Discussion

What do policy makers need to know? Lessons from the decision to add pneumococcal conjugate and rotavirus vaccines to the US immunization program

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The decisions to introduce pneumococcal conjugate and rotavirus vaccines into the US immunization programs were good ones. The vaccines have performed even better than expected, markedly reducing disease not only among young children who received them but also among unvaccinated persons in the community [1,2]. But when the US Centers for Disease Control and Prevention (CDC) first considered whether to recommend routine use of these vaccines, several pieces of information — such as data on disease burden and vaccine efficacy, safety, and cost-effectiveness — had to be gathered before the decision to use these vaccines became clear.

First, policy makers had to determine the need. Do pneumococci and rotavirus cause enough hospitalizations and deaths in the US to warrant vaccinating every child? In the US, as in most parts of the world that use Haemophilus influenzae type b vaccine, pneumococcus was the most common cause of severe pneumonia and bacterial meningitis in young children [3]. Likewise, rotavirus was the most common cause of diarrhea requiring hospitalization [4]. While sub-populations at greater risk of both severe pneumococcal and rotavirus disease were identified (e.g., premature infants), targeting vaccination to these groups would miss the vast majority of cases and thus universal vaccination was the best option.

Next, policy makers had to determine that the vaccines were both safe and effective, turning to evidence from randomized controlled clinical trials. For rotavirus vaccines, data were carefully reviewed to assess risk of intussusception, an adverse event that led to the withdrawal of a previous rotavirus vaccine from the US market in 1999, and age restrictions were put in place to keep the theoretical risk as low as possible [4]. The pneumococcal conjugate vaccine (Prevnar) was safe and highly efficacious in a large US trial [5]. While the two rotavirus vaccines (RotaTeq and Rotarix) differed in composition and schedule, they were similarly efficacious [6,7].

Policy makers also discussed practical matters, such as how the new vaccines would fit into the existing schedule of vaccinations and well-baby visits.

Cost-effectiveness models assessed the balance between disease burden and its associated costs (medical and societal) with the cost of providing vaccine routinely to children. Even though the first cost-effectiveness estimates for pneumococcal conjugate vaccine did not include money saved through indirect effects, these early estimates helped justify the decision to provide vaccine through a ‘catch-up’ program to all children up to age 2 years [8]. For rotavirus vaccines, the cost of lost time from work for parents caring for sick children who did not require medical care comprised a significant proportion of total costs and was a key consideration [9].

The data were reviewed in detail by technical working groups that included selected members of CDC’s Advisory Committee on Immunization Practices (ACIP), subject matter experts, and representatives of professional organizations for pediatrics and family medicine. After this, the full ACIP reviewed summarized data and voted on vaccine recommendations, which were ultimately adopted by CDC [3,4]. Once the vaccines were recommended, CDC conducted post-marketing surveillance and epidemiological studies to evaluate the effect of the vaccination programs and make sure that the recommendations were sound. These evaluations reaffirmed the health benefits of vaccination including documenting indirect benefits, a finding that came somewhat as a surprise for both vaccines [1,2]. Continued monitoring for intussusceptions as millions of children are vaccinated against rotavirus has provided additional assurance on the safety of the vaccination program [10].

The US added pneumococcal and rotavirus vaccines in 2000 and 2006, respectively, when these vaccines were first licensed. Today, a lot more information is available on their safety and performance in routine use as well as efficacy in clinical trials conducted in a variety of settings. In addition, we have new pneumococcal conjugate vaccine products that cover more serotypes, making these products potentially more cost effective than the original 7-valent formulations. Taken together, these additional data should make it

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easier for each additional country to make an informed decision. Where there are gaps in local data, information on disease burden, efficacy, safety and cost effectiveness from countries with similar populations can help answer questions.

Conflict of interest statement

None declared.

References


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