



Realizing the Potential of New Vaccines

The topic

An increasing number of countries are introducing new, life-saving vaccines. Realizing new vaccine potential requires deciding which vaccines to adopt and when. Subsequently, planning for smooth introduction is essential for effective and efficient use.

Why is this topic important?

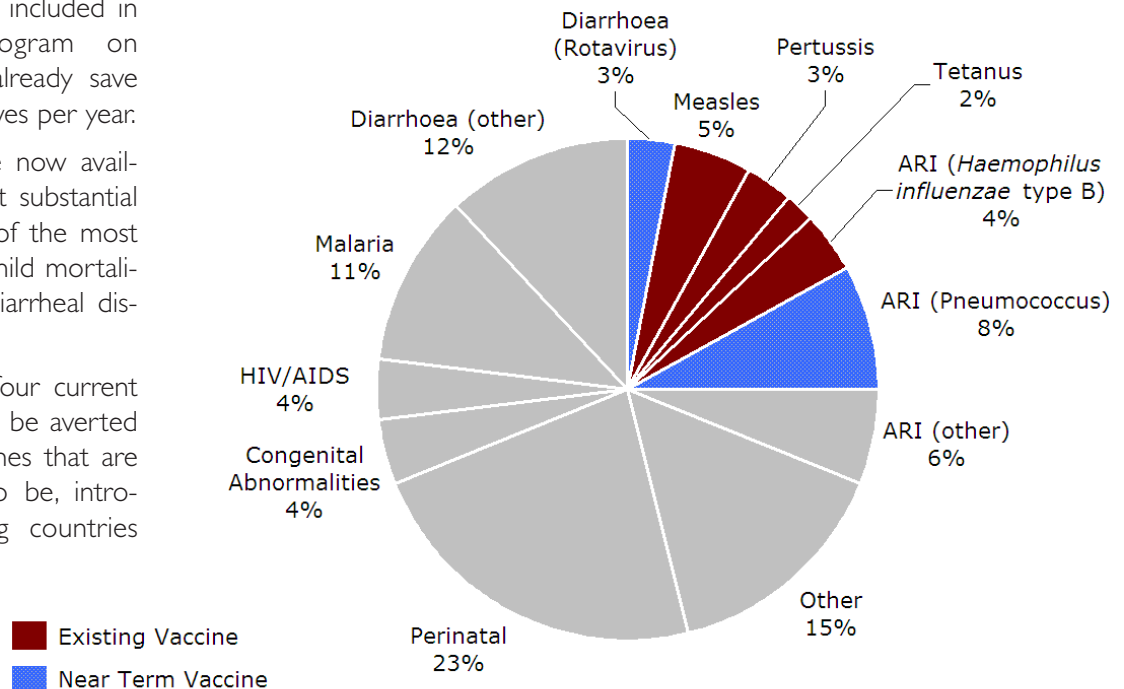
The GAVI Alliance, the World Health Organization (WHO), and others encourage the introduction of new and effective vaccines. Immunization interagency coordinating committees (ICCs), which often include USAID missions and bilateral projects, play important roles in decision-making concerning new vaccines' adoption and in planning their introduction. New vaccine introduction may affect existing vaccination services and also, indirectly, other health services. This issue of *SnapShots* discusses the potential contribution of vaccines to public health, the factors for countries to consider in deciding to adopt a new vaccine, the features of some key vaccines whose introduction is imminent, and areas that require particular attention in planning new vaccine introduction.

The growing contribution of vaccines to global health

“Traditional” vaccines included in the Expanded Program on Immunization (EPI) already save nearly three million lives per year. Effective vaccines are now available that can prevent substantial proportions of two of the most common causes of child mortality: pneumonia and diarrheal disease.

As a result, one in four current childhood deaths can be averted through use of vaccines that are currently, or soon to be, introduced in developing countries (See Figure 1).

Figure 1. Diseases preventable with current vaccines account for 25% of annual mortality in children under five (data from 2002).



Source: UNICEF/042/Thomas L. Kelly, in Immunization. GAVI Alliance.

Global and national level decision-making for adoption of new vaccines

In 2000, the United Nations established the Millennium Development Goals (MDGs), including MDG4 which calls for reducing the mortality rate for children under five by two-thirds by 2015.¹ WHO and UNICEF jointly developed the Global Immunization Vision and Strategy, which aims to protect more children in a changing world and expand vaccination beyond the traditional target group.²

At global and regional levels, WHO plays a critical role in analyzing scientific and epidemiologic data on disease burden and vaccine safety and efficacy. WHO position papers³ summarize key findings and make recommendations for vaccine use. WHO applies the criteria shown in Table 1 in formulating recommendations for new vaccine introduction and informing procurement decisions.

Table 1: WHO criteria for large-scale introduction of new vaccines.⁴

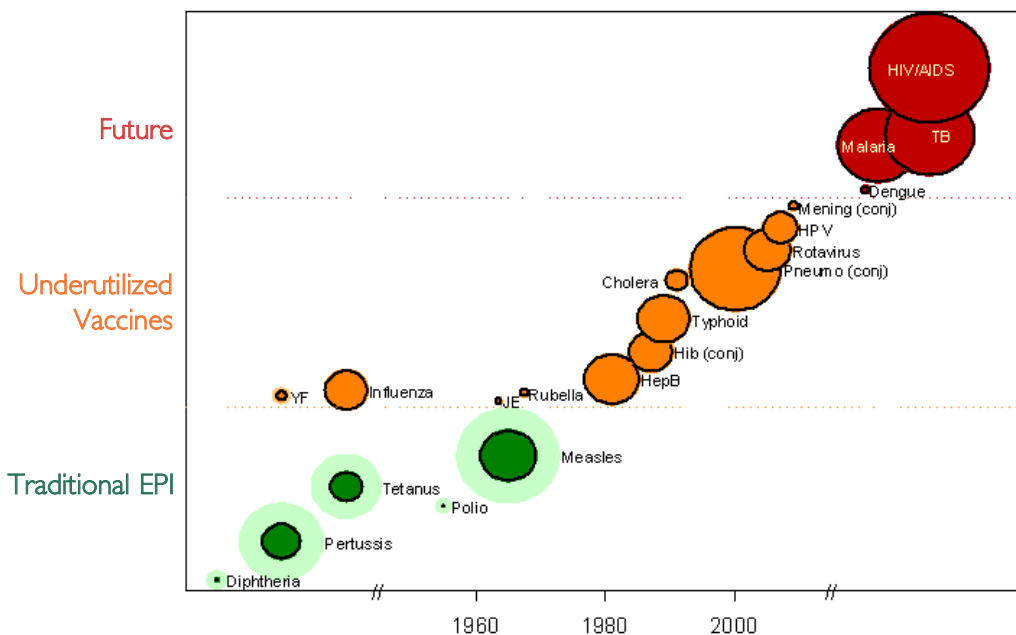
Features of vaccine	Programmatic compatibility
<ul style="list-style-type: none"> ✓ Meet current WHO quality standards ✓ Safe and has significant impact against the actual disease in target populations ✓ Minimal interference with immune response to other vaccines given simultaneously 	<ul style="list-style-type: none"> ✓ Be easily adapted to existing vaccination schedules ✓ Meet common technical limitations, e.g. storage space ✓ Be appropriately priced

In addition to analyzing the local burden of disease and vaccine safety and efficacy, countries must consider competing health priorities, likely vaccine effectiveness, alternative interventions for controlling the disease, vaccine availability, vaccine presentation, cost, cost-effectiveness, and financing.⁵ Given the higher cost of new and underutilized vaccines, long-term financial support is a key concern. The GAVI Alliance is supporting the introduction of new and underutilized vaccines in 72 countries. The terms of this support were summarized in SnapShots Issue #6 from August 2007: <http://www.immunizationbasics.jsi.com/Newsletter/SnapShotsArchive.htm>. More detailed information and instructions on how to apply for GAVI Alliance support are available on the GAVI Alliance website <http://www.gavialliance.org/support/how/index.php>.

New vaccines to meet broad and specific needs

A number of new vaccines are either currently underused or anticipated to become available in the future, as shown in Figure 2. While the benefits of some will be realized on a global basis, others, e.g., conjugate meningitis A and Japanese encephalitis (JE) vaccines, are expected to substantially reduce mortality, morbidity and life-long disability on a more limited geographic scale. Some of these vaccines are currently in limited supply, while certain others are awaiting confirmation of efficacy in Asian and African populations.

Figure 2. Vaccine development profile. (source: WHO-IVR August 2006)



Note: the halos represent deaths currently being averted, and solid circles represent deaths estimated to occur.

¹ For further information about the MDGs, go to: <http://www.un.org/millenniumgoals>.

² See <http://www.who.int/immunization/givs/en/index.html>.

³ Available at: <http://www.who.int/immunization/documents/positionpapers/en/index.html>.

⁴ See WHO position papers, e.g., http://www.who.int/immunization/wer8212pneumococcus_child_Mar07_position_paper.pdf.

⁵ "Vaccine Introduction Guidelines: Adding a Vaccine to a National Immunization Program: Decision and Implementation" http://www.who.int/vaccines-documents/DocsPDF05/777_screen.pdf.

Vaccines with global benefit include the following:

- *Haemophilus influenzae* type b (Hib) - protects against a major cause of bacterial childhood pneumonia and meningitis in developing countries
- Pneumococcal vaccine - protects against *Streptococcus pneumoniae*, another major cause of childhood pneumonia
- Rotavirus - protects against a major cause of diarrheal disease
- Human Papillomavirus Virus (HPV) vaccine - protects against cervical cancer
- Hepatitis B vaccine - protects against hepatitis B infection that can lead to liver cancer and cirrhosis

New or underutilized vaccines with more limited geographic scope include:

- Meningitis serogroup A – particularly important in the meningitis belt in Africa
- Japanese encephalitis – a growing health concern in East and South Asia
- Typhoid – widely prevalent but particularly elevated incidence in South and Southeast Asia

WHO and the GAVI Alliance have placed particularly high priority on vaccines to reduce mortality and morbidity due to childhood pneumonia and diarrheal disease throughout the world. The GAVI Alliance has funded special projects to accelerate the uptake and use of Hib, pneumococcal, and rotavirus vaccines.

Table 2. Key Features of Hib, Pneumococcal, and Rotavirus Vaccines

Vaccine	Haemophilus influenzae type b (Hib) Vaccine www.hibinitiative.org	Pneumococcal Vaccine www.preventpneumo.org	Rotavirus Vaccine www.rotavirusvaccine.org
Burden of disease	<ul style="list-style-type: none"> • Almost 400,000 deaths per year in children due to pneumonia, meningitis, “invasive Hib disease” • 3 million cases of serious disease including neurological sequelae 	<ul style="list-style-type: none"> • Estimated 700,000 to 1,000,000 deaths per year in children under five years of age due primarily to pneumonia, meningitis, sepsis 	<ul style="list-style-type: none"> • At least 530,000 deaths per year globally
Vaccine efficacy and safety	<ul style="list-style-type: none"> • >95% effective with 3 doses • Booster does not appear necessary in developing countries, but research is under way to verify this • Research is under way to confirm efficacy in HIV-positive children 	<ul style="list-style-type: none"> • >95% effective in U.S. • Vaccine trial in the Gambia, 7 deaths averted per 1,000 children vaccinated • Induces herd immunity, with protection extending beyond those vaccinated • Optimal composition will change from the 7-valent serotype vaccine (PCV-7) currently available • Possible serotype replacement issues being monitored 	<ul style="list-style-type: none"> • 90-100% protection against severe rotavirus and 74-85% protection against any rotavirus • Increased intussusception not detected, as had been suspected in an earlier vaccine product in late 1990s
WHO position	<ul style="list-style-type: none"> • Should be included in all routine infant immunization programs 	<ul style="list-style-type: none"> • Include PCV-7 in national immunization programs, especially in countries where the under-five mortality rate is greater than 50/1000 or there is high HIV prevalence 	<ul style="list-style-type: none"> • Strongly recommended where vaccine efficacy data suggest impact • Not yet recommended by WHO for Africa or Asia • GAVI Alliance support for introduction only in the European and Americas regions until 2010
Vaccine availability	<ul style="list-style-type: none"> • Multiple products now available, both as a single vaccine and in combination with DTP vaccine 	<ul style="list-style-type: none"> • Limited supply; expected to increase after 2010 	<ul style="list-style-type: none"> • Sufficient supply at present with two licensed manufacturers
Where introduced?	<ul style="list-style-type: none"> • 106 countries as of mid-2007 	<ul style="list-style-type: none"> • 13 countries as of late 2006 	<ul style="list-style-type: none"> • 11 countries, including 7 in Latin America as of end 2007
Operational considerations	<ul style="list-style-type: none"> • Requires three doses, which can be given as part of the regular vaccination schedule, (e.g. at 6, 10, and 14 weeks) • Inactivated by exposure to freezing • Cost of \$3.50/dose is likely to decline after 2008 when additional suppliers make the product available 	<ul style="list-style-type: none"> • Requires three doses, which can be given as part of the regular vaccination schedule (e.g. at 6, 10, and 14 weeks) • Inactivated by exposure to freezing • Currently available only in bulky, single-dose, pre-filled glass syringes without vaccine vial monitors 	<ul style="list-style-type: none"> • 2 or 3 doses of vaccine required, depending on manufacturer • Given orally • Timely vaccination required: first dose by 12 weeks and final dose by 32 weeks of age • Current vaccine presentation is extremely bulky • Inactivated by exposure to freezing

Planning for new vaccine introduction

Any vaccine, whether new or “traditional,” is only effective if it reaches a large majority of the target population with all required doses in potent form and in a timely way. Using a common conceptual model (Figure 3) can help ensure that all components of a sustainable immunization system receive due attention. Planning for the introduction of a new vaccine should begin at least six months before its expected arrival. Areas that require particular attention include the following:

Cold chain and logistics: Health planners need to anticipate and analyze the impact of new vaccine products with particularly bulky presentations on the cold chain and logistics systems. Several new vaccines are inactivated by exposure to freezing temperatures. Additional refrigerators and more frequent deliveries of vaccines to districts and health facilities are likely to be needed, as are extra resources to manage the waste from additional needles and syringes.

Training: Health workers require training that addresses when and how to administer new vaccines, how to correctly record doses administered, how to counsel parents appropriately on new vaccines, and how to store and transport the vaccines.

Monitoring and surveillance: Health officials must revise standard recording and reporting formats, ranging from child vaccination cards and tally sheets to monthly summary sheets and forms that aggregate data at district and higher levels. Health information systems need to be revised to permit the input, analysis, and generation of reports on new vaccines. Surveillance systems must also be revised; for some vaccines, the only meaningful surveillance is through hospital-based sentinel surveillance.

Communication and advocacy: Health planners must identify the particular information needs of key target groups (health workers, parents, community leaders) as well as the most effective and efficient ways to reach them. They should be careful to avoid information overload, and focus instead on what is relevant and critical to the concerns of different groups and the specific, immunization-related actions that they can take.

What USAID missions and projects can do to help introduce new vaccines

USAID missions, bilateral projects, and PVOs have an important role to play in deciding when, where, and how new vaccines are introduced and how they support other health investments. The voice of missions and major bilateral projects is needed in immunization interagency coordinating committees (ICCs); GAVI actually requires evidence of partner endorsement as part of its decisions to approve a country application for new vaccine support. Furthermore, much of GAVI funding comes from the U.S. government with the expectation that country-level decisions will be made with input from all partners, including USAID. USAID missions, projects, and PVOs can make important contributions to planning for the smooth introduction and effective use of new vaccines.

Figure 3. Program elements that constitute a sustainable immunization system



Further reading

The area of new and underutilized vaccines is rapidly evolving. For current, comprehensive information, please visit the following websites:

- WHO website on new and underutilized vaccines: http://www.who.int/immunization_delivery/new_vaccines-newunderutilized/en/index.html
- Hib vaccine: Hib Initiative - www.hibinitiative.org
- Pneumococcal vaccine: Accelerated Development and Introduction Project (ADIP) - www.preventpneumo.org
- Rotavirus vaccine - Accelerated Development and Introduction Project (ADIP): www.rotavirusvaccine.org
- Meningitis A vaccine - Vaccine Project (MVP): <http://www.meningvax.org>
- Human papillomavirus vaccine (HPV) - http://www.path.org/projects/cervical_cancer_vaccine.php
- Typhoid vaccine (2007 update article): <http://content.nejm.org/cgi/content/full/357/11/1069>
- Japanese Encephalitis vaccine project: http://www.path.org/projects/JE_in_depth.php

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