

Addressing the Emergence of Pediatric Vaccination Concerns

Recommendations from a Canadian Policy Analysis

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ABSTRACT

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. The views of the public, however, must be considered and respected in the formulation of vaccination policy. We have conducted an analysis of the pediatric vaccination “debate” in the Canadian context. We believe that there is common ground between those who support pediatric vaccination and those who are concerned about these programs. Based on our findings, we believe that the goal of public health authorities should be to maintain trust in vaccines by continuing to meet certain reciprocal responsibilities. To do so, we recommend the following: 1) increased investment in adverse event reporting systems; 2) request for proposals for consideration of a no-fault compensation program; 3) developing pre-emptive strategies to deal with potential vaccine risks; 4) further examination of mechanisms to improve communication between physicians and parents concerned about vaccination. All of these approaches would require additional investment in pediatric vaccination. However, such an investment is easy to justify given the benefits offered by pediatric vaccination and the ramifications of failing to maintain confidence in vaccination programs or missing a vaccine-related adverse event.

MeSH terms: Vaccination; pediatric; policy; adverse events; risk

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Vaccination concerns have reemerged as an important public health issue in several countries. In the United Kingdom (UK) and the United States (US), 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.^{1,2} While Canada has not experienced similar levels of widespread vaccine concern, focal episodes of vaccine refusal have taken place and there is also evidence to suggest that some erosion of public trust is occurring.^{3,4} A key message that emerges from other countries' experiences is that once trust in vaccines or public health is lost, it is difficult to regain.⁵ A primary goal of public health in Canada, therefore, is to ensure that confidence is maintained in the safety and efficacy of vaccines.

Establishing and maintaining trust in the safety of vaccination, however, poses several challenges. Epidemiological limitations make it difficult to demonstrate with absolute certainty that vaccines are safe. When issues of safety and effectiveness relate to the health of children, the requirements for certainty of safety are heightened. Further complicating the issue has been the polarization of the debate, which has limited effective dialogue between the contrasting viewpoints. This polarization presents an important challenge to public health officials, who must be careful to ensure that while they reinforce to the public the safety of vaccines, they do not overlook or underplay a potential threat. The failure to adequately identify and communicate a threat, even a comparatively minor one, could have profound implications when it involves the health of children. In addition to the impact on child health, such a scenario could undermine public confidence in other vaccines and lay the seeds for future anti-vaccination movements.

We have studied the evolving pediatric vaccination “debate” in Canada.⁶ Our objective was to study the issue from a neutral perspective and identify opportunities to inform vaccination policy that would be acceptable to multiple stakeholders. We present here our primary findings and key messages for public health that have emerged from this analysis.

Maintaining trust in pediatric vaccination programs

While there are some individuals who question both the safety and efficacy of vaccinations, our analysis found that many of those concerned about vaccination believe in the concept of vaccination but need to be convinced that everything possible is being done to ensure their safety. This intermediate position also appears to be prevalent among parents who are struggling with the decision, and we believe this “middle ground” should be the primary focus of policies. We recognize the need for public health officials to be strong advocates of pediatric vaccines. However, by meeting certain reciprocal responsibilities to the public, the public’s trust in vaccines can be maintained. Our recommendations are centered on meeting these responsibilities.

Increased Investment in Adverse Event Reporting Systems

An important component of the argument for vaccination is not only to protect the child but also to protect the public. And, while vaccines have predominantly been demonstrated to be safe, there have been clear examples of past vaccine-associated harm.⁷ Therefore, the primary reciprocal responsibility of public health officials to parents is to ensure the ongoing safety of the vaccinations provided to children. Establishing the safety of vaccinations is challenging for several reasons. Pre-licencing trials are able to establish safety to an extent that would be clearly acceptable for most pharmaceuticals (in the range of 1 in 10,000 adverse reaction).⁸ However, given the population-wide exposures of vaccination, lower rates of adverse events could translate into important numbers of cases at a population level. Furthermore, identifying idiosyncratic reactions or individual susceptibility to vaccination using broad epidemiological studies is challenging.⁹ Ironically, as the introduction of vaccines has resulted in the decline of vaccine-preventable diseases, the requirements for safety increase since the vaccine is being provided to a healthy individual and the risk of acquiring the condition, at the individual level, is low.¹⁰ The important proviso is that if enough individuals choose to make this same risk-benefit decision and decide to not vaccinate, herd immunity

may be reduced and the risk of acquiring the condition will correspondingly escalate.

Canada has already taken important steps to ensure the safety of pediatric vaccinations by adding an active surveillance system – the IMPACT system – to the traditional, passive vaccine adverse event reporting system.¹¹ The IMPACT system is, in many ways, more advanced than similar systems designed to detect vaccine adverse events present in other countries. However, our observation was that better efforts need to be made to communicate to parents that such a system exists, thereby reassuring the public that vaccine safety is a high priority.

Beyond communicating existing efforts, further investment is required to optimize both the detection of and the response to potential vaccine adverse events. For instance, the US has a new system called Vaccine Safety DataLink, which links computerized histories of vaccination to hospitalization records and other medical information for members of eight large managed-care organizations in order to detect unexpected and/or rare vaccine adverse events.¹² Because of Canada’s public health care system, we have the opportunity to establish a similar system. Administrative databases could provide opportunities to conduct time-series analyses, case-control studies and self-matched case-series analyses to identify the possibility of vaccine-related harm.¹³ There are some important limitations to embarking upon such approaches, including the inherent limitations of database research. Therefore, an appropriate oversight mechanism, analogous to an independent review committee for clinical trials, should be established to monitor the system.

Request For Proposals for Consideration of a No-fault Compensation Program

The second major reciprocal responsibility of public health to parents is to provide compensation to children in the event that they suffer harm from a vaccine. Given that vaccines are, in part, a public good being provided not only for the benefit of the individual but also for other members of society, it is reasonable and appropriate to consider compensating those who have experienced documented vaccine-related harm.¹⁴ However, there are many potential

pitfalls associated with no-fault compensation systems that need to be carefully considered. Existing programs in the US and Quebec have been criticized both by those in favour of and those against vaccination.¹⁵ Others have argued that the programs have provided immediate relief for parents, allowing them to avoid the legal system. Given the complexities of this topic, we recommend that either Health Canada or the Canadian Institutes of Health Research (CIHR) have a special call for proposals to evaluate the merit and potential structure of a national vaccination no-fault compensation program.

Developing Pre-emptive Strategies to Deal with Potential Vaccine Risks

Hypotheses may develop at an early stage about potential harms associated with vaccines. At times, these may be based on theoretical models or low-level epidemiological evidence. Failing to respond adequately to a risk at an early stage may result in a wide exposure for an otherwise healthy population. Inappropriately responding to a risk and withdrawing a vaccine may result in vaccine shortages that could also produce harm. Thus, having a system in place to rapidly determine if potential harms are real and/or important is critical to both evaluating the benefits and harms of vaccine withdrawal and maintaining trust in vaccines. Canada’s management of influenza vaccine-associated oculo-respiratory syndrome demonstrates an example of a successful risk-management approach concerning vaccine-related harm.¹⁶ A formalization of this approach as well as integration of strategies similar to the blood system risk-management model would also be worth considering. This includes the introduction of partial measures to protect against a risk as a full risk assessment is conducted, followed by calibration of these measures as new evidence becomes available. Communication of all efforts to the public would also be an essential component to this strategy to demonstrate to the public that their concerns are being taken seriously.

Further Examination of Mechanisms to Improve Communication Between Physicians and Parents Concerned About Vaccination

The issue of physician-parent conflict over vaccination occurred frequently during our

analysis. Disputes over pediatric vaccination have the potential to threaten parent-physician relationships, ultimately compromising the care of the child. While it is beyond our objectives to determine how to address this, some suggestions would include having standard information to present to concerned parents, establishing a point of closure to the discussion, and developing web-based resources for concerned parents, targeted to their specific belief systems. Whatever strategy is used, the disagreement over vaccination should not influence future care of the child as, arguably, these are the children that would need to be followed particularly closely. Such an approach would also demonstrate physicians' commitment to the care of these children that could eventually influence future immunization decisions.

CONCLUSION

The approaches that we have described would begin to address some of the ongoing challenges of formulating pediatric vaccination policy, and components of these recommendations are already being undertaken.¹⁷ All of these approaches would require additional investment in pediatric vaccination. However, such an investment is easy to justify given the benefits offered by pediatric vaccination and the ramifications of failing to maintain confidence in vaccination programs or missing a vaccine-related adverse event. Finally, none of what we have described is meant to underplay the commitment of those in public health to protecting children's health and the excellent progress they have made in this regard. We also recognize the commitment and devotion of those who are concerned about vaccination and their efforts to advocate on behalf of children. We believe our recommendations should be acceptable to

both of these viewpoints as they are focussed on the health of children. Ultimately, in this respect, the goals of all those involved in the vaccination debate are the same.

REFERENCES

1. Bedford H, Elliman D. Concerns about immunization. *BMJ* 2000;320:240-43.
2. Gust DA, Strine TW, Maurice E, Smith P, Yusuf H, Wilkinson M, et al. Underimmunization among children: Effects of vaccine safety concerns on immunization status. *Pediatrics* 2004;114(1):e16-22.
3. Public Health Agency of Canada. Rubella: Ontario. *Infectious Diseases News Brief* 2005.
4. Ritvo P, Irvine J, Klar N, Wilson K, Brown L, Bremner KE, et al. A Canadian national survey of attitudes and knowledge regarding preventive vaccines. *J Immune Based Ther Vaccines* 2003;1(1):3.
5. Ward L. Minister outlines steps to boost image of MMR jabs. *The Guardian* February 21, 2002.
6. Sabatier P. Knowledge, policy-oriented learning, and policy change. An advocacy coalition framework. *Knowledge: Creation, Diffusion, Utilization* 1987;8:649-92.
7. Plotkin SA. Lessons learned concerning vaccine safety. *Vaccine* 2001;20(Suppl 1):S16-9; discussion S1.
8. Fritzell B. Detection of adverse events: What are the current sensitivity limits during clinical development? *Vaccine* 2001;20(Suppl 1):S47-S48.
9. Keller-Stanislawski B. Feasibility of improving safety beyond certain limits in clinical trials. *Vaccine* 2001;20 Suppl 1:45-46.

10. Chen RT, DeStefano F, Pless R, Mootrey G, Kramarz P, Hibbs B. Challenges and controversies in immunization safety. *Infect Dis Clin North Am* 2001;15(1):21-39, viii.
11. Scheifele DW, Halperin SA. Immunization Monitoring Program, Active: A model of active surveillance of vaccine safety. *Semin Pediatr Infect Dis* 2003;14(3):213-19.
12. Chen RT, Glasser JW, Rhodes PH, Davis RL, Barlow WE, Thompson RS, et al. Vaccine Safety Datalink project: A new tool for improving vaccine safety monitoring in the United States. The Vaccine Safety Datalink Team. *Pediatrics* 1997;99(6):765-73.
13. Andrews NJ. Statistical assessment of the association between vaccination and rare adverse events post-licensure. *Vaccine* 2001;20(Suppl 1):S49-53; discussion S45-48.
14. In support of a compensation plan for vaccine-associated injuries. Infectious Diseases and Immunization Committee, Canadian Paediatric Society. *CMAJ* 1986;135(7):747-49.
15. Ridgway D. No-fault vaccine insurance: Lessons from the National Vaccine Injury Compensation Program. *J Health Polit Policy Law* 1999;24(1):59-90.
16. National Advisory Committee on Immunization. Supplementary statement for the 2002-2003 influenza season: Update on oculo-respiratory syndrome in association with influenza vaccination. *Can Commun Dis Rep* 2002;28:ACS-6.
17. F/P/T Advisory Committee on Population Health and Health Security (ACPHHS). National Immunization Strategy: Final Report 2003: Public Health Agency of Canada, 2003.

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RÉSUMÉ

On s'interroge sur les risques et les avantages de la vaccination pédiatrique depuis ses tous débuts. De telles préoccupations commencent à resurgir dans certains segments de la population et pourraient miner les programmes de vaccination nationaux. Les points de vue du public doivent néanmoins être pris en compte et respectés lors de la formulation des politiques de vaccination. Nous avons analysé le « débat » sur la vaccination pédiatrique dans le contexte canadien. À notre avis, il y a des points communs entre les partisans de la vaccination pédiatrique et les personnes que ces programmes inquiètent. D'après nos constatations, nous croyons que l'objectif des autorités de santé publique doit être de préserver la confiance envers les vaccins tout en continuant de s'acquitter de certaines responsabilités réciproques. À cette fin, nous recommandons : 1) d'investir davantage dans les systèmes de notification des manifestations indésirables; 2) de lancer des appels d'offres en vue d'un programme d'indemnisation sans égard à la responsabilité; 3) d'élaborer des stratégies préventives pour composer avec les risques possibles des vaccins; et 4) d'examiner plus avant les mécanismes visant à améliorer la communication entre les médecins et les parents préoccupés par la vaccination. Toutes ces approches exigent des investissements supplémentaires dans la vaccination pédiatrique. De tels investissements sont toutefois faciles à justifier, vu les avantages de la vaccination pédiatrique et les retombées négatives d'un bris de confiance envers les programmes de vaccination ou du fait d'avoir négligé une manifestation postvaccinale indésirable.