Ontario Vaccine Deliberation

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VACCINE DELIBERATION

ONTARIO

What is the Purpose of this Booklet?

This booklet is meant to stimulate and inform discussion and reflection for the Ontario Vaccine Deliberation. While it includes a variety of perspectives, it cannot encompass the diversity of all possible perspectives. Reading it is the first step of being involved in a 4-day public deliberation event on childhood vaccination in Ontario (see **What is a public deliberation?** on page 4).

This booklet is not intended to be either for or against vaccines.

In this booklet, you will find information on a range of issues related to childhood vaccination, such as history about the development of vaccines, the science behind vaccines, and both the good that has come from vaccines as well as some of the things that have gone wrong with vaccines. The information presented in this booklet, and the discussions that will take place in October, are focused on *early childhood vaccinations* (see **Ontario's publicly-funded immunization schedule** on page 11).

People draw on different types of information to support their opinions. There is a range of available information about vaccines on the Internet, in the media, in academic journals and other sources, and it is difficult to know which information to trust. The scientific information presented in this booklet has been collected from peer-reviewed publications – that is, information that has been verified by experts in the field. When deciding what scientific information to include, we used, as much as possible, meta-analyses to report current scientific perspectives. A **meta-analysis** is the 'gold standard' in scientific research because it is a study that analyses the findings of multiple studies. This analysis allows for greater statistical power, which leads to greater confidence in conclusions presented by the meta-analysis. The information included in this booklet is not based on unsubstantiated articles found on blogs or other websites, published in low-quality or predatory academic journals, or retracted scientific papers.

We hope that you will find the information presented interesting, and that it will answer many of your questions. It may also raise new questions for you. Bring these questions, as well as your insights and perspectives, to the deliberation to which you have been invited on October 14, 15, 28, and 29. There, you will meet Ontarians from all walks of life who, like you, have been selected to represent a wide diversity of perspectives.

What is a Public Deliberation?

A **public deliberation** is a community discussion about a particular topic that is based on the idea that members of the public, such as yourself, should have a voice in the issues that affect them. Public deliberation is a democratic process that includes citizens, not just policy makers or experts, in important policy decisions.

The importance of deliberative democratic discussion

Deliberative democratic events, such as the event you will attend in Waterloo, shift the discussion about important societal issues from telling people what they need to know about an issue to recognizing that individuals in society are sources of information and have important things to say about policy. We hope to both educate and seek advice in this deliberative democratic event. Our intention is to help inform effective policy by bringing together people who have different backgrounds, opinions and life experiences, and encouraging them to work together on challenging issues. By bringing together the knowledge, perspectives, and advice of a group of Ontarians, we can make recommendations for policy that reflect diverse social realities. We believe this will add to the trust we can put in the outcomes of these processes.

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Introduction

Canadians hold different beliefs about many things. We pride ourselves on our diversity of culture, religion, race and opinion on a range of topics. In spite of this diversity, we are governed by laws and policies that are intended to treat us equally. Deliberative democracy is based on the idea that we should all have the opportunity to provide input about decisions on issues that affect us all. This is especially so for issues that are considered controversial.

Childhood vaccination is one such issue. In Canada, public health experts rely on vaccines to protect children from serious diseases (see **Herd Immunity** box). Most Canadian parents vaccinate their children. However, some parents may also have concerns about the efficacy and safety of vaccines and the recommended immunization schedule for children. These concerns have led some parents to delay vaccinating or choose not to vaccinate their children.

What is Herd Immunity?

Non-vaccinated individuals, including infants and people with medical conditions that make them unable to receive vaccines, are protected by the "herd" or "community" of vaccinated people.

There are different reasons why parents may be hesitant about vaccines. They may not feel they can trust the medical community, or they may have concerns about vaccine efficacy and safety. Recently, several celebrities have been strong advocates against vaccines and this may influence some parents' decisions to delay or refuse vaccination for their children. Parents trying to make a good decision for their children find arguments in favour of and against vaccination in media reports, magazines, radio, TV, and the Internet. Healthcare practitioners and the scientific literature may also provide different messages about the efficacy and safety of vaccines. This different information complicates the decision-making process for parents.

To move forward on this important topic – that is, to develop collective positions and recommendations about vaccines that take into account the diverse perspectives on vaccines in our society – we need to have a *reasoned* and *respectful* conversation. Unlike many other decisions that we face in daily life that affect only ourselves, vaccination decisions that we make as individuals also affect our children, our families, and our communities. It is therefore important that policies about childhood vaccination take into account as many perspectives as possible. Moreover, we want this *conversation* to include as wide a range of relevant perspectives as possible. Listening to and working with people with different perspectives is important for creating inclusive and fair policies that both respect personal choice and protect the public's health.

What is 'Immunization', 'Vaccination', and 'Immunity'?

The words "immunization" and "vaccination" are often used interchangeably. **Immunization** is the strengthening or fortifying of a person's immune system against infectious disease microorganisms by controlled exposure to those microorganisms or a closely related agent. A person can gain **immunity** against a contagious disease by (1) surviving the illness or (2) exposure to a dead or weakened version of the infection in a **vaccine**. In both cases, the immune system builds protection against that virus such that the body will not become ill if it encounters the actual disease.

A Brief History of Vaccination

While vaccines are 19th and 20th century scientific developments, the practice of immunization dates back much further. The ancient Greeks observed that survivors of the plague of Athens (c. 430 BCE) did not become re-infected upon re-exposure to the deadly bacteria. There is historical documentation of efforts throughout Asia, Europe, and the Middle East from the 11th century onward to *inoculate* people (create resistance) against smallpox by controlled exposure to the infectious disease. Participants usually contracted mild forms of smallpox and survived. Edward Jenner overcame the dangers associated with direct exposure to the disease by creating the first smallpox vaccine in 1798.

Jenner's Vaccine Discovery

Jenner (Figure 1) immunized a 13 year-old boy from smallpox by exposure to *cowpox,* a bovine disease that was closely related to smallpox but had no risk to human health. Having observed that Dutch milk maids never contracted smallpox, he reasoned that the *vaccinia* virus (cowpox) could be a safe substitute for the *variola* virus (smallpox) in inoculation practices.

Figure 1. Edward Jenner

With the invention of the small pox *vaccine* (insertion of *vaccinia* virus below the skin membrane), it became possible to develop other viral substitutes to deadly diseases. These vaccines create immunity without the risks of the actual disease. Other approaches were also developed. In 1897, Louis Pasteur figured out how to weaken the cholera virus to make a safe cholera inoculation. In 1904, Pasteur was able to inactivate the protein in the anthrax virus, making it safe for vaccination.

The 20th century was marked by the development of vaccines against many of the deadliest and most debilitating infectious diseases: tuberculosis (1921), diphtheria (1923), pertussis (whooping cough) (1926), yellow fever (1932), typhus (1937), polio (1952), measles (1963), and many more.

Controversies on Childhood Vaccinations

While the number of Canadian parents who hold strong anti-vaccine beliefs and choose not to vaccinate their children is generally low (fewer than 3%), increasing numbers of parents (25- 35% in Canada) demonstrate some degree of uncertainty or negativity towards vaccines. Some parents who have concerns about vaccinating their children will nevertheless agree to vaccinate them, perhaps reluctantly, while others will refuse, and some will try to negotiate a personalized schedule in place of their province's immunization schedule (see **Ontario's Publicly-funded Immunization Schedule** on page 11).

Canadian health agencies and medical bodies strongly endorse vaccines. For example, *the Canadian Immunization Guide* is a publication of the Public Health Agency of Canada (PHAC) that summarizes the recommendation of the National Advisory Committee on Immunization. It describes vaccines as "a cornerstone of public health and their use has significantly contributed to the prevention and control of infectious diseases in Canada and internationally."

Both the Public Health Agency of Canada and Canadian Pediatrics Society tie vaccination to responsible parenting. In *A Parent's Guide to Vaccination* (PHAC, 2016):

"Parents are responsible for the well-being of their children, including protecting them from illness caused by diseases that are vaccine-preventable…Vaccinating your children is the best way to keep them safe from many serious and potentially deadly diseases."

The Canadian Pediatrics Society's parent resource, *Your Child's Best Shot* (2015), similarly instructs: "Immunizing children is one of the most important ways to promote their health." However, some parents may instead see the responsible choice to be delaying or refusing vaccination due to concerns about the efficacy or safety of vaccines. Parents may see themselves first and foremost responsible for the welfare of their own children before others. They may also believe they have the resources in place to protect their children from infectious diseases without vaccines.

Unlike many of the choices we make for ourselves and our families that only affect our individual health, such as choosing one medical treatment over another or visiting the doctor for regular checkups, vaccination has a broader public health impact. In the case of vaccination, vaccines reduce individual risk directly and through the effect on the population. When most of the population is vaccinated against a disease, it is difficult for the disease to spread, protecting even those who have not been vaccinated or who have become more susceptible. Therefore, vaccination is recommended to reduce individual and population level risk. The current rates of vaccine uptake in Canada are not that high, according to Unicef, and if uptake shifted downward, major outbreaks could become more common. Therefore, the controversy over vaccines is important in broad considerations of securing the health of Canadians (see **Public Health Perspectives** below).

Public Health

Public health involves consideration of the health of the entire population. It often involves activities to avoid risks of disease that are only effective if provided at the population level. Clean water and sewage disposal are examples. These activities require implementation at a group level and the entire population benefits from reduced risk.

Current Vaccine Requirements and Exemptions for School-Age Children in Ontario

Ontario and New Brunswick are the only provinces in Canada with legislation governing the vaccination of children entering schools or daycares. Children are expected to be vaccinated on time according to the provincial schedule unless parents pursue a legal exemption to vaccines.

Ontario's *Immunization of School Pupils Act* (ISPA) states that children and adolescents who attend school and daycare in Ontario must have proof of immunization against Diphtheria, Tetanus, Polio, Measles, Mumps, Rubella, Meningococcal Meningitis, Pertussis ("whooping cough"), and Varicella ("chicken pox").

Vaccine exemptions from these requirements can be obtained on:

1) medical grounds,
2) conscience or personal beliefs, or
3) on religious grounds.

If a child cannot be immunized for medical reasons, such as a compromised immune system, parents submit to the school or daycare a **Statement of Medical Exemption** completed by a physician or nurse practitioner. At the same time, if the child has pre-existing immunity against an illness, an exemption can be sought for that particular vaccine. For instance, if a child has had measles, exemption from measles immunization can be obtained with a statement of medical exemption completed by the child's health care provider.

Ontario's Publicly-funded Immunization Schedule

- Four doses of DTaP-IPV-Hib* at two, four, six, and eighteen months
- Two doses of Pneu-C-13° and Rot-1▫ at two and four months with a third dose of Pneu-C-13 at twelve months
- One does of Men-C-C°° and MMR▫▫ at twelve months
- One dose of Varicella at fifteen months
- One dose of MMRV□ and Tdap-IPV recommended at four years but can be taken between four and six years of age
- One dose of Hepatitis B, Meningococcal Conjugate, and HPV4 in Grade 7

This is the routine schedule prescribed for every child.
"Catch-Up Schedules" and "Alternative Schedules" are available for children who start their vaccination later or require modifications to the schedule due to medical conditions.

* Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae type b
° Pneumococcal Conjugate 13 ▫ Rotavirus
°° Meningococcal Conjugate C ▫▫ Measles, Mumps, Rubella
□ Measles, Mumps, Rubella, Varicella

Parents who do not vaccinate their children with all or some of the recommended vaccinations due to conscience or on religious grounds are required to submit to their school or daycare a **Statement of Conscience or Religious Belief Affidavit** affirming that (1) "the requirements of the *Immunization of School Pupils Act* conflict with my sincerely held convictions based on my religion or conscience." and (2) children can be excluded from school or daycare if there is an outbreak or immediate risk of an outbreak of a designated disease for which the child has not been vaccinated. In addition, since 2017 parents are required to complete an educational session before their child can be exempted.

Several US states have given a higher priority to reducing preventable outbreaks over parental choice. In response to increases in vaccine-preventable disease outbreaks in 2014 and 2015, they introduced legislation to remove personal belief and/or religious exemptions. In 2015, California removed personal belief and religious exemptions for vaccines, and Vermont removed personal belief exemptions.

Antigens in Vaccines

The current generation of Ontarian children receives more immunizations than their parents and grandparents. However, they actually receive fewer disease causing proteins, or **antigens**. Overall numbers of antigens in vaccines have been reduced from about 3,041 in 1980 to approximately 153 today. In comparison, infants are exposed to trillions of bacteria from the moment they are born. Babies' immune systems successfully respond to these bacteria as well as many other external threats.

Other US states have reduced the number of non-medical exemptions by making it more complicated to obtain an exemption. Michigan, for example, now makes parents have a face-to-face consultation with a physician in order to get even a non-medical exemption form signed by the doctor.

Reasons for Vaccine Hesitancy

There are different reasons why some parents may refuse or hesitate having their children vaccinated for some or all diseases. For some, the reasons are religious in nature. Although many different religions are practiced in Canada, when it comes to vaccines two of the most prominent religious objections are:

1) Ethical concerns relating to the use of human tissue in making vaccines
2) That the body is sacred and should not be injected with certain substances, and that it should be healed by God if that is His will

For others, the reasons for refusing or hesitating about vaccines relate more to issues of trust of the medical community or science on vaccine efficacy and safety. A controversial and now withdrawn article alleging a link between vaccines and autism (see **Andrew Wakefield** box on page 17), the **Cutter Incident** (see box on page 18), and reports of cases of biased research by pharmaceutical companies have led some parents to question whether they should vaccinate their children. Parents may feel that they cannot rely on the information communicated by official sources.

Many vaccine hesitant parents may question why healthy individuals need to be immunized in the first place, especially for diseases they may not ever be at risk of. Vaccines may be seen as unnecessary as well as unnatural interventions. Immunity gained through the course of an individual's life is seen by some to be a superior way of approaching the issue:

"Like, we didn't come into this world, you know, requiring a shot…We have a God-given immune system and it's sad that the medical field doesn't recognize that. It's like, you don't have to shoot things into the body…Let's support what we already have."
(A mother in USA)

Parents may also have concerns that receiving so many vaccines at a young age can overload the immune system of children and try to develop their own schedules for immunizing their children:

"I'll wait till they're two, that's my target. . . a lot of my friends waited till they were two . . . it seems like a good point, so they start going nurseries and different things." (A British mother)

With these concerns regarding vaccines, parents also look for alternative approaches to immunization (see **Complementary and Alternative Medicine** section).

Public Health Perspectives on Vaccines

Vaccines are widely regarded as one the most effective global public heath interventions, saving millions of lives every year. Based on available evidence, there is widespread agreement among medical scientists and physicians about the safety and public health benefits of approved vaccines. In Canada, the number of people who die from serious diseases has declined significantly following the introduction of routine immunization (see Figure 2):

Disease	Cases in Canada in peak year, before routine immunization[1]	Reported cases in Canada in 2012[2]
Diphtheria	9,010	0
Haemophilus influenzae b (Hib)	671	23
Measles	61,370	9
Mumps	43,671	49
Pertussis	19,878	4,540[3]
Polio	5,384	0
Rubella	37,917	2
Tetanus	25	2

1. Public Health Agency of Canada (2014). Canadian Immunization Guide (Part 1: Key Immunization Information > Benefits of Immunization). Evergreen Edition. Accessed 2015/06/24 at http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-02-eng.php.

2. Public Health Agency of Canada (2014). Reported cases from 1991 to 2012 in Canada – Notifiable diseases on-line. Accessed 2015/06/23 at http://dsol-smed.phac-aspc.gc.ca/dsol-smed/ndis/charts.php?c=yl.

3. Outbreaks of pertussis (whooping cough) in 2012 contributed to the number of reported pertussis cases in Canada.

Figure 2. Disease reduction rates following routine immunization

The Public Health Agency of Canada (PHAC) sees immunization as "an important, cost-effective and successful public health intervention. It effectively prevents disease, improves the health of Canadians, and reduces pressures on our health care system." PHAC cites studies from around the world that have "repeatedly shown that immunization is a proven and effective public health measure, especially when weighed against the health risks from many serious vaccine-preventable illnesses."

As well as protecting individuals, immunization programs that reach most of the population are important for public health. When a population achieves a high rate of vaccination, there is little opportunity for occasional infectious disease cases to spread throughout the community. This is called community immunity or **herd immunity**, and it is achieved when up to 95% of the population is immune (the level depends on the infectiousness of the disease). For example, measles, a highly infectious airborne disease, cannot spread if 92-95% of the population is immune. This means that non-vaccinated individuals, such as infants (less than 1 year old), and people with medical conditions that make them unable to receive vaccines, are protected.

Complementary and Alternative Medicine Perspectives on Vaccines

Many Canadians combine "conventional" and "alternative" health care practices, and parents who do not vaccinate their children may instead prefer to use Complementary and Alternative Medicine (CAM). Some CAM interventions have become increasingly accepted by "conventional" healthcare providers--for example, acupuncture for pain relief and chiropractic for some musculoskeletal conditions. Some CAM practitioners accept vaccines, but may also suggest remedies to reduce vaccine associated risks or suggest an alternative vaccination schedule.

Other CAM practitioners who oppose or are concerned about vaccines may endorse homeopathic preparations called **nosodes** (Figure 3).

Figure 3. Homeopathic nosodes

Nosodes are diluted homeopathic preparations made from the disease-causing organism or infected tissue or fluids from an infected person or animal. Under current Health Canada policy, nosodes cannot be recommended as an alternative therapy to vaccines, although they can be recommended as part of a broader treatment plan.

Parents may be attracted to the option of nosodes because they are promoted by some CAMs as providing the same or superior immune protection against infectious diseases without the risks associated with conventional vaccines. However, the professional policies on vaccination of both the *College of Naturopaths of Ontario* and the *College of Homeopaths of Ontario* state that there are no known alternatives to vaccination. Furthermore, the Canadian Pediatric Society, Health Canada, and many Canadian healthcare providers, strongly insist that there is no scientific evidence to support the safety and efficacy of nosodes.

As part of a CAM approach, some parents may also commit to strict nutritional plans (organic foods, prolonged breast feeding, herbal supplements) in the belief that such approaches will prevent or reduce the likelihood of infectious diseases.

Scientific Perspectives on Vaccines

Scientists have looked for possible adverse effects (including from both the antigens and additives) using biological (cellular), animal, and when possible, human research subjects.

In light of the controversy surrounding the falsified and now-retracted study by Andrew Wakefield (see box on page 17) suggesting a link between **MMR** (measles, mumps, rubella) vaccination and autism, scientists have further explored a potential causal link and have repeatedly concluded that the incidence of autism is no higher among children who are vaccinated than those who are not vaccinated.

Scientific research on vaccine safety has also examined the effects of adjuvants and preservatives used in vaccines, such as thimerosal and aluminum. **Thimerosal**, which contains *ethylmercury*, is used in vaccines to prevent bacterial and fungal contamination when multiple doses are stored in the same vial. Using multi-dose rather than single-dose vials is important for keeping vaccine costs low, particularly in countries with limited resources. In Canada, thimerosal is no longer used in most vaccines.

Recent **meta-analyses** (studies that combine the results of multiple studies) on the association between thimerosal and both autism and ADHD using human subjects found no evidence of a link. Animal research on the effects of thimerosal on autoimmunity suggests there may be a link in mice who are already genetically susceptible to mercury-induced autoimmunity but a **systematic review** of this research concluded that future research is needed to establish the effects of exposure. Some scientists have called for a complete removal of thimerosal from vaccines.

What is ethylmercury in Thimerosal?

Ethylmercury is a form of mercury that is chemically different from methylmercury. Methylmercury is a form of toxic mercury that collects in fish and is known to cause neurotoxicity in humans. Unlike methylmercury, ethylmercury does not accumulate in the body over time and does not have the same harmful effects.

Aluminum salts (aluminum hydroxide, aluminum phosphate, and alum) are **adjuvants** (or additives) used in some vaccines to increase immunity. Available meta-analyses do not support a link between vaccination with aluminum-containing DTP (diphtheria, tetanus, polio vaccine) and long-term adverse effects in human subjects. However, research does show evidence of localized (injection site) adverse outcomes, such as pain lasting for several days.

Andrew Wakefield

Andrew Wakefield is a British former surgeon who published a paper in 1998 claiming a link between the MMR vaccine and autism. The paper was fully retracted from *The Lancet* journal in 2010. Wakefield was found guilty by the General Medical Council of more than 30 charges of professional misconduct and ethical violations in the conduct of his research. As a result, his medical license was revoked.

Vaccine Production and Quality Control Process

Health Canada, pharmaceutical companies producing vaccines, and health care providers are responsible for maintaining quality of all vaccines produced and used in Canada.
Before new vaccines are tested on humans, they are first tested on animals in **pre-clinical trials**. If the results are good, the testing then moves to human subjects in **clinical trials**. If the results are promising on a small number of human participants, clinical trials then get larger to include hundreds or thousands of human participants. At this stage (as well as during Phase I clinical trials), information about how the vaccine influences the level of immunity, the appropriate dosage and most effective schedule of administration, and the potential for adverse side effects are evaluated.

The decision to allow the marketing of a new vaccine in Canada is regulated by the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada. BGTD is a federal authority that regulates all biological drugs including vaccines. Extensive information and data from preclinical and clinical studies, details of production, information regarding therapeutic claims and side effects, and packaging and labelling details must be submitted for consideration. BGTD also monitors production facilities and tests samples from batches of vaccines to ensure consistency in manufacturing. With all the data, BGTD considers whether the benefits of the vaccine outweigh its risks. Only then can a vaccine be approved.
Once the quality has been determined to be high, the vaccine is then evaluated by the National Advisory Committee on Immunization (NACI) to determine:

1) how the new vaccine compares to other available vaccines, and
2) who should use the vaccine and on what schedule.

BGTD also continues to monitor vaccine production and tests all new batches of vaccines for a match with the original formula. Vaccines cannot be marketed without BGTD approval.

The last step in quality control involves monitoring proper transport and storage of vaccines. Provincial authorities ensure that health care providers are following strict protocols for safe storing and dispensing of vaccines, including safety checks in the event of, for example, a power outage that interrupts refrigeration of vaccines.

Adverse Events Following Immunization (AEFI)

An **AEFI** is defined as "any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine." AEFIs range from mild events like pain and swelling around the injection site that lasts more than four days and allergic reactions (hives), to more serious temporary neurological events like seizures, and rare serious permanent effects like paralysis and death.

AEFIs are reported by physicians and caregivers to Public Health Ontario. The monitoring of AEFIs alerts public health agencies to any potential problems with a vaccine or batch of vaccines. If problems are suspected, further investigation is conducted to determine whether there has been a problem with the vaccine.

The Cutter Incident

Among the best known incidents of vaccine safety failure is the "Cutter incident". In 1955, Cutter Laboratories held a license by the United States government to market polio vaccine. The marketed vaccine was supposed to contain inactivated (dead) polio virus. However, two pools of the vaccine produced by Cutter Laboratories contained live polio virus despite passing safety checks. 120,000 doses from these defective pools were given to children. 51 children were permanently paralyzed and five children died. Other AEFIs such as headaches, stiffness in neck, and fever were reported by around 40,000 other children. The catastrophic events of the Cutter incident also set precedent for vaccine injury compensations being awarded in the US. Vaccines made in Canada were not affected.

Based on the number of cases reported, AEFIs are extremely uncommon in Ontario. During 2015 (the latest publicly available data), a total of 678 AEFI reports were submitted in the province. This is a rate of 4.9 per 100,000 population. Of these reported events, 34 (5%) were classified as "serious" and required hospitalization. This is a rate of 2.5 per 1,000,000 population.

Vaccine Injury Compensation

Because vaccination is a cornerstone of public health and strongly encouraged (even required in some circumstances), there is arguably an ethical obligation to compensate people when they suffer disability or death as a result. Most industrialized countries have some form of vaccine injury compensation program. National vaccine injury compensation programs are "no fault" schemes that provide payment for injury without needing to assign "fault" to a specific individual or industry in order to be compensated. In other words, the adverse outcome is attributable to the risk associated with vaccines. In the UK, for example, there is a one-time 'Vaccine Damage Payment' of £120,000 if a person is severely disabled as a result of vaccination against certain diseases. In the US, claims are litigated in a "Vaccine Court", an office of the US Court of Federal Claims dedicated to vaccine injury claims.

These programs are intended to relieve injured parties from needing to take civil action against vaccine manufacturers. Personal injury cases have a high burden of proof for cause of injury, and so the few cases that make it to court are rarely successful. Personal litigation for injury also potentially disrupts the availability of vaccines if manufacturers are forced to put too much effort into court cases. No-fault programs avoid these problems, and allow compensation to be given even when the vaccine was not at fault.

Canada does *not* have a national vaccine injury compensation program, with the exception of Quebec. Quebec has had a provincial vaccine injury program in place since 1985. Currently, Canadians outside of Quebec who believe they have been harmed by vaccines need to pursue civil action (personal injury claims) against the vaccine manufacturer to seek compensation.

Summary

We live in a society governed by laws and policies that affect us all. Therefore, it is important that policy and other decisions are informed by a range of diverse perspectives. From a public health perspective, vaccines offer a critically important strategy for significantly reducing rates of infectious diseases. However, some people are concerned about the efficacy and safety of childhood vaccinations. As a result, some parents may choose to delay vaccination or choose not vaccinate their children. By bringing together people from many different backgrounds, and with many different opinions and life experiences, our aim is to work together on this challenging issue.

Your role in the deliberation

During the deliberation, you will hear more about childhood vaccinations from both expert speakers and your fellow deliberants, who will bring their own perspectives to the discussion. You are not expected to be an expert on this topic.

During the deliberation, you will be asked to discuss with other deliberants some of the issues related to childhood vaccinations. These may include issues such as:

Should vaccines be required?
What information about vaccines should be presented to parents?
How should society address adverse events following vaccination?
Is vaccination an individual choice or a societal obligation?

We hope that you will bring your opinions, values, and ideas about childhood vaccinations to the deliberation. You will work together to make recommendations that can be used to more effectively inform policy decisions on childhood vaccinations.

Glossary of Terms

Adjuvant

An adjuvant is an ingredient, such as aluminum salts, added to some vaccines that helps create a stronger immune response in the body. The use of adjuvants often allows for smaller amounts of an inactivated virus or bacteria to be used in a vaccine.

Adverse effect following vaccination (AEFI)

An AEFI is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

Antigen

An antigen is a toxin or other foreign substance that induces an immune response when introduced in the body. Antigens are found on all viruses and bacteria. By injecting antigens into the body in the forms of vaccine, the body learns to produce antibodies in response. Some vaccines use weakened versions of the virus or bacteria and other vaccines use dead cells from the virus or bacteria.

Clinical trials

Clinical trials are research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. Clinical trials follow strict scientific standards to produce the best data available for health care decision-making. Clinical trials are one of the final stages of the research process, after lab and animal studies.

Ethylmercury

Ethlymercury is a form of organic mercury that is converted into inorganic mercury when processed by the body. It is formed when the body breaks down thimerosal, a preservative used in some vaccines. Ethylmercury is chemically very different from methylmercury, which is a form of highly toxic mercury often found in fish such as tuna and salmon. Unlike methylmercury, ethylmercury does not accumulate in the body.

Herd immunity

Herd immunity, also called community immunity or herd effect, is a form of indirect immunization that occurs when a large portion of a population is immune to an infection or disease, thereby providing protection to individuals who are not immune. Herd immunity is important for those members of society who cannot be or have yet to be vaccinated, such as infants and those with compromised immune systems.

Immunization

Immunization is the strengthening or fortifying of a person's immune system against infectious disease microorganisms by controlled exposure to those microorganisms or a closely related agent.

Immunity

Immunity is the ability of an organism to resist a particular infection or toxin by the action of specific antibodies or sensitized white blood cells.

Meta-analysis

A meta-analysis is a type of study that uses a statistical analysis that combines the results of multiple scientific studies. This approach increases statistical power and leads to more robust conclusions about an effect.

Methylmercury

Methylmercury is a highly toxic form of organic mercury often found in fish. It accumulates in the human body over time and can cause short and long-term neurological effects. It is not used in vaccines.

MMR vaccine

The MMR vaccine is the vaccine for measles, mumps, and rubella. It immunizes against all three of these diseases in a single vaccine.

Nosodes

Nosodes are diluted homeopathic preparations made from the disease-causing organism or infected tissue or fluids from an infected person or animal. Nosodes are marketed as offering similar or superior immune protection against infectious diseases without the risks associated with conventional vaccines. In Canada, nosodes cannot be recommended as an alternative therapy to vaccines.

Pre-clinical trials

Pre-clinical trials are the stage of research that occurs before human research. Before testing a drug or medical intervention in people, researchers must find out whether it has the potential to cause serious harm. There are two types of clinical research. *In vitro* studies are performed with micro-ogranisms, cells, or molecules. *In vivo* studies are performed on whole, living organisms, usually animals.

Public deliberation

A public deliberation is a community discussion about a particular topic that is based on the idea that members of the public should have a voice in the issues that affect them. Public deliberation is a democratic process that includes citizens, not just policy makers or experts, in important policy decisions.

Statement of Medical Exemption

A Statement of Medical Exception is a form completed by a physician or nurse to exempt a child from school and daycare requirements to demonstrate childhood vaccination. A Statement of Medical Exemption is required if a child cannot be immunized for medical reasons, such as a compromised immune system.

Statement of Conscience or Religious Belief Affidavit

A Statement of Conscience of Religious Belief Affidavit is a form that exempts a child from school and daycare vaccination requirements on the grounds that they object, for conscience or religious reasons, to vaccinating their children. In Ontario, this affidavit must be signed by a notary public. Parents may be required to complete an educational session to have the formed signed.

Systematic review

A systematic review is a type of scientific literature review that collects and critical analyses multiple research studies to answer a research question. They provide a complete summary of the available scientific literature.

Thimerosal

Thimerosal is used in vaccines to prevent bacterial and fungal contamination when multiple doses are stored in the same vial. Thimerosal contains a form of mercury called *ethylmercury* (which is different from methylmercury).

Vaccine

A vaccine is a substance used to stimulate the production of antibodies and provide immunity against one or several diseases. Vaccines are prepared from the causative agent of a disease, its products, or a synthetic substitute, treated to act as an antigen without inducing the disease.