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Designing a No-Fault Vaccine-Injury Compensation Programme for Canada: Lessons Learned from an International Analysis of Programmes

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Designing a No-Fault Vaccine-Injury Compensation Programme for Canada: Lessons Learned from an International Analysis of Programmes

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EXECUTIVE SUMMARY

This report provides both an in-depth analysis of several distinct types of no-fault programmes and research-based recommendations for the design and implementation of a model programme that could be implemented in the Canadian context. To do so, we reviewed the international programmes implemented in thirteen jurisdictions and conducted in-depth case studies of the programmes implemented in the United States, the United Kingdom, New Zealand and in the province of Quebec.

Why Canada needs a no-fault compensation programme for vaccine-related injuries

Immunization programmes are considered a corner-stone of Canadian public health and are responsible for the dramatic decline in the incidence and severity of many vaccine-preventable diseases. However, every year in Canada, despite the best practices of both vaccine manufacturers and health care professionals, a few individuals will sustain serious harm and bear the burden of this harm while contributing to a public good. In these cases, there is a compelling argument that those who are injured should receive compensation through a no-fault programme.

The core argument for implementing government compensation for vaccine-related injuries hinges on the ethical principle of reciprocity. While not strictly mandatory, many vaccinations are intended not only for the protection of the vaccinated but also for the protection of others (Harris and Holm 1995; Krantz et al. 2004; Ross 2005; Salmon et al. 2006). When vaccination rates hit a particular threshold and are sustained, the transmission of the pathogen from person to person is disrupted and the incidence of the disease falls accordingly. This property of vaccination programmes, known as *herd immunity*, also protects those in the community who, for a variety of reasons, cannot be vaccinated, are ineffectively vaccinated, or refuse to be vaccinated. As a consequence, governments all over the world have introduced policies to maximize vaccination rates – for example requiring a suite of vaccinations for school attendance or requiring health care workers to show proof of immunization against a variety of vaccine-preventable diseases. Thus when someone is seriously injured because they participated in a government vaccination programme (and contributed to a broader public good), there is an ethical argument for providing compensation for the injuries sustained, which frequently include lost wages, uninsured medical costs, and rehabilitative supports (Rea and Upshur 2001).

No-fault compensation programmes have been introduced in at least 13 jurisdictions around the world, including the province of Quebec. Canada stands alone with Russia as the only two G8 nations to not have a national programme.

Utility of a no-fault approach

Since the injuries related to vaccines generally occur despite best practices in both manufacturing and delivery, injured parties in Canada cannot use negligence to establish fault (Kutsela 2004; Manitoba Law Reform Commission 2000; Peppin 2005). In addition, most vaccine-related injuries are idiosyncratic in

nature making it nearly impossible to predict who might have a serious adverse event (Institute of Medicine 1985; Jacobson et al. 2001). Though there have been many Canadian vaccine injury cases tried over the past few decades in Canadian courts, *because of these features of vaccine injury there has not been a single successful vaccine injury case in Canada* (Manitoba Law Reform Commission 2000). This has led several of the presiding judges in these cases to include in their judgments an acknowledgement of the unfairness of a legal system that lacks the mechanism to provide compensation in cases where people are clearly injured while participating in a public good (see for example *Morgan v City of Toronto*).

A no-fault approach for vaccine-related injuries includes the following features:

- The recognition that there are situations of *unavoidable* or *unintended* medial injuries that merit compensation. Traditional tort litigation on the other hand is premised on the principle aim to punish wrong-doings (punitive) and to deter the public from doing harm to others (deterrence).
- Because there is no fault presumed, compensation is needs-based rather than punitive, and is, thus, both relatively *modest* and *proportionate* to the injury.
- Unlike jury trials, no-fault compensation processes are more likely to be *consistent* both in the type of *award* and in the *amount of compensation*.
- No-fault programmes can *rapidly* resolve injury claims by either using a fixed table of vaccine-associated injuries or an administrative or judicial review of each case (as opposed to civil litigation which is adversarial, prohibitively expensive, and nearly always more time consuming) (Bismark and Paterson 2006).
- No-fault compensation programmes move vaccine injury cases out of the tort arena into a publicly administered or regulated programme saving vaccine manufacturers hundreds of millions of dollars in legal fees, help to stimulate vaccine innovation and manufacturing thereby keeping the costs of vaccines low for public programmes (Evans 2006).
- Giving those injured access to a reasonable, restitutive process weakens the power of vaccine's fiercest critics.

Lessons learned from other jurisdictions

How are no-fault programmes typically run?

- Worldwide, most no-fault programmes are government-run and national in scope. They generally fall under the administration of state ministries related to health and social welfare or labour (as in the case of the United Kingdom) or there is federal/national legislation that governs an arms-length overseeing agency, as in the case of New Zealand. Only in Sweden is the no-fault programme covered under a private drug insurance scheme (see Table 1).

What vaccines are usually covered?

- Most no-fault compensation programmes were implemented in the 1970s and 1980s when vaccine programmes targeted infants and school-aged children. Thus, some programmes restrict eligibility for compensation to government recommended vaccinations given to infants and children. In some instances, vaccinations required by state mandates are included in the programme.
- In the case studies we examined, the programmes covered most government recommended vaccines (including adults) or any vaccines administered by a recognised health professional. In many cases, there is supporting legislation that either lists vaccines by name, as in the United Kingdom, or covers all vaccines related to the listed vaccine-preventable diseases, as in Quebec's programme (see Table 2).

How does a claimant demonstrate that the vaccine caused an injury?

- Most no-fault programmes are designed for an administrative review of the injury, similar to other accident insurance or disability schemes, and do not require the claimant to seek legal representation or solicit expert medical review (beyond their attending physician's report).

- The assessment of claims is typically overseen by a medical director and follows a combination of an administrative review of eligibility criteria and a medical assessment performed by outside consultation from medical experts (as in the United Kingdom and New Zealand).
- Only the US has a system that resembles civil litigation, with the government acting as the defendant and the injured party as the plaintiff in each case. Both parties are represented by lawyers, produce expert witnesses, and argue their cases before a special master (specialized judges). Also unique is the province of Quebec's tribunal system where claims are heard by a three-person medical tribunal and decided by a 2/3 majority opinion. One tribunal member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.

What types of medical and non-medical costs do most programmes cover?

- Most programmes are designed to cover *uninsured* medical costs, while others include special disability benefits, death benefits, economic damages (lost wages) and, in some cases, non-economic losses. New Zealand is unique in that it compensates for all unexpected injuries with a demonstrable economic loss, e.g. a sore arm that resulted in lost work would be compensable. The United States also compensates all injuries that result in measurable damages, whereas the United Kingdom has a high threshold, requiring over 60% permanent disability caused *solely* by an adverse event following immunization. Similarly, Quebec only compensates in cases of serious injury or death.
- Only the United States routinely covers the claimant's legal fees because its system is structured to require legal representation.
- In many jurisdictions, the settlement amount is calculated by agencies that typically deal with disability or accident claims. Compensation is frequently determined according to the rules governing accident or disability scales (as in Quebec) or determined by a life-planner (as in the United States). Lump sum settlements are issued in jurisdictions where there is a strong social safety net such as the United Kingdom & Norway.

How are most programmes funded?

- Because no-fault programmes for vaccine-related injuries tend to be fairly modest in scale, compared to other entitlement programmes, most are funded from general revenues. In the United States, the programme is funded by a special vaccine excise tax (paid by the purchasers) and in Sweden, Taiwan and Norway, a premium is paid by the vaccine manufacturer's themselves.

How predictable are the number of claims and settlements among the various no-fault compensation programmes and what kinds of programme components impact the overall payouts?

- Despite radical differences in approaches, administration, and eligibility criteria, data from all four jurisdictions studied shows that the average number of claims and compensation amounts are relatively stable and predictable and represent both an affordable and reasonable expenditure as part of an overall national vaccination immunization programme. Still, the predicted number of settlements and the cost of any scheme does depend greatly on eligibility criteria, filing requirements, and the public's knowledge of the programme.
- The number of cases compensated is directly related to the eligibility requirements imposed by each system.

Design of a Canadian no-fault compensation programme—our recommendations

Our review of the lessons learned from international programmes and the four case studies has led us to the following recommendations for a national compensation programme for adverse events following vaccination.

- The principle aim of a Canadian no-fault compensation programme should be to fairly compensate those likely injured from a vaccine recommended by the federal government through agencies such as the National Advisory Committee on Immunization (the organization charged with a routine review of

vaccination) or through official recommendations of the Public Health Agency of Canada (e.g., made during the emergency release of a vaccine during an outbreak or pandemic).

- The programme should ideally be administered by an arms-length agency, e.g., the Public Health Agency of Canada, but independent of the branches of government responsible for the promotion and safety of vaccines.
- Based on international experiences, a reasonable statute of limitations for filing claims should be set (e.g., 3 years from injury onset), in addition to requiring sufficient documentation to substantiate the injury and its aetiology.
- The injury itself must result in some measurable *uninsured* damages or costs. In the case of death, a death benefit would be paid out similar to an accidental death insurance benefit.

Proposed adjudication of claims process (See Figure 1)

STEP 1. Determine basic eligibility criteria are met.

STEP 2. The claimant, in consultation with the programme's administrator, would have the choice of:

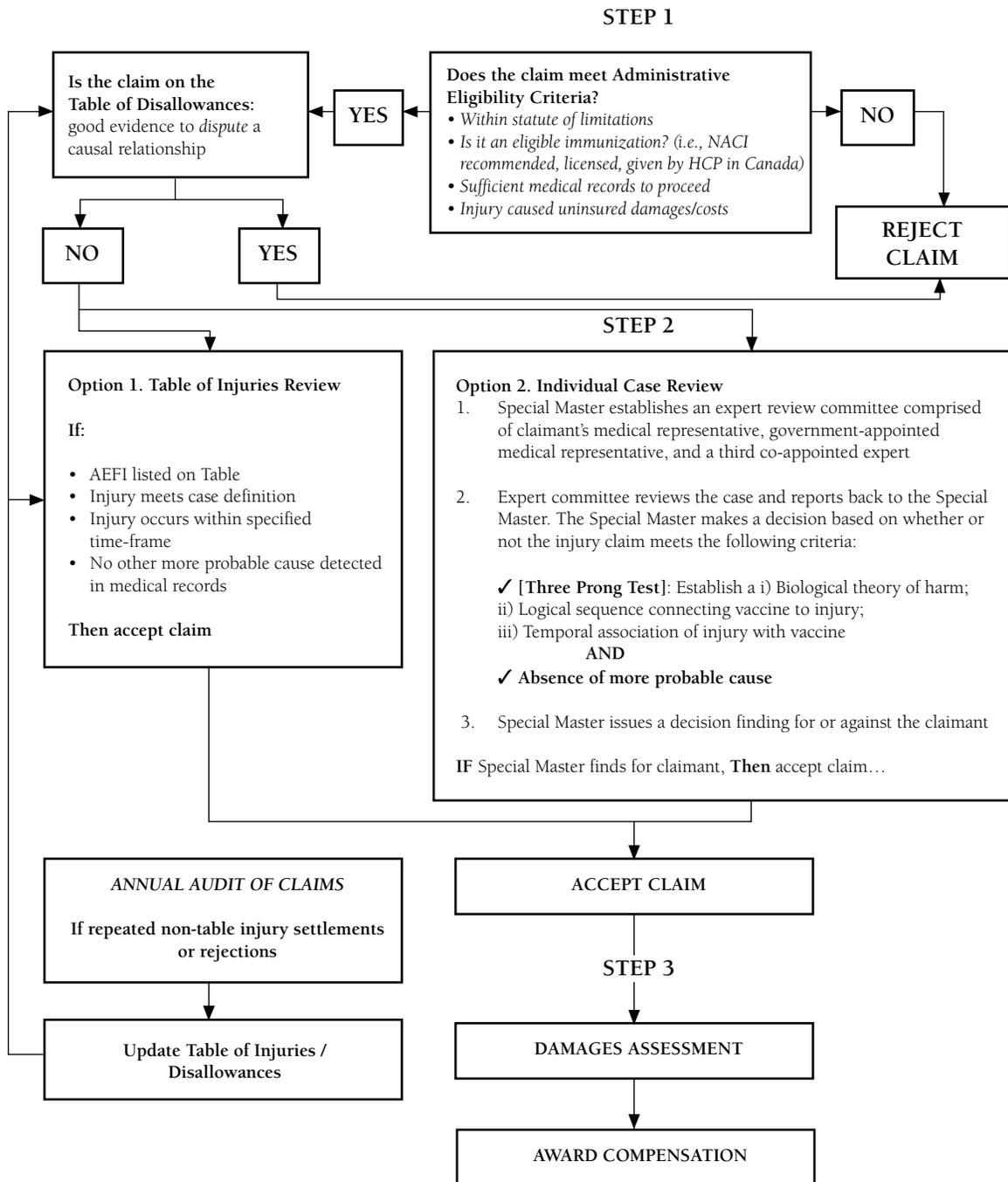
1. Table of Injury Review: Claimants can choose to have their case proceed to a Table of Injuries Review, a review based on a predetermined table listing all NACI recommended vaccines and scientifically substantiated adverse events associated with the listed vaccines. If a claimant meets the pre-existing Table of Injury requirements (see Figure 1), compensation would be granted.
2. Individual Case Review (Tribunal): In cases where the claimant's injury does not fall on the Table of Injuries, the claimant could choose a committee hearing overseen by a Special Master. The claimant would have the power to appoint one committee member, the Public Health Agency of Canada would appoint a second, and the third member would be decided by consensus of the two appointed members. Each committee member would be tasked with reviewing the case and presenting a reasoned opinion to the Special Master who would be empowered to make a binding decision. In these cases, causation would be determined by meeting a three-prong causality test which includes establishing a i) biological theory of harm; ii) logical sequence connecting vaccine to injury; and iii) temporal association of the injury with a vaccine. No other more probable explanation for the injury is established in the proceedings.

STEP 3. Once a claim is decided as compensable in principle, either through a table process, or individual case review, the degree of disability and compensation would ideally be determined by a federal bureau with expertise in adjudicating disability claims.

Annual review and audit

The Table of Injuries would be created and annually updated by a federal advisory committee, likely in cooperation with existing advisory committees such as the National Advisory Committee on Immunization (NACI). Annual audits of claims and settlements would be used to further refine and tailor the Table of Injuries. In addition, a Table of Disallowances could be populated to deal with common or popular theories of harm where there is a substantial body of evidence to summarily deny an association between vaccines and particular injuries.

Figure 1. Proposed adjudication process for a national, no-fault compensation programme for vaccine-related injuries



BACKGROUND

In 1972, a five year old girl in Quebec named Nathalie Lapierre received a measles vaccination and, subsequently, developed viral encephalitis and severe, permanent disabilities. Her father, Jacques Lapierre, launched a lawsuit against the Quebec government for compensation for the harm sustained. Initially, the Superior Court of Quebec found that while no one was at *fault* for Nathalie's serious injuries, her case merited compensation because it was an undisputed fact that her injuries were caused by complying with a government recommended vaccination schedule, and such compliance was of benefit to the community. This ruling was subsequently over-turned by the Supreme Court of Canada who maintained that Quebec law did not allow awarding a settlement when there was no *fault* in the delivery or manufacturing of a vaccine (Ministère de la Santé et des Services Sociaux Québec 2011; Templeman-Kluit 2008). As a result, the family's attempt to receive compensation for injuries failed.

In response to the case, in 1986, the Quebec government passed amendments to the Public Health Act to create a provincial no-fault programme to provide compensation for vaccine-related injuries in cases similar to the Lapierre's (R.S.Q., chapter S-2.2, Division III (70-78)). The programme the Quebec government put in place provides compensation to those who developed a serious and permanent injury to any vaccine issued against the vaccine-preventable-diseases listed in the statute *if* a medical tribunal agrees that the vaccine was the most likely cause of the injury (Ministère de la Santé et des Services Sociaux Québec 2011).

There are now at least thirteen countries that have created no-fault vaccine injury compensation programmes (Evans 1999; Isaacs 2004). In Canada, Quebec remains the only province to institute a programme to compensate those injured from immunization despite recurrent recommendations to close this policy gap by professional organizations such as the Canadian Paediatric Society (1986). In one of the earliest statements of support for implementing a programme, the Canadian Paediatric Society recommended implementing a programme in response to a period of heightened public concern over the safety of the diphtheria-pertussis-tetanus (DPT) vaccine, a relatively reactive vaccine then associated with encephalitis and neurological injury (Canadian Paediatric Society 1986). Indeed, many jurisdictions created no-fault compensation programmes to address public concerns over the safety of the DPT vaccine (Canadian Paediatric Society 1986). Federally sponsored workshops or expert-planning exercises designed to coordinate and rationalize immunization policy nationwide have also frequently identified the lack of a mechanism to compensate rare vaccine-related injuries as a policy gap. No-fault compensation for all treatment injuries, including those that are vaccine-related, has also been proposed as part of a broader reform of the Canadian tort system by Justice Krever in the *Commission of Inquiry on the Blood System in Canada* and by Robert Pritchard in *Liability and Compensation in Health Care* (Canadian Paediatric Society 1986; Krever 1997; Pritchard 1990).

In 2001, a report signed by leading vaccine experts reiterated the need for such a programme: "By 2005, every Canadian should have access to a vaccine injury compensation for long-term sequelae caused by vaccines" (Health Canada 2001, 13). The report recommended that the federal government create an expert advisory committee to develop the rationale, programme components, and criteria for compensation. The authors of the report argued that compensation should be based on the findings of a causality assessment and that any programme should be designed to provide all Canadians with an equitable compensation process (Health Canada 2001, 13-4).

Understanding and evaluating no-fault approaches to vaccine-related injuries

The interest in no-fault approaches to vaccine-related injuries has been rekindled to some degree by the recognition of the fact that immunization programmes are becoming increasingly complex and, at the same time, our culture is becoming more sensitive to the risks of immunization. Policy makers are confronted with the ethical and legal dilemma of how to fairly compensate those injured by immunization and it is anticipated that it will become increasingly difficult to maintain public support for recommended immunizations without providing a reasonable process to receive just compensation for legitimate injuries sustained from vaccinating (Wilson 2007). The purpose of this study was to examine the need for and potential utility of a no-fault approach to vaccine indemnification in Canada. To do so, we reviewed the

history and rationale of vaccine indemnification worldwide and, using four specific case studies, assessed the different approaches to no-fault compensation.

Our study, conducted between 2007 and 2009, consisted of a literature review, semi-structured interviews with key informants, and the analysis of four international no-fault compensation programmes using an analytic framework we developed from existing literature (Isaacs 2004; Ridgway 1999). The aim of the study was to provide both an in-depth analysis of several distinct types of no-fault programmes and to create research-based recommendations for the design and implementation of a model programme that could be implemented in the Canadian context.

The literature review for this study included the identification of research related to no-fault programmes worldwide in social sciences and humanities, legal and medical databases. We also identified any government reports, programme evaluations or reviews that were publicly available. Finally, *access to information* requests provided up-to-date programme data for Quebec, New Zealand, and the United Kingdom (the United States data was largely available through government websites). Ethics approval was obtained to conduct expert informant interviews in Canada, the United States, the United Kingdom, and New Zealand. Drawing on published sources (peer-reviewed research, government reports), access to information requests, and stakeholder informant interviews with programme experts, scientists, representatives of vaccine manufacturers, programme lawyers, claimants, and no-fault policy specialists, we assessed and compared the strengths and weaknesses of the four no-fault compensation programmes we chose as case studies.

In interviews spanning between one to two hours, informants were asked a range of questions related to the history of, rationale for, and overall programmatic structure of the no-fault compensation programme in their jurisdiction. Building on Geoffrey Evan's (1999) descriptive framework of international no-fault programmes world wide, we queried informants on: a range of technical and administrative components related to filing and eligibility requirements (e.g., level of disability, statute of limitations), the rules governing compensation (e.g., what kinds of injuries are compensated), how the connections between injuries and vaccines are established in each system, what vaccines are covered by the programme, how the programme is funded, the possible recourse to traditional tort law for compensation, overall costs of the programmes, and any calculations of cost-savings or benefits attributable to the programme. Informants were also asked to identify perceived strengths and weaknesses in their programmes, make suggestions for reform, and to describe what the features of an ideal approach to vaccine-related injuries would be (see Table 2).

Section I gives an overview of the rationale for vaccine indemnification programmes and a comparison of their implementation in identified jurisdictions. Section II provides a detailed description and analysis of the four international compensation systems examined. After compiling and evaluating the existing programme options, we hosted workshops and solicited expert feedback from stakeholders (vaccine manufacturers and legal advisors, government policy makers and vaccine scientists) to solicit feedback and to assess the feasibility of different components and no-fault models emerging from our analysis. The culmination of this research is the recommendations outlined in Section III of this report.

SECTION I

Why countries have adopted a no-fault approach to vaccine-related injuries

“It is nearly impossible to predict who might suffer an adverse vaccine reaction, absent a known allergy, immunodeficiency, or previous neurological deficit.” (Mariner 1992, 256)

Universal immunization is a public good

Vaccines are often described as the most effective medical intervention for the prevention of once devastating infectious diseases and are, also, amongst the safest pharmaceutical therapies available. When vaccination rates hit a particular threshold and are sustained, the transmission of the pathogen from person to person is disrupted and the incidence of the disease falls accordingly. This property of immunization programmes, known as *herd immunity*, also protects those in the community who, for a variety of reasons,

cannot be vaccinated, are ineffectively vaccinated (the immuno-compromised, the very young, and the elderly), or refuse to be vaccinated (Fine 1993).

Immunization though technically voluntary is implemented with coercive policies

The importance of herd immunity has influenced vaccination policy. Vaccinations are not strictly compulsory under federal or provincial laws (Peppin 2005), yet research suggests that current policies to promote vaccination can be viewed as coercive (compelled by force, intimidation, or authority). Increasingly, vaccination is a requirement for participation in public programmes (day-care, camps) and for employment. Those who choose not to be vaccinated against diseases like influenza have been shown to cause risk to fellow citizens, especially if they are in frequent contact with vulnerable subgroups (see for example Carman 2000; Glanz 2009; Simonsen 2005).

In Canada, the promotion and provision of nationally recommended immunizations has become a matter of public policy; provinces and territories have adopted policies known to increase compliance to recommended immunizations (Peppin 2005). Children are required to receive certain vaccinations to attend school or day-care in many jurisdictions. While exemptions can be obtained for medical, philosophical, or religious reasons, the availability of this option is not well publicized. In several healthcare institutions, vaccination is a requirement for employment. In some cases, healthcare workers can opt-out of receiving recommended vaccines, however employers have reserved the right to restrict the employees' duties or temporarily lay-off a worker without pay in the event of an outbreak. In a recent report from the Manitoba Law Reform Commission, the authors argue that there is, "considerable governmental and social pressure to participate in the immunization process" (Manitoba Law Reform Commission 2000, 15; Peppin 2005). For example, a recent survey of paediatricians indicates that parents not wishing to vaccinate their children may face estrangement from health care practitioners (Flanagan-Klygis et al. 2005).

Rare but serious injuries from immunization occur despite best practices

Despite the great benefits from a universally immunized population, side-effects from vaccines have been observed and have the potential to cause serious injuries and permanent harm. Infrequently, injuries can be caused by a particularly "hot" or immunologically reactive batch of vaccine but more often, injuries are related to idiosyncratic and therefore unpredictable immune responses to the immunization, or an underlying predisposition for injury. Injuries caused by vaccines are extremely rare occurring at rates from 1 in 40,000, as in thrombocytopenia after MMR vaccine (France et al 2008), to less than one serious event per million doses, as in Guillain-Barré Syndrome (GBS) related to influenza vaccine (Haber 2004). Because vaccines are given to millions of individuals, even risks as low as these will result in a predictable number of injuries following mass immunization campaigns.

Pre-clinical trials can identify risks that occur at a rate greater than 1 in 10, 000 and post-clinical surveillance can identify risks as rare as 1 in 1 million, thus serious adverse events following immunization are not typically identified before a vaccine is licensed for use, and are not decipherable until the immunization has been used for many years in its target population. Even with years of experience with a particular vaccine technology, the precise aetiology of rare adverse events is often poorly understood and the possible or probable relationship between the adverse event and immunization can remain uncertain despite the best efforts of researchers (Kohl 2005).

Civil litigation is an inappropriate remedy for vaccine-related injuries

For many reasons, civil litigation is not an effective mechanism of redress in cases of vaccine-related injury (Law Reform Commission of Saskatchewan 2007; Manitoba Law Reform Commission 2000; Fowler 2010; Wilson 2007). In his review of the United States' federal swine flu vaccine-injury compensation programme, Richard Gaskins argued that civil litigation fails to provide just compensation for vaccine-related injuries and instead is at high risk for iniquitous, idiosyncratic, and unfair judgments for both manufacturers and claimants.

Judicial doctrines like duty to warn, informed consent, and assumption of risk, based on paradigms of commercial relations between private individuals, cannot fully capture the responsibilities that hold between

the individual and society as a whole. They operate capriciously in some cases to impose unfair costs on manufacturers or the government, in other cases to leave the entire burden of injury on the individual. In addition, the high cost of administering compensation rules through the judicial system imposes unnecessary burdens on plaintiff and defendant alike (Gaskins 1980).

In Canada, there has not been a single successful suit for compensation for an injury sustained from routine vaccination (Law Reform Commission of Saskatchewan 2007; Manitoba Law Reform Commission 2000; Templeman-Kluit 2008). The principle axiom of the common law of torts hinges on the proof of *fault* (Gilmour 2006). It is impossible to be compensated for *unavoidable* injury or injury sustained during activities a normal person would have hazarded (Gilmour 2006; Manitoba Law Reform Commission 2000).

Those injured by adhering to routine immunization could sue the individual health care professional delivering the vaccine, the vaccine manufacturer, or the provincial agency providing the vaccine. However, the plaintiff must show that the injuries sustained were caused by defective manufacturing or design, or negligence in the operation of vaccinating such as failure to secure informed consent, or failure to warn of adverse events (see for example *Lapierre c. P.G. (Qué.)*, [1985] 1 R.C.S. 241); Peppin 2005). In *Reibl v. Hughes* [1980], the plaintiff unsuccessfully argued that he was not fully informed of the risks of vaccination. However, the judge argued that compensation was not merited because an average person would still likely proceed with vaccination despite full disclosure of risks because of the rare nature of vaccine injuries (Manitoba Law Reform Commission 2000).

Litigation for vaccine injuries has other drawbacks. It is adversarial, prohibitively expensive, and time consuming. For example, in the precedent setting *Rothwell v. Raes* (1988), the legal costs exceeded one million dollars, involved over seventy-four days of court time, and it took nine years for a final decision at the Ontario Court of Appeals (Manitoba Law Reform Commission 2000). As Osgoode law professor Joan Gilmour has argued (2006), “Lawsuits are slow, complex, costly despite the greater availability of contingency fees, unpredictable, and in the case of medical liability claims, usually unsuccessful” (74). In the recent vaccine injury case of *Morgan v. City of Toronto* (2006), Judge Sanderson argued that, “... even when it can be credibly postulated that a vaccine has caused serious adverse consequences, the barriers standing in the way of recovery are formidable...Complex and protracted litigation such as this is notoriously costly, given the need for expert scientific evidence and medical proof” (*Morgan v. City of Toronto* 2006, 441).

While vaccine-injured citizens and their families have coverage for a range of medical expenses under provincial and territorial health insurance, they do not receive compensation for all costs sustained. For example, families cannot receive compensation for death (funeral costs), personal suffering, and income loss from permanent disability.

No-fault schemes have the advantage of being able to rapidly resolve injury claims by either using a fixed table of vaccine-associated injuries or an administrative or judicial review of each case. Because there is no fault presumed, compensation is needs-based rather than punitive, and is thus both relatively modest and proportionate to the injury. Most jurisdictions attempted to design their programmes to take advantage of the no-fault approach which the literature suggests would offer more timely and consistent compensation, a more effective process for complaint resolution, improve provider accountability, improve public trust in immunization, contribute to an overall culture of safety, and provide compensation proportionate to injuries sustained (Bismark and Paterson 2006; Dyer 2005; Gilmour 2006; O’Connell 1984; Ridgway 1999; Studdert 2001).

A key component in any no-fault compensation programme is the determination of eligibility rules for compensation. Principally, this involves a causality test (showing that the vaccine *caused* the injury), and other eligibility rules including filing deadlines (statutes of limitations), and the types of vaccines covered by the programme (see Table 1). There are few formal evaluations of no-fault programmes (Bismark and Paterson 2006; Bismark et al. 2006; Gilmour 2006; Studdert 2001), but the principal findings suggest that they have been effective in providing compensation to those likely injured, have reduced civil litigation, and have provided a formal venue to effectively respond to concerns over vaccine safety (Evans 1996; 1999; Isaacs 2004; Ridgway 1999).

Table 1. Vaccine injury compensation programmes worldwide. Data compiled from Evans 1999 and Isaacs 2004, and government websites. Note that some countries with programmes have been omitted, e.g., South Korea due to lack of data on these programmes. The following abbreviations are used: Denmark (Dnmrb), New Zealand (New Zeal.), Switzerland (Switzer.)

Year	Germany 1961	France 1964	Japan 1970	Switzer. 1970	Denmark 1972	New Zeal. 2005	Sweden 1978	U.K. 1979	Quebec 1988	U.S. 1988	Taiwan 1988	Italy 1992	Norway 1995
Admin.	State (pension system) under federal regulation	Min. of Health & Solidarity	Min. of Health	States under federal regulation	National Social Security Office	Accident Compensation Corp. (Crown Corp.)	Private Drug Insurance	Dept. for Work & Pensions	Min. of Health and Social Services	Dept. of Justice / Health and Human Services	Dept. of Health	Min. of Health	Min. of Health and Social Services
Vaccines Covered	Gov. Rec.	Required	Gov. Rec.	Gov. Rec.	Gov. Funded	Any given by a health care practitioner	All licensed vaccines	Gov. Rec. / Listed in Legis.	Gov. Rec. / Listed in Legis.	Gov. Rec. / Listed in Legis.	All Mandatory	All Mandatory	Gov. Rec./ Children
Eligible Comp.	Un-expected injury	Any injury directly attributable to vaccine	Disability or death	Un-expected serious injury	Any injury likely caused by vaccine	Un-expected injury	Injuries listed in FASS or medical literature	Injury resulting in >60 permanent disability	Serious injury or death	Any injury likely caused by vaccine	Injuries listed on the Table of Injuries	Perm. injury or death	Unknown
Types of Comp.	Costs: medical, funeral; disability pension	Costs: medical, funeral; disability pension, death benefits, non-economic	Costs: medical, funeral; disability pension	Costs: medical, funeral; disability pension, death benefits, non-economic	Costs: medical, death benefits, non-economic	Medical costs, disability pension, death benefits	Medical costs, lost wages, death benefits	Lump sum payment	Medical costs, rehabilitation, death benefits	Medical costs, lost wages, non-economic, attorney's fees	Costs: medical, funeral	Medical costs, disability pension, death benefit	Lump sum
Funding	General revenues	National Treasury	Multiple Levels of Gov.	General Revenues (Canton)	National Treasury	Specific Tax Revenue	Drug Co.'s premium	National Fund	National Treasury	Excise Tax	Drug Co.'s premium & Local Gov.	National Treasury	National Treasury & Drug Co.'s premium

The key issues arising from international experiences with no-fault programmes are of three types:

- a) Concerns that the causation test and / or eligibility criteria are too restrictive leading to under-compensation of claims which can drive claimants back into the tort system (civil litigation). This, in turn, increases the profile of vaccine injuries and the potential for public controversy over vaccine safety.
- b) Concerns that the causation test and / or eligibility criteria are too generous leading to over-compensation of claims which in turn can undermine the public's perception of safety of vaccines.
- c) Concerns that the eligibility requirements or administrative processes are onerous or too complex creating unnecessary barriers to access compensation.

The main drivers for policy implementation in other jurisdictions have varied but included the following factors: episodes of widespread concern over vaccine safety, a fall in vaccination rates, surges in civil litigation, vaccine manufacturers threatening to withdraw from the vaccine market, vaccine shortages, the disruption of routine vaccination programmes, and outbreaks from vaccine-preventable diseases.

Canada was largely shielded from these forces. Unlike the United Kingdom, Canada did not experience the same crisis in confidence in government regulatory bodies overseeing the safety of medical treatments (such as thalidomide) that drove the United Kingdom to implement an indemnities policy (Baker 2003). Unlike the United States, Canada was not driven to implement a no-fault compensation programme to protect the vaccine supply.

The *absence* of the political, economic, and social pressures, that propelled the implementation of policies in other jurisdictions, reduced the impetus for the development of a Canadian solution to rare vaccine adverse events, despite expert support for the idea and the enduring ethical arguments to do so. However, there are several indicators that suggest that the parameters that kept no-fault compensation off the political agenda are subject to change (Picard 2002).

Changes to the legal environment

Recent changes to the rules on the formation of national class-action lawsuits raise the spectre of inter-provincial and even international cooperation in supporting lawsuits against manufacturers for alleged vaccine-related injuries. Even if civil cases are not likely winnable in Canada, the risk of litigation, as in a recent B.C. class action vaccine-injury case (Kent 2003), can cost manufacturers tens of millions of dollars. While data on the manufacturer's legal costs related to vaccine injury are not currently available, in a recent review of the no-fault issue by the Saskatchewan Law Reform Commission, the authors argued that manufacturers' legal costs in fighting and settling injury cases in Canada are likely high, "...many claims may be settled out of court, though reluctance of manufacturers to publicize law suits makes it difficult to determine the frequency of settlements. Claims are most apt to be settled if liability is clear" (Law Reform Commission of Saskatchewan 2007, 20).

Increasingly complex immunization schedules / targeting adults

While new immunization technologies are significantly safer than those used during the formulation of many indemnification programmes, immunization programmes have become increasingly complex, and the targeted infectious diseases increasingly rare, diminishing the real and perceived benefits-to-risk ratio that is so critical to maintaining public support for immunization.

There is also an increasing number of immunizations targeting adults and employees who must be immunized (e.g., nurses, physicians, allied health care professionals, teachers, day-care workers and child minders), not necessarily for their own benefit, but for public safety. When adults experience even transient, serious, adverse events following immunization, such as Guillain-Barré Syndrome (GBS) following annual influenza immunization, the lost wages and the inconvenience of illness can have a large impact on family income.

Support for vaccines is broad but shallow

As in other jurisdictions, a single high-profile case of vaccine-related injury can mobilise public panic over

immunization safety. Research has shown that support for immunization is broad but shallow in Canada (Ritvo 2003; Wilson et al. 2006) indicating that a future crisis in public confidence in immunization is probable. Recent research also suggests that it is easier for those injured by immunization to connect with vaccine critics and legal supports via Web 2.0 platforms (Chin et al. 2010; Keelan et al. 2007; Wilson and Keelan 2009). This encourages those injured to align themselves with groups that are highly critical of immunization and suspicious of public health officials. Vaccine critical groups (largely antivaccinationists) are sceptical of the benefits or safety of universal immunization programmes, and have a large and influential online presence. The dissemination of anti-vaccination viewpoints through social networks can amplify the impact of a single vaccine injury case. The lack of recourse or due process for victims of vaccine injury in Canada feeds into the vaccine critical movement (Keelan et al. 2007; Wilson 2007).

The experience of other jurisdictions suggests that in times of crisis (precipitated by public controversy over the safety of immunization, an increase in vaccine-related injury litigation, or a threatened vaccine supply) governments normally enact no-fault compensation programmes to deal with vaccine-related injuries sustained from mass immunization campaigns. The history and experience with vaccine-related injuries in many other western countries also suggests that it is highly probable that Canada will be faced with circumstances that will require the development of a nation-wide indemnities programme or policies to protect vaccine manufacturers from liability. In fact, with the release of the H1N1 vaccine during the 2009 swine flu immunization campaign, the federal government was forced to accept liability for the manufacturer Glaxo-Smith-Kline (GSK) in order to release the H1N1 vaccine in time for the fall of 2009. However, it is unclear how those injured could receive just compensation for H1N1 vaccine-related injuries. Equally unpalatable for the ongoing success of national immunization programmes, are the prospects that injured parties will be forced into lengthy court battles against the federal government or barring any realistic alternative to civil litigation, citizens will turn to the media to vet their concerns and complaints. The reactive design of a no-fault scheme, under such circumstances, or in the wake of a public controversy, would be suboptimal.

Arguments against no-fault compensation for vaccine-related injuries

The obligation to compensate for vaccine-related injuries diminishes if immunizations are purely voluntary

If the goal of government-sponsored immunization programming is purely to provide citizens with the opportunity to take advantage of medical technologies to protect themselves, and *not others*, against vaccine-preventable diseases then the reciprocal responsibilities of government to compensate those injured by immunization is weakened. The argument still remains that the tort process is not an effective mechanism to provide compensation where injury does occur.

Concerns have been raised that no-fault compensation programmes can distort the public's perception of vaccine safety and undermine confidence in immunization

Experts in many jurisdictions have raised concerns that the very existence of a compensation programme for vaccine-related injuries could undermine the public's confidence in immunization (see for example Offit 2008a, Offit 2008b). This concern is amplified in jurisdictions that allow for compensation in cases of injury where there is a high degree of scientific uncertainty surrounding the causal link between immunization and injuries. Critics have pointed to the publicity generated by American no-fault cases that forwarded claims that childhood vaccines are linked to autism. Despite these concerns, there is no published evidence that no-fault compensation programmes have impacted immunization uptake. On the contrary, one could argue that in the most recent public controversy over the purported linkages between vaccines and autism, the lengthy public omnibus hearings held in the United States' National Vaccine Injury Compensation Program have reassured the public first that there is no evidence supporting the vaccine-autism theory and that the issue was truly vetted and rejected.

Low priority

While the ethical case to implement such a programme is clear, there are several other policy priorities related to immunization that have both a national scale and significance. Consultation with experts suggests that bolstering and increasing the capacity and funding for the National Immunization Strategy, including

the creation of a vaccine registry, implementing a national barcode system, ensuring continued access to new vaccines, and other issues related to barriers to licensing of novel vaccine technologies, especially new adjuvants, would all trump the formation of a coherent national policy to redress vaccine injuries. However, many experts see a no-fault compensation programme as a necessary feature of a comprehensive national vaccine safety strategy (Health Canada, 2001).

Costs

In conjunction with the discussion above, concerns over costs have been cited as a key barrier to launching a national programme (Templeman-Kluit 2008). An analysis of other jurisdictions shows that the total costs for no-fault programmes are relatively modest and represent a small fraction of overall spending on immunization. Adverse events while extremely rare, have been estimated to occur at a rate of less than 40 per 100,000 doses distributed in Canada and are implicated in approximately 20 (probable) – 34 (possible + probable) cases of serious injury per year and only 3 deaths have been associated with immunization in the period between 1997 and 2004 (Public Health Agency of Canada 2006). Only a portion of these injuries would result in substantial uninsured damages or ongoing costs and a need for compensation.

Experience from other jurisdictions suggests that the predicted number of settlements and the cost of any scheme will depend greatly on eligibility criteria, filing requirements, and the public's knowledge of the programme (See Table 2). New Zealand for example has a vaccine-injury case-load ten times the United States or the United Kingdom, at 21.5 cases per million. The case-load does not appear to depend on the likelihood of receiving a settlement, as the United Kingdom's case load is similar to the United States at 2 per million with a claim success rate in the United Kingdom of between 1–2% (over the past few years) versus the United States' claimant success rate of 72%. However, the number of cases compensated is directly related to the eligibility requirements imposed by each system.

SECTION II: CASE STUDIES

The United States National Vaccine Injury Compensation Program (NVICP)

The United States has historically used a no-fault approach to protect manufacturers from civil litigation concerning injuries associated with government-recommended vaccination. An ad-hoc programme was created in 1976 where the government assumed injury liability for an emergency mass immunization campaign against the feared swine flu pandemic. The government did so in response to manufacturer's refusal to release the vaccine without liability protection (Gaskins 1980).

A more sustained crisis occurred in the United States in the late 1970s and early 1980s when a large number of companies stopped producing children's Diphtheria-Pertussis-Tetanus (DPT) vaccine in response to civil litigation over injuries alleged to be caused by the whole-cell pertussis component. Shortages forced officials to abandon booster shots for children and several whooping cough outbreaks were attributed the disruption in the schedule. One analysis showed that at the height of the liability crisis 40% of pharmaceutical liability claims were related to childhood vaccines while profits from vaccines contributed to less than 15% of all pharmaceutical sales (Sturges 1986).

The American Academy of Pediatrics, vaccine manufacturers, and parents of injured children lobbied for the enactment of a no-fault compensation programme (Ridgway 1999). In 1986, the US Congress passed the *National Childhood Vaccine Injury Act* (Public Law 99-660) which created the *National Vaccine Injury Compensation Program* (NVICP) and a special claims office in the US Court of Federal Claims to adjudicate vaccine injury cases. The Act barred virtually all civil litigation for vaccine-related injury (for cases of compensation over \$1000) as an initial measure requiring those injured by vaccines to first bring their cases before the NVICP. It also raised the plaintiff's burden to litigate cases based on provider's "failure to warn" of adverse events (Shah 2010). So long as the injuries sustained were presumed to be unavoidable and the manufacturers complied with FDA requirements for product labelling (directions for use and sufficient warnings), manufacturers were shielded from injury liability (Shah 2010). This effectively blocked the most popular legal arguments in vaccine injury cases and made successful civil litigation less feasible and a less appealing option for injured parties (Neraas 1988).

Table 2. Overview of no-fault compensation programmes for vaccine-related injuries: four case studies. Data capture from programme inception until 2009

Country (Year Implemented)	QUE (1988) Compensation for Victims of Vaccination Program	UK (1977) Vaccine Damages Payments Unit, Department for Work and Pensions	US (1988) United States National Vaccine Injury Compensation Program	NZ (2005) Accident Compensation Corporation
Civil Litigation for vaccine-related injuries	No restrictions	No restrictions	Restricted civil litigation. Must first proceed through Vaccine Court	Civil litigation for treatment injuries is statute-barred
Total cases adjudicated since programme inception (average per annum)	99 (4.5)	5,542 (129)	13,162*(709) *includes 5,605 autism cases	344 (86)
Average annual case load (per million)	(since 1988) 0.7	(since 1999) 2.11	(since 1999) 2.15	(since 2005) 21.5
Average # of awards per year per million	0.2 (1.3/7)	0.05 (3/61)	0.3 (21/330)	11 (42.5/4)
Eligibility Criteria				
Vaccines Covered	Any vaccine targeting a vaccine-preventable disease listed in the Public Health Act, e.g. diphtheria	Specific vaccines listed in the regulations of the Vaccine Damages Payments Act (largely restricted to those given to <18yrs)	Specific vaccines listed in Vaccine Injury Table (statutory) maintained by Health and Human Services, e.g., polio vaccines	Any vaccine given by a recognised health professional in New Zealand
Filing Deadlines	3 years after death or onset of symptoms	Children >2 but 6 years after immunization or before their 21st birthday	2 years after death; 3 years after symptom onset	1 year after injury onset
Proof Needed	Balance of Probabilities Determined by Expert Review	Balance of Probabilities Determined by Expert Review	Meets Table of Injuries Criteria Balance of Probabilities (3 Prong Standard to prove causation)	Balance of Probabilities Determined by Expert Review
Type of Injury	Any serious permanent injury	Sole cause of disability; 60% disability	Table injuries or proven injuries	Any demonstrated injury leading to damages
Causality Assessment Processes	3 – Member Expert Panel Adjudication (petitioner nominates 1 member)	Expert Review	Table of Injuries; Judicial Review	Expert Review
Compensation	Uninsured medical costs, rehabilitation, death benefits	Lump sum £120,000	Annuity for medical costs, lost wages, non-economic, attorney's fees	Medical costs, disability pension, death benefits
Appeals Process	Yes	Yes	Yes	Yes
Number that Appeal	50/99	Approx 5 %	Approx 45 for 2009	Unknown
Legal Representation	Limited (except in appeals)	Limited (except in appeals)	Nearly all claimants	None
Legal Fees	Not routinely Costs awarded in several appeal cases.	None	Legal fees reimbursed for both successful and unsuccessful cases.	None
Evidence for Averted Civil Litigation	Yes-anecdotal	Yes-anecdotal	Yes (published studies, internal government review, anecdotal)	N/A

The original goals of the United States' system were threefold. First, the advocates of the legislation sought to protect manufacturers and deliverers from civil litigation in order to ensure a reliable supply of vaccines for national programmes. Second, the programme was intended to compensate those injured from vaccine-related injuries in a fair and efficient manner. Third, the programme was enacted to protect the integrity of government-sponsored immunization programmes, maintaining public confidence in vaccines and government agencies (Gokiewicz 2008).

Eligibility rules and administration

The Vaccine Court, the popular name for the Office of the Special Masters (OSM), was created as an adjunct to the US Court of Federal claims. The OSM coordinates the NVICP activities in cooperation with two other government agencies: the Secretary of Health and Human Services (HHS), who serves as the defendant in the injury cases, and the Department of Justice (DOJ), who provides legal representation to the Secretary. The special masters of the OSM adjudicate each case, acting as trial judges. There is an appeals process which proceeds first to a judge of the US Court of Federal Claims, and then to the Court of Appeals for the Federal Circuit (Court of Appeals), and finally to the US Supreme Court.

Unlike administrative-style no-fault compensation programmes, in the US judicial approach almost all claimants have legal representation. The hearing process is similar to civil litigation in that evidence is heard from both sides and expert testimony is crucial for a successful case. Claimant's legal costs are reimbursed if substantiated and deemed reasonable regardless of the judgment, if the special master finds a good faith, reasonable basis for the claim (United States Court of Federal Claims 2011, 126). Once a petitioner's claim is accepted as compensable, the file is contracted to a disability life-planner who assesses the scope and life-long costs of the injuries sustained. The life-planner then calculates a settlement which is paid out as an annuity to the person or, in the case of minors, to their guardians.

Claim adjudication

Similar to other disability entitlement schemes, the NVICP was originally designed around a Table of Injuries, a pre-adjudicated table listing known injuries associated with vaccines (Division of Vaccine Injury Compensation 2006; Gokiewicz 2008). The table defines the window period within which injuries must occur in order to be considered causally-linked to the vaccine and, additionally, the case definitions for each vaccine-associated injury. The table of injuries was created by a committee of experts and was intended to reflect the best scientific evidence related to known adverse events following immunization. To be awarded compensation in a table case, the vaccine received and the injury claimed must meet the definitions and temporal requirements listed on the table. The vaccine must have been administered in the United States, and there cannot be a preponderance of evidence that the condition was due to other factors unrelated to the vaccine. A successful table case does not require a petitioner to establish that the injury was caused by a vaccine in *their particular case*, but rather that their case meets the conditions of a possible causal association, thereby meriting compensation.

The original legislation governing the vaccine injury programme was interpreted by the OSM to allow claimants whose case did not satisfy table criteria (e.g., in cases where petitioners made claims for novel or unexpected injuries associated with a vaccine) to have their petition reviewed on a case-by-case basis to establish causation, or a link between their injury and an immunization, in their particular case. While table cases accounted for most of the vaccine injury claims for the first decade of its existence, after 1995, two trends drove claimants away from table claims to claims based on proving causation (off-table cases) (Division of Vaccine Injury Compensation 2006). First, the only changes or updates to the table in the decades following its formulation were made to restrict eligibility, e.g. narrowing case definitions (Gokiewicz 2008). With an increasingly narrow table of injuries, more and more claimants chose an off-table process that involved a full hearing at the OSM to prove causation; at the same time, the success rate for petitioners dropped markedly and this led to an increase in appeals of OSM decisions to the Court of Appeals (Gokiewicz 2009). Recognising that the original intent of the legislation was, in part, to facilitate citizens' access to compensation for injuries associated with immunization, judges' appeal decisions from the Court of Appeals expanded and codified the process for proving causation in off-table cases, moving

away from both scientific understandings of probable causation and traditional tort based standards of causation (Green and Grey 2006; Golkiewicz 2008). This made it much easier to prove causation in particular cases under the NVICP than would be possible in traditional civil litigation, making civil litigation much less attractive, despite the more limited damages awarded under the NVICP (punitive damages are eliminated under the NVICP). This in itself fulfills the spirit and intent of the program and its supporting legislation.

The legal standard of causation inscribed in the legislation is a preponderance of evidence, a standard roughly approximating a probability of fifty per cent “plus a feather”, or more likely than not, that the vaccine caused the injury. However, unlike civil litigation, while probabilistic evidence from current medical research may be considered by the special master, claimants can meet the standard of probable causation based on reliable **circumstantial evidence** (Green and Grey 2006; Golkiewicz 2008). Thus, scientific notions of *proof of cause*, which generally entail a much higher degree of certainty, have been increasingly trumped by circumstantial evidence in Court of Appeals decisions. The lack of specific direction as to the weighing of evidence (i.e., scientific versus circumstantial) in the statute governing the OSM has created a vacuum that has been largely filled by case precedent through the OSM or in the Court of Appeals.

The case *Althen v. HHS* created a three part sufficiency test to determine whether a vaccine causes an adverse event. These criteria are (1) the existence of a medical theory causally connecting the immunization to the injury; (2) a logical sequence of cause and effect demonstrating that the vaccine was the reason for the injury; and (3) the petitioner can show a proximate temporal relationship between vaccination and injury. The only additional hurdle faced by petitioners is situations where the defendant (in this case the government) argues that the preponderance of evidence suggests that the injury was caused by factors unrelated to the vaccine. The three prong standard can be established using circumstantial rather than “direct, objective conclusive scientific evidence” and causation can be found even in the face of contrary epidemiological evidence.

An assessment of these changes was captured by Gary Golkiewicz, then the Chief Special Master of the programme, who argued that “... we now operate under a table that is very stringent and a causation and fact standard that is far more lenient (Golkiewicz 2008).” To illustrate this, the percentage of successful claims (excluding autism cases) before 1998 was approximately 50% and after 1998 rose to approximately 74% in 2009 (Golkiewicz 2009).

Programme evaluation

Since the programme’s inception, 13,198 petitions were filed (as of 10 November, 2009) and 2,372 claims have been successful (including cases that were settled/conceded by the government without going to a hearing). The administrative overhead for the programme is approximately \$17 million USD, cost-shared by HHS, the DOJ, and the Court of Federal Claims, or approximately 23% of compensation paid to petitioners for the fiscal year of 2009.¹ Claimant’s settlements and awards are paid out of a trust fund which is funded by a special vaccine excise tax of seventy-five cents on every antigen. Revenue from the excise tax for 2009 was \$146,670,750 USD. In August of 2009, the trust balance was \$3,050,779,483² suggesting that the programme is over-funded and the level of excise tax should be revisited. Though the programme was originally designed for children’s immunizations, in recent years the number of awards to adults has increased dramatically to over 52% of awards (Golkiewicz 2009). Most of the increase in adult claims is due to claims made for injuries related to the annual flu vaccine.

In his 1999 review of the US programme, Derry Ridgway found that despite some steep barriers to filing claims and accessing appropriate legal representation, many of the original core objectives of the programme were being met. In particular, since its inception, there has been no major supply shortages caused by manufacturers withdrawing from the market due to liability issues (Ridgway 1999, 76) and this finding largely holds true today.

1. Email addressed to JK in response to an information request from the OSM 11/2009.

2. US Treasury, Bureau of Public Debt, August 19, 2009

While the existence of the NVICP has undoubtedly provided a stable litigation environment for manufacturers, the impact it has had on public confidence in immunization remains more uncertain. During the most recent controversy over vaccine safety involving a broad coalition of parents, activists, and practitioners, who alleged that there is a link between childhood vaccines and the development of autism, the NVICP has served as critical independent civic structure to vet and review this popular theory of harm. While leading scientific agencies, such as the Institute of Medicine, had, by 2003, vetted the epidemiological evidence and various theories connecting autism and routine childhood vaccines, finding no association, the issue retained popular support in various media venues in the United States and created considerable anxiety for parents. Public controversy over the purported link between vaccines and autism led to thousands of petitions filed in the NVICP by parents of autistic children who had undergone routine immunization. The OSM chose to vet the thousands of autism petitions through a series of test cases, the Omnibus Hearings, held between 2007–2009. Overseen by special masters, not vaccine scientists, and through a programme designed to give petitioners a great deal of latitude to prove their claims (and a much lower evidentiary hurdle than civil litigation), the NVICP hearings provided petitioners with a best case scenario to prove their claims. The NVICP also provided a venue for an exhaustive and public review of the science behind the claims being made by autism activists, such as Jenny McCarthy (audio files and complete transcripts of the hearings were made available on the US Court of Federal Claims' website).

During the hearings, the NVICP independently settled a case of neurological injury (described as autism) raising the spectre that the omnibus hearings would find for the petitioners despite a strong scientific consensus discounting the link between autism and vaccines. Paul Offit, a leading vaccine scientist, sharply criticised the evolution of court decisions towards a more permissive settlement environment and pleaded for a more robust scientific definition of *causation* in non-table injury cases (Offit 2008a, 2008b). However, in the end, the OSM's omnibus proceedings conclusively found against the petitioners. The omnibus cases were unsuccessful largely due to the compelling testimony by vaccine experts and scientists at the hearings and the large body of evidence compiled by the Institute of Medicine to examine the purported link.

Offit's analysis did however highlight a series of claims settled where good scientific evidence existed to negate a causal association or where a contested biological theory was given undue credibility in the proceedings (Offit 2008a, 2008b). If the era post 1995 was marked by an imbalance toward a higher standard of scientific causation, recent years have been marked by the reverse trend. Several approaches are being reviewed to rebalance the adjudication process including a half a billion dollar contract with the Institute of Medicine to update research regarding vaccine safety for eight recommended vaccines.³ This scientific review should assist the government in excluding certain popular biological theories of harm as it did in the US omnibus hearings. Second, the Vaccine Safety Advisory Committee intends to use findings of the research to update the Table of Injuries. The Table has not been expanded to include many adverse-events following immunization (AEFI) currently identified by the Institute of Medicine, including adverse events receiving compensation in other jurisdictions or in earlier US government programmes, e.g., compensating for GBS following influenza immunization as in the 1976 swine-flu immunization campaign.

Given the competing interests between maintaining public confidence in vaccines (supporting robust scientific analysis of risks from vaccines) and providing petitioners with fair, but easy access to compensation and finally in keeping petitioners from crippling manufacturers through civil litigation, it is not surprising that the NVICP will require ongoing fine-tuning, and periodic revision. The most destabilizing force in any no-fault compensation programme remains how high or low the bar should be to determine causation and what level of scientific uncertainty is tenable in settling injury claims (should the system err on the side of scientific certainty or give petitioners the benefits of doubt). If the NVICP has been criticised for erring too much on the side of petitioners, the United Kingdom's Vaccine Damages Payments Unit, discussed in the next section, has been criticized for moving in the opposite direction.

3. Interview with US government official 05/01/08.

United Kingdom: Vaccine Damages Payments Unit, Pensions, Carers and Disability Services (Department for Work and Pensions)

In the United Kingdom, the ground-work for a no-fault compensation programme for vaccine-related injuries was laid by the 1972 *Royal Commission on Civil Liberty and Compensation for Personal Injury*, led by Lord Pearson. The Commission was created to address public concerns over compensation for personal injuries in the wake of children injured by the drug, thalidomide. While the Pearson commission made a broad set of recommendations to reform civil litigation for injuries associated with medical treatment, more specifically his report advised that children injured by government-recommended immunizations should receive compensation. In 1979, in response to widespread controversy over serious neurological injuries attributed to the pertussis (whooping cough) vaccine, the government implemented Pearson's recommendation in the form of the *Vaccine Damages Payment Scheme* (Robinson 1981). The purpose of the scheme was to "ease the burden" of affected families while recognising that injured children in the United Kingdom would already have access to a range of cradle-to-grave social welfare entitlements. Awards are a singular lump sum that is tax free, currently £120,000 (an amount that has been increased several times since the programme's inception (Owens 2009)).

Eligibility rules and administration

The programme's eligibility requirements reflect its focus on ethical concerns over serious damages sustained by children while contributing to a social good. To meet the criteria of having sustained serious or permanent injury, the immunization must be, on the balance of probabilities, *solely* responsible for causing 60% or more disability (originally 80%) in the individual (covered in Section 2 of the General Benefits Regulations). Injuries sustained in-utero or through contact with a recently immunized person are eligible for compensation. This rare situation arises when unprotected bystanders are exposed to infection from viral shedding from the immunization. However, the vaccine cannot have exacerbated an underlying condition (e.g., claims where the injuries were caused by a combination of factors including the immunization and its interaction with non-vaccine related conditions are rejected). Eligible vaccines are listed in the regulations and must have been given in the United Kingdom before a child reaches the age of majority (their eighteenth birthday). In recent years, targeted government-recommended and funded immunizations for groups other than children have led to the following programme expansions: the inclusion of recipients of adult poliomyelitis, rubella, HPV, pandemic influenza A (H1N1), and meningococcal group C.⁴

The Vaccine Damage Payment Scheme is managed by the Department for Works and Pensions, Disability and Carers Service. It has a small administrative staff to process claims, two policy advisors, and a medical director who oversees the medical review of each case. The filing process is fairly straightforward, requiring either the individual or the health care professional to fill in a simple claim form to open a file. The statute of limitations requires that claims are filed before the injured party (or deceased) reaches their twenty-first birthday or six years from the immunization in question. In addition, injury claims are not processed until after a child reaches the age of two, due to difficulties in assessing the degree of permanent disability before that age (Owens 2009). In the event a child under two dies after a vaccination, they are ineligible for compensation under the current programme rules. Similar to any disability scheme, the claim process allows the administrators of the programme to gather any necessary medical documents or files related to the claim, and disability is measured using standardised coding and formulations developed for work-place and general disability claims.

Claim adjudication

The Department's Medical Advisory Service provides expert medical advice across the Department for all medically-related benefits claims, e.g., disability assessments for people claiming a range of disability benefits including Employment Support Allowance, Incapacity Benefit, Disability Living Allowance and Industrial Injuries Disablement Benefit (ATOS 2011). The Medical Advisory Service is currently contracted

4. Joint Interview with 4 UK government officials 14/05/2008.

to the private company ATOS Health Care, a company specialising in disability assessments for the Department. The consulting medical advisor is instructed to determine if, on the balance of probabilities, the vaccine caused a particular injury (based on a chart review and in some cases a physical examination of the patient) using the following criteria:

- Expert medical opinion exists linking the claimed adverse event and the particular vaccine in question;
- An appropriate temporal relationship exists between the act of vaccinating and the onset of symptoms that led to the injury and the administration of the vaccine;
- No other more probable explanation for the symptoms that led to the injury (including pre-existing conditions that may have contributed to the reaction).⁵

In cases where the background incidence of the disease is similar to immunized populations, the claim is usually rejected, i.e., encephalopathies following immunization.⁶ In other words, in cases where there is nearly equal probability that the occurrence was a natural event versus vaccine-related, compensation is denied. In addition, certain popular theories of harm are automatically rejected because extensive review has shown no relationship and there is clear scientific consensus on the issue—for example, cases alleging MMR vaccine causes autism are summarily rejected.⁷

Generally, the Medical Director accepts the solicited opinion from medical advisors and makes a recommendation to the Secretary of State whether or not to accept or deny the claim. The claimants are provided with a reasoned decision to explain why their claim was, or was not, successful. Claimants do have recourse to a three-tiered process of appeal consisting of the following: (1) Tribunal Appeal; (2) Upper Tribunal Appeal; (3) Judicial Review. Approximately five per cent of all rejected claims are appealed, however, only one per cent of these cases heard by the Appeal Tribunal are successful.⁸ During the appeals process, the claimant can hire medical experts and legal representation to present new evidence in their case. They also, at any point, have recourse to tradition civil litigation; however, any award in civil litigation will be deducted against the amount awarded under the no-fault scheme.

Claims are usually resolved in three months, although a tribunal appeal can take years. Since 1972, 5,572 claims have been reviewed by the scheme, or approximately 150 per year. Note that, similar to other international schemes, there was a surge in cases at the programme's inception. Nine hundred twenty nine awards have been issued (as of 30 September 2009); however, the vast majority of these claims were related to the DPT vaccine in the late 1970s, and, subsequently, in the past ten years the number of claims (averaging 50-200 claims per year), successful claims (0-5 per year), and total payouts (£0-£500,000) has dropped dramatically. Claims are generally rejected because the expert opinion asserts that there is not a probable link between the injuries and the immunization. For example, recent controversies over a purported link between the Measles-Mumps-Rubella (MMR) vaccine and autism led to a surge in claims of injury. By 2004, there was clear consensus against this biological theory and such claims are now summarily dismissed (Owens 2009).

Programme evaluation

There have been a few evaluations of the effectiveness of the programme. In its early years, there was criticism that the programme's policy to compensate cases 'more likely than not' was compensating more injuries than would meet the strict scientific criteria of causation (Robinson 1981). Robinson's (1981) evaluation argued that the programme was, however, meeting its principal policy goals in providing the just compensation for probable vaccine injuries. He further argued that more restrictive eligibility criteria might satisfy scientists, but would increase the likelihood that the policy goals would not be met. The fears that

5. Joint Interview with 4 UK government officials 14/05/2008.

6. Joint Interview with 4 UK government officials 14/05/2008.

7. Joint Interview with 4 UK government officials 14/05/2008.

8. Joint Interview with 4 UK government officials 14/05/2008.

lowering the bar to prove causation might falsely attribute injuries to immunization (thereby undermining public confidence in immunization) did not materialize in the years following the programme's implementation (Robinson 1981). Public confidence in immunization rebounded after the programme was implemented and remained very high until the recent controversy over the safety of the MMR vaccine.

However, the interpretation of probable cause by the medical director and consulting medical advisors has become increasingly narrow in the last ten years. This has created a very high bar for claimants and the success rate has dropped accordingly. The drop in successful claims has led to vocal criticism by advocacy groups who claim that the strict interpretation of causality veers from the original goal of the programme to provide just and rapid compensation for those who, on the balance of probabilities, were injured (Owens 2009, Vaccine Risk Awareness Network 2011).

In 1998, a review of the programme led to a lowering of bar for the eligibility requirements with respect to the determination of disability. Previously, claimants had to demonstrate a minimum of 80% disability but this was reduced to 60%. These changes led to a review of 393 rejected claims, of which eighteen decisions were reversed (Owens 2009).⁹

The United Kingdom has implemented an injury compensation programme that is relatively restrictive in both core areas that determine eligibility for compensation: the causality assessment and types of injuries considered. The claimant's injury must satisfy the criteria of at least 60% disability, and this disability must be directly related, through biological mechanisms, to the immunization given. The programme has, historically, met its core objective to provide compensation for those very likely injured while participating in immunization programmes. The programme, also, meets many of the objectives of using a no-fault approach to treatment injury. It provides fair, relatively consistent compensation with a rapid adjudication process. The process is non-adversarial and the civil servants involved in the programme are tasked with aiding and assisting claimants in the process. There is no need for legal representation unless the claimant rejects the judgment. The process is transparent, and the final decision and expert opinion is made available to the claimant who has a limited recourse to an appeals process.

Unlike the approach taken in New Zealand, which will be described in the following section, this is not a high-profile government programme, and there is debate over whether or not publicity for this programme is desirable. It appears that few claimants are aware that the programme exists until they are confronted with a serious injury and health professionals or social services identify their cases as possible claims.

There is currently no process-evaluation that identifies how most claimants are made aware of the programme. The programme is easily found via Google UK (from a search executed in September 2009) using keywords "vaccine damage" (first hit), although other keyword searches such as "vaccine injury" returned only injury lawyers (sponsored websites) and vaccine-critical organizations that focus largely on the United States compensation programme. This may be the reason that many claimants are reportedly dissatisfied with the amount of compensation offered under the scheme (US settlements are ten-fold on average).

The narrowing of the interpretation of probable cause to adhere with strict scientific criteria may satisfy medical professionals, vaccine manufacturers (in the absence of the threat of litigation), however there is an argument that it will ultimately fail to meet the original policy objectives and lead to calls for reform.

New Zealand's Accident Compensation Corporation (ACC)

In New Zealand, no-fault compensation for vaccine-related injuries is part of a comprehensive no-fault approach to medical misfortune (injuries related to medical treatment). The origin of the programme can be traced to the formation of the Accident Compensation Corporation (ACC) in 1974, and the prohibition of civil litigation for personal injury arising from accidents. Vaccine-related injuries only came under the scheme when the government passed legislation in 2005 to include compensation for any injuries suffered while receiving treatment from health professionals (Accident Compensation Corporation 2009). Any unexpected injury that causes any degree of measurable damage is covered under the scheme.

9. The statistics quoted come from supporting documents to Owens (2009).

Vaccine injury cases represent a tiny fraction of ACC activities overall. Since the introduction of the Treatment Injury legislation on 1 July 2005, the ACC received 27,174 claims for treatment related injuries. Of the 23,260 claims, 15,343 (66%) were accepted and 7,917 (34%) were declined (Accident Compensation Corporation 2009).

Since the inclusion of vaccine-related injuries under the scheme in 2005 (until 2009), there has been 344 vaccine-related injury claims filed and 170 accepted for compensation. The principle reasons for declining claims were, in order of frequency:

- 113 no compensable injury;
- 41 the injury was an ordinary consequence of treatment;
- 14 no causal link between the immunization and injury (Accident Compensation Corporation 2009).

Eligibility rules and administration

The injury claim process must be supported by a registered medical professional and the two required forms for filing a claim are often sufficient for the medical officer to assess the causal relationship between the injury and the vaccine. The ACC does however collect further information when required, i.e. extensive clinical records, reports from registered health professionals, and, in complicated claims, external clinical advice. Medical experts on staff and consultant experts assess whether the claimant should receive compensation. The assessment of causation follows the general ACC protocols and relies heavily on internal review of the likely cause of injury. Of the 344 decided claims, external expert advice was sought only in twelve claims, and the median costs of soliciting expertise in these more complex cases was NZ \$788 dollars (Accident Compensation Corporation 2009). If a claim is declined, the petitioner can appeal to the Disputes Resolutions Services, an independent review agency. Claims are rapidly processed and typical claim resolution for the ACC in general is measured in weeks (Bismark and Paterson 2006).

Uniquely, New Zealand allows payout for publicly-insured medical costs. If the injured seeks treatment from a private provider the fees are reimbursed even in cases where the treatment would have been covered under the public system. This allows successful claimants to access a range of privately offered services that frequently translate into more rapid access to treatment than might be expected in the publicly funded system. Since the programme's eligibility requirements regarding the severity of the injury are broad, the payouts are relatively small when compared with other jurisdictions, and the compensated injuries, relatively minor (payouts generally range from a few hundred dollars to several thousand dollars. If a claim is accepted, compensation can include any or all of the following costs:

- Treatment costs
- Compensation for salary or wages lost because of the injury
- Domestic help, such as home help or childcare
- Travel costs, such as to and from treatment
- Equipment, such as crutches, wheelchairs and visual aids
- Home improvements to accommodate the injury such as rails or wheelchair ramps

Programme evaluation

While there has been no specific study published evaluating the vaccine-injury component of the New Zealand ACC, there are several studies evaluating the effectiveness of no-fault compensation approaches to treatment injury (Bismark 2006, Studdert 2001). The ACC has met its goal to provide fast and arguably fair compensation to those who qualify. A review of vaccine related injury claims shows that most injuries compensated through the ACC have been relatively minor, with compensation in the thousands of dollars rather than hundreds of thousands and millions in other jurisdictions. Several serious cases of neurological injury following immunization have received compensation under the scheme. New Zealand's unusually high claim rate (indexed to population) reflects its relatively permissive definition of injury and the highly

public role the ACC plays in New Zealand public policy. Research on the ACC suggests that unlike most jurisdictions, most New Zealanders are aware that compensation is available for unexpected injuries related to medical treatment, including immunization. This suggests that the key barriers in other jurisdictions to filing claims and meeting eligibility criteria are absent in the New Zealand model (see Table 2).

As a model, the New Zealand approach to compensating relatively minor injuries works well in the context of a larger bureaucracy created to redress treatment injuries, however it would be difficult to construct a programme based on this model in Canada. It does, however, provide an important baseline for the scope and costs of a system with extremely low barriers for receiving compensation.

Quebec's Compensation for Victims of Vaccination Program

In Canada, despite discussions in Manitoba, Saskatchewan, and Ontario, only the Quebec government has instituted a programme to compensate those injured from immunization. The Quebec programme (CVVP—Compensation for Victims of Vaccination Program) was created to respond to a failed lawsuit mounted by Jacques Lapierre, the father of Nathalie Lapierre, a child who suffered from viral encephalitis after a measles vaccination (*Lapierre v. A.G.* 1985). Though the immunization took place in 1972, when the child was five, the case was not resolved until it came to the Supreme Court of Canada in 1985. During the process of litigation, the Superior Court of Quebec found against the government, noting that while there was no-fault involved in the case, there was an undisputed compensable harm caused by a government-recommended immunization. Part of the decision related to the judge's assertion that vaccinating was not strictly voluntary in Quebec due to government-sponsored moral pressure to comply with recommendations to vaccinate to protect not only the individual but also the community from threats from preventable infectious disease (Ministère de la Santé et des Services Sociaux Québec 2011). This ruling was over-turned by the Supreme Court of Canada. While recognizing the inherent justice of awarding a settlement to the Lapierre family, the Supreme Court of Canada maintained that Quebec law did not allow for a settlement where no fault could be assigned and the family's attempt for legal redress failed.

Responding to the Lapierre case, the Quebec government passed amendments to the Public Health act to create a no-fault programme for vaccine-related injuries (R.S.Q., chapter S-2.2, Division III (70-78)). The programme is run by the Office of Public Health, under the Ministère de la Santé et des Services Sociaux Québec (the agency that determines cause), the Société de l'assurance automobile du Québec (the agency that determines the awards according to the *Automobile Insurance Act*), and the Tribunal Administratif du Québec (adjudicates appeals). All vaccines against diseases listed in the *Conditions Respecting Compensation for Victims of Vaccination* are included in the no-fault compensation Programme (a section of the Public Health Act, regulation under the R.Q. C. S-2.2, R.1.)

Eligibility rules and administration

In order to qualify for compensation, the vaccine-preventable disease (as opposed to a specific vaccine itself) must be listed in the regulations, and the vaccine must have been given in Quebec. The victim must have sustained, "Severe permanent damage, physical or mental, including death" (Turmel 2010) and the claim must be filed within 3 years of the immunization or the apparent onset of injury or death. There must be a *probable* causal link between the immunization and the injury.

Claim adjudication

The Ministry requires the individual to fill out a claim form and a medical document release form that allows the office to collate a full set of medical records. In addition, claimants are required to have a physician fill out a claim form on their behalf. Currently, the injured party must request a paper copy of all forms from the Ministry—no electronic copies are available, although, there are plans to make the forms more accessible.¹⁰

Claims are adjudicated by a medical committee or panel comprised of an expert chosen by the Ministry of Health and Social Services, the claimant, and a mutually agreed upon chair. Normally, the claimant's

10. Interview with Quebec government expert 18/04/2008. See also the programme's website (Ministère Santé et des Services Sociaux Québec 2011).

appointee is provided with a list of possible chairs from the government's appointee, thus in practice, both the chair of the committee, and the government's appointee are recommended by the Ministry.¹¹ Committee members are appointed by the Ministry of Health and Social Services and are usually drawn from a small group of experts in relevant fields such as vaccinology, immunology, and paediatric neurology.¹²

Once a chair is chosen, the committee is provided with the claimants' medical documents and directions regarding the adjudication procedures. The committee is tasked with determining, on the balance of probabilities, whether or not the injuries claimed could be attributable to the immunization (Turmel 2010). The committee members can request additional expert opinions and can, and often do, interview or examine the claimant. The committee members are responsible for reviewing the medical records and any relevant medical literature, participating in both teleconferences and face-to-face committee meetings that can include the claimant, and, finally, contributing to and reviewing the draft consensus report. Once the committee has reviewed the documents, a meeting is arranged in the presence of the claimant; the chair moderates the discussion until a majority consensus is reached regarding the cause of the injuries, with respect to the immunization. The stated purpose of the meetings is to both understand the cause of the injury and to give the claimant a reasoned explanation of what happened. The chair of the committee then writes a report that explicitly addresses the probable cause of the injury and its relation to immunization and, also, the extent or degree of permanent injury experienced by the claimant. The chair's report must reflect the consensus of at least two of the three committee members. If one member dissents, the dissenter is required to file a separate report reflecting his or her opinion regarding both causation and the degree of injury (Turmel 2010). These reports are sent to the Minister of Health who ultimately decides if the case is compensable or not—although the Minister has never over-ridden the recommendations of the committee (Ministère Santé et des Services Sociaux Québec 2011).

If a claimant is successful, their case is forwarded to the Services aux Accidentés du Québec (SAAQ), the agency that oversees no-fault compensation for motor-vehicle injuries. Compensation is determined using the criteria specified under the *Automobile Insurance Act*. The determination of compensation for vaccine injuries follows the same protocols as those for motor vehicle accidents using actuarial tables of earning potential and medical costs and the SAAQ coordinates services for rehabilitation (Société de l'assurance automobile du Québec 2011).¹³ The compensation provided under the Quebec programme is comprehensive and includes compensation that takes into consideration the full impact of the injuries on a person's life (corporal damages). It includes lost wages, rehabilitation services, domestic and personal services and uninsured medical costs. Payments are generally calculated in the form of an annuity and are indexed to inflation.¹⁴

Once a decision has been made whether or not to compensate, the claimant is officially informed and given the option of accepting the decision, or they have the right to file an appeal within 60 days to the Tribunal Administratif du Québec (TAQ), an arms-length agency responsible for adjudicating appeals of administrative decisions of the government. The TAQ has the power to over-rule decisions made by the committee.¹⁵ Appeals can be based on the claimant disputing the reasoned judgment regarding the cause of the injury or can argue that their injuries are not adequately represented in the decision. As of October 2010, 55 of the 109 cases adjudicated by the medical tribunal were appealed to the TAQ (Turmel 2010), either to reopen the causality assessment or to appeal the settlement amount awarded.

The TAQ appeal process can consist of a conciliation meeting or a formal tribunal hearing. At a formal tribunal hearing, typically, two administrative judges (usually a lawyer and physician) preside over the case and make a final written judgment. There is no higher administrative body to appeal decisions of the TAQ. The process for the appeal resembles a typical administrative court proceeding where both the claimant and

11. Interview with Quebec government expert 18/04/2008, petitioner's medical committee member 29/07/2008.

12. Interview with Quebec government expert 12/02/2008.

13. Interview with Quebec SAAQ government expert 12/02/2008.

14. Interview with Quebec SAAQ government expert 12/2/2008.

15. Interview with Quebec government expert 18/04/2008.

government have representation, can call witnesses, and submit evidence for review. Cases take several years from filing the appeal to be heard and can take a significant number of days in court to resolve. TAQ-level appeals of medical committee decisions are usually unsuccessful leaving the claimant to pay legal and expert witness fees. While claimants can proceed without a lawyer, they can also choose to hire representation or apply for legal aid for the TAQ hearing. While lawyer or expert fees are not normally reimbursable under the TAQ proceedings, there have been two successful appeals for the court to pay expert costs of the claimants. When the burden of proof falls on the claimant, the judges reasoned that it was only fair that reasonable costs be recovered to argue the case. The co-appointed medical committee adopted by Quebec is unique in several ways. It provides the claimants with the opportunity to self-appoint a medical professional to act on their behalf in the deliberations over causation and over the extent of their injuries. Though the purpose of the adjudication is to determine if there is a causal link between the stated injuries and the immunization, this system provides a role for an attending physician or someone with first-hand knowledge of the case, regardless of their expertise in the science of vaccine injuries, paediatric neurology, immunology or vaccinology. However, the claimant's physician does not function as an advocate for the claimant. The directive to all committee members is to review the probable cause of the injury and assess whether or not there is a probable causal link between the immunization and the injury in question using the best evidence and science and their knowledge of the case. The presumption is that a fair review of the case with the best evidence serves everyone's interests. Unlike other causality-assessment bodies, such as PHAC's ACCA, the committee does not use a codified approach to determining causation in these cases; committee members judge each case based on their interpretation of scientific literature and their own judgment.

However, the process is structured to be simultaneously less adversarial yet more inclusive of the claimant than other systems. Members of the committee are able to meet directly with the claimant and, in cases where the claim is ultimately rejected, the chair of the committee and the other members often attempt to explain in person their rationale for rejecting the claim. The full report sent to the Ministry is also issued to the claimant and claimant's requests for further explanation and information are also entertained by Ministry of Health and Social Services.

Programme evaluation

Since the programme's inception until October 2010 approximately three million dollars has been paid to twenty-seven successful claimants and the total programme costs have been reported as three and a half million dollars (Turmel 2010). In the one-year period between April 2006 and March 2007, \$126,487.29 was paid to claimants and the total expenses related to the Programme added up to \$160,530.41 (compensation, administration costs, payments to physicians and experts and other expenses).¹⁶ The total percentage of administrative costs to settlement pay-outs was 27%. Expert committee members are paid approximately \$800 per case. Administrative fees by SAAQ to oversee any awards cost approximately \$1600 per case in 2007–08. In a one year sample, the average time between the injury claim and settlement was approximately one year, although claims have been settled in as little as one month to over ten years if the case goes to a tribunal appeal. As of October 2010, a total of 109 cases had been evaluated by a medical committee. Twenty-seven (25%) of these received compensation (Turmel 2010).

There has not been a systematic evaluation of the CVVP, however, it has largely fulfilled its original mandate to compensate cases of serious vaccine injury where the link between the vaccine and injury is uncontested by a medical committee (a committee of peers). Each claimant that has been compensated under the programme would have had no realistic recourse to civil litigation for compensation for their injuries. Victims of vaccine-related injuries receive monetary and non-pecuniary supports identical to automobile accident victims and, in the spirit of no-fault, the awards are more consistent and proportionate to injury than awards for medical malpractice in civil litigation, although some experts have argued that the awards are too modest and there has not been an evaluation of claimant experiences with the programme.

16. Follow up email correspondence to JF Letourneau (in French) from Interview with Quebec government expert 18/4/2008.

Few Quebecers are likely aware of the programme, and, thus, it is unlikely that the programme has had any direct impact, either positive or negative, on attitudes toward immunization or compliance to recommended immunizations. Having a process to adjudicate vaccine injuries has likely stemmed public controversies over vaccine injury since the rare instances of severe injury, as in the Lapierre case, are now compensated. However, since the TAQ process was put into place, 55 or approximately half of all committee cases were appealed for either disputes over the causality assessment or the determination of the degree of injury related to immunization.

SECTION III: RECOMMENDATIONS

Policy options

Vaccine-related injuries are rare, frequently unavoidable, and require highly specialised expertise to assess the causal relationship between a particular injury and immunization. Despite divergent approaches to compensation and differing eligibility criteria, the number of serious injury claims in three of the four jurisdictions studied fell within the expected range of less than one to two serious adverse events per million, with less half of these injuries justifying compensation (Table 2). New Zealand's claim rates (ten times the next highest claim rate) illustrate the dramatic difference in policy objectives and programme scope between New Zealand's programme and the three other jurisdictions examined. New Zealand's programme is part of a comprehensive accident and disabilities scheme that provides compensation for any unexpected treatment injury, at the same time, barring all civil litigation for medical misfortune, while the three other jurisdictions approach vaccine-related injuries as ethically distinct from other treatment injuries. These three programme's restitutive approach hinges on the idea that vaccines (unlike other medical procedures) provide critical benefits to society beyond an individual's protection and cannot be freely refused by citizens in most cases; thus, when citizens are seriously injured from participating in these programmes there is an ethical imperative to compensate them for these injuries.

The case-load of the jurisdictions studied, and the number of awards issued, indicates that the systems are working to compensate those likely to be seriously injured by immunization.

A review of the problems arising from programmes in other jurisdictions suggests that any no-fault compensation scheme will benefit greatly from the following design features:

1. Clear and internally consistent programme objectives;
2. The ability to resolve claims in a timely fashion;
3. Consistent adjudication of claims (i.e., the same type of claim receives the same type of compensation);
4. Perceived independence or arms-length structure from agencies promoting immunization;
5. Where possible the claim process is structured so that claimants can avoid the costs and expense of legal representation;
 - a. Have a codified process to determine causation;
 - b. Maintain sufficient expert capacity to draw upon to determine causation in complex/novel types of injury cases or during a the release of a novel vaccine;
 - c. Designed such that *access* to the programme is facilitated by medical rather than legal representation;
6. Fair statutes of limitation (take into consideration the fact that, due to the rarity of vaccine-related injuries, it may take some time before a link between an injury and immunization is postulated);
7. Transparent & accountable to the public (communications capacity is critical and a communication strategy is highly desirable);
8. Cross-linkages with scientific agencies to assess novel theories of harm.

Each of these design features will be discussed in turn.

Determining the core policy objectives

The rationale for implementing no-fault compensation programmes varies across jurisdictions and chiefly includes:

- Providing just compensation for those who may have been injured by a vaccine (usually determined by a preponderance of evidence and no other reasonable cause for injuries);
- Providing reasonable liability protection to encourage the development of novel immunization technologies (increasingly a requirement for the release of new vaccines in emergency situations);
- Ensuring uptake of recommended immunizations and maintaining public confidence in immunization;
- Improving injury surveillance potentially identifying vulnerable subpopulations or predictable sources of injury (New Zealand only).

As stated earlier, the common core objective for most no-fault compensation programmes is to provide just, timely, and proportionate compensation to those whose injuries can be credibly associated with an immunization. Despite differences in its application, in all jurisdictions this core programme objective has been successfully met. In the four jurisdictions studied, the average time to process claims is generally superior to civil litigation (measured in months to years versus greater than five years for most civil litigation). In most jurisdictions, compensation schemes only provide for *uninsured* costs and losses. The focus is on providing for the unmet needs of those injured and, thus settlements take into account existing insurance, disability entitlements, and other monetary and non-monetary supports. Unlike civil litigation, there are no punitive awards since there is no rationale in most injury cases for a deterrent against the manufacturers or deliverers of vaccines, and pain and suffering awards are either non-existent or modest when compared to jury awards. Because each jurisdiction has a specialised unit for adjudicating injury cases, awards are more consistent than a jury trial and, being based on need, they are more proportionate to the actual injuries sustained.

The success in meeting other programme objectives is less clear. Assessing the impact no-fault programmes have had on manufacturer's civil litigation costs is notoriously difficult, however Rigway's 1999 study and anonymous interviews from leading vaccine manufacturer's legal advisors support the assertion that there have been significant cost savings to manufacturers, particularly in the United States but also notable in Canada. Vaccine innovation and development flourished in the period following the implementation of international no-fault programmes. The programme has allowed legislators to justify statutes that reduce the likelihood of a manufacturer being held liable for unavoidable, rare, and unpredictable vaccine-related injuries. Beyond the cost-savings of reduced litigation, manufacturers have benefited by the fact that the United States NVICP cases cannot set precedent in civil litigation and the US Health and Human Services has a broad policy objective to settle cases without acknowledging a causal association between vaccine and injury. This process acts as a pressure valve to keep likely un-winnable, but equally expensive and image-damaging vaccine-related injury cases, out of the civil litigation system.

Arguably in the United Kingdom and Quebec, indemnification programmes have also reduced the number of un-winnable civil cases filed in the tort system, and reduced the litigation costs for manufacturers. For example, while Quebec has avoided high-profile vaccine injury cases, civil cases have been filed in Ontario and British Columbia, and a high-profile case of injury in Manitoba prompted the Manitoba Law Reform Commission (an independent government agency) to commission a report on the issue (Manitoba Law Reform Commission 2000).

While litigation restrictions have been put in place in both New Zealand and the United States (for different reasons) it is **unclear** that legislated liability protection for manufacturers is necessary in Canada. The existence of a no-fault programme would provide those with injuries recourse that is otherwise unavailable through civil litigation. However, changes to the Canadian litigation environment have made filing cases of injury easier and more feasible, though not necessarily, more winnable. Liability protection that requires the

injured to first apply to a national no-fault compensation programme before being allowed to proceed to civil litigation adds an additional barrier to filing un-winnable cases and gives citizens the freedom to reject a no-fault settlement in favour of a higher risk civil lawsuit.

Despite the assertion that no-fault compensation programmes have the potential to improve transparency and can help maintain buy-in and trust for government-sponsored immunization programming there is little evidence to support this assertion. In a review of the literature, we found no study examining attitudes towards immunization that identified injury indemnification as a key issue in individual's decision-making regarding immunization (see for example Cooper et al. 2008). On the contrary, it is more likely that any measured rebound in public confidence and immunization uptake in the 1990s was a response to a broad set of policy interventions to restore public trust in immunization (including replacing the whole-cell pertussis vaccine with a less reactive one). This assertion is supported by the fact that expert informants in every jurisdiction, other than New Zealand, claimed that the general public awareness of these programmes is poor and, therefore it would be difficult to imagine that there could be an impact on individual decision-making surrounding immunization.

In summary, the core objective of a Canadian no-fault compensation programme should be to justly compensate those injured, fully recognising that their injuries were sustained while they were contributing to a public good. There is little evidence to support a policy objective to increase immunization uptake or maintain public confidence in immunization through an indemnification programme and it can be argued that these objectives can be perceived to interfere with the ethical mandate of the programme. Nor is liability protection for manufacturers a key driver in expert advocacy for a Canadian no-fault programme.

That said, experience from other jurisdictions suggests that a no-fault programme for vaccine-related injuries would be best supported by a comprehensive and integrated approach to vaccine safety and communications (related to adverse events following immunization). An ideal program would have the capacity to oversee or coordinate the following set of secondary objectives:

To:

- I. To identify novel signals of vaccine-related injury and/or biological theories of harm presented by petitioners in a manner complementary to existing passive and active surveillance systems;
- II. Liaise with national and provincial/territorial AEFI (Adverse Events Following Immunization) experts and public health agencies to coordinate expertise to provide ongoing analysis and evaluation of injuries;
- III. To serve as a repository for information regarding AEFI;
- IV. To liaise with the Canadian Institutes for Health Research and where necessary commission scientific research to examine emerging theories of harm;
- V. Communicate decisions to the public (in a transparent, clear, and accessible manner) and to monitor the public understanding of vaccine injury cases and intervene if harm or misrepresentation is detected.

The institution of the core policy objective and the five secondary objectives would greatly reduce the risk of civil litigation for manufacturers.

Eligibility criteria

Vaccines and types of injuries covered under the programme

Most programmes either include in their supporting legislation or regulations a list of vaccine-preventable diseases or a list of vaccines covered. In ideal cases, there is language in the legislation that allows for the list to be automatically updated when new vaccines are licensed or added to routine immunization schedules (e.g., in the United States all government-insured vaccines are automatically added to the Vaccine-injury Table). To be consistent with the chief objective of the proposed programme, it would make sense to include any immunization recommended by the National Advisory Committee on Immunization as described in the most recent Canadian Immunization Guide (generally published every two years). In the case of emergent

threats and novel vaccines released under emergency situations, recommendations from the Public Health Agency of Canada for immunization should also trigger an addition of the recommended vaccine to the programme. Typical eligibility restrictions would require that the immunization be licensed in Canada and given by a recognised health professional in Canada. This avoids the programme assuming liability for vaccines not administered in controlled settings and products called vaccines but not recognised by Health Canada as such (i.e., homeopathic vaccines).

Most, but not all, compensation programmes place restrictions on the type and severity of injury that is eligible for compensation. Presumably, some measurable harm must arise from the immunization that exceeds the minor inconvenience of common adverse events following immunization (such as fever that resolves with over-the-counter treatment, sore arms, and/or aches or fatigue that resolve in a few days). In some cases, a minimal hospitalisation associated with acute care and treatment, rather than observation, is a requirement for compensation (actual rather than potential harm). The United Kingdom has one of the steepest eligibility hurdles for compensation, requiring at least 60% permanent disability for any claim. Similarly, Quebec's scheme requires that the injury be both permanent and serious. Conversely, both New Zealand and the United States have liberal definitions of injury that allow, for example, claims for any unanticipated outcome that creates unexpected burden on the claimant, such as unsightly scars requiring cosmetic surgery or transient injuries that result in even modest missed wages or medical costs. Given the time and effort required to file claims in the United States, despite their eligibility for compensation, it is not surprising that these types of injuries have not been a major source of claims. On the other hand, in New Zealand, compensation for *any* treatment injury is perceived by the public as an entitlement and is part of a extremely popular accident benefits programme. This accounts for the disproportionately large number of petitions for minor injuries and also the high number of successful claims. Other than in New Zealand, the eligibility requirements pertaining to the scope of injury does not seem to have had an impact on the number of petitions filed, suggesting that claimants' filing behaviours are somewhat independent of the chances of being deemed disabled enough to merit compensation. However, a high bar for the type of injury compensated, naturally, has an impact on the number of *successful* claims. In the United Kingdom, for example, in a sample of data taken up to May 2008, 91 of the 4,532 cases that met the relatively stringent causality test were rejected because they failed the 60% disability hurdle.¹⁷

A reasonable compromise would be to limit claims to serious injury where measurable damages have occurred that resulted in uninsured medical, or rehabilitative costs, or lost wages. A fixed sum of \$1000 in uninsured damages, or a fixed minimum percentage of claimant's income, could be used to set minimums for damages claims in order to maintain the spirit of compensating for serious adverse events. In the extremely rare case of death associated with a vaccine, funeral costs should be provided with a standard death benefit of \$250,000 (similar to other insurance schemes). Eligibility requirements for injuries could be determined using minimal hospital stays for acute events and standard insurance assessment scales of transient and permanent disability to index compensation for the range of rehabilitative, supportive, and monetary losses sustained by the victim.

Filing requirements

Another contentious eligibility criteria is the statute of limitations placed on filing claims for vaccine-related injuries. This varies considerably from as little as one year to almost ten years after the vaccination or onset of symptoms of the adverse event. Most schemes allow adults some restricted period of time to apply for compensation for injuries they sustained as minors. In cases where the connection between an injury and immunization can take many years or may only occur after a specialist raises the issue, filing deadlines can also create unfair barriers to accessing compensation. In all cases, a permissive or a long duration for filing claims is confounded by the need for substantial evidence (complete medical records) and expert support for the claim. In countries without centralised health record systems, obtaining records from private practitioners can be extremely difficult. This issue is a concern in Quebec where many filed claims never proceed to adjudication because the claimant fails to produce adequate medical records.¹⁸ These cases are

17. Supporting documents provided during joint interview with 4 UK government officials 14/05/2008.

18. Interview with government official, Quebec's Indemnities for Victims of Immunization Program 18/04/2008.

not even recorded in official statistics however they were estimated by a government official to be about 50% of all claims originally filed.¹⁹ One possibility would be to ensure that the special master has sufficient powers to subpoena medical records from health care professionals and health care institutions.

Given the above considerations, a statute of limitations of three years from injury onset would be a reasonable compromise, however, disallowances based on this criteria should be carefully monitored and reviewed on an annual basis. A process of appeal to the programme director or medical officer should be allowed in special circumstances. By definition, imposing a statute of limitations alone imposes a rigid eligibility restriction. Given the uncertainty surrounding many adverse events following immunization and the long duration required to substantiate injury claims with scientific evidence, some flexibility is desirable in specific cases (for example where the emergence of robust scientific evidence supporting new categories of adverse events occurs years after a vaccine programme has been implemented).

Causality assessment

A critical component of any vaccine-injury compensation programme is the assessment of the relationship between the immunization and the injury it is claimed to have *caused*. Causality assessment is defined by the WHO as the, "... systematic review of data about an AEFI [adverse event following immunization] case to determine the likelihood of a causal association between the event and the vaccine(s) received" (WHO 2001). Causality assessment for injury compensation cases differs from the WHO's approach in that the focus is on determining causality, in a specific instance, to determine eligibility for compensation, rather than performing population-based surveillance for adverse events following immunization.

In injury cases, there are two distinct parts to a test of causality. First, the injured must establish "general causation", or in other words, they must establish whether or not there is good evidence that the immunization *can* cause this type of injury. Second, the injured must establish *specific* causation, the demonstration that the immunization was, more likely than not, the cause of the injury in their particular case. The meaning of causation varies from scheme to scheme but typically involves establishing:

- A biological theory of harm
- A temporal association between injury and vaccine
- A logical sequence connecting the injury to immunization
- The absence of more probable cause for the injury (specificity of the association)

In some jurisdictions, such as the United Kingdom, the *strength* of the purported association is also taken into account, in other words, establishing causation leans more towards scientific evidence of a probable rather than possible association (see Figure 2 for the steps taken in a WHO causality assessment process).

In the case of vaccines with a long track record, there is often a substantial body of literature and a consensus-opinion related to types of injuries associated with the vaccine. In the case of new vaccines or novel injuries, causality assessment relies

Figure 2. A codified causality assessment process. Extracted from the WHO "Adverse Events Following Immunization (AEFI): Causality Assessment". Available online from http://whqlibdoc.who.int/aide-memoire/a87773_eng.pdf

2. Evaluate and assess factors.
 - 2.1 Is this event known to be related to the vaccine? (*Consistency of findings, Strength of association.*)
 - 2.2 What is the frequency of occurrence of this adverse event? Very common (>1/10); common (>1/100); uncommon (>1/1000); rare (>1/10 000); very rare (<1/10 000), or not previously reported.
 - 2.3 Are similar events known to occur with other diseases? (*Specificity of association.*)
 - 2.4 Is this event explainable by the biological properties of the vaccine? (*Biological plausibility.*)
 - 2.5 Is the vaccination-to-event interval compatible with the event? (*Temporal relation.*)
 - 2.6 Has the patient had similar symptoms in the past?
 - 2.7 Is there a history of concomitant or preceding drug therapy?
 - 2.8 Is there a history of a concomitant or preceding condition?
 - 2.9 Are there other factors that could affect the occurrence of the event?
3. Determine causality category using WHO criteria
 - 3.1 Is this an unknown event in relation to this vaccine?
 - 3.2 Is this a new event?
 - 3.3 Is there lack of sufficient data to reach a more definite conclusion?
 - 3.4 Would the case benefit from a second review if more data became available?

19. Email correspondence with government official, Quebec's Indemnities for Victims of Immunization Program.

more heavily on expert's judgment of the plausibility of the association based on observational studies, case reports of injuries, and the validity of any experimental data supporting a causal association.

Depending on the policy objectives, a key decision in developing a no-fault compensation programme is to define the degree of certainty (that the injury is related to immunization) required to be eligible for compensation. In the United Kingdom, to meet the definition of causation requires that the expert determine that it was more probable than not that the vaccine **alone directly caused** the injury. The interpretation of probable is drawn from scientific rather than legal definitions and thus presents a higher burden for claimants in cases where there is scientific uncertainty.

In the United States, meeting the three-prong eligibility test (in the absence of an alternative cause) using circumstantial evidence from the case rather than probabilistic evidence from research is generally sufficient for compensation. While in the context of the legal proceedings, this approach meets the definition of a preponderance of evidence, in practice, the process is closer to establishing a reasonable or possible cause, in scientific terms. The US approach would garner less controversy, and still fulfill its policy objectives, if it relied on scientific and expert opinion to substantiate the three-prong test of causality rather than allowing causation to be established with circumstantial evidence.

However, redeploying a strict (scientific) test of 'more probable than not' would exclude classes of adverse events that have been the focus of civil litigation and government indemnification programmes, such as the aforementioned Guillian-Barré Syndrome (GBS) following influenza immunization. In this case, there is a body of evidence (peer reviewed research) suggesting an association between influenza vaccine and GBS, however, there is some degree of uncertainty among experts about how robust the data supporting this association is (Health Canada 2002, Juurlink et al. 2006). There would be a diversity of expert opinion in deciding cases of GBS following influenza immunization if a strong *scientific* interpretation of *probable cause* were the foundations of an eligibility test. If the causality test was met when *possible* or *reasonable cause* was demonstrated with good scientific evidence, the outcomes would be more consistent.

Other jurisdictions fall along a spectrum between compensating, in cases with less scientific certainty over probable cause, and requiring a strong interpretation of probable cause. Both approaches have attracted criticism. In schemes that have a steep causality test, there are likely true vaccine-related injuries that are not compensated; contrarily, in those with too permissive a standard, there is compensation for injuries that are not likely caused by immunization. In the more restrictive case, the policy objectives to provide just compensation are undermined and more permissive systems risk raising unfounded concerns over vaccine safety.

If the core policy objective is to provide just compensation, then the causation test should err toward the side of compensating when immunization is established as a possible cause of the injury. However, the case should be substantiated with scientific research rather than circumstantial evidence. If a more likely cause is demonstrable in the particular case then the causation test would not be met. This still gives the claimant the benefit of the doubt and puts the burden on experts to bring forward a reasoned counter-explanation for the injury.

This approach provides a more concrete adjudication process than those based on a scientific understanding of cause, which would require a much higher degree of certainty.

Proving causation using a hearing or case review approach

The most common approach to assessing causation is to require the claimant prove both general and specific causation for their case. Most jurisdictions take an administrative or non-adversarial approach when determining both general and specific causation. They frequently rely on reasoned expert opinion solicited solely by the programme's medical director, as in the United Kingdom or New Zealand. Hired consultants, or in-house government experts are guided by the specific criteria used in each programme (i.e., the threshold required to meet eligibility for compensation) and make their decision through a documentary review of the claimant's medical records or in some cases, additional interviews with claimant. In Quebec, the expert review committee includes a member nominated by the claimant who usually has direct clinical

Table 3. Divergent approaches to the causality test and their policy implications

Reasonable / Possible cause	Probable cause
Low certainty	High Certainty
More successful claims	Fewer successful claims
More claims awarded that may not be associated with immunization	More claims denied that may be associated with immunization
Weaker agreement with scientific notions of cause	Stronger agreement with scientific notions of cause
Claimants given the benefit of the doubt	Claimants not given the benefit of the doubt
Increased potential for unfounded concerns over vaccine safety	Decreased potential for concerns over vaccine safety

experience with the injured party. In all models examined, the judgment of causation depends on the individual expertise of the review committee members or hired consultant’s reasoned opinion.

Only the United States uses an adversarial model as the first process to determine eligibility for compensation. As described in the case study, adversarial processes normally require claimants to argue their case against the government using supporting experts and evidence. To make this system fair, claimants must have access to legal representation and compensation must include legal fees and court costs. While this system still allows compensation without finding legal fault, an adversarial process erodes many of the touted benefits of a no-fault approach to treatment injury. It is more costly, claims take longer to adjudicate, and it pits citizens against government health officials and leading vaccine experts.

A judicial process makes sense in cases where the public would not perceive a government programme to be fair, neutral, or objective in adjudicating claims. This type of criticism has been raised against some administrative systems where the key players involved in deciding injury cases are simultaneously engaged in promoting immunization, have financial ties to vaccine manufacturers, or have professional and financial interests in promoting immunization. Naturally, when claimants have the sense that claims are not being vetted with due process or that there are vested interests in *not* finding injuries associated with immunization, they are unlikely to be satisfied with the explanation for why their claim was rejected and are more likely to appeal the decision.

In Quebec, for example, there is evidence that more than half of all claimants to the system are dissatisfied with the committee decision, as 55 of the 109 medical committee cases were appealed to the independent Tribunal Administratif du Quebec. This occurred despite the fact that claim settlements in Quebec are quite modest, those injured still have access to coverage under Quebec’s health and social welfare system, and individuals largely bear the costs of tribunal appeals (which can exceed the average settlement). Tribunal (TAQ) hearings closely approximate the US judicial model; however, judicial appeals have not been successful in contesting causality decisions in Quebec. While claimants may perceive the medical committee process to be systematically biased or unfair, this is not borne out by the appeal decisions issued by TAQ.²⁰

Two approaches could be adopted from different no-fault models to ensure the perception of objectivity and fairness in the adjudication process. One possible remedy would be to have an independent overseer (i.e., a special master, rather than a medical expert chair a medical committee or expert panel). Another option (modeled after the United Kingdom), would be to house the programme in an agency responsible for disability or entitlement programmes rather than in an agency responsible for promoting immunizations.

20. This analysis is based on a review of all publicly accessible appeal decisions of the TAQ. In interviews with an anonymous unsuccessful claimant to Quebec’s program, and the claimant’s lawyer involved in the TAQ appeal, both argued that the medical committee system was biased and unfair and were equally unhappy with the TAQ judgment.

Streamlined causality test using a table of injuries

A second approach to adjudicating both general causation and specific causation is to use a predetermined table of injuries. Tables of injuries are frequently used in insurance schemes to assess disability entitlements and automobile accident claims. In its broadest application, the claimant would merely have to demonstrate that their case fulfilled the basic table criteria in order to receive compensation. A claim of thrombocytopenia purpura following Measles-Mumps-Rubella immunization would have to meet the case definition of thrombocytopenia (the industry standard is the WHO-Brighton case definitions) demonstrated through their medical records or laboratory findings (see Table 4). The injury must also have occurred within 7–30 days of the MMR immunization. If both conditions are met, the person would have met the causation test for compensation.

While tables require expert assessment of the injury to see that it meets the case definition for the injury, the outcomes based on this process are more predictable than establishing specific causation and less open to appeal.

The following adjudication process would be followed in Table cases:

- Step 1. Verify diagnosis, case definition, and temporal association.
- Step 2. If both are met, then the claim is accepted, if not the claim is rejected.
- Step 3. Determine degree of injury, and calculate settlement.

Since a table of injuries pro-actively defines classes of compensable cases, it requires significant expert input and ongoing review by an appointed inter-disciplinary causality assessment committee.

However, a table approach makes it more feasible to:

- Solicit expert opinion both nationally and internationally;
- To hold extended deliberations;
- To discuss the implications of additions and deletions of eligible injuries;
- Provide an opportunity to commission research relevant to categories of vaccine injury;
- Allow more time to develop communications to explain the benefits versus risks of immunizing to the public.

A system based on a table of injuries has numerous advantages. Structurally, it provides more transparent, consistent, predictable, and rapid assessments of each claim. Essentially, a table codifies a set of compensable associations between specific immunization and injuries. A table of injuries works best with vaccines with a long track record or well-documented injuries associated with immunization versus injuries alleged to be caused by novel vaccines, injuries with complex or vague case definitions, unexpected injuries, or unintuitive biological theories of harm. Thus, any programme will still require a process whereby claimants can request an expert review of their case. However, if the US experience is generalisable, and if claimants can choose between a table process and individual case review, a table will only be as useful as it is perceived

Table 4. Sample table of injuries entry (US Vaccine Injury Table)

Measles, Mumps, and Rubella Vaccines (MMR, MR, M, R)	Adverse Event	Time Interval
	A. Thrombocytopenia purpura	7-30 days
	B. Vaccine-strain measles in an immunodeficient recipient	0-6 months
	C. Any acute complication of sequelae (including death) of above events	n/a

to be fair, up-to-date, arms-length from competing interests, and provides a lower bar to establish eligibility for compensation.

A table approach may or may not include the stipulation that clearly-documented contradictory findings (for example, evidence of another more likely cause of thrombocytopenia) would cause the claim to be rejected. However, since the claim process is meant to be technocratic and process-driven, government experts would not be tasked with seeking out new evidence or information that would cause the claim to be rejected. In other words, if a claimant met the table criteria, in the absence of any glaring alternative explanation found in the routine review of the medical file, the programme would find in favour of the petitioner.

One risk of using a table of injuries, in combination with a more permissive causation test, is that tabled associations between vaccines and injuries could be perceived as having been *proven* by the public. This could unfairly undermine the public's perception of immunization safety. It might be prudent in such cases to avoid the term causality altogether to make it clear that the eligibility criteria are based on a scientifically possible association and that causality is not necessary implied.

Maintaining the language of scientific uncertainty is equally, if not more, difficult in individually-adjudicated cases because the public generally perceives the causality in these cases to have been proven. This is particularly true in settings where there is a tribunal or judicial hearing of the case. Even in cases where the government settles for policy reasons, the public can misattribute the action as proving that an injury was caused by immunization. In the US Poling case (*Poling v. The Secretary of Health and Human Services*), the government settled a case concerning a severely disabled girl whose underlying metabolic disorder, in conjunction with a febrile reaction to immunization, may have contributed to permanent neurological damage, including symptoms of autism. The government did not concede causation but settled the case because they felt that it would technically meet the causation test for compensation. The press coverage following the settlement alleged that the government had conceded that vaccines *can* cause autism. This reveals the difficulties officials had communicating the difference between settling a case for policy reasons and proving causation.

In summary, the ideal programme would include a Table of Injuries and a list of disallowances designed to address the majority of petitioner's claims. Petitioners should also have access to individual claim adjudication for novel theories of harm or those not addressed by the Table.

Compensation

There are several distinct models for compensating injuries associated with immunization. In the United Kingdom, a country with a cradle-to-grave social safety net, a lump sum is given, primarily, to acknowledge that the harm was sustained in the pursuit of a greater good and, secondarily, to offset the burden of the injury sustained. In Quebec, compensation is determined based on need for uninsured medical treatments, rehabilitation (including education) or lost income. The Quebec model of compensating injuries uses the actuarial tables and rules and regulations governing automobile accident victims and makes use of an existing large-scale administrative entity. Similar federal entities involved in determining disability benefits could be harnessed for a no-fault compensation programme in Canada in order to capitalise on the scale and existing capacity of such programmes (which currently deal with tens of thousands of annual claims versus the less than one hundred claims anticipated in a national vaccine-injury compensation programme). The principle guiding compensation should be to provide for demonstrable uninsured costs related to the injury.

Funding options

Most no-fault compensation schemes are relatively small programmes (compared to other entitlement programmes) and are funded by general revenues. In Switzerland and the United States, there is an excise tax placed on all covered vaccines. The advantages of an excise-tax is that it directly funds the compensation for injuries and can be indexed to fund the programme. The difficulty with this approach is setting up a tax scheme appropriately scaled for both novel vaccines and those with a long safety track record and one that is easily modified if, over time, the average annual case loads drops or rises. In the United States, for example, the excise tax system set up at the programme's inception (when the estimated number of serious adverse events was much higher), has resulted in a large reserve fund of the equivalent of approximately 3.3

billion dollars (September 2010). A criticism of the US funding model is that the excise tax money was restricted to compensation only and cannot be used for overhead, administration or funding research to assist in adjudicating claims.

In Canada, an excise tax could be implemented to earmark funds for a no-fault compensation programme under the *Excise Tax Act* but the actual funds would flow into general revenues. Given the difficulties in setting appropriate tax levels to avoid the kind of surpluses seen in the US system (some surplus is not only desirable but necessary), it will raise the spectre of having money flow from this tax into other government programmes. Since the costs of any excise tax will ultimately be borne by both the federal and provincial/territorial governments (provinces and territories are the principal purchasers of vaccines), this may create tensions if mechanisms to oversee programme expenditures and some opportunity to index the tax to programme needs are not implemented. If Canada adopts an excise tax, consideration should be given to use the tax to fund all the programmes' objectives and not just the compensation to those injured. The federal government could also simply fund the programme through general revenues, as it has in the past, for special federal vaccine purchasing programmes, such as the Immunization Trust Fund (Keelan, Lazar et al. 2008).

Administrative body

With the exception of Germany, most jurisdictions have approached vaccine indemnification as a national issue because of the scale-efficiencies in adjudicating cases at the national level. In their recommendations for causality assessment, WHO guidelines include setting up a centralised vaccine safety surveillance system that includes post-licensure safety monitoring and causality assessment for reported injuries. Thus the expertise, authority, and responsibility for reviewing injuries falls primarily on federal governments. All of these features suggest a national approach is both warranted and desirable (either a federal programme or a federally-coordinated programme).

While provinces and territories have largely retained jurisdiction over the determination and delivery of public health programmes, in recent years, provinces and territories have signalled that the federal government should play a strong role in coordinating and subsidising immunization programming across the country in the interest of equity and access to new vaccines (Keelan et al. 2008). There are many arguments supporting a strong federal role in a no-fault compensation programme for vaccine-related injuries. The federal government, through its criminal powers, oversees the licensing of drugs and performs safety monitoring and surveillance, is responsible for immunization programmes on aboriginal lands and for military personnel. Through constitutional powers stemming from *peace, order, and good government*, one could argue that the federal government has a duty to ensure the safety of Canadians through timely access to vaccines and thus shares responsibility for the integrity of immunization programmes. In addition, the federal government, through the Public Health Agency of Canada and its various expert advisory committees has the capacity in both expertise (through its federal and F/T/P expert working groups) and administrative structures to oversee such a programme.

There is also evidence that the provinces and territories would support a federal programme to address vaccine-related injury indemnification. The National Immunization Strategy was adopted at the 2003 Conference of F/P/T Deputy Ministers of Health (F/P/T Advisory Committee on Population Health and Health Security (ACPHHS) 2003). The objectives of the Strategy were ultimately funded by the federal government through a dedicated trust. The long-term goal of the architects of the National Immunization Strategy was to institute a permanent body charged with implementing a broadly collaborative F/T/P policy process to negotiate comprehensive and harmonized immunization policies across the country. Core components of the strategy included setting national goals and objectives, ensuring collaboration on immunization programme-planning, research, and evaluation, securing the vaccine supply and setting up a national vaccine registry (Keelan et al. 2008). Arguably, the administration and implementation of a no-fault compensation programme falls within the mandate of the NIS.

One option would be to propose a model programme for all jurisdictions. The federal government could use its funding powers to finance provincial and territorial no-fault schemes, for example, funds from the

Immunization Trust could be ear-marked to support the programme. The strengths of this approach are that the provinces and territories would receive financial support to fill a recognised policy gap. However, this approach would not ensure that all Canadians would have access to the same compensation, and some provinces may choose not to provide compensation at all. Finally, smaller provinces will lack the expert capacity to effectively adjudicate injury cases creating further inequity.

Another option would be to establish, similar to the United States, a special federal administrative court to adjudicate claims under the Department of Justice in collaboration with the Public Health Agency of Canada. Legislation would be required to constitute a federal administrative court with the authority to hear vaccine injury cases, and provinces could be given the opportunity to opt-out and receive financing for their own programme. The United States opted for a judicial model largely because of historical features particular to the United States that are not measurably appropriate for Canada. In addition, there would be steep constitutional barriers to create a federal judicial body to hear vaccine-related injury cases, with the possible exception of vaccines released during a public emergency or pandemic.

Alternatively, the federal government could follow the lead of most international models and create a federal entitlement programme. The legislation could allow for provinces or territories to opt out if they create an equivalent programme. The programme could be co-administered by Service Canada and the Public Health Agency of Canada and include the following components:

- A standing causality assessment committee (responsible for a table of injuries)
- A special master to adjudicate individual claims
- A programme director to manage communications and claims processes
- An administrator to assist claimants with the filing process
- A disability/injury assessor
- Consulting experts to serve on individual review committees

This approach would ensure equitable access to compensation across the country, efficient processing of claims, and use of expert and national advisory committees. However, it is highly likely that Quebec would choose not to participate in a national programme.

Periodic review and table of injury updates

A process should be implemented to review tribunal cases to identify injuries of interest related to unexpected novel theories of harm, or a clustering of injury claims related to a specific immunization. An annual audit should be performed to assess the consistency of committee decisions. If individually reviewed claims are reliably being settled in favour of the claimant than the standing committee overseeing the table would consider whether the claim should be included on the table. Conversely, table injuries should be periodically reviewed if there is a significant change in the state of immunization science or technology. Finally, a list of disallowances could be developed to process popular claims where there is a substantial body of evidence to dispute a causal association between vaccines and specific injuries, as in the recent purported vaccine-related autism cases.

Linkages with scientific agencies

The establishment of a no-fault compensation programme will require expertise from, and collaboration with, existing national scientific advisory committees and professional organizations representing both the medical profession and disabled citizens. If there is divergence in decisions over similar cases, or scientific uncertainty that creates ambiguity in assessing certain types of cases, the agency should consider providing funds to CIHR for a Request for a Proposal (RFP) to provide a stronger evidence-base for these decisions. This approach was recently taken by US officials to fund an evidence-based review of vaccine safety for eight routine childhood vaccines.

Table 5. A comparison of components of the proposed no-fault compensation programmes with those in other jurisdictions.

Country	Proposed National Programme	QUE (1988-)	UK (1977-)	US (1988-)	NZ (2005-)
Core Policy Objective	Provide just compensation for victims of treatment injury	Provide just compensation for victims of treatment injury	Ameliorate burden of vaccine-related injuries sustained in the pursuit of a public good	<ul style="list-style-type: none"> • Limit civil litigation against manufacturers • Compensate for costs pertaining to vaccine-related injury • Maintain public confidence in immunization 	<ul style="list-style-type: none"> • Provide just compensation for victims of treatment injury • Improve patient safety
Civil Litigation for Vaccine-related injuries	Options: No Restrictions or must proceed first through the programme	No restrictions	No restrictions	Restricted civil litigation allowed: must first proceed through Vaccine court	Civil litigation for medical injuries is statute-barred
Av. Case Load	Est. 0.72-2 per million	(1988-) 0.7 per million	(1999-) 2.11 per million	(1999-) 2.15 per million	(2005-) 21.5 per million
# Awards	Est. 0.2-0.3 per million	0.2 per million (1.3/7)	0.05 per million (3/61)	0.3 per million (21/330)	11 per million (42.5/4)
Compensation	Uninsured medical and rehabilitation costs, and lost wages	Uninsured medical costs, rehabilitation, death benefits	Lump sum £120,000	Annuity for medical costs, lost wages, non-economic, attorney's fees	Medical costs, disability pension, death benefits
Appeals Process	Yes	Yes	Yes	Yes	Yes
Legal Representation	Not required	Limited (except in appeals)	Limited (except in appeals)	Nearly all claimants	None
Legal Fees	None	Not routinely TAQ has awarded court costs in several cases	None	Legal fees reimbursed for both successful and unsuccessful cases	None

CONCLUSIONS

Canada should implement a national no-fault compensation programme for vaccine-related injuries. The programme's chief objective should be to compensate those who have likely been injured by immunization. Eligibility for compensation would require that the injured received a government-recommended, licensed vaccine given by a recognised health professional in Canada. A reasonable statute of limitations for filing claims of up to 3 years after immunization or onset of symptoms would be implemented, however, a process of appeal would be reserved for extraordinary circumstances. An ideal programme would have at its core a Table of Injuries designed to address the majority of claims filed. The Table injuries should be based on the most up-to-date scientific research and should provide compensation in cases where evidence supports that it was at least scientifically and clinically possible that the injury was caused by immunization and there are no other more probable causes for the injury presented in the medical records. Petitioners should also have recourse to an individual hearing or case review overseen by a special master (see Figure 1). Compensation should be provided based on the principle that all uninsured expenses resulting from the injury would be included in a settlement. A lump sum should be paid in the event of the death of the injured party.

The no-fault compensation programme should be supported by the following:

- A federal bureaucracy to adjudicate claims and compensate injuries including a special master, programme director, part-time medical director, claims processing administrators, and a disability assessor. The Programme Director should also be tasked with overseeing a communication strategy for the programme and coordinating activities between the programme and offices of the National Immunization Strategy, and F/T/P scientific advisory committees and vaccine safety research agencies.
- A standing expert advisory committee to oversee the table of injuries. The core committee membership should include experts in vaccinology, immunology, neurology, pediatrics, public health ethics, health law, and public health policy

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