In the last 50 years immunization has saved more lives than any other health intervention.
Immunization Communication Tool

2013 CONTRIBUTORS

This document is a project of the British Columbia Immunization Committee Professional Education Working Group (PEWG)

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BC HealthFiles Immunization Working Group

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Photos in this tool are of actual BC immunization advocates.
The A-S-K Approach
A framework for immunization communication

Health care providers have an essential role to provide the public with evidence based information regarding immunization. This ensures the continuous success of immunization programs. The following approach provides a systematic method to answer difficult immunization questions and helps to enhance immunization communication between health care providers and the public.

Available at: http://immunizebc.ca/healthcare-professionals/immunization-communication/the-ask-approach
## 1: VACCINE SAFETY

### 1.1 Are vaccines safe?

<table>
<thead>
<tr>
<th>Clinical Evidence</th>
<th>Client Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong> Vaccines are safe, effective and necessary, ‘with huge benefits to children’s health — all through their lives.’²</td>
<td><strong>YES</strong> Vaccines are safe, effective and necessary, ‘with huge benefits to children’s health — all through their lives.’²</td>
</tr>
<tr>
<td>Vaccines are among the safest tools of modern medicine. In Canada, serious side effects occur very rarely. For example, the estimated annual reported rate of anaphylaxis ranges from 0.4 to 1.8 reports per 1,000,000 doses of vaccine distributed in Canada. The vast majority of side effects from vaccines are minor and temporary, such as a sore arm or mild fever. Since vaccines are usually given to healthy people, especially children, tolerance for adverse events following immunization is low.³ For this reason, we have multiple overlapping systems that review adverse events to ensure vaccine safety. Refer to Section 1.3 How is vaccine safety monitored in Canada?</td>
<td>According to the Public Health Agency of Canada, in the last 50 years, immunization has saved more lives in Canada than any other health intervention.¹</td>
</tr>
<tr>
<td>Many unfounded claims have been made about the dangers of vaccination by anti-vaccination activists, celebrities and rogue scientists. However, the claims have not held up to scientific scrutiny. Despite this, these ideas have been popularized in the lay press and have made their way to the internet. As a result, well-meaning parents, influenced by negative things they hear and read, are refusing to have their children vaccinated.⁴</td>
<td>Vaccines in Canada are effective and safe — much safer than the diseases they prevent. Vaccine-preventable diseases can lead to pneumonia, deafness, brain damage, heart problems, blindness, paralysis and carry a risk of life-long disability or death.² You may have questions about the risks associated with immunization. Immunization, like other medical procedures, carries some risk, but this risk is very small. The risk from vaccine-preventable disease is much greater. It is important to discuss the risks and benefits with your health care provider. Public health officials take vaccine safety concerns very seriously. For this reason, we have multiple overlapping systems that review the different components involved with vaccine safety. The benefits of immunization are substantial and well documented.⁵ Refer to Section 1.3 How is vaccine safety monitored in Canada?</td>
</tr>
<tr>
<td>IT’S JUST LIKE Your risk of being struck by lightning. According to the National Weather Service, the risk of being struck by lightning in a given year is about 1 in 1,000,000. About the same risk of experiencing anaphylaxis after administration of a vaccine.⁶</td>
<td>Try not to focus on the wrong risk!</td>
</tr>
</tbody>
</table>
1.2 How are vaccines approved in Canada?

**Vaccine Development and Approval**

It can take up to 10 years or longer to develop and receive approval for a vaccine.

- **Lab Studies**
  - Step 1: Antigen Research
  - Epidemiology of a Disease
  - Infectious Agent

- **Pre-Clinical**
  - Step 2: Animal Studies
  - Immunogenicity - immune response needed to prevent disease
  - Challenge studies in animal models
  - Safety studies - no toxicities that would prevent their use in people

- **Clinical Phase I**
  - Step 3: Human Studies 10–100
  - Immunogenicity
  - Local/systemic reactions

- **Clinical Phase II**
  - Step 3: Human Studies 50–500
  - Optimal dose/schedule in target population
  - Safety assessment

- **Clinical Phase III**
  - Step 3: Human Studies 300–30,000
  - Efficacy in target populations
  - Safety assessment

---

**Biologics and Genetic Therapies Directorate (BGTD):**

- Approval of Product Monograph
  - Health professional information
  - Scientific information
  - Consumer information

- Inspection of Manufacturing Facilities

- Laboratory Analysis of Vaccine
  - Safety
  - Purity
  - Potency

---

**Canadian Approval of Vaccine**
1: VACCINE SAFETY

1.2 How are vaccines approved in Canada?

Clinical Evidence

Biologics and Genetic Therapies Directorate (BGTD)
The BGTD of Health Canada is the regulatory authority responsible for establishing the safety, efficacy and quality of all biologics for human use, including vaccines.7

Steps in place to ensure vaccine safety:

1. Before approval, the BGTD has regulatory processes to ensure that lab and clinical studies provide evidence of product safety and meet the highest standards of quality.

2. Before and after approval, the BGTD also has regulatory processes to ensure the highest quality of manufacturing is used to produce vaccines.

3. Vaccine manufacturing facilities are inspected and given a license by regulators.

4. Every new lot of vaccines produced has to be cleared by regulators before approval to sell in Canada.

5. Regulators and public health authorities continuously monitor vaccines after they have been approved to detect any previously unrecognized safety concerns.

Vaccine safety is an international concern. Information on possible safety concerns is communicated very rapidly among different countries.

Client Knowledge

Biologics and Genetic Therapies Directorate (BGTD)
The BGTD of Health Canada is the national body that regulates the safety and effectiveness of vaccines.

Before vaccines are released to the public, they go through many phases of evaluation. This process may take many years because of the time that is needed to gather the scientific information necessary to ensure a vaccine is safe and effective.

The following are steps the BGTD has in place to ensure vaccine safety:

1. Vaccines are only approved after they are proven to be safe and effective.

2. Vaccine manufacturing facilities are inspected and given approval by the BGTD.

3. Every new lot of vaccines produced has to be cleared by the BGTD before approval to sell in Canada.

4. The BGTD and public health authorities continuously monitor vaccines after they have been approved to detect any previously unrecognized safety concerns.

EXAMPLE On November 2, 2012 there was a voluntary recall of GSK Infanrix Hexa®:

“GlaxoSmithKline, in consultation with Health Canada, would like to inform you of its decision to voluntarily recall one Lot (A21CB242A) of Infanrix Hexa® vaccine as a result of detection of contamination in the environment where material used to make the recall vaccine had been placed. No contamination was found in the vaccine.”

- The recall was a precautionary measure.
- No contamination was found in the vaccine.
- No reported adverse events appeared to be linked to the reasons for recall.

Refer to Endnote 8.
1.3 How is vaccine safety monitored in Canada?

**Ensuring vaccine safety is vitally important.**

In Canada, there is active and passive surveillance and causality assessment.

**Active Surveillance**

**IMPACT**, Immunization Monitoring Program ACTive, is a pediatric hospital-based national active surveillance network for adverse events in children following immunization, vaccine failures, and selected infectious diseases that are, or will be, vaccine-preventable.9

IMPACT complements existing national surveillance systems, supports public health action, informs policy dialogue with Federal, Provincial, Territorial and other national stakeholders, and assists in meeting Canada’s international commitments for vaccine safety monitoring and disease reporting.10

**Passive Surveillance**

**CAEFISS**, Canadian Adverse Events Following Immunization Surveillance System, is a voluntary reporting system in which AEFI reports collected by provincial and/or territorial public health authorities are forwarded for collation. The national CAEFISS database is overseen by the Public Health Agency of Canada’s Vaccine Safety Section within the Surveillance and Outbreak Response Division of the Centre for Immunization and Respiratory Infectious Diseases. While reporting nationally is voluntary, several provinces and territories have laws requiring that healthcare professionals report AEFI (Ontario, Quebec, Saskatchewan, Manitoba, Nova Scotia, and New Brunswick).10

Ensuring vaccine safety is vitally important.

In Canada, there is active and passive surveillance and causality assessment.

**Active Surveillance**

**IMPACT**, Immunization Monitoring Program ACTive, is a pediatric hospital-based national active surveillance network for adverse events in children following immunization, vaccine failures and selected infectious diseases that are, or will be, vaccine-preventable.9 Adverse events can best be thought of as unfavorable effects following vaccination.

**Passive Surveillance**

**CAEFISS**, Canadian Adverse Events Following Immunization Surveillance System, is a reporting system in which parents voluntarily report to their health care providers any adverse events following immunization. Each report is reviewed by a medical health officer and the information is sent to the Public Health Agency of Canada for further review.

This reporting of adverse events following immunization helps certain governmental agencies monitor vaccine safety for children.
1.3 How is vaccine safety monitored in Canada?

**IMPACT Explained**

A nurse at each of the 12 children’s hospitals across Canada reviews all admissions to the hospital. Each year, these IMPACT nurses screen more than 90,000 children admitted to the 12 hospitals.

IMPACT nurses record specifics about the illness and get a detailed immunization history from the parents, family doctor or clinic, to determine if the illness happened after vaccinations.

These nurses then forward reports of adverse events following immunization (AEFI) to the Vaccine Safety Unit at the Immunization Division of the Public Health Agency of Canada (PHAC).
1.3 How is vaccine safety monitored in Canada?

The graphic below illustrates the major systems that review, monitor, or are involved with adverse events following immunization, all of which helps to ensure vaccine safety.

**AEFI**  
Adverse Events Following Immunization Process

**AEFI**  
An AEFI case is voluntarily reported to public health by a primary care provider, or parent/guardian of an individual experiencing the adverse event. An AEFI case is reported on a "HLTH 2319 Form: Report of Adverse Event (Reaction) Following Immunization."

At BC Children’s Hospital the Immunization Monitoring Program ACTive (IMPACT) surveillance system also identifies and reports AEFIs.

**MHO**  
When public health receives a completed HLTH 2319 Form, reportable events are entered into a Public Health electronic information system and are reviewed by a local Medical Health Officer (MHO) or RN designate who then provides a recommendation for future immunization.

**BCCDC**  
The provincial AEFI data set in the public health electronic information system is reviewed weekly for clusters and serious events by the BC Centre for Disease Control (BCCDC) using a standard algorithm.

Twice a month the BCCDC sends the provincial AEFI data set (with personal identifiers removed) to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS).

**CAEFISS**  
CAEFISS is a voluntary reporting system that compiles AEFI data sets into a national database. The Centre for Immunization and Respiratory Infectious Diseases (CIRID) monitors AEFIs in Canada using the data contained in the CAEFISS. Both the CIRID and CAEFISS are part of the Public Health Agency of Canada (PHAC).

**WHO**  
The World Health Organization’s (WHO) International Drug Monitoring Program has operated in Sweden since 1978. This program collects and aggregates case reports from over 75 countries and uses this global data set to monitor for unusual trends in adverse events. The PHAC contributes to this program and is represented on the WHO Global Advisory Committee on Vaccine Safety.
### 1. How is vaccine safety monitored in Canada?

#### Clinical Evidence

**Causality Assessment**

In Canada, there is active and passive surveillance and causality assessment.

The *Advisory Committee on Causality Assessment* (ACCA) was established to review all adverse event following immunization (AEFI) case reports meeting criteria for severity or ‘unexpectedness.’ This group is composed of specialists in pediatrics, public health, epidemiology, infectious diseases, immunology, neurology and adverse event surveillance.

Selection criteria for case review includes neurological AEFI such as meningitis, encephalitis, encephalopathy and febrile seizures requiring hospitalization; AEFI resulting in a fatal outcome or permanent disability and other AEFI requiring hospitalization.\(^7\)

The ACCA reviews approximately 60–70 cases each year submitted from both the active (IMPACT) and passive (CAEFISS) reporting systems.

The ACCA reviews each case using the WHO-UMC (World Health Organization-Uppsala Monitoring Centre) causality assessment criteria to determine if the adverse event was related to the administration of the vaccine(s).\(^7\)

This assessment results in a consensus of the likelihood of causality and the results of these are reported back to the provinces and territories from which the assessments were received.

Based on its review, the ACCA can advise that regulatory action be taken including recommending that the federal government consider changes regarding the approval of the vaccine or recommending further research.\(^{11}\)

The ACCA also reports the results of its reviews back to the surveillance systems (i.e. IMPACT and CAEFISS) and publishes its reviews in medical journals.\(^{11}\)

The act of performing standardized causality assessment in individual case reports by an expert multidisciplinary group is very important not only in the identification of potential new or serious signals, but also to provide arm’s length oversight for vaccine safety.\(^{12}\)

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#### Client Knowledge

**Causality Assessment**

In Canada, there is active and passive surveillance and causality assessment.

The *Advisory Committee on Causality Assessment* (ACCA) is comprised of various specialists. This group reviews individual cases to determine if the adverse event (undesirable after effect) was related to the administration of the vaccine(s).\(^7\)

Based on its review, the ACCA makes recommendations. Examples of recommendations include further research needed as well as recommendations that the federal government consider changing the approval of a particular vaccine.

This type of causality surveillance is very important in providing oversight for vaccine safety in Canada.
1: VACCINE SAFETY

1.4 Who makes recommendations for vaccine use in Canada?

Clinical Evidence

National Advisory Committee on Immunization (NACI)

The NACI provides recommendations for current and newly approved vaccines for use in humans in Canada.\textsuperscript{13}

The NACI is a national committee of recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health.

The NACI regularly reviews all scientific information available on the safety and efficacy of vaccines and publishes its recommendations on vaccine use in the Canadian Immunization Guide (CIG) and Canadian Communicable Disease Reports (CCDR).

The NACI members and liaison members conduct themselves within the context of the Public Health Agency of Canada’s Policy on Conflict of Interest, including yearly declarations of potential conflicts of interest.

The broad stages in the preparation of a NACI recommendation statement are:

- **Knowledge retrieval and synthesis** (transparent process on the methods to systematically retrieve, assemble and evaluate evidence)

- **Synthesis of the body of evidence** of benefits and harms, considering the quality of the evidence and magnitude of effects observed

- **Translation of evidence into a recommendation**\textsuperscript{14}

Client Knowledge

National Advisory Committee on Immunization (NACI)

- NACI stands for the National Advisory Committee on Immunization.

- The NACI is a national committee of recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health.

- The NACI makes recommendations for current and newly approved vaccines for use in humans in Canada.

- The NACI falls under the Public Health Agency of Canada.\textsuperscript{7}
1.5 How was the Human Papillomavirus (HPV) vaccine approved in Canada?

Since 2006, Gardasil® has been approved in 127 countries and more than 118 million doses have been distributed worldwide in over 77 countries.

As of 2012, 46 national authorities have recommended its use and it has been funded through public sector programs in 40 countries.

Since 2007, Cervarix® has been approved in 130 countries and more than 41 million doses have been distributed worldwide in over 130 countries.

As of 2013, many national authorities have recommended its use and it has been funded through public sector programs in more than 30 countries.

The following is a timeline of how the HPV vaccine was approved in Canada:15

**HPV Timeline**

- **Vaccine Development**
  - Pre Clinical: Animal Studies Began in 1995
  - Phase 1 & 2: Immunogenicity and Safety – Clinical Human Studies with HPV type 16 Began in 1998
  - Phase 3: Efficacy and Safety – Clinical Human Trials Began in 2002

- **Vaccine Approval**
  - Studies were completed in North America, Europe, Latin America and the Asia Pacific Region
  - Nearly 100% of women developed protective antibodies for the 4 strains of HPV in the vaccine
  - The vaccine prevented nearly 100% of pre-cancerous changes in the cervix for 2 strains of HPV
  - Health Canada approved Gardasil® for use in Canada in 2007

- **Vaccine Introduction**
  - The NACI recommended the use of the HPV vaccine in Canada in a statement in February 2007
  - BC introduced the Gardasil® vaccine in 2008
  - BC introduced the Cervarix® vaccine in 2012

- **Post-Approval Surveillance**
  - A post marketing surveillance paper was completed in 2009. International post marketing safety and surveillance data was reviewed for both vaccines. This review concluded that both vaccines are safe.
  - Vaccine studies have shown good protection at least eight years after completion of a HPV vaccine series. The antibody level is much higher after vaccination than after natural infection with HPV.
  - Mathematical modeling data have predicted HPV vaccine protection will last for at least 15 years and probably lifelong.
2.1 Will multiple injections overwhelm my baby’s immune system?

**Clinical Evidence**

**NO** Babies 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.\(^\text{16}\)

Theoretically, babies 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.\(^\text{16}\)

Vaccines never “use up” antibodies because the body constantly replaces them.

Because of progressive vaccine science we are giving fewer antigens now than we did 20 years ago.\(^\text{16, 17}\)

In 1980 the DPTP vaccine alone had 3017 antigens.\(^\text{16}\)

As the diagram below demonstrates, today at the two month immunization visit there are a total of 51 antigens in the recommended vaccines.

**Client Knowledge**

**NO** Your baby’s immune system is AMAZING. It could handle thousands of vaccines even if they were given at the same time.

New babies come into contact with millions of germs and their immune system protects them.

Because your baby is always making more and more protective antibodies, vaccines never use up or overwhelm your baby’s immune system.

**IT’S JUST LIKE** When you give blood your body constantly and quickly makes more.

**What is an antigen?**

Antigens are anything foreign that your body has not encountered before. The most common antigens are viruses and bacteria. Specific antigens are used in vaccines to induce immunity.

**DID YOU KNOW?** Scientists have estimated that babies could handle up to 10,000 shots at one time.

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**The Two-Month Visit**

<table>
<thead>
<tr>
<th>One Vaccine</th>
<th>Four Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPTP</td>
<td>DTaP-IPV-HB-Hib, Meningococcal C, Pneumococcal, Rotavirus</td>
</tr>
<tr>
<td>1980</td>
<td>2012</td>
</tr>
<tr>
<td>3,017 ANTIGENS</td>
<td>51 ANTIGENS</td>
</tr>
</tbody>
</table>
2: MULTIPLE INJECTIONS

2.2 Is it important to follow the BC routine immunization schedule?

**Clinical Evidence**

YES Following the BC routine immunization schedule ensures the maximum achievable protection, as early as possible.

This also minimizes the time infants and children are susceptible to serious vaccine-preventable diseases.

Vaccine-preventable diseases such as invasive pneumococcal disease (IPD), *Haemophilus influenzae* type b (Hib), and meningococcal meningitis can have the most serious consequences for infants and young children 0–24 months.18 In the first year of life these diseases have a much higher incidence and mortality rate.

**IMPORTANT CONSIDERATION**

Give all vaccines a client is eligible for at every visit. This means fewer office visits and fewer periods of discomfort. It increases the probability that children will be fully immunized and protected at the appropriate age.19

**Client Knowledge**

YES The BC routine immunization schedule is safe and ensures your child is protected from vaccine-preventable diseases as early as possible. If infants and young children were to get these diseases it could be very serious and even life-threatening.18

The Canadian Paediatric Society, the College of Family Physicians of Canada and the National Advisory Committee on Immunization recommend following a routine immunization schedule.

Immunization schedules may vary from province to province. Please refer to ImmunizeBC.ca for the BC immunization schedule.

**DID YOU KNOW?** It is important to immunize early and on time. Infants and toddlers are at much higher risk for serious complications and death from vaccine-preventable diseases. They are at increased risk because of a less mature immune system and physical development, such as a smaller windpipe.

**FIVE IMPORTANT REASONS FOR YOUR CHILD TO FOLLOW THE BC ROUTINE IMMUNIZATION SCHEDULE:**

1. You will ensure the earliest protection possible against serious vaccine-preventable diseases.
2. You will minimize the number of visits to your healthcare professional for shots.
3. You will decrease the risk of your child developing anxiety and needle fear.
4. The BC immunization schedule is based on scientific evidence and NACI recommendations.
5. There is no increase in side effects when several vaccines are given at the same time.
2: MULTIPLE INJECTIONS

2.3 Should I space out my baby’s shots?

Clinical Evidence

NO Alternate or selective immunization schedules which delay or omit vaccines leave infants and children at risk of developing vaccine-preventable diseases while vaccines are delayed. Unfortunately there are healthcare professionals who advocate for and have published alternate immunization schedules.

The concerns with alternate schedules include:

1. There is no evidence that the alternative schedules are based on scientific evidence which would ensure infants and children get the best and earliest protection against vaccine-preventable diseases.

2. Delayed schedules leave infants and children vulnerable to serious vaccine-preventable diseases (such as invasive pneumococcal disease [IPD], meningococcal meningitis and *Haemophilus influenzae* type b [Hib]) when they need protection the most. 20

3. One of the published alternate immunization schedules would require infants/children to endure 18 visits to a healthcare professional for shots versus six visits if you followed the recommended BC immunization schedule.

4. Children have an increased risk of anxiety and needle fear as they increase in age. The BC immunization schedule has only one visit between the ages of 19 months and six years. One of the alternate schedules has six visits for the same time period.

Client Knowledge

NO You should not space out your baby’s shots or change the routine immunization schedule.

Some vaccine-preventable diseases are still common in Canada and delaying shots can leave your infant at risk of these diseases and may result in hospitalization or death.

Alternate or selective immunization schedules also subject your child to multiple visits to your healthcare professional for shots which can increase their risk of developing anxiety and needle fear.

Please refer to Dr. Paul Offit’s article “The Problem with Dr. Bob’s Alternative Vaccine Schedule.” 20

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**Example of an alternate immunization schedule**

<table>
<thead>
<tr>
<th>Age at visit</th>
<th>Number of Shots</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months</td>
<td>35</td>
</tr>
<tr>
<td>4 months</td>
<td>35</td>
</tr>
<tr>
<td>6 months</td>
<td>35</td>
</tr>
<tr>
<td>12 months</td>
<td>35</td>
</tr>
<tr>
<td>18 months</td>
<td>35</td>
</tr>
<tr>
<td>2 years</td>
<td>35</td>
</tr>
<tr>
<td>2 1/2 years</td>
<td>35</td>
</tr>
<tr>
<td>3 years</td>
<td>35</td>
</tr>
<tr>
<td>3 1/2 years</td>
<td>35</td>
</tr>
<tr>
<td>4 years</td>
<td>35</td>
</tr>
<tr>
<td>4 1/2 years</td>
<td>35</td>
</tr>
<tr>
<td>5 years</td>
<td>35</td>
</tr>
<tr>
<td>5 1/2 years</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
</tr>
</tbody>
</table>

**BC Immunization Schedule**

<table>
<thead>
<tr>
<th>Age at visit</th>
<th>Number of Shots</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months</td>
<td>5</td>
</tr>
<tr>
<td>4 months</td>
<td>10</td>
</tr>
<tr>
<td>6 months</td>
<td>15</td>
</tr>
<tr>
<td>12 months</td>
<td>20</td>
</tr>
<tr>
<td>18 months</td>
<td>25</td>
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<tr>
<td>2 years</td>
<td>30</td>
</tr>
<tr>
<td>2 1/2 years</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
</tr>
</tbody>
</table>

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*Please refer to Dr. Paul Offit’s article “The Problem with Dr. Bob’s Alternative Vaccine Schedule.”* 20
2: **MULTIPLE INJECTIONS**

### 2.4 Does my baby really need all of these shots?

**Clinical Evidence**

**YES** There are four key reasons to give all recommended vaccines:

1. **Babies are most at risk for vaccine-preventable diseases and their effects within the first two years of life.**

   The severe consequences of vaccine-preventable diseases can lead to hospitalization and death. For example, if an infant contracts pertussis (whooping cough), swelling related to infection puts them at higher risk for severe breathing difficulty and death because of the smaller size of an infant’s trachea.

2. **It is important to protect your baby as soon as possible.**

   In the first two years of life, infant B cells are immature and are unable to make antibodies to encapsulated bacteria that cause very serious infections. Examples of these serious infections are invasive pneumococcal disease, *Haemophilus influenzae* type b (Hib) and meningococcal meningitis.

3. **Vaccines given at the same time work just as well together.**

   There is a practical advantage to giving more than one vaccine at the same visit. Prior to a vaccine’s approval in Canada, research must show that the immune response to each antigen is comparable to that found in persons receiving these vaccines at separate times.¹

4. **Babies do not experience more side effects when more than one vaccine is given at a time.**

   No increase in the frequency or severity of clinically significant side effects has been observed.¹ Ideal combination vaccines must have fewer adverse reactions or, at the very least, no more than if administering single-antigen products separately. The safety of each new combination product is rigorously evaluated prior to approval and compared against the safety of single-antigen products or existing combination vaccines. Immunizing children with multiple vaccines at one time minimizes the number of days that children experience discomfort related to their immunizations. It also may minimize needle fear.

**Client Knowledge**

**YES** Vaccine-preventable diseases could seriously harm or even kill your baby.

Babies have strong immune systems which can protect them against many germs, but there are some germs which they can’t fight very well. There are vaccines to protect against these germs.

**FOUR KEY REASONS TO GIVE ALL RECOMMENDED VACCINES:**

1. **Babies are most at risk for vaccine-preventable diseases and their effects within the first two years of life.**

2. **It is important to protect your baby as soon as possible.**

3. **Vaccines given at the same time work just as well together.**

4. **There is no increase in side effects when several vaccines are given at the same time.**

**IT’S JUST LIKE** You protect your child against a danger you can’t see when you apply sunscreen to shield them against harmful UV rays. Similarly, immunization protects against other dangers you can’t see — harmful and potentially deadly viruses!

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**Here’s How Your Baby Gets the Best Protection**

[Infanrix-Hexa® and PediaCare® vaccine]

- **1st VACCINE** (TWO MONTHS) — SOME PROTECTION
- **2nd VACCINE** (FOUR MONTHS) — MORE PROTECTION
- **3rd VACCINE** (SIX MONTHS) — BETTER PROTECTION
- **4th VACCINE** (18 MONTHS) — BEST PROTECTION

The number of shots your baby needs can change by type of childhood vaccine.

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*1 Refer to Section 6.2 Can we stop immunizing now that these diseases are gone?*
## 2: MULTIPLE INJECTIONS

### 2.5 Will multiple injections weaken my baby’s immune system?

<table>
<thead>
<tr>
<th>Clinical Evidence</th>
<th>Client Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NO</strong> Vaccines do not weaken the immune system. Rather, they harness and train it to rapidly defend against vaccine-preventable diseases before illness can occur.¹</td>
<td><strong>NO</strong> On the contrary, vaccines strengthen the immune system and make it ready to fight vaccine-preventable diseases. Immunizing against one vaccine-preventable disease can also protect your baby from other infections.</td>
</tr>
</tbody>
</table>

**EXAMPLE** In Germany, a study of 496 vaccinated and unvaccinated children found that children who received immunizations against diphtheria, pertussis, tetanus, *Haemophilus influenzae* type b (Hib) and polio within the first three months of life, had fewer infections and vaccine-related and unrelated pathogens than the unvaccinated group.²¹

Bacterial and viral infections, on the other hand, often pre-dispose children and adults to severe, invasive infections with other pathogens.

**EXAMPLE** Getting immunized against chickenpox also reduces your child’s chance of contracting flesh-eating disease.

A child’s risk of developing certain infections such as flesh-eating disease is 40–60 times greater when they have been infected with chickenpox virus.¹

**IT’S JUST LIKE** When you go to the gym and work out, it doesn’t make your body weaker, it makes you stronger and less susceptible to injury over time. Getting a vaccine is like getting an immune system work out!

**EXAMPLE** Individuals with pneumococcal pneumonia are more likely to have had a recent influenza infection than matched controls. Similarly, varicella infection increases the risk of severe invasive group A streptococcal infections such as necrotizing fasciitis, toxic shock syndrome, and bacteremia.¹⁶
3: VACCINE MISCONCEPTIONS

3.1 Do vaccines cause autism?

**Clinical Evidence**

**NO** More than 20 studies have refuted this hypothesis.²²

The controversy around a possible link between the measles, mumps and rubella (MMR) vaccine and autism first appeared in the medical journal *The Lancet* in 1998.²³ The principle author was Dr. A. Wakefield. Wakefield’s study involved only 12 children who had inflammatory bowel disease, eight with autism. However, since then more than 20 reputable studies have refuted this hypothesis.

**EXAMPLE** A Danish retrospective cohort study of all children born in Denmark between 1991 and 1998 (537,303 children):

• Compared rates of autism and autistic-spectrum disorder in groups of children vaccinated with MMR and unvaccinated groups.
• Concluded no difference in the rates of autism between these groups.
• Concluded no temporal clustering of cases (autism) at any time after immunization.²⁴

**The Lancet** published a full retraction of the Wakefield study following the judgement of the UK General Medical Council’s (GMC) Fitness to Practice Panel on Jan. 28, 2010; ‘it has become clear that several elements of the original paper by Wakefield et al are incorrect’.²⁵

• The GMC Panel found Dr. Wakefield guilty of serious professional misconduct as it related to his 1998 study linking the MMR vaccine to autism.
• The GMC Fitness to Practice Panel concluded that Dr. Wakefield’s name should be erased from the medical registry:
  “The Panel concluded that it is the only sanction that is appropriate to protect patients and is in the wider public interest, including the maintenance of public trust and confidence in the profession and is proportionate to the serious and wide-ranging findings made against him.”²⁶

Refer to the Vaccine/Autism Myth Timeline on the following page.

**Client Knowledge**

**NO** There is no increased risk of autism with vaccinations, including the MMR vaccine.

Because children with autism are often diagnosed at around the same time as they get their shots, people sometimes think that it’s related to the shots themselves.

Just because some things happen close together, does not mean that they are related.

**IT’S JUST LIKE** If you eat a ham sandwich and then get hit by a car. The ham sandwich did not cause the car to hit you.

Many studies show that the MMR vaccine does not cause autism.

**EXAMPLE** A study of 537,303 children in Denmark showed that the likelihood of autism was the same in kids who were immunized as those who were not.

**DID YOU KNOW?** Measles still kills an estimated 158,000 children each year. Approximately 430 die from measles-related complications each day. Yet measles can be completely prevented with two doses of a safe and effective vaccine.²⁷

Refer to the Vaccine/Autism Myth Timeline on the following page.
3: VACCINE MISCONCEPTIONS

3.1 Do vaccines cause autism?

**Vaccine/Autism Myth**

This timeline chronicles the controversy around a possible link between vaccines and autism, starting with the contentious Wakefield study in 1998.

- **1998**
  - Dr. A. Wakefield’s study involves only 12 children who had inflammatory bowel disease, 8 with autism.

- **2001**
  - The American Academy of Pediatrics convenes a committee to examine a possible link between thimerosal content in vaccines and autism.
  - 9 study researchers and dozens of reviewers conclude there is no autism-vaccine link.

- **2002**
  - Danish researchers publish a study in the New England Journal of Medicine.
  - They study 537,303 children over 7 years.
  - The researchers conclude there is no autism-vaccine link.

- **2004**
  - It is discovered that a law firm looking to sue a vaccine manufacturer paid Wakefield.
  - 10 of the 13 co-authors withdraw their names from the Wakefield study.
  - The U.S. Institute of Medicine Immunization Safety Committee conducts a review and finds no evidence of an autism-vaccine link.

- **2006**
  - The U.S. Food and Drug Administration releases a statement saying there is no evidence to link vaccines with autism.

- **2007**
  - CDC researchers publish a study on thimerosal content in vaccines in the New England Journal of Medicine.
  - They study 1,046 children ages 7 to 10.
  - They find no autism-vaccine link.

- **2009**
  - Italian researchers publish a 10-year study in the journal Pediatrics.
  - They find no developmental delays in children given a thimerosal-containing pertussis vaccine as infants.

- **2010**
  - In the Lancet, researchers state Wakefield’s 1998 work is “an elaborate fraud.”
  - They conclude that Wakefield changed the medical histories of the 12 patients in the original study.

- **2011**
  - FEB The Lancet retracts Wakefield’s 1998 article, saying elements of the article were incorrect.
  - MAY The British Medical General Council, which is in charge of medical licensing in the United Kingdom, strips Wakefield of his license.
  - OCT Researchers publish a thimerosal study in the journal Pediatrics. They find no autism-vaccine link when comparing 256 children with autism to 752 children without autism.
3: VACCINE MISCONCEPTIONS

3.1 Do vaccines cause autism?

Part of a study conducted in Montreal examined the relationship between pervasive developmental disorders (PDD) and measles, mumps and rubella (MMR) immunization rates. This study found that as MMR vaccine uptake decreased, the PDD rates significantly increased.

![MMR Vaccine Coverage and Pervasive Developmental Disorders (PDD) Rates Over Time](image)

3.2 Can my child be immunized if they have a cold or fever?

**YES** In general, minor or moderate acute illness, with or without fever, is not a contraindication to most immunizations.

Acute illness with or without fever:

- Does not interfere with the response to a vaccine.
- Does not increase the risk of adverse events following immunization.
- Is not a reason to delay vaccines and there is also the risk associated with missing an opportunity to give a recommended vaccine.

**YES** In general, minor or moderate acute illness such as teething, stomach upsets, and common colds, with or without fever, frequently occur in young children and are not a reason to delay shots.
3: VACCINE MISCONCEPTIONS

3.3 Do vaccines cause chronic diseases?

Clinical Evidence

**NO** There have been many studies that have looked at whether a relationship exists between vaccines and the development of chronic diseases. Research studies have found that vaccinations do not cause asthma, multiple sclerosis (MS), Type 1 diabetes and chronic fatigue syndrome.

**Asthma:** Scientific evidence does not suggest a role of vaccine exposures in the development of asthma.

A large international study analyzed immunization rates and rates of asthma and other allergic diseases. Researchers obtained rates 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. They found no correlation between immunization rates and asthma/allergy rates.

**Multiple Sclerosis (MS):** There is no evidence that immunization causes MS or even flare-ups of MS.

**Diabetes:** There are no studies that reveal any significant differences in vaccination rates of children with Type 1 diabetes compared with the rates of healthy children without diabetes.

**Chronic Fatigue Syndrome (CFS):** Studies comparing vaccinated adults and those unvaccinated did not show any increased risk of CFS after vaccination.

**PLEASE NOTE** Guillain-Barre Syndrome (GBS) in some studies, has been estimated at a rate of one excess case per 1 million doses of inactivated influenza vaccine. Despite this association, there is currently not enough evidence to prove that the influenza vaccine causes GBS. GBS is more likely to occur after influenza or gastrointestinal infection than from influenza vaccine.

GBS is an autoimmune disorder of the peripheral nerves, characterized by paralysis. Most patients completely recover, however, 10% may die and 20% will have some permanent disabilities.

Client Knowledge

**NO** There have been many studies that have looked at whether a relationship exists between vaccinations and the development of chronic diseases. Research studies have found that vaccinations do not cause asthma, multiple sclerosis (MS), Type 1 diabetes and chronic fatigue syndrome.

**PLEASE NOTE** Guillain-Barre Syndrome (GBS), a rare autoimmune disorder, has been associated with the inactivated influenza vaccine at a rate of one per 1 million doses of this vaccine. Despite this association, there is currently not enough evidence to prove that the influenza vaccine causes GBS. Most patients completely recover, however 10% of those who have this disorder can die and 20% will have some permanent disabilities.

A person is more likely to acquire GBS after being infected with the flu virus than they are from receiving the flu vaccine.
Clinical Evidence

The following components (ingredients) are in vaccines because they ensure vaccines work and they also help to keep vaccines safe.

**Thimerosal**

Thimerosal is a preservative that is currently only in multidose influenza vaccines in Canada. It is made of thiosalicylic acid and mercury. The mercury contained in thimerosal is an organic form called ethylmercury. Studies have shown that ethylmercury, at the levels contained in vaccines, is easily eliminated from the body and does not cause neurological problems.

- Ethylmercury is more easily excreted from the body than methylmercury (half life of seven days as opposed to 50 days for methylmercury).

**EXAMPLE** Eating a 6 oz. can of white albacore tuna would mean that you are absorbing 65.73 mcg of methylmercury. That’s over two and a half times the amount of mercury from a thimerosal-containing flu vaccine (which tops out at 25 mcg/dose). And remember, the methylmercury from the tuna remains around much longer than the ethylmercury from the vaccine.

The Institute of Medicine (IOM) – Immunization Safety Review Committee did an extensive review of research studies and literature and found no causal relationship between thimerosal containing vaccines and autism.

The IOM committee members are leading authorities in their respective fields (pediatrics, neurology, immunology, internal medicine, infectious diseases, genetics, epidemiology, public health, nursing and ethics) and are required to declare conflicts of interest.

Client Knowledge

The following components (ingredients) are in vaccines because they ensure vaccines work and they also help to keep vaccines safe.

**Thimerosal**

**DID YOU KNOW?** In Canada, with the exception of the flu vaccine, thimerosal has not been used in any childhood vaccines since 2001. It was not removed because of safety concerns, but rather because of public concern.

Vaccines are made with ingredients that make them safe and effective. Vaccine components are used in very small amounts and their use in vaccines has not been linked to disease or illness.

Preservatives such as thimerosal prevent vaccines from becoming contaminated with bacteria or fungi, particularly when the vial contains more than one dose (multi-dose vials).

**DID YOU KNOW?** Eating a can of white albacore tuna exposes you to two and a half times the amount of mercury compared to the amount that is in a flu shot, and the mercury found in vaccines is excreted from the body much faster.

The evidence is clear that thimerosal does not cause autism. (Refer to section 3.1 Vaccine/Autism Myth Timeline).

In the mid 90s the definition of autism expanded and now includes more behaviors and learning problems. As a result more children fall under what is known as autistic spectrum disorders.

Thimerosal has been used in vaccines for the past 80 years. Studies have shown that the small amount of thimerosal used to preserve vaccines is safe.
## 4: THE SAFETY OF VACCINE COMPONENTS

### 4.1 Vaccine Components

#### Clinical Evidence

**Formaldehyde**

Formaldehyde is used in the vaccine production process to kill or inactivate viruses and bacteria.

- The vaccines are purified to remove almost all the formaldehyde and the quantity left in a vaccine does not exceed 0.1 mg.
- Formaldehyde is naturally found in the human body and is an essential intermediate for metabolism.
- Infant circulation naturally contains approximately 1.1 mg of formaldehyde (10 times the amount found in vaccines).³³

**Gelatin**

Gelatin is used as a stabilizer and is sourced from cows and pigs. The gelatin in vaccines is the same gelatin in many products we eat.

- There are no reported cases of variant Creutzfeld-Jakob disease (*Mad Cow Disease in humans*) linked to bovine gelatin despite tens of millions of vaccines manufactured using bovine-derived material.³³
- The gelatin used must be sourced from countries whose cattle are free of Bovine Spongiform Encephalopathy (*Mad Cow Disease in cattle*).
- According to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines and injections.³⁵
- The World Health Organization reported that Islamic Legal Scholars determined that the transformation of pork products into gelatin alters them sufficiently to make it permissible for observant Muslims to receive vaccines containing pork.³⁵

Currently, some of the routine childhood vaccines used in BC contain trace amounts of gelatin. Refer to the specific vaccine product monograph for details.

#### Client Knowledge

**Formaldehyde**

Formaldehyde is naturally occurring in the human body and helps with metabolism.

**DID YOU KNOW?** There is approximately 10 times the amount of formaldehyde in a baby’s body at any one time than there is in a vaccine.³³

**Gelatin**

Gelatin is used as a stabilizer in vaccines which helps protect ingredients from breaking down while vaccines are being made, stored and transported.

Gelatin is a protein found in many foods we eat such as some yogurts, 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.

Gelatin, which is contained in some vaccines, is prepared from cows known to be free of mad cow disease.³³

Gelatin may also come from pigs. Religious groups, such as Jews, Muslims and Seventh Day Adventists follow dietary rules that prohibit pork products. That said, some religious leaders and scholars from these groups have approved the use of gelatin-containing vaccines for their followers.³⁴, ³⁵
4: THE SAFETY OF VACCINE COMPONENTS

4.1 Vaccine Components

**Clinical Evidence**

**Aluminum**

Aluminum is the most abundant element on earth and is in the air we breathe, the water we drink and the food we eat. Aluminum:
- Is well tolerated by plants and animals.\(^{36}\)
- Is a vaccine adjuvant.
- Has been safely used in vaccines for 70 years.\(^{33}\)

The ability of the body to rapidly eliminate aluminum accounts for its excellent record of safety.\(^{37}\)

About half of the aluminum in food or in vaccines is:
- Eliminated from the body in less than 24 hours.
- More than three-quarters is eliminated within two weeks.
- Virtually all is eliminated in three years.\(^{37}\)

Because large quantities of aluminum can cause serious neurologic effects in humans, the Agency for Toxic Substances Disease Registry (ATSDR) established guidelines.

**Current BC Schedule: 2 Month Vaccines**

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Adjuvant</th>
<th>Aluminum Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infanrix Hexa®</td>
<td>Aluminum Hydroxide</td>
<td>0.82 mg (per dose)</td>
</tr>
<tr>
<td>Rotarix™</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Prevnar™ 13</td>
<td>Aluminum Phosphate</td>
<td>0.125 mg (per dose)</td>
</tr>
<tr>
<td>NeisVac-C®</td>
<td>Aluminum Hydroxide</td>
<td>0.5 mg (per dose)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>1.4 mg</strong></td>
</tr>
</tbody>
</table>

The ATSDR guideline allows for 2 mg/kg/day. Therefore, a 6 kg infant could have a total of 12 mg aluminum/day.\(^{33}\)
- A 6 kg breastfed baby consumes = 900 mL breast milk/day (average 0.04 mg aluminum/L in breast milk). Therefore, all 4 vaccines + breast milk = 1.4 mg + 0.04 mg = 1.44 mg aluminum. This is extremely safe!
- A 6 kg formula fed baby consumes = 900 mL formula/day (average 0.225 mg aluminum/L). Therefore, all 4 vaccines + formula = 1.4 mg + 0.225 mg = 1.6 mg. This is extremely safe!

For exact amounts of aluminum in vaccines consult product monographs.

**Client Knowledge**

**Aluminum**

Aluminum is the most abundant element on earth and is found in the air we breathe, the food we eat and the water we drink.

**DID YOU KNOW?** The average dose of an antacid has about 1000 times more aluminum than a vaccine.\(^{37}\)

Aluminum helps vaccines to work faster, better and longer. Vaccines only have very small amounts of aluminum.

**DID YOU KNOW?** In the first six months of life the amount of aluminum a baby receives from vaccines is significantly less than the amount they receive through breastfeeding or formula feeding.

The aluminum in vaccines is quickly eliminated by healthy babies and is not harmful.\(^{37}\)

**THE BOTTOM LINE** The amount of aluminum in vaccines is extremely small and does not pose a health risk to your child.
4: THE SAFETY OF VACCINE COMPONENTS

4.1 Vaccine Components

Clinical Evidence

Human Cell Lines

Vaccines do not contain human cells or tissue.\(^{11}\)
Viruses are necessary for the production of certain vaccines and the cell lines are used as the medium for the viruses to grow in.

What is a human cell line?

Cell lines are a population of cells, separated from their original tissue source, derived from a single cell and containing the same genetic make-up. Cell lines are self-sustaining, replicate easily in the lab environment and do not require any new inputs.

Some vaccines use cells that came from two fetuses aborted in the 1960s. They were not aborted to make the vaccine, but for medical reasons.\(^{11}\)

Ethicists from the US National Catholic Bioethics Centre concluded the use of human cells in vaccine production was not contrary to their religious practices or beliefs.\(^{38}\)

Ethicists from the US National Catholic Bioethics Centre concluded the use of human cells in vaccine production was not contrary to their religious practices or beliefs.\(^{38}\)

An ethical concern is that the cells were obtained through abortion, which some people believe to be a moral issue.

KEY POINT Human cell cultures may be used in the process of making certain vaccines, but all cells are removed during the purification process. Trace amounts of some proteins may remain in the vaccine.\(^{11}\)

Currently the vaccines which use human cell lines in the production process are measles, mumps, rubella, varicella, hepatitis A, rabies, tetanus, diphtheria, pertussis and polio.

Animal Cell Lines

Vaccines do not contain animal cells or tissue.\(^{11}\)

The continuous Vero cell line was developed in 1962 from kidney cells of an adult African green monkey.\(^{39}\)

This cell line is regularly validated by the World Health Organization (WHO) and European Pharmacopoeia for safety and the requirements for absence of bacteria, fungi, mycoplasma and viruses.

Downstream purification has resulted in excellent safety production of 100 million doses of inactivated polio vaccine (IPV) over a twelve-year period, more than 20 million doses of rabies vaccine over a ten-year period, and more than 1 billion doses of oral polio vaccine (OPV) over an eight-year period.\(^{40}\)

Client Knowledge

Human Cell Lines

Vaccines do not contain human cells or tissue.\(^{11}\)

Human cell lines are widely used for safety testing and production of medical products, not just vaccines.

Cells are used in the process of making certain vaccines, but all cells are removed during the purification process. Some vaccines use cells that came from two fetuses aborted in the 1960s. They were not aborted to make the vaccine, but for medical reasons.\(^{11}\)

Ethicists from the US National Catholic Bioethics Centre concluded the use of human cells in vaccine production was not contrary to their religious practices or beliefs.\(^{38}\)

A statement from the Vatican: “…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.”\(^{41}\)

IT’S JUST LIKE When a transplant recipient receives an organ from someone who died in a car crash — it does not make the recipient responsible in any way for the death.

Animal Cell Lines

Vaccines do not contain animal cells or tissue.\(^{11}\)

Animal cultures may be used in the process of making certain vaccines, but all the cells are removed during the purification process. Trace amounts of some proteins from the cells may remain in the vaccine.\(^{11}\)
NO  It is better to get the vaccine because infection with a wild virus or bacteria can increase risk for morbidity and mortality. Immunity after most vaccines is similar to immunity that is induced from disease, but without the risk of disease. Vaccines provide protective levels of the same kinds of antibodies and immune cells that are made after a disease. Vaccine induced antibodies are produced prior to exposure to an infection so they are ready to fight immediately when exposed to the disease in real life. Some vaccines, such as tetanus, actually produce a stronger immunity than occurs through infection with tetanus toxin.

NO  Certain diseases can kill or seriously harm your baby before its body is able to mount an effective immune response. A vaccine triggers the body’s natural immune response into action to protect your baby against the disease without the risks of disease. Vaccination is like a dress rehearsal for your child’s immune system so it is prepared for the ‘real show.’

DID YOU KNOW? Healthy children who have chickenpox are 40–60 times more likely to get flesh-eating disease (necrotizing fasciitis) than those without chickenpox. The risk of death from flesh-eating disease is 10 percent.12

**Clinical Evidence**

**Client Knowledge**

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**Chickenpox: The disease, the vaccine and the risks**

**Chickenpox Disease**

- Of every 1,000 children who get chickenpox:
  - About 100 will require medical attention
  - About 12 will suffer from infected blisters
  - About 2-3 will be hospitalized

- Average child will have itchy rash of 250-500 blisters

**Chickenpox Vaccine**

- Of every 1,000 children who get the vaccine:
  - About 1 will have a severe allergic reaction

- Of every 100-200 children who get the vaccine:
  - 100-200 children will have mild injection site reactions
  - 100-150 children will have a low-grade fever
  - 30-50 children will develop a mild varicella-like rash

- Of every 1,000,000 children who get the vaccine:
  - About 1 will have a severe allergic reaction

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Sources:
- [http://jid.oxfordjournals.org/content/197/Supplement_2/S127.long](http://jid.oxfordjournals.org/content/197/Supplement_2/S127.long)

Chickenpox can cause other serious health problems including:
- Bacterial infections of the skin
- Infection of the blood (septicemia)
- Infection of the lungs (pneumonia)
- Inflammation of the brain (encephalitis)

It’s much safer to get the vaccine than to get the disease.
5.2 Are there risks associated with the vaccine that are worse than the risks of disease?

Clinical Evidence

**NO** The risks associated with vaccines are much less than the risks associated with disease. An example is rotavirus. It is much safer to get immunized against rotavirus than to take the risk of getting sick with the virus and its associated complications.

The rotavirus vaccine is being offered to protect infants against a group of gastrointestinal viruses that infect approximately 95% of children worldwide by five years of age.

**Risks associated with rotavirus disease:**
- Approximately 4–8 days of vomiting, profuse watery diarrhea and fever.
- Symptoms can range from mild to very severe, with rotavirus gastroenteritis being the most likely reason for gastroenteritis related hospitalization.
- Children less than two years of age have the highest burden of disease and face the most complications (dehydration, electrolyte imbalance and metabolic acidosis).

The National Advisory Committee on Immunization (NACI) states:
- 35% of infants with rotavirus gastroenteritis will require physician consultation.\(^{43}\)
- 15% will require an emergency room visit.\(^{43}\)
- 7% will require hospitalization.\(^{43}\)

Providing rotavirus vaccine will protect infants from potentially serious complications of this illness.

Client Knowledge

**NO** The risks associated with vaccines are much less than the risks associated with disease. An example is rotavirus. It is much safer to get immunized against rotavirus than to take the risk of getting sick with the virus and its associated complications.

In Canada, by five years of age, almost all children are infected with rotavirus.\(^{44}\) This causes extreme vomiting and diarrhea and can make children very sick, leading to dehydration and hospitalization.
Vaccines have improved the lives of every Canadian. For instance, before tetanus immunization was available, the fear of tetanus (lockjaw) hovered over every cut and puncture wound. Older adults will easily recall the vigour with which every childhood scrape was disinfected to protect against lockjaw. In addition, at the height of the polio epidemic in the 1950s families and friends spent their summers in fear of paralytic polio. As you can see, because most children today are immunized, many of these diseases have almost disappeared — but not completely. This is why we need to continue to immunize. If we stop, and immunization rates decrease, these diseases can and will come back.

**Example** There was a measles outbreak in Toronto in 2008 and mumps in Nova Scotia in 2007.
5.4 Examples of vaccine-preventable diseases

Measles  
Mumps  
Rubella  
Tetanus  
Pertussis  
Polio  
Varicella

Source: Immunization Action Coalition
www.immunize.org
6: WHY VACCINES ARE NECESSARY

6.1 Were diseases declining pre-vaccination due to better sanitation and clean water?

**Clinical Evidence**

**NO** Until vaccines became available there was no significant change in the number of cases of diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, *Haemophilus influenzae* type b (Hib), hepatitis B, meningococcal disease, and chickenpox.

However, before vaccines became available the mortality rate from some of these infections was decreasing.

Hib was the most common cause of bacterial meningitis and a leading cause of other serious invasive infections in young children before the introduction of Hib vaccines in the 1980s.1

In 1985, before the first Hib vaccine was approved, there were 485 invasive Hib cases seen at the network of Canadian Pediatric Hospitals (IMPACT). In 2000, only four cases were recorded by the IMPACT centres — 99% fewer than in 1985.48

Since the introduction of the Hib vaccine the majority of pediatric cases occur in unimmunized children or in children too young to have received their primary series.48

**Client Knowledge**

**NO** What was changing before vaccines became available was the death rate from some of these infections. Improvements in social and economic conditions led to declining death rates for many common infections.11

**Did you know?** Until recently, *Haemophilus influenzae* type b (Hib) was a leading cause of meningitis (inflammation of the brain), epiglottitis (severe inflammation of the throat which interferes with breathing) and other invasive infections in children, affecting about one child in every 250 by five years of age.48

**REFERENCE** Refer to Section 5.3, Table 1: Summary of Diseases in BC Before and After Vaccine.

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*6.1 W ere diseases declining pre-vaccination due to better sanitation and clean water?*

**Haemophilus influenzae** type b (Hib) Disease: Reported Cases, Canada, 1979–2004*

![Graph showing reported cases of Hib disease from 1979 to 2004.](image)

*1979–1985: reported Hib meningitis only
1986–2004: all invasive forms (meningitis and septicemia)

Source: Canadian Immunization Guide, 7th edition
Vaccine-preventable diseases are rare in North America because of vaccination. History has shown rates of disease increase if we stop immunizing.

**Herd Immunity**

When most people in a community have received a vaccine for a particular disease, the chance of an outbreak of that disease is greatly reduced, which is known as herd immunity. Depending on a number of factors, immunization levels must reach up to 75% to 94% in order to achieve herd immunity. Herd immunity protection for communities is vital to achieve as it protects the small number of people who cannot be immunized for various reasons (e.g., medical reasons) or for whom the vaccine did not work.

**Did you know?**  Just like smallpox has been eradicated, there are other vaccine-preventable diseases that can be eliminated completely such as polio and measles. With high enough immunization rates we could eliminate these diseases completely.

---

**Clinical Evidence**

**NO**  Vaccine-preventable diseases are rare in North America because of vaccination. History has shown rates of disease increase if we stop immunizing.

**EXAMPLES**

- In the 1970s anti-vaccination groups spurred the cessation of pertussis vaccine programs in eight countries. This resulted in pertussis disease rates rising ten to a hundred times higher than neighbouring countries that maintained their immunization programs.
- The UK saw 10,000 cases of pertussis and 36 deaths in 1978.
- Japan saw 13,000 cases of pertussis and 113 deaths between 1976–1979.
- During the 1990s there were over 140,000 cases of diphtheria and 4000 related deaths in the former Soviet Union due to suspension of vaccine programs.
- These diseases can and do come back even in BC. Following the 2010 Winter Olympic Games, Vancouver had an outbreak of measles. Of the 80 cases, 75% were either unimmunized or had an unknown immunization history.

**Client Knowledge**

**NO**  If we stop immunizing, the diseases will come back. In some cases they are just a plane ride away.

**EXAMPLE**  Ireland saw measles outbreaks soar from 148 cases in 1999 to 1,200 cases in 2000. This was the result of significant decreases in measles, mumps and rubella (MMR) immunization rates due to concerns of an unfounded link between the MMR vaccine and autism. As a result, some children died in this outbreak.

**IT’S JUST LIKE**  If we were to start bailing out a boat that had a slow leak and the boat was filled with water. We have been bailing (vaccinating) fast and hard, and now it is almost dry. We could say, “Good. The boat is dry now, so we can throw away the bucket and relax.” But the leak hasn’t stopped — the diseases are still present. Before long we would notice water seeping in, and soon it might be back up to the same level as when we started.

**Did you know?**  When most people in a community have received a vaccine for a particular disease, the chance of an outbreak of that disease greatly decreases. This type of community protection is known as herd immunity. The level of vaccination needed to keep disease away ranges from 75% to 94%.

**THE BOTTOM LINE**  When enough people stop immunizing within a community, the rates of vaccine-preventable diseases start to increase. This can lead to serious illness and death.
7: DO VACCINES WORK?

7.1 Are routine vaccines effective in reducing the spread of disease?

**Clinical Evidence**

**YES** In the last 50 years, immunization has saved more lives in Canada than any other health intervention.¹

Vaccines are effective in preventing disease. In fact, vaccines are so effective that most of the diseases they protect against are now very rare¹¹ — many times only found in unvaccinated people.

**EXAMPLE** The graph below compares invasive pneumococcal disease (IPD) before and after the pneumococcal vaccine was introduced.

**Client Knowledge**

**YES** Vaccines work!

Anyone not unimmunized is vulnerable to vaccine-preventable diseases.

**EXAMPLE** A single dose of measles vaccine given at 12 or 15 months is estimated to be 85% to 90% effective. With a second dose, almost 100% of children are protected.

If a person who has had the chickenpox vaccine gets chickenpox disease, they will get a much milder form of the disease and will not be as sick.

**IT’S JUST LIKE** Seat belts are not 100% effective at protecting you while driving, but they significantly reduce your risk of being injured.

**REFERENCE** Refer to Section 5.3 for a summary of diseases in BC and Canada, before and after the introduction of vaccines.

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**Rates of Invasive Pneumococcal Disease in BC by Age Group, 2002 and 2010**

- **Incidence Rate per 100,000 population**
- **Year of Report**
  - 2002
  - 2010

In BC, universal immunization for pneumococcal disease started in 2003.

**Immunization Programs & Vaccine-Preventable Diseases Service, BCCDC, Oct 2013. Case counts of Invasive Pneumococcal Disease (IPD) determined from confirmed cases reported to BCCDC through enhanced surveillance for cases ≤ 14 years of age under Schedule A, Reportable Diseases, BC Public Health Act. Incidence rates calculated using population estimates by age group and census year.**

7: DO VACCINES WORK?

7.1 Are routine vaccines effective in reducing the spread of disease?

**Clinical Evidence**

**YES** An example is varicella. Since 2004 when the publicly funded varicella immunization program was introduced in BC, the number of related hospitalizations has dropped by up to 84% in hospitals participating in active surveillance.\(^{54,55}\)

According to the BC Centre for Disease Control, about 35,000 cases of chickenpox occurred in BC each year before routine varicella immunization for infants was introduced. Approximately one in 200 children who got the disease were hospitalized every year, with one to two deaths occurring annually.

### Table 1. Hospitalizations (except those < 1 year apart) for varicella and complications in BC, April 2001–2003\(^{56}\)

<table>
<thead>
<tr>
<th>Varicella</th>
<th>Number of hospitalizations</th>
<th>Percent of hospitalizations*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varicella without complications</td>
<td>188</td>
<td>65.5</td>
</tr>
<tr>
<td>Varicella pneumonia and/or pneumonia in (due to) chickenpox</td>
<td>21</td>
<td>7.3</td>
</tr>
<tr>
<td>Varicella encephalitis and/or postinfectious encephalitis and/postchickenpox encephalitis</td>
<td>13</td>
<td>4.5</td>
</tr>
<tr>
<td>Impetigo, streptococcus, cellulitis, abscess, fasciitis</td>
<td>8</td>
<td>2.8</td>
</tr>
<tr>
<td>Varicella meningitis</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td>Ataxia</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td>Toxic shock syndrome, streptococcal sepsicemia</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>Varicella with other complications</td>
<td>66</td>
<td>23.0</td>
</tr>
<tr>
<td><strong>Varicella total</strong></td>
<td><strong>287</strong></td>
<td></td>
</tr>
</tbody>
</table>

* Percent of hospitalizations may add up to >100% due to multiple presenting conditions.

**YES** An example is varicella. Since 2004 when the publicly funded varicella immunization program was introduced in BC, the number of related hospitalizations has dropped by up to 84% in hospitals participating in active surveillance.\(^{54,55}\)

A Canadian study by Tan et al (2012) concluded up to an 86% decline in admissions to Canadian Immunization Monitoring Program Active (IMPACT) hospitals since the introduction of the chickenpox vaccine.\(^{54}\)

**THE BOTTOM LINE** Publicly funded chickenpox vaccination programs have led to a significant decline in chickenpox-related hospitalizations in Canadian children.\(^{54}\)
**8: IS A HEALTHY LIFESTYLE ENOUGH TO PROTECT ME OR MY CHILD?**

### 8.1 Will a healthy lifestyle protect against vaccine-preventable diseases?

<table>
<thead>
<tr>
<th>Clinical Evidence</th>
<th>Client Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NO</strong> A healthy lifestyle will support overall health and the immune system. But lifestyle choices alone cannot prevent people from acquiring vaccine-preventable diseases.</td>
<td><strong>NO</strong> A healthy lifestyle is important to help maintain your overall health, but this alone will not protect you or your child from contracting a vaccine-preventable disease. Even healthy people die from vaccine-preventable diseases.</td>
</tr>
</tbody>
</table>

**Nutrition:** There are many benefits to eating a nutritious and well-balanced diet. However, these benefits do not include protection against vaccine-preventable diseases.

**EXAMPLE** Although infections such as measles and pertussis are much more likely to kill a child who is malnourished or who has immune system defects, these infections can also kill healthy, well-nourished children.

**Breastfeeding:** Maternal antibodies are passed to an infant through breastfeeding. Breastfeeding has been shown to protect against many illnesses including: ear infections, allergies, intestinal disorders, colds, viruses, diabetes, urinary tract infections, and Sudden Infant Death Syndrome (SIDS) to name a few. However, breastfeeding alone does not protect against vaccine-preventable diseases.

Babies receive passive protection via transfer of antibodies through the maternal placenta. However, this protection is temporary and depends on what the mother is immune to.

**EXAMPLE** If the mother is immune to pertussis — antibodies readily cross the placenta, and are found in infant sera in concentrations comparable to those in maternal sera — but the half life of transplacental pertussis antibodies is about six weeks with disappearance by four months of age.

**Breastfeeding:** Breast milk provides some protection against certain infections but this protection can be overcome if the baby is exposed to large amounts of germs.

**EXAMPLE** Breastfeeding as protection against rotavirus

Breastfeeding is recommended, and should be promoted, but its effects are limited to postponing rather than preventing rotavirus.
There are many health professional groups in BC that assist people in leading healthy lifestyles. It is important for both members of the public and health care professionals to be aware of each group’s scope of practice and their professional position on immunization. All health care professionals should consider their role in preventing disease as well as supporting public health agencies within their community.

**Midwives:** According to the College of Midwives of BC, midwives should inform their clients that routine childhood vaccinations are outside the scope of midwifery practice. However, midwives should recommend that their clients speak with their physician or public health nurse about childhood vaccinations.59

**Naturopathic Physicians:** According to the College of Naturopathic Physicians of BC, when a patient opts not to immunize, naturopathic physicians must not issue written statements, certificates or verbal discussions that could be misconstrued or misrepresented, including but not limited to:60

- Immunization(s)
- Alternative immunization
- Alternate to immunization
- Flu shot
- Natural immunization
- Homeopathic immunizations

**Chiropractors:** The Canadian Chiropractic Association supports public health promotion and prevention strategies that encourage well being and accepts vaccinations as a preventable procedure for certain diseases. However the responsibility of vaccination is not within their scope of practice.61

**Homeopathic Practitioners:** The policy of the Faculty of Homeopathy at the Royal London Homeopathic Hospital supports vaccination.11
ENDNOTES


12 British Columbia Centre for Disease Control Communicable Disease Control Manual, Chapter 2: Immunization Program. Section 9: Adverse Events Following Immunization; February 2013.


15 Quick Reference: Immunization Communication Tool For Immunizers. HPV 2010. ImmunizeBC.


19 British Columbia Centre for Disease Control Communicable Disease Control Manual, Chapter 2: Immunization Program, Section 4: Vaccine Administration; March 2005.


ENDNOTES

34 The Children’s Hospital of Philadelphia. Vaccine Ingredients: What you should know. Q&A. Vaccine Education Centre. Volume 2; Fall 2012.
43 Canada Communicable Disease Report. November 2010; Volume 36.ACS-14 NACI.
ENDNOTES


