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# **Immunity**

Our body helps us stay healthy. Our immune system defends our body from diseases. Infectious diseases are caused by germs, like bacteria and viruses, and can spread from one person to another. Diseases enter our body through antigens.

The cells in our immune system identify the antigen as a foreign substance.

Our immune system sends white blood cells to find the diseased cells and to produce antibodies against the disease. Two types of antibodies are produced. The first, fights off the disease and the second, creates memory cells that continue to circulate in our body and will recognize the disease in the future. That way if the disease invades our bodies again our immune system will recognize it and kill it faster.

We have three types of immunity:

- 1. **Innate or Natural:** the body we are born with has things to protect us; for example, our skin. It also has immune cells that immediately recognize and respond to anything foreign, but do not produce antibodies.
- 2. **Active:** develops throughout our lives when we are exposed to diseases directly or through vaccination. These cells develop and produce antibodies.
- 3. **Passive:** is "borrowed" immunity and lasts a short time; for example, antibodies in breast milk give a baby temporary immunity to diseases the parent has had.







# **Immune Health**

A strong immune system helps you to cope with infectious diseases. Some ways to boost your natural immune system are:

- Eating healthy when possible
- Considering taking vitamin supplements, if you can't get adequate nutrition through your diet, and your care provider recommends them
- Staying active, exercising regularly, and maintaining a healthy weight
- Addressing stress and maintaining good mental health. Mental health affects how we think, feel, and act.

Public health is the health of a population as a whole. Public health measures, such as clean water and immunization improve the quality and length of your life. Governments play an important role in supporting health. Canada has national, provincial, territorial, and municipal public health agencies responsible to implement measures that support public health.

Indigenous health care services in Canada are made up of a complicated patchwork of policies, legislation and agreements that assign responsibility to federal, provincial, municipal, and Indigenous governments in different ways in different parts of the country. For most off-reserve status and non-status Indigenous peoples, public health care services are financed by the national health insurance plan and administered through provincial or territorial governments. For on-reserve communities the federal government finances and administers public health services through Indigenous Services Canada (ISC). Individual communities have negotiated to transfer varying levels of health care responsibility to the community or council level.

Social determinants of health, like access to health care, a clean physical environment, or a good income, also affect health quality. Right now, Indigenous, Black, and racialized peoples live within a social context that creates more health challenges than for other people in Canada. For example, Indigenous, Black, and other racialized peoples cannot currently access all the same public health measures as other Canadians.

Indigenous, Black, and racialized peoples experience more illness and more severe illness than other people in Canada. They are more likely get an infectious disease and more likely to have more complications, more severe complications, and deaths from infectious diseases than non-Indigenous peoples. For example, right now, tuberculosis (TB) rates are 300 times higher in some Inuit communities than in other communities in Canada.







## **Immune Health and Wellness**

A strong immune system helps you to cope well with infectious diseases. Some ways to boost your natural immune system are:

- Eating healthy when possible
- Considering taking vitamin supplements, if you cannot get adequate nutrition through your diet, and your care provider recommends them
- Staying active, exercising regularly, and maintaining a healthy weight
- Addressing stress and maintaining good mental health. Mental health affects how we think, feel, and act
- Nourishing spirit

Prior to colonization, the health of many Indigenous people was protected by an active lifestyle, a sense of belonging, customary laws, language and strong families and community. Access to traditional foods, plant medicine, ceremonies, Elders and healers, and a connection to the land contributed to Indigenous health and well-being.

Many Indigenous communities are working to reclaim these protections. Below are tips and tools that some communities are accessing to support health and wellness.

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Many Indigenous peoples have inadequate access to public health services. There may also be factors that negatively affect health, such as lack of access to clean water. Indigenous peoples are therefore at higher risk of getting, having more serious complications, and dying from infectious diseases than non-indigenous people.

For example, right now, tuberculosis (TB) rates are 300 times higher in some Inuit communities compared to communities in the rest of Canada.







# Infectious disease and Indigenous history

Starting from 1492, contact with Europeans brought new infectious diseases, like smallpox, the flu, measles, whopping cough and, later, tuberculosis and sexually transmitted infections. The time period in the 15th and 16th centuries is often called "The Great Dying". During this time, up to 90% (approximately 50 million) of the Indigenous population of the Americas died, in most part due to these new diseases. Indigenous peoples had never encountered these diseases before and did not have the antibodies to the infection. As Western medical advances were made, Indigenous people did not have the same access to medical care including vaccines.

Lack of access to basic medical care has played a role in the high rates of infectious diseases and death rates in Indigenous populations. Infectious disease and ill-health were also used as tools of colonization for the intentional assimilation and attempted eradication of Indigenous people in Canada. From the 1930s to 1980s, residential schools used children for nutrition and surgical experiments. In the '30s and '40s Indigenous peoples were severely affected by tuberculosis, partly because they were malnourished and experienced horrible conditions in residential schools and lived on overcrowded reserves. The death rate from that time is the highest ever reported in humans.

Many people with tuberculosis were put in separate "Indian Hospitals" far from home. There they suffered physical and sexual assaults, were deprived of food and drink, and used in unethical medical experiments including for vaccines. Due to the intentional experimentation on Indigenous peoples and the resulting traumas, many Indigenous peoples today lack trust in public health agencies, the medical community and health care providers.







## **Vaccine Benefits**

Before vaccines started being used there was a large decline in child mortality in industrialized countries from the end of the 19<sup>th</sup> century onwards owing largely to a reduction in mortality from infectious diseases associated with improvements in housing, nutrition, clean water and sanitation.

Having said that, immunization has made one of the greatest contributions to global human health, especially in the developing world. Vaccines currently prevent about 6 million deaths worldwide every year

Over the past 50 years, immunization has led to the elimination, containment and control of diseases that were once very common in Canada. Today, although these disease-causing bacteria and viruses still exist, such diseases, and their consequences for health, are rarely seen in Canada.

If the current vaccination programs were reduced or stopped, diseases controlled through immunization would re-appear in Canada.

# **Herd Immunity**

Infectious diseases are controlled, in part, from herd, or community immunity. Herd immunity happens when so many people in a community become immune to an infectious disease that it stops the disease from spreading. Typically, 80 to 95% of a population needs to be immune to a disease to stop its spread.

When a large percentage of a population becomes immune to a disease, the spread of that disease slows down or stops. Many viral and bacterial infections spread from person to person. This chain is broken when most people do not get or transmit the infection. This helps protect people who are not vaccinated or who have low functioning immune systems and may develop an infection more easily, such as pregnant people and babies.







# **Rights**

Vaccines are not mandatory in Canada, meaning your consent, is required to administer a vaccine. In British Columbia, school-aged children students are required to provide immunization records. This regulation does not currently apply to students who attend schools in First Nations communities. In New Brunswick and Ontario, proof of immunization is required for children and teenagers to attend school. In these same provinces, exemptions for medical or social conscience or religious reasons are available.

## **Informed Choice**

Canadian and Indigenous midwives are guided by a principle called Informed Choice. This means the midwife is responsible for giving all the available information about an intervention, treatment or test – what it is, the benefits (how it is meant to help), the risks (how it might hurt), implications for others (or, how it might affect your community), current scientific evidence, possible treatments, community standards (what is normally done) and what your options are. In collaboration with their midwives, clients have final decision-making authority. Informed choice also means you can take time to ask questions, reflect, seek guidance from trusted family and friends, healers and elders and work with your midwife to make a final decision.

### **Informed Consent**

All Canadians have "the right to information on risks associated with a medical intervention and the right to be free from unwanted physical interference". This means it is your right to know the possible risks associated with a medical intervention and it is your right to decline the intervention. Each province and territory have legal guidelines about informed consent.

Vaccination is offered as part of pregnancy, postpartum and newborn care. It is an intervention intended to help you or your baby. It has benefits and risks. It requires your informed consent. Your midwife can offer an informed choice discussion on the topic.

If you find yourself in a position where a healthcare provider refuses to be your care provider because you decline a vaccine, you can submit a report to their provincial College for help finding a resolution.







# **Disease and Vaccine**

### What is an Infectious disease?

Infectious diseases are spread between people by germs, like bacteria and viruses. Germs are a normal part of our environment and our bodies get both sick and stronger every time they encounter them.

There are many kinds of Infectious diseases that have different histories for different people in different places and times, including today.

"Immune" means that you cannot get the disease again. Some people get immune to an infectious disease by getting sick and fighting the illness. This kind of immunity can last a lifetime for some diseases, like measles, or it can be short-lived, like for the flu. Another way people become immune to a disease is through vaccination. This kind of immunity might decrease after a while which is why people need to get booster shots.

The infectious diseases we talk the most about in pregnancy, postpartum and the newborn period are pertussis, (whooping cough) and Influenza (the flu). Rubella, Hepatitis A, B or C, Varicella (chickenpox), Tuberculosis or travel diseases can also be discussed

#### What is a Vaccine?

**Vaccines** are products that produce immunity to a specific disease. When you are immune to a disease, you can be exposed to it without becoming sick. Most vaccines are given by injection needle, but some are given by mouth or sprayed into the nose.

## There are several different kinds of vaccines. Two main types are

- Live or Cellular (or attenuated or whole) vaccines

  Contain a weakened live germ and are the most likely to create immunity that will last a lifetime.
- Inactivated or Acellular (or killed) vaccines
   Contain a killed germ or part of a germ. They do not usually create immunity that lasts a lifetime so extra, or booster, vaccines are needed

Vaccines contain trace amounts of other specific ingredients (also called components). Some of these ingredients help boost the effectiveness of the vaccine, and others help to keep the vaccine stable during transport and storage. Vaccines contained in multi-dose vials need a preservative to prevent germs from growing in the vial after the first dose has been removed. The preservative thimerosal is no longer used in routine childhood vaccines in Canada, except for influenza vaccines produced in multi-dose vials.

Theoretically, the live germ in a vaccine given in pregnancy can cross the placenta and cause infection of the fetus. We do not have evidence about this either way, so to be safe live vaccines are not recommended in pregnancy. If someone does receive a live vaccine in pregnancy. It is not considered a reason to end the pregnancy. It is considered safe to get any kind of vaccine when breast/chest feeding.







# **Contraindications**

In Canada, someone should NOT get a vaccine if they have had an anaphylactic reaction to the same vaccine or to a vaccine component. An exception is anaphylactic (allergic) reactions to eggs. Some flu vaccines contain trace amounts of egg protein. Studies have shown this does not seem to increase the risk of allergic reactions even in people who have had anaphylactic reactions to eggs.

Pregnant people and people who are immunocompromised should not receive live vaccines. Some flu vaccines contain trace amounts of gentamicin and polymycin/neomycin. Someone who has a severe allergy to these ingredients should not have these vaccines.

There is a higher rate among Indigenous peoples than other people in Canada. In some communities, the Bacille Calmette-Guérin (BCG) vaccine is given at birth to protect newborns against TB. BCG vaccination should not be given to persons who are immunocompromised, and it should not be given during pregnancy. Even though no harmful effects of BCG vaccination on the fetus have been observed, further studies are needed to prove its safety. There is screening to ensure the vaccine will be safe for the person receiving it.

# **Vaccine Components or Ingredients**

The main ingredients in all vaccines are the antigens that trigger the body's immune system to identify and attack those types of disease cells. They cannot cause the disease itself. Vaccines also contain small amounts of other ingredients. Each ingredient serves a specific purpose.

# Formaldehyde

Formaldehyde is used in some vaccines to kill or disable the germs. We make formaldehyde in our bodies. The amount of formaldehyde naturally found in an infant's body is about 10 times more than in one vaccine.

# **Thimerosal**

Thimerosal is a preservative that contains ethylmercury

Thimerosol has been used in vaccines in small amounts since the 1930s. In 2001, Canada removed thimerosal from childhood vaccines except some flu vaccines. This was done to reduce mercury in kids before there were studies that proved it was not harmful.

Ethylmercury is not the same kind of mercury that has contaminated Indigenous lands.

The Inactivated flu vaccine used in pregnancy contains thimerosal. The National Advisory Committee on Immunization (NACI) in Canada has concluded it is safe for pregnancy.







#### **Aluminum Salts**

Adjuvants are substances added to some vaccines to strengthen the body's immune response to the germ cells. Aluminum is an adjuvant used in some inactivated flu vaccines, like the one offered in pregnancy.

Aluminum is found everywhere in nature. There is less aluminum in vaccines than in breast milk or infant formula. Many studies have shown that the amount of aluminum in vaccines is so small it cannot cause harm and that the benefits of using vaccines with aluminum outweigh the possible risks.

Some researchers, health care providers and members of the general public are concerned about the safety of aluminum in vaccines partly because aluminum can cross the blood brain barrier. It is difficult to prove if aluminum in vaccines can or cannot cause neurological problems.

In 2012, the Global Advisory Committee on Vaccine Safety, a group of experts brought together by the World Health organization (WHO), reviewed the safety of aluminum salts in vaccines and the safety of inactivated flu vaccines in pregnancy and concluded both were safe. Based on available evidence, the National Advisory Committee on Immunization (NACI) considers aluminum adjuvants in vaccines safe.

## Vaccines and autism

Some people have concerns that Autism Spectrum Disorder (ASD) might be linked to the vaccine's children receive.

In 1998, a study done by a British doctor, Andrew Wakefield, claimed that the measles, mumps, rubella (MMR) vaccine caused autism in young children. He was producing his own MMR vaccine. It was later found he falsified the data . from his study and the study was retracted by The Lancet, the journal that published the study. Since then, many larger studies have explored the same topic and have proven that there is no difference in the rate of autism between children with the vaccine and children without it.

No links between any vaccine components and ASD have been proven.

# **Product Labels or Monographs**

A vaccine is tested by its manufacturer before being made available to the public. The information from those tests are described in the vaccine monograph. The monograph includes results of the animal studies and clinical trials used to test the vaccine, the vaccine components, the recommended dose and how the vaccine should be given. The information in the monograph is not always up to date. Manufacturers can only include the results from their pre-use studies so if there are studies of a vaccine after it has been implemented for general use that information will not be included in the vaccine monograph.







# **Adverse Events After Immunization (AEFIs)**

Vaccines can cause side effects and reactions, also called adverse events.

After being vaccinated, it is common to have mild side effects that do not last very long. Common vaccine side effects may include:

- a low fever
- stiffness, slight swelling, and soreness where the needle went in

Rarely, some people have allergic reactions to vaccines. Allergic reactions usually happen shortly after the vaccine is given so your healthcare provider will ask you to stay for 15 to 20 minutes after vaccination.

Signs of a serious allergic reaction to a vaccine include:

- swelling of the face
- breathing problems (wheezing)
- blotchy skin on the body (hives)

A very rare, or serious adverse event (SAE) is an anaphylactic allergic reaction. This occurs to 1 in 1,000,000 people, or 0.0001% of the time someone gets a vaccine. It is more likely someone will experience an allergic reaction after eating food than after receiving a vaccine. It is estimated that 3,500 Canadians experience anaphylactic shock each year from eating the wrong foods. Of those 3,500, about a dozen will die, or 0.34% of the time someone eats the wrong food. If someone has an allergic reaction after vaccination, medication can be given to stop the reaction and prevent death from the reaction.

Side effects, reactions and adverse events are categorized in part by how frequently they occur. Side effects and AEFIs can be vaccine product specific.







# Common categories of vaccine side effects, reactions, and adverse events

Туре	Frequency	
Common	Occurring in 1% to 10% of people	Anxiety
	(1-10/100)	Fainting
		Hyperventilation
		Reactions where you get the
		needle:
		→ Redness
		→ Swelling
		→ Muscle pain
		→ Joint stiffness
		Fatigue
		Pain
		Headache
		Chills
		Fever
		Nodule*
Rare, or AEFI	Occurring in less than 0.01% of	Extensive pain and swelling at
	people (less than 1/10,000)	injection site
		Guillain-Barre Syndrome*
		Allergic reactions:
		→ Hives
		→ Swelling of deep layers
		of the skin
		$ ightarrow$ Swelling and pus $^*$
		→ Allergy-induced Asthma
Serious Adverse Event (SAE)	Occurring in 0.0001% of people	Anything life-threatening
	(1/1,000,000)	and/or needs hospitalization,
		lengthens a hospitalization, or
		causes permanent disability or
		death
		Anaphylaxis
		Ocular-respiratory Syndrome
		(ORS)*

<sup>\*</sup>Nodules and abscesses at the injection site are most often related to improper vaccine administration.

<sup>\*</sup>ORS includes eye infections, swelling in the face and mild respiratory symptoms. From the early to mid-2000s it occurred 76 times out of 1,000,000 vaccines.





<sup>\*</sup>Guillain-Barre syndrome is a rare disorder in which your body's immune system attacks your nerves and can cause paralysis (which is usually temporary). It is a medical emergency.



### Surveillance

The Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) is a joint provincial/territorial/federal reporting system to track, assess. prevent and communicate about AEFIs.

# **Reporting AEFis**

The Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) tracks AEFIs. Anyone can make a report.

The Canada Vigilance Program (CVP) is how Health Canada collects and assesses reports of suspected AEFIs to health products, including vaccines. Anyone can anonymously make a report. The Immunization Monitoring Program ACTive (IMPACT) uses specially trained nurses to look through all pediatric (child) hospital admissions for selected, or specific, AEFIs.

## After an AEFI

After an AEFI is reported it must be determined what caused it and if further vaccines should be done.

The Canadian Immunization Research Network (CIRN) has 13 special immunization clinics (SICs) for people who have experienced an AEFI or have a condition that may put them at higher risk of an AEFI. These cases are tracked and reviewed. It is challenging to know if an adverse event is caused by a vaccine or just related in time to a vaccine (that is, it occurred after vaccination, but may not be related to the vaccine).

## **Vaccine Safety**

The World Health organization (WHO) and the Public Health Agency of Canada (PHAC) state that vaccines are safe.

# Testing, approval, and monitoring

Vaccine testing begins in a laboratory. If lab studies show that a vaccine has potential, it is usually then tested in animals.

If the vaccine is shown to be safe in animals, studies in people (called clinical trials) are next. People taking part in these studies are volunteers and are informed about the possible side effects. There are three phases (stages) of studies in people. The first phase starts with very few people; by the third phase hundreds or even thousands of people will be included.

If a vaccine is being developed for children, it is usually tested on adults first. When the clinical trials are completed, the vaccine must meet Canadian licensing standards In Canada, the <u>Biologics and Genetic Therapies Directorate (BGTD)</u>, which is part of Health Canada, approves vaccines for use. The BGTD also supervises all aspects of vaccine production and quality control throughout its lifecycle. This includes monitoring for AEFIs.







# Safety studies

The ideal scientific method for testing something is called a randomized control trial (RCT). A RCT has two groups of people – the group who gets a vaccine and the group who doesn't. A blinded RCT is when no one – not the participants nor the researchers – knows which group they are in. The numbers of what happens in each group are counted and compared then everyone finds out who was in what group.

Observational studies look at what happens with vaccination after it has been approved for use. Cohort studies compare children before and after they are vaccinated after they have been approved for use. If there is a disease outbreak, case-control studies look at vaccinated and unvaccinated children to see who was more likely to get sick.

# **Vaccine safety in pregnancy**

The World Health Organization says it can be hard to assess the safety of vaccination in pregnancy. Some reasons are:

- Pregnant people are not usually included in RCTs
- It is difficult to separate the general risks of pregnancy from the risks with a vaccine.
- There are so many factors leading to an AEFI, it is difficult to know what causes it.
- Rare side effects (less than 1 person in 10,000 exposures) are hard to pick up before a vaccine is approved because there might not have been 10,000 people or more who got the vaccine during the clinical testing. 10,000 exposures is the number you need to detect rare events.







# Pertussis (whooping cough) and the Tdap (Tetanus, Diphtheria and Pertussis) Vaccine

### Recommendations

Offer the Tdap vaccine to all pregnant people during the second or third trimester, preferably between 21 and 32 weeks of pregnancy, during every pregnancy, even if they had the vaccine before.

Household members of pregnant people should also be vaccinated against pertussis.

## **Pertussis**

Pertussis is caused by bacteria and infects the lungs and airways. It usually starts like a cold then a cough that gets worse until people can have bursts of extreme, fast coughing and make a "whoop" sound when they breathe in. Sometimes the coughing is severe enough to cause choking and vomiting. Symptoms usually lasts about 1-6 weeks but can take many more weeks or months longer to go away.

In babies there might not be a whoop cough, but they sometimes temporarily stop breathing (apnea). Rarely, pertussis can cause brain damage or even death. It is most dangerous for unvaccinated children under 1 year of age.

## **Transmission**

Pertussis spreads through droplets in the air from coughing or sneezing. It is most contagious in the first 10 days after infection when people might just have a runny nose and during the two weeks after coughing starts. People are no longer contagious after 5 days of antibiotics.

Family members are the most likely people to pass it on to babies.

#### Incidence

Worldwide, there are about 20 to 40 million cases or pertussis. Each year in Canada between 1,000 and 3,000 people get sick from pertussis (or about 0.005% of the Canadian population). This may be an underestimate because many older people are not tested for pertussis.

There are cyclical outbreaks of the disease about every 2-5 years. During low transmission periods the incidence is about 2 cases per 100 000 people. During outbreaks between 2010 and 2014, it reached 13.9 per 100,000 people or a bit less than 5000 cases.

Between 2006 to 2015, the highest rate of pertussis cases was among unvaccinated babies less than 1 year of age at 71.2 cases for every 100,000 people.







After the 2010-2014 outbreak, Canada's National Advisory Council of Immunization (NACI) recommended for Tdap in pregnancy during outbreaks and if the pregnant person had not been immunized in adulthood. In 2018 the NACI changed the recommendation to routine Tdap vaccination in pregnancy regardless of previous immunization history or outbreaks.

Researchers are not completely sure why we've had pertussis outbreaks but have proposed the following reasons:

- waning immunity (immunity lessens over time after vaccination and fewer people have natural, or lifelong immunity)
- the vaccine is not 100% effective
- immune blunting (the possibility that the antibodies given from the parent to the baby interferes with the baby's ability to make their own antibodies
- we are detecting and counting cases of pertussis more than we used to
- the bacteria change
- There are more unvaccinated people now

### **Effectiveness**

Most studies on Tdap in pregnancy are based in England since it has been recommending a routine Tdap vaccine in pregnancy since 2012. In unvaccinated infants less than 2 months of age, vaccine effectiveness was estimated to be over 90%, or the Tdap vaccine prevented pertussis in infants about 90% of the time, with no death observed among infants whose childbearing parent received Tdap before 36 weeks of pregnancy.

## **Risk factors**

The people who get pertussis the most are unvaccinated newborns. They are also the most likely to get severely sick, to be hospitalized and, rarely, to die.

Between 2006 to 2015 in Canada, the highest rate of pertussis was among unvaccinated babies unvaccinated less than 1 year of age at 71.2 cases per 100,000 people. The overall rate of pertussis in 2015 in Canada was 20 cases per 100,000. Being unvaccinated, pregnant, immunocompromised, or Indigenous increases your chances of getting pertussis and of experiencing severe illness from it.

# Risks

Serious complications for babies can include pneumonia, collapsed lungs, bleeding in the eyes and between the skull and brain, seizures, brain damage, hernias, and death.

In Canada, from 2006 to 2015, 33.6 babies younger than 1 year of age for every 100,000 people (0.00034%) were hospitalized for pertussis compared to less than 1 person for every 100,000 of the general population (0.00001%).

In Canada, for every 1000 people who have pertussis, 1 person dies (0.001%). A total of 1-4 people dies from pertussis in Canada every year, mostly babies younger than 3 months of age (or 0.00002% of the population). Worldwide, there are 400,000 deaths from pertussis each year.







#### **Treatment**

Pertussis can be treated with antibiotics.

# **Tdap Vaccine**

The Tdap vaccine is a killed or inactive vaccine. It includes killed germs from tetanus, diphtheria, and pertussis. A Tdap vaccine is offered in pregnancy to protect newborns from pertussis. A vaccine for pertussis only is not available in Canada. The Tetanus and diphtheria vaccines have a strong history of safety in pregnancy.

Babies younger than 2 months of age cannot be vaccinated directly. However, when a pregnant person gets the vaccine it stimulates their body to make antibodies against the disease. Those antibodies are then passed on to the baby through the placenta to achieve temporary immunity.

#### **Risks and Effectiveness**

There has been a significant decrease in pertussis since Canada started vaccinating. Even with vaccination this number cycles up and down about every 2 to 5 years and pertussis is still one of the most common infectious diseases.

Various studies show a Tdap vaccine in pregnancy prevents 68-91% of pertussis infections in newborns in Canada. Between 2017 and 2020, there were two major systematic reviews of over 1700 articles and 22 studies about pertussis immunization in pregnancy.

They showed that Tdap vaccination in pregnancy improves outcomes for newborns. It reduces the number of cases of newborns with pertussis by about 85%, hospitalizations by 90%, severe infections by 91%-94%, and death by 95%.

They showed no significant differences regarding safety between vaccinated and unvaccinated childbearing people except that childbearing people who were vaccinated had more fever and infection of the placenta (chorioamnionitis) There were no bad outcomes associated with the fever and chorioamnionitis and the overall conclusion was that a Tdap vaccine in pregnancy has more benefits than risks.

There have been seizures from fever in less than 1% of newborns whose childbearing parent has received the Tdap vaccine in pregnancy and the childbearing parent themself can experience a brief period of swelling where they get the needle.

### **Unknowns**

We do not know if the antibodies to the baby through pertussis vaccination in pregnancy interfere with the baby's ability to make its own antibodies (this is called immune blunting) and could therefore reduce the infant's immune response to a vaccine at 2 months of age. Immune blunting seems to disappear by about 6-12 months of age.

Continual, post-approval studies on Tdap vaccination in pregnancy have only been occurring since it was implemented for routine use in Canada in 2018.







# Seasonal Influenza (flu) and the Flu Vaccine

### **Recommendations:**

Offer the inactivated flu vaccine to all pregnant people, at any stage in pregnancy, or people who might be pregnant in the upcoming flu season. All household contacts should be vaccinated.

Pregnant people with suspected or documented seasonal flu infection, regardless of whether they have been vaccinated, should be treated with Tamiflu (oseltamivir).

If, during the flu season, a flu vaccine was not received during pregnancy it should be given to the parents as early as possible post-partum. Infants cannot receive a flu vaccine until they are 6 months old.

## Influenza (flu)

Influenza, or the flu, is a virus. Seasonal flu normally happens every year from about November to March. There are 2 types of flu viruses that cause infection in people - influenza A and influenza B. Influenza A and B are associated with seasonal influenza and most outbreaks and epidemics of influenza. A third type of influenza, Influenza C, is relatively rare, mild and does not usually cause epidemics or outbreaks.

The influenza viruses are unique among respiratory viruses in that they can change a lot from season to season. Different strains affect various kinds of groups of people differently so there are some strains that are more dangerous for pregnant people than others.

During the flu season, Health Canada reports on types of flu strains, how many people have gotten the flu and how effective the vaccines are on a weekly basis.

The flu ranges from having no symptoms to mild to severe complicated illness. It can cause a fever, cough, muscle pain, headaches, fatigue and more. Some people, mostly children, experience vomiting and diarrhea. Most people get better in 7 to 10 days, but some people can get severely ill. Complications from the flu include pneumonia and respiratory failure, worsened chronic health conditions and even death.

#### **Transmission**

The flu mostly spreads through coughing and sneezing and through respiratory secretions on hands, tissues, etc. It can live on surfaces for up to 8 hours. Infected people can spread it to others starting one day before the first symptoms until about 5 days after the 1<sup>st</sup> symptoms.

#### Incidence

There is average of 30,000 cases of influenza in Canada every year (or 0.8% of the Canadian population).







#### **Risk factors**

The people at greatest risk of flu-related complications are adults older than 65 years of age, children younger than 6 years of age, people with chronic health conditions, residents of long-term care homes, pregnant people, and Indigenous peoples.

### **Risks**

Pregnant people are not more likely to get the flu, but they are more vulnerable to its effects, especially during the 2<sup>nd</sup> and 3<sup>rd</sup> trimesters. Some studies suggest that fetuses are at increased risk of preterm birth, low birth weight or negative developmental effects as a result of maternal fever during the 1<sup>st</sup> trimester.

The Society of Obstetricians and Gynaecologists (SOGC) states pregnant people are at increased risk of flu-related serious complications.

# Hospitalizations

In Canada, there are an average of 12,200 hospitalizations for flu-related complications.

Healthy pregnant people with the flu in their 2<sup>nd</sup> and 3<sup>rd</sup> trimester of pregnancy are two to four times more likely to be hospitalized than other people. This is the same rate as non-pregnant people with high-risk conditions who get the flu. 3-5/1000 of healthy, unvaccinated pregnant people (or 0.3-0.5% in their 3<sup>rd</sup> trimester will be hospitalized for flu-related complications.

#### **Newborn outcomes**

The flu in pregnancy may negatively affect newborn outcomes. One study of 12,000 pregnant people in Nova Scotia in 2012 showed the chances of having a preterm birth and a low-birth-weight baby are higher for unvaccinated pregnant people.

#### Death

The death rate for influenza in Canada is 500 to 1500 cases per year, or 0.02% of the Canadian population. Together, influenza and pneumonia, a common complication of the flu, are ranked among the top 10 leading causes of death in Canada. A large study established that about 3,500 people in Canada die every year from the flu (or 0.094% of the Canadian population).

# During the 2009 H1N1 pandemic

Healthy, pregnant people in their 2<sup>nd</sup> and 3<sup>rd</sup> trimester were more likely to be hospitalized and to die compared to non-pregnant people.

As much as 32% of pregnant people were hospitalized. In England, pregnant people who were infected in the 3rd trimester had more stillbirths, premature births, and infant deaths. These same people were more likely to be in intensive care in the hospital and to have pneumonia.







Even though pregnant people only made up 1% of the population, 5% of the deaths attributed to H1N1 were of pregnant people.

The H1N1 is the most recent pandemic in Canada, Studies discussing risks with the flu are often talking about H1N1 or new, pandemic strains of the flu.

## **Benefits**

There are no documented benefits to having the flu. There are many different strains so getting the flu once does not protect you from other types of flu. Also, immunity to a flu strain from an infection or vaccination does not usually last much longer than a year.

### **Treatment**

Usually treatment is making the person feel as comfortable as possible. An antiviral (against viruses) medication called Tamiflu (Oseltamivir) is recommended for very ill pregnant people with the flu. This medication is considered safe from monitoring Tamiflu use in pregnant people during the 2009 H1N1 pandemic. Many flu strains are resistant to Tamiflu, so it does not always work as a treatment against the infection.

# **Influenza Vaccines**

Vaccination for the flu in pregnancy is intended to protect both the childbearing parent and fetus as well as the newborn. The recommendation for routine flu vaccination in pregnancy in Canada began in 2007. Flu vaccines for pregnant people are inactivated and therefore considered safe for use in pregnancy.

Flu vaccines contain formaldehyde.

### **Effectiveness and Benefits**

The average rate of influenza flu vaccines is 60%. This means it prevents people from getting the flu 60% of the time. Because the flu changes from season to season the effectiveness rate of the vaccine changes from year to year.

You can see the effectiveness of a flu vaccine for a specific year here:

https://www.canada.ca/en/public-health/services/diseases/flu-influenza/influenza-surveillance.html

A systematic review of many studies on flu vaccination in pregnancy concluded that for every 100 healthy, non-pregnant adults vaccinated, 1.4 to 3.4 influenza or flu-like illnesses are prevented.

A randomized control trial (RCT) showed a flu vaccine in pregnancy reduced flu-type illness with fever in pregnant people by over 30% and flu infections in babies 0- to 6-months of age by 63%.

A review of over 5,000 people who got the flu vaccine in pregnancy in 2012 showed that vaccinated pregnant people were much less likely to experience stillbirth than unvaccinated people.







# Safety

The Canadian Adverse Event Following Immunization Surveillance System (CAEFIS) has not shown evidence of safety concerns after tracking inactivated flu vaccines in pregnancy for decades.

General reviews and studies from the H1N1 pandemic show Tamiflu is safe in pregnancy and breast or chest feeding. A review of the randomized control trial (RCT) on the safety and effectiveness of the inactive flu vaccine in pregnant people stated the study showed only "uncertain or very limited protection against influenza-like illnesses and influenzas" and that more testing is required.

## **Risks**

A small study reported that an H1N1 flu vaccine in pregnancy was associated with miscarriage within 1 month of the vaccine. This has not been seen in larger studies, so is likely a chance finding.

Oculorespiratory syndrome (ORS) is an adverse event first associated with the flu vaccine in Canada in 2000-2001. ORS includes eye infections, swelling in the face and mild respiratory symptoms. From the early to mid-2000s it occurred 76 times out of 1,000,000 vaccines.

## **Unknowns**

There is debate around the effectiveness estimate of the flu that is calculated every year.







# **Practical Information**

## Where to get a vaccine

Vaccination services vary by province and territory. Your midwife, or any health care provider, can help you find out where to get a vaccine.

Free vaccines are available through health units (also called public health clinics, community health centres, and CLSCs in Quebec), school, college and university health services, pharmacies, and some doctors', nurse practitioners' and midwives' offices. You do not need to have a family doctor to get a vaccine.

Where to get a vaccine, what it might cost and how to keep track of your vaccine records varies for Indigenous peoples depending on where they live. In many Indigenous or remote or Northern communities, the community health nurse is usually the one who gives vaccines.

Influenza (flu) vaccines are usually available between November and March.

Find a vaccine clinic using your postal code: <a href="https://vaccines411.ca/en">https://vaccines411.ca/en</a>

#### Call 8-1-1

**8-1-1** is a free-of-charge provincial health information and advice phone line available in every province and territory. By calling **8-1-1**, you can speak to a health service navigator, who can help you find health information and services, including where to get a vaccine. Services are offered in a wide variety of languages and for the deaf or hard of hearing using Video Relay Services (VRS) or Teletypewriter (TTY).

### Cost

Influenza (flu) vaccines are always free for pregnant people.

Usually, vaccines that are not on a province's list of recommended vaccines cost money. Whether or not a vaccine costs money depends on which province or territory you live in. Travel vaccines often cost money. The Tdap vaccine during pregnancy is not always free.

Vaccines that cost money are usually available at travel clinics and pharmacies.







# **Keeping records**

Canada does not have a national immunization record keeping database. It is the individual or care giver's responsibility to keep track of their immunizations. You will often get, or can ask for, a paper booklet to help keep track. There is now a Canadian app that does the same thing: https://www.canimmunize.ca/en/home

Health care providers do not necessarily share your vaccine information with each other (any time health care providers want to share your medical information they need your permission). This means if you have different types of care providers or are changing providers you might need to tell them your vaccine history.

Some midwives can give you the vaccine themselves. When they do this, they will write the type of vaccine and its lot number, like a bar code, and the date you received it. When you say good-bye to your midwife, make sure to get that information to share with the family doctor, pediatrician or community nurse who will be seeing you and your baby next. If you move provinces your vaccine record only moves with you. Provinces do not share vaccine records if you receive a flu or Tdap vaccine in pregnancy.

### Infant and Childhood Vaccination

Recommended routine infant and childhood vaccines usually occur soon after you have said good-bye to your midwife. We know, however, that many clients would like to talk about it with their midwife. They may not be able to answer all your questions, but they can probably help you figure out what your questions are and how you might find some of the answers.



