

# **ASSESSING NEW VACCINES FOR NATIONAL IMMUNIZATION PROGRAMMES**

**A framework to  
assist decision  
makers**



**Immunization Focus  
World Health Organization  
Regional Office for the Western Pacific  
Manila**

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## Glossary and acronyms

CVP	The Bill and Melinda Gates Children's Vaccine Program (CVP) is funded by the Bill and Melinda Gates Foundation. It is a five year \$100 million programme to speed the introduction of new and under utilised vaccines.
DTP (or DTwP)	Diphtheria-tetanus-pertussis (whole-cell) vaccine
DTaP	Diphtheria-tetanus-acellular pertussis vaccine. The acellular vaccine is made from purified parts of the pertussis bacteria.
EPI	Expanded Programme on Immunization. As the WHO's smallpox eradication programme was approaching its target (achieved in 1977), the WHO expanded the programme to include six diseases that formed the basis of EPI, launched in 1974. In future, this may be more appropriately called the Expanding Programme on Immunization, as more vaccines continue to be added to national immunization programmes.
Expert Committee	A committee established by a government to provide technical advice on a specific issue (e.g., to advise on immunization). Generally needs to include a broad range of expertise.
GAVI	The Global Alliance for Vaccines and Immunization (GAVI) is a partnership, formed in 1999, to ensure that all children of the world have access to needed vaccines. The partners include national governments, public health and research institutions, CVP, IFPMA, Rockefeller Foundation, UNICEF, World Bank Group, and WHO.
GFCV	The Global Fund for Children's Vaccines (GFCV) has been created by GAVI to provide the funds needed to meet the GAVI objective of ensuring that every child in the world has access to needed vaccines. It is a charitable foundation under US law. GAVI will review funding proposals made by national governments with the concurrence of the ICC. The Fund's managers will be guided by GAVI on the disbursement of its funds.
Hib	<i>Haemophilus influenzae</i> type b – a bacterium.

ICC	An Interagency Coordination Committee (ICC) can be of different forms and can have different names. The aim of the committee is to provide a forum where the national government, multilateral and bilateral aid agencies and other relevant groups can share information to improve coordination of programmes.
IFPMA	The International Federation of Pharmaceutical Manufacturers Association (IFPMA) has the mission of representing the pharmaceutical and vaccine industry engaged in research, development and manufacturing of medicines and vaccines.
New vaccine	Vaccine not currently used in the national immunization programme. It can include both newly available vaccines and vaccines that have been available for some time but not used in the programme.
Surveillance	The continuing, systematic collection of health data analysed and disseminated to enable public health decision-making and action to protect the health of populations. ( <i>Information for action</i> )
UNICEF	The United Nations Children's Fund (UNICEF) was founded in 1946 to advocate for the protection of children's rights, to help meet their basic needs, and to expand their opportunities to reach their full potential.
Vaccine	<ol style="list-style-type: none"> <li>1) Biological substance that is administered to individuals to elicit immunity (protection) against a specific disease.</li> <li>2) Combination vaccines (e.g. DTP) protect against more than one disease.</li> <li>3) Live viral vaccines (e.g. poliomyelitis, measles) contain attenuated (weakened) version of the disease-causing virus. The vaccine virus causes a mild infection, usually with no or minimal symptoms, that creates immunity against that virus.</li> </ol>
WHO	The World Health Organization (WHO) was founded in 1948 as a special agency of the United Nations. It promotes technical cooperation for health among nations, carries out programmes to control and eradicate disease, and strives to improve the quality of human life.

## Purpose

Many new vaccines are available now and even more will be over the next decade. They include vaccines for diseases not previously immunized against, improvements to existing vaccines, and combination vaccines. The new vaccines could save up to eight million lives a year.<sup>1</sup>

The decision to add a new vaccine to an immunization programme is often influenced by social values, perceptions, and political concerns and is not just a technical one. This document aims to help policy makers make decisions on new vaccines by clarifying the technical and operational issues through a series of technical questions. It is recognised, however, that many other issues may influence the final decision.

## Background

In 1974, the World Health Organization (WHO) launched the Expanded Programme on Immunization (EPI). The EPI originally aimed to protect children against six diseases, and was adopted globally. Since then, WHO has recommended new vaccines for inclusion in immunization programmes, including:

- yellow fever in 1986 (for Africa only);
- hepatitis B in 1992;
- Hib in 1997 (according to national capacities and priorities);<sup>2</sup> and
- Japanese encephalitis in 1998 (where affordable, for endemic areas).<sup>3</sup>

These new vaccines have not been adopted in many countries, despite immunization being among the most cost-effective health interventions.<sup>4</sup> Policy-makers may not consider a vaccine because of cost, even though an expensive vaccine may be more cost-effective (i.e., yielding a better return on investment) than other government spending. Another obstacle is the lack of knowledge of how much illness, disability and death (disease burden) the pathogen (disease-causing agent) causes.

A rational technical decision on a vaccine requires information on:

- disease burden;
- vaccine safety and effectiveness;
- vaccine cost; and
- net impact (on immunization programme as well as health sector).

The information on these four areas can be combined by economic analysis (e.g., cost-benefit) that allows comparison of new vaccine introduction with alternative government investments. Annex 1 provides an outline of the principles of economic analysis.

The framework presented in this document can be used to help build a case for new vaccine introduction, by gathering the information to demonstrate that introducing the vaccine would be cost-beneficial and operationally possible. An economic assessment has already suggested that hepatitis B, Hib, and conjugate pneumococcal vaccines would be cost-effective in nearly all countries.<sup>5</sup>

The Global Alliance for Vaccines and Immunization (GAVI) was formed in 1999 to accelerate new vaccine introduction. The GAVI partners have created the Global Fund for Children's Vaccines (GFCV) to fund poorer countries (annual per capita income less than US\$1000) for new vaccines and infrastructure development.

The Asian Vaccination Initiative (AVI) of the Asian Development Bank (ADB) can offer loans for immunization programmes to countries in the region. There are also other potential partner agencies to support the funding of new vaccine introduction, once a good case has been made.

## **Vaccines available for inclusion in immunization programmes**

Several 'new' vaccines could be of potential benefit to Western Pacific countries (Table 1). Annex 2 provides more detail on some of the vaccines likely to be of relevance to the regions' countries.

As well as new single disease vaccines, there are also combination vaccines. These can either reduce the number of injections currently given, or else allow the addition of a new vaccine without additional injections. Depending on the formulation of the combination, they can also be introduced without placing additional burdens on the logistics. In general, combination vaccines provide the ideal way to add a new disease to the immunization schedule, because they place fewer burdens on the programme, are more convenient for health workers and parents, and reduce the potential for unsafe injections and discomfort for the person receiving the vaccine by minimising the number of injections necessary. However, combination vaccines can be expensive and their comparative cost must be taken into consideration when deciding on the introduction of new vaccines.

**Table 1. Vaccines of potential value to NIPs in the Western Pacific Region**

<b>Currently available</b>	<b>Combinations (available)</b>	<b>Under development</b>
Japanese encephalitis Hepatitis A Hepatitis B Hib Cholera Typhoid Varicella Mumps Rubella Influenza	DTP-HepB DTP-Hib DTP-HepB-Hib Hib-HepB  Measles-mumps-rubella Measles-rubella	Pneumococcus (conjugate) – <i>available in US</i> Meningococcus (conjugate) – <i>available in UK</i> Respiratory Syncytial Virus Shigella HIV/AIDS Malaria Dengue Rotavirus Influenza (live, intranasal)

## **A framework for decision-making on new vaccines**

The following set of questions is suggested as a framework:

1. Is the disease a public health problem?
2. Is immunization the best control strategy for this disease?
3. Is the immunization programme working well enough to add a vaccine?
4. What will be the net impact of the vaccine?
5. Is the vaccine a good investment?
6. How will the vaccine be funded?
7. How will the addition of the new vaccine be implemented?

Working through the questions will help the decision-making about a new vaccine. The framework's aim is to support rational, logical, and consistent decisions for any new vaccines. It gives a structure to be changed as needed. The questions suggest an orderly process. In practice, the order may differ and be more complex.

Working on the issues openly, and including community values, will lead to better decisions. One way is an Expert Committee reviewing information and recommendations

prepared by technical staff. The Interagency Coordinating Committee can also play a role by providing a perspective on international values and standards.

## 1. Is the disease a public health problem?

This is the most fundamental question. It can be difficult to answer when there are limited data on the disease burden: the total number of cases of illness, disability, and death caused by the pathogen (disease-causing agent). The disease burden equals the maximum potential benefit of the vaccine.

Lack of data on disease burden can lead to a perception that the disease is not important, especially when:

- the pathogen causes a clinical condition (e.g., pneumonia) also caused by others;
- there is little testing to identify the cause of the disease;
- complications of the disease are not well known; and
- occasional serious consequences of the disease are ignored.

Using or developing surveillance systems (or routine morbidity and mortality statistics) to enable measurement of disease burden will allow monitoring the impact of the vaccine's introduction. However, this may not be feasible for specific pathogens in a developing country. If routine surveillance is not appropriate or feasible measuring disease burden will require special studies, but even these may only provide a partial picture. For example, the WHO protocol for measuring Hib disease burden focuses on Hib meningitis because of the difficulties in measuring the other outcomes,<sup>6</sup> but most of the Hib disease burden is in fact from pneumonia rather than meningitis.

Developing routine reporting and/or surveillance systems will not only help overall management of health services, it will also identify the major disease priorities, and help with new vaccine decisions. However, special studies may be needed to estimate the likely proportion of a clinical condition (e.g., pneumonia attributable to Hib) due to that agent.

A creative new approach to estimate disease burden is a vaccine trial, as used for Hib disease in Gambia,<sup>7</sup> and in Chile.<sup>8</sup> The disease burden was estimated from the amount of disease prevented by the vaccine.<sup>9</sup> This may be an alternative in situations where a considerable disease burden is strongly suspected, but neither surveillance nor special studies are feasible. A vaccine study in Lombok (Indonesia) with Hib vaccine and several studies, including one in Bohol (Philippines), with pneumococcal vaccine will better define the burden for both diseases in Asia.

Given the difficulties (and costs) of fully assessing the disease burden, it may be appropriate to estimate the local burden based on data from similar countries.

Answering the following questions will assist in deciding how to estimate disease burden:

- Can routine surveillance data, morbidity, and/or mortality statistics provide adequate information on disease burden?
- If not, can systems be introduced/enhanced to estimate disease burden from routine data?
- Are there special studies available on disease burden?
- If not, can such studies be conducted?
- Are disease burden estimates from similar countries available and applicable?

## **2. Is immunization the best strategy for this disease?**

If an alternative control strategy is more cost-effective, a new vaccine should not be considered. For example, controlling leprosy through case treatment has been shown to be more cost effective than BCG immunization, unless the incidence of disease is greater than 1 per 1 000 per year.<sup>10</sup>

The comparison of alternative treatments may require a comprehensive economic analysis (as outlined in Annex 1). Judgement is needed on what level of analysis is appropriate for comparing different control strategies. Key factors will be disease burden, vaccine effectiveness, and comparative costs of the different control strategies.

The following questions need to be addressed:

- Are there any other ways to control the disease?
- If so, how do they compare in terms of:
  - effectiveness
  - safety
  - costs
  - practicality/feasibility
  - time effects (how soon it works, and what happens over time – e.g. development of antibiotic resistance)?

## **3. How well is the immunization programme working?**

A new vaccine can increase programme coverage by increasing public support (through reducing injections/visits or giving extra protection) or by revitalising the programme. But the priority for a programme that is not working should be to fix the existing problems, not add a new vaccine. The Global Alliance for Vaccines and Immunization (GAVI) requires at least

50% DTP3 coverage as a criterion for funding a new vaccine. If routine coverage is low, increasing coverage will usually prevent more diseases than adding a new vaccine. Increasing coverage also means that proportionately more disadvantaged children are reached.

Fixing problems in the current programme may be more important than adding a new vaccine. Ideally, any problems should be addressed as part of the process of adding a new vaccine, as all of them can reduce the benefit (or increase the cost) obtained from adding the new vaccine. Reducing vaccine wastage becomes especially important as most new vaccines are more expensive.

An assessment of the programme to identify critical needs, as well as the ability of the programme to add a new vaccine, is important. This is particularly true for financial assessment. WPRO helped the Asian Development Bank (ADB) in developing an assessment framework for the Asian Vaccine Initiative (AVI) (Annex 3). A more detailed WHO assessment tool is also available,<sup>11</sup> as is a tool for financial assessment.<sup>12</sup> External agencies may want an assessment before supporting funding (grant or loan) investments in the immunization programme. Many aspects of programme performance need to be assessed, including:

- coverage (the key indicator of programme performance);
- vaccine supply (procurement and quality of vaccine);
- vaccine stock management (including wastage);
- cold chain;
- safe injection practices;
- immunization delivery;
- surveillance (for disease, immunization coverage, and adverse events following immunization); and
- communication.

#### 4. What will be the net impact of the vaccine?

To answer this question requires the assessment of:

- disease burden;
- vaccine effectiveness;
- vaccine safety;
- impact on the immunization programme (including on local vaccine producers); and
- other possible impacts.

These assessments will require making assumptions, as information is unlikely to be comprehensive or certain. **Sensitivity analysis** is the use of both a low and a high estimate, to look at the effect of the assumptions on the net assessment.

##### 4.1 How much disease will be prevented?

The disease burden is the starting point (see section 1 above). Consideration of the age distribution of that burden in relation to the timing of the vaccine and its effect is needed to assess the impact of the vaccine. For example, children may not be protected until they have completed the course of vaccines. Children born before the vaccine is added will not get benefit of immunization unless there is a catch-up programme for them. However, there may be indirect effects of immunization on community (or ‘herd’) immunity that leads to less disease by preventing transmission of disease in the community.

Another issue is that immunization of infants, by preventing disease in the very young, can increase the average age of infection. At moderate levels of immunization coverage, immunization can actually increase the disease burden if the disease is much more serious in adults than in children (e.g., chickenpox).

For example, a rubella immunization programme might *increase* the incidence of congenital rubella syndrome (CRS), by increasing the proportion of infections in adults. This has been reported from Greece.<sup>13</sup>

Vaccine efficacy describes protection under ideal conditions, such as a controlled trial. Vaccine effectiveness describes protection in the field, and is usually lower than efficacy. In a trial, vaccines tend to be given to healthier people who will respond better. Errors in vaccine storage, preparation or administration that can impair the vaccine are less likely to occur in a trial.

For an immunization programme, effectiveness is the key measure. But data may only be available for efficacy, and not necessarily in similar populations. Effectiveness has been shown to be lower for some vaccines in developing countries than in industrialised countries. Therefore, in estimating the impact, it may be wise to assume lower vaccine effectiveness than suggested by the efficacy data. This can be part of the sensitivity analysis.

The likely vaccine effectiveness, immunization coverage and age specific disease burden are combined to assess the amount of disease likely to be prevented, merging the answers to these questions:

- What is the age specific disease burden (including complication rates) in relation to the age that vaccine would be given (including potential danger from increasing the average age of infection)?
- What are the likely indirect effects of immunization on reducing disease transmission?
- What is the likely vaccine effectiveness?
- What is the likely vaccine coverage?

## **4.2 What are the possible negative effects of the vaccine?**

It is the responsibility of the national regulatory authority (NRA) to ensure that only safe products are licensed. But no vaccine is absolutely safe, and an estimate of the burden of vaccine reactions needs to be in the assessment, based on the known vaccine reaction profile of the vaccine. In addition, the consequences of unsafe injections should also be included.

Answering the following questions will help identify possible negative consequences:

- What vaccine reactions are likely from the new vaccine?
- What programme errors could arise from the new vaccine?
- Could there be any other adverse effects from the vaccine?

## **4.3 What additional resources will be needed?**

Potential logistical, operational, and social marketing implications of the new vaccine, and its effect on the other vaccines in the NIP, need to be considered. For each potential effect, the resource implications in terms of amount and cost need to be estimated.

- What will be the additional requirements and costs of programme operations? Areas to consider include:
  - vaccine;
  - transportation;
  - storage;
  - immunization materials (immunization records, worker time, injection supplies, and disposal materials);
  - training of health workers;
  - social marketing; and
  - any new resources (e.g., more demanding temperature storage requirements).

#### **4.4 How will perception of the programme be affected?**

A new vaccine may change the attitudes of parents and/or health workers to the immunization programme. That change may be negative or positive, depending on the perception of the new vaccine and whether additional visits and/or injections are needed. The change in perception can lead to changes in coverage of the other vaccines, as well as affecting the new vaccine. The consequences of the new vaccine on the other vaccines in the immunization schedule need to be considered with these questions:

- Will addition of the new vaccine increase or decrease the overall perception of the value of immunization (dependent on the convenience, safety, and side effects of the new vaccine)?
- Will there be any extra visits or injections?
- Can the vaccine be marketed in such a way that there is a demand for it?

#### **4.5 How much risk will it place on the credibility of the NIP?**

The issue of sustainability has been partly discussed above in section 3. Introduction of a new vaccine will have both financial and operational implications for the immunization programme. A critical issue is whether the new vaccine can be introduced in such a way that additional work for staff is minimized. Funding is, of course, of critical importance. If funding cannot be sustained and the new vaccine is later dropped, this can hurt the credibility of the NIP, which is addressed with these questions:

- Is funding for the new vaccine likely to be sustainable?
- Does the addition of the new vaccine significantly increase or complicate the workload of staff at any level?

#### **4.6 What will be the impact on any local vaccine producer?**

The impact on local vaccine production in countries where vaccine is produced is an important consideration. For combination vaccines, one component may be produced locally but a combined vaccine may not be technically or financially possible. The role of local vaccine production needs careful consideration in relation to economic and health benefit for the country.

- Will using the new vaccine in the NIP threaten the viability of local production?
- Could the new vaccine be manufactured locally through a technology transfer?

#### **5. Is the vaccine a good investment?**

Economic analysis enables comparison of different investments as well as provides an estimate of the cost per health outcome. The net cost is the total cost of additional resources for introducing the new vaccine minus any savings in treatment and other costs from disease prevented. The net health impact is the disease, disability and death avoided minus any adverse events from the vaccine.

Economic analysis aids decision-making to enable the most efficient use of limited resources. It should not be confused with the fiscal cost of introducing the vaccine. The two key questions are:

- What is the cost per health outcome?
- How does this cost per outcome compare with alternative investments?

#### **6. How will the vaccine be funded?**

Even for a 'cost-saving' vaccine new funding will be needed. This is the fiscal cost for new vaccine introduction, and new funds will be needed to enable introduction. Showing that the vaccine is highly cost-effective helps to obtain loans, funding from government or donors, or a combination of all.

The government may be able to fund the candidate vaccine, or may need to seek external funding. Whatever the initial source of funding, there should be some plan for longer term funding. In practice, it may be difficult to do more than secure short-term funding for a new vaccine. However, if there is serious doubt regarding the sustainability of the funding, it may not be advisable to proceed. The questions to answer are:

- What is the total cost of introducing the new vaccine?
- Where can the funds be found to cover this cost (short- and long- term)?

## **7. How will the addition be implemented?**

Once funding is secured, adding the new vaccine requires careful planning to minimise disruption to the immunization programme and maximise the benefits from the new vaccine. Any changes to the immunization schedule need to be coordinated. This requires anticipation of changes and knowledge of other new vaccines that may have a high priority for introduction.

The introduction of the vaccine may require additional logistical resource if an extra vaccine is added. Even if the new vaccine is just replacing an existing one, there may be different storage requirements for the vaccine, or it may come in a different formulation requiring more space. Depending on the scale and complexity of the additional logistical and training requirements, and the capacity of the programme, it may be best to implement the addition in a phased manner. Sometimes, a pilot introduction may be needed to evaluate how the change is implemented in a small area before extending the change nationally.

It is important to evaluate the impact of the introduction of the new vaccine on the NIP and to assess if the actual benefits are in line with the estimations. This evaluation should be planned as part of the process of adding the vaccine. If actual benefits are not in line with estimations, the reasons for the difference should be explored.

Surveillance for adverse events following immunization (AEFI) is needed to monitor vaccine safety, especially for new vaccines that do not have an established safety record. Guidelines are available to help establish a system.<sup>14</sup>

A plan for implementation is needed that answers the following questions:

- Are any other changes planned to the immunization schedule?
- If yes, how to coordinate with the new vaccine introduction?
- Will the implementation be phased, piloted or introduced nationally?
- If the introduction is being piloted, are the questions that the pilot is to answer clearly formulated?
- How will the addition be evaluated (including monitoring impact on disease and on AEFI)?

# Conclusion

The decision to add a new vaccine is complex. It needs a wide range of information. Economic analysis can integrate the information, and compare alternatives. The decision is always political, but thoughtful analysis helps decision-making to be rational and transparent.

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# Annex 1: Economic analysis

The basic principle is to combine all the inputs and outcomes of a programme in one of four main ways:

- convert all inputs and outcomes into money values (cost benefit analysis or CBA)
- convert all health outcomes to a standardized measure (e.g., disability adjusted life year or DALY) and cost all inputs in money values (cost utility analysis or CUA)
- focus on a single health outcome (e.g., deaths, hospitalizations, or cases) and cost the inputs needed to achieve that outcome (cost effectiveness analysis or CEA)
- calculate costs to achieve defined outcomes (cost-minimisation analysis).

The ideal is CBA, but for this all health outcomes need to be costed and that can be problematic. A CEA avoids the need to cost health outcomes, but can only focus on a single outcome, limiting comparison. The use of CUA enables many different types of health outcomes to be standardised, but there is still the issue of valuing outcomes. Valuing health outcomes is not needed if the vaccine is cost saving.

## Perspective

The costs and benefits of the new vaccine will accrue to different parties: government (including publicly funded health services); private health services; individuals and their families. The outcome of the economic analysis may depend on the perspective of the analysis. A societal perspective will include costs and benefits to all parties, while a more restricted analysis may be from the perspective of government, or just for government funded health services. In general, economic analysis should be from a societal perspective, but the funder may wish an analysis from their perspective.

## Costs and valuations

The health outcomes prevented by the vaccine need to be quantified (e.g., days of illness, hospitalisations, disabilities and deaths). Vaccine reactions are a negative health outcome. The health outcomes have costs as well as valuations.

Economic analysis should be based on the marginal rather than the average cost (i.e., the cost of one extra or one less unit of activity).

## Discounting for the future

The value of a sum of money is greater in the present than the future. Hence, in economic analysis any expenditure or savings in the future must be discounted to present value. The annual discount rate used in economic analyses varies from 3% to 10%, based on the real interest rate. The results of the economic analysis can be very sensitive to the discount rate chosen, depending on the timing of the impacts of the vaccine.

Clearly, future financial costs and benefits need to be discounted to present values. But, there is debate about whether future health outcomes should also be discounted to present value.

## **Sensitivity analysis**

Uncertainty about costs, valuation, discount rate, and other assumptions is dealt with by sensitivity analysis. The value of a parameter is changed and the effect of that change identified on the outcome of the analysis to identify how sensitive the result is to the valuation of that parameter. In some cases, a threshold value will be identified where the value of the parameter changes the result of the analysis.

## **Confidentiality**

It is likely that confidential information (e.g., price of vaccine) will be needed for the analysis. In addition, the result of the analysis may have commercial implications. Therefore, the analysis may need to be kept confidential.

## Annex 2: Details of selected new vaccines

### *Haemophilus influenzae* type b (Hib) vaccine

#### Disease

Bacterial infection causing a wide range of clinical illness; most often pneumonia, meningitis, septicaemia, and epiglottitis. Causes an estimated 3 million cases and 400,000 to 700,000 deaths annually, globally. Disease most often in those aged 4-18 months, and rare under 3 months or over the age of five years.

#### Status of use

Widely used in developed countries with dramatic reduction in Hib disease.

#### Use in Western Pacific countries

American Samoa, Australia, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Fiji, French Polynesia, Guam, Marshall Islands, New Caledonia, New Zealand, Niue, Palau, Wallis and Futuna.

#### Potential for Western Pacific countries

Disease burden poorly quantified in most countries of region that do not use vaccine.

#### Target population

All infants and children aged under five years.

#### Vaccine type

Polysaccharide cell coat of bacterium (PRP) conjugated to a protein carrier. Four different types of conjugate vaccines are available. All extremely safe and effective in large randomised controlled trials except one (PRP-D) that was not effective in the Alaska trial. The others are:

**PRP-T:** PRP bound to tetanus toxoid - produced by SmithKline Beecham and Aventis Pasteur. Three dose primary series in the first year of life is adequate for protection, but the manufacturers recommend a booster dose in the second year.

**HbOC:** PRP bound to a mutant diphtheria toxoid (CRM<sub>197</sub>) produced by Wyeth-Lederle. Three dose primary series in the first year of life is adequate for protection, but the manufacturer recommends a booster dose in the second year.

**PRP-OMP:** PRP bound to meningococcal outer membrane protein - produced by Merck. Gives early protection after a single dose, but lower levels of antibodies after a primary series in the first year of life compared to other two conjugates. Two dose primary series in the first year of life (no benefit from a third dose) and a booster dose at 12-15 months of age.

#### Formulation

Liquid (all); and lyophilised powder (PRP-T only) reconstituted with diluent or with DTP.

### **Combination products**

Hib-HepB (PRP-OMP from Merck); DTwP-Hib (HbOC from Wyeth-Lederle; PRP-T from SmithKline Beecham); DTwP-Hib-HepB (PRP-T from SmithKline Beecham). There are Hib combinations with DTaP (acellular pertussis) but these are not recommended for infants as they generate lower levels of Hib antibodies.

### **Issues for introduction**

Cost; uncertainty about local disease burden; implications for local vaccine manufacturer. Combinations allow introduction without extra injections. The UNICEF price for DTwP-Hib-HepB vaccine in 2000 is US\$3.50 per dose.

### **WHO position statement**

Recommended according to national capacity and priority [Weekly Epidemiological Record 6 March 1998; 73 (10): 64-8].

## **Influenza nasal vaccine**

### **Disease**

Viral infection that causes annual winter epidemics in temperate zones, and throughout the year in the tropics. Influenza pandemics (world-wide epidemics) have greater impact, especially the 1918-9 pandemic that killed an estimated 20 million people.

Main public health burden arises from the complications of influenza (leading to hospitalisations and deaths) that are more common in people aged 65 years and over, and in those with certain chronic medical conditions (e.g., heart or lung disease, diabetes).

### **Status of use**

Under development. Early trials appear promising.

### **Use in Western Pacific countries**

Not available.

### **Potential for Western Pacific countries**

Not clearly quantified. Likely to be substantial, especially with ageing of populations.

### **Target population**

Older people; people with chronic medical conditions.

Possibly also for children in the future if aiming to prevent viral transmission.

### **Vaccine type**

Cold adapted (i.e., modified) live influenza virus. Would need new formulation every year to match changing strains of influenza viruses in circulation. (Safe and efficacious inactivated injectable vaccine has been available for many years).

### **Formulation**

Intranasal spray.

### **Combination products**

Nil.

### **Issues for introduction**

Relative priority compared to other new vaccines.

### **WHO position statement**

Not available.

## **Japanese Encephalitis vaccine**

### **Disease**

Most important cause of viral encephalitis in Asia, causing at least 50,000 cases and 10,000 deaths per year, mostly in children. Virus transmitted by mosquito, mostly from pigs, at seasonal intervals.

### **Status of use**

Mouse-brain derived inactivated vaccine in widespread use. Cell culture derived inactivated and live vaccines available in China.

### **Use in Western Pacific countries**

China, Viet Nam.

### **Potential for Western Pacific countries**

Affects several countries in region, including Cambodia, China, Korea, Japan, Laos, Malaysia, Philippines, Viet Nam.

### **Target population**

Infants and young children.

### **Vaccine type**

See ' Status of use' . New vaccines may be available in future.

### **Formulation**

Lyophilised powder for reconstitution with diluent (mouse-brain inactivated vaccine)

### **Combination products**

Not available.

### **Issues for introduction**

Cost of vaccine. Additional injection.

Only relevant for JE endemic countries.

### **WHO position statement**

Recommended in JE endemic areas where affordable [Weekly Epidemiological Record 30 October 1998; 73 (44): 337-44].

## **Meningococcal (conjugate) vaccine**

### **Disease**

Bacterial infection with *Neisseria meningitidis* causing meningitis and septicaemia. Estimated 300,000 cases and 30,000 deaths annually, globally. Can be endemic (mostly infants) or epidemic (more older children and young adult) patterns of disease. Most disease caused by serogroups A, B, and C.

### **Status of use**

New conjugated type C vaccine introduced into UK in 1999. The plain polysaccharide (unconjugated) vaccine has been in use for many years for epidemic control.

### **Use in Western Pacific countries**

Nil. (Unconjugated vaccine used in China)

### **Potential for Western Pacific countries**

Burden of disease not adequately known, but may be potential for the conjugate vaccines as it is effective in infancy, where disease burden is likely to be highest.

### **Target population**

Infants for endemic disease (conjugate vaccine). Age group for epidemic response dependent on epidemiology.

### **Vaccine type**

Polysaccharide cell coat of bacterium conjugated to a protein carrier (as with Hib). Only meningococcal C conjugate vaccine currently available. Plain polysaccharide vaccine (available for A, C, Y and W-135 serogroups) has been available for many years, but is not recommended for children aged under two years, as efficacy is reduced.

### **Formulation**

Liquid formulation.

### **Combination products**

Combination of all four serogroups (unconjugated) available, but not combined with other vaccines.

### **Issues for introduction**

Relative priority. No suitable vaccine yet for infant (except type C in UK).

### **WHO position statement**

Polysaccharide vaccine recommended for epidemic control; but the role of conjugate vaccines yet to be established [Weekly Epidemiological Record 10 September 1999; 74 (36): 397-303].

## **Pneumococcal (conjugate) vaccine**

### **Disease**

Bacterial infection with *Streptococcus pneumoniae* causing invasive disease (pneumonia, septicaemia, meningitis) and non-invasive disease (otitis media, sinusitis, bronchitis). Causes 1 million deaths in children per year. Mostly affects young children and older people. Over 90 serotypes of pneumococcus, majority of disease caused by a few serotypes.

### **Status of use**

Only recently (late 1999) recommended for use in the USA.

### **Use in Western Pacific countries**

Nil.

Philippines trial of Aventis Pasteur's 11-valent vaccine starting in 2000 and will take 3 years to just complete recruitment.

### **Potential for Western Pacific countries**

Disease burden poorly quantified in region.

Vaccine likely to prevent substantial amount of pneumonia and meningitis and deaths.

### **Target population**

All infants and, potentially, the elderly.

### **Vaccine type**

Polysaccharide cell coat of bacterium conjugated to a protein carrier (as with Hib). The only currently licensed vaccine is a 7-valent (i.e., containing 7 serotypes of pneumococcus) vaccine from Wyeth-Lederle. This vaccine is not suitable for developing countries as it is missing some important serotypes. The 9- and 11-valent vaccines are being tested in several developing country sites, including one trial in the Philippines. There is also a 23-valent polysaccharide vaccine that has been available for many years, but is not recommended for children aged under two years, as efficacy is reduced.

### **Combination products**

Nil yet.

### **Issues for introduction**

Cost; availability of vaccine with serotypes appropriate for population; addition of an extra injection until combination vaccines become available.

### **WHO position statement**

Position statement on the existing pneumococcal vaccine, rather than new conjugates, but notes the likely superior efficiency of the conjugate vaccines [Weekly Epidemiological Record 11 June 1999; 74 (23): 177-84].

## **Rotavirus vaccine**

### **Disease**

Viral gastroenteritis. Most common cause of infectious diarrhoea in infants and children worldwide. Globally, causes more than 125 million cases per year, 25% of diarrhoeal deaths and up to 5% of all deaths under age five years. Four serotypes responsible for the majority of disease.

### **Status of use**

Seven vaccines under development. The Wyeth-Lederle vaccine was licensed and recommended for universal use in the USA, but withdrawn when ~1 in 10,000 risk of intussusception (bowel obstruction) in vaccinees identified in post-marketing surveillance.

### **Use in Western Pacific countries**

Nil.

### **Potential for Western Pacific countries**

Likely to be important disease burden in young children.

### **Target population**

Infants.

### **Vaccine type**

Several vaccines under development. They are all live vaccines using rotavirus from a different species and genetically modified to express the proteins of the different serotypes. The Wyeth-Lederle vaccine used rhesus rotavirus, Merck a bovine virus.

### **Formulation**

Oral liquid.

### **Combination products**

Not available. Can be given at the same time as oral polio vaccine (OPV) and other vaccines.

### **Issues for introduction**

Safety concern may hamper the testing needed for licensure of other vaccines, as very large trials will be needed to evaluate risk of intussusception.

### **WHO position statement**

Awaiting demonstration of efficacy (and now safety) in developing countries before a recommendation for use in immunization programmes [Weekly Epidemiological Record 5 February 1999; 74 (5): 33-8].

## **Varicella vaccine**

### **Disease**

Viral infection that is nearly universal in childhood (commonly called chickenpox). May be less common in the tropics. Relatively mild disease, although occasionally fatal. Disease more severe in adults.

### **Status of use**

Recommended for all children in the USA, but not in other developed countries. Even in USA, coverage is low (~60%).

### **Use in Western Pacific countries**

Recommended in US territories in Pacific – American Samoa, Commonwealth of the Northern Mariana Islands, Guam

### **Potential for Western Pacific countries**

Morbidity uncertain. Probably of limited value compared to other diseases.

### **Target population**

Infants. Non-immune adolescents and adults.

### **Vaccine type**

Attenuated live virus, Oka strain.

### **Formulation**

Lyophilised powder that requires reconstitution with supplied diluent.

### **Combination products**

Not yet available. Measles-mumps-rubella-varicella vaccine (MMRV) being developed.

### **Issues for introduction**

Relative priority compared to other diseases and high cost.

One vaccine requires storage at -15°C and use within 30 minutes of reconstitution

### **WHO position statement**

Other vaccines likely to be higher priority in most countries; if used must have high coverage to avoid shifting disease to older age groups; may be used in susceptible adolescents and adults without risking age-shift [Weekly Epidemiological Record 7 August 1998; 73 (32): 241-8].

## Annex 3: Asian Vaccination Initiative assessment framework

The Asian Vaccination Initiative (AVI) is an independent initiative of the Asian Development Bank. Through an initial assessment of immunization financing requirements, AVI seeks to identify areas of potential assistance by the Bank. The priority of AVI is an equitable and sustainable immunization programme. AVI is separate to, but works in collaboration with, the Global Alliance Vaccine Initiative (GAVI).

### A. Purpose

1. This framework is to be used for an *initial assessment* of financing issues within a National Immunization Programme (NIP). Based on existing documentation, it seeks to:
  - (i) Outline the current financial status, including financing gaps, of the NIP.
  - (ii) Identify sustainable financial options for strengthening existing NIPs. Areas of support may include the cold chain, surveillance or injection safety.
  - (iii) Identify future funding requirements for a routine (or expanded) NIP.
  - (iv) Identify potential areas for new investment in the NIP. These may include the introduction of new vaccines or Implementation of disease control initiatives.
  - (v) Identify anticipated and potential funding sources.
  - (vi) Where possible, provide a cost-effectiveness analysis of current and / or planned immunization activities.
2. The framework does not attempt to undertake a comprehensive review of a NIP (refer WHO Assessment Guidelines). It does however seek to provide relevant and timely information to countries so sustainable financial planning can take place. It is based on the comparative advantages of the ADB (financial and economic expertise) and therefore should offer a tool, and results that provide added value to a country's immunization program. It may be used with a specific investment in mind, in which case the focus may be narrower.
3. It is intended to be consistent with, and complementary to, the WHO assessment tool that provides more detailed suggestions in relation to adding new vaccines.
4. The framework provides a starting point to be modified according to need and local circumstances. It is important that the government, Interagency Coordinating Committee, and other key stakeholders concur with the framework and terms of reference for the assessment.

### B. Overview

5. This framework identifies key information that can facilitate the analysis of current costs and cost projections for a NIP as well as current and future financing needs. Background and contextual information should allow for a wise investment decision.

6. Areas that will require comment and/or analysis include:
  - (i) Background and context of the programme
  - (ii) Strengths and weakness of the programme
  - (iii) Current, and future, costs of the programme (including cost-effectiveness analysis of activities)
    - (a) For a routine, or expanded NIP
    - (b) With the introduction of new vaccines
    - (c) With increased disease control initiatives
  - (iv) Current, and future, financing of the programme
    - (a) Traditional and emerging sources
    - (b) The need and potential for additional funding
    - (c) Constraints
  - (v) Recommended investments
    - (a) Cost-effectiveness analysis of investment
    - (b) Likely impact of a new investment on the programme

### C. Method

7. The process for doing the assessment will depend on the country, the precise purpose, and the resources available. Some general suggestions are offered here.
8. As an initial assessment, it is assumed **only** existing information about the NIP, including planning documents, previous reviews, and financial reports will be used. Where this information is not sufficient, a more in-depth review of the immunization programme may be recommended. Information should be supplemented by interviews with key informants and observations of operations at various levels including practice in the field.
9. The assessment should be undertaken with the support of the Interagency Coordinating Committee (ICC). Major financial stakeholders should be informed of the study, and their collaboration sought.
10. The next steps are to:

#### Stage one

1. Collect, synthesize and analyze available information
2. Define gaps and areas of uncertainty that require enquiry

#### Stage two

3. Plan further data collection, if necessary
4. Collect data (information, documentation, and observations)
5. Synthesize and analyze all the data
6. Define and describe problems

### Stage three

7. Conceive solutions for the problems
8. Prioritize solutions based on cost-effect
9. Recommend actions.
11. If an international consultant is involved in the study, the collection of stage one documentation and/or information should take place prior to their arrival.
12. The source, reliability and validity of all information need scrutiny. Of particular importance are any discrepancies between sources or between service delivery levels.
13. Feeding back, at all levels of enquiry, on identified problems and potential solutions will provide opportunity for validation as well as participation in problem solving.

### D. Data collection

14. Most of this information should be readily available from routine sources (e.g. Table 1), or will have been summarized in previous reviews of the NIP. Existing reports can be provided, and do not need to be rewritten as duplication is to be avoided. If reviews do not exist, or are out of date (>three years), the following is a guide to the basic data needed. Those marked with an asterisk (\*) are desirable but not crucial. Brief but adequate descriptions or comment will be sufficient.
15. Comment on quality of reporting mechanisms and data may be required. Explanation for discrepancies between nationally collected data and WHO/World Bank/UNDP data should be provided, where possible.

### 1. Background and context of the programme

16. Current information about the operating environment of the NIP is a necessary component of the assessment. The feasibility of any financing proposal or investment will be dependent upon the economic and political context within which the NIP must work.

**Table 1. Sources of national information**

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■	National policy and planning documents, standards, guidelines, and reports on the health system and immunization services
■	WHO and UNICEF immunization programme reviews
■	Demographic and Health Survey (DHS)
■	UNDP Human Development Report
■	World Bank and other agency reports on health sector, government reforms, etc.
■	Current budget allocations and data on expenditures

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#### a. Demographic

- (i) Population statistics, including
  - (a) total
  - (b) under 5' s (or other age relevance for specific vaccine)
  - (c) women of child-bearing age
- (ii) Ethnic composition

- (iii) Vital statistics, including
  - (a) birth rate (any gender imbalance)
  - (b) infant mortality rate/1,000 live births
  - (c) maternal mortality rate
  - (d) under five deaths per 100,000
  - (e) life expectancy rates
- (iv) Major cause(s) of death, including
  - (a) age-standardized deaths rates
  - (b) vaccine-preventable deaths

**b. Economic**

17. This data will provide information on the government's commitment (through spending patterns) to the health sector in general, and the immunisation programme in particular. It also places the feasibility and sustainability of an investment into immunization in an economic context.
- (i) Development status
  - (ii) poverty levels
  - (ii) Gross domestic product (GDP) per capita
  - (iii) Percent of GDP spent by government
  - (iv) Percent of GDP allocated (or spent) on health percent of public health costs supported by external sources
  - (v) Per cent of (government) public health funds spent on the immunization programme
  - (v) Balance of payments\*
    - debt service/exports
  - (vi) Annual growth rate previous year\*
  - (vii) Average annual growth for previous five years\* Annual growth rate previous year

**c. Political**

18. The political context will influence the support provided to an immunization programme
- (i) Form and structure of government
  - (ii) Key decision makers for health spending, and for the immunization programme, and their position (authority) within government
  - (iii) Relationship between Ministry of (Public) Health, and Ministry of Finance (or equivalent)

**d. Health Sector**

- (i) Burden of disease, including vaccine preventable diseases
  - trends
- (ii) Quality of disease surveillance

- (iii) Description of sector
  - status of ongoing or planned health reforms, and impact on immunization services
  - health policies, strategies and planning
  - structure of health services, and place of immunization programme
  - management responsibilities and reporting process
  - human resource capacity
- (iv) National regulatory authority (NRA)
- (v) Financing for health services, including internal and external sources (and trends)
- (vi) Financial reporting and transparency of funding allocations and expenditure
- (vii) Role of private sector
- (viii) Role of other organizations
  - aid agencies – multilateral, bilateral
  - international non-government organizations
  - Interagency Co-ordinating Committee

**e. Immunization & vaccines –legal status**

19. The legal status of vaccines and immunization may provide impact on proposed changes, including introduction of new vaccines.
  - (i) Legal status of vaccines
  - (ii) Immunization schedule in legislation
    - legal process needed to change the immunization schedule
  - (iii) regulatory authority for vaccines
    - Management capacity
  - (iv) Children’ s legal right to immunization
  - (v) Legal requirements for immunization
  - (vi) Those legally permitted to vaccinate

**2. The Immunization programme**

20. The purpose of this data is to determine strengths and weakness of the program and therefore identify areas that may need investment. Information is needed on the scale of problems, the likely cost of the solution(s), and their relative importance/priority. Previous reviews should be used in the first instance as source documents. Recommendations from these reviews should be included, and comment provided on whether the recommendations were implemented, and if so, to what extent and success implementation occurred.
21. Information should be provided on the various levels that the NIP operates. This will include national, sub-national, and service delivery, with the number of levels dependent on the health sector’ s structure. Use of sub-national and service delivery information should aim to cover both rural and urban areas, high and low performing areas, densely and sparsely populated areas, and areas serving mobile populations. Review is both of policy (if

present) and actual practice, noting reasons for any differences.

22. The AVI priority is **equitable coverage** of the population for immunization services. Particular attention should be paid to minority, marginalized or 'unreachable' populations.
23. (WPRO has developed a quantitative indicator of programme sustainability, based on a subset of some of the information that is covered here. This provides a score that may be helpful to focus on the issues.)

**a. Management (capacity)**

- (i) Policy and planning documents (e.g., National Immunization Plan, Annual Work Plan)
  - implementation of plans
  - evaluation or review process
  - outcomes (analysis of failure)
  - planned expansion
- (ii) Administration systems
  - performance based pay structures
- (iii) Leadership, position of EPI manager in hierarchy
- (iv) Expert Advisory Committee
- (v) Experiences with introduction of new vaccines

**b. Immunization delivery services**

- (i) Role of service providers, public and private
- (ii) Role of other organizations
  - aid agencies – multilateral, bilateral
  - international non-government organisations
  - Interagency Co-ordinating Committee
- (iii) Human resources
  - capacity and quality
  - training
- (iv) Immunization schedule
- (v) Frequency of services, by region/rural
- (vi) Strategies to reach under-served populations
  - obstacles to access
  - potential for incentives (providers and users)
- (vii) Experiences with introduction of new vaccines
- (viii) Administration
  - Record keeping, reporting
  - follow-up for defaulters
- (ix) Capacity to undertake or absorb changes

**c. Surveillance**

- (i) Methods of surveillance
  - standards, guidelines, case definitions
- (ii) Reporting process and timing
  - response to no reporting
- (iii) Data analysis and response – national, regional, local
  - availability of maps
- (iv) Data quality checks, validation, and feedback
- (v) Integration with other health sector surveillance

**(1) Disease surveillance**

- (i) Vaccine-preventable diseases
- (ii) AFP surveillance indicators
- (iii) Other surveillance indicators
- (iv) Laboratories/sample collection and processing

**(2) Coverage surveillance**

- (i) Methods
  - Routine/campaigns
- (ii) Trends, reported vs survey, projected vs actual
  - Areas/population with lower coverage
  - Proportion of areas not meeting target
- (iii) Drop-out rate (eg measles-BCG; DTP3-DTP1)

**(3) Adverse events following immunization (AEFI) surveillance\***

- (i) System for reporting AEFI
- (ii) Quality of reporting
- (iii) Ability to investigate AEFI

**d. Vaccine supply**

- (i) Vaccine source(s)
  - price, including shipping and handling
  - quality
- (ii) Procurement method(s)
  - reliability of supply
  - access to international mechanisms
- (iii) National regulatory authority (6 functions)

**e. Logistic systems**

- (i) Management and administration
  - vaccine and equipment forecasting (calculation of requirements)
  - wastage data (incl. supplied vs used)
- (ii) Vaccine stock management
  - storage, preparation
  - lot release/quality checking before vaccine distributed
  - interruptions in supply
  - open vial policy and vaccine vial monitors (VVMs)
  - waste disposal
- (iii) Capacity to introduce new vaccines
- (iv) Cold chain
  - Performance
  - Status of cold chain and transport equipment
    - standardised equipment
    - quality
    - forecasting of replacement needs
  - Maintenance capacity
    - spare parts
    - skill base
  - Response to cold chain failures (protocols)

**f. Safe injection practices**

- (i) National plan
  - training and supervision of health workers
- (ii) Type(s) of injection equipment
- (iii) Disposal and destruction of used materials

**g. Communication**

- (i) Communication strategy
  - current resources
- (ii) Reach
- (iii) Funding for communication
- (iv) Social mobilization – national/community leaders

## **E. Costs and financing requirements for the NIP**

24. This is the focus of the assessment, and will require collection and compilation of a range of financial documents. Comment will need to take into account the global and regional context of immunization financing, including the role of GAVI (reversal of decline in donor funding?), and post-polio dividends. Expenditure data rather than cost data will be used at this stage, but acknowledgement should be made of government contribution to services, which contribute to immunization programs (eg PHCs).
25. This information will be used in conjunction with the above data to undertake cost-effectiveness analyses.

### **1. Management**

- (i) Capacity
- (ii) Line responsibility
  - budget development
  - budget reporting

### **2. Systems**

- (i) Accounting system
  - line items
  - reporting system
- (ii) Reporting system
  - actual expenditure versus budget
  - accountability
- (iii) Ability to absorb and manage increased funding

### **3. Budget**

- (i) Method of compilation
  - data source, basis for forecasting
- (ii) Current budget
  - budget lines for immunisation, including vaccine purchase
  - income, eg user fees
- (iii) Trend over past three years
- (iv) Forecasting
  - infrastructure replacement
  - improvements /strengthening
  - new vaccines

#### **4. Expenditure**

- (i) Reported expenditure, current and past three years
  - overheads
  - capital items
  - recurrent costs, incl. Training
  - payments to vaccinators (fee for service, incentives)
- (ii) Strategy for cost reduction, including identification of cost efficiencies

#### **5. Sources**

- (i) Contributions
  - Components (public sector, private sector, insurance, household, and donors)
  - trends, over past three years
  - anticipated future contributions
- (ii) Strategy for sustainable financing
  - self sufficiency
  - alternative strategies (eg user incentives)
- (iii) Options for additional financing
  - GAVI, ADB

#### **F. Recommended investments**

- 26. The assessment needs to bring together all the elements into a conclusion about the programme and its priority needs. This enables recommendations about financing options, including new investments, for the programme.
- 27. This assessment framework is designed to highlight major financial concerns. The design of a project, or investment may require more in-depth investigation and analysis to ensure feasibility and sustainability.

#### **G. Likely impact of a new investment**

- 28. Informed speculation by relevant stakeholders, together with the results of the assessment will provide a basis for comment.
- 29. If a new vaccine is being considered, information will be needed on disease burden and vaccine safety and effectiveness, as well as likely coverage. The impacts on the rest of the immunization programme as well as the wider health sector also need assessing. (refer WHO assessment to introduce new vaccines)

The Immunization Focus of the WHO office of the Western Pacific Region has established the following mission statement and objective:

*To eliminate sickness and death caused by vaccine-preventable diseases through the development of strong, sustainable national immunization programmes capable of delivering high quality vaccines in a safe and effective way to all children and adults who require them*

The Immunization Focus achieves this objective by working with national immunization programmes in all countries and areas of the Region. It accomplishes its objective through immunization of children against tuberculosis, poliomyelitis, pertussis, diphtheria, tetanus, measles, and hepatitis B; protection of newborn infants against neonatal tetanus by immunizing pregnant women and women of child bearing age; and immunization of broader than usual age groups during disease control activities.

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This document aims to help policy analysts and decision-makers when considering the addition of new vaccines to national immunization programmes. It reflects the growing international concerns that all children of the world should have access to life-saving vaccines wherever they happen to live. There are vaccines that countries can consider now, and more new vaccines are becoming available. The document provides a set of questions to work through the technical issues for adding a new vaccine to the national immunization schedule.

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