4

Vaccine Decision-Making

Key Points

* **Decisions on introducing new vaccines have long-term implications for immunization costs as well as logistics systems and service delivery. The choice of vaccine presentation also affects cost and ease of delivery.**
* **In making these decisions, policymakers should consider disease burden; vaccine safety and efficacy; cost, cost-effectiveness, and affordability; operational feasibility and delivery requirements; and public perceptions and demand.**
* **Independent technical committees, often called national immunization technical advisory groups (NITAGs), can help ensure that decisions on new vaccine introduction are transparent, credible, and grounded in evidence.**
* **A variety of tools and assistance are available to help countries with decisions on new vaccines and to strengthen decision-making processes. PAHO's ProVac Initiative is an impressive model of decision support.**

New vaccines have the potential to greatly reduce disease and mortality, but adding a vaccine to a national immunization program has consequences for budgets, logistics systems, service delivery, and, in some cases, public perceptions of and support for immunization. Moreover, decisions about new vaccines have long-term implications because unless a vaccine is later replaced by an improved one, it will likely remain in the national schedule indefinitely.

This brief outlines factors that countries should weigh in deciding whether to introduce a new vaccine, with special emphasis on issues related to cost and financing. It also explores relevant decision-making tools, institutions, and processes. (For more detailed guidance, see the World Health Organization's comprehensive guide to vaccine decision-making, which is listed at the end of this brief.)

Among the most important considerations in adoption decisions are:

- Disease burden and public health importance
- Vaccine effectiveness and safety
- Delivery requirements and operational feasibility
- Cost
- Cost-effectiveness
- Affordability
- Acceptability and public demand

Disease Burden and Public Health Importance

As the starting point in considering a new vaccine, countries must weigh the importance of the disease the vaccine is intended to prevent. Questions include:

- What is the disease burden relative to other health problems to which resources might be directed?
- If the burden is currently low, what is the risk of an epidemic or major resurgence?
- How effective are other approaches to combating the disease?
- Is control of the disease central to the national health strategy and international commitments?

Vaccine Effectiveness and Safety

Countries must evaluate the extent to which the new vaccine will contribute to control of the disease. Some vaccines, such as the yellow fever vaccine, can prevent virtually all disease if high coverage is achieved, while others may offer only partial protection. The duration of the protection afforded by a vaccine can also be an important consideration.

Vaccine safety is also of paramount importance. In general, vaccines that have been approved after rigorous testing and stringent regulatory review and have been recommended by WHO have proven to be safe wherever they have been used.

Delivery Requirements and Operational Feasibility

Countries must evaluate whether the vaccine can be delivered effectively to the target population. Delivery can be relatively straightforward if the vaccine can be provided during existing immunization contacts—for example, if its schedule coincides with that of another vaccine already in the national program. The challenges are greater if the vaccine must be provided to a different age group or to a hard-to-reach special population. The most prominent example is the human papillomavirus (HPV) vaccine, which is currently recommended for girls age 9 to 13 and is being delivered through schools in some countries.

Cost

In estimating the cost of a new vaccine, program managers must consider not only the cost of the vaccine itself but also the additional cost of logistics and delivery systems, which can depend on vaccine presentation and packaging. Introducing a vaccine also involves startup costs, including the cost of training health workers, expanding the cold chain and logistics system, and, in some cases, catch-up campaigns.

How a country procures a vaccine also affects costs. (See Briefs 11 and 12.) UNICEF and the Pan American Health Organization (PAHO), which procure vaccines on behalf of many countries, make public the prices they pay. In general, the costs of newer vaccines can be expected to fall as new manufacturers enter the market and competition increases, but the extent and timing of price declines are difficult to predict.

Cost-Effectiveness

Information on disease burden, vaccine efficacy, and cost can be combined to estimate the cost-effectiveness of a new vaccine, which can be useful in weighing the value of introducing the vaccine against other possible uses of limited resources. While cost-effectiveness analysis can be a powerful tool, it requires considerable data as well as technical expertise. PAHO's ProVac Initiative has worked with many countries in the Americas and, more recently, with countries in other regions to build local capacity to carry out vaccine cost-effectiveness analyses. (See the upcoming sidebar.)

Affordability

In principle, countries should introduce any vaccine that promises to alleviate substantial disease burden and that represents good value for money. In practice, however, affordability is the limiting factor for many countries, which must find space in their budgets for the costs of new vaccines and their delivery. There is no absolute standard of affordability because budgetary room, or fiscal space, depends on how quickly immunization and health budgets are growing, other potential funding sources, and the feasibility of reallocating funds from other uses or making efficiency gains.

Ministries of health must also balance new vaccine introduction against other immunization program objectives, such as expanding coverage of existing vaccines or making coverage more equitable.

PAHO's ProVac Initiative

The ProVac Initiative, created by PAHO in 2004, supports countries in the Americas in making evidence-based decisions on new vaccine introduction, with an emphasis on economic assessment. Nearly all countries in the largely middle-income region must pay the full cost of vaccines in their national programs, so rigorous economic analysis is particularly important in their adoption decisions. Founded on the premise that countries should develop their own capacity to make vaccine decisions based on national data, the initiative offers data, tools, training, and other support.

At the heart of ProVac's approach are user-friendly cost-effectiveness models. The TRIVAC model supports evaluation of the health impact, cost, and cost-effectiveness of Hib, rotavirus, and pneumococcal conjugate vaccines, while CERVIVAC does the same for HPV vaccines. A new model that will incorporate additional vaccines is being developed and tested. ProVac trains national technical staff in the use of these tools and works to enhance the use of evidence in policymaking, including through national immunization technical advisory groups (NITAGs). It has also established a network of regional academic "centers of excellence" to gather regional data and develop methodological guides. As of 2015, ProVac had supported 24 economic analyses in 16 countries in the Americas; many of these analyses contributed to decisions to introduce vaccines into national programs.

To meet demand for decision-making support outside of the Americas, PAHO established the ProVac International Working Group (IWG) in 2011 in collaboration with the U.S. Centers for Disease Control and Prevention, the Sabin Institute, WHO, PATH, and Agence de Médecine Préventive to transfer ProVac tools and approaches to other regions. During this two-year initiative, the ProVac IWG trained national staff from 17 countries and supported cost-effectiveness analyses in nine countries. Discussions are underway on ways to continue this work, which could be particularly valuable to countries that no longer receive Gavi support.

Acceptability and Public Demand

Vaccine introduction decisions do not rest only on technical and cost considerations. A new vaccine must also be acceptable to the target population. Beyond this, policymakers tend to respond to popular demand. Fear of seasonal meningitis epidemics in the Sahel region of Africa helped spur the development and rapid introduction of a new meningitis A vaccine, and concern over growing dengue epidemics will undoubtedly influence decisions on dengue vaccines. In contrast, some vaccines that address important public health concerns, including rotavirus vaccines, have not inspired comparable public demand.

Professional advocacy—sometimes supported by vaccine manufacturers—can draw attention to the potential benefits of a vaccine, but it can also distort public priorities and create a perception of inappropriate influence. These risks highlight the importance of a transparent and evidence-based process for making introduction decisions.

WHO Recommendations

Although each country must consider the relevant factors in its local context, WHO recommendations can provide useful guidance. WHO produces—and regularly updates—recommendations on the use of particular vaccines and publishes them in the form of position papers. These papers synthesize the best available information on vaccine safety and efficacy and are endorsed by the Strategic Advisory Group of Experts (SAGE), a group of outside advisors to WHO on immunization.

Decision-Making Institutions and Processes

Decisions on vaccine introduction inevitably encompass political and other considerations, but these decisions should ideally rest on a foundation of evidence and analysis. WHO recommends that countries establish independent technical committees to advise policymakers on new vaccine adoptions and other immunization policy decisions. These bodies, known generically as national immunization technical advisory groups (NITAGs), should have the capacity to assess evidence on disease burden, vaccine safety and efficacy, vaccine service delivery, and other scientific and technical topics important to immunization decisions. According to WHO, which offers guidance on the creation and strengthening of NITAGs, 82 countries had committees that met a set of basic criteria regarding composition and functionality as of 2016.

Ideally, NITAGs should be able to evaluate economic as well as epidemiological and biomedical evidence on vaccines, but these committees often lack the necessary expertise. A 2010 survey found that only about one-fourth of NITAGs included health economists.

Sri Lanka is an example of country with a strong advisory body, the Advisory Committee on Communicable Diseases, whose mandate extends beyond immunization to other aspects of infectious disease control. (See Brief 26.)

Vaccine Design, Formulation, and Presentation

Once a country has decided to introduce a new vaccine, such as a rotavirus or pneumococcal conjugate vaccine, it must choose the particular product to use. Vaccines can differ in their basic design as well as in their formulation, presentation, and packaging.

Vaccine Design

Vaccines against a particular disease often vary in aspects of their design that have potential implications for efficacy and other important

characteristics. For example, the two currently available pneumococcal conjugate vaccines include different bacterial serotypes, or strains. Vaccines can also make use of different adjuvants (ingredients that boost immune response).

Vaccine Formulation and Presentation

Vaccine formulation and presentation should not affect efficacy, but they can have implications for delivery and cost. One aspect of formulation is whether the vaccine (or, more precisely, the antigen) is available as a standalone product or in combination with other vaccines. For example, the Hib and hepatitis B antigens are now usually provided in combination vaccines that also include diphtheria, tetanus, and pertussis. Another aspect of formulation is whether the vaccine is provided as a liquid or as a freeze-dried powder that must be reconstituted before use.

Strictly speaking, presentation differences include the number of doses and total volume per vial, but the term *presentation* is sometimes used to encompass differences in formulation and even vaccine design within a vaccine class. In choosing a particular vaccine presentation, program managers must consider not only the purchase price of a product but also ease of delivery, training needs, cold chain requirements, and wastage rates. These non-price considerations also have cost implications, and it is useful to compare the total cost per dose delivered (or per immunized child, if products differ in the number of doses required) of different products.

Another important consideration is whether the supply of a particular vaccine is secure. Some vaccine presentations are available from only one manufacturer, while others have several suppliers. Interruptions in vaccine supply can lead to stock-outs and to children missing immunizations; switching to other presentations can be disruptive and costly.

Support for Immunization Decision-Making

WHO, Gavi, and other agencies offer support for various aspects of immunization decision-making:

- Gavi offers support through partner agencies for establishing and strengthening NITAGs. For example, the SIVAC Initiative, implemented by the International Vaccine Institute and Agence de Médecine Préventive, has worked with 29 countries in Africa and Asia. WHO and its regional offices promote and support this work in many non-Gavi middle-income countries. It has also established an online NITAG resource center.
- The WHO-CHOICE program offers a range of tools to help countries assess the cost, impact, and cost-effectiveness of health technologies, including vaccines.
- The most comprehensive initiative to help countries make evidence-based decisions on immunization matters, including new vaccine introduction, is PAHO's ProVac Initiative. It was created to help countries in the Americas but has provided technical assistance to countries in other regions through the ProVac International Working Group.
- PATH developed the Vaccine Presentation Assessment Tool to model the logistical and financial impact of introducing a new vaccine or vaccine presentation.

Sources and Further Reading

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