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This chapter meets the following **IMMUNIZATION COMPETENCIES FOR HEALTH PROFESSIONAL (PHAC, 2008)**: <http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf>

#2: Vaccine-Preventable Diseases

- ◆ Competency: Demonstrates an understanding of the rationale and benefit of immunization, as relevant to the practice setting.

#6: Communication

- ◆ Competency: Communicates effectively about immunization, as relevant to the practice setting(s).

#13: Immunization Issues

- ◆ Competency: Addresses immunization issues using an evidence-based approach.

#14: Legal and Ethical Aspects of Immunization

- ◆ Competency: Acts in accordance with legal and high ethical standards in all aspects of immunization practice.

1.0 COMMUNICATION OF IMMUNIZATION BENEFITS AND RISKS

Immunization programs are highly successful in controlling and reducing the incidence of vaccine-preventable diseases. Because vaccine-preventable diseases are uncommon in Canada, it is difficult for the general public to compare the actual risks and consequences of getting these diseases to the actual risks of expected side effects and adverse events following immunization. In Canada, public immunization programs are voluntary. (However in some provinces (e.g., Ontario), a written immunization record or proof of immunization is required, by law, for diphtheria, tetanus, polio, measles, mumps and rubella unless there is a valid written exemption. Parents/guardians are required to provide this information to their local public health unit and to update the information as necessary). This means that individuals and caregivers can freely decide whether or not to immunize their children and themselves. This ethical principle is known as *autonomy*, defined as self-determination to choose or refuse something. In most situations, the choice to not immunize is based on personal reasons that are concerned with vaccine safety, the perceived harm they may cause and negative perceptions of risk from receiving immunizations. Such individuals may be unaware that unimmunized individuals or those infected with or suspected of having a communicable disease can be legally excluded from daycare, school and work in an outbreak situation under *The Saskatchewan Public Health Act, 1994* (available at: <http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/P37-1.pdf>).

A higher standard of safety is generally expected of vaccines compared to other medical interventions. As vaccines are given to healthy people, especially infants and children, there is a low tolerance for adverse events. Past and present public and mass media (e.g., celebrities [like Jenny McCarthy] and faulty ‘scientific’ studies [like Dr. Andrew Wakefield and colleague’s investigation of MMR vaccine, irritable bowel disease and autism links]) have falsely stated and promoted incorrect information about vaccines and vaccine safety. As a result, many people are concerned about the risk of temporary or permanent adverse events from immunizations and may lose perspective on the individual and societal benefits of immunization. **Regrettably, many people do not realize the risk associated with disease vulnerability when they chose not to immunize.**

Clients may have specific concerns and questions about immunizations, such as:

- Isn’t natural immunity from a disease better than the immunity from a vaccine?
- Is homeopathic immunization a suitable alternative?
- Weren’t diseases disappearing long before vaccines were introduced?
- Why continue to immunize if the preventable diseases have disappeared from Canada?
- Why do some children get the disease despite being vaccinated?
- Do multiple vaccines weaken, suppress, or overwhelm the immune system?
- Is it safer to give partial doses of vaccine or to give vaccines one at a time at separate visits?
- Why does my child need so many shots?
- Are vaccines effective?
- Are vaccines safe?
- Do vaccines contain harmful ingredients?
- Do vaccines cause autism, multiple sclerosis, diabetes, arthritis or inflammatory bowel disease?

Immunization providers must be aware of current anti-vaccination sentiments, and be fluent in addressing immunization-related myths, concerns and question from the public. By consistently providing evidence-based information, immunization providers can collectively dispel misinformation and increase client understanding of how and why vaccines work. Refer to [Appendix 3.1: Recommended Websites, Books and Articles for Parents and Caregivers](#) for immunization resources to share and [Appendix 3.3: Immunization Facts](#) for key immunization messages as presented in the Canadian Immunization Guide (Evergreen Ed.).

For individuals who choose to immunize, their personal reasons are often based on their assessment of the perceived benefits of immunization, the low risk of harm from vaccines, and a belief that immunizing their children contributes to the common good of society. This last principle is referred to as *utilitarianism*, as immunization is viewed as an individual's responsibility to maximize social and community benefits (protection against disease) through immunization. As a result, conflicting ethical issues arise in society when autonomy collides with utilitarianism. This conflict may also arise among health professionals. When the personal immunization-related beliefs of a health professional are in conflict with evidence-based recommendations, these professionals should direct/refer their clients to other health professionals (e.g., public health nurses) so that they can get accurate, evidence-based information to assist them in being better informed and educated so that they can make a fully informed decision they are confident with.

1.1 Principles of Benefit and Risk Communication

It is the responsibility of the immunization provider to communicate honestly and effectively with clients, caregivers or client representatives regarding the benefits and risks of immunization, and the risks of remaining unimmunized.

The goal of risk communication is the development of an informed decision making partnership with the mutual understanding that clients have input into the decision regarding whether or not to immunize. Principles of immunization benefit and risk communication are essential to facilitate and guide discussions with clients about immunization and include the following (CIG evergreen online):

- Adopt a respectful client centred approach. Effective decision making is best done in partnership between the health care provider and the parent or client.
- Respect differences of opinion about immunization. When an individual expresses reluctance or refusal to immunize themselves or their children, assess both the strength of their beliefs and the underlying reasons for their beliefs and decisions.
- Represent the benefits and risks of vaccines fairly and openly. Compare the known and theoretical risks of a vaccine with the known definite risks associated with the vaccine-preventable diseases. Remind clients that vaccine-preventable diseases have not been eliminated. Refer to [Appendix 3.2: Relative Risks of Vaccine-Preventable Diseases and Immunization](#).
- Communicate current knowledge, taking into account what an individual already knows and the level of detail requested. Provide a variety of information formats (e.g., visual, audio, printed material and web sites). Provide guidance on how to assess web site reliability.



- Make the most of each opportunity to present standardized clear, evidence-based messages regarding vaccines and immunization programs. Encourage questions and discussion, address misinformation, and provide valid and appropriate resources, including appropriate web sites, for those who want more information.
- Inform clients of all recommended vaccines for themselves and their children that are appropriate for this visit (including those that are not publicly funded).

2.0 PURPOSE AND SCOPE OF INFORMED CONSENT

It is the professional and legal responsibility of the immunization provider to obtain valid informed consent prior to immunization.

Obtaining a valid, informed consent from every client is a professional and legal responsibility as a required prerequisite before providing immunization services. Informed consent legally protects the immunizer and the vaccinee, as it provides documentation to support the fact that all risks and benefits were explained by the provider and appeared to have been understood by the client. Informed consent for immunization is dependent upon the provision of verbal and written information regarding the benefits and risks of receiving and not receiving immunizations, potential side effects related to immunizations and their management, vaccine constituents, recommended schedules, and other issues which may be identified by the client. Health practitioners need to be aware of the regional/jurisdictional policies which govern informed consent and should familiarize themselves with those policies.

2.1 Elements of Informed Consent

- Specific to the immunization service;
- Client-centered;
- Voluntary;
- Consent is obtained without fraud or misrepresentation;
- Standard information is provided to the client (or representative);
- The capability of the client (or representative) providing consent is assessed;
- The client (or representative) has the opportunity to ask questions and receive answers; and
- The client (or representative) has the right to refuse or revoke their consent at any time and must notify the immunizer.



2.2 Methods of Obtaining Informed Consent

The person providing informed consent may provide consent in person (implied), in writing, or by telephone or fax depending on regional/jurisdictional policy. Health Authorities collect personal information under the Health Authorities Act and other legislation. The information may be used and disclosed in accordance with the *Freedom of Information and Protection of Privacy Act* available at: <http://www.publications.gov.sk.ca/details.cfm?p=527>.

2.21 Written Consent

Written documentation must follow regional/jurisdictional policy and should include the following elements:

- Client identification (name and date of birth);
- Statement that the person providing consent has reviewed and understood the standard information;
- Statement of consent or refusal;
- Name of vaccine series;
- Date of consent;
- Name of person consenting or refusing; and
- Relationship of the person consenting to the person being immunized, if not the same.

2.22 Telephone Consent

The following elements must be documented for telephone consent:

- Client identification (name and date of birth);
- Statement of consent or refusal;
- Name of vaccine series;
- Date of consent;
- Name of person consenting or refusing;
- Relationship of the person consenting to the person being immunized, if not the same; and
- Name of person obtaining informed consent.

3.0 STEP BY STEP PROCESS FOR OBTAINING INFORMED CONSENT

The intent of this informed consent standard of practice is to achieve a more client-centered, consistent, and expedited approach.

Step 1: Determine Authority to Provide Informed Consent

Adults (18 years and older)

- Adults or their substitute decision maker (SDM) must provide informed consent prior to immunization.
- Adults or their SDM have the right to refuse or revoke consent for immunization.

Mature Minors (13 – 17 years)

- Health care directives can be given at the age of 16 years.
- There is no legal age of consent for health care in Saskatchewan. Children aged 13 years and older can legally consent to, refuse and revoke immunizations on their own behalf if they demonstrate capability and understanding of the standard information.
- Mature minors have the authority to give, refuse, or revoke consent for their own immunizations when the health care provider feels they have demonstrated capacity to make that decision.
- For school-based immunization programs efforts must first be made to obtain parental/representative consent. If a student presents without parental/representative consent, it is the health care provider's professional responsibility to inform them about a mature minor's right to provide consent on their own behalf. How this is handled operationally may vary between jurisdictions, and may include:
 - An age below which, in general, parental consent is required.
 - An age above which, in general, older children are assumed to be able to give consent.
 - An in-between range in which parents are notified, consent sought, but in the absence of expressed parental consent, the child's consent will be accepted.

Children (12 years and younger)

- All biological and adoptive parents have the authority to give, refuse and revoke informed consent for their children's immunizations, except when their decision-making rights have been legally revoked and another legal guardian has been appointed (e.g., social worker) or when their child has self-consented as a mature minor.
- Foster parents, relatives who have temporary day-to-day guardianship (by court order or by an informal consensual arrangement) or a social worker may sign the consent for immunization. Parents who have temporarily relinquished the custody of their children, whether voluntarily or involuntarily, to the Ministry of Social Services or to a First Nations Child and Family Services should be encouraged, if they are available and willing to do so, to sign the consent as well.

- A foster parent may not refuse a foster child’s immunization without the authorization of the child’s social worker. If you are not satisfied that the social worker has authorized a refusal, bring the matter to the attention of the child’s social worker and inform your supervisor.
- If a parent has sole custody and the other parent has some access, only the primary custodian may provide consent for immunization.
- If a PHN becomes aware of a situation where both parents have custody and have opposing views regarding immunization, defer immunization pending joint consultation with parents. The onus is on the parent to bring forward information regarding custody arrangements.
- If there is any dispute between the parents regarding which has the authority to sign the consent, a copy of the custody order or agreement should be requested.
- If the parent who originally provided consent is no longer the legal guardian or is deceased, obtain a new consent from the current guardian. Retain both consents.

Step 2: Assess Ability to Give Informed Consent

- Assess if the client (or representative) is capable of giving or refusing informed consent (e.g., assess language, communication methods, hearing and cognitive abilities).
- The immunization provider should first seek consent from the adult presenting for immunization. Implicit consent may be obtained from observation of the adult’s verbal or nonverbal communication methods that may include gestures, vocalizations, communication boards, or electronic devices.
- The person accompanying the adult may be able to assist the immunization provider in interpreting the client’s communication (e.g., a case worker informs the immunization provider that the adult’s behaviour means he or she consents to immunization).
- If a person lacks capacity to make a decision, regardless of age, ensure “*an appropriate guardian or substitute decision maker is present to give consent*” (CIG evergreen online).

Step 3: Provide Standard Information and Resources

- **All information applies to the individual eligible for immunization.**
- **Provide standard information for each vaccine series before administration.** Provincial immunization fact sheets can be accessed at:
<http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets>
- **Standard information addresses:**
 1. The voluntary nature of immunization.
 2. That consent is obtained for a vaccine series.
 3. That consent is valid as per regional/jurisdictional policy, until completion of the series, or consent is revoked.
 4. Vaccine information as outlined in the Saskatchewan immunization fact sheets:
 - Disease(s) being prevented;
 - Benefits of vaccination (personal, community);
 - Risks of not getting immunizations (possibility of getting disease);
 - Eligibility for the vaccine(s)

- Common and expected side effects;
 - Possible serious, severe or unusual adverse events;
 - Contraindications; and
 - Awareness that immunization information will be recorded in a provincial database known as Panorama.
- If the client does not understand English, provide translated versions or use an interpreter if available. Refer to [SIM Chapter 4 Appendix 4.2 Where do I document](#) for guidance.
 - **Defer the consent process and do not proceed with immunization if provision of the standard information is refused. Document all details in the client’s health record.**

Step 4: Confirm Understanding of Standard Information

- Use clinical judgment to confirm that the person providing informed consent demonstrates an understanding of the standard information.
- Ways to assess understanding include:
 - Assessing non-verbal cues.
 - Assessing questions that the client (or representative) asks.
 - Exploring and clarifying reasons for silence or refusal to engage in discussion.
- **Defer the consent process and do not proceed with immunization if the client does not demonstrate understanding of the standard information. Document all details in the client’s health record.**

Step 5: Provide Opportunity for Questions

- Provide the client (or representative) with time and opportunities to ask questions and voice concerns, and have them answered to their satisfaction.

Step 6: Confirm Consent

- Upon completion of steps 1 to 5, confirm that the person providing consent is ready to proceed (e.g., “Are you ready to proceed?”).

Step 7: Document Informed Consent or Informed Refusal

- Document that informed consent has been given or if any service or part of a service is refused, deferred, revoked or contraindicated. Refer to [SIM Chapter 4 Appendix 4.2 Where do I document](#) for guidance.
 1. Document in Panorama the vaccines for which a client gives informed consent or informed refusal.
 2. Document Panorama if the client refuses any vaccines for which they are eligible at the time of each visit.



- **Defer and immediately consult a supervisor/manager/MHO if a client or representative refuses the urgent administration of post-exposure immunoprophylaxis (e.g., rabies).**
- When mature minor consent or refusal is obtained, identify in the documentation that it was the decision of the mature minor and the steps taken to reach that decision.

4.0 CHECKLIST FOR OBTAINING INFORMED CONSENT FOR A VACCINE SERIES

1. Determine the authority for the client or representative to provide informed consent.
2. Assess capability to give informed consent – was the discussion understood?
3. Provide standard information:
 - a) Confirm the voluntary nature of immunization.
 - b) Inform the client or client representative that consent is obtained for a vaccine series and is valid until completion of the series or until the client or representative revokes the consent.
 - c) Provide the vaccine information as outlined in Saskatchewan Immunization Fact Sheets:
 - Disease(s) being prevented.
 - Benefits of vaccination.
 - Risks associated with not getting immunized.
 - Eligibility for the vaccine(s).
 - Common side effects of vaccines.
 - Possible serious, severe or unusual adverse events and their frequency as noted in [Appendix 3.2: Relative Risk of Vaccine-Preventable Diseases and Immunizations](#).
 - Contraindications.
 - Awareness of entry of immunization information into provincial database (Panorama).
4. Confirm that the client or representative understands the standard information.
5. Provide opportunity for questions and answers.
6. Confirm consent and question the client if they are ready to proceed.
7. Document the client's or representative's informed consent or refusal.

5.0 REFERENCES

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6.0 APPENDICES

Appendix 3.1: Recommended Immunization Websites, Books and Articles for Parents and Caregivers

Trusted Immunization Resources

The Saskatchewan Ministry of Health recommends these trusted websites and factual books because they are excellent immunization information resources for the public

Everyone is encouraged to read “*Immunization Information on the Internet: Can you trust what you read?*” when they are researching immunization information on the internet. The goal of this fact sheet is to help you decide if vaccine information you find on the Internet is accurate and truthful.

<http://resources.cpha.ca/immunize.ca/data/0288e.pdf>

Canadian Resources

Health Canada

<http://www.phac-aspc.gc.ca/im/index-eng.php>

The Public Health Agency of Canada offers a wealth of vaccine information such as:

- [Vaccinations for children](#)
- [Vaccine safety](#)
- [Frequently asked questions](#)
- [Vaccine-preventable diseases](#)
- [National immunization schedules](#)

Canadian Paediatric Society

www.caringforkids.cps.ca

Caring for Kids is a website for parents developed by the Canadian Paediatric Society. It contains easy-to-read documents on:

- [Vaccines for children and youth](#)
- [General immunization information](#)
- [Plus other information on child and youth health, safety, growth and development](#)

ImmunizeBC

<http://www.immunizebc.ca/>

An excellent user-friendly site for the public and healthcare professionals.

Saskatchewan Ministry of Health

[Immunization Programs and Services](#)

- Vaccine fact sheets
- Routine immunization schedule
- Immunization program information

Immunize Canada

<http://www.immunize.ca/en/parents.aspx>

Immunize Canada provides factual and evidence-based information and resources on:

- [Immunization: Get the facts](#)
- [Vaccines and the diseases they prevent](#)
- [Vaccine safety](#)
- Reducing vaccine pain for [babies](#) and [children](#)
- [Provincial and territorial schedules](#)
- [Common questions and misconceptions](#)

American and International Resources

VaxAware

<http://vaxaware.com/>

VaxAware is an online immunization awareness video series to help spread an understanding of vaccine safety and the importance of immunization.

Vaccine Information You Need

<http://www.vaccineinformation.org/>

This website is for parents and has vaccine information for all ages.

- [Vaccine basics](#)
- [Videos](#)
- [Vaccine safety](#)
- [Vaccine preventable diseases](#)
- [Frequently asked questions](#)

Centers for Disease Control and Prevention (CDC)

<http://www.cdc.gov/vaccines/>

Visit this comprehensive website for straightforward information.

- [Vaccines: the basics](#)
- [Vaccines and preventable diseases](#)
- [Basic and common questions](#)
- [FAQs about vaccines and diseases they prevent](#)
- [Vaccine side effects and safety](#)

Appendix 3.1 Recommended Immunization Websites, Books and Articles for Parents and Caregivers (cont.)

Immunization Action Coalition (IAC)

www.immunize.org

This site offers a range of educational materials for health professionals and the public.

- [Vaccine ingredients](#)
- [Clear answers and smart advice about your baby's shots](#)
- [Top ten reasons to protect your child by vaccinating](#)
- [Evidence shows vaccines unrelated to autism](#)
- [Compelling personal testimonies](#)

National Network for Immunization Information (NNii)

www.immunizationinfo.org

This nonprofit group provides current, science-based information.

- Are Vaccines Safe? Evaluating Information About Immunizations on the Internet (pamphlet)
- Vaccine Information
- Cause or Coincidence?
- Disease 'parties' (e.g., chickenpox party)

Vaccine Education Centre

<http://vec.chop.edu/service/vaccine-education-center>

This site has a parent newsletter and online videos and books by Dr. Paul Offit of the Children's Hospital of Philadelphia

- [Parents PACK](#) - Possessing, accessing and communicating knowledge about vaccines
- [Vaccine Safety](#)
- [Vaccine Science](#)
- [Vaccine-related news](#)
- [Vaccines on the Go: What You Should Know](#)

Recommended Books

Your Child's Best Shot: A Parent's Guide to Vaccination [Canadian Paediatric Association, 4th Edition, 2015]

A comprehensive Canadian reference written specifically for parents. It provides clear answers to common parental questions and concerns. **Ask for this book at your local library.**

A Parent's Guide to Immunization [Health Canada, 2014]

This Canadian resource is a free online book. <http://www.phac-aspc.gc.ca/im/iyc-vve/pgi-gpv/assets/pdf/pgi-gpv-eng.pdf>

Parents' Guide to Childhood Immunization [Centers for Disease Control and Prevention, 2014]

This American booklet introduces parents to 14 childhood diseases and the vaccines that can protect children from them. Copies can be ordered or printed from the site.

Vaccines and Your Child: Separating Fact from Fiction [Dr. Paul A. Offit & Charlotte A. Moser, 2011]

The authors answer questions about the science and safety of modern vaccines. They explain how vaccines work, how they are made, and how they are tested. Most important, they separate the real risks of vaccines from feared but unfounded risks. **Ask for this book at your local library.**

Complete Idiot's Guide to Vaccinations [Dr. Michael J. Smith & Laurie Bouck, 2009]

Here is all the information readers need to know about every vaccine, including: how vaccines work; which are required and recommended; which have been challenged; risks of not vaccinating; vaccines for travelers, injuries, and special populations, including seniors. **Ask for this book at your local library.**

Do Vaccines Cause That? [Dr. Martin G. Myers & Diego Pineda, 2009]

A thoughtful and clearly written book looking at vaccine recommendation and common safety concerns. **Ask for this book at your local library.**

Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure [Dr. Paul Offit, 2010]

A national expert on vaccines challenges the modern-day false prophets who have misled the public about autism and vaccines. He considers the manipulation of science in the popular media and the courtroom, and he explores why society is susceptible to the bad science and risky therapies put forward by many anti-vaccination activists.

Ask for this book at your local library.



Appendix 3.2: Relative Risk of Vaccine-Preventable Diseases and Immunizations

Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
<p>Diphtheria – Caused by highly contagious bacteria which are spread through direct contact with nasal and throat secretions or through raw milk.</p>	<p>Disease occurs 2-5 days after exposure. Can occur in any mucous membrane or on the skin. Fever, pus and mucus discharge from infected site, and an obstructive membrane may form over the airway.</p>	<p>Case fatality rate: 5 – 10% without antitoxin and antibiotic treatment. Diphtheria does not provide life-long immunity. Complications are caused by a potent toxin released by diphtheria bacteria and include heart failure, paralysis, upper airway obstruction, pneumonia, and death.</p>	<p>Local reactions include redness, swelling and tenderness at the injection site. Fever and irritability occur less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare.</p>
<p>Tetanus (lockjaw) – Caused by non-contagious bacterial spores, found worldwide in soil and animal feces which enter the body through a wound and multiply in the low oxygen environment.</p>	<p>Disease occurs 7-10 days after exposure to bacteria. Generalized tetanus symptoms include lockjaw, neck stiffness, difficulty swallowing, generalized rigidity and severe convulsive spasms of all skeletal muscles.</p>	<p>Case fatality rate: over 10% without tetanus immune globulin treatment and immunization. Tetanus does not provide life long immunity. Complications are caused by potent neurotoxins released by tetanus bacteria. Severe spasms can cause fractures in the spine and long bones. Spasms in the vocal chords and respiratory muscles can cause serious breathing difficulties, including pneumonia.</p>	<p>Local reactions include redness, swelling and tenderness at the injection site. Fever and irritability occur less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare. The risk of Guillain-Barré Syndrome (GBS) following immunization with tetanus – containing vaccine is 0.4 per one million doses of vaccine given (very rare).</p>
<p>Pertussis (whooping cough) – Caused by bacteria transmitted through direct contact with respiratory or airborne droplets of respiratory secretions. Older persons are often the source of infection for children. Infected individuals are most contagious in the first 2 weeks of disease.</p>	<p>Disease occurs usually 7-10 days after exposure. First 2 weeks: runny nose, fever, sneezing and cough. Next 6-10 weeks: bursts of excessive, rapid coughing mostly during the night (caused by thick mucus in lungs) and post-cough vomiting followed by high-pitched ‘whoop’ sound upon taking a breath. Recovery takes weeks to months.</p>	<p>1-3 Canadian infants die per year mostly because they are not immunized or not immunized on time. Pertussis does not provide life long immunity. Timely antibiotic treatment is required. Complications are caused by potent toxins and other compounds released by pertussis bacteria. Complications include apnea, pneumonia, collapsed lungs, and rib fractures. Neurological complications may be permanent and include seizures and encephalopathy.</p>	<p>Local reactions include redness, swelling and tenderness at the injection site. Fever and irritability occur less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare.</p>



Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
<p>Haemophilus influenzae type b (Hib) – Hib bacteria are spread through contact with nose and throat secretions and droplets. Hib colonizes in the nasopharynx (nose and throat) and may enter the bloodstream and cause invasive disease.</p>	<p>Hib caused up to 60% of meningitis in children before the vaccine was introduced. Meningitis: neck stiffness, fever, decreased mental status. Epiglottitis: pain and swelling of the epiglottis resulting in possible life-threatening airway obstruction.</p>	<p>Hib meningitis case fatality rate: 5% with antibiotic treatment. Infants and children less than 6 years are most susceptible to serious invasive disease caused by the type b strain, including meningitis, epiglottitis, bacteremia, septic arthritis, pneumonia, and cellulitis. 10 - 25% of Hib meningitis survivors have permanent neurological damage and 6% have permanent deafness. Osteomyelitis and pericarditis are rare.</p>	<p>Local reactions include redness, swelling and tenderness at the injection site. Fever and irritability occur less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare.</p>
<p>Polio – Caused by transmission of the three highly contagious polioviruses via the fecal-oral route. It has been eradicated in Canada but could be imported by international travel.</p>	<p>Polio occurs 7-10 days after exposure. Aseptic meningitis: fever, malaise, headache, nausea and vomiting for 2-10 days. Paralytic polio: occurs 1-10 days after aseptic meningitis and symptoms progress over 2-3 days. One side of the body usually affected. Many will recover, but weakness and paralysis lasting 12 months is usually permanent.</p>	<p>Polioviruses are present in stool for 3-6 weeks. 95% of those infected have no symptoms but can spread the viruses to others. Non-paralytic aseptic meningitis: 1 - 2% of polio infections. Paralytic polio: 1% of polio infections (25% of these will have postpolio syndrome). Death-to-case ratio for paralytic polio infection: 2 - 5% in children; 15 - 30% in adults.</p>	<p>Local reactions include redness, swelling and tenderness at the injection site. Fever and irritability occur less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare.</p>
<p>Measles – One of the most highly contagious communicable diseases for susceptible people who were not immunized or are under immunized. The wild virus is spread through airborne droplets and direct contact with nasal and throat secretions. The virus is often imported by international travel.</p>	<p>Measles occurs 10-12 days after exposure. First 2-5 days: increasing fever, cough, runny nose or red eyes. 1-2 days before and 1-2 after the rash, white spots are visible on the inner cheeks (Koplik spots). The rash begins on face and head and spreads down body and limbs, lasting 5-6 days before fading.</p>	<p>It is a very serious disease in immunocompromised individuals. It is more severe in infants and adults. 30% of all cases have one or more complications including: diarrhea (8%); otitis media (7%); croup; pneumonia (6% of cases but causes 60% of measles-related deaths); encephalitis (case fatality rate 15%; 25% of survivors have permanent neurological damage); seizures (less than 1%); death occurs in 1/1000 cases; subacute sclerosing panencephalitis is an extremely rare brain disease that occurs approximately 7 years after a person has measles (1/100,000 cases). Measles disease provides life-long immunity.</p>	<p>MMR vaccine may prevent measles disease when given to susceptible individuals within 72 hours of exposure. Swelling, redness and tenderness is mild at the injection site and lasts for 1-2 days. Fever is common and occurs 8-10 days after MMR immunization and last 1-2 days. A non-infectious rash may occur 8-10 days after immunization in 2% of children, and lasts 1-2 days. Parotitis and/or swollen lymph glands: less than 1%. Transient</p>



Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
			arthralgia or arthritis in 25% of susceptible post-pubertal females. Encephalitis: less than 1 case per 1 million doses. Transient thrombocytopenia: less than 1 in 30,000 doses.
Mumps – Virus is spread via respiratory droplets and multiplies in the nose and throat, and regional lymph nodes. Virus can be detected in saliva, cerebrospinal fluid, urine, blood, and breastmilk.	2 weeks after exposure: myalgia, anorexia, malaise, headache, and low-grade fever. Unilateral or bilateral parotitis occurs in first 2 days of disease in infected individuals, and resolves in 10 days. Infected tissues and organ are very inflamed and painful.	Complications include: unilateral or bilateral parotitis: 30 - 40%; orchitis: 20 - 50% in post pubertal males; oophoritis: 5% in post pubertal females; pancreatitis 2-5% cases; deafness: 1 per 20,000 cases (80% unilateral); encephalitis: 0.5%. 20% infected individuals are asymptomatic but can spread virus to non-immune persons. 40% to 50% may have only respiratory symptoms. Mumps disease provides life-long immunity.	See MMR vaccine above.
Rubella – Virus is spread via direct contact with or droplet spread of nasal and throat secretions from infectious individuals. Rubella in the first 20 weeks of pregnancy results in anomalies, death, abortion and premature deliver in up to 90% developing fetuses.	Rubella develops 14-17 days after exposure. 50% of infections are mild and subclinical, especially among young children. First 1-5 days of disease: low grade fever, malaise, lymphadenopathy (for several weeks), upper respiratory symptoms, and maculopapular rash which starts on face, then head to foot for 3 days. Finger, wrist and knee arthralgia and arthritis may present in adult women.	Risk of Congenital Rubella Syndrome (CRS) is 85% in maternal infections in the first 10 weeks of pregnancy. CRS may include miscarriage, stillbirth, and fetal malformations such as congenital heart disease, cataracts, deafness, and mental retardation. 70% adult women have arthralgia or arthritis for 1 month, chronic arthritis is rare; encephalitis: 1/6,000 cases, mortality rate is up to 50%, more frequent in adult women. Rubella disease provides life-long immunity.	See MMR vaccine above.
Hepatitis B – Virus is spread by exposure to blood and body fluids of an acutely or chronically infected person. Infected individuals can spread the virus 1-2 months before they develop symptoms. Direct exposure	Children and 50% of adults are asymptomatic. 60-150 days after exposure, 50% of adult infected experience malaise, fever, headache, and myalgia, then develop jaundice, dark urine, light-coloured stools and right upper abdominal quadrant pain.	There is no specific treatment for HB. Risk of chronic infection depends on age at time of infection: infants: 90 - 95%; children 1 – 5 years: 30 -50%; adults: 5%. Chronic HB infection results in high morbidity and mortality rates from cirrhosis, liver failure and hepatocellular carcinoma. Fulminant hepatitis occurs in 1-2% of infected persons and has a high case-fatality rate (> 60%). HB infection increases the risk of developing hepatitis D infection. HB	Local reactions include redness, swelling and tenderness at the injection site. Fever, fatigue, and irritability occur less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare.

Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
<p>can occur via unprotected sex or sharing intravenous drug use and tattooing / piercing equipment. Indirect contact may be through a needle-stick injury.</p>	<p>During convalescence, malaise and fatigue may persist for weeks or months.</p>	<p>infection provides life-long immunity and most adult infections result in complete recovery.</p>	
<p>Hepatitis A - transmitted via the fecal-oral route, which can occur from direct person-to-person contact, contamination objects or environment or through contaminated food or water. The virus may remain infectious in the environment for several weeks</p>	<p>Symptoms (anorexia, nausea, fatigue, fever, fever and jaundice) appear after an incubation period of 15 to 50 days (average 28 days). Cases are infectious 2 weeks before the symptom onset & remain infectious for 1 week after the onset of jaundice.</p>	<p>Viral shedding can be greatly prolonged in immunocompromised individuals. Approximately 25% of adult cases are hospitalized. The overall case fatality rate is approximately 0.5%, but can reach 2.6% in adults over 60 years of age. Individuals with chronic liver disease and immunocompromising conditions have an increased risk of progressing to fulminant hepatic failure resulting in death. Chronic hepatitis and carrier states are not associated with HA; however, relapsing hepatitis lasting up to a year occurs in 15% of cases.</p>	<p>Reactions are generally mild and transient, and are usually limited to soreness and redness at the injection site. Other less frequent reactions include headache, irritability, malaise, fever, fatigue and gastrointestinal symptoms. Injection site reactions occur less frequently in children (21%) than in adults (56%) as do mild, systemic events (2% to 9% versus 16%).</p>
<p>Human papillomavirus – human papillomaviruses are the most common sexually transmitted pathogens. They are transmitted sexually by direct epithelial (skin or mucosa) to epithelial contact, and vertically to an infant exposed to the virus in the maternal genital tract</p>	<p>Infection with one HPV type does not prevent infections from other types. Most HPV infections are asymptomatic in men and women. Clinical manifestations include anogenital warts, cervical cell abnormalities, and cervical, vaginal, vulvar, penile, and head and throat cancers.</p>	<p>High-risk HPV types 16, 18, 31, 33, 45, 52, 58, and others, can lead to cervical and anogenital cancers, as well as certain cancers of the head and neck. Low-risk HPV types 6 and 11, and others, can cause genital warts. Recurrent respiratory papillomatosis caused by HPV types 6 and 11 may be acquired from mother at birth or occur in adulthood.</p>	<p>Local reactions include pain, swelling, and redness at the injection site. Fever occurs less frequently. These reactions last 1-2 days. Anaphylactic reactions are very rare.</p>
<p>Influenza – Highly contagious viruses are spread via respiratory secretions. School-aged children have the highest attack rates in community outbreaks and serve as main source of community transmission.</p>	<p>Influenza A causes moderate to severe illness. Influenza B causes milder illness and mostly affects children. 1-4 days after exposure, 50% of people develop sudden fever, myalgia headache, sore throat, and non-productive cough which last 2-3 days. Fatigue may persist for several weeks post-infection.</p>	<p>Highest rates of influenza-related complications and death occur among young children, the elderly and immunocompromised persons. Secondary bacterial pneumonia is the most frequent complication. Viral pneumonia is uncommon but has a high fatality rate. Myocarditis and exacerbation of existing respiratory conditions may occur. Mortality rate is 0.5-1 per 1000 cases, majority among those ≥ 65 years.</p>	<p>Local reactions include pain, swelling, and redness at the injection site. Fever headache, malaise and myalgia may also occur. These reactions last 1-2 days. Anaphylactic reactions are very rare. Risk of GBS estimated to be 1 excess case per million doses of influenza vaccine.</p>



Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
<p>Meningococcal Disease – Bacteria are spread via droplet aerosol or direct contact with nasopharynx secretions of infected person. In 1% of colonized individuals, bacteria enter into bloodstream, and in 50% of these individuals, the bacteria crosses the blood-brain barrier to cause purulent meningitis.</p>	<p>Invasive disease occurs 3-4 days after exposure. Meningitis is the most common presentation of invasive disease. Symptoms include sudden onset fever, headache, stiff neck, photophobia, altered mental status, nausea and vomiting. Sepsis occurs without meningitis in 5%-20% of invasive disease, and symptoms include sudden fever, petechial rash, shock, hypotension, acute adrenal hemorrhage and multiorgan failure. Uncommon presentations: pneumonia (5 - 15% cases), arthritis (2% cases), otitis media (1% cases), and epiglottitis (< 1% cases).</p>	<p>Meningitis case fatality rate: 9 - 12%. Septicemia case fatality rate: 40%. Sequelae occur in up to 20% of survivors and include hearing loss, neurological damage, loss of limbs from gangrene, and kidney damage. Risk factors for meningococcal disease development include immune deficiencies from congenital conditions, functional or anatomical asplenia and immunosuppressing disease like HIV. Antecedent upper respiratory infections, household crowding, and smoking/second hand smoke are risks factors for spread of bacteria.</p>	<p>Polysaccharide and conjugate vaccines: redness, tenderness, and swelling at injection site in up to 59% of recipients lasting 1-2 days. Fever occurs in 3%-5% of recipients. Headache and malaise up to 7 days following immunization occur in 60% of recipients. Anaphylactic reactions are very rare.</p>
<p>Pneumococcal Disease – Bacteria are spread by direct contact with respiratory droplets of bacterial carriers. Carriers of bacteria in their upper respiratory tract are more likely to develop disease if they have underlying medical or pulmonary conditions or immunosuppression related to disease or medical treatment.</p>	<p>The major clinical symptoms are pneumonia, bacteremia and meningitis. Otitis media also occur in young children. Pneumonia symptoms are generally abrupt and include fever, shaking chills, pleuritic chest pain, productive cough, dyspnea, tachypnea and hypoxia. Bacteremia symptoms are similar without severe respiratory symptoms. Meningitis symptoms include headache, neck stiffness, lethargy, vomiting, irritability, fever, cranial nerve signs, seizures and coma.</p>	<p>Before routine use of conjugate vaccine among young children in the USA, 17,000 cases of invasive disease included 13,000 cases bacteremia, 700 cases meningitis and 200 deaths; 5,000,000 cases of otitis media occurred annually. Pneumococcal pneumonia is a common bacterial complication of influenza and measles. Among adults 36% cases are community-acquired and 50% cases are hospital-acquired. Complications of pneumonia include empyema, pericarditis and endobronchial obstruction (atelectasis and lung abscess formation). Case fatality rate is 5 - 7%; much higher among the elderly. Invasive diseases: Pneumococcal meningitis case fatality rate: 30%; up to 80% among the elderly. Neurologic sequelae common among survivors. Bacteremia in 25%-30% of persons with pneumococcal pneumonia: case fatality rate is 20%; up to 60% among the elderly. Otitis media occurs in 60% of infants less than 12 months old.</p>	<p>Anaphylactic reactions are very rare with either vaccine formulation. Conjugate vaccine: Fever within 7 days of immunization occurs in 24%-35% children. Redness, swelling and pain at injection site in 50% of recipients; more common with 4th dose in infants. Decreased appetite and irritability occur in 80% recipients. These reactions last 1-2 days. Polysaccharide vaccine: redness, swelling and pain at injection site in 30 - 50% of recipients; more common with second doses. Fever: 2%. These reactions last 1-2 days.</p>



Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
<p>Rotaviruses (RV) – These are spread by fecal-oral transmission and can also be transmitted through close person-to-person contact and fomites such as toys and hard surfaces. RV can survive on hands for at least four hours and remain viable on surfaces or fomites for days. Hand washing is an important preventive measure. RV can also be spread through contaminated food and water, and through respiratory droplets. Viral shedding can begin a few days prior to the onset of symptoms and can continue until 21 days after the onset of illness.</p>	<p>Most children have been infected with RV by 5 years of age. In a 2005 study, RV caused 55% of laboratory-tested gastroenteritis cases that were seen in physician offices and pediatric clinics across Canada. RV infections can occur with a variety of presentations including asymptomatic infection, mild disease to severe infection leading to severe dehydration and death. After an incubation period of 18 to 36 hours, there is typically an acute onset of fever (53%-89%) and vomiting (89%-97%). This is usually followed by diarrhea, which typically lasts for 5 to 7 days. There are often fewer than 10 non-bloody, but mucousy bowel movements per day. There are few distinguishing singular features among those who have RV gastroenteritis versus those with other causes of gastroenteritis. The presence of all 3 symptoms (fever, vomiting and diarrhea) is reported more commonly with RV than with other gastrointestinal viruses (61.8% versus 38.7%).</p>	<p>RV illness is seasonal (fall-winter). It generally follows peak respiratory disease health care demands. The social impact is minimal but broad. Studies have found that out-of-pocket costs (e.g., rehydration therapy, non-prescription drugs, diapers and transport) and time lost from work are considerable for the families of affected children. RV positive cases were more likely to visit the emergency room (27% versus 14%, p=0.0082), to be hospitalized (13% versus 4% p=0.0079) and to receive IV hydration (13% versus 3%, p=0.0027) than were RV negative gastroenteritis cases. While a paediatrician’s visit(s) was adequate for the overwhelming majority of children in the Toronto-area study with RV diarrhea, 17% went on to an ER visit and 6% were either hospitalized or received IV hydration in the ER.</p> <p>Summary for preschoolers in Canada:</p> <ul style="list-style-type: none"> • 1 child in 7 will have sought health care. • 1 child in 20 will have visited an ER or been hospitalized. • 1 child in 62 will have been hospitalized. • No deaths from RV. 	<p>Rotavirus vaccines are safe and effective in term and pre-term infants.</p> <p>Common reactions: ≥ 1% and < 10% - diarrhea, irritability, fussiness.</p> <p>Uncommon reactions: ≥ 0.1% and < 1% - flatulence, abdominal pain, dermatitis, runny nose, cough, fever, loss of appetite, vomiting.</p> <p>Although a previous rotavirus vaccine in the 1990’s was linked to intussusception, the current rotavirus vaccines have not been associated with an increased risk of intussusception in babies who receive the vaccine.</p> <p>No deaths have been attributed to the current rotavirus vaccines available in Canada.</p>



Disease and Method of Transfer	Clinical Disease Features	Risks and Complications Associated with Disease	Adverse Events Associated with Vaccine
<p>Varicella – Varicella zoster virus (VZV) is highly contagious and spreads via direct contact with the fluid within the lesions or inhalation of aerosolized particles from lesions, and via mucus membrane contact with airborne droplets of respiratory secretions. VZV is communicable from 1-2 days before onset of rash through first 4-5 days until crusts have formed over the first crop of lesions.</p>	<p>14-16 days after exposure in adults, fever and malaise occur 2 days before rash. Children generally have rash as disease onset, followed by fever and malaise. Rash progresses from macules to papules to vesicular lesions before crusting starting on the head, down to the trunk and limbs and on mucous membranes. 2-4 crops of pruritic lesions occur over several days. They may rupture or become purulent before drying and crusting over. Immunocompromised children may develop a severe and prolonged form of varicella disease with high complication rates. Healthy adults may have a more severe disease and have a higher incidence of complication compared to healthy children.</p>	<p>In the pre-vaccine era (before 1995), annual USA hospitalization rates were 2-3/1,000 cases health children and 8/1,000 cases in healthy adults. Death occurred in 1/60,000 cases (103 per year, mostly among immunocompromised children and adults). Reactivation of varicella virus as herpes zoster (shingles) may occur later in life (estimated that 50% of those over 80 will have had shingles). Adults account for 5% cases but 35% of mortality rate. Fatality rate 1-14 years is 1/100,000 cases; 15-19 years is 2.7/100,000 cases; 30-49 years 25.2/100,000 cases. The risk of complications varies with age and is highest among infants <12 months and those >15 years. Secondary <i>Staphylococci</i> or <i>Streptococci</i> bacterial infections of skin lesions are the most common cause of hospitalization and outpatient medical visits. Invasive group A <i>Streptococcal</i> infections can also cause severe illness and death: 5/100,000 cases. Secondary bacterial pneumonia is common in infants <12 month old. Central nervous system manifestations are more common in adults and include cerebellar ataxia (1/4000 cases) and encephalitis (1.8/10,000 cases and leads to seizures and coma). Maternal varicella infection occurring 5 days before delivery-2 days after delivery causes severe neonatal infection and a 30% fatality rate. Congenital varicella syndrome: up to 2% of fetuses born to mothers infected at 13-20 weeks gestation. Rare complications: aseptic meningitis, GBS, thrombocytopenia, hemorrhagic varicella, myocarditis, arthritis, orchitis, uveitis, iritis and hepatitis. Disease usually provides life-long immunity.</p>	<p>Redness, swelling and pain at injection site in 24% of children and 24% of adolescents (33% following 2nd dose). Varicella-like rash at injection site within 2 weeks of immunization: 3% of children. Generalized rash within 3 weeks of immunization in 4%-6% of recipients. Fever within 42 days of immunization: 10% - 15%; most attributed to other concurrent illnesses. These reactions are mild and last 1-2 days. Risk of herpes zoster (shingles) after immunization is much less than risk from wild disease (32% lifetime risk). Anaphylactic reactions are very rare.</p>

(Adapted from BCCDC Immunization Program, 2009; Source: 2011 Pink Book; NACI statements).

Appendix 3.3: Immunization Facts

- 1. Vaccines work - immunizations are the most effective way to protect against vaccine preventable diseases.**
 - Serious disease can occur if a person, their child and family are not immunized.
 - Immunization protects individuals who receive the vaccine **and** those with whom they come in contact, especially people who cannot be or are incompletely vaccinated due to medical conditions or age.
- 2. Vaccines strengthen the immune system, not weaken it.**
 - Vaccines stimulate, strengthen and train the immune system to defend against vaccine preventable infections before illness can occur. Immunization does not significantly add to the body's daily exposure to antigens.
- 3. Vaccines are safe for everyone.**
 - The vaccines used in Canada are highly effective and extremely safe. Vaccines are among the safest medical products available. Serious side effects, such as severe allergic reactions, are very rare.
- 4. The risks of vaccine preventable diseases are many times greater than the risk of a serious adverse reaction to a vaccine.**
 - Diseases like polio, diphtheria, measles and pertussis (whooping cough) can lead to paralysis, meningitis, pneumonia, choking, brain damage, heart problems, and even death.
 - Although these diseases are rare in Canada, if immunization programs were reduced or stopped, they would re-appear in epidemics causing sickness and death.
 - Serious reactions to vaccines are very rare and it is often very difficult to determine if a reaction was directly linked to a vaccine or if it was an unrelated event which only occurred by coincidence after the vaccine was administered.
- 5. Research shows that vaccines are not linked to autism, multiple sclerosis (MS), asthma, or sudden infant death syndrome.** Canadian and international research using rigorous scientific methods has shown that:
 - Measles-mumps-rubella (MMR) vaccines do not cause autism
 - Thimerosal-containing vaccines do not cause autism
 - Hepatitis B vaccine does not cause multiple sclerosis (MS) or relapses of pre-existing MS
 - Pertussis vaccine does not cause brain damage
 - Vaccines do not cause sudden infant death syndrome
- 6. Getting multiple injections at one visit is an effective way of ensuring up to date immunization.**
 - Multiple injections of vaccines do not overwhelm the immune system and ensure that people are up to date with the vaccines required for their age and risk factors. Infants and children have similar immune responses whether vaccines are given at the same time or at different visits.
 - Delaying vaccines may leave a child or adult vulnerable to vaccine-preventable diseases.
- 7. Vaccine preventable diseases can occur at any time because the bacteria and viruses that cause these infections have not been eliminated and spread quickly and easily among people who are not immune.**
 - Bacteria and viruses that cause pneumonia, meningitis, diphtheria, pertussis, polio, measles, mumps, rubella, varicella, hepatitis A and hepatitis B are present in Canada and other parts of the world.
 - Travellers can carry diseases from other countries into Canada. Unless a disease has completely disappeared worldwide, there is a real risk that outbreaks will occur in Canada.
 - Tetanus is distributed in soil and will never be eliminated so the risk of getting tetanus continues to exist for all people who are not immunized.

8. *Haemophilus influenzae* type b (Hib), *Streptococcus pneumoniae* (pneumococcal disease) and *Neisseria meningitidis* (meningococcal disease) are carried in the nose and throat of some healthy people, so these diseases continue to be a threat.
9. **Unvaccinated individuals have a much greater chance of getting a vaccine-preventable disease than people who have been vaccinated, even in countries with high levels of immunization.**
 - It may be impossible to avoid being exposed to a vaccine-preventable disease. For example, an unvaccinated person can get measles by breathing the air in a room that was occupied hours before by a measles-infected person (e.g., in a doctor's office).
 - Immunization can reduce the risk of severe disease if you do happen to get infected.
 - When disease is spreading in a community, a small percentage of vaccinated people may get sick because no vaccine can be 100% effective in everyone. However, a much larger percentage of unimmunized or under-immunized people exposed to the disease will become ill and can continue spreading the disease to others. In Canada in 2011-2014, measles importations led to many outbreaks in most provinces and territories. Where immunization status of those who got the disease was known, approximately 80% were not adequately immunized,
10. **Vaccine-preventable diseases re-appear quickly if immunization coverage drops.**
 - In Japan, pertussis immunization coverage dropped from 90% to less than 40% because of public concern over two infant deaths following vaccination in 1975 (later found **not to be** caused by the vaccination). Following the drop in immunization, surveillance data collected over a three year period showed that during this time the number of pertussis cases increased to approximately 13,000 and the number of deaths to over 100 per year.
 - In Ireland, measles immunization coverage dropped to 76%, following false allegations of a link with autism. In 2000, the number of measles cases increased from 148 to 1,200, and several children died due to the complications of measles.
 - The potential for re-emergence of diphtheria if immunization levels decline was demonstrated during the 1990s in the Commonwealth of Independent States (former Soviet Union) when over 40,000 cases and 4,000 deaths were reported.
11. **Vaccines may contain additional substances to ensure effectiveness and safety – these substances are safe.**
 - The main ingredients of vaccines are killed or weakened viruses or bacteria or their parts. These are called antigens and they train the immune system to recognize and prevent disease.
 - Additional substances may be required in the vaccine to ensure effectiveness and safety:
 - Very small amounts of preservatives, such as phenol, 2-phenoxyethanol or thimerosal, may be added to a vaccine to prevent the growth of microbes in the vaccine when it is used.
 - Adjuvants, such as aluminum salts and squalene, may be added to strengthen the immune response to the vaccine. Without an adjuvant, people might require more frequent or higher doses of vaccines to be protected.
 - Additives, such as gelatin, human serum albumin or bovine reagents, are added to vaccines to help vaccines remain effective while being stored.
 - Substances, such as formaldehyde, antibiotics, egg proteins or yeast proteins, may be needed for the vaccine manufacturing process.