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**SPECIAL ISSUE**

## **Controversies and Challenges in Pediatric Vaccination Today**

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**The issues related to introduction of a new vaccine in National  
Immunization Program of a developing country**

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## REVIEW ARTICLE

## The issues related to introduction of a new vaccine in National Immunization Program of a developing country

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### Abstract:

With significant reduction in incidence of diseases covered under Expanded Program of Immunization (EPI), other infections have gained public health importance globally or at least in some regions. Recent advances in vaccinology have led to development of new vaccines targeting these diseases. However, the decision to include a new vaccine in national immunization schedule is not straight-forward as there are numerous issues in prioritizing investments of a national immunization programme. These include policy issues (whether introduction of the new vaccine is in sync with immunization policy of the country) as well as technical or programmatic (whether implementation of the decision is technically feasible). First, careful assessment is made of the disease burden in the particular country, and possibility of other preventive measures is explored. Second, the efficacy quality, safety and costs involved with the particular vaccine are studied. Third, the technical issues (vaccine presentation, logistics, vaccine availability and sustainability, etc) are considered. All these issues need to be tackled systematically, providing best possible immunization schedule as per the needs and resources of the country.

**Keywords:** Expanded Program of Immunization, new vaccines, national immunization programme

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### Introduction

The Expanded Program on Immunization (EPI) has been one of the most successful global public health campaigns of the last century. With significant reduction in incidence of six originally targeted diseases (diphtheria, measles, pertussis, poliomyelitis, tetanus and tuberculosis), other infectious diseases have gained public health importance globally or in some parts of the world. Recent advances in vaccinology have led to development of new vaccines targeting these diseases.

Without inclusion of a vaccine in National Immunization Program of a country, many children who are in most need are deprived of access to the new vaccine options. Although inclusion of a new vaccine in national schedule adds the cost of vaccine and logistics to the health budget of a country, it also results in savings by reduction of the disease burden. Still, the decision to include a new vaccine in

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national schedule is not straight-forward as there are numerous issues in prioritizing investments of a national immunization programme. These issues need to be tackled systematically, providing best possible immunization schedule as per the needs and

resources of the country. This article summarizes the rational approach towards such decision-making.

### ISSUES IN DECISION-MAKING

Issues involved in decision are not only policy issues (whether introduction of the new vaccine is in sync with immunization policy of the country), but also technical or programmatic (whether implementation of the decision is technically feasible). Table-1 lists various issues involved in the decision making.

**Table-1. Issues involved in introduction of a new vaccine in National Immunization Program (Adapted from reference no. 1)**

#### *Policy issues*

- Assessment of public health priority
  - Assessment of disease burden in the country
  - Other preventive measures available (including other vaccine, if any)
- Assessment of candidate vaccine
  - Efficacy, quality and safety
  - Economic/ financial issues

#### *Technical/ programmatic issues*

- Vaccine presentation
- Programmatic strength (logistic issues)
- Supply availability

#### **Assessment of public health priority**

Prioritization of various public health measures within limited resources is the most challenging task for any country. Public health importance of a disease varies from country to country. Hence, assessment of disease burden of the disease in question vis-à-vis other diseases is the first important step in decision making. Introduction of vaccine against the disease with highest disease burden will naturally have greatest impact on infant/childhood mortality and morbidity on national basis. This is one of the most

important evidence to convince the policy-makers to introduce the candidate vaccine.

The disease-burden is assessed not only in terms of incidence and prevalence, but also in terms of annual hospitalizations, disability rate and mortality rate of the disease in question. Ideally, either data from surveillance systems of the country or well designed, multi-centric studies or metaanalyses of studies from the country should form the basis of such assessment. However, in the absence of local studies, data from countries with similar social and demographic characteristics can be used. If the data available is incomplete, then mathematical models can be used (with due caution) in assessment of disease burden. The rapid assessment tools, references surveillance protocols and guidelines of the WHO can also be used to assess the disease burden. Such tools and guidelines are available for assessment of disease burden of *Haemophilus influenzae* type b (2, 3), rotavirus (4), shigella (5), respiratory syncytial virus (6), rubella (7) and yellow fever (8).

For assessment of disease burden, data on causative organism rather than clinical syndrome is needed. For example, in India, diarrhea and pneumonia remain the leading causes of non-neonatal mortality accounting for 20% and 19% of all under-5 deaths respectively (9). However, only a proportion of these are preventable by vaccines (Rota virus, *Haemophilus influenzae* type b and pneumococcus).

Since policy decision for introduction of a vaccine in national immunization schedule involves political establishment, thus the perception of the public about the disease and the vaccine is very important in a democratic country. The more important and visible the disease is, and safer and more effective is the vaccine perceived to be, the better is the acceptance and uptake of the new vaccine is. Any misconception or opposition to the vaccine should be cleared using various channels of communication. This helps in taking the decision faster.

When deciding about the priority of a particular vaccine, it is also important to consider other vaccines which are likely to be available in near future. For example, if today some country is deliberating on introduction of 7-valent conjugate pneumococcal vaccine, vaccine introduction could be postponed as newer vaccine with enhanced coverage

(10 or 13 valent) is likely to be introduced in near future (10). Such a vaccine would obviously have greater impact on disease burden. Similarly, vaccine introduction could be postponed if it is likely that another vaccine would become available in near future against another disease that presents a greater burden.

### **Assessment of other interventions available**

The proposed vaccine should be compared with other preventive measures (including any existing vaccine) available in terms of effectiveness, safety and feasibility before making a decision on introduction of the vaccine in national immunization schedule.

### **Assessment of efficacy, quality and safety of the vaccine**

The vaccine needs to be efficacious in preventing the disease in immunized individuals. However, it must be noted that the data on efficacy should also be preferably taken from countries with similar disease epidemiology to one considering the vaccine. This is because the efficacy of a vaccine can vary with nutritional status, co-infections and other factors.

The vaccine being considered for introduction should meet international standards of quality and safety. The data on safety should be obtained not only from clinical trials but also from post-marketing surveillance from other countries with similar profile. Such data, if available, is very useful as it can throw light on rarer adverse events associated with the vaccine. The effect of introduction of vaccine on efficacy and safety of other vaccines given at the same time also needs to be explored. It is also important to note that the risk: benefit ratio of a vaccine can vary from country to country depending upon disease burden.

### **Economic/ financial issues**

The vaccines other than *EPI vaccines* are very “expensive”, when cost is compared on dose-to-dose basis. Hence, cost-effectiveness analysis is essential before any decision on the vaccine introduction is taken by a developing country. The total cost (cost of vaccine and logistics) is compared to the potential savings as a result of reduced treatment of the disease. The cost-effectiveness is also compared with that of another vaccine or another public health

program under consideration. Various methods and tools adopted by the WHO for cost-effectiveness analysis can be used for this purpose (11, 12).

Due care is taken to assess financial sustainability (over medium to long term) of the immunization program after introduction of the new vaccine. If any financial shortfall is expected, then appropriate sources of funding also need to be explored before finalizing introduction of the vaccine.

### **Vaccine presentation**

The proposed vaccine may be available as monovalent/combination, single dose/multi dose and liquid/lyophilized. A number of issues need to be considered while choosing the presentation/formulation. These include:

- Current and proposed immunization schedule
- Number of injections per visit
- Cold storage space
- Vaccine wastage
- Injection safety equipment
- Staff training and supervision
- Recording and reporting mechanisms
- Programme costs

In the preferred presentation is unavailable, the country can either postpone introduction or start with another option and switch to preferred option later.

In some cases two different preparations may be required. For example, if the country decides to introduce hepatitis B vaccine, it may require monovalent vaccine to be given at birth (to prevent perinatal transmission) as well as combination (with DTP or DTP-Hib) for subsequent doses.

### **Vaccine supply availability and quality**

This is a crucial issue for developing countries with large populations. The newer vaccines are often manufactured by a limited number of manufacturers and it takes some time to augment production following introduction of vaccine in national

immunization program. In addition to current supply situation, future trends need to be assessed carefully before decision-making. A country may decide on phased introduction depending on supply availability. The introduction of conjugated pneumococcal vaccine has been delayed in most countries because of logistic and procurement issues (10).

Assessment of required doses would obviously depend on target population, estimated coverage and wastage. For vaccine doses requirement in next few years, we need to estimate increase in target population as well as vaccine coverage.

Not only quantity, but the quality of vaccine to be procured also needs to be assessed. Many developing countries prefer to use vaccines procured through UNICEF. These vaccines are already prequalified by the WHO through a standardized procedure and packaging and transporting conditions are identified for proper cold chain maintenance. In case the country decides to procure its own vaccines, then a number of issues are to be looked into. A technical committee should review the technical issues including efficacy and data of the brand concerned as well as the packaging and transportation conditions required.

Further, post-marketing surveillance is critical to ensure vaccine quality after licensing. An elaborate protocol must be formulated for strict compliance later on.

### **Programmatic strength**

Needless to say, the national immunization program of the country must be functioning well with existing vaccines before finalizing introduction of the new vaccine. Otherwise, vaccine addition would further worsen the failing system and will have long-term repercussions. Careful assessment of requirement of additional cold chain capacity, safe injection supplies and disposal, staff training and supervision, advocacy and awareness programs (IEC activities) is essential before finalizing introduction of the new vaccine. Any shortfall in this regard (financial or otherwise) must be addressed beforehand for smooth introduction of the vaccine.

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