

**Law Reform Commission of Saskatchewan**

**September, 2007**

**Consultation paper: Vaccination and the Law**

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## 1. Introduction

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).” Vaccination was responsible for the global eradication of smallpox in 1977.<sup>1</sup>

Most people in Saskatchewan, and elsewhere in Canada, now 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.”<sup>2</sup> 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.”<sup>3</sup> 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

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<sup>1</sup>Public Health Agency of Canada (PHAC), “Canadian National Report on Immunization, 1996,” *Canadian Communicable Diseases Report*, Volume: 23S4 - May 1997.

<sup>2</sup>Ipsos-Reid, *Childhood Vaccinations: Canada’s largest ever survey of Canadian parents and their attitudes toward childhood vaccinations*, September 6, 2001.

<sup>3</sup>Registered Nurses Association of Saskatchewan, “Guidelines for immunization administration & immunization program,” 2004.

effects of vaccinations.<sup>4</sup> In 2004, the province endorsed the National Immunization Strategy (NIS) developed by Health Canada and Provincial Departments of Health.<sup>5</sup>

Relatively high rates of childhood vaccination are maintained through publicly funded childhood immunization programs. 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 will be provided free of charge to children and specifically targeted groups of adults and seniors. 95% of preschool and school age vaccinations are administered by public health nurses in Regional Health Authorities and First Nations Health Services.<sup>6</sup> Following the recommendations of the National Immunization Strategy, a provincial registry of vaccination data has been established as the key component of the Saskatchewan Immunization Management System (SIMS).<sup>7</sup>

Nevertheless, public health professionals are concerned about the “sustainability” of vaccination programs.<sup>8</sup> Many of these concerns are matters of the organization, delivery, and funding of public

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<sup>4</sup>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).

<sup>5</sup>Public Health Agency of Canada (PHAC), “The National Immunization Strategy,” *Canadian Communicable Diseases Report*, Volume 30-15, 1 August 2004

<sup>6</sup> The immunization program is described in the “Guidelines for immunization administration & immunization program” (above). Approximately 30% of adult vaccinations are also administered through public health programs.

<sup>7</sup>Rosalie Tuchscherer, “Saskatchewan Immunization Management System,” *Canadian Immunization Conference*, Nov 2004. “SIMS is a computerized immunization database. SIMS is a confidential, web enabled, computerized information system that collects immunization data about all children receiving services within a Regional Health Authority.”

<sup>8</sup> “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.

health services. But there are also broader concerns. In particular, both public complacency about the importance of vaccination, and doubts about the safety and effectiveness of vaccines, appear to be increasing. The Canadian Public Health Association suggests that:

Understanding the true value of vaccines is difficult when members of a society can no longer recall the impact, and fear, of a disease that seems to have vanished from their lives. It is imperative, therefore, that parents of young children understand the importance of maintaining a schedule of vaccinations for their children, and that adults recognize the importance of timely booster doses of selected vaccines.<sup>9</sup>

A recent article in the *Canadian Journal of Public Health* observes 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 undermine national vaccination programs.<sup>10</sup>

Public health officials point out that high rates of vaccination coverage are required to prevent outbreaks. This is a result of what is sometimes called the “herd effect.” When most of the population that is most at risk is immunized, an infectious disease will not be able to spread in the population to those who lack immunization. But when vaccination rates are too low to produce the herd effect, those who are not immunized are at risk. It is important to note that it is not only those who have refused scheduled vaccinations who may become ill in an outbreak. Immunization is never 100% effective, so some individuals who have been vaccinated will contract the disease in an outbreak. In addition, 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 adults if childhood vaccination levels are low.

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<sup>9</sup>“The Value of Immunization in the Future of Canada's Health System” (above).

<sup>10</sup>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.

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 with just 148 the previous year, because immunization rates fell to around 76%.<sup>11</sup> By international standards vaccination rates are high in Canada, but they are not uniformly high enough to suppress outbreaks. While nearly 95% of children two years of age receive the basic childhood vaccines, a survey in 2002 estimated that only 65% -75% of children seven years of age had received all scheduled vaccines and boosters.<sup>12</sup> Vaccination rates appear to be significantly lower than average among recent immigrants and underprivileged groups.

Vaccination is a relatively safe medical procedure. Most adverse effects are minor and temporary, such as swelling or soreness about the vaccination site. Severe allergic, possibly life-threatening, reactions do occur, but in Canada this kind of reaction is reported in less than one in every one million doses of vaccine. No long-term effects have been demonstrated to result from any routinely-administered childhood vaccine currently in use in Canada. Health care professionals argue that the dangers of vaccine-preventable diseases are many times greater than the risks of a serious adverse reaction to the vaccine.<sup>13</sup>

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 for reporting adverse events and suspected adverse events following immunization. Adverse effects are reported to CAEFISS by health care

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<sup>11</sup>See Public Health Canada, *Vaccine Safety: Frequently Asked Questions* ([www.phac-aspc.gc.ca/im/vs-sv/vs-faq\\_e.html#2](http://www.phac-aspc.gc.ca/im/vs-sv/vs-faq_e.html#2)).

<sup>12</sup>Public Health Agency of Canada (PHAC), “Measuring Up: Results from the National Immunization Survey 2002,” *Canadian Communicable Diseases Report*, Volume 30-05 1 March 2004.

<sup>13</sup>See The Division of Immunization Laboratory Centre for Disease Control, *Addressing Concerns Regarding Immunization and Vaccines*, Ottawa, n.d. and Public Health Canada, *Vaccine Safety: Frequently Asked Questions* ([/www.phac-aspc.gc.ca/im/vs-sv/vs-faq\\_e.html#2](http://www.phac-aspc.gc.ca/im/vs-sv/vs-faq_e.html#2)).

providers. In Saskatchewan, Nova Scotia, Ontario, and Quebec, reporting of adverse effects is mandatory. Data collected by 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 for serious adverse events following vaccination. IMPACT operates in 12 pediatric centres across Canada. At each centre a nurse monitor and clinical investigator perform active case-findings based on a regular review of admissions involving vaccinations.<sup>14</sup>

However, despite the attention given by public health authorities to vaccine safety, there are real risks. Parental concern about vaccination safety appears to be increasing. While opposition to vaccination is not yet as high as in the United States,<sup>15</sup> organizations such as the Vaccine Risk Awareness Network advise parents against routine childhood vaccination.<sup>16</sup>

The importance attached to achieving universal vaccination by public health professionals and the real and perceived risks of vaccination raise questions about the balance between public needs and private rights. As concern grows about both the threat of new and reemerging infectious diseases and vaccine safety, these questions become more pressing. Several legal issues that have long been part of public and professional discussion of vaccination are beginning to attract increased attention. These issues are the topic of this consultation paper.

**Compensation for vaccine-related injury** – In Saskatchewan, the courts may award monetary damages to compensate for injury from an adverse effect of vaccination under the general law of

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<sup>14</sup>Public Health Agency of Canada, “Canadian Adverse Events Following Immunization Surveillance System (CAEFISS),” [www.phac-aspc.gc.ca/im/vs-sv/caefiss\\_e.html](http://www.phac-aspc.gc.ca/im/vs-sv/caefiss_e.html), 2006. CAEFISS was formerly known as VAAE.

<sup>15</sup>“Addressing the Emergence of Pediatric Vaccination Concerns” (above).

<sup>16</sup>See the VRAN website ([www.vran.org](http://www.vran.org)). According to VRAN, it “continues the work of the Committee Against Compulsory Vaccination (formed in Ontario in 1982).”

negligence and products liability. 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 the basis that the injury has occurred, similar to workers' compensation programs. A similar system has been established in the United States and several European countries. The Manitoba Law Reform Commission has recently proposed that Manitoba should adopt a public compensation program<sup>17</sup>.

**Mandatory vaccination** – While vaccination is encouraged and advised by health officials, public health nurses, and doctors, it is not compulsory in Saskatchewan. 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 have filed 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. Advocates of mandatory vaccination argue that it makes an important contribution to ensuring the coverage necessary to protect the population from out-breaks of preventable diseases.

**Informed consent and refusal** – There can be little doubt that public acceptance of and confidence in childhood vaccination programs require public education and dissemination of information about risks and benefits to parents. Ideally, a parent's decision to vaccinate should be informed; and equally, a decision to refuse vaccination should be informed. Vaccination is a medical procedure. In Saskatchewan, it can ordinarily only be performed, like other medical procedures, with the consent of the patient, or in the case of children, with parental consent. The consent requirement is part of the common law, and has evolved through judicial decisions. The courts have insisted that consent is valid only if the patient has been fully informed of the risks and benefits of the proposed procedure. Applying this rule to vaccination is sometimes difficult. Practice appears to vary, from providing a pamphlet or information sheet with general information about vaccination, to more

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<sup>17</sup>Manitoba Law Reform Commission, *Compensation of Vaccine-damaged Children*, Report #104, 2000.

detailed discussion with the patient or parent. Some parents do not believe they are given adequate information. Some jurisdictions, including Ontario, have legislated consent requirements. Legislation may contribute to establishing uniform practices and help satisfy public concerns.

The role of consent is of course somewhat different if vaccination is mandatory. Parents are still able to refuse vaccination for their children in Ontario and other jurisdictions with similar childhood vaccination regimes, but the vaccination may be administered without positive consent if the parent has not filed a statement in the approved form to claim an exemption. This may contribute to a sense that vaccination programs have not been fully justified to the public. On the other hand, some advocates of mandatory vaccination are concerned that parents can refuse vaccination without being informed about benefits. They suggest that parents should be able to claim an exemption only on the basis of an “informed refusal.” It can be argued that, whether vaccination is mandatory or not, public acceptance of childhood vaccination programs would be increased if more attention was given to providing full information about risks and benefits in a timely fashion.

**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 important, both to identify and correct problems, and to give the public confidence that health care officials take adverse effects seriously. 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, mandatory reporting by public health nurses who administer most childhood vaccines is, as a matter of policy, mandatory. However, in Ontario and some other jurisdictions, mandatory reporting is required by law, and applies to all health-care providers. Legal recognition of a duty to report may ensure that the obligation is universally respected, and increase public confidence.

The Commission believes these are important issues. As a result of recent outbreaks of both old and new infectious diseases, both public health officials and the public are giving renewed attention to vaccination. The issues outlined above impact both the effectiveness of vaccination programs and

public confidence in them. If vaccination is recognized as a public good and a public duty, the public must be satisfied that it is as safe and efficient as possible, and that children and other citizens who suffer injury as a result of vaccination programs are compensated in a fair manner. The law cannot and should not dictate medical policy and procedures. It can, however, provide a legal framework that contributes to efficiency, safety, and public confidence.

The balance of this report provides background information that the Law Reform Commission of Saskatchewan believes will assist the reader in responding to a number of questions relating to four major issues: Compensation for Vaccine Damage, Mandatory Vaccination, Informed Consent and Informed Refusal, and Reporting Adverse Effects. The Commission solicits your feedback in relation to these issues. The specific questions the Commission has posed are summarized here, and are repeated after each section of the report. The Commission welcomes any comments or questions you may have in relation to these questions, and in relation to any other aspect of the subject of vaccination that you wish to comment upon. Contact information for the Commission can be found at the beginning of this report.

## **2. Summary of Consultation Questions**

### Compensation for Vaccine Damage:

1. Should a publicly-funded program be established in Saskatchewan to compensate individuals who suffer vaccine-related injuries?
  
2. If a public compensation program is established, should it apply to:
  - (a) Approved childhood vaccinations?
  - (b) All approved vaccinations regardless of the age of the victim?
  
3. Should compensation be provided for:
  - (a) Permanent disability and death?
  - (b) Death and disability, whether permanent or not?
  - (c) Any loss resulting from an adverse effect of vaccination?
  - (d) Pain and suffering?
  
4. Should proof of claims be simplified by use of a Table of Injuries or similar approach to avoid the need to provide proof of the causal link between vaccination and harm in individual cases?

### Mandatory Vaccination:

5. Should approved childhood vaccinations be a mandatory requirement for school attendance in Saskatchewan?
  
6. If vaccination is mandatory, should exemptions be permitted
  - (a) On religious grounds?
  - (b) On other conscientious grounds?
  - (c) Only if the applicant for exemption has been informed of the benefits and risks of

vaccination?

Informed Consent and Informed Refusal:

7. Do current practices provide enough information about risks and benefits to assist parents and patients to give informed consent to vaccinations?

8. Should Saskatchewan enact guidelines governing informed consent similar to those in the Ontario *Health Care Consent Act*?

9. Should parents be required to consider information about risks and benefits before refusing vaccination of their children?

Reporting Adverse Effects:

10. Should Saskatchewan enact legislation requiring health care providers to report all adverse effects of vaccinations?

### **3. Compensation for vaccine damage**

#### **A. Introduction**

Vaccination is a cornerstone of public health. Broad coverage of target populations, optimally 95%, is regarded by public health officials as the most effective means of preventing outbreaks of infectious diseases. Immunization of infants and children is particularly important to limit the resurgence of diseases that vaccination has made largely a memory in Canada.<sup>18</sup> Vaccination is not only encouraged to protect the individuals receiving it. Public health authorities present it to the public as a responsibility, something good citizens do for the collective good.

The public duty aspect of vaccination would not be problematic if vaccination had no risk attached to it. But like any medical procedure, there are risks in vaccination, which may rarely be disabling or life-threatening. For that reason, it is important to ensure that individuals adversely affected by vaccination receive appropriate compensation for injury caused by vaccination. A report on compensation for vaccine related injuries issued by the U.S. Congress put the case for compensation well:

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

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<sup>18</sup>See above, Introduction.

the many serves also those not immunized.<sup>19</sup>

In the United States, childhood vaccination is mandatory, but the argument is no less compelling if vaccination is not mandatory. As the Manitoba Law Reform Commission observed, “although 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.”<sup>20</sup>

In the United States and Western Europe, compensation for serious injury from the adverse effects of vaccination is provided by public compensation programs operating on principles similar to workers’ compensation. In Canada, a public compensation program has been established only in Quebec. Compensation programs have been established both in jurisdictions like the United States and France in which vaccination is mandatory, and in jurisdictions such as Quebec and Great Britain, which do not have mandatory vaccination laws.

In Saskatchewan and most Canadian provinces, compensation is available if negligence can be proved in a negligence action brought in court. Whether negligence law provides adequate and appropriate compensation will be discussed below.

## **B. Adverse effects of vaccination**

4,000 to 5,000 adverse effects of vaccination are reported in Canada each year. The majority are minor reactions. Mild fever, swelling about the injection point, and persistent crying in infants are

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<sup>19</sup>*Compensation for Vaccine-Related Injuries*, Congress of the United States, Office of Technology Assessment, November 1980.

<sup>20</sup>*Compensation of Vaccine-damaged Children*, Report (above).

the adverse effects most often reported.<sup>21</sup> 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%. A nodule may develop at the injection site, lasting a few weeks, and up to 70% develop redness and swelling when booster shots are administered.<sup>22</sup> 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 5-10%, 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 issues, they are unlikely to cause financial loss or impairment of health.

More serious reactions are rare, but of greater concern to both parents and public health officials. These include:<sup>23</sup>

**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.

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<sup>21</sup>“Canadian National Report on Immunization, 1996” ( 9. Surveillance of Adverse Events Temporally Associated with Vaccine Administration) (above).

<sup>22</sup>See Health Canada, “Comparison of effects of diseases and vaccines,” in *Canadian Immunization Guide - 2002*.

<sup>23</sup> Descriptions of adverse effects are adapted primarily from *Compensation for Vaccine-Related Injuries* (Congress of the United States) (above). Canadian data is, unless otherwise noted, from “Canadian National Report on Immunization, 1996” ( 9. Surveillance of Adverse Events Temporally Associated with Vaccine Administration) (above).

**Infection with live virus.** Some live virus vaccines rarely 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 4,000,000 doses of the vaccine administered, 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.<sup>24</sup>

**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 percent of patients still have a residual weakness after three years. Guillain-Barre syndrome appears to be rarely 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 vaccination, but the reported rate of 1.4 cases per million doses compares with the rate of one per million in the years in which the vaccine was not administered. In Canada, Guillain-Barre accounts for about 0.07% of reported adverse effects.

**Anaphylactic shock** (very severe form of allergic reaction). This is a life threatening 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.

Note that adverse effects are reported to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) when there is a temporal association between administration of the vaccine and symptoms.<sup>25</sup> 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.

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<sup>24</sup>Health Canada, “Comparison of effects of diseases and vaccines,” in *Canadian Immunization Guide - 2002*. (above).

<sup>25</sup> “Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)” (above).

There are other serious conditions that have been suspected of an association with vaccination. A possible link between thimerosal, used as a preservative in vaccines, and autism has caused concern among parents, and has been widely-publicized both in 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.

### **C. Is negligence law adequate?**

The law of negligence is a branch of tort law, developed primarily by the courts over the last two centuries. In general, tort law imposes liability on persons who cause death or injury. Negligence law imposes liability for damage caused by failure to take reasonable care for the safety of another person. The remedy is an award of damages. An action in tort could be brought in a vaccine injury case against a health care provider who negligently administered a vaccine, or against the manufacturer of a vaccine who was negligent in producing the vaccine or in testing it for safety.

The standard of care applied to health care providers requires them “to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing.”<sup>26</sup> 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. Consent is not a formality. For consent to be informed, the patient must be given sufficient information to weigh the risks and benefits.<sup>27</sup> Failure to obtain informed consent will lead to an award of damages even if the vaccine was not

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<sup>26</sup>*Crits v. Sylvester* (1956), 1 DLR (2nd) 502 at 508 (Ont. CA), aff’d [1956], SCR 991.

<sup>27</sup>For further discussion of consent, see below “6. Informed Consent.”

negligently administered.

If a vaccine is unsafe, it is the pharmaceutical company that produced the vaccine that is potentially liable. The branch of negligence law known to lawyers as “products liability” is well developed.<sup>28</sup> Negligence in the manufacturing process, such as contamination of the vaccine with foreign substances, will give rise to a claim. In vaccination injury cases, “defective design” has also been alleged. If a product is inherently unsafe due to negligence in developing and testing it, the manufacturer is liable for harm caused by the product. In a vaccine injury case, it would be necessary to show that the adverse effects of the vaccine rendered it unsuitable for use.<sup>29</sup> Finally, a manufacturer may be liable for failure to warn of dangers. The manufacturer may supply the information about risks to a “learned intermediary,” such as a health care provider, who then discloses to the consumer.<sup>30</sup>

Although negligence law provides broad grounds for claiming compensation in vaccine injury cases, it has some serious limitations. 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 defendant’s behaviour fell short of the required standard of care. This may prove difficult in many vaccine 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 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. Thus, for example, a link between Guillain-Barre syndrome and vaccination has not been satisfactorily demonstrated in the twenty years since it was suspected. In *Rothwell v.*

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<sup>28</sup>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).

<sup>29</sup>*Rothwell v. Raes* (1988), 54 D.L.R. (4th) 193 (Ont. H.C.J.), aff’d (1990), 76 D.L.R. (4th) 280 (C.A.).

<sup>30</sup>*Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634.

*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.<sup>31</sup> 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 demonstrated to exist, it is not a matter that needs to be disclosed.

Litigation of negligence claims can be costly and time consuming as well as uncertain. The Manitoba Law Reform Commission observed that in *Rothwell v. Raes*:

The 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.<sup>32</sup>

Very few vaccine injury claims have been litigated in Canada. Those that have been have not been favourable to the plaintiffs. The Quebec case of *Lapierre v. Attorney-General of Québec* is a companion to *Rothwell*. Although a causal connection was found in *Lapierre*, 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.<sup>33</sup>

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. Although only a minority of claims were successful, large damage awards were made in some cases. The cost and uncertainty of litigation for both plaintiffs and defendants was a major factor in the decision to establish a public compensation program after the courts were flooded with

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<sup>31</sup>*Rothwell v. Raes* (1988) (above).

<sup>32</sup> *Compensation of Vaccine-damaged Children* (above).

<sup>33</sup>*Lapierre v. Attorney-General of Québec* (1985), 16 D.L.R. (4th) 554 (SCC).

claims following the swine flu epidemic of the 1970's.<sup>34</sup> Prior to 1988, vaccines accounted for 4-15% of American pharmaceutical sales, but produced 40% of liability claims and 60% of the insurance costs of the pharmaceutical industry.<sup>35</sup> It is reported that:

The 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 making vaccines, resulting in serious vaccine shortages throughout the United States.<sup>36</sup>

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.<sup>37</sup>

The Manitoba Law Reform Commission is more succinct: “In practical terms, the tort process holds

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<sup>34</sup>*Compensation for Vaccine-Related Injuries* (Congress of the United States) (above).

<sup>35</sup>S.A. Sturges, “Vaccine-Related Injuries: Alternatives to the Tort Compensation System,” 30 *St. Louis U.L.J.*, 1986.

<sup>36</sup>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.

<sup>37</sup>R. Gaskins, “Equity in Compensation: The Case of Swine Flu,” *Hastings Center Report*, February, 1980.

out very little promise for an efficient and fair remedy for those children who suffer vaccine-related injury and illness.”<sup>38</sup>

These criticisms of the tort system may be too harsh. The small number of claims going to court in Canada may reflect the low incidence of serious vaccine injury. Medicare covers medical expenses that became the subject of claims in the United States. In addition, 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. It may be that the cases that have gone to trial in Canada are the hard ones in which issues of causation and negligence are most difficult. Causation is an issue even in no-fault compensation systems. There is no guarantee that a no-fault system would have awarded damages in the *Rothwell* case.

A public compensation program may be a better alternative than the tort system to compensate vaccine injuries. But before that conclusion can be reached, it is necessary to examine public compensation programs closely.

#### **D. Public compensation programs**

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.<sup>39</sup> Quebec established its compensation program in 1987 in response to the perceived failure of courts in *Lapierre*. But even if the tort system is not as inadequate as critics suggest, a case might be made for a public compensation system. The authors of “Addressing the Emergence of Pediatric Vaccination Concerns” identify a public compensation

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<sup>38</sup>*Compensation of Vaccine-damaged Children* (above).

<sup>39</sup>above.

program as a key element in re-establishing public trust in vaccination.<sup>40</sup> 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 in fact achieve this goal more effectively than the courts.

Public compensation programs for vaccine 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).<sup>41</sup>

The Quebec compensation program<sup>42</sup> is typical, though there are some significant differences in scope in the existing programs. It 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 plan 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; negligence need not be proved. However, a causal relationship between the vaccination and the injury must be established on a balance of probabilities. It appears that causation questions are approached in a somewhat less strict manner than in the

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<sup>40</sup>“Addressing the Emergence of Pediatric Vaccination Concerns: Recommendations from a Canadian Policy Analysis” (above).

<sup>41</sup>G. Evans, "Vaccine Injury Compensation Programs Worldwide," 17 *Vaccine* 1999.

<sup>42</sup>*Public Health Protection Act, R.S.Q. c. P-35, Division III.1 Indemnities for Victims of Immunizations.*

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 *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.<sup>43</sup> Compensation under the program does not preclude suing in tort for additional damages.

Between 1987 and 2000, 117 claims were made, of which 20 were compensated. About \$2.7 million in benefits have been paid out. The average award has been about \$135,000.<sup>44</sup> The low success rate for claimants appears to be partly accounted for by 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 that are no longer regularly used in Canada.<sup>45</sup>

The Quebec example suggests that there are several questions about the substance of compensation programs that should be carefully examined.

**Scope of coverage.** Although childhood immunization programs have attracted the most concern, Quebec compensates all persons injured by all vaccines in use in the province. The American National Vaccine Injury Compensation Program<sup>46</sup> covers only vaccines routinely administered to

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<sup>43</sup>*Automobile Insurance Act*, R.S.Q., c. A-25.

<sup>44</sup>Manitoba Law Reform Commission, *Compensation of Vaccine-damaged Children* (above).

<sup>45</sup>Andre Picard, "Only Quebec pays out for vaccine injuries," *Toronto Globe & Mail*, 18 Nov 2002.

<sup>46</sup> *National Childhood Vaccine Injury Act*, 42 U.S.C.A.

children, and the British *Vaccine Damage Payments Act*<sup>47</sup> covers only vaccines administered to persons under the age of 18. The Manitoba Law Reform Commission recommended following the British model, arguing that:

[I]t 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:

[T]he 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.<sup>48</sup>

The increasing importance public health programs attach to adult influenza vaccination may make the Quebec approach more attractive.

**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, on the other hand, is not limited to cases of serious disability. The difference in approach is largely accounted for by the absence of universal medicare in the United States. Many smaller 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.

However, in one respect the Quebec formula is questionable. Because it requires permanent

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<sup>47</sup>*Vaccine Damage Payments Act 1979* (U.K.), 1979, c. 17.

<sup>48</sup>*Compensation of Vaccine-damaged Children* (above).

disability, it does not compensate for loss of income when a vaccine-induced injury is debilitating but 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 more acceptable in a program that covers only children. Temporary disability may have significant financial consequences for adults.

All compensation programs except the American program limit compensation to loss of income and expenses incurred as a result of disability. The American program applies tort principles, and 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: in 2003, the average was \$1,427,169, compared to \$134,000 in Quebec and \$63,000 in Britain.<sup>49</sup> 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 vaccine 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

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<sup>49</sup>Betty Pang, “The National Vaccine Injury Compensation Program: A Program Evaluation,” *Harvard Law*, April 29, 2003.

of the advantage of no-fault.<sup>50</sup>

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 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 has the capacity to simplify causation issues. This would particularly be the case if the table recognized causation on the basis of statistical probabilities derived from temporal connections. In some cases, this is perhaps the best medical science can do to establish the link between vaccination and harm. However, the Table of Injuries used in the American program has been criticized, and some types of adverse events have recently been removed from it.<sup>51</sup>

### **Questions for Consideration**

**1. Should a publicly-funded program be established in Saskatchewan to compensate individuals who suffer vaccine-related injuries?**

**2. If a public compensation program is established, should it apply to:**

**(a) Approved childhood vaccinations?**

**(b) All approved vaccinations regardless of the age of the victim?**

**3. Should compensation be provided for:**

**(a) Permanent disability and death?**

**(b) Death and disability, whether permanent or not?**

**(c) Any loss resulting from an adverse effect of vaccination?**

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<sup>50</sup>Craig Brown, “Hepatitis C: Eight Questions About No-fault Compensation for Blood-Product Harm”, 18 *Windsor Y.B. Access. Just.* 217, (2000).

<sup>51</sup>“The National Vaccine Injury Compensation Program: A Program Evaluation” (above).

**(d) Pain and suffering?**

**4. Should proof of claims be simplified by use of a Table of Injuries or similar approach to avoid the need to provide proof of the causal link between vaccination and harm in individual cases?**

## 4. Mandatory vaccination

### A. Mandatory vaccination law in Canada and the United States

Compulsory small-pox vaccination during out-breaks of the disease was first required in England in 1853, and in the Province of Canada in 1863. In Ontario, mandatory childhood small pox vaccination was enacted in 1885-86, and extended to make vaccination a requirement for school attendance in 1914.<sup>52</sup> In 1982, this requirement was extended to all scheduled childhood vaccinations.<sup>53</sup> Unlike the earlier legislation, the 1982 legislation allowed parents to claim an exemption on the basis of religious belief. It was amended in 1984 to extend the exemption to matters of conscience as well as religious belief.<sup>54</sup> The *Immunization of School Pupils Act* now provides:

#### Duty of parent

3. (1) The parent of a pupil shall cause the pupil to complete the prescribed program of immunization in relation to each of the designated diseases.

#### Exception

(2) Subsection (1) does not apply to the parent of a pupil in respect of the prescribed program of immunization in relation to a designated disease specified by a physician in a statement of medical exemption filed with the proper medical officer of health and, where the physician has specified an effective time period, only during the effective time period.

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<sup>52</sup>*Vaccination Act 1914* R.S.O. 1914, c. 219. On the history of vaccination law in Canada, see Katherine Arnup, "Victims of Vaccination?: Opposition to Compulsory Immunization in Ontario, 1900-90," *Canadian Bulletin of Medical History*, 9(2) (1992).

<sup>53</sup>*An Act to Protect the Health of Pupils in Schools*, S.O. 1982, c.41.

<sup>54</sup>*An Act to Amend the Immunization of School Pupils Act*, 1982, S.O. 1984, c. 62.

(3) Subsection (1) does not apply to a parent who has filed a statement of conscience or religious belief with the proper medical officer of health.

Failure to comply with the legislation is a summary conviction offence (s. 5), and grounds for suspension of an unvaccinated pupil from school (s.6).<sup>55</sup> In practice, school and public health authorities periodically require proof of vaccination of pupils whose vaccination records are not on file. Parents of unvaccinated students are then given an opportunity to either vaccinate their children, or file an exemption, before further action is taken.

New Brunswick is the only other Canadian jurisdiction with legislation requiring all standard childhood vaccinations as a condition of school attendance.<sup>56</sup> Manitoba requires all grade one students to be vaccinated against measles.<sup>57</sup> Both New Brunswick and Manitoba allow exemptions on religious and conscientious grounds. In Saskatchewan and other provinces that do not make routine vaccination mandatory, public health legislation permits mandatory vaccination to be ordered during an epidemic. Conscientious objectors are exempt from such orders. The Saskatchewan *Public Health Act* provides:

45(1) The minister may make an order described in subsection (2) if the minister believes, on reasonable grounds, that:

- (a) a serious public health threat exists in Saskatchewan; and
- (b) the requirements set out in the order are necessary to decrease or eliminate the serious public health threat.

(2) An order pursuant to this section may:

- (a) direct the closing of a public place;
- (b) restrict travel to or from a specified area of Saskatchewan;

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<sup>55</sup>*Immunization of School Pupils Act* R.S.O. 1990, c. I.1.

<sup>56</sup>*Education Act*, S.N.B. 1997, c. E-1.12, s. 10.

<sup>57</sup>*Public Health Act Regulation 388/88: Diseases and Dead Bodies*, s. 24.1

(c) prohibit public gatherings in a specified area of Saskatchewan;

(d) in the case of a serious public health threat that is a communicable disease, require any person who is not known to be protected against the communicable disease:

(i) to be immunized or given prophylaxis where the disease is one for which immunization or prophylaxis is available; or

(ii) to be excluded from school until the danger of infection is past where the person is a pupil;

64(1) A person who conscientiously believes that immunization or prophylaxis would be prejudicial to his or her health or to the health of his or her child or ward, or who for conscientious reasons objects to immunization or prophylaxis, may swear or affirm an affidavit to that effect before a justice of the peace, commissioner for oaths or notary public.

(2) A person described in subsection (1) is excused from compliance with any regulation, bylaw or order pursuant to this Act that makes immunization mandatory if the person delivers personally or by registered mail to the local authority for the area in which the person resides a duly attested affidavit described in that subsection.<sup>58</sup>

Mandatory vaccination has been a more important part of American public health law than in Canada. Childhood immunization is mandatory in all states in the United States. Most, like Ontario and New Brunswick, require immunization as a condition of school attendance. 47 states have exemptions for religious belief, and 15 extend the exemption to persons who have other philosophical or conscientious objections to vaccination.<sup>59</sup> Unlike its Canadian counterparts, the American legislation has been tested in the courts. The leading authority remains a 1905 Supreme Court decision, *Jacobson v. Commonwealth of Massachusetts*. Jacobson relied on the *Bill of Rights*, arguing an “inherent right” to reject unwanted healthcare. The Court rejected this argument, holding that the state could require individuals to be vaccinated for the common good. A person who refuses vaccination is not merely refusing a medical procedure, he or she is endangering the health of fellow

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<sup>58</sup>*The Public Health Act, 1994*, S.S. 1994, c. P-37.1

<sup>59</sup>W.A. Orenstein and A.R. Hinman, “The immunization system in the United States - the role of school immunization laws,” *Vaccine*, Oct 1999.

citizens. The court took the position that Jacobson “sought to enjoy the benefit of his neighbors being vaccinated for smallpox without personally accepting the risks inherent in vaccination.”<sup>60</sup> American courts have consistently upheld mandatory vaccination since the decision in *Jacobson*.<sup>61</sup>

Although mandatory vaccination laws have not been litigated in Canada, it is likely that they would be upheld by the courts. The *Canadian National Report on Immunization, 1996* stated that:

Unlike some countries, immunization is not mandatory in Canada; it cannot be made mandatory because of the Canadian Constitution. . . . Three provinces have legislation or regulations under their health-protection acts to require proof of immunization for school entrance. . . . It must be emphasized that, in these three provinces, exceptions are permitted for medical or religious grounds and reasons of conscience; legislation and regulations must not be interpreted to imply compulsory immunization.”<sup>62</sup>

This statement is often quoted by opponents of mandatory vaccination, but it may be misleading. Because healthcare is primarily a matter for the provinces, not the federal government, the constitution would likely prevent enactment of a federal mandatory vaccine law except in a national emergency. However, the division of powers set out in the constitution permits provincial mandatory vaccination laws. If there is a constitutional bar to mandatory vaccination, it would be found in the *Charter of Rights*. While an argument might be made against mandatory vaccination, it is likely that Canadian courts, like their American counterparts, would conclude that *Charter* rights are not violated when actions that may harm others are proscribed or would find that such a proscription was demonstrably justifiable in a free and democratic society and therefore saved by section 1 of the *Charter*. Legislation that allows exemptions on religious and conscientious grounds would be less vulnerable to challenge than legislation that did not.

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<sup>60</sup>197 US 11 (1905).

<sup>61</sup>See e.g. *Zucht v King*, 260 US 174, 176 (NY, 1922) *Matter of Fosmire v Nicoleau*, 75 N.Y.2d 218, 226 (1990), *Wright v Dewitt School Dist. No. 1*, 385 S.W. 2<sup>nd</sup> (AK, 1967).

<sup>62</sup>*Canadian National Report on Immunization, 1996* (above).

## B. Arguments for mandatory vaccination

High vaccination rates, particularly among school-age children, are necessary to maintain sufficient immunity in the population to prevent outbreaks of infectious diseases. Transmission of an infectious disease results from contact between infected and susceptible individuals. Outbreaks can be prevented only when immunity rates are high enough that it is unlikely that infected and susceptible individuals will come into contact. Even in an immunized population, an outbreak can occur if clusters of susceptible individuals remain.<sup>63</sup> Since school-aged children usually have the highest susceptibility to vaccine-preventable diseases, childhood immunization has been identified as a particularly effective public health measure. Vaccination protects not only the children who receive the vaccination and develop immunity, but also children who have been vaccinated but fail to develop immunity, children who are unvaccinated, and susceptible adults in the community.

There is little doubt about the effect of maintaining high vaccination rates on public health. When vaccination rates fall, the incidence of infectious diseases rises. For example, a study published in *Lancet* in 1998 found that:

Pertussis [whooping cough] incidence was 10 to 100 times lower in countries where high vaccine coverage was maintained than in countries where immunization programs were compromised by anti-vaccine movements. Comparisons of neighbouring countries with high and low vaccine coverage further underscore the efficacy of these vaccines. Given the safety and cost-effectiveness of whole-cell pertussis vaccines, our study shows that, far from being obsolete, these vaccines continue to have an important role in global immunization.<sup>64</sup>

Another study showed that unvaccinated children were 22 times more likely to contract measles

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<sup>63</sup>This is the “herd effect.” See K.E. Nelson *et al*, eds., *Infectious Disease Epidemiology*, 2004.

<sup>64</sup>E.J. Gangarosa *et. al.*, “Impact of anti-vaccine movements on pertussis control: the untold story,” *Lancet*, Jan 31, 1998.

than vaccinated class-mates, and outbreaks of measles were more likely when the unvaccinated exceeded 4.3% of the population. At least 11% of vaccinated children in measles outbreaks acquired infection through contact with an unvaccinated class-mate.<sup>65</sup>

Advocates of mandatory vaccination argue that it is needed to reach and maintain high enough levels of population immunity to protect against outbreaks of infectious disease. The American epidemiologists Ornstein and Hinman conclude, for example, that:

School immunization laws have had a remarkable impact on vaccine-preventable diseases in the United States, particularly in school-aged populations. Enforcement of laws through the exclusion of unvaccinated children from school is a critical factor in assuring success.<sup>66</sup>

Advocates suggest that compulsory vaccination is a complement, not an alternative, to a well-organized public health system for delivering vaccination services. It is defended on several grounds:

1. As a back-up to identify unvaccinated children who would otherwise be missed. Thus, it has been suggested that:

School laws harness the resources of other programs such as education to the immunization effort. They establish a safety net to assure high levels of coverage each and every year. But they cannot replace efforts to assure age appropriate

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<sup>65</sup>D.R. Feikin, "Individual and community risks of measles and pertussis associated with personal exemptions to immunization," *Journal of the American Medical Association*, 284(24), 2000.

<sup>66</sup>"The immunization system in the United States - the role of school immunization laws," (above). See also D. A. Salmon *et. al.*, "Public health and the politics of school immunization requirements," *Am J Public Health*, 2005.

immunization in the first two years of life.<sup>67</sup>

The Saskatchewan Immunization Management System (SIMS) includes a registry of children known to the system through contact with health care providers, and records vaccination records for these children. An “over-due client report” can be generated and mailed to parents when vaccinations are not up to date. However, the system can miss significant numbers of children. SIMS identifies mobility of clients, missing postal addresses, and lack of integration with First Nations health care systems as problems. As of 2003, 80% of two-year olds known to the system had up to date vaccinations, but the rate varied from 62% to 96% by health region (excluding the northern health regions not in the system).<sup>68</sup> This suggests that vaccination coverage is below the levels required to ensure good population immunity in at least some parts of the province. Children who are not in the system, or whose parents cannot be contacted, could be caught by school-based checks on immunization status.

2. To require parents who have decided not to vaccinate their children to reconsider. Advocates of compulsory vaccination argue that many parents who do not vaccinate their children until school age will do so when required to either vaccinate or formally claim an exemption. Many parents are vaguely concerned about vaccine safety and poorly informed about the benefits of vaccination. It has been observed that:

Today, however, vaccines are becoming a victim of their success--many individuals have never witnessed the debilitating diseases that vaccines protect against, allowing complacency toward immunization requirements to build. Antivaccination sentiment is growing fast in the United States, in large part due to the controversial and hotly disputed link between immunizations and autism. The internet worsens fears regarding vaccination safety, as at least a dozen websites publish alarming information about the risks of vaccines. . . . A variety of factors are at play: religious and philosophical beliefs, freedom and individualism, misinformation about risk, and

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<sup>67</sup>“The immunization system in the United States - the role of school immunization laws,” (above).

<sup>68</sup>“Saskatchewan Immunization Management System”(above).

over perception of risk.<sup>69</sup>

A properly designed compulsory vaccination law provides an opportunity to educate parents considering an exemption about vaccination, and correct misconceptions.<sup>70</sup> Some American public health officials are concerned about extension of traditional religious exemptions to include less clearly defined conscientious and philosophical exceptions (similar to the exemption allowed under Ontario legislation).<sup>71</sup> However, only about 1% claim exceptions when required to do so under the current laws in place in the United States.<sup>72</sup>

3. Poor vaccination coverage of under privileged socioeconomic groups. Children who infrequently come into contact with health-care providers are less likely to be vaccinated than others. In New York, modernization of the state compulsory vaccination law was justified by the Legislature on the grounds that:

Studies indicate that the majority of these unprotected persons are in the lower socio-economic group who reside in congested urban areas and who are generally apathetic towards immunization. The typical victim is a child less than six years of

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<sup>69</sup>S.P. Calandrillo, "Vanishing vaccinations: why are so many Americans opting out of vaccinating their children?" *Univ. Mich. J. Law Reform*, 2004 Winter; 37(2).

<sup>70</sup>D.A. Salmon *et. al.*, "Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study," *Arch. Pediatr. Adolesc. Med.* 2005 May; 159(5).

<sup>71</sup>This trend has resulted in part from judicial decisions striking down narrow religious exemptions on the ground that they do not afford equal rights to persons who are not members of organized religions that object to vaccination. In Arkansas, for example, the exception was extended in 2002 as a direct legislative response to *Re McCarthy*, 212 F. Supp. 2d at 949 (Ak). See Rick Hogan, "From Litigation to Legislation Philosophically Opposed to Compulsory Child Immunization," *Law and Bioethics Report*, Volume 4, Issue 4, Summer 2005.

<sup>72</sup>"The immunization system in the United States - the role of school immunization laws," (above).

age in an underprivileged family.<sup>73</sup>

Other studies suggest that recent immigrant children are less likely to receive vaccinations than other segments of the population.

In Saskatchewan, First Nations people, especially in cities, continue to have less access to regular health care than the rest of the population. Children living in inner-city environments are also less likely to have up-to-date residence data in SIMS. A recent survey found that childhood vaccination rates in the Riversdale district of Saskatoon may be as low as 40%.<sup>74</sup> A mandatory vaccination program targeting school attendance might bring many of these children into the system.

### **C. Arguments against mandatory vaccination**

There is a long history of opposition to compulsory and mandatory vaccination in both the United States and Canada.<sup>75</sup> The most active Canadian organization critical of vaccination in recent years has been the Ontario Committee Against Compulsory Vaccination, which was formed in 1983 to oppose enactment of mandatory vaccination in Ontario. It played a role in securing amendment of the legislation to allow exemptions, but has been philosophically opposed to all compulsory vaccination laws. The Vaccine Risk Awareness Network (VRAN) now “continues the work of the Committee Against Compulsory Vaccination.” It focuses on warning parents of the presumed dangers of vaccination.<sup>76</sup> VRAN works with critics of vaccination in the United States and Europe,

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<sup>73</sup>New York State Legislature Findings, re amendment of section 2164 of the Public Health Law (1968).

<sup>74</sup>Study prepared for the Saskatoon Health Region, *Canadian Journal of Public Health*, no. 6, Nov/Dec 2006.

<sup>75</sup>“Victims of Vaccination?: Opposition to Compulsory Immunization in Ontario, 1900-90,” (above).

<sup>76</sup>See the VRAN website ([www.vran.org](http://www.vran.org))

but appears to have adopted a more moderate position than American organizations such as Vaccine Liberation, which opposes all vaccinations.<sup>77</sup>

Some opponents of mandatory vaccination base their opposition on a wholesale attack on vaccination, questioning its effectiveness, safety, and the science supporting it. For example, a popular anti-vaccination book, *Vaccination: The "Hidden" Facts*, by Ian Sinclair summarizes its argument in these terms:

This book covers the 200 year history of vaccination, includes graphical evidence and statistics showing that vaccines never saved us, the true reasons for the decline in death rates from infectious disease, scientific evidence on the dangers and ineffectiveness of vaccines, the fallacy of the germ theory and the true causes of childhood infection and its beneficial nature. Includes natural health philosophy and its approach to the prevention and treatment of childhood illness.<sup>78</sup>

More moderate opponents usually do not argue that vaccination is of no value, but question mandatory vaccination on three principle grounds:

1. Concerns about individual and parental rights. It is of course a general principle that a patient must ordinarily give informed consent to medical treatment. Parental consent is ordinarily required for treatment of children who are too young to consent on their own behalf. There are exceptions to the general rule. At common law, for example, treatment may be given to a patient in an emergency who is unable to consent. Like other rights, the right to consent to medical treatment is limited when the right may cause harm to others.<sup>79</sup> Compulsory vaccination laws operate as a statutory exception, based on the presumed danger to others presented by a significant number of

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<sup>77</sup>See the Vaccine Liberation website ([www.vaclib.org/index.htm](http://www.vaclib.org/index.htm))

<sup>78</sup>Published by Ian Sinclair, New South Wales, 1992.

<sup>79</sup>There is no need here to examine the law of medical consent in detail. For a full account of the law in Canada, see Barney Sneiderman, John O. Irvine, and Philip H. Osborne, *Canadian Medical Law - Introduction for Physicians, Nurses and Other Health Care Professionals*, 2<sup>nd</sup> ed., Carswell, 1995.

unvaccinated individuals in the population. The law in Ontario and most states in the United States attempts to balance individual and collective rights by allowing religious and conscientious exemptions from mandatory vaccination. However, organizations like VRAN believe that mandatory vaccination is an unwarranted violation of the right to consent to medical treatment.<sup>80</sup>

Critics regard mandatory vaccination as an effort to coerce parents to vaccinate their children, suggesting that parents are not fully informed about their right to claim an exemption, or encouraged to consider alternatives. Thus in 2001, VRAN objected to enforcement of the Ontario vaccination laws in the schools:

Once again, officials are doing the rounds of Ontario schools and threatening to expel children whose vaccine records aren't complete, or who aren't up to date with all their shots.

Already, some Ontario school children have recently been rounded up and sent home with warnings that they **MUST** be vaccinated - with no mention of exemptions. The fear and coercion continues despite the availability of exemptions under the Immunization of School Pupils Act (Ontario), and despite Health Canada's clear statement that vaccines are not mandatory in Canada. Parents and students, and school administrators continued to be misinformed by public health officials.<sup>81</sup>

Although pamphlets and other materials distributed to parents of children whose vaccinations are not up to date do refer to the available exemptions, VRAN does not believe the exemption information is prominently and fully explained in them.

2. Concerns about vaccination safety. A study in the United States found that 69% of parents who elected not to vaccinate their children did so because of “concern that the vaccines might cause

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<sup>80</sup>See “Informed Consent and Your Rights,” VRAN website (above).

<sup>81</sup>“Health Officials Violate Public Trust,” VRAN website (above).

harm.”<sup>82</sup> A recent Canadian analysis suggested that “concerns about the measles/mumps/rubella (MMR) vaccine and thimerosal preservatives, respectively, have threatened confidence in vaccination programs despite public health reassurances about their safety.”<sup>83</sup>

Although vaccination is relatively safe, and public health officials stress that the danger of adverse effects is outweighed by the benefits of individual and population immunity, adverse effects do occur.<sup>84</sup> Serious reactions such as anaphylactic shock are rare, but well known, complications. Pertussis vaccines were reformulated, for example, because of an unacceptable incidence of pertussis-like symptoms following vaccination.<sup>85</sup> Safety issues are compounded by unproven claims, ranging from highly improbable (that vaccination destroys the natural immune system), to plausible (links between thimerosal preservatives and autism).<sup>86</sup> While many fears about vaccine safety are based on misinformation, the risks are real.

Critics argue that parents should be able to make decisions about the health of their children in all cases in which the child’s life and health is not in immediate and serious jeopardy. Universal vaccination may not meet this criterion. Even if public health requires high rates of immunization,

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<sup>82</sup>“Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study” (above).

<sup>83</sup>“Addressing the Emergence of Pediatric Vaccination Concerns: Recommendations from a Canadian Policy Analysis” (above).

<sup>84</sup>For more detail about known adverse effects, see “2. Compensation for vaccine injury.”

<sup>85</sup>Center for Disease Control, “Pertussis Vaccination: Use of Acellular Pertussis Vaccines Among Infants and Young Children Recommendations of the Advisory Committee on Immunization Practices, March 28, 1997 / 46(RR-7).

<sup>86</sup> Despite some early suggestive research findings, an exhaustive review by the CDC in 2004 concluded that “neither thimerosal-containing vaccines or MMR vaccine are associated with autism.” Center for Disease Control (U.S.), *Vaccines and Autism: An Institute of Medicine (IOM) Report*, 2004. According to Health Canada, “Since 1994, all routine childhood vaccines, with the exception of the flu vaccine, administered in Canada have not contained thimerosal.” (Health Canada, “Thimerosal in Vaccines,” *Questions and Answers*, May, 2004).

the risk of disease in an unvaccinated individual is low as long as most members of the population are vaccinated. It can be argued that the notion that those who refuse vaccination are taking the benefit of mass immunization programs without taking the responsibility does not apply so long as only a small minority elect to forego vaccination on conscientious grounds. The exemptions available under mandatory vaccination laws in Canada and the United States do allow conscientious objection, but critics regard even these laws as unnecessarily coercive.

3. Alternatives to mandatory vaccination. Most provinces in Canada have maintained good vaccination coverage without mandatory vaccination laws. Despite the opinion of American public health officials that mandatory vaccination is critical to achieve good coverage, there is no conclusive evidence that Ontario's vaccination law has improved coverage. Although mandatory vaccination might function as a useful back up to other measures to achieve good coverage, it can be argued that effort would be better spent improving the public health system and providing reliable information to parents about vaccination. The reaction of organizations such as VRAN to the Ontario law suggests that enforcement of mandatory vaccination may increase public skepticism. A recent proposal to address vaccination concerns in Canada recommended public education and increased attention to preventing and compensating risks rather than mandatory vaccination. As the authors of the proposal suggest, public health officials and most concerned parents share common ground, a genuine concern for the health of children.<sup>87</sup>

### **Questions for Consideration**

#### **5. Should approved childhood vaccinations be a mandatory requirement for school attendance in Saskatchewan?**

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<sup>87</sup>“Addressing the Emergence of Pediatric Vaccination Concerns: Recommendations from a Canadian Policy Analysis” (above).

**6. If vaccination is mandatory, should exemptions be permitted:**

**(a) On religious grounds?**

**(b) On other conscientious grounds?**

**(c) Only if the applicant for exemption has been informed of the benefits and risks of vaccination?**

## **5. Informed consent and informed refusal**

There can be little doubt that public acceptance of and confidence in childhood vaccination programs require public education and dissemination of information about risks and benefits to parents. Ideally, a parent's decision to vaccinate should be informed; and equally, a decision to refuse vaccination should be informed. The law requires that medical procedures can ordinarily be performed only with informed consent of the patient or a parent. The legal consent requirement could in principle contribute to the public education effort. In practice, however, the consent requirement may not be effective to achieve either its legal purpose or a broader educative 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 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.

### **A. Informed consent: The present law**

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.

Consent requirements are part of the common law, and have evolved through judicial decisions. The courts have insisted 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.<sup>88</sup>

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, have consented to the treatment.”<sup>89</sup> Very remote or improbable risks do not need to be disclosed, but the degree of improbability required to allow it to be disregarded depends on the seriousness of the risk.<sup>90</sup>

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 assert 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.”<sup>91</sup> Public health officials regard such statements as overstatements at the very least, but even supporters of vaccination programs have expressed concerns about the quality of information provided to patients receiving vaccinations and their parents.

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. It may be included in a “consent form” the patient or parent is asked to sign. The printed information may or may not be explained by the administering health

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<sup>88</sup>*Allan v. New Mount Sinai Hospital* (1980), 28 O.R. 356.

<sup>89</sup>*Reibl v. Hughes*, [1980] 2 S.C.R. 880.

<sup>90</sup>*Kitchen v. McMullen* (1989), 100 NBR (2d) 91.

<sup>91</sup>*Compensation of Vaccine-damaged Children* (above).

care professional, and additional information may be offered only if it is requested. The extent of disclosed risk varies, from description of common side-effects, to warning of symptoms of more serious reactions.

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

Ultimately, however, 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.<sup>92</sup>

Similarly, because consent cannot be fully informed unless it relates directly to the proposed treatment, reliance on general consents to medical care are 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%) 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.<sup>93</sup>

## **B. Legislated consent requirements**

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

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<sup>92</sup>Vaccine Awareness Network web-site (above).

<sup>93</sup> Margaret L. Russell, “Influenza vaccination in Alberta long-term care facilities” *Canadian Medical Association Journal*, 2001 May 15; 164(10).

consent to treatment that apply consistently in all settings.”<sup>94</sup> 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 (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.

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<sup>94</sup>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.

6. The likely consequences of not having the treatment.

Although the *Health Care Consent Act* 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, guidelines adopted by the Ontario College of Nurses for administration of influenza vaccine instruct that:

According to the *Health Care Consent Act* and the College of Nurses of Ontario (CNO) 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 treatment . . . .<sup>95</sup>

Stricter application of the informed consent requirement would address some public concern about vaccine safety. However, some health care practitioners are concerned that increased emphasis on risks and adverse effects may discourage some parents from immunizing their children. It does appear that some parents are disturbed when risks are described and expressed statistically, even if the risk is very small. The authors of the study which made this finding observed that “this zero-risk tolerance group tended to have a lower income and to prefer a nonnumeric statement of risk.”<sup>96</sup> But most parents are willing to accept risks well within the range recognized by public health officials. 86% 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 vaccination.<sup>97</sup> Adults appear to be even less risk-

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<sup>95</sup>College of Nurses of Ontario, *Practice Guidelines: Influenza Vaccinations*, 2005.

<sup>96</sup>T. R. Freeman and M.J. Bass, “Determinants of maternal tolerance of vaccine-related risks,” 9 *Family Pract.*, 9 (1992).

<sup>97</sup>“Determinants of maternal tolerance of vaccine-related risks” (above). See also Sanford R. Kimmel, “Vaccine adverse events: separating myth from reality,” *American Family Physician*,

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, and an American study found that informing adult patients of the possible risks of Guillain-Barre syndrome did not significantly increase refusal rates.<sup>98</sup> Fuller disclosure of risk would almost certainly create some problems for public health providers, but the manner in which information is presented to patients and parents is probably the important factor in maintaining confidence in vaccination programs.

### **C. Informed refusal**

The role of consent is of course somewhat different if vaccination is mandatory. Parents are still able to refuse vaccination for their children in Ontario and other jurisdictions with similar childhood vaccination regimes, but the vaccination may be administered without positive consent if the parent has not filed a statement in the approved form to claim an exemption. This may contribute to a sense that vaccination programs have not been fully justified to the public. On the other hand, some advocates of mandatory vaccination are concerned that parents can refuse vaccination without being informed about benefits. In many states, the law requires a parent to do no more than simply check a box indicating she does not wish her child to receive immunizations.<sup>99</sup> It has been recommended that an "informed refusal" approach to vaccination exemption should be adopted. Under such a

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Dec 1, 2002.

<sup>98</sup>“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).

<sup>99</sup>“Vanishing vaccinations: why are so many Americans opting out of vaccinating their children?”(above). The American Medical Association has pointed to an apparent increase in the number of so-called "exemptions of convenience."

regime, parents could claim an exemption only after counseling.<sup>100</sup>

Although the concept of informed refusal originated in the context of mandatory vaccination, it may have a place even when vaccination is not mandatory. Legislation setting out requirements for informed consent might also require that all parents should be informed of the risks and benefits of vaccination prior to making a decision about vaccination. In any event, it seems clear that, whether vaccination is mandatory or not, public acceptance of childhood vaccination programs would be increased if more attention was given to providing full information about risks and benefits in a timely fashion.

### Questions for Consideration

**7. Do current practices provide enough information about risks and benefits to assist parents and patients to give informed consent to vaccinations?**

**8. Should Saskatchewan enact guidelines governing informed consent similar to those in the Ontario *Health Care Consent Act*?**

**9. Should parents be required to consider information about risks and benefits before refusing vaccination of their children?**

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<sup>100</sup>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):

## 6. 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 important, both to identify and correct problems, and to give the public confidence that health care officials take adverse effects seriously. 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, mandatory reporting by public health nurses who administer most childhood vaccines is, as a matter of policy, mandatory. However, in Ontario, mandatory reporting is required by law, and applies to all health-care providers. The *Health Protection and Promotion Act*<sup>101</sup> 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.

(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 health providers to inform patients of symptoms of adverse effects that should be reported.

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<sup>101</sup>R.S.O. 1990, c. H.7.

Legal recognition of a duty to report may ensure that the obligation is universally respected, and increase public confidence in vaccination programs.

### **Question for Consideration**

**10. Should Saskatchewan enact legislation requiring health care providers to report all adverse effects of vaccinations?**