

# **Principles and considerations for adding a vaccine into a national immunization programme**

**From decision to implementation**

*Excerpted sections for the April 2012 SAGE session:  
Impact of vaccine introductions on  
immunization and health systems*

**23 March 2012**

# Contents

## Preface

### 1. Introduction and Background

- 1.1 Purpose of this guide
- 1.2 Background on global immunization efforts and the introduction of new and under-utilized vaccines
- 1.3 Guiding principles for adding vaccines to national immunization programmes while strengthening immunization and health systems

### 2. Deciding on the introduction of a vaccine

- 2.1 Overview: issues to consider when deciding about introducing a vaccine into the national immunization programme
- 2.2 The disease
  - 2.2.1 The public health and political priority of the disease
  - 2.2.2 Disease burden
  - 2.2.3 Other disease prevention and control measures
- 2.3 The vaccines
  - 2.3.1 Performance and characteristics of available vaccines
  - 2.3.2 Availability of vaccine supply
  - 2.3.3 Economic and financial issues
- 2.4 Immunization and health systems
  - 2.4.1 Strength of the immunization programme and health system (programmatic feasibility)
  - 2.4.2 The decision-making process

### 3. Planning and managing the vaccine introduction

- 3.1 Planning for a successful vaccine introduction
  - 3.1.1 Updating immunization plans and policies and integrating them with the national health plan
  - 3.1.2 Developing a vaccine introduction plan
- 3.2 Choosing the immunization strategy
  - 3.2.1 Phased or simultaneous introduction
  - 3.2.2 Deciding whether to introduce more than one vaccine at a time
  - 3.2.3 Optimal schedule for routine immunization
  - 3.2.4 The delivery of routine doses in periodic campaigns
  - 3.2.5 Catch-up and supplemental immunization
  - 3.2.6 New delivery strategies
  - 3.2.7 Using the opportunity of a new vaccine introduction to implement integrated approaches towards disease control and to increase access to other immunizations and health interventions
- 3.3 Selecting the vaccine, presentation and formulation
- 3.4 Assuring quality and procuring the vaccine and injection supplies
  - 3.4.1 Assuring vaccine quality
  - 3.4.2 Procurement options
  - 3.4.3 Forecasting supply needs

- 3.5 Vaccine management and logistics
  - 3.5.1 Estimating additional storage requirements for the new vaccine
  - 3.5.2 Updating the logistics management information system (LMIS)
- 3.6 Ensuring injection safety and safe waste disposal for the new vaccine
- 3.7 Training and supervision of health personnel
  - 3.7.1 Staff training
  - 3.7.2 Supportive supervision
- 3.8 Advocacy, communications and social mobilization
- 3.9 Updating information systems

#### **4 Monitoring and evaluation**

- 4.1 Introduction to M&E best practices
- 4.2 Coverage monitoring
- 4.3 Disease surveillance
- 4.4 Vaccine safety monitoring (vaccine pharmacovigilance)
- 4.5 Assessing programme implementation and lessons learned: Post Introduction Evaluations

### **5 Maximizing the opportunity of a new vaccine introduction to strengthen the overall immunization programme and health system**

#### **References/resource list (with links to Webpages)**

#### **Annexes (possibilities):**

1. Specific issues for selected new and under-utilized vaccines
2. Example of Fact sheet on observed rate of vaccine reactions
3. Additional information on economic and financial issues
4. WHO summary tables of recommended vaccine schedules for routine immunization
5. WHO/UNICEF guidance note on criteria to determine if a given vaccination is a routine or supplemental dose
6. Building blocks of a health system from the WHO Health System Framework

Sections included in the attached pages are highlighted.

## (Under Chapter 1 on Introduction and Background)

### 1.3 Guiding principles for adding vaccines to national immunization programmes while strengthening immunization and health systems

Experience has shown that the introduction of a new vaccine can have a significant impact – both positive and negative – on the overall national immunization programme and the country's health system. In recognition of this fact, the working group that guided the development of this document has identified five guiding principles that countries can follow in planning and implementing a vaccine introduction while strengthening their overall immunization programme and health system (see box).

#### **Principles for adding a vaccine to a national immunization programme while strengthening the immunization and health systems**

Optimal vaccine introduction that strengthens health systems benefits from:

- 1) A strong decision-making, planning, and prioritization process with accountable governance that is coordinated and integrated within the health system.
- 2) A well-performing or improving immunization program to obtain full benefit from existing vaccines, including:
  - A well-trained and motivated health workforce
  - Functional cold storage, logistics and vaccine management systems
  - Safe immunization practices and monitoring of adverse events
  - High-quality disease surveillance and immunization coverage monitoring
  - Resource and performance accountability
- 3) Maximizing opportunities to deliver vaccines as integral components of comprehensive health promotion and disease prevention and control efforts so that vaccines are delivered as part of a package of effective, feasible, and affordable interventions based on national contexts.
- 4) Sufficient allocation of human and financial resources to introduce the new vaccine and sustain its use without diverting from other programmes and services.
- 5) A guaranteed appropriate and sufficient vaccine supply.

## Part of Chapter 2 on Deciding on the Introduction of a Vaccine

### 2.4 Immunization and health systems

#### 2.4.1 *Strength of the immunization programme and health system (programmatic feasibility)*

When deciding whether to introduce a vaccine into the national immunization programme, decision-makers must consider the potential impact of the introduction on both the programme and on the overall health system, including its ability to provide other critical health services. If there are already serious weaknesses in the immunization programme, adding the new vaccine may cause additional burdens and thus worsen the programme's performance. For example, if the current programme is failing to reach a large proportion of the target population, the new vaccine will be able to offer only limited benefits to those who need it most. In such cases, delaying the introduction of the vaccine until key programme weaknesses can be addressed may be the best option.

Decision-makers must also decide whether the immunization and health systems are capable of handling, storing and administering the vaccine adequately, considering its specific characteristics, such as the number of doses in the regimen and interval between doses, the strictness of the schedule for the vaccine, its heat stability and freeze tolerance, and cold storage space requirements. Looking beyond the immunization programme, if the current workforce is insufficient, inadequately trained or poorly motivated to handle the current package of health services, adding a new vaccine to the programme may result in more stress on these workers, poor coverage of the new vaccine as well as those already in the programme, and less time and attention paid to other critical health programs and services.

However, the introduction of a vaccine into the NIP may also present opportunities to improve the immunization and health systems. For example, the training of health workers for the new vaccine presents opportunities to refresh their skills and knowledge in immunization and other related health services. The vaccine introduction can also lead to strengthening of national immunization technical advisory committees (NITAGs) in making evidence-based decisions, improved planning, and upgrading of the cold chain and logistics system.

Therefore, it is important to review the immunization programme in order to identify weak areas before a vaccine is introduced or that can be explicitly strengthened in the process of introducing the new vaccine. This review should involve a pre-introduction assessment of the immunization programme that allows for sufficient time to address identified weaknesses (see Section 3.1 for further discussion on pre-introduction assessments). At the same time, it is also critical to identify major health system-related issues that can affect the performance of the immunization programme, and to develop strategies to address them.

The following box lists possible benchmarks that could be used to assess the strength of the NIP to accommodate a new vaccine. It is obvious that not many developing countries could meet all these conditions before introducing a vaccine. However, this list can assist in identifying weak areas that could be improved – or in the case of multiple, serious deficiencies – to provide evidence of the need to potentially delay introduction of the vaccine until major areas can be strengthened. Once a decision to introduce a vaccine has been made, EPI managers can use the WHO pre-introduction checklist to prepare their detailed plans for the roll-out (see Section 3.1).

## **Examples of possible benchmarks for assessing the readiness of the national immunization programme and health system for adding a new vaccine**

### **1) A strong decision-making and accountability process that is transparent, coordinated and integrated with the overall health sector**

- The vaccine introduction fits in with the priorities and plans outlined in the national health sector plan, national development plan, or other key government policy documents.
- There is a functioning national immunization technical advisory group (NITAG) or equivalent technical committee to make recommendations to the government about the vaccine introduction, based on a rigorous and transparent review and analysis of epidemiological and economic data.
- The plan or proposal for the new vaccine has been reviewed by a Health Sector Coordinating Committee (HSCC) or similar mechanism to ensure coordination of health programmes and funding requests.
- All key decision-makers in relevant agencies (Ministry of Health, Ministry of Finance, Ministry of Education for vaccines delivered through schools) are involved in making the final decision about introducing the vaccine.

### **2) A well-performing or improving immunization programme to obtain full benefit from existing vaccines**

- An immunization multi-year plan and annual work plans are in place, with regular updating of policies.
- Overall coverage rates of existing vaccines meet national targets or reflect satisfactory improvement, and have not fallen in the last five years.
- Drop-out rates between vaccine doses have decreased in the past five years or are at acceptable levels.
- Differences in coverage rates between high- and low-performing districts and between the lowest and highest income groups (e.g., quintiles) are decreasing or are at acceptable levels.
- Specific objectives are met or well underway for vaccines already in the programme. For example, high coverage with DPT-HepB-Hib is achieved, catch-up measles vaccination has been conducted, or two-dose measles strategy has been established.

### **3) A sufficient or expanding, well-trained and motivated health workforce**

- An assessment has been conducted of the size, distribution, and level of satisfaction/motivation of the health workforce in terms of its ability to provide the current package of health services and to add the new vaccine to the national immunization programme.
- If additional personnel are needed to handle the extra workload, they are included in the cMYP and budget, and in the national health sector plan and budget.
- Appropriate pre-service and in-service training and on-site supportive supervision of health staff is provided.
- If staff turnover is a critical problem, there is a realistic plan and budget in place (as part

of the national health plan) to replace staff and reduce the turnover rate.

#### **4) Functional vaccine management, cold chain and logistics systems**

- National cold-chain policy and vaccine management systems include an updated cold chain inventory, as well as plans for the maintenance and replacement of equipment.
- The cold chain system has adequate volume capacity and performance for vaccines already in the programme at all levels (central, provincial/regional, district, and facility).
- Cold storage space is sufficient to meet or is being expanded to meet any additional demands of the new vaccine at all levels of the health system, with an adequate spare capacity to meet campaign or unforeseen needs.
- There is sufficient dry storage space at all levels to accommodate injection materials for the current vaccines and the new vaccine, as well as medicines and other health commodities.
- Vaccine stock-outs at national or sub-national levels have been infrequent in the last five years.
- There are two-year to five-year forecasts for all vaccines already in the programme (including planned/likely campaigns) and for the new vaccine, including the transition period when current vaccines are being replaced.
- There is effective vaccine wastage monitoring and acceptable levels of wastage.

#### **5) Safe immunization practices and monitoring and management of adverse events**

- All injectable vaccines are given with auto-disable (AD) syringes.
- Proper diluents and reconstitution methods are used for lyophilized vaccines.
- There is capacity to procure, distribute and properly dispose of additional injection materials for the new vaccine.
- There is a surveillance and reporting system for adverse events following immunization (AEFI) in place that is capable of investigating and responding to possible adverse events, or plans to improve this capacity with training.

#### **6) High-quality disease surveillance and immunization coverage monitoring**

- There is timely and reliable surveillance for major vaccine-preventable diseases.
- Credible data exist on coverage of all vaccines provided through the national immunization programme, including a breakdown by sub-national levels.
- Coverage evaluation surveys are conducted periodically to validate routinely-collected data and ideally include coverage data by socio-economic group and gender.

#### **7) A financially sustainable programme**

- The decision to introduce the vaccine has been based on a careful consideration of the short-term additional costs associated with new vaccine introduction, as well as the longer-term financial implications for sustaining the programme (e.g., after donor support ends).
- The Government has committed to financing the national immunization programme, and budget allocations and disbursements have increased over time.
- The vaccine introduction, including co-financing for GAVI-supported vaccines, will be funded with additional resources and will not lead to a reduction in government funding

for other vaccines, other immunization programme components, or other health services and programmes.

- Multi-year plans include a budget that is linked to the national health budget to secure current and future funding for vaccines and other costs.

#### **2.4.2 The decision-making process**

There is increasing recognition among governments, donor and international agencies of the importance of having a systematic and transparent process for making a decision about introducing a vaccine into the national immunization programme. Also critical is that all key stakeholders both in and outside of the health sector are consulted to obtain their input and buy-in, to ensure ownership in the programme, and to ensure that the vaccine introduction is aligned with the national health plan or strategy and budget. If the process is perceived as secretive, rushed or not thorough, it can lead to opposition among powerful leaders or groups, negative reports in the media, and a lack of community acceptance of the new vaccine. On the other hand, a decision made in a systematic way with the input of all key stakeholders and that addresses their concerns is more likely to result in a successful introduction of the vaccine.

More and more countries are recognizing the importance of establishing a national immunization technical advisory group (or NITAG) to make recommendations to the Government about the national immunization programme, including whether or not to introduce vaccines, based on a rigorous review of the evidence. NITAGs should consist of national experts in a broad range of disciplines – such as senior pediatricians, immunization and vaccine experts, epidemiologists, public health experts, health economists, health system experts and social scientists – who are capable of analyzing the different types of evidence and issues that should be considered in making an informed decision. NITAG members should have a broad health perspective to ensure that the impact of the vaccine on health systems and programmes is considered. The NITAG and its members should be perceived as objective, independent and not representing a particular interest group. The independence of the committee and its reliance on evidence-based decision making reinforces the credibility of the decision, helps resist pressure from any interest group, and enhances the ability to secure government and/or donor funding for the vaccine. NITAGs function best when they are supported by a secretariat or technical sub-committee to collect and synthesize the evidence. More information on NITAGs can be found at [\[link to IVB website\]](#).

Decisions about introducing a vaccine should be approved not only by top decision-makers within the health and finance ministries, but also by other relevant agencies and ministries, such as the Ministry of Education, in the case of vaccines, such as HPV, that may be delivered through schools. In addition, the country's Health Sector Coordinating Committee (HSCC) or similar group should be involved in reviewing any proposals to funders and plans for the new vaccine introduction to ensure their consistency with the national health plan and priorities, and that they are not contradictory or duplicative with other proposals to funders or other plans. HSCCs can also help ensure that plans for the vaccine introduction are coordinated with other sectors of society, such as civil society and NGOs, to secure their buy-in and assistance in planning and implementing the new vaccine introduction. In addition, Inter-agency Coordinating Committees (ICCs) play an important role in many countries in coordinating partner activities of the immunization programme, including the preparation of proposals for support for new vaccines and the subsequent roll-out and evaluation of the vaccine introduction.



<b>Groups involved in making decisions and in coordinating plans for introducing a vaccine into the national immunization programme</b>	
<b>Group or agency</b>	<b>Description/role</b>
National Regulatory Authority (NRA)	An agency responsible for assuring the quality of the medical products, including vaccines, used in the country and in issuing licenses for new products.
National Immunization Technical Advisory Group (NITAG)	A group of experts responsible for advising the government on technical issues related to the national immunization programme, including vaccine introductions, based on scientific evidence.
Inter-agency Coordinating Committee (ICC)	A committee made up of representatives of the MOH, WHO, UNICEF and other domestic and external partners to improve coordination among partners for the support of immunization programs.
Health Sector Coordinating Committee (HSCC)	The highest level group in a country responsible for coordinating and monitoring of the national health sector plan and for ensuring that all new activities, including a vaccine introduction, are consistent with the national health strategy, national health plan and budget.

The NITAG and government policymakers may have to make decisions beyond just whether or not to introduce the vaccine, especially if there are policy and financial implications. These decisions can include:

- Whether to conduct nation-wide or geographically-targeted vaccination, in the case of diseases, such as JE and cholera, which may be a threat primarily in certain high-risk areas or populations in the country;
- The age group and schedule: Some newer vaccines, including HPV, are given beyond infancy. Thus, the feasibility of reaching older age groups and the need for alternative delivery strategies, such as school-based immunization, may have to be considered;
- Whether or not to conduct catch-up immunization and in which age groups. Catch-up immunization for older age groups, when coupled with routine immunization for infants or young children, can rapidly reduce transmission of a disease. However, the larger the age group to be immunized, the higher the costs and logistical challenges.
- The choice or preference of vaccine, formulation and presentation, in consideration of the costs, storage requirements, and training needs for each product.

These issues are discussed further in Chapter 3.

## Part of Chapter 3 on Planning and managing the vaccine introduction

### 3.1 Planning for a successful vaccine introduction

#### 3.1.1 *Updating immunization plans and policies and integrating them with the national health plan*

Once the decision to introduce the vaccine has been made, the national comprehensive multi-year plan (cMYP) and budget needs to be updated to include all of the activities to prepare for, implement, monitor and evaluate the introduction. The cMYP is normally a three to five year plan that sets out the goals, objectives, strategies, indicators/milestones, and activities to achieve these milestones for the entire national immunization programme, integrating into one plan all routine immunization activities, supplemental immunization activities (SIAs) and other related initiatives. The immunization programme budget and financing plan also needs to be updated to incorporate the vaccine introduction (as discussed in Section 2.3.3). Guidelines for developing a cMYP and the cMYP costing and financing tool can be found at [\[do link\]](#).

As discussed in Chapter 2, developing or updating the multi-year plan should begin with a situation analysis of the current performance of the immunization programme. Updating the plan for the new vaccine introduction thus presents an opportunity to identify weak areas of the immunization programme and health systems that may impede the successful introduction of the vaccine or progress of the overall immunization programme, and to make plans to strengthen these areas. To assist in the detailed planning for the new vaccine introduction, WHO has developed and field-tested a pre-implementation checklist as a useful aide in determining what changes and activities are needed to ensure a successful vaccine introduction [\[link to tool once available\]](#).

In planning for a vaccine introduction, it is also critical to consider all possible effects of this addition on the national immunization programme and health system, including possible new burdens and stresses. For instance, some newer vaccines require more time to administer to infants than other routine EPI vaccines (e.g., rotavirus vaccine requires a relatively large volume of liquid to be swallowed by the infant). Based on a situation analysis of current services, programme planners may need to consider if additional health workers or an increase in the number of EPI sessions will be required to ensure both high coverage of the new vaccine and that other immunization and health services do not suffer. Vaccine introductions can also require new delivery strategies (e.g., school-based), expansion of cold chain and dry storage systems, additional waste management facilities, and expansion of disease surveillance to include the newly-targeted disease. All of these changes have cost implications that must be added to the budget (see box).

There may also be “hidden costs” that countries need to consider ahead of time. For instance, if a country cannot sufficiently expand the cold chain system at all levels in time before introducing a vaccine into the NIP, it may have to increase the frequency of vaccine deliveries to provinces and districts. These extra deliveries mean more fuel, more vehicle repairs and maintenance, and additional salary costs and per diems for the drivers.

The objectives, strategies, cost and financing information from the updated cMYP should also be integrated into the national health sector plan and budget. The dates of the plan should be synchronized as much as possible with those of the national health sector plan.

**Possible costs to include when estimating the  
funding needs for a vaccine introduction**

- Training of all relevant health workers at all levels, including refresher training
- An increase in personnel, such as central EPI staff or health workers to handle the additional workload with the new vaccine, an increase in salaries or other personnel costs.
- An increase in the number of EPI sessions due to the extra time needed to administer the new vaccine and/or to an increase in demand for immunization services that it may generate
- Expansion of the cold chain, dry storage and vaccine transport systems
- Extra fuel to operate additional cold chain equipment and vehicles required to accommodate the new vaccine (especially for vaccines with large storage requirements)
- Possible additional personnel costs for more frequent vaccine deliveries (e.g., drivers)
- Maintenance and repair of additional equipment and vehicles needed to accommodate the new vaccine
- Repairs, expansion or addition of waste management facilities to handle the additional waste generated by the new vaccine
- Development of an effective social mobilization plan
- New delivery strategies, such as school-based vaccination
- Revision and printing of immunization forms, guidelines and procedures
- Establishment or strengthening of disease surveillance for the new vaccine, including expansion of laboratory capacity, as needed
- Strengthening AEFI surveillance, reporting and management for the new vaccine and all EPI vaccines

**3.1.2 *Developing a vaccine introduction plan***

In addition to updating the cMYP to include the new vaccine, immunization programmes should develop a detailed introduction plan. The plan should outline all activities and steps required for a successful vaccine introduction by programme component, stipulate what institutions and government departments are responsible for each activity, and include a timeline and detailed budget. The WHO pre-implementation checklist cited above is also a useful tool for developing the introduction plan. It prompts countries to list actions to address problems identified in the assessment, to prioritize these actions, set deadlines for each one, and work backwards from the deadline to develop a timeline. Based on country experiences with recent vaccine introductions, it is critical that enough time is allowed to plan and implement all of the many activities involved in introducing a vaccine and that the introduction not be rushed. For instance, if staff training is estimated to take four months to complete throughout the country, and it will take three more months to plan the training and develop and revise training materials, then the process needs to begin at least seven months before the planned launch of the new vaccine.

Given the many programme components and technical areas of an immunization programme, many countries have established technical sub-committees for such areas as advocacy and communications; cold chain, logistics and vaccine management; training and supervision; disease surveillance; and safety or AEFI monitoring. These sub-committees can play a critical role in assessing, preparing for and implementing the various aspects of a vaccine introduction. Thus, if countries do not have active sub-committees for particular technical areas, the introduction of a vaccine into the national programme can provide the stimulus for establishing or re-activating such committees. The technical sub-committees and other groups involved in planning and implementing the vaccine introduction should involve a broad range of stakeholders and communities, political and religious leaders (as appropriate) to ensure their buy-in, minimize potential negative impacts, and improve the likelihood of a successful introduction. Involving health workers in the planning also helps to ensure their cooperation and their input in developing practical strategies, as well as in identifying and addressing potential problems in implementing the vaccine introduction.

**Questions to ask when planning for a vaccine introduction to ensure broad cooperation with key stakeholders and coordination with other health programmes**

- Have the national immunization policy and national health sector plan been revised to include the introduction of the vaccine?
- Do time periods for the revised cMYP align with those of the national health plan or strategy? If not, is it possible to modify the time periods so they coincide? Are key officials involved in the planning for the vaccine introduction, including preparation of the revised cMYP, such as officials from:
  - MOH Planning Department, Planning Commission or equivalent
  - Primary health care or health services divisions of the MOH
  - EPI program, including EPI manager
  - Ministry of Finance
  - Other relevant ministries or government agencies, e.g., Ministry of Education for school-based vaccination programmes?
- Do active technical sub-committees exist for all critical programme components (e.g., advocacy and communications, cold chain and vaccine management, training, etc.) and are they involved in the planning and implementation of the vaccine introduction?
- Are representatives of different stakeholders (professional associations, civil society organizations, NGO health care providers, women's groups, etc.) involved in planning and implementing the vaccine introduction?
- Are health workers at all levels of the health system involved in the planning for the vaccine introduction?
- Is enough time being allowed to adequately plan all aspects of the vaccine introduction?

## Chapter 5 Maximizing the opportunity of a new vaccine introduction to strengthen the overall immunization programme and health system

The introduction of a vaccine provides many opportunities to improve the overall immunization programme, as well as the health system. Many of the activities carried out to prepare, implement and monitor the vaccine introduction – from using an evidence-based decision-making process to preparing multi-year plans and budgets based on a programme assessment; training health workers on the new vaccine; improving and expanding the cold chain, strengthening disease surveillance, and AEFI monitoring and reporting systems; and conducting advocacy and communications activities to promote the new vaccine– all provide opportunities to improve the immunization programme as a whole and to identify best practices that could be applied to other health programmes and services. Conversely, the immunization programme can learn from the best practices of other health programmes. These synergies become more possible as countries integrate the introduction of vaccines and other health programmes into a national health strategy or plan (e.g., by adopting the International Health Partnership Plus (IHP+) process aimed at incorporating all donor-funded health projects into “one plan, one budget and one report”) [[do link to IHP+ website](#)].

Low-income countries often receive financial and technical support from partners for the introduction of a vaccine, which expands the possibilities for creating long-term benefits to immunization and other health programmes. It is important to note, however, that these possibilities remain unfulfilled unless the immunization programme, health ministry and partners have the interest and time to plan and execute initiatives that take advantage of the opportunities provided by this support. Some vaccine introductions in recent years have been rushed, with insufficient time for planning and preparation. Advocating for sufficient lead time may be key to translating the ideas in this section into reality.

Health ministries should therefore examine weaknesses in the immunization programme and in different components of the broader health system and use the opportunity of the new vaccine introduction and accompanying funding to strengthen these areas. See Box 1 for examples of how countries have used the introduction of a new vaccine to improve immunization and health services and programmes.

### **Box 1. How countries have taken the opportunity of introducing a new vaccine and GAVI support to strengthen their immunization and health systems**

- In the Dominican Republic, the introduction of DPT-HepB-Hib (pentavalent) vaccine provided the impetus to strengthen many components of the immunization programme, as well as the health system, with technical and financial support from external donors. Improvements were made to the training of health workers on new norms and procedures, injection safety and waste management practices, the immunization information system at all levels; monitoring, supervision and evaluation; and vaccine management and logistics – practically eliminating once frequent vaccine stock-outs. The government also used this opportunity to establish a system of accreditation of public and private health facilities to ensure standards of quality, equity, efficiency and effectiveness.
- Example of Mali and creation of AEFI committee (**still to come**).
- Example of Peru and work force planning and cold chain improvements (**still to come**).

Vaccine introductions can also provide the opportunity at the service delivery level to improve the coverage and timeliness of other EPI vaccinations as well as other important maternal and child health services. Ways in which a vaccine introduction can lead to increased coverage of and access to other immunization and health interventions include the following:

- The **high demand for the new vaccine** – spurred by effective communications and social mobilization activities – can bring in children or adolescents who have not previously been immunized or are behind in their immunization schedule. This has been shown to be true especially for vaccines, such as pneumococcal and meningococcal vaccines that target highly visible diseases well known to the community. Countries may want to assess the potential for this increased demand through formative research (e.g., KABD surveys discussed in Section 3.7), and take the opportunity of this increased demand to get children up-to-date on all their vaccinations and to provide them with other preventive and curative health services both during routine visits and special campaigns. For instance, the new vaccine can be added to the package of services provided during Child Health Weeks (or Days) or periodic intensive routine immunization (PIRI) campaigns. The popularity of and awareness about the new vaccine could increase attendance of these integrated health campaigns, thus increasing access to other critical health services.
- In a number of countries, the introduction of a new vaccine begins with an **initial launch campaign** in which the new vaccine is heavily promoted, provided through mass vaccination campaigns, and even door-to-door in low-coverage areas. These launches thus provide an excellent opportunity to get the target population caught up on other immunizations and to provide other important health services.
- The introduction of vaccines that target major causes of pneumonia and diarrhea also present the opportunity to provide **coordinated packages of interventions**, in accordance with the Global Action Plans for the Prevention and Control of Pneumonia and Diarrhea. When children are vaccinated with pneumococcal, Hib or rotavirus vaccines, the sessions can be set up to enable health workers for example to also educate mothers about the importance of exclusive breastfeeding, the use of Oral Rehydration Solution (ORS) and hand washing with soap, as well as to provide vitamin A, zinc supplements and other appropriate interventions. This requires detailed planning and coordination with the relevant health programmes and departments.
- Some new vaccines target **new age groups**, such as school-aged children, adolescents, and adults. The introduction of vaccines targeting children beyond infancy – such as HPV, typhoid and meningococcal conjugate vaccine – provides opportunities to reach the older target population, often through school-based programmes, with other age-appropriate vaccines (e.g. TT and dT boosters) and other health interventions. These can include the distribution of deworming medicines and iron tablets, and treatment of trachoma and schistosomiasis.

See Box 2 for questions that programme planners can ask themselves when planning a vaccine introduction to maximize opportunities for increasing coverage of other EPI vaccines and important health interventions.

**Box 2. Questions for immunization programme managers to consider for using the opportunity provided by a vaccine introduction to increase coverage and timeliness of all immunizations and other critical health services**

- Will there be a particularly high demand for the vaccine amongst the public?
- Will delivery of the vaccine involve new delivery strategies (e.g., outreach, school-based delivery) that can provide new opportunities to deliver other critical, age-appropriate vaccinations and health services? Which ones?
- Will the vaccine target new age groups that can be reached with other health interventions/services?
- Can the new vaccine be provided at PIRIs, Child Health Weeks or other periodic campaigns?
- During vaccine launch campaigns:
  - Will other vaccines be available?
  - What other health interventions can be provided at the same time?
- What other opportunities are there to combine the introduction of the new vaccine with other health services (e.g., zinc distribution, cervical cancer screening, pneumonia and diarrhea prevention and control interventions)?

Below are examples of ways that a country planning to introduce a vaccine might maximize opportunities to strengthen the overall immunization and health systems. This list is organized by the six building blocks that make up a health system (service delivery; health workforce; information; medical products, vaccines and technologies; financing; and leadership/governance) as defined in the WHO Health System Framework (see Annex \_\_\_ and [link or reference to WHO documents](#)).

**Box 3. Examples of opportunities during a new vaccine introduction to strengthen immunization and health systems**

- **Immunization and health system review:**
  - In preparation for the new vaccine introduction, conduct an assessment of the immunization programme that also identifies weak health system components as they affect the delivery of immunizations.
  - Use available funding (e.g., from vaccine introduction or health system strengthening grants) to make improvements to areas identified in the assessment.
- **Decision-making:**
  - Use the experience of and lessons learned from NITAGs or other technical committee to introduce or improve evidence-based decision-making for other health programs.
- **Regulation:**
  - Use the licensure process for the new vaccine to provide and strengthen the evidence base for the licensure of vaccines by in-country regulators.
  - Use the experience with licensure of the new vaccine to improve the regulatory process for pharmaceuticals and other health commodities and to better align the regulatory processes for vaccines with that of other pharmaceuticals.

- **Planning and budgeting:**
  - EPI managers can use the opportunity of the vaccine introduction to participate more fully in the overall MOH budgeting process and to advocate for the EPI among MOH and MOF officials.
  - Explore opportunities to introduce the multi-year planning process to other health programs, such as by promoting the process within the MOH.
- **Service delivery, advocacy and coordination with other health services:**
  - Use the opportunity of the vaccine introduction to review and streamline, if necessary, the national immunization schedule and improve the timeliness of immunizations.
  - Use the social mobilization campaigns for the new vaccine to promote:
    - Other vaccines and immunizations in general
    - Other health interventions for the targeted disease or syndrome.
  - Use the opportunity of a new vaccine that is in high demand and/or that targets new age groups to increase coverage for all EPI vaccines and other health services, especially to under-served populations.
- **Human resources, training and supervision:**
  - Be sure that training for the new vaccine includes sufficient refresher training on immunization practices (as needed), based on findings from supervisory visits or an assessment of health worker knowledge, skills and practices.
  - Include training in the provision and promotion of other interventions for coordinated disease prevention and control, such as for pneumonia and diarrhea (when introducing Hib, pneumococcal, meningococcal and rotavirus vaccines).
  - Ensure that supervision for the new vaccine is integrated with ongoing supervision for other immunization and health services and use the opportunity to increase the frequency of supervisory visits.
- **Cold chain and logistics management:**
  - When expanding the cold chain to accommodate the new vaccine, replace old or substandard equipment with improved equipment at the same time, as funds permit.
  - Plan an expansion of the cold chain and logistics system that will not only accommodate the vaccine being introduced, but also other vaccines that are likely to be introduced in the foreseeable future, as funding permits.
- **Information systems and monitoring impact:**
  - Use the vaccine introduction to improve immunization information systems and procedures in order to increase the overall accuracy and timeliness of EPI information for example, by including training in data collection, analysis and monitoring (including calculating coverage, drop-out and wastage rates).
  - Introduce the Post Introduction Evaluation (PIE) methodology to other health programmes as a possible model for evaluating other health interventions and services.
- **Disease surveillance:** When planning surveillance against the disease targeted by the new vaccine, think about:
  - How disease surveillance capacity can be improved overall (e.g., new skills of laboratory



workers, new test equipment).

- How surveillance for the new disease can build upon existing surveillance systems and programmes to increase efficiencies and save costs (e.g., by adding disease to existing sentinel site surveillance of other diseases).
- **Vaccine safety monitoring and reporting:**
  - Take the opportunity of the vaccine introduction to improve AEFI reporting forms and procedures.
  - Explore opportunities to extend or improve adverse events monitoring to other health interventions (e.g., TB, malaria, HIV treatment) and to link AEFI surveillance with post-marketing surveillance for pharmaceuticals.