COMMENTARY

The Case for a Vaccine Injury Compensation Program for Canada

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ABSTRACT

Despite its being deliberated since at least the 1980s, a national vaccine injury compensation program still does not exist in Canada. The omission of such a program stands as a gap in Canadian immunization policy in comparison to many other equivalently developed countries. This article outlines the arguments for a compensation program and the design elements that would be best suited to a program in the Canadian context.

Key words: Vaccines; immunization; program development; compensation and redress; insurance; liability

La traduction du résumé se trouve à la fin de l'article.

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At least 13 jurisdictions worldwide have instituted vaccine injury compensation programs.[1] Since the 1980s, Canada has considered the possibility of establishing its own compensation program, support for which has been endorsed by the Canadian Pediatric Society.[2] A variety of factors, including uncertainty over the number of claims that would arise and the cost of the program, inhibited implementation of a program except in Quebec where a specific, and high-profile, case of vaccine injury drove public policy. Currently, Canada and Russia remain the only G8 countries without a vaccine injury compensation program.

A combination of factors suggests that the time may be right for Canada to once again strongly consider the implementation of a compensation program. The introduction of several new vaccines along with changes to the legal environment that may increase class action lawsuits against vaccine manufacturers are perhaps foremost amongst these. In other jurisdictions compensation programs have been introduced reactively to deal with such emerging challenges and, therefore, may not have been not optimally designed. In order to avoid such a scenario in Canada, we completed a detailed analysis on the need for and design of such a program.[3] We present the primary arguments in the current environment for a compensation program, and the main design features we believe it should have.

Arguments for a vaccine injury compensation program

Ethical

Mass immunization programs are among the most successful interventions to reduce morbidity and mortality worldwide. A key factor in the success of these programs is the creation of herd immunity, wherein once a large-enough proportion of the population is immunized, the effective person-to-person transmission of the pathogen is disrupted, thus preventing sustained outbreaks. Such a property of immunization programs means that individuals are not only vaccinated for their own benefit but also for the benefit of others – those who do not develop immunity to vaccines, those who are not vaccinated and those who cannot be vaccinated for medical reasons. School policies requiring immunization for entrance are largely based on this rationale. However, the fact that individuals are vaccinated for the benefit of others, and that governments justifiably use aggressive policies to maintain vaccination rates to protect the public, strongly supports the argument that in the rare instance that an individual is harmed from a vaccination – which they are receiving partly for the public's benefit – they should be provided with just compensation.[4]

Biological

Immunizations have consistently been proven to be extremely safe.[5] However, as they are biologically active agents, the possibility of harm in rare instances exists and has been recognized. Prelicensure studies can usually identify harms in the rate of 1:10,000 but lesser risks can be significant at a population level.[6] Documented risks at lower than the aforementioned rates include thrombocytopenia and anaphylaxis from the MMR vaccine, intussusception from previous rotavirus vaccines, and Guillain-Barré Syndrome from the influenza vaccine.[7] These adverse events, while rare, can have serious impacts on individuals, and while Canada's public health system can cover medical costs, other costs – for example, income replacement, long-term disability, pharmaceutical and outpatient allied health professional services – may not be covered by an individual's private insurance.

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Table 1. Caseload and Compensation Experience From 4 No-fault Compensation Programs (From Program Inception Until 2009)

	Country or Province (Year Implemented)			
	QC (1988)	**UK (1977)**	**US (1988)**	**NZ (2005)**
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 program inception (average per annum)	99 (4.5)	5542 (129)	13,162* (709) *includes 5605 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	0.05	0.3	11
Compensation	Uninsured medical costs, rehabilitation, death benefits	Lump sum £120,000	Annuity for medical costs, lost wages, non-economic losses, attorney's fees	Medical costs, disability pension, death benefits

Source: Adapted from ref. 3.
QC: Quebec; UK: United Kingdom; US: United States; NZ: New Zealand.

Security of Vaccine Manufacturers

One of the primary motivations for the introduction of a vaccine compensation program in the United States (US) was the hostile legal environment that vaccine manufacturers faced, which resulted in numerous vaccine manufacturers ceasing production.[8] Even if vaccine manufacturers are successful in all the claims against them, the legal costs of preparing for the cases can be prohibitive. Compensation programs, depending on how they are structured, can relieve some of the legal pressure on vaccine manufacturers by either prohibiting civil action against manufacturers or requiring that cases first go through the no-fault process. This permits security of vaccine supply as well as an environment in which vaccine innovation can occur. While Canada has traditionally had much less problem with legal action, changes in the Canadian legal environment could create a scenario wherein vaccine companies are placed at increased risk of lawsuits. Given the comparatively small number of vaccine manufacturers operating in Canada, the removal of one manufacturer from the market because of legal concerns would have a serious impact on vaccine supply.

Key components to a Canadian vaccine injury compensation program

Objective and Administration

The principle aim of a Canadian no-fault compensation program should be to fairly compensate those who have a demonstrable injury from vaccines endorsed by public health officials. Vaccines that should be covered would include any recommended by the federal government through agencies such as the National Advisory Committee on Immunization or the Public Health Agency of Canada.

Ideally, the program would be publicly funded and federally run in order to take advantage of economies of scale. To maintain the credibility of the adjudication process in the eyes of the public, we believe it is essential that the program be administered independent of the branches of government responsible for the promotion and safety of vaccines. However, the program should be contained within a public health entity such as the Public Health Agency of Canada, given that much of the expertise in this area would reside in these organizations and the creation of a separate entity would create undesirable duplication of expertise.

Establishing Causation

The first stage of any adjudication process would be to establish that the applicant can meet basic eligibility criteria for compensation. This would include meeting a statute of limitations for filing claims and having sufficient documentation to support a claim. Further, in non-fatal injuries, evidence needs to be presented that the injury resulted in measurable uninsured damages or costs.

If the claimant is determined to be eligible, the second stage would evaluate if his or her injury falls within a table of injuries which consists of known adverse events from vaccination. If a claimant's injury meets the table of injuries criteria – i.e., the case definition for the adverse events, and having occurred during the specified time period following the vaccination – compensation will be provided. In cases where the claim does not fall within the table of injuries, the claimant can request individual case review by a tribunal. The tribunal would be overseen by a Special Master – usually a lawyer who sits in the place of a judge to oversee the proceedings and make determinations according to the law – and would consist of one member selected by the claimant, one by public health authorities and one by consensus. The tribunal would deliberate to determine if causation was met. We would recommend that the primary test for causation in this instance would be a three-pronged test established as precedent in the US courts. This test requires establishing a i) biological theory of harm; ii) logical sequence connecting vaccine to injury; and iii) temporal association of the injury with a vaccine. Furthermore, no other more probable explanation for the injury must exist.[9] In either option, if a claim is determined to meet compensation requirements, a separate federal department would determine the level of compensation based on the nature of the injury and the impact on the individual. Importantly, causation determined in this manner does not necessarily imply biological causation. The adjudication process is a process that is intentionally designed to be a more permissive test in order to encourage plaintiffs to have their cases heard through the program rather than pursuing civil litigation against providers or manufacturers.

Arguments against a vaccine injury compensation program

We foresee two potential arguments against the implementation of a compensation program in Canada: the perception that such a

program may undermine confidence in vaccines; and concerns about the cost of such a program and its relative priority versus other immunization program needs. To date, there is insufficient empirical evidence to support the argument that vaccine compensation programs either improve or decrease vaccine confidence. While the US program has been criticized for lending legitimacy to anti-vaccine arguments, particularly pertaining to vaccine links with autism, we have argued that the courts' impartial adjudication of these claims may have provided credibility to public health officials' assertions of safety.[10,11] Most importantly, in the US instance, the intervention of the courts likely saved the vaccine industry from the enormous costs of litigation related to autism claims. The purpose of vaccine compensation programs should not be framed as impacting vaccine confidence, but rather be primarily considered from an ethical perspective.

When Canada was considering no-fault compensation in the 1980s, a concern was the potential cost of such a program. This was reasonable given the lack of a precedent. However, since then the experience of numerous programs is that costs are both manageable and predictable (Table 1). In the US, costs have been considerably less than expected, resulting in a large surplus from the revenues generated by the excise tax on vaccines that was intended to cover the cost of the program. We estimate that the cost of a program in Canada would be several million dollars per year and this would primarily consist of administrative costs. Of course, if a safety issue with a specific vaccine were to arise, costs would increase, but this would only reinforce the argument for the compensation program.

CONCLUSION

The continued absence of a vaccine injury compensation program in Canada stands out as a gap in vaccine policy. We believe that governments in Canada should strongly consider preemptively introducing such a program before circumstances arise that may force the hasty introduction of a program to address the public's and vaccine manufacturers' concerns.

REFERENCES

1. Evans G. Vaccine injury compensation programs worldwide. *Vaccine* 1999;17(Suppl 3):S25-S35.
2. Canadian Pediatric Society. In support of a compensation plan for vaccine-associated injuries. *CMAJ* 1986;135:747-49.
3. Keelan J, Wilson K. A proposal for a no-fault compensation programme for vaccine injuries. Munk School Briefings. Toronto, ON: Munk School of Global Affairs, February 2011.
4. Rea E, Upshur R. Semmelweis revisited: The ethics of infection prevention among health care workers. *CMAJ* 2001;164(10):1447-48.
5. Public Health Agency of Canada. Canadian Immunization Guide, Seventh Edition, 2006.
6. Fritzell B. Detection of adverse events: What are the current sensitivity limits during clinical development? *Vaccine* 2001;20(Suppl 1):S47-S48.
7. Plotkin SA. Lessons learned concerning vaccine safety. *Vaccine* 2001;20(Suppl 1):S16-S19; discussion S1.
8. Evans G. Update on vaccine liability in the United States: Presentation at the National Vaccine Program Office Workshop on strengthening the supply of routinely recommended vaccines in the United States, February 12, 2002. *Clin Infect Dis* 2006;42(Suppl 3):S130-S137.
9. US Court of Federal Claims. The role of traditional tort law and the impact of Althen, Capizzano, and Pafford on the proof of causation in the vaccine cases. Available at: http://www.uscfc.uscourts.gov/sites/default/files/061025.pdf (Accessed January 31, 2012).
10. Offit PA. Vaccines and autism revisited—the Hannah Poling case. *N Engl J Med* 2008;358(20):2089-91.
11. Keelan J, Wilson K. Balancing Vaccine Science and National Policy Objectives: Lessons From the National Vaccine Injury Compensation Program Omnibus Autism Proceedings. *Am J Public Health* 2011;101(11):2016-21.

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RÉSUMÉ

Bien qu'on en délibère depuis au moins les années 1980, il n'existe pas encore, au Canada, de programme national d'indemnisation pour préjudice causé par la vaccination. L'absence d'un tel programme constitue une lacune dans la politique canadienne d'immunisation par rapport à celle de beaucoup d'autres pays au même stade de développement. Notre article présente l'argumentation en faveur d'un programme d'indemnisation et les éléments structuraux qui conviendraient le mieux à un tel programme dans le contexte canadien.

Mots clés : vaccins; immunisation; mise au point de programmes; indemnisation et réparation; assurance; responsabilité légale