiotic resistance.³⁴ Examples:
 - There was a decrease in antibiotic resistance to pneumococcal bacteria after the introduction of the 13-strain pneumococcal vaccine. Fewer antibiotics were dispensed because the vaccinated children were not getting sick with the disease. There was a similar decrease in bacterial resistance to antibiotics for *Haemophilus influenzae* type b (Hib) after the vaccine was introduced.³⁴
 - Influenza vaccines protect against infections caused by the influenza virus, but they also protect against secondary bacterial infections such as pneumonia and ear infections.³⁴ Research has shown that influenza vaccination in young children may contribute to a reduction in amoxicillin prescriptions for these secondary infections.⁵⁰
- One of the risks of not vaccinating is that children could get very sick with a vaccine-preventable disease. Another risk is the use of antibiotics in a young child to treat an infection that could have been prevented with a vaccine. Research has shown:
 - Using antibiotics in the first three years of life can increase the likelihood of asthma, eczema, and hay fever in children.^{51 52}
 - Even when antibiotics are warranted, they kill the important healthy bacteria in a child's body. This could put a child at risk of an antibiotic resistant infection in the future.
- Some people think that if their child gets sick with a vaccine-preventable disease, they are able to be treated with antibiotics and avoid severe illness. This is not accurate for a few reasons.
 - First, increases in antibiotic resistant bacteria have caused treatment to be more challenging in some cases.³⁴
 - Second, some diseases, like pertussis, can be treated with antibiotics to stop the spread of the disease, but they do not have any effect on the severe coughing episodes that can last for months.⁵³
 - Third, the rapid progression from infection to severe sickness can, sadly, be too fast to save some children from morbidity and mortality, such as with meningococcal disease.³⁴
- The UN has estimated that by 2050 the global death toll by antibiotic resistance will skyrocket to be greater than the deaths by cancer and diabetes combined.
- To preserve antibiotics and save lives, it is important to get all recommended vaccines to prevent sickness and thus prevent unnecessary antibiotic use.

Motivational interviewing example:

"Are vaccines really necessary if we don't see these diseases anymore?"

OARS

Skill	Examples
Open-ended questions	"How important is it to you that your child is protected against vaccine-preventable diseases?"
Affirmations	"You are great at seeking out current information."
Reflections	Simple: "Your understanding is that nobody gets measles or whooping cough in Canada anymore." Complex: "You mentioned that we may no longer need vaccines in Canada, but you are here today to discuss getting your child vaccinated."
Summaries	"We discussed that many vaccine-preventable diseases are in our communities. We also talked about recent measles outbreaks and that many diseases are just a plane ride away. Where does that leave you at this point?"

Ask-Provide-Verify

Ask-Provide-Verify	<p>Ask: "Can you tell me what you know about vaccine-preventable disease risks in Canada?"</p> <p>Provide: "Can I provide you with some information on why we still need vaccines?"</p> <p><i>Parent agrees:</i> "It's true that many of these diseases are now rare in Canada thanks to vaccines. However, we still have disease outbreaks in our communities and many other serious diseases are just a plane ride away..."</p> <p>Verify: "Does this information make sense?"</p>
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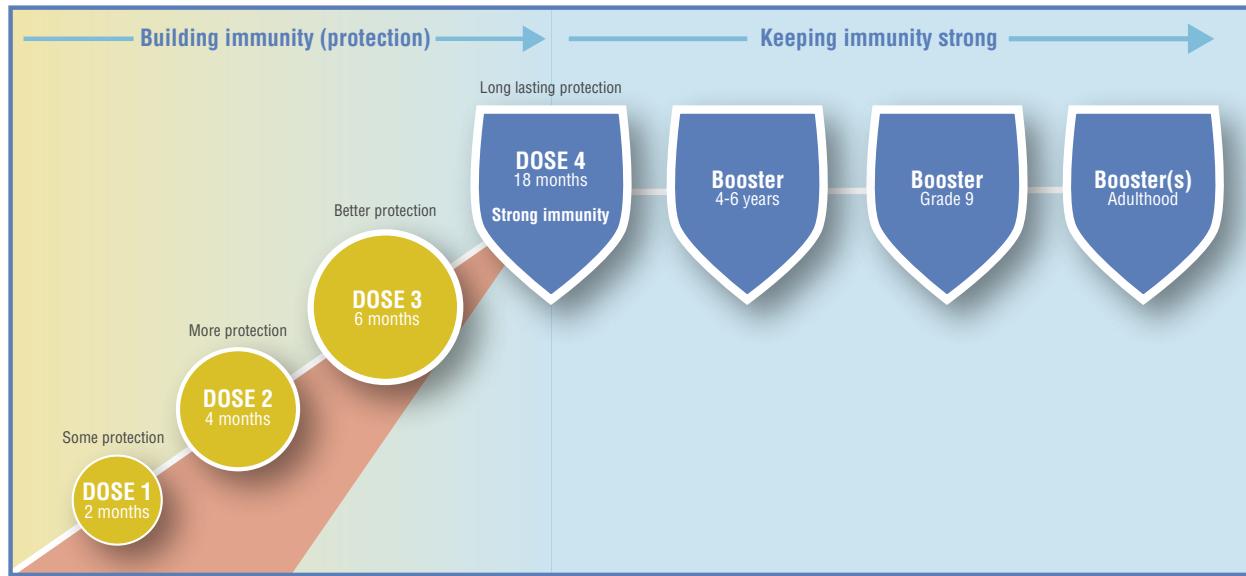
2. The childhood immunization schedule

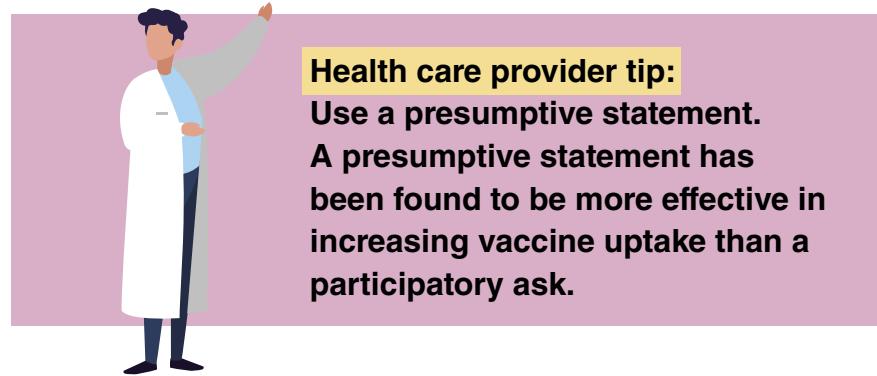
Key messages for the public

- For best protection, your child should follow the recommended immunization schedule and get all vaccines on time.
- Vaccines start at a young age to protect your child early in life before they are exposed to vaccine-preventable diseases, and when they are at highest risk of getting sick or dying if they were to contract them.
- Babies and young children are at greater risk from vaccine-preventable diseases because their immune systems are less mature and less able to fight off infection.
- Delaying vaccines puts children at risk of becoming sick with vaccine-preventable diseases when they need the protection most.
- Every dose within the immunization schedule is important. Most vaccines require more than one dose to produce immunity and long-lasting protection.
- Getting multiple vaccines at the same visit is safe for your child and ensures they are protected earlier rather than later.⁵⁴
- Vaccines do not overwhelm or weaken a child's immune system. Rather, they strengthen it by providing protection against diseases.⁵⁴
- Even combination vaccines, which protect against multiple diseases, are easy for your child's immune system to handle.⁵⁴

Why multiple doses of vaccines are needed

How diphtheria, tetanus, and pertussis vaccines work



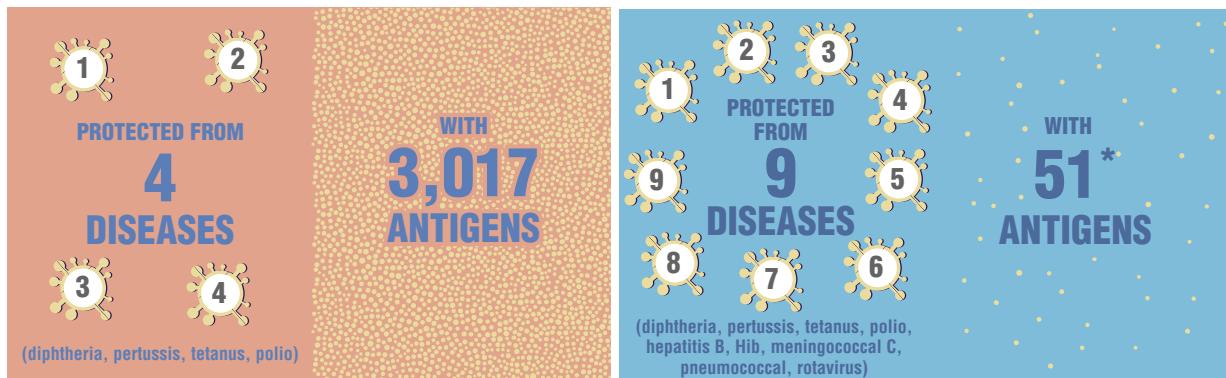


- Vaccines are made using killed, weakened ('attenuated'), or synthetically manufactured versions of the disease-causing germ or parts of the germ called antigens. Antigens are what cause the body's immune system response. Vaccines contain only a tiny fraction of the antigens that your child encounters in their environment every day.⁵⁴
- Although the number of vaccines children receive has increased in recent years, the number of antigens in vaccines has significantly decreased.⁵⁴

More protection with fewer antigens

Even though children receive more vaccines today than 40 years ago, the actual number of antigens is significantly less, thanks to advances in science.

2-month visit: 1980 2-month visit: 2020



*The number of antigens may vary slightly dependent on the specific vaccine products in use.

- Following the recommended schedule minimizes the number of clinic visits and periods of discomfort for your child and may reduce your child's risk of developing needle fears.
- When your child gets vaccinated on time, you not only protect your child, but you also protect their family, friends, and community too.

Six reasons to follow the recommended schedule

1



The schedule is safe, effective, and based on science.

2



It is designed to protect children early in life before they are exposed to dangerous diseases.

3



Delaying vaccines leaves children unprotected when they are most at risk for serious disease complications.

4



Protection provided by maternal antibodies and breastfeeding is not enough.

5

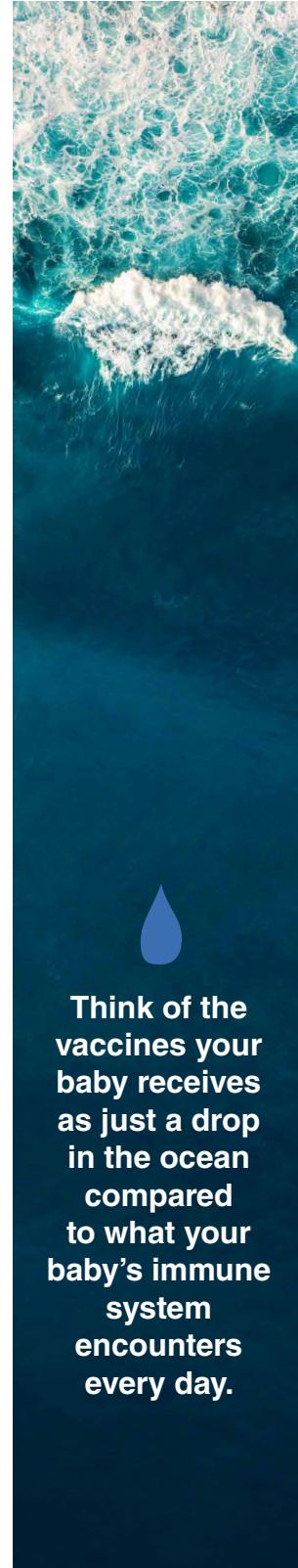


Following the schedule minimizes the number of clinic visits and periods of discomfort, and may reduce the child's risk of developing needle fears.

6



When a child gets vaccinated on time, it protects not only the child, but their friends, family, and community too.



Think of the vaccines your baby receives as just a drop in the ocean compared to what your baby's immune system encounters every day.

More information for health care providers

Vaccines and the immune system

- Every day, a healthy infant's immune system successfully fights off millions of antigens they encounter in their environment. Vaccines contain only a tiny fraction of the antigens that infants encounter every day.⁵⁴
- Infants are born with thousands of antibodies that are ready to fight against many different diseases, as well as the immune cells to create an antibody response to many vaccines at one time.⁵⁴
- Theoretically, infants have the capacity to produce one billion antibodies. Therefore, it is estimated that they could handle up to 10,000 vaccines at any one time.⁵⁴
- Vaccines never use up the body's ability to develop new immunity.

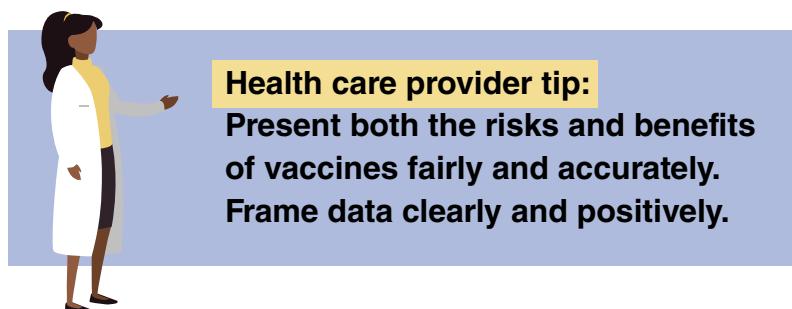
Combination vaccines

- Combination vaccines are manufactured so that two or more vaccines that could be given individually can be administered as one injection.
- Combination vaccines reduce the number of injections needed while protecting against the same number of diseases.
- Side effects of combination vaccines are similar to those of the individual vaccines given separately.⁵⁵
- Before a new combination vaccine is approved, it is tested alongside the recommended vaccines and must be shown to be as effective and safe as the individual vaccines.⁵⁵
- Most of the vaccines available in combinations are not available separately. If one component of a vaccine is declined, all other components are also declined. For instance, refusing the measles vaccine means that a child cannot be vaccinated against rubella and mumps, either, because the measles vaccine in Canada is only available in combination with the mumps and rubella vaccines.

The routine childhood immunization schedule

- Recommendations for when a vaccine is given are based on several factors:
 - Age-specific risks for disease and for complications resulting from disease.
 - The ability of persons of a certain age to produce an optimal immune response to the vaccine.
 - In infants, potential interference with the immune response by passively transferred maternal antibody.

- The recommended schedule is safe, effective, and based on science. It ensures the maximum achievable protection is provided as early as possible.
- Every dose within the immunization schedule is important. Many vaccines require multiple doses to build strong immunity, or to boost immunity that declines with time. Other vaccines need an additional dose in case the person doesn't respond to the first dose. The number of doses needed depends on the vaccine.
- Research shows that getting multiple vaccines at the same visit is safe and that routine childhood vaccines work just as well when they are given at the same visit as when they are given at separate visits.⁵⁴
- Delaying or spacing out vaccines leaves children at risk of getting diseases at an age at which they are most likely to have serious complications.
- Infants and young children are most at risk for many (but not all) vaccine-preventable diseases and their effects within the first two years of life. The severe consequences of vaccine-preventable diseases can lead to hospitalization, life-long disability, and death. For example, if an infant contracts pertussis (whooping cough), they are at higher risk for severe breathing difficulty and death because of the smaller size of an infant's airway.
- Vaccine-preventable diseases such as invasive pneumococcal disease (IPD), *Haemophilus influenzae* type b (Hib), and meningococcal disease can have the most serious consequences for children less than 2 years of age.
- In the first two years of life, an infant's B cells are immature and are unable to make antibodies to encapsulated bacteria that cause serious infections such as IPD and Hib. This is why polysaccharide vaccines are ineffective in infants and why conjugate vaccines are used, which are very effective under two years of age.⁵⁶
- Evidence has shown that multiple injections at one visit cause less pain than waiting a few days between the administration of injections. It also increases the likelihood that children will be fully immunized and protected at the appropriate age.⁵⁷



Motivational interviewing example:

"I have heard that getting several vaccines at the same time can overload my child's immune system."

OARS

O pen-Ended Questions	"Can you tell me more about what you've heard?"
A ffirmations	"You want what is best because you love your child."
R eflections	Simple: "You're concerned that your baby's immune system cannot handle this." Complex: "On one hand, you are concerned about overwhelming your child's immune system, and on the other hand, you want to protect your child."
S ummary	"You have read a lot and you want to make the right decision. How can I help?"

Ask-Provide-Verify

Ask-Provide-Verify	Ask: "Can you tell me what you already know about the immune system and vaccines?" Provide: "Can I share more with you about your baby's immune system?" <i>Parent agrees:</i> "Your baby's immune system is amazing and can safely handle multiple vaccines given at the same time..." Verify: "Does this information about your baby's immune system make sense?"
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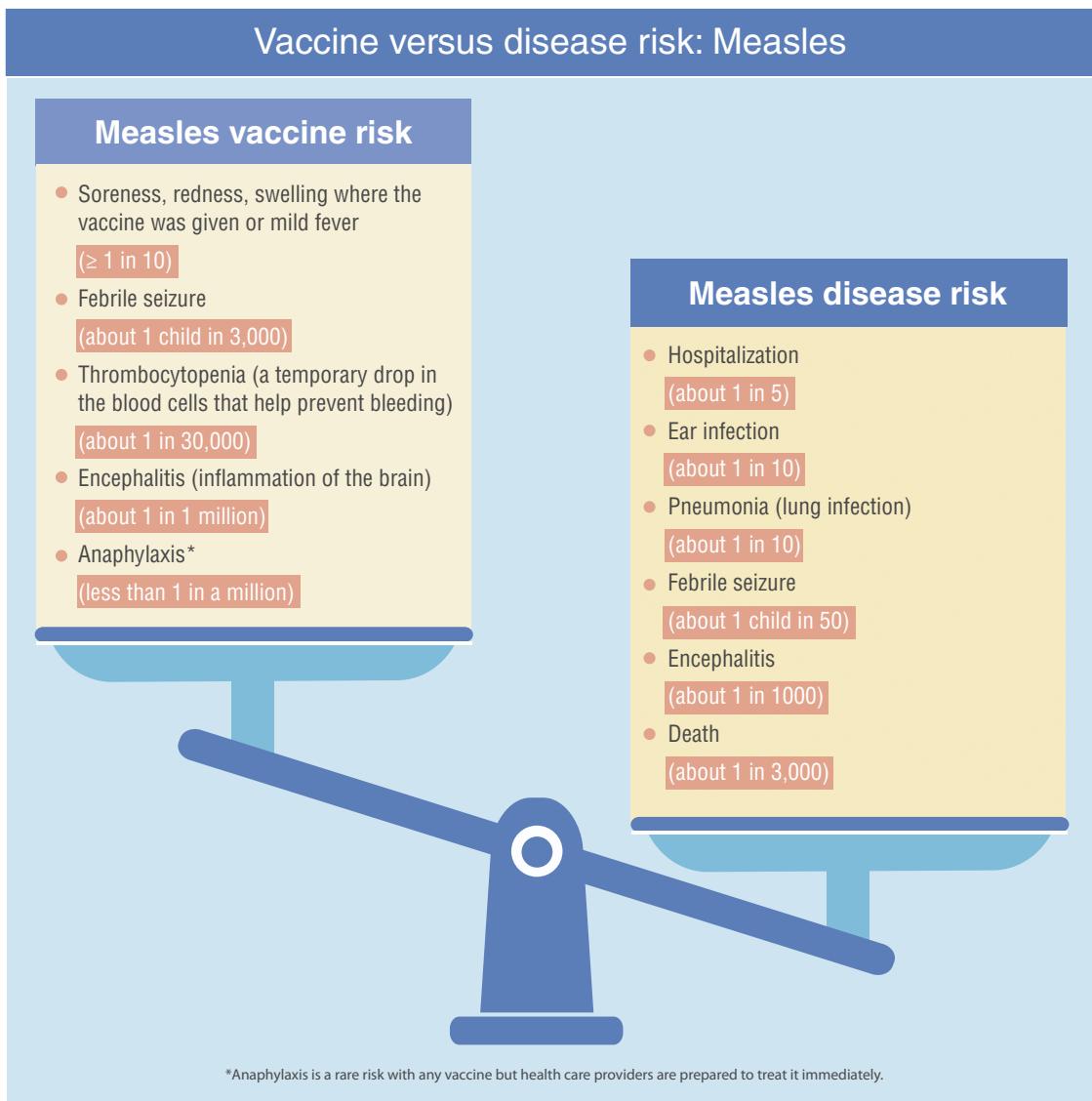
3. Vaccine side effects: vaccine risk versus disease risk

Key messages for the public

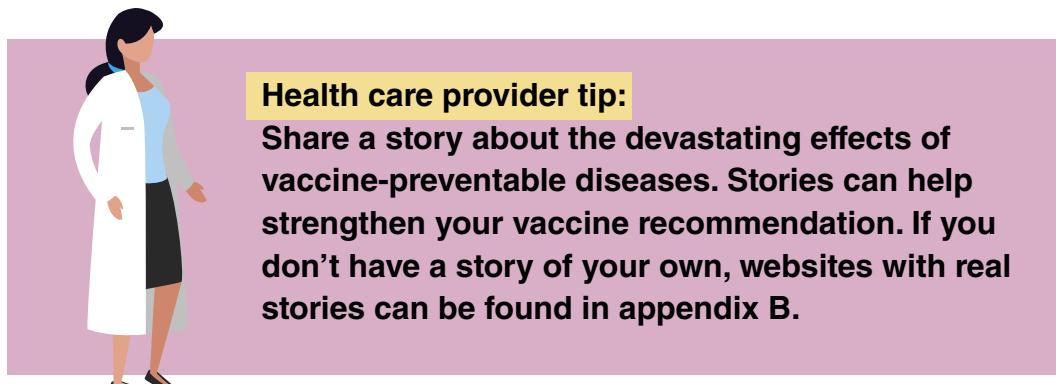
- Because vaccines are given to healthy people, including children, they are held to the highest safety standard—even higher than most drugs used for treatment.
- Like any medicine or supplement (including vitamins), vaccines can cause side effects. Usually vaccine side effects are minor, such as a sore arm or mild fever, and resolve quickly. Many people who receive vaccines have no side effects at all.
- Serious side effects are very rare. For example, the chance of having a severe allergic reaction (anaphylaxis) is rare with an estimated frequency of 1.3 episodes per million doses of vaccine administered. Anaphylaxis is preventable in many cases and treatable in all. It should be anticipated in every vaccinee.⁵⁹
- The risks from the diseases that vaccines prevent are much greater than the risk of vaccine side effects.⁵⁸
- These diseases can cause serious health problems such as lung infection (pneumonia), deafness, brain damage, heart problems, blindness, paralysis, life-long disability, and even death.
- Parents who choose not to vaccinate often do so to avoid risk, but choosing not to vaccinate is the riskier choice, putting both their child and others at risk.
- It's true that in Canada, where the rates for many vaccine-preventable diseases are very low, a child's risk of getting one of these diseases may also be low. However, any unvaccinated child is at risk of getting a vaccine-preventable disease, as these diseases still occur here in Canada and elsewhere in the world. Many of these diseases are just a plane ride away. You don't want your child lacking protection if they ever need it.



You always buckle your child in their car seat to protect them, even though the risk of a crash may be low. For the same reason, it is important to vaccinate your child, even though the risk of getting some vaccine-preventable diseases in Canada may be low.



Source: Public Health Agency of Canada, Measles vaccine: Canadian Immunization Guide



More information for health care providers

- The risks from the diseases that vaccines prevent are much greater than the risk of vaccine side effects.³²
- Complications from vaccine-preventable diseases can be severe and life-threatening. For example:
 - Chickenpox (varicella) infection can cause pneumonia.
 - Polio infection can cause permanent paralysis.
 - Measles infection can cause encephalitis (swelling of the brain).
 - Mumps infection can cause deafness.
 - *Haemophilus influenzae* type b (Hib) infection can cause brain damage or even death.
 - Rotavirus infection can cause severe vomiting and diarrhea, which can result in dehydration and hospitalization.
- Effective treatments or cures do not exist for many vaccine-preventable diseases like measles, mumps, and polio.
- Serious adverse events following immunization are very rare.
- It is often difficult to determine if a reaction was directly linked to a vaccine or caused by something else that only occurred by coincidence after the vaccine was administered.⁶⁰
- Health assessment and history-taking prior to immunization to identify contraindications to receipt of a vaccine and to reduce the risk of a serious side effect are routinely conducted. For example, a child who is severely immunocompromised will be deferred from receipt of live vaccines, or a child who has had a severe allergic reaction to a previous vaccine dose will not be given a subsequent dose in most circumstances.⁶¹
- Post-vaccination observation is used to identify any signs and symptoms of serious side effects to a vaccine, such as anaphylaxis. Should anaphylaxis occur, all health care providers need to be prepared to treat it.⁵⁹
- The post-marketing safety of vaccines is monitored through the reporting of adverse events following immunization (also known as an AEFI).⁶² An AEFI is any untoward medical occurrence after a vaccine has been given that the provider suspects may have been caused by the vaccine.⁶²
- Refer to the “Vaccine testing, approval, and monitoring” section of this tool for more information on AEAEFs.

4. Vaccines and long-term health problems

Key messages for the public

- There is no evidence that vaccines cause health problems such as autism, asthma, SIDS, or autoimmune diseases such as diabetes and multiple sclerosis.
- We learn about a vaccine's safety during clinical trials before it is approved and monitor it continually as millions of doses are administered after its approval.⁶⁰
- We've been monitoring the safety of vaccines for more than 50 years and we can say that the chance a vaccine will cause unanticipated long-term health problems is extremely low.

Health care provider tip:

Use motivational interviewing techniques to understand a person's vaccine concerns. Refer to appendix A for more information.



More information for health care providers

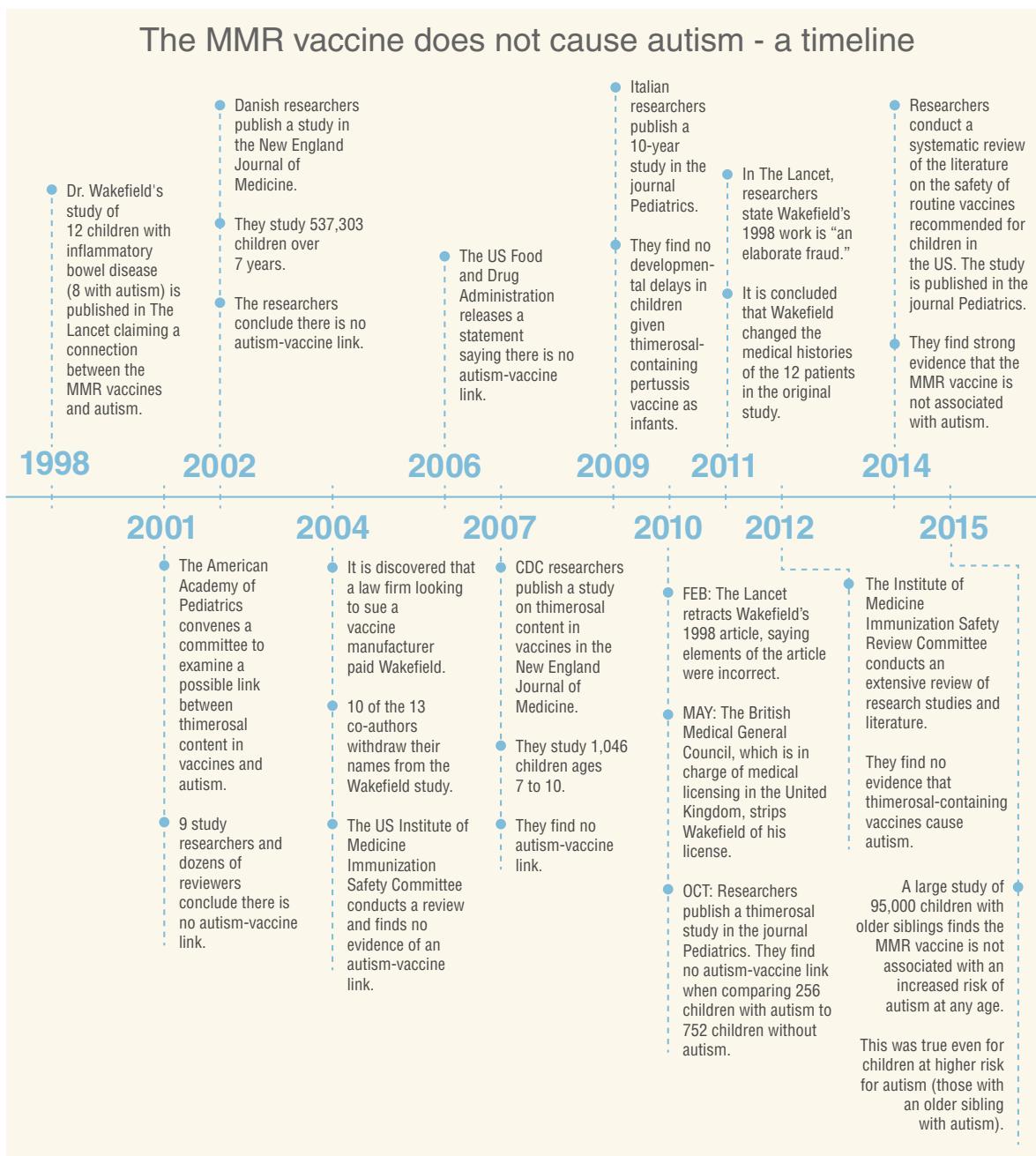
Many of the conditions that have been purported to be caused by vaccines are those for which a specific causal pathway has not been elucidated. As the research on these conditions advances our understanding of the often complex multi-factorial causal pathways, the need to implicate vaccines is reduced.

Autism

- Many studies have shown that vaccines do not cause autism.⁶³
- Many studies have also shown that thimerosal (a mercury-based preservative used in some influenza vaccines) does not cause autism.⁶⁴
- It is not known exactly why some children develop autism. Current research suggests there are likely many causes and that both genetics and environment probably play a role.⁶⁵
- Because children with autism are often diagnosed after the age when they receive some vaccines, some people think that the vaccines caused the autism. However, just because one thing happens after another, it does not mean there is a link between them.
- The prevalence of autism in children has increased in recent years likely due to a growing awareness of autism and changes to the condition's diagnostic criteria, not because of vaccines.
- Much of the controversy around a possible link between vaccines and autism came from a single small study published in the medical journal The Lancet in 1998 that hypothesized that the measles, mumps, rubella (MMR) vaccine caused autism.⁶⁶ The study was found to be

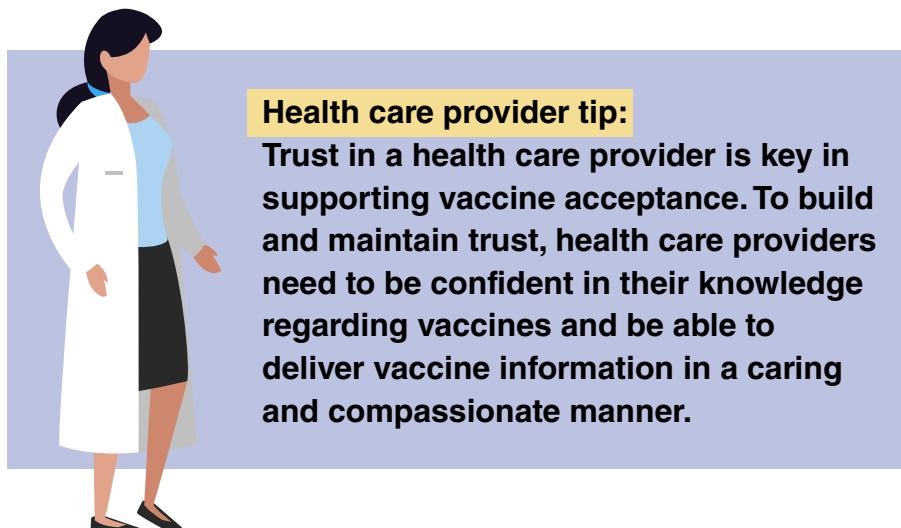
fraudulent and was withdrawn by the journal that published it.⁶⁷ The author lost his license to practice medicine.

- Many large, high-quality scientific studies around the world have since been conducted and have found no link between the MMR vaccine and autism. A summary of several of these studies and their conclusions is available at www.immunize.org/catg.d/p4026.pdf.
- The timeline below details the controversy around vaccines and autism and highlights many of the studies that have disproven a link between the MMR vaccine and autism.



Asthma and allergic diseases

- There is no evidence that vaccines cause asthma or allergic diseases.
- Several large studies have looked at the risk of developing asthma following receipt of a number of different childhood vaccines.⁶⁸
- One study looked at 18,407 children with asthma and found that children who received routine childhood vaccines had no greater risk for asthma compared with children who did not receive these vaccines.⁶⁹
- A large international study analyzed rates of asthma and allergies for six- and seven-year-olds from 91 centres in 38 countries, and for 13- and 14-year-olds from 99 centres in 41 countries. Researchers found no correlation between immunization rates and rates of asthma and allergies.⁷⁰
- Another large study that looked at the risk of allergies following pertussis vaccination in 669 children found no differences in the incidence of allergic diseases in children who did or did not receive the pertussis vaccine.⁷¹
- A recent study led by BC researchers found that the 26% decrease in asthma incidence from 2000 to 2014 in young BC children correlates with a large decrease in use of antibiotics in infancy over this same time period, perhaps through the adverse impact of antibiotic consumption on gut bacterial flora.⁷²



Health care provider tip:

Trust in a health care provider is key in supporting vaccine acceptance. To build and maintain trust, health care providers need to be confident in their knowledge regarding vaccines and be able to deliver vaccine information in a caring and compassionate manner.

Sudden infant death syndrome (SIDS)

- Infants receive multiple vaccines between two and four months of age. This period is also when the risk of SIDS is highest. This has led some people to question if the two are related. An example of how the hepatitis B vaccine was shown to not cause SIDS:
 - In 1999, a news program in the US aired a story claiming that the hepatitis B vaccine caused SIDS. At the time of the introduction of the hepatitis B vaccine for routine use in all infants, about 5,000 children died every year from SIDS. Within 10 years of the

introduction of the hepatitis B vaccine the use of the vaccine increased to about 90 percent of all infants receiving hepatitis B vaccine and the incidence of SIDS in that age group decreased dramatically to about 1,600 cases each year. The cause of the decrease in SIDS cases was attributed to the introduction of the “Back to Sleep” program by the American Academy of Pediatrics (AAP). However, since immunizations are given to about 90 percent of children less than 1 year of age, and about 1,600 cases of SIDS occur every year, it would be expected, statistically, that every year about 50 cases of SIDS will occur within 24 hours of receipt of a vaccine. However, because the incidence of SIDS is the same in children who do or do not receive vaccines, we know that SIDS is not caused by vaccines.⁷³

- Many large studies have found that vaccines do not cause (or are not linked to) SIDS.⁷³
- Case-control studies and analyses of the US Vaccine Adverse Event Reporting System have shown no positive association between immunizations and subsequent SIDS.⁷⁴
- Some studies have found that infants who died of SIDS were less likely to have been immunized.⁷³

Autoimmune diseases

Diabetes

- Several studies have shown that vaccines are not associated with an increased risk of developing diabetes.⁷⁵
- One study looked at 21,421 US children who received the *Haemophilus influenzae* type b (Hib) vaccine between 1988 and 1990. The children were followed for ten years after receiving the vaccine. The risk for diabetes was no different for the children who received the Hib vaccine than for a group of 22,557 children who did not receive the vaccine.⁷⁶
- Another study used data from the US Vaccine Safety DataLink and compared 252 children with diabetes (confirmed by medical records) with 768 children who did not have diabetes. They found no increased risk of type 1 diabetes associated with any of the routinely recommended childhood vaccines.⁷⁷
- In 2011 the Institute of Medicine reviewed studies of adverse events following immunization for several vaccines. One of the things they looked at was whether the tetanus component of the DTaP vaccine caused type 1 diabetes. They concluded that development of type 1 diabetes was not caused by the DTaP vaccine.⁷⁸

Multiple sclerosis (MS)

- Several studies have been done that have found no evidence that vaccines cause MS or flare-ups of MS.⁷⁹
- A large 2019 study of more than 200,000 people in Germany, including 12,000 with MS, found that vaccines are not a risk factor for MS. Instead, the study showed a consistent link between higher vaccination rates and a lower likelihood of developing MS.⁸⁰

- Studies on the influenza vaccine and MS have found that the influenza vaccine does not worsen MS symptoms and that the vaccine is more likely to prevent than cause worsening of MS.⁷⁹

Guillain-Barré syndrome (GBS)

- GBS has been associated with the inactivated influenza vaccine at a rate of one per 1 million doses of this vaccine.⁸¹
- Despite this association, there is currently not enough evidence to prove that the influenza vaccine causes GBS.⁸¹
- Most patients completely recover from GBS; however, 10% of those who have this disorder can die and 20% will have some permanent disabilities.⁸²
- Studies suggest a person is more likely to experience GBS after being infected with the influenza virus than from receipt of the influenza vaccine.⁸¹
- Other studies have looked at a number of other vaccines and have shown that these vaccines were not associated with an increased risk of GBS.⁸³

Motivational interviewing example:

"I have heard that vaccines can cause autism."

OARS

Open-Ended Questions	"Can you tell me more about what you have heard?"
Affirmations	"You are looking for trust-worthy information."
Reflections	<p>Simple: "You have heard there is some connection between autism and vaccines."</p> <p>Complex: "You have read information claiming that vaccines cause autism on the internet, and you are wondering how to prevent your child from getting sick."</p>
Summary	"Autism frightens you; you have a family member who is autistic and you wonder if vaccines could have caused it. Do I have that right?"

Ask-Provide-Verify

Ask-Provide-Verify	<p>Ask: "Can you tell me about what you've read about vaccines and autism?"</p> <p>Provide: "Can I share some research studies with you about vaccines and autism?"</p> <p>Parent agrees: "Many studies have shown that vaccines do not cause autism..."</p> <p>Verify: "What do you think about the studies I've shared?"</p>
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5. Vaccine ingredients

Key messages for the public

- The ingredients in vaccines are necessary and are safe in the amounts used.⁸⁴
- You may have heard or read that some vaccine ingredients are harmful, but this is true only at much higher amounts than those present in vaccines. Any substance, even water, can be harmful at a high dose.
- The ingredients in vaccines have not been proven to cause harm (disease or illness) in the small amounts used in vaccines.⁸⁴
- All vaccine ingredients play necessary roles either in making the vaccine or in ensuring that the vaccine is safe and effective.⁸⁴
- We are not always aware of it, but we are exposed to many of the substances present in vaccines every day. For example, aluminum is in the air we breathe, the food we eat, and the water we drink, and we are exposed to small amounts of formaldehyde in the air, some foods, and some manufactured products.

Health care provider tip:
Keep messages short and simple. Research has shown that for parents who are already vaccine-hesitant, messaging that too strongly advocates for vaccination can be counterproductive.



More information for health care providers

This section provides information on specific vaccine ingredients that people frequently ask questions about, including why they are in vaccines and their safety.

Aluminum

- Aluminum is used as an adjuvant in many vaccines. Adjuvants enhance the immune response (help the vaccine work better) and allow for fewer quantities of active ingredients and fewer doses of vaccine.
- Aluminum-containing adjuvants have been used safely in vaccines since the 1930s. That is over 85 years!⁸⁵
- Aluminum is one of the most abundant elements and is in the air we breathe, the water we drink, the food we eat, and many health products.⁸⁴

- The amount of aluminum in vaccines is extremely small and does not pose a health risk.⁸⁶
- Infants receive more aluminum from their diet in the first six months of life than from vaccines.⁸⁵
- Infants quickly remove aluminum from their bodies without harmful effects.
- The ability of the body to remove aluminum accounts for its excellent record of safety.
- About half of the aluminum from vaccines is eliminated from the body in less than 24 hours, and more than three-quarters is eliminated within two weeks.⁸⁶
- For aluminum to be harmful, people must have kidneys that don't work well or at all, and they must receive large quantities of aluminum for months or years.⁸⁶
- Because large quantities of aluminum can cause serious neurologic effects in humans, Health Canada regulates the amount of aluminum that can be present in vaccines.
- Health Canada follows standards set by the World Health Organization and allows for no more than 1.25 mg/dose as a safe level in vaccines.⁸⁷

Aluminum content in vaccines versus other sources

During the first 6 months of life, babies receive more aluminum in their diet than from all vaccines combined.



38 mg

Babies receive about 38 milligrams of aluminum in infant formula during the first 6 months of life.



7 mg

Babies receive about 7 milligrams of aluminum in breast milk during the first 6 months of life.



3 mg

Babies receive about 3 milligrams of aluminum from all vaccines combined during the first 6 months of life.

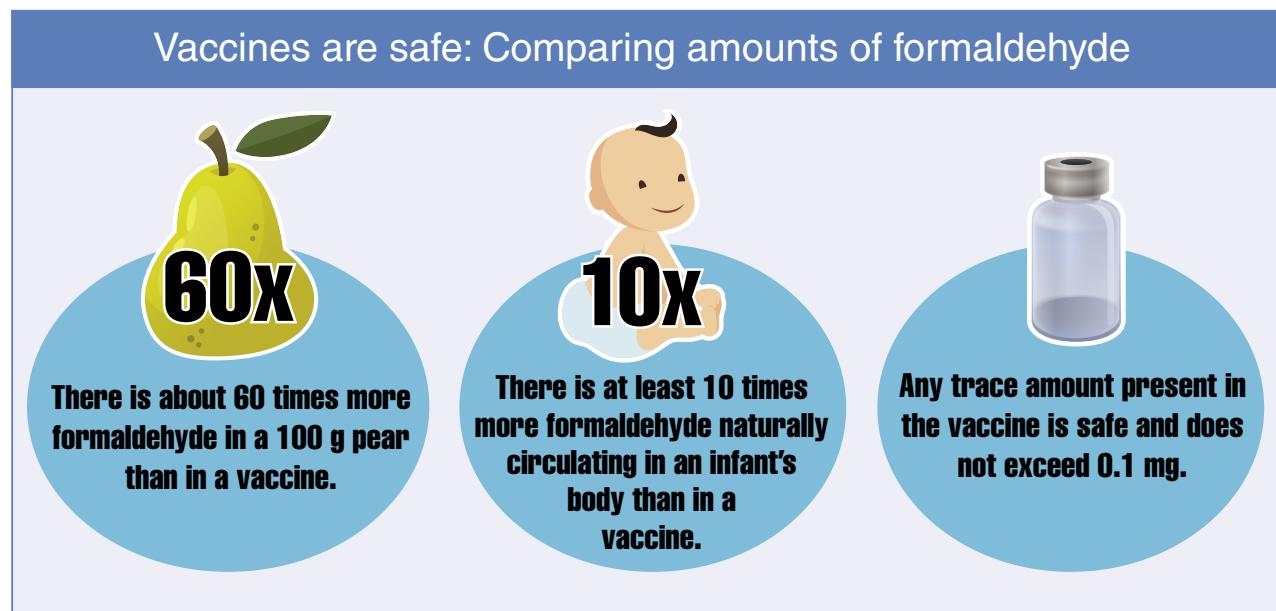
These amounts are extremely safe.



Health Canada follows standards set by the World Health Organization that allow for no more than 1.25 mg/dose as the safe level of aluminum in a vaccine.

Formaldehyde

- Formaldehyde is used during the manufacturing process of some vaccines to kill viruses or inactivate bacterial toxins.
- The vaccines are purified to remove almost all the formaldehyde and the quantity left in a vaccine does not exceed 0.1 mg. This amount is safe.⁸⁴
- Formaldehyde is essential in human metabolism and is required for the synthesis of DNA and amino acids (the building blocks of protein). Therefore, all humans have detectable quantities of naturally produced ('endogenous') formaldehyde in their circulation.⁸⁴
- The amount of formaldehyde found in an infant's circulation is at least ten times greater than that found in any vaccine.⁸⁴



Gelatin

- Gelatin is used in some vaccines as a stabilizer.
- Stabilizers help protect ingredients from breaking down while vaccines are being made, stored, and transported.
- The gelatin in vaccines is the same material used in many products we eat, such as Jello, marshmallows, and many candies such as gummy bears.
- About one out of every two million people may have a severe allergic reaction to gelatin.⁸⁵
- Gelatin in vaccines is sourced from cows and pigs.⁸⁶

- Because some religious groups, such as Jewish people, Muslims, and Seventh Day Adventists, follow dietary rules that prohibit pork products, some parents are concerned about using vaccines that contain gelatin. However, all religious groups have approved the use of gelatin-containing vaccines for their followers for the following reasons:
 - Most vaccines are injected, not consumed (exceptions are some oral vaccines such as the rotavirus vaccine, which does not contain gelatin).
 - The gelatin in vaccines has been highly purified and hydrolyzed, so it is much smaller than that found in nature. Thus, religious leaders believe it to be different enough that it does not break religious dietary laws.
 - Religious leaders from these groups believe that the benefits of receiving vaccines outweigh adherence to religious dietary laws.⁸⁶
- The gelatin used in vaccines must be sourced from countries whose cattle are free of bovine spongiform encephalopathy (mad cow disease in cattle).⁸⁴
- There are no reported cases of variant Creutzfeldt-Jakob disease (mad cow disease in humans) linked to bovine gelatin, despite tens of millions of vaccines manufactured using bovine-derived material.⁸⁴

Thimerosal

- Thimerosal is a mercury-based preservative used in vaccines produced in multi-dose vials.
- Preservatives prevent germs (bacteria and fungus) from growing in the vial after the first dose has been removed.
- In the body, thimerosal is metabolized to ethylmercury and thiosalicylate.
- Ethylmercury is different from methylmercury (the type of mercury found in the environment that can cause mercury poisoning). Ethylmercury is broken down and excreted much more rapidly than methylmercury and is much less likely to accumulate in the body and cause harm. It has a half-life of seven days as opposed to 50 days for methylmercury.⁸⁴
- Studies have shown that thimerosal, at the levels contained in vaccines, is easily eliminated from the body and does not cause neurological problems.⁸⁹
- In Canada, thimerosal is only used in some influenza vaccines provided in multi-dose vials. The amount of thimerosal is not greater than 50 µg per 0.5 mL dose.
- Thimerosal has not been included in any routine childhood vaccines produced since 2001. It was removed as a precautionary measure to maintain public confidence in vaccines, not because there was evidence that thimerosal in vaccines was dangerous.⁹⁰
- Studies have shown that the small amount of thimerosal used to preserve vaccines is safe.⁹¹
- The evidence is clear that thimerosal in vaccines does not cause autism (refer to the “Do vaccines cause long-term health problems” section for more information about how vaccines do not cause autism).

- A very small proportion of the population have a severe allergy ('hypersensitivity') to thimerosal. For such individuals, thimerosal-containing vaccines should not be used; instead single dose formulations that are thimerosal-free are offered.⁹²
- The amount of mercury in a thimerosal-containing influenza vaccine does not exceed 25 µg/dose. This is about the same amount as is found in a six-ounce can of Canadian albacore tuna, which has no serving limits and is considered safe to eat.^{93 94}

Animal and human cells

- Animal and human cell cultures may be used in the process of making certain vaccines, but the vaccines do not contain animal or human cells or tissue.⁹⁵
- The purification process removes nearly all of the cell components so that only trace amounts of DNA and protein may be present in the vaccine.⁹⁶
- Viruses are necessary to produce certain vaccines and the cells are used to grow the virus. Human cells are often better than animal cells at supporting the growth of human viruses.
- Some vaccines use continually growing cells that came from two fetuses aborted in the 1960s. They were aborted for medical reasons, not to make vaccines.⁹⁶
- Ethicists from the US National Catholic Bioethics Center concluded that the use of human cells in vaccine production was not contrary to their religious practices or beliefs.⁹⁷
- A statement from the Vatican says, "Parents have a serious obligation to protect their children from disease whenever possible, and in doing so they are not signaling their approval for abortion."⁹⁸
- Vero cells have been used to produce safe and effective vaccines for decades. The cells were derived from the kidney of an African green monkey in the 1960s.⁹⁸

Blood products

- Human blood products are not typically found in vaccines. The exceptions to this are two rabies vaccines (Imovax® Rabies and RabAvert®) that contain albumin derived from human blood.

Egg or chicken products

- Some vaccines (e.g., the influenza, MMR, and MMRV vaccines) contain egg or chicken protein.
- Egg or chicken protein is present in these vaccines because the viruses used to make them are grown in eggs or in cells isolated from chicken embryos.
- People with egg allergies can be safely immunized with these vaccines.⁸⁹

Antibiotics

- Trace amounts of antibiotics are present in some vaccines because they are used to prevent bacterial contamination during the manufacturing process.
- The antibiotics most likely to cause allergic reactions (e.g. penicillins, cephalosporins, sulfonamides) are not present in vaccines.⁸⁴
- If hypersensitivity or non-anaphylactic allergy to a vaccine component is suspected, investigation is indicated and may involve immunization in a controlled setting. Consultation with an allergist is advised.

Yeast

- Some vaccines are made in yeast cells.
- The vaccines are purified to remove almost all of the yeast, but trace amounts of yeast protein may remain in the final product.
- If hypersensitivity or non-anaphylactic allergy to a vaccine component is suspected, investigation is indicated and may involve immunization in a controlled setting. Consultation with an allergist is advised.

Motivational interviewing example:

"I have heard that some vaccine ingredients are toxic."

OARS

Open-ended questions	"Can you clarify what you mean by toxic?"
Affirmations	"You value safety and transparency."
Reflections	Simple: "You worry vaccines are not safe." Complex: "You've heard conflicting information and are uncertain about making this decision."
Summaries	"You think it's important to protect your child against diseases, but you are worried about the safety of vaccine ingredients."

Ask-Provide-Verify

Ask-Provide-Verify	Ask: "Can you tell me what you've heard about vaccine ingredients?" Provide: "Can I provide you with some information on vaccine ingredients?" Parent agrees: "It is important to consider the amounts of each ingredient in vaccines..." Verify: "What do you think about the information I've shared?"
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6. Vaccine testing, approval, and monitoring^A

Key messages for the public

- Vaccines are very safe. They are among the safest tools of modern medicine.
- Vaccines are held to the highest safety standards because they are given to healthy people, including children.
- Vaccines undergo extensive testing and must be proven to be safe and effective before they are approved for use.
- The approval process for vaccines is more stringent than most drugs available in Canada.⁹⁹
- It can take up to ten years or longer for a vaccine to be developed, tested, and approved for use by Health Canada.
- A vaccine's safety is continuously monitored following its approval.
- Canada has several advanced systems in place (at the local, provincial, and national levels) to carefully monitor and detect any vaccine safety concerns.
- In the very rare event that a lot (batch) of vaccine results in an unexpected side effect, these systems can ensure that the rest of the lot is not used.

More information for health care providers

By the time a vaccine is approved for use in Canada, its safety will have been studied for many years through a variety of methods. It can take up to 10 ten years or longer for a vaccine to be developed, tested, and approved for use by Health Canada.

Vaccine testing

- Laboratory and animal testing are first conducted before vaccines are studied for use in humans.
- If the vaccine is shown to be safe in animals, clinical trials (studies in humans) are next.
- Vaccine testing involves volunteer study subjects who have consented under clinical trial requirements, which include ethic board reviews for participation.
- Vaccine testing involves three phases of clinical trials. Phase one involves fewer than one hundred volunteers, phase two involves hundreds of volunteers, and phase three involves thousands of volunteers.

A Content in this section has been adapted from the Canadian Immunization Guide: Part 2 – Vaccine Safety

- These trials provide crucial information on vaccine safety, the immune response to the vaccine, as well as efficacy. Efficacy is how well the vaccine prevents the disease.
- When all phases of the clinical trials have been successfully completed, the vaccine must meet Canadian licensing standards before it can be considered for approval by Health Canada.

Vaccine approval

- Health Canada's Biologic and Radiopharmaceutical Drugs Directorate (BRDD) regulates vaccines used in humans in Canada.
- The BRDD approves a vaccine for use only if there is sufficient scientific evidence to show that it is safe, effective, and of suitable quality—and only if the benefits of the vaccine greatly outweigh any risks associated with it.
- The BRDD regulates all aspects of vaccine production to ensure the highest quality of manufacturing is used to produce vaccines.
- Manufacturing facilities are regularly inspected to ensure that all stages of production meet good manufacturing practices.
- Each individual lot (batch) of vaccine is subject to the lot release program before sale in Canada.
- As part of this program, manufacturers must submit results of key quality control tests performed throughout the manufacturing process of each individual lot of vaccine to the BRDD for review.
- The BRDD also performs its own testing of most vaccine lots.
- The purpose of the lot release program is to ensure that the lots used today conform to the same specifications as the ones used during clinical trials.

Vaccine recommendations¹⁰⁰

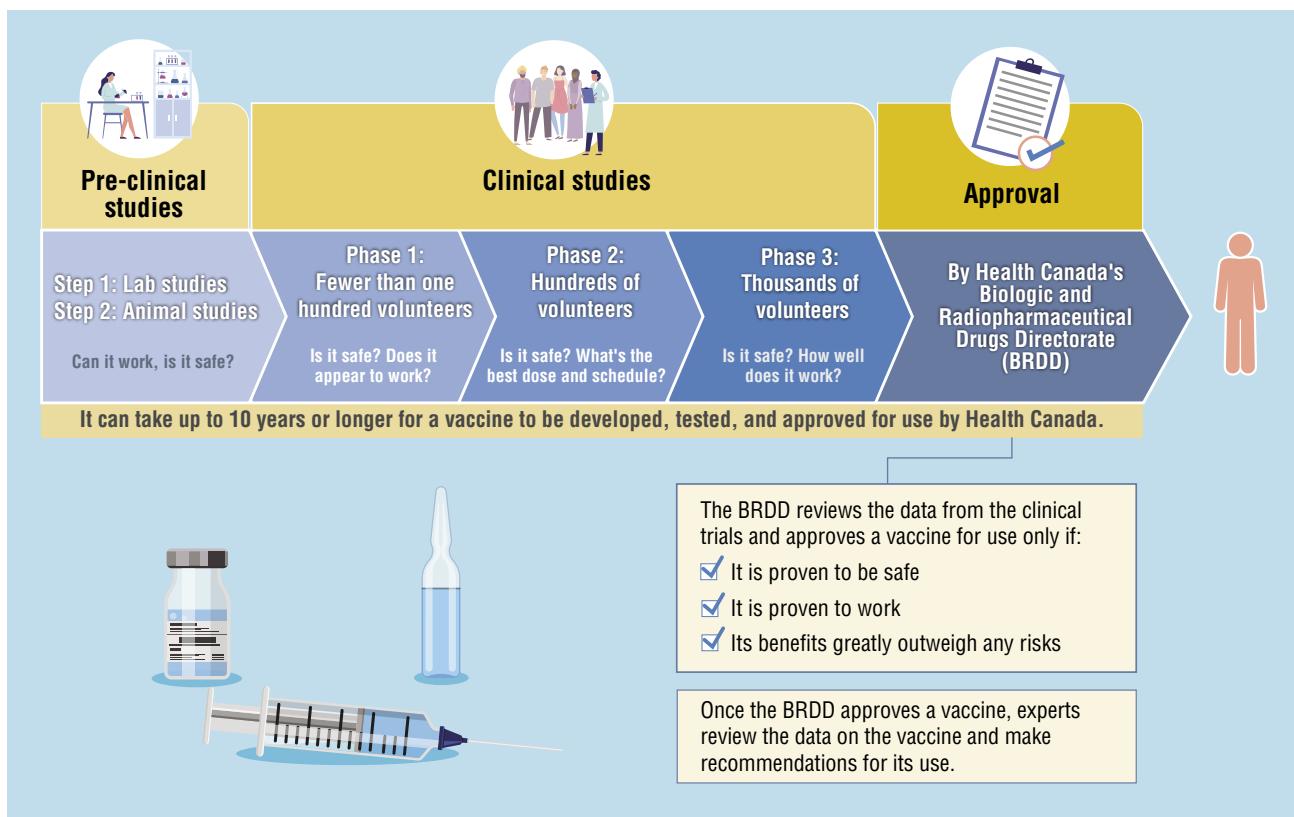
The National Advisory Committee on Immunization

- Canada's National Advisory Committee on Immunization (NACI) makes recommendations for the use of approved vaccines in Canada.
- NACI consists of a group of experts in pediatrics, infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmacoeconomics, social science, and public health who must abide by conflict of interest requirements to be part of NACI.¹⁰¹
- NACI regularly reviews all scientific information available on the safety and efficacy of new vaccines and vaccines that are already in use.
- NACI's knowledge syntheses, analyses, and recommendations on vaccine use in Canada

are published in literature reviews, NACI statements and updates, and in vaccine-specific chapters of the Canadian Immunization Guide.

- In Canada, the provinces and territories are responsible for the development of publicly-funded immunization programs. Each provincial or territorial ministry of health uses NACI's recommendations and other sources of information to develop its program and schedules for children and adults. Following an assessment of recommendations, evidence, and regional information and data, provinces and territories determine the best schedule for their region.

How vaccines are tested and approved



Vaccine safety monitoring

- The purpose of ongoing post-marketing vaccine safety monitoring is to detect possible adverse events that occur at a higher level of frequency than expected based on clinical trials or historical experience, and those that occur too rarely to have been detected even in a large clinical trial.
- An adverse event following immunization (also known as an AEFI) is any untoward medical occurrence after a vaccine has been given that may or may not have been caused by the vaccine.

- By law in BC, a health care provider who suspects an AEFI must report the event to the medical health officer.¹⁰²
- Individuals (or their parents) are also advised to notify their health care provider about any concerns that arise following immunization. Once reported, AEIIs are entered into BC's electronic information system.
- Once an AEFI report is received, a local medical health officer or registered nurse reviews the report and makes a recommendation for future immunization. All AEIIs are reported to the BC Centre for Disease Control (BCCDC) for provincial surveillance and from there to the Public Health Agency of Canada for national surveillance, as well as further assessment and investigation, if needed.
- The BCCDC receives and reviews all reports from around the province. By gathering all the reports in one place for the whole province, there is greater opportunity to identify any safety signals and take action if appropriate.
- The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), which is part of the Public Health Agency of Canada, receives, tracks, and regularly analyzes reports from across the country to search for vaccine safety signals. With an even larger number of reports than at the provincial level, there is even greater opportunity to identify any rare safety concerns.
- Vaccine safety is also monitored at the international level. The World Health Organization's International Drug Monitoring Program collects reports from over 75 countries (including Canada) and uses this global data set to monitor for any vaccine safety concerns.

Immunization Monitoring Program ACTive (IMPACT)

- Canada has a unique program called IMPACT that complements existing national surveillance systems.⁶²
- IMPACT is a pediatric hospital-based national active surveillance network for adverse events in children following immunization and selected infectious diseases that are, or will be, vaccine-preventable.
- Nurse monitors at 12 children's hospitals across Canada (including BC Children's Hospital) review all admissions to the hospital for certain serious illnesses. If a child with any of these illnesses had recently received a vaccine, a report is sent to the local health unit and to the Public Health Agency of Canada to be investigated further. These events are reported even if another cause may ultimately be found for the illness.
- The active nature of the surveillance ensures a high level of vigilance for severe AEIIs in children.

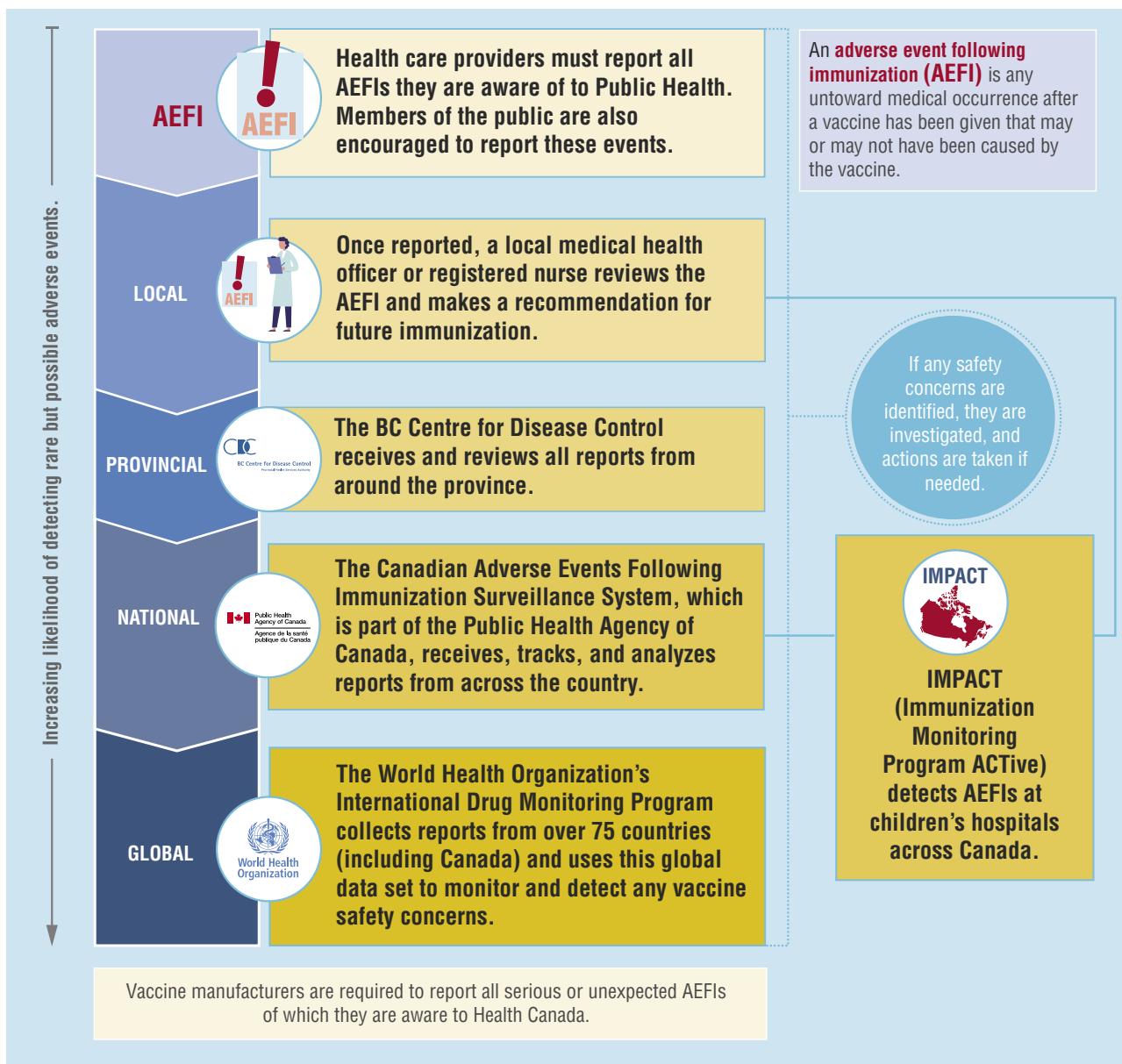
More information about the IMPACT program can be found at: <https://www.cps.ca/en/impact>.

Mandatory reporting by vaccine manufacturers

- Vaccine manufacturers are required to report serious or unexpected adverse events to the Canada Vigilance Program, as mandated by the Food and Drugs Act and Regulations. The Canada Vigilance Program is Health Canada's post-market surveillance program that monitors the safety profile of health products once marketed to ensure that the benefits of the products continue to outweigh the risks.

How a vaccine's safety is continuously monitored

The purpose of ongoing vaccine safety monitoring is to detect possible adverse events that would occur very rarely, too rarely to have been detected even in a large clinical trial.



Vaccine Vigilance Working Group (VVWG)

- The VVWG was created in 2004 as part of the National Immunization Strategy to strengthen vaccine safety in Canada.
- It includes representatives from all federal and provincial/territorial immunization programs, as well as Health Canada regulators and IMPACT.
- The group's activities include providing a national vaccine safety sentinel network that can rapidly share and disseminate information to appropriate stakeholders regarding vaccine safety issues or signals.

Vaccine safety monitoring works!

Examples:

- In November 2012, there was a voluntary recall of one lot of Infanrix Hexa® vaccine by GlaxoSmithKline. It was recalled following the detection of contamination in the environment where material used to make the vaccine had been. The recall was a precautionary measure, and no contamination was found in the actual vaccine. Further, no reported adverse events following immunization appeared to be linked to the reasons for the recall.¹⁰³
- In December 2009, the Public Health Agency of Canada (PHAC) vaccine surveillance report indicated that seven confirmed cases of anaphylaxis following immunization with the Arepanrix (A/H1N1) vaccine from a specific lot number were reported. A total of 172,000 doses were distributed, but after placing its use on hold, over 14,700 doses were kept from use. With the doses not used being accounted for, the frequency of anaphylaxis following immunization with vaccines from the same lot was 4 per 100,000 doses distributed, which was higher when compared to the usual 0.1-1 per 100,000 doses. Pending further investigations, unused vaccines from this lot were withdrawn from use.¹⁰⁴
- In the US, between 2005 and 2008, there were several reports of Guillain-Barré syndrome (GBS) in adolescents after receiving the meningococcal vaccine, Menactra®. To investigate whether GBS was caused by the vaccine or whether it was coincidental, two large studies (involving 2 million vaccinated adolescents) were conducted. The results of these studies showed that there was no link between Menactra® and GBS.¹⁰⁵
- In 2003, the IMPACT (Immunization Program Monitoring Active) surveillance network detected a number of cases of vaccine-associated disseminated BCG mycobacterial infection. Eight of the nine cases identified were in First Nations, Metis, and Inuit (FNMI) children, and seven of those children had an underlying genetic immune deficiency. A national surveillance study helped to identify the frequency of severe combined immunodeficiency (SCID) in FNMI populations. This lead to a re-evaluation of routine BCG vaccination practices in First Nations and Inuit communities and also identified the need for SCID newborn screening in Canada.¹⁰⁶
- In 2000–2001, oculo-respiratory syndrome emerged in Canada following the receipt of influenza vaccine. The syndrome was characterized by a set of symptoms including red eyes, cough, and difficulty breathing. The symptoms were mild, and in most cases resolved within 48 hours. Following this detection, investigations took place to determine the cause. As a result, the vaccine manufacturing process was changed and the syndrome is now rare.¹⁰⁷

Causality

- It's often difficult to determine if an adverse event was caused by the vaccine, or by something else that happened around the same time the vaccine was given (such as an infection or onset of a chronic condition that would have occurred even if the person was not vaccinated).
- As a result, the details of all AEFI reports are carefully reviewed. Rates of adverse events in people who are vaccinated are compared to rates of the same events in people who are not vaccinated.
- This can help to determine if there is a true safety concern with the vaccine.
- Some types of events are further investigated to clarify the cause. For instance, people who have allergic reactions may be tested to find out which component of the vaccine caused the reaction.

7. Immunization when ill^B

Key messages for the public

- In general, minor or moderate illnesses (such as the common cold, ear infections, and gastrointestinal illness), with or without fever, are not a reason to delay vaccines.
- These illnesses do not interfere with the effectiveness of vaccines or increase the risk of vaccine side effects.
- Antibiotic and antiviral therapy is not a reason to delay most vaccines.
- Severe acute illnesses may be a reason to delay vaccines.

More information for health care providers

- Opportunities for immunization should not be lost because of unfounded concerns (a concern that is not a precaution or contraindication to the receipt of a vaccine).
- In general, people with minor or moderate acute illness (with or without fever) may receive vaccines. These illnesses do not:
 - interfere with the response to a vaccine, or
 - increase the risk of adverse events following immunization.
- The routine administration of recommended vaccines should not be postponed in persons with minor illness, such as an:
 - upper respiratory tract infection,
 - otitis media,
 - mild gastrointestinal illness, or
 - concurrent antibiotic therapy.
- Antibiotics have no effect on response to inactivated vaccines or live vaccines in Canada. Similarly, antivirals do not interfere with the immune response to inactivated vaccines. However, some antivirals may impair the immune response to certain live vaccines e.g., varicella and live attenuated influenza vaccine (LAIV).
- Severe acute illness may be a reason to defer immunization. The risks and benefits of vaccinating a severely ill person need to be carefully assessed (refer to the BCCDC Immunization Manual, Appendix C: Contraindications and Precautions for Immunization).

B Content in this section has been adapted from the Canadian Immunization Guide: Part 2 – Vaccine Safety - Contraindications, precautions and concerns⁹²

8. Natural immunity and alternatives to vaccines

Key messages for the public

- There are no safe and effective alternatives to vaccines.
- Vaccination is the very best way to protect yourself, your family, and your community from vaccine-preventable diseases and their serious consequences.
- Some people think natural infection (getting the disease) is better than getting the vaccine, but natural infection can seriously harm or kill a person. It's much safer to get the vaccine than to get the disease.
- A healthy lifestyle (for example, eating healthy and exercising) will support overall health and the immune system, but it will not protect against vaccine-preventable diseases. Even healthy people die from vaccine-preventable diseases.
- Homeopathic remedies, known as nosodes, do not prevent diseases and are not vaccine alternatives.¹⁰⁸
- Newborn infants get immunity to some vaccine-preventable diseases through the transfer of maternal antibodies across the placenta. However, this protection is dependent on what the mother is immune to and is temporary.¹⁰⁹ This is why vaccinating according to the recommended routine schedule is essential.
- Breastfeeding provides important protection against many diseases but breastfeeding alone does not provide sufficient protection against vaccine-preventable diseases. Breastfed infants should receive all routinely recommended vaccines on schedule.¹¹⁰

More information for health care providers

Natural infection

- Natural infection can cause serious harm. For example:
 - Meningococcal infection can cause deafness, loss of limbs, and brain damage.
 - Chickenpox can cause pneumonia and increases the risk of severe invasive group A streptococcal infection by 40- to 60-fold.¹¹¹
 - Pertussis can cause pneumonia, seizures, brain damage, or even death (these complications happen most often in infants less than one year of age).
 - Pneumococcal infection can cause serious and life-threatening infections such as meningitis, septicemia, and pneumonia.
 - Measles can cause pneumonia and encephalitis.

- Rotavirus can cause severe vomiting and diarrhea, which can result in dehydration and hospitalization.
- It's much safer to get the vaccine than to get the disease (refer to the "Vaccine side effects: vaccine risk versus disease risk" section for more information).
- Vaccination produces immunity, but without subjecting the recipient to the disease and its potential complications.
- Vaccines produce an immune response and immunological memory similar to that produced by the natural infection.¹¹²
- In some circumstances, natural infection may result in longer-lasting immunity than vaccination (which may require booster doses to provide long-lasting immunity). However, the protection from vaccines is typically sufficient and does not pose the same risks as contracting the disease.
- Some vaccines (e.g., tetanus and HPV) induce a better immune response than natural infection.¹¹³
- Even though an individual has had invasive pneumococcal disease (IPD), there are many different strains of pneumococcal bacteria to which they would be susceptible. Pneumococcal conjugate vaccines (PCV) and pneumococcal polysaccharide vaccines (PPV) provide protection against many strains.

Healthy lifestyle

- There are many benefits to a healthy lifestyle, but these benefits do not provide specific protection (i.e., humoral or cell-mediated immunity) against vaccine-preventable diseases.
- Even healthy people infected with vaccine-preventable diseases like influenza and meningococcal disease can become severely ill or even die.

Nosodes

- Nosodes are homeopathic remedies that were once marketed as alternatives to vaccines.
- Nosodes are not, and never have been, approved by Health Canada to be vaccine alternatives.¹⁰⁸
- There are no high-quality, well-designed studies proving that nosodes prevent disease.¹⁰⁸
- According to Health Canada, homeopathic products should not be promoted as an alternative to vaccines because there are no substitutes for vaccines.¹⁰⁸
- Health Canada requires that the labels on all homeopathic nosode products include the following statements to make it clear that they are neither vaccines nor vaccine alternatives:
 - "This product is neither a vaccine nor an alternative to vaccination."

- 
- “This product has not been proven to prevent infection.”
 - “Health Canada does not recommend its use in children and advises that your child receive all routine vaccinations.”¹⁰⁸
 - Children given nosodes instead of vaccinations are at risk of developing serious and potentially life-threatening diseases.

Protection from placental transfer of antibodies

- Maternal IgG antibodies are transferred across the placenta to the fetus during the final months of pregnancy.¹¹⁴
- These antibodies provide the infant with important protection against certain vaccine-preventable diseases early in life when they are most vulnerable.
- However, this protection is only temporary, which is why vaccination according to the recommended schedule is essential.
- Maternal IgG has a half-life of about 3–4 weeks in the newborn, waning during the first 6–12 months of life.¹¹⁰
- The level of protection the infant receives is dependent on maternal antibody concentrations and the protection provided against vaccine-preventable diseases is better for some than others.
- When given during pregnancy, the influenza and pertussis vaccines can boost maternal antibody levels, and thus the level of protection the infant will receive (refer to the “Vaccines and pregnancy” section for more information).¹¹⁰

Protection from breast milk

- Antibodies passed through breast milk (primarily IgA antibodies) provide important protection against a variety of diseases and infections such as asthma, ear infections, gastrointestinal infections, respiratory diseases, and diabetes.¹¹⁵
- However, the main source of protective antibodies against vaccine-preventable diseases is passive immunity achieved through placental antibody transfer of IgG antibodies (IgG antibodies are present at much lower quantities in breast milk).¹¹⁴
- Any protection against vaccine-preventable diseases through breastfeeding is limited.
- Breastfeeding alone does not provide sufficient protection against vaccine-preventable diseases, which is why it is essential that breastfed infants are vaccinated according to the recommended schedule.

9. HPV vaccine

Key messages for the public

- The HPV vaccine helps prevent several types of cancer.
- It protects against the types of HPV that cause most cervical cancers and some cancers of the anus, mouth and throat, penis, vagina, and vulva.
- It also protects against the types of HPV that cause most cases of genital warts.
- HPV is one of the most common sexually transmitted infections (STIs).¹¹⁶
- The HPV vaccine is routinely given at a young age because:
 - It provides a better immune response when given to preteens compared to older teens.¹¹⁶
 - It is best given before sexual activity (before exposure to HPV).
- There is no evidence that being vaccinated against HPV encourages earlier sexual activity.¹¹⁷
- The HPV vaccine is very safe and effective.¹¹⁶

Health care provider tip:

Give a strong recommendation. The strength of a health care provider's recommendation can greatly influence a person's decision to vaccinate their child or get vaccinated themselves.



More information for health care providers

HPV infection

- HPV is one of the most common sexually transmitted infections (STIs). About 75% of sexually active people will contract HPV at some point in their lives.¹¹⁶
- There are many different types of HPV.
- The types that cause genital warts are not the same as the types that cause cancer.
- Anyone who has any kind of sexual activity with another person involving oral, genital, or anal contact can get HPV. Sexual intercourse is not necessary to get infected.
- The more sexual partners you have, the higher the risk of being infected with HPV.
- Men who have sex with men are also at higher risk of HPV infection.
- Most people infected with HPV do not show any signs or symptoms and can pass the virus onto others without even knowing it.
- Most often an HPV infection will clear on its own. For some people, HPV will not go away and cells infected with the virus can become cancerous over time.

HPV vaccine timing

- HPV vaccines are ideally given between the ages of 9 and 14 for two reasons:
 - Research shows that preteens have a better immune response to the vaccine than older teens.¹¹⁶
 - The vaccine is best given before sexual activity (i.e., before any exposure to HPV).
- Most people become infected with HPV within 2-5 years of becoming sexually active, so it is important they get the vaccine before they begin sexual activity.
- While the HPV vaccine is best given before sexual activity, persons for whom the vaccine is recommended should still get the vaccine even if they are already sexually active. This is because they are unlikely to have been exposed to all the types of HPV contained in the vaccine.

HPV vaccine: 4 things you need to know

1

The HPV vaccine prevents several types of cancer.



The HPV vaccine protects against the types of HPV that cause most cervical cancers and some cancers of the anus, mouth and throat, penis, vagina, and vulva.

The vaccine also protects against the types of HPV that cause most genital warts.

2

The HPV vaccine is given at a young age for two reasons:



1. To protect children before they are ever exposed to the virus.
2. Preteens have a better immune response to the vaccine than older teens.

3

The HPV vaccine is very safe.



Vaccines are approved for use in Canada only if they meet very strict standards for safety and effectiveness.

Over hundreds of millions of doses of the HPV vaccine have been given safely worldwide.

4

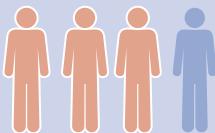
The HPV vaccine works very well.



A 2019 study showed that the HPV vaccine has cut pre-cervical cancer rates in B.C. by more than half.

Research has also shown that fewer teens are getting genital warts since HPV vaccines have been in use.

Did you know?



75%

of sexually active people will get HPV at some point in their lives.

HPV vaccine and sexual risk behaviours among teens

- There is no evidence that the HPV vaccine causes teens to engage in sexual activity at an earlier age, or of an association between the HPV vaccine and sexual risk behaviours among teens.
- A study published in 2018 in the Canadian Medical Association Journal used data from the BC Adolescent Health Survey (a survey administered in schools to capture adolescent physical and emotional health indicators) to conduct an analysis on sexual health behaviours and risk factors in adolescent girls before and after the implementation of BC's school-based HPV vaccine program. They found that since the implementation of the school-based program, sexual risk behaviours reported by adolescent girls either

decreased or stayed the same, providing evidence against any association between HPV vaccination and risky sexual behaviours.¹¹⁷

- A 2012 study published in Pediatrics compared the medical records of 493 girls who received the HPV vaccine and 905 who didn't. The study found no differences between the two groups in regard to incidence of pregnancies, tests for or diagnosis of sexually transmitted infections, and contraceptive counseling. Based on these results, the authors of the study concluded that "the HPV vaccine in the recommended ages was not associated with increased sexual activity-related outcomes."¹¹⁸
- The studies described above addressed sexual behaviors and sexual activity-related outcomes in girls as the initial HPV programs were girls only, prior to expanding to boys.

HPV vaccine effectiveness

- The HPV vaccine is highly effective. Studies in Canada, the United States, and other countries have shown that HPV vaccination is preventing cancer-causing infections, genital warts, and cervical pre-cancers.¹¹⁶
- A 2019 study showed that BC's school-based HPV immunization program has cut the rates of cervical pre-cancer (abnormal cells on the cervix that can lead to cancer) in women by more than half.¹¹⁹
- A 2018 modelling study published in The Lancet looked at cervical cancer elimination in Australia. Australia was one of the first countries to introduce a national HPV program, and it has achieved high vaccination coverage across both sexes. The projected timeframe predicted that cervical cancer could be eliminated in Australia within the next 20 years if high-coverage vaccination and screening is maintained.¹²⁰

HPV vaccine safety

- HPV vaccines are very safe. Vaccines are approved for use in Canada only if they meet strict standards for safety and effectiveness. The HPV vaccine was well studied in clinical trials and was approved once studies showed that it was safe and effective.
- Since vaccine licensure, hundreds of millions of doses of HPV vaccine have been given worldwide. Vaccine safety monitoring has continued to show that the HPV vaccine is safe.¹¹⁶
- Findings from more than 160 studies have shown that HPV vaccines are safe, and the body of scientific evidence overwhelmingly supports their safety.¹²¹
- Common reactions to the HPV vaccine are similar to reactions from other vaccines and include redness, swelling, and soreness in the arm where the vaccine was given. Fever, fatigue, headache, and muscle or joint ache may also occur. As with other vaccines, fainting has occurred following HPV vaccination. Fainting can occur with any medical procedure, not just the HPV vaccine, and people recover quickly.¹¹⁶

- Serious adverse events are rare following HPV immunization and, in most cases, when they are reported, there is insufficient data to support a causal association.¹¹⁶
- The vaccine safety profile of HPV vaccines has been reviewed by both the World Health Organization (WHO) Global Advisory Committee on Vaccine Safety and the USA National Academy of Sciences Institute of Medicine (IOM).
- Based on the IOM review, to date there has been no published evidence to support an association between HPV vaccine and any of the following conditions: Guillain-Barré syndrome, transverse myelitis, acute disseminated encephalomyelitis, multiple sclerosis, brachial neuritis, chronic inflammatory disseminated polyneuropathy, amyotrophic lateral sclerosis, neuromyelitis optica, pancreatitis, transient arthralgia, or thromboembolic events. There was also no evidence to support an association with chronic regional pain syndrome or postural orthostatic tachycardia syndrome.¹¹⁶
- Deaths following receipt of the HPV vaccine were observed in pre-licensure trials; however, they occurred no more frequently than in the placebo groups. AEFI reports have also included deaths, but the rate is no greater than what is expected to occur by chance alone.¹¹⁶
- The WHO Global Advisory Committee on Vaccine Safety did a systematic review of the literature on HPV vaccines and infertility. They concluded there is no evidence available to suggest that getting the HPV vaccine will affect future fertility. However, women who develop an HPV precancer or cancer could require treatment that would limit their ability to have children.¹²²

A story from Japan: Suspended recommendations for HPV vaccine to cause thousands of cancer deaths

In 2013, a cluster of adverse events suspected to be linked to the HPV vaccine were reported in the Japanese media. This prompted the Japanese government to suspend its proactive recommendations for the HPV vaccine. This was despite having no evidence to support a link between the cluster of adverse events and the vaccine—and an overwhelming amount of data supporting the safety of the vaccine.

A study published in *The Lancet Public Health* has concluded that in Japan, “The so-called vaccine crisis, which led to a rapid drop in HPV vaccination from over 70% uptake in 2013 to current rates of less than 1%, is estimated to be responsible for 5000–5700 cervical cancer deaths among girls born between 1994 and 2007 who missed vaccination. In addition, 24,600–27,300 preventable cervical cancer cases are estimated to occur in the same age group due to missed vaccination. Looking ahead, the study forecasts that for each year that the crisis continues, an additional 700–800 cervical cancer deaths could occur.”¹²³

Motivational interviewing example:

“Why does my child need the HPV vaccine when they are not sexually active?”

OARS

Skill	Example
O pen-ended questions	“What is your greatest concern about this?”
A ffirmations	“You are really trying to make sense of this.”
R eflections	Simple: “Your understanding is that kids who aren’t sexually active don’t need to be protected.” Complex: “You think that having the vaccine is like giving the green light to becoming sexually active.”
S ummaries	“You understand that the HPV vaccine provides the best protection before sexual activity and that the immune response is greater in preteens. Where does this leave you with your child getting the HPV vaccine today?”

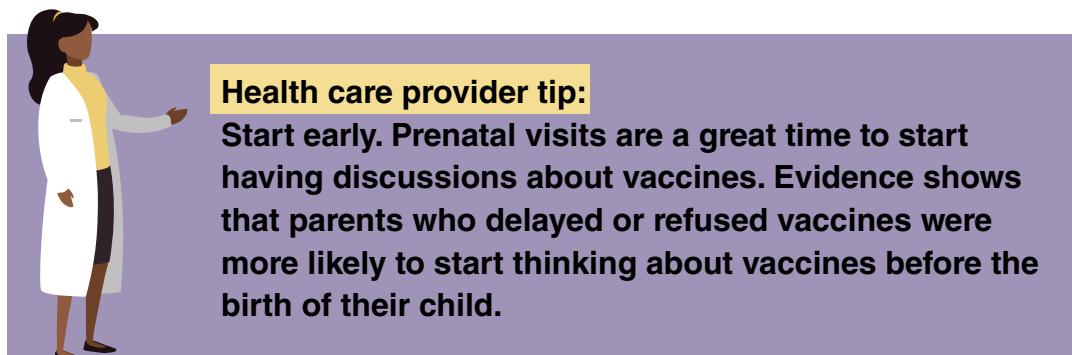
Ask-Provide-Verify

Ask-Provide-Verify	<p>Ask: “Can you tell me what you already know about the HPV vaccine?”</p> <p>Provide: “Can I share some information about why the timing of the HPV vaccine is important?”</p> <p><i>Parent agrees:</i> “There are two key reasons why the HPV vaccine is recommended when it is...”</p> <p>Verify: “Does this new information make sense?”</p>
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10. Vaccines and pregnancy

Key messages for the public

- Getting the recommended vaccines while you are pregnant is important for your health and the health of your baby.
- The influenza (flu) and pertussis (whooping cough) vaccines are recommended in every pregnancy.¹¹⁰
- When you get vaccinated during pregnancy, you help protect your baby from influenza and pertussis after birth by passing on antibodies. This helps protect your baby until they are old enough to get vaccinated.¹¹⁰
- Influenza is more dangerous for people who are pregnant and can lead to serious pregnancy complications, including risk of premature labour and delivery.¹¹⁰
- Pertussis can be life-threatening for babies.
- Getting the influenza and pertussis vaccines during pregnancy is safe and helps prevent harm to you and your baby.¹¹⁰



Vaccination during pregnancy provides important protection

Influenza vaccine

Influenza (flu) vaccination during pregnancy lowers the risk of influenza hospitalization in:

Pregnant people by about 40%

40%



Babies less than 6 months old by about 72%

72%

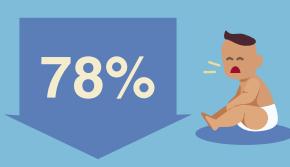


Pertussis vaccine

Pertussis vaccination during pregnancy lowers the risk of:

Pertussis in babies less than 2 months old by 78%

78%



Hospitalization due to pertussis in babies less than 2 months old by 91%

91%



More information for health care providers

Vaccines before pregnancy:

- All routine vaccines should be up to date before pregnancy. This is important because some vaccines cannot be given during pregnancy but provide important protection for the pregnant person and their newborn. For example, the measles, mumps, rubella (MMR) vaccine should not be given during pregnancy (and must be given at least four weeks before becoming pregnant), but rubella infection during pregnancy can cause miscarriage and serious birth defects.¹¹⁰
- Newborn infants get temporary immunity to certain vaccine-preventable diseases for which the pregnant person is immune through the transfer of maternal antibodies across the placenta. This transfer of antibodies can help protect the infant during the first few months of life when they are most vulnerable.¹¹⁰

Vaccines during pregnancy:

Influenza vaccine

- It is recommended that all people at any stage of pregnancy get an inactivated influenza vaccine during each pregnancy.¹¹⁰
- Changes in the immune system, heart, and lungs during pregnancy make a person more prone to severe illness and hospitalization from the flu.
- There is evidence that infants born to recipients of influenza vaccine during pregnancy are less likely to be premature, small for gestational age, or of low birth weight. In addition, influenza vaccination in pregnancy decreases risk of stillbirth and protects newborns from influenza and influenza-related hospitalizations.¹¹⁰

Safety and effectiveness of influenza vaccines during pregnancy

- Results from multiple studies have concluded the influenza vaccine is safe and effective for pregnant people and their infants.¹¹⁰
- A 2018 study showed that getting an influenza vaccine reduced a pregnant person's risk of being hospitalized with influenza by about 40%.¹²⁴
- A 2014 study concluded that influenza vaccination reduced the risk of acute respiratory infection associated with lab-confirmed influenza among pregnant people by about one half.¹²⁵
- Evidence shows that infants born during the influenza season to people vaccinated during pregnancy are less likely to be premature, small for gestational age, or of low birth weight.¹¹⁰
- Vaccination of pregnant people protects their newborns from influenza and influenza-related hospitalization through placental transfer of antibodies.

- A 2016 study showed that influenza vaccination during pregnancy reduced the risk of an infant getting lab-confirmed influenza by about 70%.¹²⁶
- Influenza vaccination in pregnant people reduces the risk of hospitalization due to influenza in their infants younger than six months old by an average of 72%.¹²⁷
- There is good evidence that vaccination with the inactivated influenza vaccine during pregnancy is safe.¹¹⁰
- Active surveillance following influenza vaccination during pregnancy has not shown evidence of harm to pregnant people or their fetuses. While the cumulative sample size of these studies is relatively small, especially for the first trimester, passive surveillance has not raised any safety concerns, despite widespread use of the influenza vaccine in pregnant people over several decades.⁸¹
- Surveillance following the use of the 2009 pandemic H1N1 influenza vaccine in hundreds of thousands of pregnant people (more than 100,000 in Canada and almost 500,000 in Europe) did not reveal any safety concerns.⁸¹
- Research studies have never proven a cause and effect relationship between the influenza vaccine and miscarriage. A 2013 study showed no link between miscarriage rates and influenza vaccination in pregnancy.¹²⁸
- A 2017 study found no increased risk between influenza vaccination in pregnancy and birth defects in infants.¹²⁹
- Canada's National Advisory Committee on Immunization (NACI) has concluded that vaccines that contain thimerosal (now only in multi-dose vials of influenza vaccine) are safe in pregnancy and should be used if indicated.¹¹⁰

Pertussis vaccine

- It is recommended that all pregnant people should be given a tetanus, diphtheria, pertussis (Tdap) vaccine during every pregnancy, irrespective of their Tdap immunization history.¹¹⁰

Safety and effectiveness of the Tdap vaccine during pregnancy

- Multiple studies have been done on the Tdap vaccine and have concluded that it is safe and effective for pregnant people and their developing babies.¹³⁰
- The Tdap vaccine should ideally be provided between 27 and 32 weeks of gestation. This allows time for the passage of the protective antibodies to the fetus. However, the vaccine may be given earlier and can be provided up until delivery.¹¹⁰
- High levels of antibody are transferred to the fetus, protecting the newborn from pertussis during the first two months of life when the morbidity and mortality from pertussis infection is highest.¹³¹
- Tdap immunization in pregnancy is estimated to protect approximately 90% of infants less than three months of age.¹³¹

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- A 2017 USA CDC evaluation found Tdap vaccination during the third trimester of pregnancy lowers the risk of pertussis in infants less than two months old by 78% and the risk of hospitalization by 91%.¹³²
 - A 2016 literature review of 59 studies on the immunogenicity, safety, and effectiveness of Tdap administration in pregnancy provided good evidence that routine Tdap immunization programs during pregnancy are a safe and effective way to protect infants less than one year of age from severe outcomes of pertussis infection.¹³³

Other vaccines

- In certain situations, other vaccines may be recommended during pregnancy. For more information, refer to Canadian Immunization Guide, Part 3: Vaccination of Specific Populations.

Safety of other vaccines during pregnancy

- Inactivated vaccines are generally considered safe in pregnancy.¹¹⁰
- The HPV vaccine should not be given during pregnancy because data on efficacy and safety of HPV vaccination in pregnancy are limited.¹¹⁰
- In general, live vaccines are contraindicated in pregnancy, as there is a theoretical risk to the fetus.¹¹⁰
- There are no data to indicate that any of the currently approved vaccines are teratogenic or embryotoxic, or have resulted in specific adverse pregnancy outcomes.¹¹⁰

Vaccines after pregnancy

- If a pregnant person misses getting recommended vaccines before or during pregnancy, it is important they get them as soon as possible after their infant is born.

Vaccines and breastfeeding

- In general, routinely recommended vaccines are safe for breastfeeding people and their infants. Data on the effects of immunization of breastfeeding people on their infants are limited; however, no adverse events related to the administration of routine vaccines in breastfeeding people have been reported.¹¹⁰
- Some less common vaccines, such as the yellow fever vaccine, should not be given while breastfeeding.¹¹⁰
- There is no evidence that immunization during breastfeeding will adversely influence the immune response of the breastfeeding person or their infant.¹¹⁰

Appendix A: Motivational interviewing and vaccine hesitancy

Motivational interviewing (MI) is “a collaborative, goal-oriented style of communication with particular attention to the language of change. Its aim is to strengthen a person’s own motivation and commitment to their goals by eliciting and exploring their own reasons for change within an atmosphere of acceptance and compassion.”¹⁵

MI has been shown to be effective at addressing vaccine hesitancy and increasing vaccine acceptance.¹⁷ When a person presents to a health care professional and feels ambivalent about whether to move forward with immunization (is vaccine-hesitant), an MI conversation is encouraged. MI is less about the health care provider talking to a person about vaccines and more about the health care provider listening and working with the person. It considers the person’s level of knowledge and specific needs while respectfully accepting their beliefs. MI helps to build a trusting relationship that allows for collaborative discussions about vaccines.

MI is based on three main components:

- the spirit of MI: compassion, acceptance, partnership, and evocation (CAPE), which is the foundation for every MI conversation and conveys a way of being that facilitates the evolution of a trusting relationship;¹⁵
- the four MI processes (engaging, focusing, evoking, and planning), which work together to help the individual define their goal of change and move towards it;¹⁵ and
- the foundational MI skills—Open-ended questions, Affirmations, Reflections, and Summaries (OARS) and Elicit-Provide-Elicit (Ask-Provide-Verify)—enable health care providers to understand and address an individual’s concerns.¹⁵

These three components are described in greater detail in the graphic on the next page.

MI is complex and it is recognized that many health care providers will not have received formal MI training. It is also recognized that a full MI approach (which can take multiple hours or visits) may not be feasible in the context of a routine immunization appointment. In these cases, a “mini” MI approach is encouraged. Mini MI involves using all the components of MI, but not to the same depth or level of detail as would be used in a full MI approach.

MI training for health care providers

Health care providers can access a quick MI training as part of the WHO health worker training module: [Conversations to build trust in vaccination](#).

Formal MI training in British Columbia is available through the Centre for Collaboration, Motivation and Innovation (CCMI): <https://centrecmi.ca/motivational-interviewing>.

Health care providers can also consider reading Miller and Rollnick's 3rd edition of *Motivational Interviewing: Helping People Change*.

► THE SPIRIT OF MI (CAPE)

Compassion

Caring about what is important to another person and feeling moved to help.

Acceptance

Respecting another person and their right to change or not change.

Partnership

Working together with another person and recognizing them as equal.

Evocation

Bringing out another person's ideas, strengths, and knowledge about the situation and themselves.
This can include encouraging to explore.

► THE 4 PROCESSES

Engaging

The process of building and supporting a relationship where trust and respect go both ways.

Focusing

The ongoing process of choosing and keeping a specific direction.

Evoking

Bringing out another's strengths, knowledge, and ideas about the situation and themselves.
This can include encouraging to explore.

Planning

Being with someone while they form specific actions to take.

► THE SKILLS OF MI (OARS + Ask-Provide-Verify)

Open-Ended Questions

Questions that don't result in "yes" or "no" answers.

example

"What do you think about vaccines?"

Affirmations

Validate strengths, efforts, and accomplishments.

example

"You are great at seeking out information."

Reflections

Encourage deeper consideration or meaning.

example

"You're worried about vaccines overwhelming your child's immune system."

Summaries

Ensure clear communication.

Ask

Ask what the person already knows.

example

"Can you tell me what you already know about the immune system and vaccines?"

Provide

Provide information.

example

"Your baby's immune system is amazing and can safely handle multiple vaccines given at the same time..."

Verify

Verify understanding of the information.

example

"Does this information make sense?"

Source: Definitions of the Spirit of MI and The 4 Processes are from the Centre for Collaboration Motivation & Innovation (CCMI) adapted from Miller W, Rollnick S. Motivational Interviewing: Helping people change. 3rd ed. New York: Guilford Press; 2012.

Appendix B: Websites with immunization stories

As a health care provider, sharing your story about why you chose to vaccinate or sharing a story about a vaccine-preventable disease strengthens your vaccine recommendation. Many people won't remember a statistic, but they will remember a story.³⁰

If you do not have a story of your own to share, you can find real stories on the websites below. These websites contain stories shared by health care providers and the public about the devastating effects of vaccine-preventable diseases and why they think vaccines are important. Some of the websites, including I Boost Immunity, also provide an opportunity for health care providers and the public to share their own real-life stories to help spread the word about the importance of vaccines.

Canada

ImmunizeBC: immunizebc.ca

I Boost Immunity: iboostimmunity.com/resources/stories

USA

Voices for Vaccines: voicesforvaccines.org/gallery

Immunization Action Coalition: immunize.org/reports

Vaccine Education Center: chop.edu/centers-programs/parents-pack/personal-stories

Families Fighting Flu: familiesfightingflu.org/family-stories

National Meningitis Association: nmaus.org/nma-stories

Parents of Kids with Infectious Diseases: pkids.org

National Foundation for Infectious Diseases: nfid.org/category/real-stories-real-people

Vaccinate Your Family: vaccinateyourfamily.org/why-vaccinate/personal-stories

Shot by Shot: shotbyshot.org/story-gallery

Appendix C: Reducing immunization injection pain

Fear of pain with immunization and fear of needles have been identified as important drivers of vaccine hesitancy or refusal in different studies.²⁶ Research has shown that parents are more comfortable with and more accepting of their baby's vaccinations when pain is controlled.²⁷ However, the fear of immunization pain and distress felt by many parents is often overlooked by health care providers. It is important that health care providers address pain head-on and provide evidence-based strategies for reducing immunization injection pain. Links to reducing immunization injection pain guidelines are included below.

Reducing immunization injection pain guidelines

BC Centre for Disease Control Immunization Manual, Appendix D: Reducing immunization injection pain:

bccdc.ca/health-professionals/clinical-resources/communicable-disease-control-manual/immunization

Reducing pain during vaccine injections: clinical practice guideline: cmaj.ca/content/187/13/975

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