

Compulsory School-Entry Vaccination Laws and Exemptions: Who Is Opting Out in Ontario and Why Does It Matter?

Lois et exemptions en matière de vaccination
obligatoire avant l'entrée à l'école : qui choisit
d'être exclu en Ontario et pourquoi cela a-t-il
de l'importance?



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Abstract

School-entry vaccination regulations are a policy instrument that has been widely used in some jurisdictions as a mechanism to ensure high immunization coverage rates. Exemptions to school-entry vaccination, which can be allowed on medical or non-medical grounds, present a number of ethical and policy challenges. In this paper, we consider the situation in Canada, where school-entry vaccination laws are rare. We present newly available aggregate-level registry data from Ontario comparing the use of medical and non-medical immunization exemptions to school-entry vaccination and the implications for population health.

Résumé

La réglementation en matière de vaccination avant l'entrée à l'école est une politique qui a été largement utilisée par certains gouvernements afin d'assurer un taux élevé de couverture vaccinale. Les exemptions à la vaccination avant l'entrée à l'école, qui peuvent être accordées selon des critères médicaux ou non, posent un certain nombre de défis éthiques et politiques. Dans cet article, nous examinons la situation au Canada, où les lois de vaccination avant l'entrée à l'école sont plutôt rares. Nous présentons de nouveaux ensembles de données provenant de l'inscription en Ontario, en comparant l'utilisation des exemptions à la vaccination avant l'entrée à l'école (de nature médicale ou non) ainsi que les répercussions sur la santé de la population.

IMMUNIZATION HAS BEEN CALLED ONE OF THE GREATEST PUBLIC HEALTH achievements of the last century (US Department of Health and Human Services 2000). In addition to the protection afforded by a vaccine to an individual, non-immune persons in a community can be protected from person-to-person disease transmission if a threshold proportion of immune persons exists, referred to as “herd” immunity (Fine 2004; Orenstein et al. 2004).

Governments and public health officials have long used schools as an effective community setting in which to implement collective vaccination policies. School-based policies are generally of two types: regulatory instruments (e.g., school-entry vaccination laws) and mechanisms for service delivery (i.e., immunizations administered in the school setting.) In jurisdictions such as the United States, state-level compulsory

vaccination laws are widely used and have been demonstrated to be highly effective towards achieving high coverage rates for routine universal childhood immunizations (Hinman et al. 2002; Hodge and Gostin 2001).

Vaccination Exemptions: Ethical and Policy Challenges

From ethical and policy standpoints, compulsory vaccination laws require that the state make provisions for those who do not consent to immunization (Gostin 2000). Individuals are usually afforded the opportunity to opt out on medical or non-medical grounds, also referred to as an “exemption.” Exemptions, however, can entail a number of policy challenges. First, exemptions (in sufficient number) can compromise herd immunity (Colgrove 2006: 4). Second, it has been argued that exemptions are inherently inequitable: exempted individuals avoid personal risks while maintaining collective benefits (Salmon et al. 2006). Non-medical exemptions are sometimes labelled “religious,” “moral,” “conscientious” or “philosophical,” indicating policy trade-offs prioritizing personal values. Third, and less often emphasized, are the individual consequences of exemptions. Even in highly immunized populations, modelled measles risk (Salmon et al. 1999) and case-control-based pertussis risk (Glanz et al. 2009) have been demonstrated to be substantially higher among unvaccinated than vaccinated children. While undervaccination owing to late or missed immunizations is a significant problem (Guttmann et al. 2006), children who have received no vaccinations, particularly related to non-medical exemptions, are also of concern.

Unvaccinated children are significantly different from their undervaccinated counterparts. Unvaccinated children are more likely to have good primary care (Guttmann et al. 2006), to be male, white, of higher socio-economic status and clustered geographically (Smith et al. 2004), increasing personal and population disease transmission risk through local susceptibility. For example, children exempted for religious and philosophical reasons have been demonstrated to be 35 times more likely than vaccinated children to contract measles, in addition to increasing community risk by upwards of 30% (Salmon et al. 1999).

Given the range of issues related to exemptions recently recapitulated in the United States (Omer et al. 2009), we wanted to examine the current situation for Canada. Our analysis focused on Ontario, one of only two provinces with a compulsory school-entry vaccination law.

Data and Methods

We reviewed federal and provincial legislation on compulsory vaccination, including school-entry laws (Canadian Legal Information Institute database, <http://www.canlii.org>). We then examined exemptions in Ontario, using data from the Immunization

Registry Information System (IRIS). IRIS contains electronic immunization records for school-aged children in Ontario based on unvalidated retrospective parental report. While parental recall is one of the least accurate methods of immunization information collection (Bolton et al. 1998), it is likely that parents use written immunization records (the province provides standard “yellow cards” through health units and providers for individuals to maintain themselves), provider records or both to supplement their recall.

Data are maintained separately by each of Ontario’s 36 public health units and aggregated periodically by the Ontario Ministry of Health and Long-Term Care (2006). IRIS has acknowledged limitations, including a lack of formal protocols for recording non-compulsory vaccines, incompatibility between health units, an inability to assess coverage rates in real time and a reliance on demographic information collected by boards of education and participating private schools for denominator values used in immunization coverage reports (Association of Public Health Epidemiologists in Ontario 2009). Prior to 2004, data were available only on total exemptions. More detailed aggregate information was recently provided to the researcher for the 2004/2005 and 2005/2006 school years (including registered day nurseries). This encompassed medical and non-medical exemptions across 16 birth-year cohorts for three sets of vaccines: diphtheria–pertussis–tetanus, polio and measles–mumps–rubella (MMR).

We compared (a) medical and non-medical exemptions and (b) birth cohorts. For the birth cohort comparison, we grouped children (1) born in 1997 and earlier and (2) born in 1998 and after. Nineteen ninety-eight was chosen as the dividing year for two reasons. First, “up-to-date” standards for immunization coverage are typically assessed at age 7 (Haimes et al. 2005; PHAC 2006). This grouping was intended to accommodate children with lapsed immunizations but “caught up” by age 7. Second, a widely publicized paper in *The Lancet* in 1998 (Wakefield et al. 1998) alleged a link between MMR vaccination and autism. The paper was compellingly refuted (National Advisory Committee on Immunization 2006: 233), and after a partial retraction by some of the study authors (Murch et al. 2004), it has since been fully retracted by the journal (Editors of *The Lancet* 2010). It has been argued that the events surrounding the paper “triggered a collapse in [public] confidence” in MMR vaccine (Horton 2004: 747). High non-medical exemptions for younger children, particularly for MMR, might provide an indication of public vaccination perceptions related to that era.

The Limited Scope of School-Entry Regulation in Canada

Compulsory immunization laws of any kind are rare in Canada, limited mainly to federal authority for health protection (e.g., armed forces). It is up to each province/territory to determine which immunizations will be included in routine schedules, to

decide which immunizations will be publicly paid for and to organize how immunizations will be delivered. Provincial/territorial (P/T) programs are informed by national-level expert advice but are not enforced through any legislative mechanism, even in the presence of the new National Immunization Strategy (NIS 2003). Evidence of immunization against specific vaccine-preventable diseases is compulsory at school entry in only two provinces: Ontario (1990) and New Brunswick (1997). In other provinces, immunization enforcement is a matter of local or school authority.

Limited and out-of-date regulation

Canadian school-entry vaccination laws are both limited and outdated. Only six vaccines are compulsory in Ontario and New Brunswick: diphtheria, tetanus, polio, measles, mumps and rubella. In contrast, the Ontario publicly funded routine immunization schedule includes five additional immunizations prior to school age (not including annual influenza): pertussis, *Haemophilus influenzae* type b (Hib), varicella, meningococcal group C conjugate and pneumococcal conjugate; New Brunswick also includes hepatitis B vaccine in infancy (PHAC 2009). New Brunswick also includes hepatitis B vaccine in infancy (PHAC 2008).

The rapid expansion of P/T immunization programs in the last five years, related to federal funding for the NIS, has contributed, in part, to this disparity. Even so, school-entry regulations are disproportionately out of date. Routine Hib immunization, for example, has been part of all P/T schedules since 1992 and has been administered routinely in all jurisdictions using a combination vaccine (pertussis, polio, tetanus, diphtheria and Hib) since 1998 (Health Canada 1999; PHAC 2006). Hib is not compulsory in either Ontario or New Brunswick, although both provinces have recently amended their regulations (in 2007 and 2006, respectively).

Exemptions

Exemptions to school-entry vaccination are easily obtained and allowable on medical and non-medical grounds. In Ontario, non-medical exemptions were formerly available only on religious grounds (original 1982 legislation); prompted by anti-vaccination lobby efforts, an amendment was added in 1984 allowing objections of conscience (Arnup 1992), and this is reflected in the current law (1990). Medical exemptions require a physician's statement attesting to prior immunity or contraindication; non-medical exemptions may be obtained simply with a parental affidavit, signed before a commissioner. This is concerning, given that higher non-medical exemption rates have been documented in jurisdictions where administrative procedures are comparatively easy (Rota et al. 2001; Salmon et al. 2005).

Who is opting out in Ontario?

In Ontario, we found that the overall immunization exemption rate is low: less than 2%. This is comparable to or slightly lower than other estimates in the literature based on data from public health (Toronto 2009) and physician billing (Guttmann et al. 2006) sources, respectively. Such figures represent approximately 35,000 to 40,500 students in any given school year. Of these, approximately 23,000 to 24,500 students have been exempted for non-medical reasons. Non-medical exemptions exceeded medical exemptions for all required vaccines. While older children had slightly higher overall exemption rates, younger children were much more frequently exempted for non-medical reasons.

TABLE 1. Exemptions to compulsory school-entry vaccination in Ontario

Antigen group	School year	Total exemptions		Exemptions for children born in 1998 and onward (%)		Exemptions for children born in 1997 and prior (%)	
		Total exemption rate across all birth cohorts (exempted/enrolled; %)	Ratio of non-medical to medical exemptions	Total exemption rate, born 1998 and onward (exempted/enrolled; %)	Ratio of non-medical to medical exemptions	Total exemption rate, born 1997 and prior (exempted/enrolled; %)	Ratio of non-medical to medical exemptions
Diphtheria–Pertussis–Tetanus	2004/2005	(37,624/2,515,360) 1.50%	1.68	(7,612/632,599) 1.20%	4.32	(30,012/1,882,761) 1.59%	1.38
	2005/2006	(36,186/2,241,677) 1.61%	1.75	(7,801/598,429) 1.30%	4.31	(28,385/1,638,664) 1.73%	1.43
Polio	2004/2005	(36,840/2,511,499) 1.47%	1.81	(7,715/663,753) 1.16%	4.23	(29,125/1,877,746) 1.55%	1.50
	2005/2006	(35,356/2,436,623) 1.45%	1.95	(5,429/498,749) 1.09%	5.33	(29,927/1,937,874) 1.54%	1.64
Measles–Mumps–Rubella (MMR)	2004/2005	(40,501/2,514,378) 1.61%	1.51	(7,546/632,845) 1.19%	4.81	(32,954/1,881,533) 1.75%	1.22
	2005/2006	(38,490/2,436,600) 1.58%	1.61	(7,726/653,733) 1.18%	4.77	(30,764/1,782,867) 1.73%	1.29
				Mean ratio	4.63	Mean ratio	1.41
				Mean ratio, 2004/2005	4.45	Mean ratio, 2004/2005	1.37
				Mean ratio, 2005/2006	4.80	Mean ratio, 2005/2006	1.45

Source: Ontario Ministry of Health and Long-Term Care. 2008 (August 18). *Immunization Exemptions 2004/05 and 2005/06*. [Unpublished.] Toronto: Author.

Do Exemptions Matter in Canada? Policy Directions

This was a preliminary look at the nature of exemptions to school-entry vaccination laws in the Canadian setting, with a descriptive examination of Ontario exemptions based upon newly available aggregate data. In the presence of a limited scope of compulsory immunization laws in Canada, the overall exemption rate is low. Non-medical exemptions exceed medical exemptions, however, and younger children appear to have been more frequently exempted for non-medical reasons.

The ability to link these data with individual-level characteristics is not yet possible and reflects continuing gaps in public health reporting (Manuel 2006) and the evolving state of immunization information systems (Toronto 2009). Longitudinal individual-level data, models or both, collated with geographic distribution of exemptions, will be important to ascertain discrete estimates of personal and population risk related to opting out in Ontario. Nonetheless, the preliminary findings presented here are of public health and policy concern.

First, in the presence of continuing underimmunization with regard to national childhood coverage targets (Frescura 2007), increased propensity towards non-medical exemptions in communities constitutes another barrier to achieving the levels of immunization coverage required to prevent disease transmission. Our findings corroborate other studies demonstrating an increasing rate of specifically non-medical exemptions claimed by parents on behalf of their children (Salmon et al. 2005). Given that children with non-medical exemptions tend to be geographically clustered (Salmon et al. 1999; Calandrillo 2004; Omer et al. 2009), such findings present potential risks for transmission of disease and consequently, an impact on population health. As recently as 2005, for example, a large outbreak of rubella (over 300 cases) occurred in a religious community in Ontario opposed to immunization, including 10 cases in pregnant women with the associated risk of congenital rubella syndrome in their newborns (National Advisory Committee on Immunization 2006: 299).

Second, we reflect upon the notion that even in the presence of limited state intervention into individual behaviour, the finding that younger children (born in 1998 and after) appear to have been exempted much more frequently for non-medical reasons suggests that, consistent with trends such as for MMR vaccination in the United Kingdom, Canadian parents too may be increasingly weighing perceived personal risk over personal and population benefit when it comes to making decisions about immunization for their children. Accordingly, effective and accurate communication of vaccination risk has been a dominant concern among immunization advocates.

Finally, a detailed examination of the ethical and legal issues related to non-medical exemptions in Canada is beyond the scope of this paper, but a few issues are presented here for future consideration. Compulsory immunization policies present

tensions and trade-offs between individual rights and liberties and societal goals. Non-medical exemptions are one way of dealing with these trade-offs. Different jurisdictions have interpreted these trade-offs differently, however, and a rethinking of this policy issue is perhaps warranted in Canada. In the United Kingdom, for example, in the wake of significant decreases in childhood MMR vaccination coverage, the issue of compulsory vaccination was revisited and not recommended by certain analysts (Salmon et al. 2006). In contrast, in the United States, where compulsory school-entry immunization laws exist in all states, non-medical exemptions are not uniform; many states do not allow philosophical/conscientious exemptions, and this approach has not been found to be unconstitutional (Calandrillo 2004). It has been argued that compulsory immunization laws “demonstrate a public commitment to vaccination” (Salmon et al. 2005). If policy makers were to update (and potentially extend) compulsory school-entry vaccination laws in Canada, such developments should be incumbent upon a more in-depth policy discussion regarding a national responsibility to ensure a reliable supply of safe and effective vaccines for collective immunization programs (Verweij and Dawson 2004; Salmon et al. 2006).

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