CHAPTER 11

Public Engagement on Childhood Vaccination: Democratizing Policy Decision-Making Through Public Deliberation

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Introduction[1]

Immunization is considered one of the most successful and cost-effective public health interventions by the World Health Organization, preventing

[1] Since writing this chapter, the introduction of vaccines for COVID-19 has dramatically affected public discourse on vaccination. Because the main focus of this chapter is on democratization of risk in the context of childhood vaccination, the COVID-19 vaccine is strictly speaking not within the scope of the chapter. However, much public discourse on COVID-19 vaccines has focused on the vaccination of children, and controversy has surrounded questions of whether vaccination should be mandatory. We therefore include an appendix at the end of the chapter that outlines key developments since the COVID-19 vaccine became available.

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an estimated 2 to 3 million deaths per year globally (WHO 2018). Yet, there is a growing concern that vaccination rates are insufficient to effectively control the spread of infectious diseases. According to the 2018 assessment report by the WHO Strategic Advisory Group of Experts on Immunization, major outbreaks of measles and diphtheria had recently occurred in several regions across the world attributable to low national vaccination coverage or pockets of low coverage within a region. When a sufficiently high proportion of a population becomes immune to a disease, either through vaccination or from having previously been infected, "herd immunity" is achieved, which inhibits the spread of the infectious disease. Herd immunity protects susceptible individuals who are not vaccinated or under-vaccinated[2] for a variety of reasons (e.g., allergies, medical complications, accessibility of vaccines), by reducing the risk of infection (Fine et al. 2011; WHO Strategic Advisory Group of Experts on Immunization 2018). The percentage of a population required to be vaccinated to achieve herd immunity varies according to the disease, where herd immunity threshold estimates range from 75% for mumps to 94% for pertussis and measles (Plans-Rubió 2012). These high thresholds create challenges from a public health perspective as it is difficult to vaccinate large proportions of populations to achieve herd immunity. It is important to note that vaccination is generally preferred as a mechanism for achieving herd immunity (as opposed to substantial portions of the population being exposed to the illness) as vaccines typically are safer, with fewer long-term health implications than the disease itself.

As with most health interventions, there are benefits and risks associated with vaccination. Vaccination confers individual benefits of gaining immunity as well as collective benefits in the form of herd immunity. But vaccination does not fully prevent infection and there is always a possibility of contracting the disease during an outbreak, even among

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[2] Under-vaccinated here refers to selective, delayed, or partial vaccination.

people who are vaccinated (Law Reform of Commission of Saskatchewan 2009). In addition, some individuals experience adverse events when being vaccinated, even among vaccines deemed safe and effective and which meet regulatory standards (Keelan and Wilson 2011; Looker and Kelly 2011). Most of the adverse events are minor and short term, such as localized soreness or swelling at the injection site. The government approval process is such that approved vaccines have low risk of serious or life-threatening injuries. In Ontario, the annual report on vaccine safety for 2017 documented 696 reports of adverse events following immunization (Public Health Ontario 2017). Of these, 558 were classified as mild (sore arms, rashes, allergic skin reactions), and 26 were classified as serious (see p. 44 of the Report for a detailed description of the adverse events), equivalent to 3 per 1 million doses distributed. Given the benefits and risks associated with vaccination, there is considerable diversity in public opinion about when and how to vaccinate children and formal recommendations can vary by country or region (Song et al. 2014).

There has been some controversy relating to claims about vaccine safety and efficacy. Understandably, public health officials tend to be wary of any claims that undermine belief in the safety and efficacy of vaccines since this translates into lower vaccination rates, which in turn compromises the goals of achieving herd immunity. Indeed, many claims about lack of vaccine safety and efficacy have been shown to be unfounded (Asturias et al. 2016; Conklin et al. 2021). While these considerations are both important and prominent in scholarly literature, our focus here is somewhat different. In the context of the theme of this book on democratization of risk decision-making, our attention is on the role of public voices in making decisions about vaccination policy. Our argument is that key policy decisions rely not only on expert knowledge and scientific data, but also on values and consideration of how to make trade-offs between competing values. For example, if the safety and efficacy of vaccines are accepted, policy decisions still need to be made about whether vaccination is compulsory, mandatory, or simply recommended. Making this decision requires that a trade-off is made between values that, in this situation, are in conflict with each other. Favouring values of protection and public health may indicate a policy decision of mandatory or even compulsory vaccination. On the other hand, favouring values of autonomy and diversity may indicate a policy of recommendation only. In line with principles of deliberative democracy, our argument is that such decisions therefore require meaningful democratic consideration and public input.

To date, there has been little opportunity for the Canadian public to engage and provide input into public policy decisions regarding childhood vaccination. Developing mechanisms for public dialogue and input is important to inform policy decisions that are reflective of the needs, interests, and values of Canadian publics. Public trust is crucial for the successful implementation of any public health program. Chafe et al. (2011) asserted that a loss of public confidence is the biggest threat to the Canadian healthcare system and increased public engagement is a means to restore confidence and rejuvenate healthcare reform. However, "despite extensive stakeholder engagement frameworks, few strategies for public input have been implemented at major agencies that award funds for research, recommend expensive drugs and vaccines, or set major health priorities" (Chafe et al. 2011, p. 165). Active and meaningful public engagement in health service delivery and health research is considered essential to quality improvement of health services, greater responsiveness to public needs, and more legitimate, transparent, and accountable decision-making (Esmail et al 2015; Kovacs Burns et al. 2014; Manafo et al. 2018).

Public engagement through deliberative processes has garnered increasing interest from public health researchers and policy makers on a number of health-related topics, including priority setting, planning and governance of health services, and health technology assessment (Degeling et al. 2015). Calls for deliberative approaches into vaccine-related discussions and policy decisions have also been made (Hendrix et al. 2016) and implemented (Marshall et al. 2014; Parrella et al. 2016; The Keystone Center 2009). In this chapter, we describe an academic-led public deliberation event on childhood vaccination in Ontario, Canada (O'Doherty et al. 2021), and examine this public engagement on childhood vaccination for its role in the democratization of science and policy. To our knowledge, there has not been any official, government-sponsored public engagement event for members of the public in Ontario to deliberate on the topic of childhood vaccination. Broadly speaking, public deliberation is based on deliberative democratic ideals that lay citizens should have a voice in the discussions and debates about important social issues and their potential decision options. Public deliberation is useful for policy issues that involve competing ethical values about a public good, high controversy, and considerations of both technical/expert and cultural/real-world knowledge (Solomon and Abelson 2012). It seeks to create conditions that allow for respectful dialogue among citizens and

between policy makers and citizens. The process of deliberation fosters the exchange of opinions and reasons for or against particular propositions. Public deliberation aims to arrive at public decisions that all parties view as legitimate (Abelson et al. 2003; Blacksher 2013; Chambers 2003). In this sense, public deliberation is distinct from other participatory approaches in health and health care. Whereas other participatory approaches may have the primary goal of advancing health equity and social justice through redistribution of resources and empowerment of marginalized and minority groups, the purpose of public deliberation is to create spaces for public dialogue on an issue and to develop policy solutions that are broadly perceived as legitimate (Blacksher 2013).

We begin by providing a brief overview of the current regulatory context in Ontario with regard to childhood vaccination. We then outline the Ontario Vaccine Deliberation and the recommendations that were generated and endorsed by the participants through small and large group discussions during the deliberation. We draw on the Ontario Vaccine Deliberation, as well as other research, to illustrate the importance of engaging publics in childhood vaccination decision-making. Our discussion focuses most heavily on the three main issues that were raised by members of the public during the deliberation: (i) mandatory vaccination and non-medical exemptions, (ii) communication about vaccination, and (iii) compensation for individuals and families who experience serious adverse events following immunization. Further, we discuss the collective recommendations made by the Ontario Vaccine Deliberation group in the context of the broader literature on vaccination and deliberative processes.

Current Regulatory Context in Ontario

In Canada, the federal, provincial, and territorial governments share responsibility in the delivery of health care, including immunization (Public Health Agency of Canada 2014). At the national level, the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada (HC) is the federal authority responsible for regulating the quality, safety, and efficacy of all biologic drugs, including vaccines. The National Advisory Committee on Immunizations (NACI) makes recommendations to the Public Health Agency of Canada (PHAC) for the use of vaccines that are currently or newly approved for use in humans. NACI is an independent advisory body of experts in the fields of pediatrics, infectious diseases,

immunology, medical microbiology, internal medicine, and public health. Additionally, the National Immunization Strategy provides a framework for interjurisdictional collaboration on immunization planning and programming.

The provincial and territorial governments are responsible for the administration and delivery of immunization-related programs within their jurisdiction. Provincial/territorial immunization policies and schedules are developed in consultation with an expert advisory committee based on identified priorities, resource availability, and recommendations from expert sources such as NACI. In Ontario, the Provincial Infectious Diseases Advisory Committee on Immunization (PIDAC-I) advises Public Health Ontario (PHO) and the Ontario Ministry of Health and Long-Term Care (MHLTC) on matters related to vaccination.

Childhood vaccination is not compulsory under federal, provincial, or territorial laws in Canada. Currently, Ontario and News Brunswick are the only two provinces that require vaccination for children for school attendance. It should be noted that there is no standard approach to mandatory vaccination as vaccination programs that are described as "mandatory" vary widely across different countries (MacDonald et al. 2018). Mandatory vaccination has been distinguished from compulsory vaccination in legal aspects: parents are legally free to not vaccinate their children in the former, whereas vaccine refusal is treated as a crime and comes with legal penalties in the latter (Giubilini 2019; Navin and Largent 2017). However, a mandatory vaccination program may withhold access to valuable social goods or services (e.g., enrollment in public school or daycare) if parents refuse to vaccinate their children. In jurisdictions with mandatory vaccination legislation, exemptions are granted for medical clauses and may be granted for religious and conscientious clauses. Ontario's *Immunization of School Pupils Act* (ISPA) requires that children and adolescents attending primary and secondary schools be vaccinated against designated diseases, unless they have a valid exemption (Government of Ontario 2017). Parents keep a record of immunization for their children, which will be submitted and updated with a local public health unit upon school entry. Proof of immunization is required for nine infectious diseases: diphtheria, tetanus, polio, measles, mumps, rubella, meningococcal disease, pertussis (whooping cough), and varicella (chicken pox) for children born in 2010 or later (Ontario Ministry of Health and Long-Term Care 2018).

Valid exemptions in Ontario include (1) medical exemptions and (2) non-medical exemptions based on reasons of religion or conscience. Medical exemptions are granted upon receipt of a statement signed by a physician or registered nurse that vaccination may be detrimental to the health of the person (ISPA 1990), such as if the child has a medical condition that prevents receiving the vaccine. A medical exemption is also granted if the vaccine is deemed unnecessary for reason of past infection or laboratory evidence of immunity (ISPA 1990). As of September 2017, legislation requires that parents must complete an immunization educational session at a local public health unit prior to submitting a non-medical exemption for their children (Government of Ontario 2019). Parents receive a certificate at the end of the session, which they submit along with a statement of religious or conscientious belief signed by a commissioner for taking affidavits if they choose to proceed with the application.

Information on the rationale for childhood vaccination, vaccine schedules, disease risks, and risks of adverse reactions are publicly available via official government websites, distributed by healthcare centres and community resource centres. For example, the Public Health Agency of Canada provides *A Parents' Guide to Vaccination* which can be downloaded freely, ordered in print, and is distributed by some healthcare providers (Public Health Agency of Canada 2018). Free resources are also available online from various national institutions and organizations, such as the Canadian Paediatric Society (2019) and CanImmunize (2021). Communication about possible risks in a transparent manner is certainly critical to promote public trust and support for vaccination programs. It is also necessary to enable people to make informed choices regarding immunizations. However, survey research with Canadian parents has found that safety concerns remain, even among parents who are supportive and vaccinate their children according to recommended vaccination schedules (Greenberg et al. 2017).

The term, "vaccine hesitancy," has been used to describe a broad continuum of public attitudes and associated behaviors toward vaccination, ranging from total acceptance to complete refusal (Bedford et al. 2018; Dubé et al. 2013; Larson et al. 2014). Vaccine hesitancy is defined by the WHO Strategic Advisory Group of Experts (SAGE) Working Group on Vaccine Hesitancy as a "delay in acceptance or refusal of vaccination despite availability of vaccination services" (MacDonald 2015, p. 4163). Individuals who are seen to be vaccine-hesitant may refuse all

vaccines, refuse some vaccines but agree to others, delay and seek alternative vaccination schedules, or accept vaccines but are unsure of doing so (Larson et al. 2014).

Parental decision-making about childhood vaccination is increasingly recognized as being nuanced and complex. The knowledge deficit model, which presumes that laypeople are resistant to vaccination due to misunderstanding or ignorance of science, has been increasingly criticized (e.g., Goldenberg 2016, 2021; Hobson-West 2003). Goldenberg (2016) argued that vaccine hesitancy is better framed as a problem of public mistrust of scientific institutions and experts, including the values underlying expert consensus in support of vaccination and their ties to the pharmaceutical industry. Moreover, many parents approach vaccine safety with consideration of the personal needs of their children and view the potential of rare but serious adverse events as a safety priority, rather than viewing it as a reasonable risk (Goldenberg 2016). From a public health perspective, the risks associated with serious adverse events are balanced by the benefits of wide-scale immunization in the population. However, individual and public perceptions of what constitute reasonable risks can be evaluated quite differently compared to those viewing health decision-making through a population lens. Parental decisions to accept or refuse a vaccine for their children are also grounded in factors other than risk information based on scientific data (Hobson-West 2003), such as past experiences with other vaccines or health services, religious and moral convictions, alternative health discourses (e.g., homeopathy), and access to conflicting information and controversies about vaccination in the media, among others (Dubé et al. 2013; Hobson-West 2003; MacDonald 2015).

From a public health perspective, it is thus important to understand publics' responses to vaccination and the reasons underlying them. In the context of living in a democracy, an additional requirement is to create spaces in which there can be meaningful dialogue about specifically those issues that are potentially divisive when making public policy decisions. In the sections below, we demonstrate how public deliberation can be a practical approach for dialogue and learning about public perspectives, values, and concerns that need to be addressed and taken into account in policy decision-making.

Overview of the Ontario Vaccine Deliberation

The Ontario Vaccine Deliberation was a public deliberation event on childhood vaccination in Ontario, hosted and organized by a research team from the University of Guelph (O'Doherty et al. 2021). The deliberation was held in Waterloo, Ontario, over two weekends in October 2017. Twenty-five participants, over the age of 18, took part in a 4-day deliberation event about childhood vaccination. Participants were provided with an information booklet prior to the event to ensure that everyone had the same base of knowledge of the topic (for a copy of the information booklet, see https://osf.io/t54e2/). During the deliberation, expert speakers provided information that reflected various key societal positions and interests, as well as critical technical information. Expert speakers were chosen to present on issues related to public health, complementary and alternative medicine, vaccine safety, parental perspectives, and philosophical and historical approaches to vaccination. Participants then formed small groups to discuss and deliberate on key questions with trained facilitators. Following small group discussions, participants convened as a large group to further explore issues identified, work toward a collective position on those issues, and vote on statements that represented the group's collective position. The last day of the deliberation focused on summarizing the recommendations derived from those statements and a final ratification vote to ensure all recommendations were captured accurately (see O'Doherty et al. 2021, for more details on process and outcomes).

The Ontario Vaccine Deliberation resulted in 20 recommendations in three key areas:

1. Mandatory vaccination and exemptions
2. Communication about vaccines and vaccination
3. Adverse event following immunization (AEFI) reporting and compensation.

These recommendations were the deliberative conclusions generated and recognized by the participants as theirs through intense small and large group discussions and a voting process.

Mandatory Vaccination and Exemptions

All participants of the deliberation expressed support for mandatory childhood vaccination for all children in Ontario. There was also strong agreement that parents, legal guardians, and/or custodians have a responsibility to the health of the community by vaccinating their children. These recommendations appear to reflect broader public value placed on mandatory vaccination in Ontario, or at least on the necessity of vaccinating children. Survey research with nationally representative samples had reported that a majority of Canadian parents with children aged 5 and younger were supportive of recommended vaccines for children (Dubé et al. 2018; Greenberg et al. 2017). Despite their support, a considerable percentage of parents had concerns about potential adverse reactions, including the link between vaccines and autism (Greenberg et al. 2017). Many parents also agreed that vaccination should remain a parental choice (Greenberg et al. 2017).

Mandatory vaccination programs are often controversial as they reduce individual choice and autonomy to some degree, leading to ethical concerns of coercion (MacDonald et al. 2018). Evidence for the validity of this concern is evident in controversies that followed the implementation of mandatory vaccination for COVID-19 in Canada and elsewhere (Bardosh et al. 2022; Flood et al. 2021; McLaren 2022; Smith 2022).

The main triggers for a shift to enact, strengthen, or contemplate mandatory vaccination in several countries include outbreaks of vaccine-preventable diseases (including in Italy, France, Serbia, and California), a failure of less coercive methods to increase vaccination rates, and the global goal of eliminating polio (MacDonald et al. 2018). Vaccination legislation and regulations may be changed as context or political will changes (MacDonald et al. 2018). In different political, economic, and sociocultural contexts, mandatory vaccination for children may or may not be met with majority support. For instance, amidst a recent measles outbreak in Vancouver, British Columbia, news headlines featured that a majority of Canadians supported mandatory vaccination for children entering school (Azpiri 2019; Young 2019). In Manitoba, vaccination against measles used to be required for school attendance, although this is no longer the case. In March 2018, there was an effort to reintroduce mandatory vaccination for school children in Manitoba for measles, as well as other common childhood vaccinations; however, the majority of

school board delegates from across the province voted against a motion[3] (Malone 2018). The vote demonstrated a rare instance of democratic engagement of an important group of stakeholders in decisions regarding childhood vaccination, albeit at the school board level. Arguably, the successful implementation of mandatory vaccination depends on public trust and support for such a program.

While methods such as ballots and survey polling can gauge the extent of public support for a mandatory vaccination program, these methods often do not provide a means to understand and incorporate the perspectives and values of the publics into public health decision-making. How vaccination is conceptualized can bring forth emphases on particular ethical values while masking others (O'Doherty et al. 2017). Many of the participants in the Ontario Vaccine Deliberation supported the notion that mandatory vaccination means children who are not vaccinated and without valid exemptions should be excluded from school or organized activities. A key reason included a responsibility to protect oneself and the whole society through vaccination. However, several participants were against the idea. The reasons for those opposed included the right of everyone to go to school in Canada according to the *Educational Act* and that it would not be fair to exclude children from these activities. In terms of exemptions, all participants were supportive of medical exemptions. More controversial was the issue of non-medical exemptions for religious or conscientious beliefs. For many participants, religious or conscientious beliefs should not be grounds for exemptions. The reasons provided were diverse, including that only science and medicine should provide guidelines for exemptions, and that personal and religious beliefs have no role in societal decisions. A few participants supported allowing for non-medical exemptions or abstained from voting during the engagement session. Some of these participants expressed that religious beliefs should be respected and they invoked the national image of Canada as a diverse and tolerant country that should not exclude people because of their religious choices. The persistent disagreement among the participants even after intense deliberation highlights the difficulties associated with societal decisions about mandatory vaccination, and (in the case of mandatory vaccination) consequences for non-compliance and whether non-medical exemptions should be allowed. These difficulties reflect the

[3] A key reason for the vote against the motion was that the right to education would be jeopardized by the measure.

diverse values that participants might have drawn on in their reasoning, including the values of personal choice and social responsibility to protect, or at least not harm, the community.

Academic debate surrounding childhood vaccination and non-medical exemptions has implicated various competing ethical values. These include the values of individual autonomy, fairness, beneficence, and distributive justice of benefits and burdens between those who vaccinate and those who do not (Hendrix et al. 2016). In the context of childhood vaccination, it is parental autonomy in the choices they make on behalf of their children that is central to discussions. The principle of the least restrictive alternative has also been invoked in that policies that are less intrusive on individual/parental autonomy should generally be preferred over more intrusive alternatives such as mandatory vaccination with heavy penalties for lack of compliance (MacDonald et al. 2018; Verweij and Dawson 2004). Kass's (2001) public health ethics framework holds that public health programs are required to minimize burdens and "if 2 options exist to address a public health problem, we are required, ethically to choose the approach that poses fewer risks to other moral claims, such as liberty, privacy, opportunity, and justice, assuming benefits are not significantly reduced" (p. 1780). A key ethical consideration is then under what circumstances the state is justified in intervening and constraining parental autonomy to decide whether to vaccinate or not vaccinate their children.

Claims for more intrusive vaccination programs (i.e., mandatory or compulsory vaccination) have been made on the grounds that vaccine refusal imposes unjust harm, or risk of harm, upon other people (e.g., Brennan 2018; Flanigan 2014). Verweij and Dawson (2004) proposed an ethical principle for vaccination programs whereby "participation should, generally, be voluntary unless compulsory vaccination is essential to prevent a concrete and serious harm" (p. 3123), which can be a risk to the health of a child at an individual level or a risk to the realization of herd immunity as a public good at a societal level. Under this principle, parental autonomy is important but not absolute (Verweij and Dawson 2004). Similarly, Isaacs et al. (2009) asserted that parental objections to vaccination should be respected unless they would impede public health measures to realize herd immunity. Giubilini (2019) argued for compulsory vaccination and against allowing non-medical exemptions on the basis that vaccination policies should not aim only for the pragmatic realization of herd immunity, but for the fair distribution of the burdens of its realization. With that aim, fairness is conceived to be a value that need not and

should not be compromised by the principles of individual autonomy and least restrictive alternative. Fairness, according to this perspective, requires that everyone who can be vaccinated makes their contribution to realize herd immunity as a public good; there is an individual and a collective responsibility to get vaccinated as well as an institutional responsibility to implement policies that can guarantee the realization of herd immunity (Giubilini 2019). In contrast, Navin and Largent (2017) claimed that allowing non-medical exemptions is ethically and socio-politically preferred over their elimination, and the best way to keep exemption rates low is to make the application process more burdensome. Arguably, this is the route that Ontario has taken with the requirements of notarization of application and attendance of an educational session.

While there are rich discussions about ethical values among academics and vaccine experts, much less attention has been given to the values that members of the public may draw on in their justifications for or against childhood vaccination. Members of the public may or may not invoke ethical values in the same way as academic debates have. Therefore, public deliberations like the Ontario Vaccine Deliberation provide an opportunity for members of the public to articulate and deliberate on the different values underlying vaccination and exemption policies in their own terms. Vaccination policy decisions may lead to unintended social and political consequences, particularly if they are implemented without public input. For example, the State of California passed legislation in 2016 to eliminate non-medical exemptions after a serious measles outbreak. The ethical aspects of this measure have attracted considerable debate in academic and public forums over moral obligations to respect individual/parental rights. Concerns over negative social and political consequences, including parents removing their children from public schools or daycare centers and increased political polarization, have also been raised (Navin and Largent 2017). Furthermore, there is evidence of an increase in medical exemptions in some counties that previously had the highest rates of personal belief exemptions (Delamater et al. 2017).

Communication About Vaccines and Vaccination

During the Ontario Vaccine Deliberation, there was strong support among participants for communicating about childhood vaccination through multiple channels. Suggestions included providing information to parents and prospective parents during pregnancy and after birth, as

well as providing education through the school curriculum. The latter was considered important as children could let parents know about their experiences in school. Thus, both children and parents would be educated about childhood vaccination. Participants also suggested that public health agencies need to consider alternative communication mechanisms, such as social media, advertising in health professionals' offices, and advertising in public spaces. There was strong support that information should be scientific and unbiased, addressing the risks, benefits, and concerns of childhood vaccination. Most participants agreed that information about vaccine safety and effectiveness that comes from peer-reviewed scientific studies is better than information from other sources. Two participants either opposed or abstained from voting on this recommendation. The reasons included consideration that other information, such as personal experience, can be just as valuable, and sometimes personal experience, tradition, and religious beliefs are more powerful than scientific information.

Vaccine Injury Compensation

Among participants in the Ontario Vaccine Deliberation, there was strong support for tracking and mandatory reporting of adverse events following immunization (AEFI) by health professionals to Public Health Units. There was also strong support among the participants for compensation of serious life-altering adverse events leading to diminished capacity, although participants acknowledged the difficulty of defining "serious life-altering." At the time of the Ontario Vaccine Deliberation, Québec was the only province in Canada with a public program to compensate for serious injuries or death caused by voluntary vaccination (Gouvernement du Québec 2019). The lack of a national scheme to compensate for vaccine-related injuries in Canada had been identified as a policy gap (Keelan and Wilson 2011), even though the issue had long been debated by vaccine experts and policy makers. One of the earliest statements in support of a national compensation program for government-approved vaccines was published in 1986 by the Canadian Paediatric Society (Canadian Paediatric Society 1986; Keelan and Wilson 2011). A public petition had also been created by Bob Martin, who developed Guillain–Barré syndrome after receiving an influenza vaccine

in 2010 (https://www.thepetitionsite.com/882/711/468/ceate-a-no-fault-vaccine-compensation-program-for-candians/). In December 2020, Health Canada announced a Vaccine Injury Support Program (VISP) for all provinces and territories, with the exception of Québec, which continues to be covered under its own program. "The purpose of the VISP is to ensure that all people in Canada who have experienced a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada on or after December 8, 2020, have fair and timely access to financial support" (https://vaccineinjurysupport.ca/en). The program is open to all individuals, including children. The VISP began to accept claims in June 2021. Claims are first subjected to an administrative review by a case manager. Those that are deemed admissible will go through a process of collecting medical records and then assessment by a Medical Review Board.

The VISP is premised on the notion of no-fault compensation. A global survey of WHO Member States identified 25 jurisdictions with no-fault vaccine injury compensation programs in 2018, with most jurisdictions categorized as high-income countries (WHO 2019). No-fault compensation is based on the premise that there are unavoidable or unintended risks associated with vaccination even for vaccines that are properly designed, manufactured, and delivered (Keelan and Wilson 2011; Law Reform Commission of Saskatchewan 2009; Looker and Kelly 2011; Manitoba Law Reform Commission 2000). As such, parties injured by vaccines or their legal representatives are entitled to compensation without the need to prove negligence or fault by vaccine manufacturers, vaccine providers, or the health care system. Without a formal no-fault compensation scheme, the only recourse is through civil litigation under the tort law. A tort lawsuit requires the plaintiff to prove that another party is liable for the injury due to negligence or failure to adequately warn of the risks and secure informed consent. The burden of proof is on the plaintiff to establish a causal link between the injury and the negligent act. This process is considered problematic as it is often difficult to establish negligence and causation in the case of immunization. Moreover, civil litigation is costly and time consuming, making it an inaccessible course of action for many vaccine recipients. No-fault compensation schemes are believed to provide a fairer and more efficient process for people to seek redress for vaccine-related injuries. While a causal link still needs to be established based on a balance of probabilities, the standard of proof is less strict compared to the legal standard (Keelan and Wilson 2011;

Law Reform Commission of Saskatchewan 2009; Looker & Kelly 2011; Manitoba Law Reform Commission 2000).

A lack of impetus to create a no-fault compensation program might be due to an absence of political, economic, and social pressures (Keelan and Wilson 2011). For example, the US National Vaccine Injury Compensation Program (VICP) was established in 1986 after a prolonged liability crisis when a large number of vaccine manufacturers stopped producing the Diphtheria-Pertussis-Tetanus (DPT) vaccine for children in response to civil litigations over injuries (Keelan and Wilson 2011). According to Cook and Evans (2011), the VICP has been a "key component in stabilizing the US vaccine market through liability protection to both vaccine companies and health care providers" since then (p. S74). In terms of immunization rates, there is no published evidence on whether the availability of a no-fault vaccine injury compensation program has an impact on immunization uptake (Keelan and Wilson 2011). According to Browne (2016), the Canadian Medical Association previously rejected a motion to implement a national vaccine injury compensation program due to concerns that such a program could constitute an admission to the dangers of immunization, undermine public confidence, and deter people from vaccinating themselves or their children. To the contrary, arguments have been made that no-fault compensation could increase public confidence and support in childhood vaccination (Keelan and Wilson 2011; Law Reform Commission of Saskatchewan 2009; Manitoba Law Reform Commission 2000).

On the whole, there is much agreement that there is an ethical imperative of providing a no-fault vaccine compensation program. Childhood vaccination is a preventive measure that greatly reduces the burden of many infectious diseases and benefits the community through herd immunity. However, parents do expose their healthy children to risks when they vaccinate their children. Arguments have been made that there is a community responsibility to compensate those who are injured (Looker and Kelly 2011; Manitoba Law Reform Commission 2000). Mello (2008) asserts that the ethical principles of fairness and solidarity mean members of the community should not have to bear the burdens of realizing the public good of herd immunity alone. Among individuals who are vaccinated, the injured and the uninjured bear unequal shares of the burdens and, thus, mechanisms are needed to provide "a safety net" for those whose sacrifice is large (Mello 2008). As the Manitoba Law Reform Commission observed in its 2000 report, "although vaccination is not

compulsory, there is considerable governmental and social pressure to participate in the immunization process" (p. 15). The arguments for vaccine injury compensation are even more compelling in the context of mandatory vaccination, where individual/parental choice and autonomy are relatively reduced by government mandates.

No-fault vaccine injury compensation programs vary across jurisdictions that have them. Looker and Kelly (2011) identified six common elements to these programs: administration and funding, eligibility, process and decision-making, standard of proof, elements of compensation, and litigation rights. Most of the programs are administered and funded by state or national governments, or a mixture of both as is the case in Japan. Finland, Norway, and Sweden use a manufacturers' levy, while Taiwan (China) and USA retain centralized government control by imposing a vaccine tax on manufacturers (Looker and Kelly 2011). Among the participants of the Ontario Vaccine Deliberation, there was strong support that a fund should be established with contributions from both the pharmaceutical industry and the government to compensate individuals on a case-by-case basis. We do not contend that this is necessarily the most effective mechanism to establish a sustainable source of funding for a vaccine injury compensation program. Rather, we highlight the importance of soliciting public input among other considerations in the design of vaccine-related programs and establishing potential mechanisms for public input on a longer-term basis. For example, the Manitoba Law Reform Commission (2000) recommended that the Health Minister appoint a medical expert as the Director of Childhood Vaccination Injury Compensation, who would handle vaccine injury claims. If a claim was rejected by the Director, the claimant could appeal to an administrative tribunal known as the Childhood Vaccination Injury Compensation Appeal Board. Members of the Board would consist of immunology experts, lawyers, and lay persons. We cannot claim that the recently implemented VISP is a consequence of recommendations from members of the public who participated in the Ontario Vaccine Deliberation. However, it is striking to observe that these public recommendations presaged a decision by Health Canada and are in line with international ethical and legal scholarship that rejects paternalistic arguments that a national vaccine injury compensation program would constitute an admission to the dangers of immunization and thereby deter people from vaccinating themselves or their children (see Browne, 2016).

Conclusion

In this chapter, we have argued that childhood vaccination is an issue that stands to gain from the input of public deliberation processes. The argument for involving lay publics in policy decisions about childhood vaccination is based on the observation that such decisions require not only scientific expertise, but also consideration of how competing values are to be balanced in policies that affect all members of a society (e.g., how to balance autonomy in decisions affecting one's children and ensuring community protection from infectious diseases). To be effective, such policies also require relationships of trust between government decision-makers, scientists, vaccine producers, health professionals, and publics. In this context, we have discussed how public deliberation can be a practical and meaningful approach to engage members of the public in a formal process of knowledge exchange and dialogue about childhood vaccination. Importantly, the purpose of public deliberation is not to influence people's opinions in a particular direction or to convince them to take a certain position. Rather, the purpose is to broaden the considerations that are brought to bear on a policy issue and to expand the range of voices that are part of the decision-making process. Engaging publics to deliberate on the topic of childhood vaccination can yield a better understanding of public perspectives; more importantly, public deliberation provides an avenue toward more democratic, legitimate, and accountable policy decisions.

Appendix: Applying Democratization Processes Through Public Deliberation to the COVID-19 Pandemic

As of September 26, 2022, there have been 620,413,942 cases of coronavirus disease (COVID-19) worldwide, with 6,540,871 reported deaths (Worldometer 2022). This pandemic was caused by the SARS-CoV-2 virus, a novel infectious disease affecting respiratory illnesses. Given its rapid spread, with often serious complications, including debilitation and death, this spurred the need to rapidly develop a vaccine and vaccination program for populations across the world. Many of the debates relating to COVID-19 are not strictly within the scope of this chapter since they are neither about childhood vaccination nor about democratization of risk decision-making. However, the COVID-19 pandemic has shown in

detail how the effects of infectious disease are mediated by societal factors, and controversy surrounding COVID-19 vaccines has been particularly pronounced for children. In this appendix, we therefore discuss some implications of COVID-19 vaccinations for broader debates about public responses to vaccination and for democratizing policy decision-making.

How the COVID-19 Pandemic Relates to Childhood Vaccination

As stated in the chapter, immunization is one of the most successful public health interventions worldwide, preventing millions of deaths per year, with its greatest impact on childhood diseases (WHO 2018). Routine childhood vaccination in Canada covers many illnesses, including diphtheria, hepatitis B, human papillomavirus (HPV), influenza, measles, meningococcus, mumps, pertussis (whooping cough), polio, rotavirus, rubella, tetanus, and varicella (chicken pox). This is a broad array of diseases, including both bacteria and viruses, each having different characteristics when it comes to spread, prognosis, and treatment. Due to the differences in characteristics, achieving herd immunity varies by disease, with estimates ranging from 75% for mumps to 94% for pertussis and measles (Plans-Rubió 2012).

Whereas most of these infections are primarily described as childhood diseases or are more fatal for children, this is not true for COVID-19, where risk of hospitalization and mortality increases with age (Starke et al. 2021). Moreover, it has been noted that in the case of SARS-CoV-2, the classical concept of herd immunity may not apply (Morens et al. 2022). These differences can influence decisions to vaccinate children, where parents' decisions to vaccinate for COVID-19 are related to perceived susceptibility and benefit of the vaccines, low trust in the safety of the vaccines, or if they viewed them as unnecessary (Du et al. 2021; Humble et al. 2021; Qin et al. 2022). Indeed, routine childhood vaccinations have been found to be viewed as more essential, safe, and effective compared to the COVID-19 vaccines (Temsah et al. 2021).

Although COVID-19 vaccines are approved in Canada for children as young as 6 months old, vaccines for COVID-19 were not available to children under the age of 5 until July 2022 (Shakil 2022) and were only approved for children 5 to 11 years old in November 2021 (Health Canada 2021). For these reasons, COVID-19 vaccination is somewhat distinct from other routine childhood vaccinations and so presents a somewhat separate case from that discussed throughout the chapter.

Vaccination Against COVID-19

SARS-CoV-2 is a rapidly mutating virus, with over 5 variants of concern[4] having been reported to date (September, 2022) since its discovery in early 2020 (World Health Organization 2022). To reduce and prevent illness, many vaccines have been developed worldwide. Of these (at the time of writing), six COVID-19 vaccines have been approved for administration in Canada, which use four types of technologies: mRNA vaccines (Moderna, Pfizer-BioNTech), viral vector-based vaccines (AstraZeneca, Johnson & Johnson), protein subunit vaccines (Novavax), and plant-based vaccines (Medicago) (Government of Canada 2022a, b). Notably, there are substantial differences between the vaccines administered for COVID-19 and those for childhood vaccination; vaccines for COVID-19 were developed rapidly as an emergency response to the pandemic, with several types employing new vaccine technologies, and can have lower effectiveness due to the prevalence of multiple strains of COVID-19 (Vasireddy et al. 2021). Public knowledge and trust of the vaccines have remained low, and they are viewed less favorably than routine childhood vaccinations (Temsah et al. 2021).

How the COVID-19 Pandemic Relates to Democratization

(Lack of) Public Consultation in Policy Decisions About COVID-19 Vaccination

Since the beginning of the pandemic, the regulatory context of vaccines has shifted. Although the approach to childhood vaccination is largely unchanged across Canada, a new vaccine injury compensation fund has been introduced (Vaccine Injury Support Program, VISP), and policies regarding the COVID-19 vaccination program have changed and adapted over time. Because the responsibilities for the administration and delivery of immunization programs are within the jurisdiction of the provincial and territorial governments, there has also been substantial variation in

[4] Most variants have little to no impact on disease spread or prognosis. Variants of concern are those that the World Health Organization has identified as variants that affect the virus properties, such as how it spreads, disease severity, vaccine performance, or other public health and social measures.

COVID-19 vaccination policies. For example, mandatory vaccine requirements to enter public spaces and for workers employed in certain fields (e.g., healthcare workers) varied by province and territory.

In parallel with policies on childhood vaccination, there have been rich discussions about ethics and policies about COVID-19 vaccination among academics, vaccine experts, politicians, and public health workers. Notably, and similar to the discussions on childhood vaccination, much less attention has been given to involving broader publics in discussions and decisions about how competing social values are to be traded off in policies relating to COVID-19 vaccination programs (e.g., should vaccination be mandatory or just recommended). Having limited avenues for public input, combined with the top-down policy directives, there have been disconnects between scientists, politicians, and the public. In fact, lower public trust in governments has been related to lower willingness to accept COVID-19 vaccination (Wouters et al. 2021), and it has been argued that the governmental response to COVID-19 is a key influence on public confidence in vaccination (Sabahelzain et al. 2021).

Mandatory Vaccination

As explained in the main chapter, the term "mandatory vaccination" is generally seen to encompass policies that exclude children from school or organized activities without vaccination or valid exemptions. Notably, no such policy has been implemented in schools for children with regard to COVID-19 vaccination in Canada. Despite this, there are parallels with restrictions on adults. At the federal level, the Government of Canada required all federal public servants and employees in the federally regulated air, rail, and marine transport sectors to be vaccinated in fall 2021 (Wong et al. 2021). Similarly, Ontario required hospitals, home, and community care personnel to provide proof of full vaccination or of a medical exception, while British Columbia required long-term care and assisted living workers to be vaccinated (Wong et al. 2021). Mandatory vaccination was announced and enforced in different regions, at different time points, across Canada.

A notable change with regard to vaccination in Canada was the unprecedented degree of enforcement of mandatory COVID-19 vaccination. Noncompliance without a medical exemption in several provinces and industries could have led to job loss or forced leave without pay. For example, all federal public servants in the Core Public Administration

(CPA) were required to be vaccinated, whether they were teleworking, remote working, or working on-site (Government of Canada 2021). Although this requirement was suspended in June 2022, employees who did not comply at the time were placed on administrative leave without pay (Government of Canada 2022b).

Indeed, the Ontario Vaccine Deliberation indicated that mandatory vaccination is a central and divisive issue in arriving at policy decisions. Although the COVID-19 context is quite different from the routine childhood vaccinations that were the topic of the Ontario Vaccine Deliberation, debates relating to the values of personal choice, fairness, and social responsibility to protect the community featured quite similarly in both the confines of the formal setting of the Ontario Vaccine Deliberation and broader public discourse relating to the COVID-19 vaccines.

Democratization

Despite there being many differences between routine childhood vaccination and COVID-19 vaccination, discussions in both contexts highlight the need for increased public participation and deliberation in determining vaccination policies. To date, policy decisions have been determined by public health agencies, scientists, and politicians, with limited avenues for public input. Depending on public confidence in leadership, this top-down strategy can reduce public confidence and vaccine uptake (Sabahelzain et al. 2021; Wouters et al. 2021).

As we explored in the main chapter, the case for direct involvement of broader publics in policy decisions about vaccination rests on the argument that these decisions involve multiple values that are often competing (e.g., allowing personal choice and aiming for broad vaccination coverage), that they affect all sectors of society, and that they require a certain degree of trust in the vaccines and those producing and administering them (O'Doherty et al. 2021). This argument pertains equally, or possibly even more, to the case of COVID-19. Unfortunately, there seems to have been very little opportunity for meaningful public input in high-level decisions about vaccination policy decisions for COVID-19. While public health responses and communication might have gone beyond providing more information about risks to the public to a broader array of communication strategies as a product of the pandemic (see Goldenberg 2021), overall strategies were still largely top-down, without public

input. That is, communication relating to COVID-19 and COVID-19 vaccines was typically one-way, driven by experts and government authorities. While this might be appropriate for technical aspects of the vaccine and information about the virus and its effects, it does not address the problem of how competing societal values and interests are to be represented in policy responses.

At the same time, the COVID-19 pandemic has been characterized by the spread of misinformation about COVID-19 itself and the vaccines, arguably to a larger degree than has been the case for childhood vaccination, although the dialogue around these has changed in several ways (e.g., discussion of COVID-19 vaccines is less focused on autism and childhood illnesses). Given that misinformation is spread beyond geographical borders online, it is difficult to determine how public input at a local level would influence the spread of misinformation about vaccination. However, because public deliberation processes have the potential to increase trust in policy decisions (O'Doherty et al. 2021; Solomon and Abelson 2012), we can speculate that people residing in an area that incorporates public deliberation in their decision-making processes would have more trust in information from public sources, and therefore be more likely to look for information from government sources, and possibly reduce their consumption of misinformation related to vaccination.

To our knowledge, there has not been any official, government-sponsored public engagement event for members of the public in Canada to deliberate on COVID-19 vaccination, and very little internationally (see, for example, Scherer et al. 2022). Creating mechanisms for public involvement such as public deliberations would increase citizen participation in important social issues based on democratic ideals and would allow for a more nuanced and respectful approach in understanding public perceptions and concerns regarding vaccination, with particular relevance to mandatory vaccination and communication about vaccines. Ultimately, governmental responses to public health risks such as those posed by COVID-19 stand to gain in both legitimacy and effectiveness by incorporating a wider range of perspectives and values through public dialogue.

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