

**Immunization in Canada:
a success to build on**

Scott A Halperin, MD*
Robert Pless, MD**



Scott A Halperin, MD



Robert Pless, MD

* Departments of Pediatrics, and Microbiology and Immunology,
Dalhousie University and the IWK Health Centre, Halifax, Nova Scotia.
** Division of Immunization and Respiratory Diseases, Bureau of Infectious Diseases,
Centre for Infectious Disease Prevention and Control, Health Canada, Ottawa, Ontario.
Address for correspondence and reprints: Scott A. Halperin, MD,
Clinical Trials Research Center, Dalhousie University – IWK Health Centre,
5850 University Avenue, Halifax, Nova Scotia, Canada B3J 3G9.
Phone: 1-902-470-8141; Fax: 1-902-470-7232; email: shalperin@iwkgrace.ns.ca

I Introduction

In the 200 years since the first vaccination against smallpox by William Jenner, immunization programs have prevented morbidity and saved countless lives, leading the United States Centers for Disease Control to name immunization as the number one medical achievement of the 20th century.¹ In this commentary we will review the current status of vaccines and vaccine preventable diseases, place the benefits and the risks associated with immunization in perspective, and review the system present in Canada to monitor vaccine safety. Finally, we will outline the current status of the Canadian National Immunization Strategy and challenge front line practitioners to play a role in its development as new vaccines to prevent morbidity and mortality become available.

II Background

Because of accomplishments such as the eradication of smallpox, vaccines have become a victim of their success. Since vaccines are given to healthy people to prevent disease, as the diseases that once maimed or killed have been brought under control, the public, new parents and even some health care providers have begun to question the need for continued immunization programs. And since vaccines are given to healthy people, a much higher standard of safety is expected of them. Great strides in evaluation, manufacturing and quality control have been achieved since the first immunization programs were implemented, but as all medical interventions, vaccines have their risks. So while the impact of vaccination on individual diseases has been tremendous, this control is very fragile.

When immunization programs are discontinued or the public loses confidence in them, diseases return. The challenge facing modern immunization programs is to continue to succeed in their objectives controlling infectious diseases both old and newly vaccine-preventable, while being responsive to today's consumers of health care. No other medical intervention is as dependent on full community participation. So, as Sir Graham Wilson noted in his book *The Hazard of Immunization*,² "Vaccines, of one sort or another, have conferred immense benefit on mankind but, like aeroplanes and motor-cars, they have their dangers. It is for us, and for those who come after us, to see that the sword which vaccines and antisera have put into

our hands is never allowed to tarnish through overconfidence, negligence, carelessness, or want of foresight on our part."

Challenges from consumer groups in the 1980's, responding to both real and false claims of harm from vaccination, had resulted in a number of important steps towards ever safer vaccines and vaccination programs. In the United States, for example, the passing of the National Childhood Vaccine Injury Act of 1988 led to the creation of an injury compensation plan based on the continual best evidence of true potential harm from vaccine administration, along with improved postmarket surveillance of adverse events. This included a revamped method to collect adverse event case reports as well as the establishment of a large-linked database project for more sophisticated safety analyses. In Canada, similar improvements were made except the need for a compensation plan was not felt as urgent.

Through the 1990's, immunization programs underwent more change. A number of new vaccines became available and were added to the immunization schedule. Both parents and health care providers were faced with new information to deal with, and the immunization visit became more complex. Although designed to protect infants from harm, new vaccines led understandably to more questions. A number of surveys conducted over the past few years among parents especially, have shown increasing concern about immunization.^{3,4} Although there is strong support for vaccines, parents hold important misconceptions - especially about their safety. At the same time, parents consider their health care provider to be the most trusted source of information about immunization.⁵ This makes it ever more crucial for all health care providers to understand the continued need for vaccination against infectious diseases, and communicate this to parents and patients.

III Current epidemiology and vaccine programs in Canada

In Canada, there is universal, publicly funded immunization against nine diseases (diphtheria, tetanus, pertussis [whooping cough], polio, *Haemophilus influenzae* type b [Hib], hepatitis B, measles, mumps, rubella).⁶ The National Advisory Committee on Immunization and the Canadian Paediatric Society also recommend universal infant immunization against varicella (chicken pox),

Neisseria meningitidis type C (meningococcal C conjugate vaccine) and *Streptococcus pneumoniae* (pneumococcal conjugate vaccine), and against pertussis in adolescents;⁷⁻¹³ however, publicly funded programs for these programs are not available in all provinces. Finally there are universal, publicly funded programs for adults against influenza and pneumococcus.

As a direct result of immunization, there has been a dramatic decrease in the morbidity and mortality of vaccine preventable diseases in Canada. Prior to introduction of diphtheria toxoid vaccine in Canada in 1926, the incidence of diphtheria ranged between 80 and 100 per 100,000 population; in 1924 a peak of 9000 cases of diphtheria were reported. With universal immunization, diphtheria has virtually disappeared from Canada with only 1 to 2 cases reported annually. Before immunization, between 30 and 50 deaths from tetanus were reported each year in Canada. With universal tetanus immunization, an average of 5 cases (range 1-7) have been reported over the last 10 years; the last tetanus death in Canada was in 1995. Of note, over half of tetanus cases are in adults > 50 years of age in whom vaccine induced immunity had likely lapsed; 10% of cases are in foreign born Canadians whose immunization status was not known. One of the most remarkable immunization triumphs is the elimination of polio from the western hemisphere and the prospects for global elimination within the next decade. Before universal immunization, up to 20,000 cases of polio occurred in Canada each summer. Inactivated polio vaccine was introduced in Canada in 1955 and oral poliovirus vaccine in 1962. The last major epidemic of polio in Canada was in 1959 with over 1800 paralytic cases. Smaller epidemics occurred in 1970 and 1978 with peaks of 7 and 9 paralytic cases respectively. In 1995, the World Health Organization certified the western hemisphere as polio free.

Measles is most contagious of the vaccine preventable infections; before universal immunization program, virtually all Canadians were infected by measles with substantial morbidity and mortality. Measles pneumonia occurs in 5-7% of cases and 1 per thousand infected develop measles encephalitis. Measles continues to be one of the major infectious disease killers in the developing world, particularly in populations suffering from malnutrition. Before universal immunization against measles in Canada, 300,000 to 400,000 cases occurred in 2 to 3 year epidemic cycles. These rates dropped dramatically throughout the

1970's and 1980's; however, epidemics continued to occur, albeit much smaller than in the pre-immunization era. The cause of these continued outbreaks was that with the vaccine's 90-95% efficacy and the high infectivity of the measles virus, sufficient susceptible individuals remained in the population to sustain transmission and propagate an outbreak. Therefore, in 1996-1997, all provinces changed to a two-dose measles immunization schedule. The reduction in the size of the measles susceptible pool with the use of a second dose has resulted in the interruption of natural transmission of measles in Canada. In the last several years, most cases of measles in Canada have been due to importation and transmission has not progressed beyond the immediate susceptible contacts of the index case. With continued high immunization coverage, it is likely that indigenous transmission of measles may be eliminated from the western hemisphere; progress elsewhere in the world may be slower given the high rates of coverage required to interrupt transmission.

Rubella is a generally mild infection with few serious complications in children. In adolescents and adults, infection can be associated with polyarthralgia or polyarthritis. The goal of universal rubella immunization is to prevent transmission of infection to pregnant women and subsequent infection of the fetus. Congenital rubella syndrome can result in miscarriage or severe congenital malformations including cataracts, deafness, congenital heart disease and mental retardation. Since 1983, all provinces have included rubella immunization as part of the infant MMR immunization. As a result, in the last several years fewer than 100 cases of rubella have been reported in Canada (contrasted with over 50,000 cases annually before universal immunization) with only 1 to 2 cases of congenital rubella; most of these cases are now in foreign born women from countries where rubella immunization is not part of the routine immunization schedule.

Infection by the mumps virus usually causes a mild infection which is often subclinical. Symptomatic cases are characterized by adenopathy and parotitis; complications can include orchitis and oophoritis in post-pubertal males and females respectively. Before universal immunization, mumps was the most frequent cause of viral meningitis; although most fully recover, permanent hearing loss rarely occurred. In the immunization era, mumps cases have decreased by over 99% from nearly 50,000 annually to an average of under 250 cases per year. In contrast to

mumps, hepatitis B is an infection which may be asymptomatic in up to 50% of adults and 90% of children but can have substantial long term adverse outcomes. The acute infection has a case fatality rate of 1–2%, primarily in older individuals. Anyone infected with the virus, whether symptomatically or asymptotically can become a chronic carrier; chronic carriers are at high risk of developing chronic hepatitis, cirrhosis, and hepatic carcinoma. The risk of becoming a chronic carrier is inversely related to age; up to 90% of infants infected at the time of birth will become chronic carriers. In Canada, most infections are acquired after adolescence and are related to sexual activity and injection drug use; however, over one third of cases have no identified risk factors. Currently, all provinces have universal hepatitis B immunization programs either pre-adolescence (typically school based) or during infancy (or both). In areas of the world with very high rates of hepatitis B vaccine (such as Taiwan), universal hepatitis B immunization programs have already resulted in a decrease rate of chronic hepatitis B infection and liver cancer.¹⁴

One of the most remarkable recent successes of the Canadian immunization program has been the near elimination of invasive disease due to Hib in the last decade. Hib causes epiglottitis, sepsis, pneumonia, cellulitis, septic arthritis, and was the most common cause of bacterial meningitis in children. Mortality from Hib meningitis approaches 5–10% and permanent neurologic sequelae occur in 10–15% of survivors including deafness in 15–20%. Until the early 1990's, nearly 2000 cases of invasive Hib disease were reported in Canada. With universal infant Hib immunization, less than 20 cases of invasive Hib disease are now reported each year; half of the cases are in children who did not receive immunization. Success has also been achieved with the universal pertussis immunization program, although not as dramatically as with Hib. Since widespread pertussis immunization was initiated in Canada in the 1950's, there has been a 90% decrease in the number of reported cases. However, because the whole cell pertussis vaccine used over the last 50 years had an efficacy well below 80%, outbreaks of pertussis continued to occur every 4 to 5 years. A more efficacious acellular pertussis vaccine associated with far fewer adverse events than the whole cell vaccine (fever, irritability, decrease appetite, injection site tenderness, febrile seizures) was introduced in all provinces in 1997–1998. This vaccine has

led to decreased number of cases in vaccine recipients although the incidence of whooping cough has not changed in infants too young to be immunized or in older adolescents and adults whose immunity to the whole-cell vaccine has lapsed. This has led to the recommendation for an adolescent booster with an adult formulation acellular pertussis vaccine. This is now publicly funded in several provinces and territories.

Three other vaccines are currently recommended but not publicly funded in all Canadian jurisdictions. Varicella is a common viral infection with over 300,000 cases in Canada annually. By 5 years of age, 50% of children have had chickenpox rising to 90% by 10 years of age and 95% by 15 years of age. Although most often a mild disease (although children are sick enough to miss on average 3 days of school or daycare), there are over 2000 hospitalizations each year for varicella and between 5 and 10 deaths. Complications include cerebellar ataxia, encephalitis, cellulitis and arthritis. Pneumonia also occurs, particularly in older children and adults. Varicella increases the risk of invasive group A streptococcal infection by over 50 fold and is the most common predisposing event for “flesh eating” streptococcal infection. Although varicella vaccine is recommended for all children at 12 months of age, at present, less than half of the provinces provide the vaccine as part of their publicly funded programs. In the US where universal immunization with varicella vaccine has been recommended for over 7 years, there is already evidence of a decline in the incidence of varicella disease. Concern has been expressed about the duration of protection afforded by varicella vaccine; durable protection has been demonstrated for the over 10 years for which data are available. However, it is possible that in the future a two dose schedule to provide both a booster dose and to protect those who were not protected by the first dose may be required.

Meningococcal C conjugate vaccines are available in Canada and are recommended for universal use in children. *Neisseria meningitidis* causes severe invasive disease including sepsis and meningitis. Serogroup C disease occurs in outbreaks with the highest incidence in children under 2 years of age and adolescents. In the United Kingdom which experience high rates of invasive meningococcal disease, a universal immunization program was implemented with the meningococcal C conjugate vaccines and an immediate and persistent decline in meningitis cases

was demonstrated.¹⁵ In Canada, universal programs are available in only one third of provinces and territories. *Streptococcus pneumoniae* is the other major remaining cause of bacterial meningitis and sepsis in children. The pneumococcus also is a frequent cause of pneumonia, septic arthritis, sinusitis, and is the leading bacterial cause of otitis media. The pneumococcal conjugate vaccine contains 7 pneumococcal serotypes that account for over 85% of the invasive disease in children and in clinical trials was nearly 100% effective in protecting against bacteremia and meningitis. Although only recently implemented in the United States and hampered by vaccine supply problems, the universal immunization programs have already resulted in a dramatic decline in invasive disease caused by *S. pneumoniae*.¹⁶ In Canada, only one province has implemented a publicly funded universal immunization program, despite recommendations to that effect by the National Advisory Committee on Immunization and the Canadian Paediatric Society.

Despite these dramatic and consistent successes of universal immunization programs, the accomplishments are not universally acclaimed. Anti-vaccination critics claim that the successes attributed to vaccines are due to improved sanitation and living standards. Although clean water and lack of crowding have had a major effect on reducing the burden of disease from infectious agents including vaccine preventable diseases, the near elimination of most of these diseases would not have occurred without universal immunization programs. The success of Hib vaccine in Canada and the US and meningococcal C conjugate vaccine in the UK certainly cannot be attributed to better living conditions, given their implementation and effects within the last decade. The experience in countries that for one reason or another discontinued immunization programs also graphically illustrates this fact. After the dissolution of the Soviet Union and the formation of the Newly Independent States, manufacture and distribution of vaccines was disrupted. As a result, a massive outbreak of diphtheria occurred in Eastern Europe with over 100,000 cases and thousands of deaths.¹⁷ Because of the infectious pressure, spread of disease occurred into bordering countries such as Finland, Poland and Germany; in those countries, cases were reported in individuals whose immunity had lapsed. In Japan, immunization against pertussis was discontinued because of four deaths temporally (but not causally) related to immunization. In the years

following the withdrawal, large outbreaks of pertussis occurred with over 30 pertussis-related deaths.¹⁸ Sweden and the United Kingdom had similar experiences with pertussis: in Sweden, the vaccine was withdrawn because of the impression of lack of efficacy; this resulted in a resurgence of pertussis to levels approaching those seen in the prevaccine era.¹⁹ In the UK, concern about vaccine associated adverse events led to a decline in the use of pertussis vaccine by primary care practitioners leading to large outbreaks of pertussis.²⁰ Large epidemiological studies demonstrating the safety of pertussis vaccine led to a renewal in confidence in the vaccine, increased rates of immunization, and dramatic declines in pertussis disease. Unfortunately unfounded allegations about the safety of the measles-mumps-rubella vaccine are resulting in declining use of that vaccine so the UK may be destined to relive its history of a resulting increase in the burden of a vaccine preventable disease.

IV Risk-benefit

With historic benefits of immunization so clear, and evidence that stopping vaccination or allowing coverage to fall below critical levels causing harm, it is crucial that immunization programs provide parents and patients the appropriate information to allow them to be comfortable with the decision to vaccinate, whenever appropriate from a medical standpoint. Nevertheless, all decisions carry risk. Benefit-risk concerns about vaccination arise because the act of being vaccinated is an active choice, versus the risk of disease being “out of one’s hands”. There are two areas where immunization programs adapt to assist with the immunization choice. These are 1) ensuring that ever safer vaccines are used and 2) that vaccines on the market are continually assessed for safety. In a paper entitled “The biology of vaccines and community decisions to vaccinate”, Phyllis Freeman wrote in 1997:²¹ “The very biology of vaccines makes the choice to employ them far more than a collection of individual decisions. The study of vaccine adverse events is not an effort to provide individuals with a basis for deciding whether to vaccinate but rather an effort to improve the safety and effectiveness of vaccines.” This may be an important distinction.

In Canada, a number of systems have evolved over the past 2 decades to ensure that the benefit of vaccines continually outweigh any risk. Canada’s National Advisory Committee on Immunization (NACI) meets regularly to

review recommendations for the use of vaccines in the Canadian context, and alters those recommendations as new data become available. Should an emergent vaccine safety issue be recognized, NACI is convened and a statement produced. NACI has produced statements on the mercury-based preservative thimerosal and the move for its removal from vaccines where possible as a precautionary measure,²² and on the identification of an increased incidence of allergic type reactions labelled the “Oculor-espriatory Syndrome” during the 2000–2001 influenza vaccination season, and its management.²³

Supporting the continual monitoring of vaccines administered in Canada is a series of programs that include a national, voluntary reporting system for adverse events suspected to have been related to a vaccination, an active, pediatric hospital-based network that looks for the more serious adverse events,²⁴ as well as an expert committee that reviews data from these systems on a regular basis.²⁵

Monitoring the safety of vaccines in Canada is not done in isolation of other information sources about their safety. Routine childhood and adult vaccines, as well as most other vaccines such as those for international travel, are used around the world. Safety issues and concerns span the globe, and monitoring programs and investigations carried out anywhere in the world supplement and support efforts in Canada. For example in the United States, while they have a similar system of voluntary reporting of adverse events, they have not as yet mounted any active surveillance. However, the large-linked database project entitled the Vaccine Safety Datalink conducts many ad hoc studies of vaccine safety in response to public concern or hypothesis generated by the passive reporting system, whose results are often applicable to the Canadian context. Such international collaboration, and international responsiveness to vaccine safety issues, helps ensure that vaccine safety concerns are investigated so that appropriate steps can be taken, and thus confidence in immunization programs remains strong.

V National immunization strategy

Beginning in the mid-1990's on the heels of several measles outbreaks, notably in the province of Ontario which experienced some 2,400 cases in 1995, planning began for a national immunization program to try to redress a number of inefficiencies in the way immunization is delivered in Canada. For example, mathematical modeling sug-

gested that the best way to control future measles outbreaks was to implement a nationwide second dose measles vaccine catch-up, followed by changing the immunization schedule for measles to include 2 doses of vaccine. Unfortunately, given the precedent that immunization was a provincial responsibility, the federal government elected not to purchase the catch-up dose of vaccine which the provinces had requested and promised to implement in a coordinated fashion. The resulting disjointed effort at measles control (with only some provinces implementing a catch-up dose, and others delaying the start of their two-dose schedule) may have been a contributing factor to several further provincial outbreaks. The proposed national immunization program called for national vision and goal-setting for vaccine preventable disease control; reiterated the goal of pre- and post-licensure activities to ensure stable and safe vaccine supply; targeted additional research on vaccine efficiency, cost-utility and safety and spoke to the need to enhance surveillance of vaccine-preventable disease and vaccine coverage for optimal program planning, along with better support to provincial and territorial immunization programs, among other activities. The proposal wound its way up through federal/provincial committees and was adopted by the provincial deputy ministers of health and finally translated into some seed funding as an allocation in the 2003 federal budget. Initial work will focus on improved safety and effectiveness of vaccines, better information on immunization coverage rates within Canada, and enhanced coordination and efficiency of immunization procurement. The national immunization strategy, as it is now called, once fully realized, will strive to ensure that all children in Canada will have equal access to all recommended vaccines, both new and improved, and through enhanced record-keeping, increased collaboration between the provinces and more timely health care provider and public education, that their parents can feel comfortable with the decision to immunize. The strategy's immunization safety components, building on the existing infrastructure, will help maintain that confidence.

VI Vaccines of the future

Given the past successes of universal immunization programs, one can confidently predict that new vaccines will be added to the routine immunization schedule. A safe and effective vaccine against hepatitis A already exists and

may have a role in populations where the burden of infection and disease are high. In view of the increasing mobility of the Canadian population, an argument can be made for universal protection against hepatitis A to prevent acquisition of infection during adolescent and adult overseas travel. Meningococcal conjugate vaccines including additional serogroups are already in clinical trials and will likely replace the current C conjugate vaccine. Influenza causes significant respiratory infection in both children under 2 years of age as well as the elderly. Nasal influenza vaccines will make universal childhood flu immunization programs logistically feasible and are likely to be recommended when they become available. Rotavirus vaccines, group A streptococcal vaccines, group B streptococcal vaccines and respiratory syncytial virus vaccines are all under development and in clinical trials and will be vying for a place in the future immunization schedule. Vaccines against infections that lead to cancer are also in development; a vaccine against human papilloma virus will likely be the first vaccine (other than hepatitis B vaccine) of this type available. Vaccines against hepatitis C and human immunodeficiency virus (HIV) are also on the distant horizon. Significant research is also underway to develop non-infectious disease related vaccines to treat and prevent cancer.

VII The role of the front-line practitioner

In view of the past accomplishments and limitless future for vaccines, the challenge for the primary care practitioner is to stay current with the science related to vaccines and vaccine preventable diseases. Outdated attitudes, misrepresented data, and unsubstantiated allegations do a disservice to the Canadian population who look to health care providers for guidance. Physicians, chiropractors and nurses have all been guilty of misleading the public about immunization. It is the responsibility of both the leaders and practitioners of these provider groups to ensure that the majority of their members understand the benefits of immunization and are vocal in supporting immunization with their clientele. This entails knowledge and understanding of the benefits and risks of immunization which must be explained to Canadians and an understanding of the data which demonstrate that the benefit/risk equation clearly favours immunization. Primary care practitioners must be the most vocal advocates for immunization to ensure that the Canadian population achieves the maximal

benefit of these programs. This includes equitable access to old and new vaccines throughout Canada as outlined in the National Immunization Strategy.

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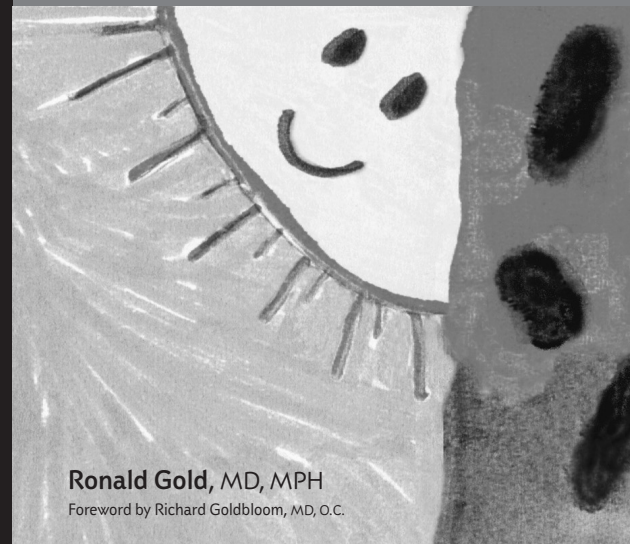
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