Optimizing Canadian Public Immunization Programs: A Prescription for Action

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ABSTRACT

Recent expansion of public vaccination programs for children and youth offers new health benefits but at substantially increased cost. As with other large public investments, immunization programs ought to be systematically evaluated for safety, effectiveness and economic value. At present, program evaluations are suboptimal in most provinces and territories. Experts in public health and vaccinology who attended a workshop in 2009 reviewed the shortcomings and produced "prescriptions for action" to improve matters. Six key recommendations were made: 1) a formal requirement should exist to evaluate all public vaccination programs appropriately; 2) greater voluntary harmonization of programs will facilitate evaluations; 3) a mechanism is needed to prioritize and coordinate program-specific evaluations; 4) new funding mechanisms are needed for basic jurisdictional studies and joint studies of broad relevance; 5) strong emphasis is needed on capacity development and training; and 6) administrative barriers to accessing health information systems and publishing evaluation studies need to be overcome. The expert group considered the need to improve program evaluations as urgent and compelling, with success achievable with dedicated funding and effective leadership. Demonstrating that Canadian immunization programs are among the world's best and safest is a sound strategy for maintaining public participation in those programs.

Key words: Vaccines, adverse effects; immunization programs: standards, utilization, economics

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Routine immunization programs are widely recognized as a leading contributor to improvements in population health during the past century.¹ In the past decade, provincial and territorial programs grew rapidly with support from the National Immunization Strategy,² adding important new vaccines for young children and adolescents (Table 1). While new vaccines have provided substantial health benefits,^{3,4} expansion has been costly because of the higher costs of products such as pneumococcal conjugates and human papillomavirus (HPV) vaccines. Whereas the cost of immunizing a child through to adolescence was \$35 in 1986,⁵ the current cost for girls is over \$800 and for boys over \$450 (Table 1). Price increases are likely to continue with future vaccines.

Immunization programs now represent a substantial public investment. As with other tax-funded programs, they ought to be systematically evaluated to ensure that best value and practices prevail. Ongoing evaluation of the safety and effectiveness of immunization programs is paramount for maintaining a high level of public trust and acceptance. The effectiveness of immunization programs can differ from clinical trial estimates because programs can have beneficial indirect effects, aim to achieve longer-term protection and involve more diverse populations following less precise dosing schedules. Careful monitoring of vaccine safety is warranted to detect any rare adverse events that become evident with wider use or repeated dosing as well as to refute false associations and concerns. Regular surveys of uptake of newer vaccines can identify needs for greater public education or marketing efforts. Ongoing

disease surveillance provides a measure of program success and can warn of the need for a booster dose or broadened coverage of an evolving target. Seroepidemiologic studies can also detect gaps in protection and provide early warning of need for boosters or improved regional coverage.

Most Canadian provinces and territories fall short of conducting optimal program-related evaluation and research, with some having the resources only to tally vaccine-preventable disease notifications and to manage reports of adverse events following immunization. To analyze the current limitations and identify desirable improvements, the Canadian Association for Immunization Research and Evaluation (CAIRE) invited 32 Canadian experts to a workshop in Ottawa (September, 2009). This broad sample included regional, provincial and federal immunization program

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Table 1. Cost of Vaccines for Immunizing a Child Through to Adolescence, British Columbia, 2009

Age	Vaccine(s)
2 mo	DPT-Polio/Hib, PCV7, MenC, Hepatitis B
4 mo	DPT-Polio/Hib, PCV7, Hepatitis B
6 mo	DPT-Polio/Hib, Hepatitis B
	Influenza (2 doses, to 23 mos only)
12 mo	MMR, MenC, Varicella, PCV7
18 mo	DPT-Polio/Hib, MMR
4-6 years	DPT-Polio
11 years	HPV (3 doses, girls only)
14-16 years	dTaP
TOTAL COST (2009\$)	\$451 (boy), \$806 (girl)

Data provided by M. Naus, Immunization Programs Director, BC Centre for Disease Control, Vancouver, BC

administrators, public health and academic vaccine researchers, epidemiologists, communication specialists and others. Invited speakers highlighted the substantial expertise in some Canadian provinces and described more advanced evaluation systems in the US and UK. Smaller "break-out" groups were challenged to propose practical improvements. These three groups then pooled their perspectives, leading to consensus on the main difficulties and "prescriptions for action" to overcome them. The challenges are discussed in the following paragraphs and the action items are listed in Table 2.

Historical challenges

The need for systematic, expert evaluation of immunization programs has risen sharply as programs have become more costly and complex. However, most Canadian jurisdictions lack an established foundation on which to build the greater evaluative capacity required. Every province and territory needs to have a minimum capacity to evaluate the safety, effectiveness and uptake rates of the vaccines being provided to the public. Historically there was a prevalent view that any post-marketing vaccine studies ought to be the responsibility of vaccine suppliers. This is now both unworkable with a globalized vaccine industry and undesirable in terms of providing the public with data of unassailable quality and transparency.

Political challenges

A political system in which 13 provinces and territories have individual responsibility for health care has led to many differences among their immunization programs. Provincial/territorial prerogatives aside, it is simply not feasible to evaluate properly a multitude of different domestic programs. A single, mutually agreeable immunization schedule and harmonized programs would be much easier (and cheaper) to evaluate in depth, although there can be merit in a planned comparison of a few alternative programs. Collaboration among 3-4 provinces would kick-start the process by demonstrating the mutual advantages of shared evaluations.

Leadership challenges

A coordinated mechanism is needed to identify cross-cutting, program-related evaluation and research priorities (e.g., need for booster doses) and to coordinate responses among the jurisdictions. Leadership in this regard was proposed for the National Immunization Strategy (NIS). While a research and evaluation component has yet to materialize, this remains a desirable component of the renewed NIS. Other models for defining evaluation and

Table 2. "Prescription for Action" to Optimize Canadian Immunization Programs

1. A requirement to evaluate all public vaccination programs appropriately for the life cycle of each product should be enshrined in legislation or regulation in every province and territory, signaling a commitment to ensure that Canadian programs are of the highest quality.
2. Jurisdictions should voluntarily commit to harmonizing the key components of new programs for the numerous advantages to be gained in sharing the evaluation tasks and costs. A mechanism to reach consensus among jurisdictions will be needed and could be facilitated federally.
3. Develop a mechanism to define program-specific evaluation priorities beyond the basics, guided by a set of criteria. A mechanism is also needed to commission specific projects and integrate overall activities to best effect.
4. Provinces should designate a percentage of vaccine purchase budgets for evaluation of the related public programs, using some of the funds at the jurisdictional level to increase their own capacity for basic aspects of evaluation and some collectively for other aspects pertinent to all, including emergencies.
5. Capacity development for program evaluations should be a high priority for all stakeholders and should include inducements for networking among provincial agencies and with academic colleagues. Substantial opportunities exist for federal leadership in this area.
6. Ministry/agency data stewards should facilitate access of authorized evaluators to health information systems for immunization program-related studies. Public health agencies should embrace the value of ethics reviews and seek approval for evaluation studies with publication potential. Ethics committees should develop skills in reviewing public health program evaluations.

research priorities beyond the basics can also be considered, such as expert workshops.⁶ The National Advisory Committee on Immunization also identifies key questions. The process to identify program-related evaluation and research priorities should be rigorous, transparent, principled and independent of the funding source(s). Given the great utility of the Erickson and De Wals framework⁷ for considering a new public vaccination program, analogous criteria for program evaluation and research should be developed. External peer review was advocated whenever feasible. Once priorities have been identified, a process is needed to commission specific projects and integrate overall activities to best effect. The commissioning process should be open to competitive applications that will be peer reviewed to select the best response.

Funding challenges

Neither provincial nor federal public health agencies have adequate funding at present for optimal program evaluation and research. Many provinces and territories have had difficulty purchasing newer vaccines, let alone evaluating them. The NIS provided significant interim funding to help establish new programs but, as noted above, was unable to assist with program "aftercare." Granting agencies such as CIHR will fund highly selected vaccine-related projects but the basic aspects of evaluation need to be funded by the core budgets of public health agencies. Rapid response studies are difficult to fund through federal contracts or CIHR grants and need to be expedited by specific contingency funds.

An innovative funding solution was adopted in Quebec in the 1990s and since 2007 in a few other provinces, involving setting

aside a small percentage of the vaccine purchase budget (e.g., for HPV) to fund program evaluation studies. This approach makes great sense. If every province did this routinely and pooled some of the funds, program evaluation and research could be substantially improved within each province and on behalf of all when collaborative studies are undertaken in the common interest (such as to validate a reduced dosing schedule). Pooled funds could also provide contingency funding for rapid response studies.

Human resources challenges

Too few skilled professionals exist within Canadian public health institutions and academia to conduct optimal immunization program evaluation and research. Until recently, this was not an attractive career path. However, with greater resourcing of personnel and project funding opportunities, program evaluation and research can be very attractive. The expert group considered program evaluation science to have the greatest growth potential within vaccinology and a high job satisfaction potential given the translational nature of the work. The largest provinces have already created central public health agencies with growing capabilities for program studies. More provinces are likely to adopt similar models which include active collaboration among the agencies and with academic centres. Active capacity-building initiatives are necessary within public health, including innovative training opportunities. A range of salary supports is needed, from studentships to career awards for accomplished scientists. Expertise is needed across the discipline but a full range of expertise is not needed at each agency: highly specialized skills are better shared than duplicated. To achieve critical mass quickly, collaborations, secondments and exchanges should be strongly encouraged among public health agencies and with academic researchers.

Other challenges

As provinces commit to enhancing program evaluation, it will become easier to remove unintended barriers. Access to administrative databases is a case in point. Each jurisdiction expends great resources on health information systems, yet the data are often difficult to access for evaluation studies. Change will require realignment of priorities between program optimization and privacy protection, which ought to be possible without compromising either one, as both are in the public interest. Developing or enhancing working relationships with data stewards and Privacy Commissioners will be an important enabler in developing this functionality.

Challenges exist with respect to ethics review and approval for program studies. At the heart of this is the blurry distinction between evaluation and research. The remedy is to consider almost all evaluation studies as research requiring ethics review and approval. Even when human subjects are not directly involved, it is optimal to demonstrate due regard for the confidentiality of their information, thereby preserving the option to publish in medical journals.

Finally, the expert group noted the absence of a timely Canadian publication forum for immunization-related issues and study results and recommended revival of the Canada Communicable Disease Reports in an updated electronic format. This too is an opportunity for federal leadership in immunization research.

SUMMARY

The expert group recommended urgent improvement and expansion of evaluations of immunization programs. Necessary developments are described in the "Prescription for Action" (Table 2). It is a tall order but entirely feasible with dedicated funding and effective leadership. The National Immunization Strategy offers a potential model for effecting change. Demonstrating that Canadian immunization programs are among the world's best and safest is a sound strategy for maintaining public participation in those programs.

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RÉSUMÉ

L'expansion récente des programmes publics de vaccination des enfants et des jeunes offre de nouveaux avantages pour la santé, mais à un coût considérablement plus élevé. Comme pour les autres grands investissements publics, il faudrait systématiquement évaluer la sécurité, l'efficacité et la valeur économique des programmes d'immunisation. À l'heure actuelle, les évaluations de programmes sont sous-optimales dans la plupart des provinces et des territoires. En 2009, des experts en santé publique et en vaccinologie qui assistaient à un atelier ont examiné les lacunes de ces programmes et produit des « prescriptions d'action » pour améliorer les choses. Six grandes recommandations ont été formulées : 1) il devrait être formellement exigé d'évaluer convenablement tous les programmes publics de vaccination; 2) une plus grande harmonisation volontaire des programmes facilitera ces évaluations; 3) il faut un mécanisme pour hiérarchiser et coordonner les évaluations de programmes; 4) il faut de nouveaux mécanismes de financement pour mener des études provinciales ou territoriales de base et des études communes présentant un large intérêt; 5) il faut insister vigoureusement sur le renforcement des capacités et la formation; et 6) les obstacles administratifs à l'accès aux systèmes d'information sanitaire et à la publication d'études d'évaluation doivent être surmontés. Le groupe d'experts a considéré qu'il était urgent et incontournable d'améliorer les évaluations de programmes, et qu'on pouvait y parvenir avec un financement particulier et un leadership efficace. Pour soutenir la participation du public, une bonne stratégie consiste à montrer que les programmes d'immunisation canadiens sont parmi les meilleurs et les plus sûrs au monde.

Mots clés : vaccins, effets indésirables; programmes immunisation : normes, utilisation, économie