

VACCINATION AND THE LAW

REPORT TO THE MINISTER OF JUSTICE

LAW REFORM COMMISSION OF SASKATCHEWAN
December 2009

The Law Reform Commission of Saskatchewan was established by An Act to Establish a Law Reform Commission, proclaimed in force in November, 1973, and began functioning in February of 1974.

The Commission is incorporated by an Act of the Saskatchewan Legislature. Commissioners are appointed by Order-in Council. Its recommendations are independent, and are submitted to the Minister of Justice for consideration.

Projects are initiated by the Commission in response to suggestions from the public and the legal community, or at the request of the Minister of Justice. After preliminary research, the Commission usually issues background or consultation papers to facilitate consultation. Tentative Proposals may be issued if the legal issues involved in a project are complex. Upon completion of a project, the Commission's recommendations are formally submitted to the Minister as final Proposals.

At present, the Commission is funded primarily by grants from the Law Foundation of Saskatchewan and the Department of Justice.

The Commissioners are:

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1. Introduction

1.1 Scope and purpose

The *Canadian National Report on Immunization (1996)* describes vaccination as "a cornerstone of improving the health of people worldwide," and as "the most cost-beneficial of all prevention strategies, resulting in huge savings to society and to health-care systems." Vaccination against childhood diseases has become routine in Canada, and much of the rest of the world. As the report observes, "for childhood vaccine-preventable diseases, the achieved rates of decrease (compared to the pre-vaccine era) have been remarkable: 95% decrease in incidence (e.g. measles), or total elimination (e.g. polio)."¹ The continuing importance of immunization has been underlined by the rapid spread of new diseases such as SARS, and most recently by the H1N1 global influenza pandemic.

Maintaining a safe, effective immunization program that has the full confidence of the public is a priority for governments and health-care providers. The legal framework in which immunization programs are delivered is one of the factors affecting the success of these programs. In a consultation paper released in 2007, the Commission observed that "several legal issues that have long been part of public and professional discussions of vaccination are beginning to attract increased attention. As concern grows about both the threat of new and re-emerging infectious diseases and vaccine safety, these questions become more pressing."

The Commission thanks all those who responded to the consultation paper. Comments received from health-care professionals, academics, and other members of the public helped us to focus on

¹ Public Health Agency of Canada (PHAC), "Canadian National Report on Immunization, 1996," *Canadian Communicable Diseases Report*, Volume: 23S4 - May 1997.

the issues that most significantly affect public confidence in vaccines and immunization programs, and thus to the success of this critical component of public health.²

1.2 Background and issues

Most people in Saskatchewan, and elsewhere in Canada, take the benefits of vaccination for granted. A national Ipsos-Reid poll in 2001 found that 90% of parents believe children should have all the standard vaccinations, and only 5% believe there is no need for children to be vaccinated.³ It has been observed that in Saskatchewan "the current high level of public trust and acceptance of immunization can be largely attributed to a history of publicly-funded childhood immunization programs by registered nurses committed to quality nursing standards of practice."⁴ The National Advisory Committee on Immunization makes recommendations for vaccination programs, identifying appropriate vaccines and administration procedures. The Saskatchewan Department of Health issues a schedule of vaccines that are provided free of charge to children and specifically targeted groups of adults and seniors. Ninety-five percent of preschool and school age children's vaccinations are administered by public health nurses in Regional Health Authorities and First Nations Health Services.⁵

²In particular, the Commission wishes to thank Professor Heather Heavin and the students in her Legal Issues in Public Administration seminar at the Johnson Shoyama Graduate School of Public Policy, University of Saskatchewan, who reviewed and commented on the consultation paper in detail.

³ Ipsos-Reid, "Childhood Vaccinations: Canada's Largest Ever Survey of Canadian Parents on Their Attitudes Toward Childhood Vaccinations", September 6, 2001.

⁴ Saskatchewan Registered Nurses Association, "Guidelines for Immunization Administration & Immunization Programs," 2004.

⁵ The immunization program is described in the "Guidelines for Immunization Administration & Immunization Programs" (above). Approximately 30% of adult vaccinations are also administered through public health programs.

In the last decade, Saskatchewan has built upon its long-standing childhood immunization program by establishing a vaccination registry and joining a national program to report and monitor adverse effects of vaccinations.⁶ In 2004, the province endorsed the National Immunization Strategy (NIS) developed by Health Canada and Provincial Departments of Health⁷. A provincial registry of vaccination data has been established as the key component of the Saskatchewan Immunization Management System (SIMS).⁸

Nevertheless, public health professionals are concerned about the "sustainability" of vaccination programs.⁹ Many of these concerns relate to the organization, delivery and funding of public health services. But there are broader concerns. In particular, an article in the *Canadian Journal of Public Health* in 2006 observed that:

Ever since the advent of pediatric vaccination, individuals have expressed concerns about both its risks and benefits. These concerns have once again resurfaced among some segments of the population and could potentially

⁶ These innovations follow recommendations of the Canadian National Immunization Conference in 1996. See "Report from the Canadian National Immunization Conference: Immunizing for Health - Achieving Our National Goals" in "Canadian National Report on Immunization," 1996 (above).

⁷ Public Health Agency of Canada (PHAC), "The National Immunization Strategy," Canadian Communicable Disease Report, Volume 30-15, 1 August 2004.

⁸ Rosalie Tuchscherer, "Saskatchewan Immunization Management System: Using Technology to Inform Service Delivery Change," Canadian Immunization Conference, December 2004. SIMS is a confidential, web enabled, computerized information system that collects immunization data about all children receiving services within a Regional Health Authority.

⁹ "The Value of Immunization in the Future of Canada's Health System," submission of the Canadian Public Health Association to the Commission on the Future of Health Care in Canada, October 2001.

undermine national vaccination programs.¹⁰

Despite the attention given by public health authorities to vaccine safety, parental concern appears to be increasing. While opposition to vaccination is not yet as high as in the United States,¹¹ organizations such as the Vaccine Risk Awareness Network advise parents against routine childhood vaccination.¹² Although the public response to the H1N1 immunization program was mostly positive, there was significant resistance to vaccination in Saskatchewan and elsewhere in Canada.

The legal issues considered by the Commission in its consultation paper arise out of public health officials' concerns about the sustainability of vaccination programs and public concerns about the safety of immunizations.

The questions identified in the consultation paper were:

(a) Compensation for vaccine-related injury In Saskatchewan, the courts may award monetary damages to compensate for injury from an adverse effect of vaccination. Experience in other jurisdictions has shown that recovery of damages is uncertain, and often slow. Quebec is the only province in Canada that has established a public compensation program for vaccination injury. It awards compensation for serious injury on no-fault principles, similar to workers' compensation programs, but without premiums to fund it. A similar system has been established in the United States and most western European countries. The Manitoba Law Reform

¹⁰ Kumanan Wilson et. al. "Addressing the Emergence of Pediatric Vaccination Concerns: Recommendations from a Canadian Policy Analysis," *Canadian Journal of Public Health*, March-April, 2006.

¹¹ "Addressing the Emergence of Pediatric Vaccination Concerns" (above).

¹² See the VRAN website (www.vran.org). According to VRAN, it "continues the work of the Committee Against Compulsory Vaccination (formed in Ontario in 1982)."

Commission has recently proposed that Manitoba should adopt a public compensation program.¹³

(b) Mandatory vaccination In Saskatchewan, vaccination is encouraged and advised by health officials, public health nurses and doctors, but it is not ordinarily compulsory. Two Canadian provinces, Ontario and New Brunswick, make scheduled childhood vaccinations mandatory for school attendance. "Mandatory" rather than "compulsory" best describes the vaccination law in these provinces; both allow an exemption if parents object as a matter of "conscience or religious belief," and file a statement to that effect with the proper authorities. Childhood vaccinations are required in all states in the United States. Most have exemptions similar to those in Ontario and New Brunswick.

(c) Informed consent and refusal Public acceptance and confidence in immunization programs require public education. This need has been particularly important in regard to childhood immunization. Parents must receive information about risks and benefits. Ideally, a parent's decision to have a child vaccinated should be informed; and equally, a parent's decision to refuse to have a child vaccinated should be informed. Vaccination is a medical procedure. Like other medical procedures administered in Saskatchewan, it can ordinarily be performed only with the consent of the patient, or in the case of children, with parental consent. The consent requirement is part of the common law. However, the practice varies from providing a pamphlet or information sheet with general information about vaccination to having a more detailed discussion with the patient or parent. Some jurisdictions, including Ontario, have legislated consent requirements.

(d) Reporting adverse effects Saskatchewan takes part in national programs to collect and analyze reports of adverse effects of vaccination. Ensuring that adverse effects are reported is

¹³ Manitoba Law Reform Commission, *Compensation of Vaccine-Damaged Children*, Report #104, 2000.

important both to identify and correct problems, and to give the public confidence that health care officials take adverse effects seriously. As a matter of public policy in Saskatchewan, public health nurses who administer vaccines must report adverse effects of vaccination that come to their attention. However, in Ontario and some other jurisdictions, reporting is required by law, and it applies to all health-care providers. Legal recognition of a duty to report may ensure that the obligation is universally respected, and may also increase public confidence in the vaccination system.

Input from public health authorities and members of the public after release of the consultation paper suggested that:

- (a) Compensation for vaccine-related injuries would be a useful part of the province's public vaccination program, and would increase public confidence in childhood vaccination.
- (b) Expanded educational programs would be useful to help ensure that parents of children eligible for vaccinations and adults who receive vaccinations are fully informed about both the benefits and risks of vaccination.
- (c) A statutory requirement to report adverse effects of vaccination would increase the integrity of vaccination programs.

This report makes recommendations on each of these topics.

There was, however, little enthusiasm for mandatory vaccination. The provincial registry of vaccination established as part of the Saskatchewan Immunization Management System (SIMS) is regarded as a more sophisticated and effective mechanism for monitoring and encouraging childhood vaccinations than making vaccination mandatory for school attendance. The Commission does not recommend adopting a mandatory vaccination requirement in Saskatchewan.

2. Compensation for vaccination damage

2.1 Vaccination and the public good

Immunization programs are a cornerstone of public health. They have been particularly important among infants and children in order to limit the resurgence of diseases that vaccination has made largely a memory in Canada. They are increasingly important as a means to contain the spread of potentially pandemic diseases such as H1N1 influenza. Vaccination is protection for the individuals receiving it. It can also be regarded as a public responsibility, something good citizens do for the collective good.

When most of the high-risk members of a population are immunized, an infectious disease will not be able to spread among those who lack immunization. But when vaccination rates are too low among the high-risk population, those who are not immunized are at risk. If childhood vaccination rates are low, a disease like rubella, which can cause severe birth defects in children of mothers infected in pregnancy, can spread outside the high-risk population of young children to the low-risk population of adults. Immunization is never 100% effective. Even some people who have been vaccinated will contract the disease in an outbreak.

High vaccination rates are required to suppress outbreaks. Health Canada regards the optimum coverage to be 95% of the target population. Ireland saw measles soar to more than 1,200 cases in the year 2000, as compared to just 148 the previous year, because vaccination rates had fallen to around 76%.¹⁴ By international standards, vaccination rates are high in Canada, but they are

¹⁴ See Public Health Agency of Canada, "Vaccine Safety: Frequently Asked Questions" (www.phac-aspc.gc.ca/im/vs-sv/vs-faq_e.html#2).

not uniformly high enough to suppress outbreaks. While nearly 95% of two-year-old children receive the basic childhood vaccinations, a survey in 2002 estimated that only 65% to 75% of seven-year-old children had received all scheduled vaccinations and boosters.¹⁵ Vaccination rates appear to be significantly lower than average among recent immigrants and underprivileged groups.

2.2. Adverse effects of vaccination

The public duty aspect of vaccination would not be problematic if vaccination had no risk attached to it. Vaccination is a relatively safe medical procedure, but, like any medical procedure, there are risks. While most adverse effects are minor and temporary, in a small number of cases severe, potentially life-threatening reactions do occur. In Canada, this kind of reaction is reported in fewer than one in every million doses of vaccine. No long-term effects have been demonstrated to result from any routinely-administered childhood vaccine currently in use in Canada.¹⁶

Vaccines used in Canada are approved and licensed by the Bureau of Biologics and Radiopharmaceuticals of the Health Protection Branch, Health Canada. Vaccines continue to be monitored after approval. The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is a national monitoring system that encourages voluntary reporting of adverse events and suspected adverse events following immunization. In Saskatchewan, Nova Scotia, Ontario, and Quebec, reporting of adverse effects is mandatory. Data collected by

¹⁵ Public Health Agency of Canada (PHAC), "Measuring Up: Results from the National Immunization Coverage Survey 2002," *Canadian Communicable Diseases Report*, Volume 30-05 1 March 2004.

¹⁶ See The Division of Immunization, Laboratory Centre for Disease Control, Health Canada, *Addressing Concerns Regarding Immunization and Vaccines: Questions, Answers and Issues*, Ottawa, n.d. and Public Health Agency of Canada, "Vaccine Safety: Frequently Asked Questions" (www.phac-aspc.gc.ca/im/vs-sv/vs-faq_e.html#2).

CAEFISS is analyzed by computer to identify problems and trends. An Advisory Committee on Causality Assessment (ACCA) meets periodically to review adverse effects data and set criteria for assessment of risks. In addition, Saskatchewan is a partner in a national program, IMPACT (Immunization Monitoring Program ACTive), an active surveillance system that watches for serious adverse events following vaccination. IMPACT operates in 12 paediatric centres across Canada. At each centre, a nurse monitor and clinical investigator perform active case-findings based on a regular review of hospital admissions involving vaccinations.¹⁷

Four to five thousand adverse effects of vaccination are reported in Canada each year. The majority are minor reactions. Mild fever, swelling around the injection point, and persistent crying in infants are the adverse effects most often reported.¹⁸ Common reactions to the widely-administered DTaP (Diphtheria, Tetanus, and acellular Pertussis) vaccine, for example, include local discomfort or inflammation in 20% of cases, and mild fever in 5% of cases. A nodule may develop at the injection site, lasting a few weeks, and up to 70% of those vaccinated develop redness and swelling when booster shots are administered.¹⁹ These problems can be regarded as the normal side-effects of medication, and are, of course, trivial in comparison to the effects of the diseases prevented by vaccination. Diphtheria has a fatality rate of 5% to 10%, tetanus of 10%, and pertussis of 1%. Diphtheria and pertussis are highly contagious, particularly among infants and children. Diphtheria has been nearly eliminated by vaccination, but a few deaths from pertussis are still recorded in Canada each year among unprotected children. Although it is important to monitor minor reactions, in part because they may be early indicators of other safety

¹⁷ Public Health Agency of Canada, "Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)," www.phac-aspc.gc.ca/im/vs-sv/caefiss_e.html, 2006. CAEFISS was formerly known as VAAE.

¹⁸ Public Health Agency of Canada, "Canadian National Report on Immunization, 1996" (9. Surveillance of Adverse Events Temporally Associated with Vaccine Administration), Volume 23S4 - May 1997.

¹⁹ See Public Health Agency of Canada, "Comparison of Effects of Diseases and Vaccines," in *Canadian Immunization Guide - 2002*.

issues, they are unlikely to cause financial loss or impairment of health.

More serious reactions are rare, but they are of greater concern to both parents and public health officials. These include:²⁰

Encephalitis (inflammation of the brain). This reaction requires hospitalization, but the patient usually recovers fully. In a small percentage of cases, encephalitis or other neurological disorder results in permanent brain damage or death. Encephalitis accounts for about .06% of reported adverse effects.

Infection with live virus. Occasionally, live virus vaccines cause symptoms of the disease they are intended to prevent. For example, live oral polio vaccine carries a risk of polio in about one in four million doses of the vaccine administered. This occurs more commonly in unvaccinated adults in contact with vaccinated children than in the children themselves. The use of live polio and cellular pertussis vaccines has been discontinued in Canada in order to prevent resultant infections.²¹

Guillain-Barre syndrome. This condition is characterized by muscle weakness, and, in severe cases, by paralysis. It is a life-threatening condition, and about 30% of patients still have a residual weakness after three years. Guillain-Barre syndrome appears to be occasionally associated with several childhood vaccines, but, because it also occurs in unvaccinated children, causation is difficult to establish. In 1979-80, it was associated with childhood influenza

²⁰ Descriptions of adverse effects are adapted primarily from *Compensation for Vaccine-Related Injuries: A Technical Memorandum*, Congress of the United States, Office of Technology Assessment, Washington, D.C., November 1980. Canadian data is, unless otherwise noted, from "Canadian National Report on Immunization, 1996" (9. Surveillance of Adverse Events Temporally Associated with Vaccine Administration) (above).

²¹ Health Canada, "Comparison of effects of diseases and vaccines," in *Canadian Immunization Guide - 2002*. (above).

vaccination at a reported rate of 1.4 cases per million doses. This compares with the rate of one case per million in the years in which the vaccine was not administered. In Canada, Guillain-Barre syndrome accounts for about 0.07% of reported adverse effects.

Anaphylactic shock. This is a very severe, life threatening form of allergic reaction. Almost all deaths due to anaphylactic shock occur within minutes of vaccination. Thus it is standard procedure to require patients to remain for a short time in the facility after vaccination so that treatment can be administered in case of an anaphylactic reaction. In Canada, anaphylactic shock accounts for 0.37% of reported adverse effects.

Adverse effects are reported to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) when there is a temporal association between the administration of the vaccine and the onset of symptoms.²² It is often difficult in the case of conditions such as the Guillain-Barre syndrome to establish that the condition was caused by the vaccine.

Other serious reactions have been suspected of vaccinations. For example, some parents believe there is a link between thimerosal, used as a preservative in vaccines, and autism. News of this suspected link was widely-publicized by the media and by anti-vaccination organizations. Research now suggests that there is no link, but the use of thimerosal has been discontinued in routine childhood vaccines used in Canada.

2.3 Compensation and public responsibility

It is important to ensure that individuals adversely affected by vaccination receive appropriate compensation. The courts may award damages when injuries have resulted from vaccinations and fault has been proven. However, the case for a public compensation program is well stated in

²² "Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)" (above).

a U.S. Congress report on compensation for vaccine related injuries:

The rationale for compensating victims of vaccine injuries is that such persons have suffered personal tragedy in the pursuit of a public good. Where vaccination is mandatory, vaccine injured persons have sustained their injuries in an effort to comply with the law as well. The purpose of mass immunization programs is not only to protect each single vaccinated individual from a disease but also to provide "herd immunity," a concept which refers to the resistance of a group or population, based on the immunity of a high proportion of individual members of the group to invasion and spread of an infectious agent. Because of "herd immunity," the immunization of the many serves also to protect the few who are not immunized.²³

In the United States, childhood vaccination is mandatory, but the argument for compensation for vaccination injury is no less compelling if vaccination is not mandatory. As the Manitoba Law Reform Commission observed:

[A]lthough vaccination is not compulsory, there is considerable governmental and social pressure to participate in the immunization process. The government promotes, encourages and facilitates the complete vaccination of all children."²⁴

2.4 Is negligence law adequate?

In the United States and western Europe, compensation for serious injury from the adverse

²³ Compensation for Vaccine-Related Injuries, Congress of the United States, Office of Technology Assessment, November 1980.

²⁴ Compensation of Vaccine-damaged Children, Report (above).

effects of vaccination is provided by public compensation programs operating on principles similar to workers' compensation. In Canada, only Quebec has established a public compensation program. Compensation programs have been established both in jurisdictions like the United States and France, that have mandatory vaccination laws, and in jurisdictions such as Quebec and Great Britain, that do not have mandatory vaccination laws. In Saskatchewan and most Canadian provinces, compensation is available only if negligence can be proved in a negligence action.

Negligence is a branch of tort law, developed primarily by the courts over the last two centuries. Negligence law makes a person liable for damage caused by the failure to take reasonable care for the safety of another person. A person who alleges injury from a vaccination can bring a negligence action in the Court of Queen's Bench against the health care provider who administered a vaccine, or against the manufacturer of the vaccine who was negligent in producing the vaccine or in testing it for safety.

Negligence might arise if, for example, a vaccine was administered to a patient with a condition or medical history that contraindicated vaccination. In addition, tort law ordinarily requires health care providers to obtain the informed consent of the patient before administering health care. In the case of a child who is unable to understand the nature and consequences of the proposed treatment, parental consent is ordinarily required in Saskatchewan and other provinces in which vaccination is not mandatory. Failure to obtain proper consent is grounds for legal action. If a vaccine is unsafe, the pharmaceutical company that produced the vaccine is potentially liable under the branch of negligence law known to lawyers as "products liability."²⁵ A manufacturer may be liable if the vaccine was contaminated during the manufacturing process. "Defective design" has also been alleged in vaccination injury cases. Finally, a manufacturer may be liable for failure to provide health care providers, and through them, patients, with sufficient information about the risks associated with a vaccine.

²⁵ See generally, G.H. Luftsping and L. Stoltz, "Product liability in the health care setting: the Canadian way," *Health Law Can.* 2002 Aug 23(1).

Although negligence law provides broad grounds for claiming compensation in vaccination injury cases, it has limitations from the point of view of the plaintiff. It is a fault-based system. The plaintiff must prove that the injury was caused by the defendant's acts or omissions, and that the plaintiff's behaviour fell short of the required standard of care. This may prove to be difficult in many vaccination injury cases. As noted above, adverse effects are reported when there is a temporal link between vaccination and symptoms, that is, when the symptoms appear shortly after the vaccination. In some cases, further research may establish a causal link. But the mechanisms of vaccine damage are not well understood, and causation may be difficult to prove. For example, a link between Guillain-Barre syndrome and vaccination has not been satisfactorily demonstrated in the 20 years since it was suspected. In *Rothwell v. Raes*, the leading Canadian case on vaccine injury, the plaintiff failed because causation between the neurological damage suffered by the plaintiff and the vaccine could not be proved.²⁶ Lack of informed consent may seem to be a less problematic ground. However, causation issues come into play here as well. If the fatal risk cannot be conclusively demonstrated, health care providers do not have to disclose the suspected risk.

Litigation of negligence claims can be costly and time consuming, and the outcomes are often uncertain. The Manitoba Law Reform Commission observed that in *Rothwell v. Raes*:

[T]he trial judgment in favour of the defendants was not rendered until nine years after the vaccine in question was given. An appeal to the Ontario Court of Appeal was dismissed two years later. At trial, there were 50 witnesses who testified for 74 days. It has been estimated that the legal costs of the *Rothwell* litigation exceeded \$1,000,000.²⁷

²⁶ *Rothwell v. Raes* (1988) (above).

²⁷ Compensation of Vaccine-damaged Children (above).

Few vaccine injury claims have been litigated in Canada. Those that have been litigated have not been decided in favour of the plaintiffs. The Quebec case of *Lapierre v. Attorney-General of Québec* is a companion to *Rothwell*. Although in *Lapierre* the court found a causal connection between the vaccination and the injury, the manufacturer of the vaccine was found not to have been negligent. The plaintiff suffered from encephalitis as a result of the vaccine. The risk of encephalitis was known, but the severity of the plaintiff's reaction was deemed to be too unusual to conclude that the vaccine was negligently designed and marketed.²⁸

Experience with tort claims for vaccine damage has been very different in the United States. Prior to adoption of a public compensation program in 1988, there were proportionally more vaccine injury cases. The courts had been flooded with claims as a result of the 1968 swine flu epidemic. Although only a minority of these claims were successful, the courts made large damage awards in some cases. The cost and uncertainty of that litigation for both plaintiffs and defendants were major factors in the decision to establish a public compensation program.²⁹ Prior to 1988, vaccines accounted for 4% to 15% of American pharmaceutical sales, but produced 40% of liability claims and 60% of the insurance costs of the pharmaceutical industry.³⁰ It is reported that:

[T]he companies that produced vaccines were under serious threats of legal action because of media reports of serious injuries or death thought to be related to adverse reactions to vaccines. The potential costs of such lawsuits were more than many vaccine companies were willing to risk, so some companies simply stopped

²⁸ *Lapierre v. Attorney-General of Québec* (1985), 16 D.L.R. (4th) 554 (SCC).

²⁹ Compensation for Vaccine-Related Injuries (Congress of the United States) (above).

³⁰ S.A. Sturges, "Vaccine-Related Injuries: Alternatives to the Tort Compensation System," 30 *St. Louis U.L.J.*, 1986.

making vaccines, resulting in serious vaccine shortages throughout the United States.³¹

In *Rothwell*, the trial judge expressed the opinion that "the normal process of litigation is an utterly inappropriate procedure for dealing with claims of this nature." R. Gaskin, an American commentator, has also concluded that the tort system cannot deal with vaccine damage claims fairly and efficiently:

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.³²

The Manitoba Law Reform Commission is more succinct: "In practical terms, the tort process holds out very little promise for an efficient and fair remedy for those children who suffer vaccine-related injury and illness."³³

³¹ Thomas E. Balbier, Jr. (Director, National Vaccine Injury Compensation Program), *Statement on National Vaccine Injury Compensation Program Before the Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy, and Human Resources*, September 28, 1999.

³² R. Gaskins, "Equity in Compensation: The Case of Swine Flu," *Hastings Center Report*, February, 1980.

³³ Compensation of Vaccine-damaged Children (above).

2.5 Public compensation programs elsewhere

In rejecting the plaintiff's appeal in *Lapierre v. Attorney-General of Québec*, the Supreme Court of Canada observed that, if immunization is regarded as a public responsibility, public compensation would be the fairest way to deal with vaccine injury.³⁴ Quebec established its compensation program in 1987 in response to the perceived failure of the courts in *Lapierre*. Even if the tort system is more adequate than critics suggest, a case might still be made for a public compensation system. The authors of a recent Canadian article, "Addressing the Emergence of Pediatric Vaccination Concerns," identify a public compensation program as a key element in re-establishing public trust in vaccination.³⁵ If the public is expected to risk injury to maintain population immunity, compensation should be based on harm, not negligence, and the public should be able to have confidence that compensation will be made with a minimum of cost and delay. The question is whether a public compensation system can achieve this goal more effectively than the courts.

Public compensation programs for vaccination injury have been established in many nations. These include: Germany (1961), France (1964), Japan (1970), Switzerland (1970), Denmark (1972), New Zealand (1974), Sweden (1978), United Kingdom (1979), Québec (1987), United States (1988), Taiwan (1988), Italy (1992) and Norway (1995).³⁶

The Quebec compensation program³⁷ is typical, but there are some differences in detail among

³⁴ Above.

³⁵ "Addressing the Emergence of Pediatric Vaccination Concerns: Recommendations from a Canadian Policy Analysis" (above).

³⁶ G. Evans, "Vaccine Injury Compensation Programs Worldwide," 17 *Vaccine* 1999.

³⁷ *Public Health Protection Act*, R.S.Q. c. P-35, Division III.1 Indemnities for Victims of Immunizations.

compensation programs. The Quebec program provides compensation for any person who suffers "grave and permanent mental or physical damage" caused by a designated vaccination or by a disease contracted from an immunized person. It also applies to injury as a result of "being a foetus of an immunized person." The vaccines covered by the program are listed in a regulation, which is intended to include all vaccines approved for use in the province. Compensation is assessed by a three-member "medical assessment committee" composed of a physician nominated by the Minister of Health, a physician nominated by the claimant, and a physician nominated by the other two members.

Compensation is awarded on a no-fault basis; that is, negligence need not be proved. However, the applicant must still establish on a balance of probabilities that a causal relationship exists between the vaccination and the injury. Causation questions are approached in a somewhat less strict manner than in the courts. The committee must request the opinion of a specialist in immunology when one of the members of the committee is of the opinion that it is necessary to do so to establish causation. The amount of compensation awarded follows the criteria for payment of benefits under the *Quebec Automobile Insurance Act*, which establishes no-fault compensation for injury in automobile accidents. Benefits include income replacement, compensation for disability, future care costs, rehabilitation costs, and death benefits.³⁸ Receipt of compensation under the program does not preclude the recipient from commencing a negligence action against the manufacturer of the vaccine or the health care provider who administered it for additional damages not covered under the no-fault scheme.

Between 1987 and 2000, 117 vaccination-related claims were made in Quebec, of which 20 were compensated. About \$2.7 million in benefits have been paid out. The average award has been about \$135,000.³⁹ The low success rate for claimants appears to be partly accounted for by

³⁸ *Automobile Insurance Act*, R.S.Q., c. A-25.

³⁹ Manitoba Law Reform Commission, *Compensation of Vaccine-damaged Children* (above).

difficulty in establishing causation, but many claims have been rejected because the injury was not permanent. Thus, for example, Guillain-Barre syndrome claims have been rejected because the claimant's disability was temporary. Half of the awards have compensated individuals who acquired polio from oral vaccines no longer regularly used in Canada.⁴⁰

2.6 Elements of an effective public compensation program

The Quebec example gives rise to several questions about compensation programs.

Scope of coverage. Although childhood immunization programs have attracted the most attention, Quebec compensates all persons injured by all vaccinations in use in the province. The American National Vaccine Injury Compensation Program⁴¹ covers only vaccines routinely administered to children. The British *Vaccine Damage Payments Act*⁴² covers only vaccines administered to persons under the age of 18. The Manitoba Law Reform Commission recommended following the British model, arguing that:

. . . it is appropriate to give priority to vaccine-damaged children. Their age, vulnerability, dependence on substitute decision makers and the importance of the childhood immunization program justify preferential treatment.

However, the Commission also noted that:

⁴⁰ Andre Picard, "Only Quebec pays out for vaccine injuries," *Toronto Globe & Mail*, 18 Nov 2002.

⁴¹ *National Childhood Vaccine Injury Act*, 42 U.S.C.A. §§300aa-1 to -34.

⁴² *Vaccine Damage Payments Act, 1979* (U.K.), 1979, c. 17.

. . . the importance of immunization in the adult community is established and is likely to grow as more "adult" vaccines are introduced. The Commission recognizes the cogency of the argument to include adults within the plan.⁴³

The increasing importance public health programs attach to adult influenza vaccination programs makes the Quebec approach more attractive than programs that apply only to vaccinations administered to people under the age of 18.

Injuries compensated. The Quebec program compensates only "grave and permanent" injury. The British Plan compensates only severe disability (defined as at least an 80% disability). The Manitoba Law Reform Commission recommended compensating "death and serious adverse mental or physical consequences." The American plan is not limited to cases of serious disability. The difference in the American approach is largely accounted for by the absence of universal medicare in the United States. A significant part of claims under the American program are made to recover medical expenses. Most of the minor adverse effects of vaccination can be regarded as acceptable side effects. If public health insurance covers required medical treatment, there is no strong policy reason to compensate further.

In one respect the Quebec formula is questionable. Because it requires permanent disability, it does not compensate for loss of income when a vaccine-induced injury is debilitating but only temporary. Most patients recover from Guillain-Barre syndrome, but may suffer from paralysis and debilitating muscle weakness for months. The permanent disability threshold might be acceptable in a program that covers only children. However, in a program that covers adults, where significant financial consequences may result from temporary disability, the permanent disability threshold is less acceptable.

All compensation programs except the American program limit compensation to loss of income

⁴³ Compensation of Vaccine-damaged Children (above).

and loss of expenses incurred as a result of disability. The American program allows recovery of up to \$250,000 for pain and suffering. This, combined with coverage of medical expenses, makes for much higher awards in the United States than other jurisdictions. For example, in 2003, the average award was \$1,427,169, compared to \$134,000 in Quebec and \$63,000 in Britain.⁴⁴

Limiting compensation to actual loss is usually regarded as an essential feature of no-fault compensation programs. The American program likely included pain and suffering awards because it was devised to completely replace tort actions. The American program, unlike the Quebec and British programs, prohibits tort actions when a claim for compensation has been made under the program.

Proof of injury. Although all vaccination injury compensation programs operate on the no-fault principle, they approach the question of causation in different ways. The Quebec compensation program requires proof of a causal link between the vaccination and the injury in all cases. As noted above, it is sometimes difficult to prove that symptoms occurring after vaccination were caused by the vaccination. It has been suggested that causation problems undermine the no-fault principle because it makes it difficult to determine whether a "compensable event" has occurred:

It is a thorny issue for medical accidents generally in that the definition of a compensable event seems sufficiently similar to the fault standard in tort to reproduce the uncertainties and attendant administrative costs of that system thus negating much of the advantage of no-fault.⁴⁵

The American compensation program attempts to reduce the causation problem to a formula in as many cases as possible by using a "Table of Injuries" specifying known adverse reactions

⁴⁴ Betty Pang, "The National Vaccine Injury Compensation Program: A Program Evaluation," *Harvard Law*, April 29, 2003.

⁴⁵ Craig Brown, "Hepatitis C: Eight Questions About No-fault Compensation for Blood-Product Harm", 18 *Windsor Y.B. Access. Just.* 217, (2000).

associated with specific vaccines within a given time period. If the complainant's injury is recognized in the Table, the presumption of causation is in the complainant's favour.

The Table of Injuries approach simplifies causation issues. In some cases, a statistical probability based on a temporal connection is the best medical science can do to establish a link between vaccination and harm.

2.7 Recommendations: Compensation

1. Saskatchewan should establish a program to compensate members of the public injured by the adverse effects of vaccination.
2. The program should be similar to the vaccination compensation programs in place in Quebec and England.
3. Compensation should be awarded by a Compensation Board established to administer the program.
4. Compensation should be awarded without requiring proof of negligence.
5. Compensation should be available for adverse effects resulting from all vaccines approved for use and administered in the province.
6. Compensation should be awarded to all persons injured by vaccinations when death or serious adverse mental or physical consequences (whether temporary or permanent) result from the vaccinations.
7. The Compensation Board should develop a "Table of Injuries" specifying known adverse

reactions associated with specific vaccines. If the complainant's injury is recognized in the Table, it should be presumed that vaccination caused the injury.

8. Compensation should not be made for pain and suffering or medical expenses otherwise covered by medicare.

9. Payment of compensation should not bar an injured party from claiming additional damages in tort from the manufacturer of a vaccine or the health-care provider who administered it.

3. Informed consent and informed refusal

Public acceptance and confidence in vaccination programs require that the public be educated. Both adult candidates for vaccination and parents of children receiving childhood immunizations must receive adequate information about the risks and benefits associated with vaccinations. A parent's decision to vaccinate should be informed; equally, a parent's decision to refuse vaccination should be also informed. The law requires that medical procedures can ordinarily be performed only if the patient or the patient's parent has given informed consent. The legal consent requirement should contribute to the public education effort. In practice, however, the legal consent requirement may not be effective to achieve either its legal purpose or a broader educational function.

Some jurisdictions have legislated consent requirements, setting out the procedures for ensuring that a consent is informed. Such legislation may contribute to establishing uniform practices and may help satisfy public concerns. There may be more the law can do to encourage a climate in which both consent and refusal are based on adequate information.

3.1 The current law in Saskatchewan

Vaccination is a medical procedure. In Saskatchewan, it can ordinarily be performed only with the consent of the patient, or in the case of younger children, with parental consent. A substitute decision-maker may be named by a prospective patient to act if the patient is no longer competent to give consent.

In Saskatchewan, consent requirements are not legislated. Instead, they are part of the common

law that has evolved through judicial decisions.

The courts have said that consent is valid only if the patient has been fully informed of the risks and benefits of the proposed procedure. In a leading case, the court held that:

Without a consent, either written or oral, no surgery may be performed. This is not a mere formality; it is an important individual right to have control over one's own body, even where medical treatment is involved. It is the patient, not the doctor, who decides whether surgery will be performed, where it will be done, when it will be done and by whom it will be done.⁴⁶

For consent to be informed, the patient must be given sufficient information to weigh the risks and benefits. In *Reibl v. Hughes*, the Supreme Court of Canada held that the test is whether "the reasonable person in the patient's position, knowing of the risks, would have consented to the treatment."⁴⁷ Very remote or improbable risks do not need to be disclosed, but the degree of improbability required to allow them to be disregarded depends on the seriousness of the risk.⁴⁸

Despite the established consent requirement in the common law, critics suggest that vaccinations are often performed without adequate disclosure of risks. The anti-childhood immunization group, Vaccine Awareness Network, asserts that "frequently parents find themselves coerced, or bullied into a decision to vaccinate their children, often against their own better judgment, and without the opportunity to adequately weigh all the risks."⁴⁹ Public health officials regard these views as overstatements at the very least, but even supporters of immunization programs have

⁴⁶ *Allan v. New Mount Sinai Hospital* (1980), 28 O.R. 356.

⁴⁷ *Reibl v. Hughes*, [1980] 2 S.C.R. 880.

⁴⁸ *Kitchen v. McMullen* (1989), 100 NBR (2d) 91.

⁴⁹ Compensation of Vaccine-damaged Children (above).

expressed concerns about the quality of information provided.

Part of the problem is applying the informed consent rules to vaccination. The extent of the required disclosure is perhaps uncertain, and practice varies. In most cases, a printed brochure or information sheet is given to the patient or parent of the patient. It may be included in a "consent form" the patient or parent is asked to sign. The administering health care professional may, but may not, explain the printed information, and additional information may be offered only if it is requested. The extent of disclosed risk varies, from a description of common side-effects, to warnings of symptoms of more serious reactions.

Simply making brochures or printed consent forms available may not be adequate to meet either public expectations or legal requirements. The Manitoba Law Reform Commission commented that:

Ultimately . . . the health care professional is obliged to see that the requisite information has been communicated and understood. Undue reliance on written brochures is, therefore, dangerous. The extent and degree of disclosure of the risks of vaccines is high because the recipient is not ill.⁵⁰

Similarly, because consent cannot be fully informed unless it relates directly to the proposed treatment, reliance on general consents to medical care is questionable. A survey of influenza immunization programs in Alberta long-term care facilities found that:

One-third of the facilities (44/133 [33.1%]) reported that they had written policies on vaccination of residents. Most of the facilities providing information about consent for vaccination (77/130 [59.2%]) required verbal consent from residents or their relatives (or both), 14 (10.8%) required written consent, and 39 (30.0%)

⁵⁰ Vaccine Awareness Network web-site (above).

did not require any consent. Several facilities of the last group commented that they either obtained consent for annual vaccination at the time of admission or required residents to actively refuse rather than actively consent to vaccination.⁵¹

3.2 The current law in Ontario

Ontario has partially codified and extended the rules governing consent to medical treatment. One of the stated purposes of the *Health Care Consent Act, 1996* is "to provide rules with respect to consent to treatment that apply consistently in all settings."⁵² The *Act* sets out general rules defining the "elements of consent" and "informed consent" that address many of the concerns discussed above:

11. (1) The following are the elements required for consent to treatment:
 1. The consent must relate to the treatment.
 2. The consent must be informed.
 3. The consent must be given voluntarily.
 4. The consent must not be obtained through misrepresentation or fraud.
- (2) A consent to treatment is informed if, before giving it,
 - (a) the person received the information about the matters set out in subsection

⁵¹ Margaret L. Russell, "Influenza vaccination in Alberta long-term care facilities" *Canadian Medical Association Journal*, 2001 May 15; 164(10).

⁵² S.O. 1996, Chapter 2, s. 1(a). Another purpose of the legislation is to provide for substitute decision making for patients who are incapable of consenting to health care, subject matter addressed in Saskatchewan by *The Health Care Directives and Substitute Health Care Decision Makers Act*, S.S. 1997, c. H-0.001.

(3) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and

(b) the person received responses to his or her requests for additional information about those matters.

(3) The matters referred to in subsection (2) are:

1. The nature of the treatment.
2. The expected benefits of the treatment.
3. The material risks of the treatment.
4. The material side effects of the treatment.
5. Alternative courses of action.
6. The likely consequences of not having the treatment.

Although the *Health Care Consent Act 1996* does not refer expressly to vaccinations, it appears to have affected vaccination practices in Ontario. Health care regions and other health care administrators have adopted uniform guidelines for informing patients and parents that reflect the requirements of the legislation. For example, the Ontario College of Nurses has adopted these guidelines for administering influenza vaccinations:

According to the *Health Care Consent Act* and the College of Nurses of Ontario (the College) standards, nurses are accountable for obtaining consent for the interventions they provide. Consent for flu vaccination must relate to the treatment being proposed, be informed, be voluntary, and not have been obtained through misrepresentation or fraud. To give informed consent, the client must be provided with the information necessary to make a decision to consent to or refuse the vaccine. This information must include the following: the nature of the treatment; expected benefits of the treatment; material risks and adverse effects of

the treatment⁵³

3.3 Options

Stricter application of the informed consent requirement would address some of the public concern about vaccination safety. However, some health care practitioners are concerned that increased emphasis on risks and adverse effects may discourage parents from immunizing their children. It appears that some parents are disturbed when risks are described and expressed statistically, even if the risk is very small. But most parents are willing to accept risks that are well within the range recognized by public health officials. Eighty-six percent of mothers in an Ontario study stated that they would accept a risk ranging from one adverse event per 100,000 to 1 million in routine childhood vaccinations.⁵⁴ Adults appear to be less risk-averse when considering vaccinations for themselves. The Alberta study of vaccination practices in long-term care homes found no correlation between practices for obtaining consent and vaccination rates. An American study found that informing adult patients of the possible risks of Guillain-Barre syndrome did not significantly increase refusal rates.⁵⁵

If informed consent legislation or guidelines improved the quality of information given to parents and patients, it would serve an educational purpose. The public would better understand the benefits as well as the risks.

⁵³ College of Nurses of Ontario, *Practice Guideline: Influenza Vaccinations*, 2009.

⁵⁴ "Determinants of Maternal Tolerance of Vaccine-Related Risks" (above). See also Sanford R. Kimmel, "Vaccine adverse events: separating myth from reality," *American Family Physician*, Dec 1, 2002.

⁵⁵ "Influenza vaccination in Alberta long-term care facilities." Other studies have, perhaps not surprisingly, found that "standing orders" for vaccination without obtaining consent in individual cases does affect vaccination rates among elderly patients in nursing homes. See M. A. McArthur *et. al.*, "Influenza vaccination in long-term-care facilities: structuring programs for success," *Infect Control Hosp Epidemiol*. 1999 Jul;20(7).

The Commission's Consultation Paper considered legislating "informed refusal," which would require parents, before refusing vaccinations, to consider approved sources of information about the benefits as well as the risks of vaccination. Such an approach has been adopted in some states in the United States.⁵⁶

The Commission is of the opinion that an informed refusal approach is inappropriate in Saskatchewan. Improved formal consent guidelines would probably do as much to educate parents and patients about the benefits of vaccination as an informed refusal approach.

3.4. Recommendations: Informed consent and informed refusal

1. Clear guidelines governing informed consent to vaccination should be developed and implemented, but need not be legislated.
2. The guidelines should incorporate and clarify the existing law of consent to medical care as it applies to vaccination.

⁵⁶ R.D. Silverman, "No more kidding around: Restructuring non-medical childhood immunization exemptions to ensure public health protection," *Ann. Health Law*, 2003 Summer;12(2).

4. Reporting adverse effects

4.1 Current law and policy in Saskatchewan

Saskatchewan takes part in national programs to collect and analyze reports of adverse effects of vaccination. Ensuring that adverse effects are reported is important, both to identify and correct problems, and to give the public confidence that health care officials take seriously the adverse effects of vaccinations. Critics of childhood vaccination argue that inadequate reporting makes it difficult to properly assess risks, and some allege that risks are hidden from the public by failure to report vaccine-related injury.

In Saskatchewan, reporting of adverse effects by the public health nurses who administer most vaccinations is required as a matter of policy. However, in Ontario, mandatory reporting is required by law, and applies to physicians, nurses and pharmacists. The *Health Protection and Promotion Act*⁵⁷ provides:

38 (3) A physician, a member of the College of Nurses of Ontario or a member of the Ontario College of Pharmacists who, while providing professional services to a person, recognizes the presence of a reportable event and forms the opinion that it may be related to the administration of an immunizing agent shall, within seven days after recognizing the reportable event, report thereon to the medical officer of health of the health unit where the professional services are provided.

⁵⁷ R.S.O. 1990, c. H.7.

(4) A medical officer of health who receives a report under subsection (3) concerning a person who resides in another health unit shall transmit the report to the medical officer of health serving the health unit in which the person resides.

In addition, the *Act* lists "reportable events" and requires physicians, nurses and pharmacists to inform patients of symptoms of adverse effects that should be reported.

Providing for mandatory reporting of adverse effects would help ensure that the obligation to report is universally respected and would also increase public confidence in vaccinations programs.

4.2 Recommendation: Reporting adverse effects

1. Reporting of the adverse effects of vaccinations by all health care providers should be required by legislation.

SUMMARY OF RECOMMENDATIONS

Compensation for injury caused by vaccination

1. Saskatchewan should establish a program to compensate members of the public injured by the adverse effects of vaccination.
2. The program should be similar to the vaccination compensation programs in place in Quebec and England.
3. Compensation should be awarded by a Compensation Board established to administer the program.
4. Compensation should be awarded without requiring proof of negligence.
5. Compensation should be available for adverse effects resulting from all vaccines approved for use and administered in the province.
6. Compensation should be awarded to all persons injured by vaccinations when death or serious adverse mental or physical consequences (whether temporary or permanent) result from the vaccinations.
7. The Compensation Board should develop a "Table of Injuries" specifying known adverse reactions associated with specific vaccines. If the complainant's injury is recognized in the Table, it should be presumed that vaccination caused the injury.
8. Compensation should not be made for pain and suffering or medical expenses otherwise

covered by medicare.

9. Payment of compensation should not bar an injured party from claiming additional damages in tort from the manufacturer of a vaccine or the health-care provider who administered it.

Consent and informed refusal

1. Clear guidelines governing informed consent to vaccination should be developed and implemented, but need not be legislated.

2. The guidelines should incorporate and clarify the existing law of consent to medical care as it applies to vaccination.

Reporting adverse effects

1. Reporting of the adverse effects of vaccinations by all health care providers should be required by legislation.