

## Childhood Immunization

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### **Topic**

*Immunization*

### **Introduction**

Childhood immunization is one of public health's greatest achievements.<sup>1</sup> As a result of successfully implemented childhood immunization programs, the incidences of vaccine-preventable diseases are at all-time low levels; measles and polio no longer circulate in the Americas; and the death of a child from a vaccine-preventable disease is a rare event.

Immunization is a clinical preventive service that is recommended for virtually every child in the world. Although immunization schedules vary from country to country, every country implements a basic set of immunizations that help infants survive so that they can grow and develop into healthy adults.

### **Subject**

In the U.S. and Canada, children are now routinely protected against 12 vaccine-preventable diseases: diphtheria, tetanus, pertussis (whooping cough), poliomyelitis, hepatitis B, invasive haemophilus influenzae disease (an invasive disease caused by *Haemophilus influenzae* that may produce any of several clinical syndromes, including meningitis or pneumonia), invasive pneumococcal disease, measles, mumps, rubella (German measles), varicella (chicken pox) and influenza.

Vaccines generally confer long-lasting immunity upon the recipient after proper administration of a single dose or a series of doses of vaccine. Vaccines differ from other clinical preventive services in that they not only protect the child vaccinated, but they have the ability to protect individuals not vaccinated. This is accomplished by interrupting the circulation of the disease-causing bacteria or virus — a phenomenon called “community immunity” or “herd immunity.” Some children cannot be vaccinated due to a medical contraindication to a vaccine. For example, children with cancer who are undergoing chemotherapy cannot receive live vaccine viruses. When community vaccination coverage levels are sufficiently high, the transmission of the prevalent form of the disease stops, which prevents children who cannot be vaccinated from acquiring the disease.

### **Problems**

Childhood immunization programs face many challenges. The number of diseases preventable through routine vaccination increases as biotechnology brings the fruits of vaccine science to benefit children. This increase in power and scope comes at the expense of an increase in the complexity of service delivery and cost of services. To date, the increased number of vaccinations has not caused a parallel increase in the number of preventive-care visits to primary-care providers. However, the cost of vaccines and the burden to families and society to pay for these vaccines have been rising rapidly.<sup>2</sup>

The very success of childhood vaccination brings the challenge of communicating to parents the importance of protecting their children when the diseases prevented through vaccination are no longer seen. A lesson that has been repeatedly observed is that complacency in the administration of vaccinations can lead to a decline in community-wide vaccination coverage levels. Once coverage levels decline below the threshold of community immunity, the disease inevitably returns because the disease-causing bacteria or viruses continue to circulate in parts of the world.

A particularly important challenge is to maintain high vaccination coverage levels in the face of vaccine safety concerns. Vaccines routinely used for children have never been safer than they are today. As new knowledge or technology is developed that can make vaccines even more safe, immunization recommendations are updated to constantly provide parents with the safest method of protecting their children from vaccine-preventable diseases.<sup>3</sup> Over the past two decades, some vaccine safety allegations have led to a loss in confidence and a decline in coverage levels, with a resulting return of epidemics of disease. Most recently, this phenomenon has been observed in the United Kingdom's measles elimination efforts, but well documented cases have occurred in many countries.<sup>4</sup>

A basic challenge is to ensure the supply of vaccines routinely recommended for children. During the past five years, there have been major disruptions in the United States' supply of vaccines against nine of the vaccine-preventable diseases of childhood. The National Vaccine Advisory Committee has made recommendations to address these disruptions. These remedies include stockpiling vaccines, streamlining regulatory practices, improving communication among key stakeholders, addressing vaccine liability concerns and providing financial incentives to vaccine manufacturers to help them stay in the market.<sup>5</sup>

### **Research Context**

The overriding objective of childhood immunization research and evaluation is to optimize children's protection from vaccine-preventable diseases. This implies having the safest and most effective vaccines administered to children in as timely and efficient a manner as feasible.

Immunization research spans most of the health-related research endeavours, including (1) disease epidemiology (incidence/distribution of disease) to identify target vaccines for development; (2) immunology (immune systems and responses) to understand and predict vaccine effects; (3) the science and technology of vaccine invention, development

and production to provide vaccines for routine use; (4) health services research to understand effective methods to reach children with vaccines; and (5) evaluation to assess and improve program effectiveness.<sup>6</sup>

Research is conducted by academia, private industry and government. Since the scope of immunization-related research is so broad, this report will concentrate on the downstream domains of health services research, program evaluation and communications.

### **Key Research Questions**

Once a vaccine is licensed for routine use in children, there are a number of critically important research and evaluation questions that can be categorized into questions concerning: (1) technical recommendations; (2) vaccine safety; (3) population-based uptake; and (4) program evaluation.

Technical recommendations become public health's population-based "prescription" for children of the administration schedule for the vaccine, and age groups and other populations targeted for vaccination. This research domain supports immunization policy decisions that have important implications for who becomes protected from the specific diseases prevented by the vaccine. For example, influenza vaccine has been traditionally targeted toward the frail elderly because their mortality and morbidity from influenza is so high. However, the epidemiology of influenza suggests that vaccination of children may be an effective adjunct to this strategy by directly protecting children from the disease and indirectly protecting vulnerable adults through interruption of disease transmission. Research questions to support technical recommendations include: (1) What is the likely impact of a recommendation to vaccinate a certain age group? (2) What is the cost/benefit ratio for a recommendation? and (3) Will vaccine-induced changes in disease epidemiology have adverse consequences?

Vaccine safety research is important because the public needs to be confident that the safest possible vaccines are in routine use. Prior to licensure, each vaccine is extensively tested for safety and efficacy. However, the initial clinical trials are not powered to discover rare adverse events. Therefore, continuous monitoring of potential vaccine adverse events must be in place prior to routine use of a vaccine. The typical research questions involve whether a vaccine is associated with a specific adverse event and whether an association is causal or not.<sup>7</sup>

The best vaccines and the best vaccination recommendations will at best be sub-optimally effective unless the vaccine achieves a high population-based uptake. There are several evidence-based interventions to improve vaccination coverage levels among children, adolescents and adults. The U.S. Task Force on Community Preventive Services conducted a systematic review of the evidence of effectiveness of many interventions to improve coverage, and recommended interventions in three categories: (1) increasing community demand for vaccines; (2) enhancing access to vaccination services; and (3) provider-based strategies.<sup>8</sup>

The Task Force's work to review the evidence has been very useful in focusing the next generation of research questions. These questions concern how to take evidence-based

interventions and implement them broadly and in a cost-effective manner. For example, reminder/recall systems have over 60 controlled studies supporting their efficacy at raising coverage in provider offices. However, actual use of recall/reminder systems by providers remains low in the U.S. Research needs to be directed to identify barriers to implementation of proven strategies, methods to overcome those barriers, and the economic cost/benefit ratios for these methods.

Although technically not research, program evaluation is an essential activity that uses scientific methods to answer specific questions. Critical evaluation questions include: (1) What are the population-based vaccination coverage levels among age- and geography-based populations? (2) Are vaccines being handled and administered properly? (3) Are effective strategies being employed to raise and sustain immunization coverage levels? and (4) Are the current vaccination recommendations optimal?

The introduction of new vaccines presents additional research questions, most of which are included in the previous four categories. For the U.S., many of the vaccines that may be licensed in the next two to three years are likely to be targeted to adolescents. Because the adolescent immunization platform is not well developed, research will be needed to identify appropriate venues for vaccination as well as strategies to reach adolescents.

### **Recent Research Results**

Every year, several hundred research studies on childhood immunization are published. The range of these studies is vast, and includes vaccines in development, disease epidemiology, effectiveness of vaccination, vaccine safety, communications and program evaluation.

### **Conclusions**

A most important task for parents and immunization providers is to educate themselves about the importance of keeping their children and their patients on track with their immunizations. Every child born into this world arrives unprotected against deadly vaccine-preventable diseases, and every child born presents an immunization challenge that must be met if we are to give all children the benefit of vaccination optimally.

Many evidence-based interventions are available to help immunization providers keep their patients on track for the recommended immunizations. These range from simple recall and reminder systems to quality improvement activities that offices can undertake. The U.S. National Vaccine Advisory Committee recently published an updated version of the Standards for Child and Adolescent Immunization Practices.<sup>9</sup> These standards help immunization providers achieve optimal protection from vaccine-preventable diseases for their patients.

Parents have access to informative books and Internet Web sites devoted to education about vaccines and vaccine-preventable diseases. These sources of information can help answer parents' questions and concerns about vaccines, vaccine safety and the diseases that are routinely prevented.

### **Implications**

The potential for vaccines to prevent suffering and death among children is great and will continue to increase as new vaccines are developed and traditional vaccines are improved to make them easier to use. Children will continue to enjoy the benefits of biotechnology as advances in vaccinology bring more diseases under control.

Realizing this potential, however, requires carefully developed vaccination policy recommendations and a delivery infrastructure that is able to conduct the essential roles of immunization programs as outlined by the Institute of Medicine in their report, "Calling the Shots." These roles include financing the purchase of vaccines, ensuring that evidence-based strategies are used to raise coverage levels, monitoring coverage levels and vaccine safety, and conducting surveillance of vaccine-preventable diseases.<sup>10</sup>

Recommendations to vaccinate children need to be re-evaluated when new information is available about vaccine impact, disease epidemiology or vaccine safety, or when a new vaccine formulation becomes available. Only through science-based immunization programs will children attain the potential benefit promised by vaccines.

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