From: Miller, Christine
To: Board of Health
Subject: Simcoe Muskoka District Health Unit Comments for 2019.HL9.2 on September 23, 2019 Board of Health
Date: September 20, 2019 4:16:32 PM
Attachments: image001.png
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Scoping Review_Vaccine Injury Compensation_Dec2017.pdf

Sent on behalf of Dr. Charles Gardner, Medical Officer of Health for the Simcoe Muskoka District Health Unit

To the City Clerk:

Please add my comments to the agenda for the September 23, 2019 Board of Health meeting on item 2019.HL9.2, Moving to Acceptance: Toronto Public Health's Strategy to Address Vaccine Hesitancy

I understand that my comments and the personal information in this email will form part of the public record and that my name will be listed as a correspondent on agendas and minutes of City Council or its committees. Also, I understand that agendas and minutes are posted online and my name may be indexed by search engines like Google.

Comments:

In 2017, the Simcoe Muskoka District Health Unit completed a comprehensive review on the subject of Vaccine Injury Compensation. The review was titled “A Scoping Review on Vaccine-Injury Compensation: Understanding Canadian Immunization Policy” (attached) and the purpose of this paper was to document information on the current dialogue on vaccine-injury compensation, in addition to an exploration of how and why this issue is relevant to supporting current and future immunization efforts in Canada.

We ascertained the following key points through our review:

- Vaccine Injury Compensation (VIC) dialogues has ebbed and flowed since the early 1980s, and continues to linger across the provinces/territories, which includes public advocacy.
- Ultimately, our review revealed that VIC programs are generally cost-effective and manageable.
- Most literature supports a national VIC program, although it is possible to administer at the provincial/territorial level (e.g. Quebec)
- The fact remains that serious Adverse Vaccine Events do occur, even if causality is difficult to ascertain.

In addition to the work of completing this review Simcoe Muskoka District Health Unit

supported a resolution tabled at the 2019 Annual General Meeting of the Association of Local Public Health Units. The resolution was developed by the Kingston, Frontenac, and Lennox & Addington Public Health and was titled “No-Fault Compensation for Adverse Effects Following Immunization (AEFI)”.

To this end we support the work of Toronto Public Health and their advocacy of Vaccine Injury Compensation as a key component of a strategy that reduces vaccine hesitancy and improves health for all Ontarians through the prevention of vaccine preventable diseases.

Sincerely,

Dr. Charles Gardner, MD, CCFP, MHSc, FRCPC
Medical Officer of Health and Chief Executive Officer
t: 705-721-7520 **or** 1-877-721-7520 **x:** 7219
e: Charles.Gardner@smdhu.org

Simcoe Muskoka District Health Unit, 15 Sperling Dr, Barrie ON L4M 6K9

Barrie

15 Sperling Drive

Barrie, Ontario

Phone: (705) 721-7520

Fax: (705) 721-1495

www.simcoemuskokahealth.org

A SCOPING REVIEW ON VACCINE-INJURY COMPENSATION

UNDERSTANDING CANADIAN IMMUNIZATION POLICY

Background Paper

simcoe muskoka
DISTRICT HEALTH UNIT

Simcoe Muskoka District Health Unit

Background Paper

This document provides information on the current dialogue on vaccine-injury compensation, in addition to an exploration of how and why this issue is relevant to supporting current and future immunization efforts in Canada. This paper was prepared with contributions from members of the Clinical Services Department at SMDHU. However, it does not necessarily reflect the views of any individuals or affiliated organizations who participated.

This report was written by Sandani Hapuhennedige in partial fulfillment of her Masters of Public Health degree requirements at the Dalla Lana School of Public Health (University of Toronto). Her preceptor, Colleen Nisbet, Director of Clinical Services at SMDHU, provided mentorship, guidance and support for the completion of this investigation and the writing of this report.

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EXECUTIVE SUMMARY

This report provides an in-depth review of the Canadian dialogue on vaccine-injury compensation, followed by a discussion on Canada's immunization policy and current priorities. However, instead of discussing the mechanics of a vaccine-injury compensation program, this report comprehensively addresses the question: Does Canada/Ontario need a vaccine-injury compensation (VIC) program? This is a research question that has been of great interest to the Vaccine Preventable Disease team at Simcoe Muskoka District Health Unit (SMDHU). Although it is important to note that this is not entirely a novel question. In fact, it is one that has been posed before, and is arguably tethered to the following two key facts: (i) serious adverse events following immunization (AEFI) are possible; and (ii) Quebec is the only province in Canada that compensates individuals who experience a serious AEFI.

Upon reflection of these two facts, SMDHU sought to answer the aforementioned research question by conducting a scoping review of the Canadian dialogue on VIC. Our findings, further described from Chapters 1 to 4, revealed that the VIC dialogue has ebbed and flowed since the early 1980s. Although it has not been consistent, this investigation confirms that there is lingering interest in VIC across the provinces and territories. Further in Chapter 4, this report discusses numerous news articles and reports that confirm said interest. In addition to these reports, the grey literature search led to the identification of public advocacy for VIC in Canada. Based on these findings alone, it appears that there was and continues to be great interest for a VIC program across many of the provinces/territories.

Fortunately, interviews with subject-matter experts revealed a few additional reports and conversations that had not been captured through the review of the academic and grey literature. Notably, the interviewees were most helpful in revealing the sociopolitical climate in Canada, and whether it was conducive to such a policy change. As described in Chapter 5, vaccine hesitancy is currently a priority area of discussion across Canada. Overall, the collated evidence allowed for inferences to be made regarding the potential reasons for inaction on VIC in Canada, despite enduring interest in its implementation. Using a policy change perspective, it is inferred that a window of opportunity likely does not exist to further pursue the VIC agenda in Canada. While there is some advocacy, there are other issues within the sphere of immunization policy that have been prioritized.

Yet, the fact remains that serious adverse events are possible. In accepting the reality of serious adverse events, there are many questions raised pertaining to whether this reality requires a response, and specifically in the form of a VIC program. Thus, in order to answer the question of whether Canada/Ontario needs a VIC program, it is important to first obtain clarification on the current sociopolitical climate, how it is enabling or compromising the VIC agenda, and therein, inform future decision-making regarding compensation.

What is the current situation?

Our scoping review of the dialogue on VIC has facilitated the identification of the following major gaps in knowledge that require further investigation:

- **Necessity & Sufficiency:** From our review, we learned that most compensation programs were a retroactive response to concerns around serious adverse injury, increasing civil action lawsuits, significant public demand and concerning shortages of vaccine supply. However, the reality is that we do not know if these factors are applicable in a Canadian context. A more thorough investigation of this question of necessity could reveal whether VIC should be further explored in Canada.
    - On a similar note, we may wish to further explore the question of necessity within the context of services and programs that already exist to manage the costs (i.e. health care, economic loss, rehabilitation) that are incurred by victims of serious vaccine injuries. It is possible that existing programs are sufficient sources of support for those who experience these serious adverse events.

- **Feasibility:** Some of the resounding concerns for a compensation program exist at the level of funding and whether it is a program that is cost-effective and cost-beneficial. To our knowledge, this information is quite limited in the literature. While Quebec has a program, there is limited evaluation research. However, in speaking with experts, we learned that, generally, VIC programs are believed to be quite cost-effective and manageable. This is further supported by Keelan and Wilson (2011). Nonetheless, further investigation could ease some of the concerns that exist with respect to the implementation of a VIC program.

- **Acceptability:** An imminent concern with introducing a VIC program in today's sociopolitical climate is the phenomenon of vaccine hesitancy. Across the globe, vaccine hesitancy has been used to explain the recent decline in immunization rates, and therein, the numerous outbreaks of vaccine-preventable diseases. Interestingly, the research on vaccine hesitancy suggests that vaccine policies can certainly have an impact on experiences of hesitancy. It is also largely impacted by fears of adverse events. As a result, the acceptability of a VIC program remains contested in the literature, with several arguments that the implementation of such a program could actually further drive fears of immunization. Consequently, we remain unsure whether VIC is an acceptable strategy for improving immunization rates.

- **Leadership & Capacity:** Specifically in the Canadian context, the VIC conversation is not without its complexity of understanding the appropriate leadership for such a program. Given that immunization is provided on a provincial/territorial level, it seems

most appropriate to adjudicate vaccine injury claims in a similar manner. And yet, the current state of the literature suggests that a national program would be most appropriate. We can infer from this dialogue that there is uncertainty as to who the responsibility should fall upon for a compensation program.

- **Causality:** Arguably, this is hardest gap in knowledge to further investigate. The issue of causality has been continuously discussed in the literature and essentially alongside any dialogue that pertains to adverse events following immunization. The reality is that our current understanding of causality is fundamentally reliant upon the ongoing exploration and generation of scientific data. With time, this evidence will surely help to either support or refute some of the temporal associations that have been suggested.

From these (5) gaps in knowledge on VIC, we draw (2) specific recommendations:

Recommendation 1: *Discern the impact of vaccine-injury compensation on vaccine hesitancy in Canada*

- We are aware of investigators who are interested in further exploring this area of research and will likely pursue a study on the impact of vaccine-injury compensation policy on experiences of vaccine hesitancy. Further described in Chapter 6, this recommendation would reveal the acceptability (and perhaps even the necessity) of such a program.

Recommendation 2: *Explore public experiences of serious adverse events following immunization and the need for vaccine-injury compensation in Canada*

- This is a recommendation that was previously provided by Wilson & Keelan (2012). Since that review article, we have still made no progress on understanding public experiences of injury and whether there is a need for a compensation program. Furthermore, our grey literature exposed us to a few individuals who believe they have experienced a vaccine injury. An in-depth exploration of these experiences might help us answer questions around necessity and sufficiency.

Moving forward, we hope to publish and further disseminate the findings of this scoping review. We may also chose to produce a robust situational analysis to highlight what is currently known, what remains unknown, and broadly, what is needed in order progress the dialogue on VIC, or at the very least, improve our understanding of this challenging concept. In the meantime, this background report supplies a history of the VIC dialogue, how it has progressed in Canada since the 1980s, and why it continues to endure today.

PRE-AMBLE

> "Public policy is a very unruly horse, and once you get astride it you never know where it will carry you"
> (Burrough, 1824)

The future is uncertain. And while the future is not necessarily an extension of the past, foresight studies and systems thinking are useful tools for reflecting on the past in order to infer lessons on how to strategically plan future programs and policies. In the 21st century, applying these tools to the world of immunization is especially relevant, given that there is an imperative to maintain steadfast responses to infectious and vaccine-preventable diseases. The fact that we, in Ontario, have already witnessed a number of disease outbreaks, such as measles, further highlights the imminent need for strategic foresight and planning.

Similar sentiments regarding the need for anticipatory approaches were shared in 2012 by the Chief Medical Officer of Health (CMOH), Dr. Arlene King. In this Annual Report by the CMOH (titled Old Foes and New Threats: Ontario's Readiness for Infectious Diseases), Dr. King further alludes to the interplay of factors that are contributing to the problem of infectious disease. Namely, Dr. King refers to the host (i.e. the population), the infectious agents themselves, and the environments in which we reside as being the complex interactions that require regular foresight to ensure the maintenance of a strong public health system. In adding to this comment, we might begin to identify immunization programs and policies as being situated within this complex interaction, and an area of public health that requires a majority of the aforementioned strategic foresight. Without a doubt, the fight against vaccine-preventable diseases has become one of today's most complex problems.

However, cue the discussion on vaccine injury, and we begin to see a more nuanced layer of complexity added to the discourse on immunization programs and policies. The sociocultural reality of modern society is the threatening and growing phenomenon of hesitancy and fear of vaccination. Truly a victim of its own success, vaccine risk has become a greater cause for concern than the potential for the risk of disease itself. In responding to these fears and concerns, we see some interest in the topic of compensation and how vaccine recipients should be insured for their contribution to a public good; this sounds like an agreeable idea in theory. And yet, when we consider the implementation and mechanics of such a program, we begin to realize that there is great ambiguity and less positive reception. This level of complexity was not well known to us when we began our exploration of the potential for a vaccine-injury compensation program, either at the national or provincial level.

Admittedly, we approached this project with certain assumptions that, as we progressed, were unfounded. Specifically, we assumed that there was a wealth of information on this topic, and that there would be sufficient empirical evidence regarding its cost-effectiveness, health impact, potential for improving immunization rates, or at the very least, the impact on vaccine confidence. As it turns out, this topic is more complicated than we had anticipated, with minimal sources of evidence, especially in a Canadian context. While there are

a few excellent reviews on this topic, there has been no further update (in a Canadian context) since the last academic review which was published in 2012.

Turning to additional sources of information, such as consultation with subject-matter experts, was an ideal strategy we employed to help us understand the reason for the apparent lack of discussion in Canada. We had the pleasure of speaking with a number of individuals, who collectively helped us realize the degree of uncertainty and confusion that is tethered to the discussion on vaccine injury, and even more so for conversations regarding compensation.

We ended our investigation with a review of the grey literature, which exposed various avenues of this discussion that we were unfamiliar with. Most notably, we identified a number of vaccine injury victims in Canada who have made many efforts to push the agenda on vaccine-injury compensation, using blog posts, petitions and other social media platforms. We further identified key legal cases that set precedent for the course of discussion and dialogue that ensued over the past three decades. Finally, in addition to these perspectives, we found numerous reports that allude to some of the perspectives of governing officials, physicians and public health professionals.

Objectives

Initial Objectives:

1. To conduct a scoping review of the literature on vaccine-injury compensation in a Canadian context

2. To create an advocacy strategy to present to the Association of Local Public Health Agencies (alPHa)

Revised Objectives:

1. To conduct a scoping review of the literature on vaccine-injury compensation in a Canadian context

2. To identify and interview immunization policy/program experts (i.e. subject-matter expert interviews) to better understand Canadian immunization policy and reveal current efforts pertaining to adverse events following immunization or AEFIs

3. To determine public perceptions and/or awareness of vaccine-injury compensation in a Canadian context using grey literature and social media sources

Overall, we could not have guessed where this project ended up taking us, as we began with the intention of creating an advocacy strategy to present to the Association of Local Public Health Agencies. This goal has since been revised, with recognition that Canada (with the exception of Quebec) does not appear to be adequately prepared to advocate for the implementation of a vaccine-injury compensation program, either at the national or provincial level. Especially as we begin to explore our sociopolitical climate and contexts, we realize that we have more questions than we have answers.

Understanding Canadian Immunization Policy is all about unpacking the complexity of vaccine injuries and identifying how the risk of adverse effects has impacted (or will impact) immunization efforts in Canada. Ultimately, this report is a guide for explaining why we find ourselves at a point in time where we are thinking about the need for strategies to bolster and protect our immunization programs. By extension, we also discuss how Canada (and various provinces) have taken action to address such imminent concerns. We further reflect on the future and relevance of the vaccine-injury compensation dialogue in Canada.

Overall, this report honestly discusses the challenges of investigating this complex public health issue. The following chapters will review the history of immunization and its challenges, trends in vaccine injury, the Canadian dialogue on vaccine-injury compensation, our current sociopolitical climate, and finally, recommendations for next steps on how to better understand this public health issue.

CHAPTER 1: ADVERSE EVENTS FOLLOWING IMMUNIZATION

Great strides have been made in controlling infectious and communicable diseases through the provision of immunization programs across the globe. It is a cost-effective health intervention that saves millions of lives and remains a cornerstone to public health action (Gust, 2012). Over the years, vaccines have become fairly inexpensive, are simple to produce and can be delivered quite easily (Mariner & Clark, 1986). Such ongoing commitment to immunization programs are heralded as being responsible for dramatically reducing the incidence of many dangerous, communicable diseases (Keelan & Wilson, 2011b).

While immunization has offered many benefits, it is not always embraced by the community (Gust, 2012). The reality is that no vaccine is 100% safe (Rothstein, 2015), though they are predominantly safe (Wilson et al., 2006). While the compositions of vaccines have changed over time to minimize the level of risk, there are still clear vaccine-associated harms, referred to as adverse events following immunization or AEFIs. Most of these common AEFIs are quite mild and include: redness, swelling, rashes, and in some cases, anaphylactic reactions (Harris et al., 2016). Typically these reported events are injection site reactions, which resolve quickly and completely (Harris et al., 2016).

Exploring the incidence of AEFIs has become a priority for immunization programs, as evidenced by current efforts across Canada. For example, Public Health Ontario (PHO) is largely involved with tracking reports of these adverse events, recognizing that it is important to communicate information about vaccine safety (Harris et al., 2016). In collaboration with local health units and agencies in the province, PHO collects and reviews reports of AEFIs, therein providing a form of passive surveillance for these events. These findings are documented in the Annual Report on Vaccine Safety in Ontario (Harris et al., 2016). Notably, in their most recent annual report on AEFIs, PHO claimed there were very few AEFIs and stated that “no unexpected safety issues were identified” (Harris et al., 2016). This statement is meant to reiterate the fact that most AEFIs are typically recognized by manufacturers and are consistent with the characteristics of the vaccine (Law, Lafleche, Ahmadipour, & Anyoti, 2014).

All provinces and territories have made similar efforts to track and surveillance AEFIs (Law et al., 2014). These surveillance efforts ultimately contribute to the Canadian Adverse Events Following Immunization Surveillance System or CAEFISS (Law et al., 2014). Managed by the Public Health Agency of Canada, this collaborative initiative allows for continuous monitoring of marketed vaccines in Canada. The collected information ultimately contributes to immunization-related decisions (Law et al., 2014). However, while there is increasing focus on AEFIs, the underlying message from public health leaders is to not lose sight of the reduced morbidity and mortality that is associated with immunization programs. In fact, it has been estimated that immunization programs have prevented approximately 2 to 3 million deaths annually (Halabi & Omer, 2017). Without a doubt, the lives saved from vaccines substantially outweighs the risk of a potential harm (Rothstein, 2015).

Unfortunately, it becomes more difficult to convince the public and vaccine recipients of these important benefits when AEFIs of the more serious variety are possible. Based on Brighton Collaboration definitions, serious AEFIs are events that are life-threatening, requiring

hospitalization, and can lead to persistent disability (Law et al., 2014). Serious AEFIs are typically unexpected, meaning that they are not consistent with the characteristics of the vaccine (Law et al., 2014). In other words, these adverse reactions are idiosyncratic in nature, therefore making them *almost* impossible to predict (Keelan & Wilson, 2011).

Even though identifying these rare adverse reactions is quite challenging (Wilson et al., 2006; Keelan & Wilson, 2011b), a few epidemiological studies have shown that there are in fact some vaccines that have a predictable level of risk for serious injury, such as the result of Guillain-Barre Syndrome (GBS) following influenza vaccine (Keelan & Wilson, 2011). In other words, even though there is uncertainty about serious AEFIs (and their causality), the literature appears to have achieved some acceptance regarding their occurrence.

Statistically speaking, the absolute risk of serious AEFIs is extremely low. For example, the absolute risk of GBS is roughly one excess case per one million vaccines (Harris et al., 2016). For the tetanus vaccine, the rates are as low as less than one per ten million vaccines (Halabi & Omer, 2017). According to the Annual Report on Vaccine Safety in Ontario, only 5.0% (or 34/678) of the reported AEFIs were classified as serious (Harris et al., 2016). The document also indicates that there were two reports of death in 2015, although the cause of death was ultimately due to other systemic issues, where no link to the vaccine was made (Harris et al., 2016). Consistent with the rates of serious AEFIs reported by CAEFISS, and other rates reported in the literature, it appears that vaccine injuries of the serious variety are indeed quite rare.

Yet, despite the rarity of these events, Wilson and Keelan (2012) suggest that these serious AEFIs should be recognized as unequal social costs that are incurred by individuals who are participating in a public good. Certainly, these authors are not alone in this sentiment, and this is further highlighted by an increasing interest in understanding how to communicate these risks in a way that ensures the sustainability of immunization programs (Greenberg, Dube, & Driedger, 2017). Specifically, there is increasing recognition by several researchers that the potential harms of vaccines should not be under-emphasized (Kutlesa, 2004).

In many ways, the exploration and surveillance of AEFIs is much like a double-edged sword; it allows for a better understanding of vaccine-related injuries, but also causes concern amongst vaccine recipients. This is further complicated by the lack of consensus within the scientific community regarding causality versus temporal associations. In other words, AEFI reports are typically focused on temporally associated events, which are “not necessarily causally linked to vaccines” (Harris et al., 2016). And as previously mentioned an AEFI might be due to an inherent property of the vaccine, or could very well be an idiosyncratic or coincidental event that is not related to the vaccine (Law et al., 2014).

At the very least there is certainly continued interest in learning more about AEFIs through active surveillance and investigation. Unfortunately, epidemiological methods have their limitations and are only able to identify the population and absolute risk of adverse events. Essentially this means that identifying individual susceptibility to a (serious) AEFI is quite difficult, and similarly difficult to understand if the experienced serious AEFI is in fact due to the vaccine (Rothstein, 2015). In many of these cases, it is difficult to draw conclusions as to whether the serious AEFI would have occurred regardless of immunization. The challenging

reality is that the evidence base for vaccine associations with serious AEFIs is often inadequate to accept or reject a causal association (Harris et al., 2016).

Consequently, AEFIs and vaccine safety issues have become one of the major obstacles to mass immunization (Jo & Kim, 2013). The following section will elaborate on these current challenges and discuss some of the efforts of public health professionals and policymakers who grapple with these mounting concerns.

CHAPTER 2: LEGAL CHALLENGES TO IMMUNIZATION

Even though fears and mistrust regarding vaccines has existed since the 18th century (Poland & Jacobson, 2011), the greater fear was predominantly with regards to the infectious disease itself. Especially circa the 1940-1950s, support for immunization was ideal; there was a stronger awareness for the benefits of receiving protection from several communicable diseases (Gust, 2012). However, once the threat of epidemics dwindled, subsequent generations became more and more unfamiliar with these diseases and their consequences (Gust, 2012). For the new generation of Canadians, the potential risk of injury from immunization is more relevant and can often be interpreted as a legitimate reason for avoiding immunization altogether (Dube et al., 2016a). In fact, one Canadian study found that 14% of parents would not tolerate any vaccine risk and forego immunization for their child (Kimmel & Wolfe, 2005). Evidently, the lack of absolute safety assurance can deter individuals from participating in mass immunization (Kimmel, 2002).

Despite the "relatively high" rates of vaccine coverage in Canada, there is concern that confidence in vaccines may be decreasing (Canadian Paediatric Society, 1986; Dube et al., 2016b, p. 2). Consequently, and as alluded to in the previous chapter, maintaining high immunization rates is becoming more and more difficult (Kimmel, 2002). Again, even though anti-vaccination movements have existed since the first half of the 20th century, the reality is that new activists and proponents of anti-vaccination are more critical, widespread, and persuasive than their predecessors (Gust, 2012). Especially in light of the Lancet article regarding measles vaccine and autism, public support for immunization (in America and globally) has dramatically shifted. According to Gust (2012), this study on vaccine-imposed autism stimulated an explosion of anti-vaccination movements, followed by significant decreases in vaccine coverage rates. Even though the findings from the Lancet article have been discredited, confidence in vaccines continue to dwindle (Gust, 2012), lending to a phenomenon of vaccine hesitancy; this will be further described in Chapter 5.

Perhaps most problematically, this change in attitudes has been paralleled with "an epidemic of lawsuits" (Gust, 2012). With increasing recognition of AEFIs, many jurisdictions have witnessed a surge of tort law claims and class-action lawsuits (Levin, 2015). Specifically in the United States, the unpredictability of these court cases and claims had a large impact on vaccine manufacturers (Looker & Kelly, 2011). This resulted in vaccine supply shortages in the 1970s, with several vaccine manufacturers leaving the industry due to the burden of defending lawsuits (Looker & Kelly, 2011). Not only did it curb the introduction and innovation of new vaccines (Levin, 2015), but also led to a rise in vaccine costs due to the imbalance of supply and demand (Canadian Paediatric Society, 1986).

Aside from tort claims and threats of litigation, the enduring challenge with immunization is the difficulty with understanding and communicating the risks of harm. As evidenced by the increasing incidents of disease outbreaks, there is limited understanding on how public health officials can effectively address the rising vaccine safety concerns (Greenberg et al., 2017). Even though there are several studies to reject these claims and causal associations, anti-immunization groups continue to create the impression that vaccines are irresponsible and dangerous (Gust, 2012).

Navigating this confusing landscape is becoming increasingly difficult, as is convincing the public that vaccines are essential. It is interesting, however, to note that several jurisdictions have turned to the implementation of a compensation program for injury as a means for responding to public concerns and reducing costs of litigation (Keelan & Wilson, 2011b). Based on recent review articles, the implementation of such programs have been generally well-accepted, and at the very least, has stabilized the vaccine market (Evans, 2006), as a result of reductions in legal pressure (Wilson & Keelan, 2012).

Arguably, we have not experienced similar levels of vaccine concern in Canada (Wilson et al., 2006). Furthermore, Canada does not have as many problems with legal action, compared to other countries, such as the United States (Wilson & Keelan, 2012), but this does not mean that we have not experienced some erosion of public confidence and trust in immunization programs (Wilson et al., 2006). This begs the question of whether Canada will potentially experience the same level of litigation, as seen in the United States, and ultimately, whether we should also consider a compensation program.

Before answering this question, it is important to note that currently Quebec is the only province with such a compensation program. In other provinces/territories, the only means for compensation has been through litigation (Canadian Paediatric Society, 1986). Unfortunately, we have a limited understanding of the number and scope of vaccine-injury related law suits in Canada. However, to date, there has not been a single successful vaccine injury case in Canada (Keelan & Wilson, 2011b). In light of these findings, the following section will provide a summary of compensation programs and how/why they were implemented in other jurisdictions. Understanding these factors may yield answers for whether Canada should adopt a similar compensation program, either at a national or provincial/territorial level.

CHAPTER 3: COMPENSATION PROGRAMS - RATIONALE & STRUCTURE

Currently, there are 19 jurisdictions (Appendix 1) with a vaccine-injury compensation (VIC) system or a general compensation program for medical injuries, inclusive of those related to vaccines (Looker & Kelly, 2011). In Canada, Quebec is the only province with such a program; this program was implemented in the late 1980s in response to a legal case alleging that a child developed encephalitis as a result of the measles vaccine (Keelan & Wilson, 2011b).

Certainly, the concerns of vaccine safety were an impetus for the implementation of these compensation programs, as described in Chapter 2. Consequently, most of the programs that have been adopted were introduced reactively and in response to some of the aforementioned challenges with immunization (Wilson & Keelan, 2012). However, while concerns for vaccine safety have predominantly preceded the adoption of a compensation program, Evans (1999) suggests that these programs began to appear for a variety of reasons. In other words, the rationales for program implementation are quite variable. Similarly, there is quite a bit of variation in the mechanics and administration of compensation, as well.

As such, the remainder of this chapter will further explore the rationale and structure of compensation programs. Although there are many comprehensive reviews on these topics, the following sections provide a summary that will facilitate a better understanding of why and how compensation has been used as a means for maintaining and/or protecting immunization programs across the globe.

Rationale for Compensation Programs

Aligned with the dialogue on vaccine injury and harm, one of the most frequently cited reasons for supporting a compensation program is that it is ethically acceptable (Collier, 2011). In fact, Keelan and Wilson (2011) state that the main rationale for implementing a compensation program is (or at least should be) rooted in ethical principles, such as the principle of reciprocity. The predominant argument is that individuals should be compensated if they incur an unequal social cost while contributing to a public good (Wilson, 2007). Participation in mass immunization confers greater immunity and protection from communicable disease for the entire population, and thus should not be viewed as solely benefiting the individual.

Clearly, vaccines are quite unique in comparison to other medicines and drugs, in that they are taken with the interest of preventing infection for both the public and the individual (Wilson & Keelan, 2012). Consequently, many would argue that there is a strong justification for providing compensation in these rare instances of serious vaccine injuries (Table 1) (Halabi & Omer, 2017). There is an even stronger justification in instances where vaccines are mandatory, which has garnered greater support for the ethical imperative vis-à-vis the principles of fairness and solidarity (Sanzo, 1991; Faden, Taylor, & Seiler, 2003). Essentially, these principles place the onus on the government and public health officials; it urges for recognition of the fact that members of the community should not be forced to bear the burden of their vaccine injury alone (Mello, 2008).

Among other theories or rationales to support compensation is that the process of litigation is "utterly inappropriate for dealing with claims of this nature" (Law Reform Commission of Saskatchewan, 2009). The predominant issue is that there is often no negligent party in these lawsuits (Looker & Kelly, 2011). This poses a challenge for claimants who suffer from the burden of providing evidence to prove that he/she has been faulted (Looker & Kelly, 2011). Not only is it time-consuming, but it can become quite burdensome given the costs and unpredictable nature of tort litigation (Keelan & Wilson, 2011b). Consequently, VIC programs are viewed as an opportunity to move AEFI claims outside of the tort arena and towards a more fair, less costly and accessible system (Collier, 2011).

However, even though these ethical principles have played a role, Mello (2008) reminds us that the enticing reasons for implementation were predominantly to curb the concerns of costs and liability. The author argues that the ethical principles are solely an 'ex-post justification', especially in the context of the United States (Mello, 2008). In other words, it would appear that the political climates and public awareness were predominant factors that led to the implementation of compensation programs in several jurisdictions. This is especially true in Hungary, where the removal of the compensation program was poorly received, which forced government officials to reinstate the VIC program (Boncz & Sebestyen, 2006).

Overall, while these are the commonly cited rationales for implementing compensation programs, the subsequent implementation of compensation programs has been quite variable. A summary of these differences is provided in the remainder of this chapter.

Table 1. Synthesis of general (non-jurisdiction specific) arguments against and in favour of vaccine-injury compensation

Supporting Arguments	Opposing Arguments
Rare, but serious adverse events can occur[1,2,3]	Concerns over causality assessment[1, 3]
Ethical principles (e.g. principle of reciprocity)[1]	Low policy priority[2]
May improve immunization rates[1]	Undermines vaccine confidence[2] and may lower vaccination rates[3]
Weakens power of "vaccine's fiercest critics"[1]	Adds legitimacy to anti-vaccination arguments[2]
Rapidly resolves injury claims (as opposed to civil and tort litigation)[1,3]	Tort liability is beneficial and encourages careful behavior (e.g. pharmacovigilance)[3]
Costs are manageable and predictable[2]	Expensive to finance[3] (and concerns with cost-effectiveness)[1]
Principle of justice/fairness where immunization is implemented with coercive policies[1]	Obligation to compensate diminishes if immunization is voluntary[1]

[1]Keelan & Wilson (2011b)
[2]Wilson & Keelan (2012)
[3]Fowler (2010)

Structure of Compensation Programs

One of the only over-arching similarities between compensation programs is that they operate in a 'no-fault' manner. The aim of this specification is to highlight the fact that vaccine injuries will occur regardless of the best practices of manufacturers and those who administer the vaccine (Keelan & Wilson, 2011b). By moving away from traditional tort litigation, the goal of no-fault programs is to resolve injury claims with ease. However, the way in which this is executed is variable across the 19 jurisdictions, and is further described in the review article by the World Health Organization (Looker & Kelly, 2011). The authors recognized and compared the following elements of compensation programs: administration, funding sources, eligibility, litigation rights, standard of proof, and process of decision making.

Of these elements, the most notable difference between compensation programs is the sourcing and allocation of funds. According to Looker & Kelly (2011), there are approximately four different structures of funding for compensation programs. While some programs are funded through general tax revenues (Table 2), others are funded using a vaccine levy (Looker & Kelly, 2011). The decision-making processes for compensation programs are also quite different, where some rely on a 'Table of Injuries' to determine if a claim should receive compensation, such as the United States. The table essentially contains a list of known adverse reactions (typically of the serious variety) and the associated vaccine (Parasidis, 2016). In comparison, several other jurisdictions operate without a Table of Injuries and rely on a committee of medical and/or legal experts to deliberate on submitted claims (Looker & Kelly, 2011). Finally, there are also large differences in the amount of compensation awarded. For example, while Quebec uses an insurance algorithm to determine the claim award (see Figure 1), other jurisdictions, such as the United Kingdom, provide a lump sum payment of £120,000 (Keelan & Wilson, 2011b).

While it remains beyond the scope of this report to go into the details of different compensation programs, the following elements were highlighted for the purposes of identifying the many different options that Canada (or any of the provinces and/or territories) can consider in implementing a compensation program. In fact, this information has already been reviewed by Keelan and Wilson (2011), where the authors provided recommendations for how to design and implement such a program in Canada. They have created an excellent blueprint for what a program in Canada could look like, and how it can be administered across the provinces/territories.

> "The concept of what constitutes adequate compensation for a given injury is not straightforward"
> (Mello, 2008)

Interestingly, while there are many programs that exist across the globe, there is very little information or formal evaluations on the outcomes and health impacts (Evans, 1999; Keelan & Wilson, 2011b). The lack of these empirical studies makes it more challenging to understand what the best course of action for Canada could be. It is certainly possible that these evaluations are currently being conducted, however, our research was unable to yield any such evidence. Similar thoughts were shared through consultation with immunization experts, who lacked clarity on what constitutes compensation and how to ensure that it is a

cost-effective, equitable, and beneficial program to implement. It appears that there are still many questions that need to be answered as it pertains to VIC programs.

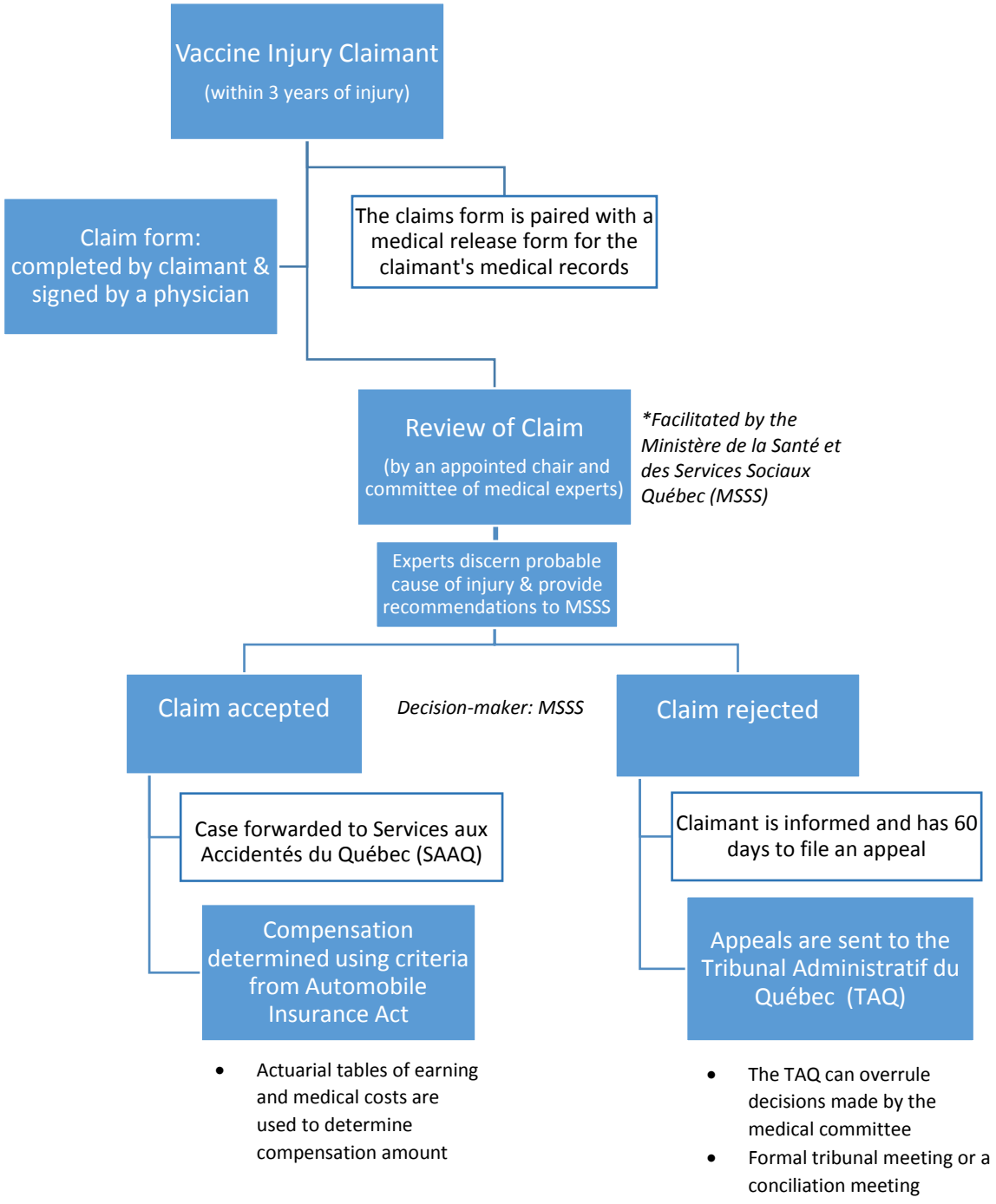
Table 2. Comparing VIC programs in the United Kingdom, Quebec and the United States

	United Kingdom	Quebec	United States
Year	1979	1988	1988
Administration	Department for Work & Pensions, Disability and Carers Service	Ministry of Health and Social Services	Department of Justice/Health and Human Services
Funding	National fund	Provincial revenue fund	Excise tax
Types of Compensation	Lump sum payment	Medical costs, rehabilitation, and death benefits	Medical costs, lost wages, non-economic, attorney's fees
Eligibility	Injury resulting in permanent disability*	Serious injury or death	Refer to Table of injuries
Total Successful Claims	Not available[1]	43[2] (until 2017)	5,680[3] (until 2017)
Total Claims Adjudicated	5,542 (until 2009)	265[2] (until 2017)	16,721[3] (until 2017)

Adapted from Keelan and Wilson (2011b)
*note: disablement is calculated as a percentage (at least 60% disabled)

[1]Statistics for United Kingdom: Gov.Uk
[2]Statistics for Quebec: Quebec Government Portal
[3]Statistics for United States: Health Resources & Services Administration

Figure 1. Adjudication process for the vaccine-injury compensation program in Quebec



CHAPTER 4: CANADIAN DIALOGUE ON COMPENSATION

The dialogue on compensation in Canada is both wide-reaching and complex. In fact, the idea of vaccine-injury compensation (VIC) at a provincial or national level has been percolating for some time. One of the earliest publications on this topic (in a Canadian context) dates back to the 1980s, when the Canadian Pediatric Society identified compensation as a crucial component for maintaining Canada's confidence in immunization programs. This article further elaborated on a rationale for a compensation plan, stating that "recipients of government-approved vaccines should be assured that generous help will be provided if they experience a serious adverse event following vaccination" (Canadian Paediatric Society, 1986, p. 747).

In the review article by Keelan & Wilson (2011), the authors refer to this conversation, in addition to a few other notable dialogues by: Health Canada, the Manitoba Law Commission, and the Law Reform Commission of Saskatchewan. Accordingly, it is important to note that Quebec is not the only province that has investigated this public health issue, though they are certainly the only province to have acted on it. For example, in the 2009 publication by the Law Reform Commission of Saskatchewan, the authors reveal the province's interest in adding a compensation program. Through consultation with the public and public health authorities, the commission reported that there was enthusiasm for implementing a VIC program. It was thought to be a useful part of their current vaccination program and also a strategy for increasing public confidence in vaccination. However, it did not come to pass.

Similarly, in an earlier report by the Manitoba Law Commission (2000), the Commission recommended a VIC program for children and provided a potential framework. The recommendations are largely aligned with elements of the Quebec program, although there are a few differences as well. Interestingly, the investigation and interest in the topic was in response to a request from the Association for Vaccine-Damaged Children, which appears to currently be affiliated with Vaccine Choice Canada (Manitoba Law Reform Commission, 2000). However, while both reports produce recommendations and suggestions for a VIC program, it appears that there was no further discussion or action to pursue its implementation.

Beyond these reports and the review article, it would appear that there has been no discussion on the topic since 2012, in a Canadian context (methodology described in Appendix 2). This was both a concerning and curious revelation as we anticipated finding more information on the topic. While there are recent articles in a global context, or with reference to other jurisdictions, there appeared to be limited Canadian information. Certainly, this sparked some interest to explore further and confirm whether there has been any progress on this public health matter, or if there was currently an agency or organization involved in advocacy or investigation. To help answer these questions, we decided to reach out to individuals, who we identified as immunization policy/program experts, to capture a better understanding of the dialogue on VIC in Canada. The following sections will elaborate on the strategies and methods employed to address this knowledge gap, which includes: (i) subject-matter expert interviews; and (ii) a search of the grey literature

Interviews with Subject-Matter Experts

Upon meeting with our experts (methodology described in Appendix 3), we learned about a few more (and recent) conversations on this topic, some of which we were unable to capture through our literature review. Primarily, we were able learn more about the Quebec program through our consultation with experts. Specifically, our experts from the Ministère de la santé et des services sociaux (MSSS) informed us of a critique of the program that was published in 2014. Authored by Pauline Gref (and published in French), this commentary roughly translates to "The compensation of victims of vaccination: looking at the adverse effects of vaccination on the compensation of victims in Quebec". While we have not yet reviewed this book, we have been informed that it provides numerous suggestions for improving the VIC program that currently exists in Quebec. In many ways, it can be viewed as an external evaluation of the program and its processes. In addition to this book, we learned that there are a few statistics of the program that are available on the MSSS website. Our experts further revealed that the MSSS has a breadth of evaluative findings from their program, although they will likely not be published.

Secondly, we learned that there was some discussion on this topic at a National Immunization Strategy (NIS) review meeting in 2013. The goal of this meeting was to review the strengths and weakness of immunization strategies, and therein, provide recommendations on "areas where ongoing work could be focussed" (Government of Canada, 2017). Among these recommendations was the idea of implementing a no-fault compensation program. Unfortunately, there was no further action on this recommendation, where the NIS team concluded that the decision to implement such a program fell within the jurisdiction of the provinces and territories. This decision highlights one of the most challenging aspects of implementing a compensation program in Canada, which is understanding the stakeholder perspectives and determining the leadership capacity to further promote the initiative.

Aside from confusion and uncertainty on the parties that would be responsible for implementation/administration, we observed considerable curiosity regarding whether a compensation program was actually needed, and further, how it would be perceived by the public. Through our literature review, we had not procured any public opinions on this topic in a Canadian context. However, we were aware of a few news articles that supported a VIC program for Canada. Notably, this is not the case in other jurisdictions, such as the United States, where we found several articles (academic and otherwise) that described prominent cases at length and the public responses at those time points.

In recognizing that there might be similar discussions in Canada, we decided to employ a search of the grey literature. We also hoped to utilize this strategy to get a better sense of public awareness/experiences with the issue, but also to discern whether there had been any further conversation on the topic since the last academic publications in 2012. Given that the grey literature is quite widespread, we decided to focus on the following areas: government documents, newspaper articles, and social media. Wherever possible, we narrowed our search

to only articles that were relevant to Canada (methodology described in Appendix 4). Notably, we did not know what we would find through doing this search, but were certainly curious to determine if there were any conversations, public or professional, that we might have missed through our literature search and expert interviews.

Grey Literature Search: Government Reports, News Articles & Social Media

Government Reports

As it turns out, our search of the grey literature was perhaps the most informative aspect of our investigation. Through using various government search engines, we found several more reports, presentations and transcripts from meetings that demonstrate various perspectives on this topic. Some of these articles were as early as 1988 and others as recent as 2015. In many cases, the topic was simply mentioned or provided as a recommendation, such as the Report of the Advisory Committee for Ontario's Immunization System Review (Advisory Committee for Ontario's Immunization System Review, 2014). In other reports, including a Hansard Brief, we saw much lengthier discussion of the topic and predominant support for adopting a VIC program in Canada. However, in some of the more recent discussions, we found greater concern for the adoption of such a program, as demonstrated through the transcript notes from the 2015 Annual General Meeting for the Canadian Medical Association.

News Articles

With regards to news articles, we found a completely new tone to the conversation on this topic that we had not captured through any of the aforementioned strategies. Through a search of Canadian Newsstream (ProQuest), we procured numerous articles which highlighted various public perspectives on this issue, as early as the 1980s. In many of the earlier articles, we observed a greater degree of support and interest for a compensation program, both from the public and from various professional groups, such as the Ontario Medical Association. As we approach the early 2000s, however, we begin to see less support, paralleled with numerous cases and class action lawsuits from individuals seeking compensation for their vaccine-related injuries. Overall, the news articles allowed us to get a better understanding of how these law suits were perceived by the public, and further, how they set precedent for how vaccine injuries were to be managed moving forward.

Social Media

In more recent years, it initially seems that there has been almost no dialogue regarding the implementation of a VIC program amongst professionals, researchers, and government officials. But as previously mentioned, the utilization of grey literature allowed us to find numerous news articles that discuss the experiences of individuals who claim to have been injured by vaccines, as recent as 2014. With the additional search through Twitter, we were able to retrieve stories, petitions, blog posts, and videos from various individuals across the country. For example, we found one individual who regularly tweets (most recently in July 2017) about the need for a VIC program in Canada, while engaging in active dialogue regarding

the difficult challenges of suffering from vaccine injury. There are also two petitions online for the implementation of a compensation program in Canada. Certainly, these are very valuable sources of evidence as they resolve the recurring question of whether there is public interest in adopting such a compensation program. This information allows us to confirm that there is in fact some degree of public advocacy for a Canadian no-fault VIC program. The extent of such advocacy remains unexplored, to our knowledge, in a Canadian context.

In summary, our research findings suggest that the dialogue on VIC has existed in Canada since the late 1970s. As evidenced by the aforementioned examples, the tone of the dialogue has shifted, with greater confusion on the mechanics of such an initiative. The dialogue has certainly ebbed and flowed, but nonetheless has endured and continues to be discussed through various platforms, such as news articles and social media. And yet, despite all of this conversation, Quebec remains the only province in Canada with a VIC program.

The Canadian Dialogue and Gaps in Knowledge

Upon reflection of these findings, we are inclined to believe that the reason for inaction at a national or provincial/territorial level is not solely due to confusion regarding the mechanics of a compensation program. We make this assumption based on the fact that there appears to be interest, advocacy and descriptive research on the topic, or in short, an understanding of what compensation entails, and yet a lack of action. Instead, we propose that there are likely other factors, many of which are under-explored, that have prevented the implementation of a compensation program. This is supported by the National Collaborating Centre for Healthy Public Policy, which argues that it is necessary to take into account the implementation context and whether the proposed intervention will be applicable within a given population (Morestin, Gauvin, Hogue, & Benoit, 2010).

With regards to the VIC discussion in Canada, it appears that we severely lack an understanding of the current contexts and stakeholder positions. While the review by Wilson & Keelan (2012) describe a few possible contexts and barriers, we have limited understanding of: (i) the full scope of the contexts; and (ii) whether these contexts have changed since the publication of these reviews. This is important information to retrieve, especially given that previous chapters identified that ethical principles are not sufficient for supporting the implementation of VIC. The fact remains that, within Canada, we have a limited understanding of the applicability of a compensation program, and therein, lack any further rationale to support VIC programs beyond that of a moral imperative. In recognizing this major gap in knowledge, we ultimately decided to investigate whether compensation has relevance in today's immunization priorities and efforts, in Canada. We hoped to uncover any factors or contexts that might be a barrier to progressing the VIC agenda.

Unfortunately, there is no article that has synthesized the factors or contexts that might have delayed or compromised the implementation of compensation programs in a Canadian context. With this limitation in mind, we chose to explore Canadian immunization policy more

broadly to understand where the dialogue on compensation fits. Such exploration was encouraged by our experts, many of whom suggested that there might be an appetite for revisiting compensation 'if the political climate changes'.

As such, the next section will provide greater breadth into the sociopolitical climates that have structured these varied dialogues in Canada. Specifically, we will reveal the current interest in learning about vaccine hesitancy and the sociopolitical climate that has influenced this direction and focus. This section will further extrapolate this information to discuss the ways in which the VIC dialogue may be rekindled.

CHAPTER 5: VACCINE HESITANCY & THE SOCIOPOLITICAL CLIMATE

Among the 19 jurisdictions that have a compensation program, a majority were implemented reactively and in response to a problematic and challenging sociopolitical climate. In the United States, some of the major concerns were pertaining to immunization rates and the supply of vaccines (Ridgway, 1999; Keelan & Wilson, 2011a). In Quebec, the Supreme Court rulings around a unique vaccine injury case eventually led to its implementation (Keelan & Wilson, 2011). In Hungary, the program was removed and then reinstated in 2005 upon public clamor and advocacy for maintaining the availability of compensation for vaccine injuries (Boncz & Sebestyen, 2006). Clearly, the sociopolitical climate and contexts have a role in stimulating both dialogue and action on this public health matter.

Sociopolitical Climate and Contextual Factors

By adopting a public policy lens, we can begin to view these contexts as being influential determinants of whether a given problem will (and can be) addressed by policy action. According to The Health Communication Unit report on health promotion policies, once the problem has been identified and adequately described, the next step is to determine readiness by asking, "Is policy an appropriate strategy?" (The Health Communication Unit, 2004). Arguably, answering this question requires a broader understanding of Canadian immunization initiatives and current policies. In other words, it does not suffice to only understand the effectiveness or mechanics of a VIC program. By accounting the broader system within which such an intervention would exist, we can begin to understand if a policy is needed and relevant in a given context.

> "The shape of the schemes will be highly influenced by the health system context"
> (Dickson et al., 2016)

Predominantly, it appears that our Canadian context currently involves an interest in immunization rates, vaccine confidence and attitudes; this was confirmed by many of our subject-matter experts. Broadly grouped under the term 'vaccine hesitancy', the reality is that Canada might not be achieving ideal rates of immunization. For example, and as described in a recent report, *Immunization 2020*, coverage remains relatively high although "it still falls short of national immunization targets" (p. 2). This is evidenced by increasing outbreaks of various diseases, such as measles, mumps and whopping cough (MOHTLC, 2015). While Canada might not be experiencing a detrimental decline in immunization rates, the recent outbreaks, among other reasons, have created concern that current programs and initiatives might be losing public confidence (Dube et al., 2016b).

Vaccine Hesitancy

In recent years, the concept of 'vaccine hesitancy' has been increasingly employed to better understand the factors that contribute to decisions about immunization (Dube et al., 2016b). Defined as "the delay in acceptance or refusal of vaccine despite availability of vaccine service", MacDonald et al. (2016) identifies hesitancy as an imminent challenge for Canada. Most notably, this dialogue hinges on the recognition that vaccine attitudes are typically not a simple dichotomy (Dube et al., 2016a). Instead, it is multi-faceted, complex, and varies across time and place (Dube et al., 2016a). Several Canadian researchers have further explored this phenomenon, using surveys and questionnaires, with the hope that it will contribute to guiding the appropriate interventions (Dube et al., 2016a).

The challenge with addressing vaccine hesitancy, however, is that its multifaceted nature means that there is truly no single intervention to improve vaccine attitudes and acceptance, and therein, bolster immunization programs/rates (Dube et al., 2016a). In fact, recent efforts, such as communicating evidence about safety, are reported as having a minimal effect on reducing the growth of hesitancy (Dube et al., 2016a). In response to this struggle, Dube et al. (2016) discuss the importance of utilizing proactive responses instead of solely using strategies that are reactive. For example, instead of waiting to respond to anti-vaccination movements, the public health community should strive to "proactively promote the importance and safety of vaccines" (Dube et al., 2016a).

Understanding Canadian Immunization Policy

On the note of proactive approaches, we began to wonder if a VIC program could be viewed as one such strategy that could promote the safety of vaccines, and therein reduce hesitancy. This aligns well with some of the arguments we have seen in the literature, which suggests that VIC programs can actually sustain public support "by demonstrating public health's commitment to vaccine recipients" (Wilson, 2007). Although it sounds counter-intuitive at first, discussing vaccine injury and the provision of a form of insurance might be a way to ameliorate some of the fears of adverse effects (Evans, 2006). Of course, there are counter-arguments which claim that VIC could actually decrease immunization rates by furthering the fears of vaccine risk and undermine confidence (Isaacs, 2004). Nonetheless, and through our expert interviews, we saw considerable interest in exploring the impact of a compensation program (real or hypothetical) on vaccine hesitancy.

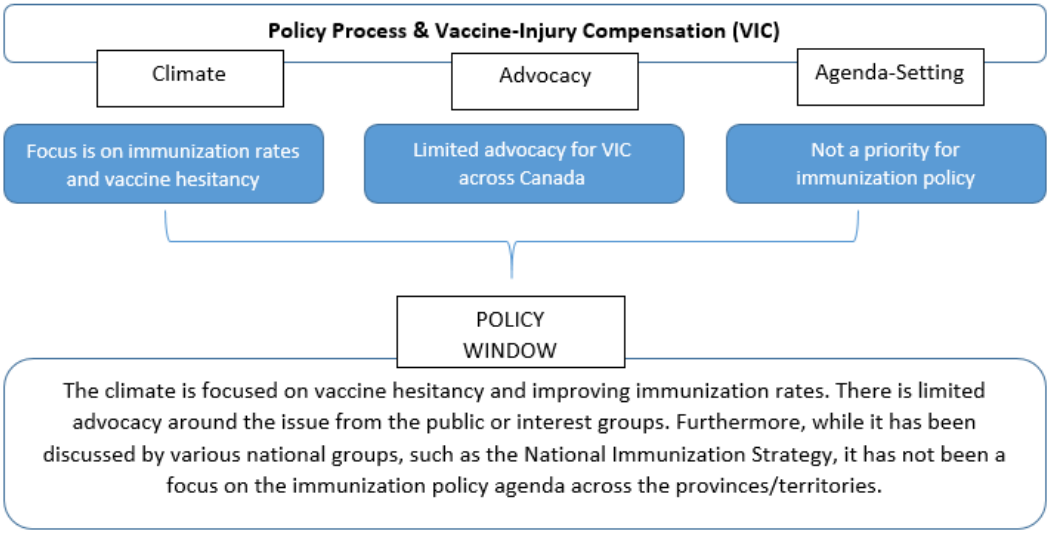
To our knowledge, the impact of VIC on vaccine hesitancy (or a similar concept) has not been discussed in a Canadian context or elsewhere. We did however capture one study which suggested using an Extended Parallel-Process Model (EPPM) to assess whether a policy regarding compensation for vaccine injuries is an effect modifier of vaccine confidence. Situated within the context of mandatory vaccines for health care workers in the United States, the researchers of this investigation allude to the role of the law in affecting behaviour change (Barnett, Errett, & Rutkow, 2013). The authors conclude that this threat-and efficacy-based

behaviour model can be used to understand the impact of a compensation program on confidence or attitudes towards immunization. Although the authors have not yet conducted this research with care providers, they have rationally explained why and how there might be a relationship between vaccine-injury compensation and attitudes towards immunization.

Overall, through recognizing this context and the prioritization of solutions for addressing vaccine hesitancy, one can suspect that there is currently no 'window of opportunity' (or policy window) to support or promote the implementation of a VIC program, nationally or otherwise (see Figure 2). However, in acknowledging the potential relationship between vaccine hesitancy and VIC, it may be possible to rekindle the dialogue, and therein, create a policy window. In other words, if we begin to see more investigation on this relationship, whether it is in a Canadian context or not, we might experience a triggering of interest to better understand the role of compensation as an intervention for vaccine hesitancy.

On the note of policy windows, we may also see an increased interest in VIC programs in the future if Canada (or respective provinces/territories) begins to revisit mandatory vaccination policies for health care workers. This discussion is drawn from recommendations provided by the National Advisory Committee on Immunization (NACI) which encourages stronger efforts to ensure the immunization of health care workers (Walkinshaw, 2011). While we are not aware of any provinces that have plans to proceed with such a legislation, it is important to note that such a decision could create a policy window. This is based on the academic consensus that restrictive policies (i.e. ones where people are fined or are denied benefits) can evoke concern for respect for individual choice (Sanzo, 1991; Faden et al., 2003; Evans, 2006; Barnett et al., 2013). Further deliberated by Sanzo (1991), the main argument is that if citizens are to assume the risk of vaccination, then "it seems incumbent upon society as a whole to provide compensation" (p. 45).

Figure 2. Sociopolitical climate and factors affecting VIC decision-making in Canada



While we await the potential for this policy window to open, the current and past sociopolitical climate can be used to explain and answer the question of why a VIC program in Canada remains intangible. As demonstrated by this investigation, answering this question certainly requires an understanding of Canadian immunization policy more broadly. While there is considerable focus in addressing vaccine hesitancy, the main goal of the Government of Canada is to increase immunization coverage rates via improvements in program delivery (Government of Canada, 2017). This includes conducting the appropriate program evaluations and research to make evidence-informed decisions. In Ontario specifically, the auditor general report has influenced areas for action, none of which are relevant to promoting the VIC agenda. As a result, while a VIC program is often noted as being a gap in immunization policy (Government of Canada, 2017), it is currently not a priority.

In summary, while we have a couple of excellent reviews to guide us in the discussion on what a compensation program could look like, there is less understanding of the factors that have either promoted or compromised the dialogue on VIC. While these factors have been mentioned intermittently, we lack a synthesized and up-to-date understanding of the contexts relevant to this topic. Hopefully we can agree, however, that the value of such a synthesis is that it allows Canada (or individual provinces/territories) to gain a better understanding as to why we remain one of two G8 countries that do not have a VIC program.

CHAPTER 6: SUMMARY & RECOMMENDATIONS

Immunization remains a cornerstone to public health. Though complicated in implementation and administration, vaccine programs continue to be our main weapon against dangerous, infectious and communicable diseases. As identified throughout this report, the current programs and efforts in Canada are far-reaching, with many coordinated campaigns and initiatives that aim to rejuvenate an area of public health that is increasingly being scrutinized. Among these policies and strategies exists the under-acknowledged proposal for a Canadian VIC program, an idea that hinges on the recognition that: (i) serious AEFIs are possible; and (ii) Quebec is the only province in Canada that compensates individuals who experience a serious AEFI.

Of course, the ideal solution to this would be to achieve the production of vaccines that are 100% safe, 100% of the time. Unfortunately, such a solution does not seem probable, though there is certainly ongoing vigilance in ensuring that the risks are minimized as much as possible. In the meantime, compensation programs are posed as a potential solution for buffering some of the hardship that individuals may endure following immunization, and therein, reduce some of the associated fears. Supported by ethical perspectives, a compensation program seems like a panacea for satisfying all parties involved in the vaccine process: the population, the manufacturers, and the government and health officials. Some researchers agree that a no-fault compensation program is truly able to "fulfill the utilitarian and communitarian expectations of a democratic society" (Halabi & Omer, 2017).

As we have come to learn, however, the reality of implementing such a program is less straightforward. This is further highlighted by the differences that exist in the mechanics and administration of existing compensation programs across the globe. As discussed in earlier chapters, the program in the United Kingdom is quite different from the program in the United States. And even the Quebec program, though similar to the one in the United States, has its own unique strategies for the administration of compensation for vaccine injury. While we do have a few excellent program blueprints to rely on, such as the Munk School Briefings article, the looming questions of necessity, causality, feasibility, capacity (i.e. leadership, resources), and acceptability, render the topic as one that is challenging to understand.

Through this review, we primarily learned that compensation programs have predominantly been a retroactive response to considerable public demand and/or to concerns around serious adverse injury, civil action lawsuits, and vaccine supply shortages. However, in a Canadian context, we lack an understanding of whether these factors are applicable. For example, we have limited knowledge of whether there is public advocacy for this policy initiative – i.e. what is the scope of public interest for a VIC program? Thus, the limited discussion on public awareness and vaccine injury experiences continues to be a barrier to creating a policy window, as confirmed by many of our subject-matter experts. To our knowledge, this barrier has been alluded to in the literature by Wilson & Keelan (2012), but has not yet been explored or further addressed. In conducting this scoping analysis, we can confirm that there are no published primary studies that have explored public perceptions or experiences of vaccine injury in a Canadian context. Consequently, we continue to have gaps in our understanding of whether a VIC program is needed in Canada.

More broadly, we continue to grapple with the question of causality. Arguably, this is the most challenging gap in knowledge to further investigate, although it is invariably a large component of the VIC dialogue. The reality is that our current understanding of causality is fundamentally reliant upon the ongoing exploration and generation of scientific data. With time, this evidence will surely help to either support or refute some of the associations that have been discussed in the VIC literature. Yet, in the meantime, the uncertainty around causality remains a major barrier for promoting the VIC dialogue in Canada.

This review also reveals that there are gaps in our understanding of the feasibility of a VIC program and the leadership for both its implementation and administration. As discussed in previous chapters, there continues to be resounding concerns regarding the cost-benefit or cost-effectiveness of implementing such a program. This discussion is further tethered to concerns around leadership, which would effectively dictate the scope and source of funding for a VIC program. While there appears to be some agreement that a national VIC program would be ideal, our review reveals that there is residual concern and confusion on how such a program would be best implemented.

Furthermore, we recognize that the VIC agenda will likely not gain traction in the present realm of immunization policy, though it may gain greater relevance and attention over time. As demonstrated by the findings of this project, vaccine hesitancy is a priority issue that is heavily influencing and informing future directions and movements in immunization policy. However, as the research base on vaccine hesitancy expands, there may be potential to stimulate conversations on compensation once again. More specifically, empirical evidence on strategies to curb hesitancy in the hypothetical presence of a compensation program could easily become a main driver for rekindling this dialogue (i.e. open a policy window). A similar suggestion was provided by Wilson & Keelan (2012), which is further discussed in the section on Recommendations.

Overall, these complex gaps in knowledge remain under-reported, which arguably explains why a VIC program in Canada (with the exception of Quebec) remains intangible. As a result, this investigative research endeavour has added to the evidence base by capturing insights on this topic to reflect the current priorities and future directions for immunization policy and programming in Canada. To our knowledge, such a comprehensive analysis has not been produced. However, in conducting this scoping analysis, we are able to infer the best next steps that have potential to address some of the aforementioned complexities and challenges. In summary, we have used these gaps in knowledge on VIC to draw two specific recommendations. Both of these recommendations are deemed as being more tangible for various jurisdictions to explore and are arguably more imminent in today's sociopolitical climate. These recommendations are described in the subsequent section.

Recommendations

The following topics are areas that we support for further investigation to better understand the benefits and/or consequences of vaccine-injury compensation:

1. The impact of vaccine-injury compensation on vaccine hesitancy

2. Public experiences of vaccine-injury and the need for vaccine-injury compensation in Canada

The first recommendation is an extension of that which was provided by Wilson & Keelan (2012). As previously stated, the authors refer to capturing empirical evidence on vaccine confidence, while this report recommends a shift in focus on the broader term of vaccine hesitancy. This term captures not only confidence, but also other factors such as complacency and vaccine attitudes. Furthermore, as a result of the recent focus on this phenomenon, we have a larger set of valid and reliable survey tools to quantify and measure this impact. We recommend using these tools to understand whether the availability of compensation for injury (real or hypothetical) has an impact on vaccine hesitancy.

Fortunately, our investigation has allowed us to confirm that there is in fact an interest in exploring whether VIC can impact vaccine hesitancy. A proposal for understanding the impact of compensation on vaccine hesitancy can likely be expected in the future, as confirmed by researcher, Eve Dubé. At this juncture, it is important to note that it would be most relevant to determine if VIC has an impact on immunization rates. However, given the challenges of collecting accurate data on immunization rates, this review recommends focusing on the impact VIC might have on the broader phenomenon of vaccine hesitancy.

The second recommendation would seek to capture empirical evidence on the needs of those who have experienced serious vaccine injuries. To our knowledge, this has not been explored in a Canadian context. However, based on our grey literature search, it appears that there are in fact several individuals who have been trying to promote this discussion in Canada. This suggests that there is in fact a wealth of information and knowledge that is waiting to be captured and explored.

Through exploring the second recommendation, the question of whether a compensation program is needed could potentially be answered. This may also reveal what form of compensation (i.e. monetary, access to services, etc;.) is preferred. Through exploration of this recommendation, we may come to learn more about the experiences of vaccine-injured victims and what resources have been used in the absence of a VIC program. Specifically, we wonder whether there are tax benefits or social services that have been sought by these victims of vaccine injury. For example, it is quite possible that an entirely new program may not be necessary and that there are opportunities to expand existing services or programs.

Concluding Thoughts

> "Implicit in any monetary policy action or inaction is an expectation of how the future will unfold, that is, a forecast" (Greenspan, 1994)

While the national task groups or governing bodies are well-positioned to tackle a compensation program for Canada, the nuances and ever-changing nature of immunization programing across the provinces creates a complex challenge for understanding whether a national program is even possible. However, despite these potential challenges with leadership and feasibility, the questions of necessity and applicability of VIC remain more imminent areas of evidence that need to be addressed. Following the outlined recommendations may in fact provide clarification on: (i) whether a vaccine-injury compensation program is acceptable (i.e. does it have an impact on immunization rates or vaccine hesitancy?); (ii) whether a vaccine-injury compensation program is needed (i.e. is there public need/interest for such a program?); and further (iii) whether there a compensation program is sufficient (i.e. what forms/sources of support are currently pursued by vaccine injury victims in Canada?; what resources are needed?)

In the absence of a systematic review or Cochrane review article, this scoping analysis on VIC provides a fairly comprehensive guide for understanding this topic in a Canadian context. Effectively, we have been able to add to the evidence that has been presented in earlier review articles and commentaries, of which there are a few. However, rather than focusing on a potential blueprint for a program, or the mechanics of a compensation program, we specifically identify the gaps that need to be addressed in order to better our understanding of whether compensation is truly needed and/or beneficial for Canada.

As such, we look forward to using the findings of this scoping review to produce a robust situational analysis of vaccine-injury compensation in Canada. This analysis will reiterate the provided recommendations, but will further comment on: the capacity of our health systems, the potential future challenges, resource gaps, and current stakeholder positions as well. To our knowledge, a situational analysis on this topic has not been investigated, which was further evidenced by our struggle to find information on this topic. Producing this evidence piece is a fundamental step to updating our knowledge on this potential policy initiative.

Ultimately, there are many questions that need to be answered as it pertains to this complex public health issue. However, in agreeing with (Eickhoff, 1998), support for VIC may evolve as the issues gain recognition and prioritization. We remain confident that rekindling the dialogue, through this scoping review and further investigation, will help us achieve greater clarity on whether a compensation program for vaccine injury can and/or should be integrated into Canadian immunization policy.

PERMISSIONS

1. National Immunization Strategy

The information regarding the National Immunization Strategy meeting and conclusion was communicated by the Public Health Agency of Canada. Current discussion pertaining to vaccine-injury compensation is briefly mentioned online, but will be further described in future updates on their website: National Immunization Strategy: Objectives 2016-2021

2. Vaccine Hesitancy Research

Confirmation of future investigation to explore the potential link between vaccine hesitancy and compensation programs was provided by Eve Dubé in August 2017.

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APPENDIX

Appendix 1: Vaccine-Injury Compensation Programs

Table A1. List of jurisdictions with a vaccine-injury compensation programs

Jurisdictions with Vaccine Injury Compensation	
Germany (1961)[1]	Quebec (1988)[1]
France (1964)[1]	United States (1988) [1]
Japan (1970)[1]	Taiwan (1988)[2]
Switzerland (1970)[1]	Italy (1992)[1]
Denmark (1972)[1]	Republic of Korea (1994)[2]
Austria (1973)[2]	Norway (1995)[2]
New Zealand (1974)[2]	Iceland (2001)[2]
Sweden (1978)[1]	Slovenia (2004)[2]
United Kingdom (1979)[1]	Hungary (2005)[2]
Finland (1984)[2]	

[1](Keelan & Wilson, 2011b)

[2](Kirkland, 2016)

Appendix 2: Database Search and Exclusion Criteria

Table A2. Database search strategy

	Ovid Medline	CINAHL	JSTOR
Keywords	"vaccine injury"; "compensation" (title, abstract, keyword)		
Retrieved Articles	98	169	304
Excluded (including duplicates)	68	162	279
Final Articles	30	7	25

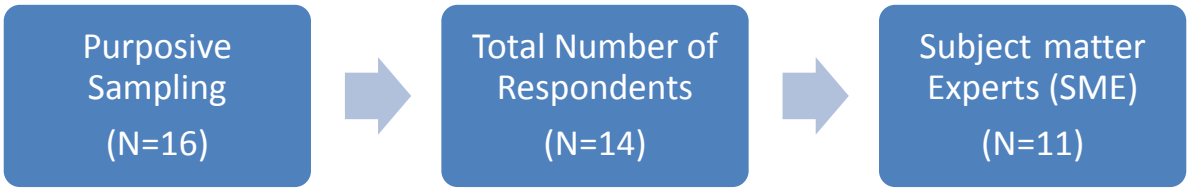
Note: This search was conducted between June and July 2017.

Table A3. Exclusion criteria for database literature search

First Round Exclusion (Title & Abstract)	Second Round Exclusion (Full Article)
Not in a Canadian context	Primary studies on causality
Only discusses vaccine injury	Primary studies on risk of disease
Only discusses vaccine fears/anti-vaccination	Notice of changes to VIC
Changes to immunization programs/schedule	Primary studies on health care providers' behaviours/perceptions
Education on vaccine adverse events	Focus on risk of litigation
Issues with specific vaccine	Vaccination for health care providers
Compensation for all medical injuries	Claims data

Appendix 3: Subject-matter Expert Interviews

Figure A1. Strategy for contacting subject-matter experts



Note: Interviews with subject-matter experts were conducted between June and August 2017. Subject-matter experts were defined as: (i) individuals with knowledge on vaccine-injury compensation; and/or (ii) individuals familiar with recent immunization programs/policies in Canada.

Table A4. List of SME affiliations and/or locations

SMEs
Kingston, Frontenac, Lennox & Addington Public Health
Ottawa Hospital Research Institute
Institut de santé publique du Quebec
Public Health Ontario
Toronto Public Health
Ministère de la santé et des Services Sociaux
University of Calgary
National Media (Montreal, Quebec)

Appendix 4: Grey Literature Search and Exclusion Criteria

Table A5. Grey literature search strategy

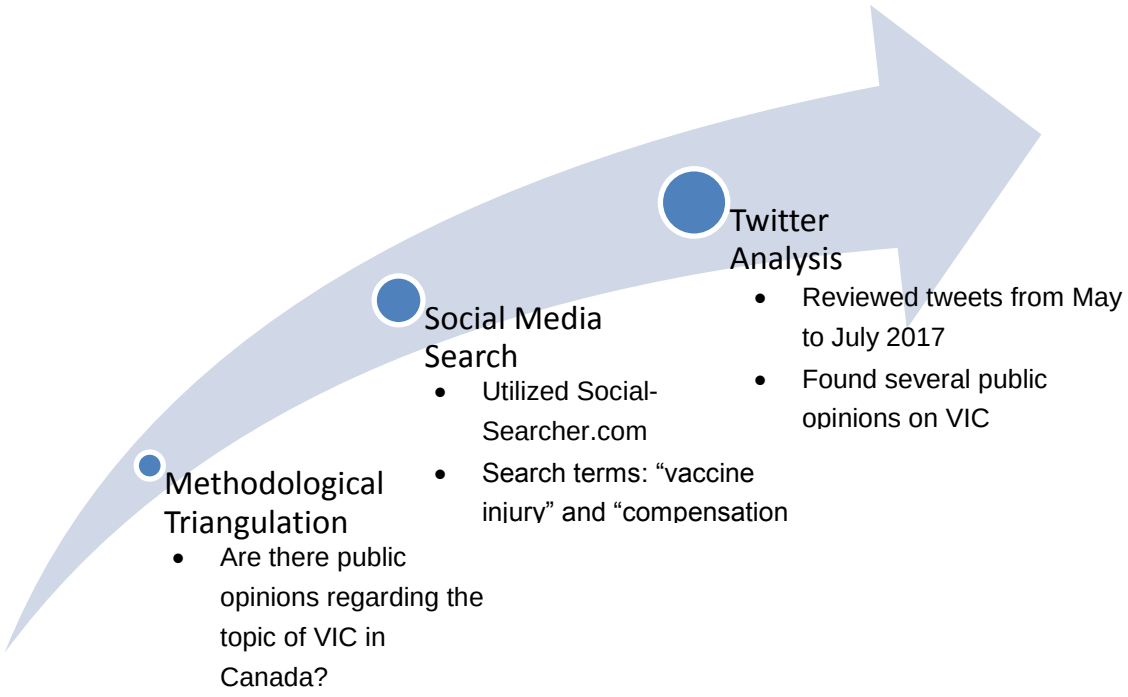
	Custom Search Canadian Government Documents	Canadian Newsstream (ProQuest)
Retrieved Articles	26	183
Excluded	20	140
Final Articles	6	43

Note: This search was conducted between June and July 2017.

Table A6. Exclusion criteria for grey literature search

Title & Content Exclusions
Not in a Canadian context
Only discusses vaccine injury
Only discusses vaccine fears/anti-vaccination

Figure A2. Process for social media: snapshot analysis



Note: This search was conducted in July 2017 and only collected data from May to July 2017. This brief snapshot can be further expanded to achieve a more comprehensive social media analysis.