Impact of New Vaccines Introduction
on Immunization & Health Systems

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Summary

Over the past two to three decades there have been major reductions in vaccine preventable diseases largely as a result of global health initiatives to improve access to new vaccines and concomitant health system improvements. Nevertheless it is clear that in many countries coverage rates remain inadequate and there continue to be inequities based on poverty and income levels, gender, geographical location and culture. Against this background the Strategic Group of Experts [SAGE] has requested an examination of impacts of New Vaccines on immunization and health systems. A group of recognised experts reviewed the available published literature so as to take stock of the current state of knowledge and identify the critical knowledge gaps. A important conclusion from this review is that while the introduction of new vaccines have had many positive impacts on both the immunization and health systems the impacts have not been automatically positive or negative. The impacts may vary depending on strengths and weaknesses in the existing health systems as well as on the type and relevance of the service delivery modality in a given set of socio-economic, institutional and cultural circumstances. In general however, the knowledge gaps are large and multiple. It will be necessary that many of these gaps are filled so that appropriate adjustments can be made for achieving more positive impacts of new vaccines introduction on the immunization and health systems.

Introduction

The last turn of the century was a watershed in the area of vaccines and immunization. Not only was it realized that immunization coverage rates in developing countries had been decreasing since the early days of the Expanded Programme on Immunization [EPI] but it became clear that there was a growing divide in access to new vaccines between the industrialized countries and the developing world. Most of the least developed countries do not reach the WHO recommended levels of health spending and for many of them a large share of total spending is in the private sector. It also became increasingly clear that Millennium Development Goal 4 [MDG4] could not be reached in many countries and new vaccines offered the potential to help countries reach their MDG targets. Since 1999 national governments, international organizations as well as country governments refocused their attention on immunization, the GAVI Alliance was created and funding for immunization –from donors and from country governments increased sharply.

After the significant progress in expanding the coverage of routine immunization with the Expanded Programme on Immunization [EPI] new opportunities are being created through the development of new or improved vaccines against diseases of global importance.

Through its Global Plan of Action for New and Under-Utilized Vaccines (NUVs) implementation WHO seeks to provide a dynamic framework for global partners to prioritize and engage in the introduction of new and under-utilized vaccines. At the same time it is important – and as was emphasised some time ago by Salisbury [1998] - that new initiatives provide examples of effective management and contribute to the development of sustainable health systems. The NUVI Global Plan of Action has evolved into a programmatic overview of all activities required for the successful introduction of new vaccines with particular attention to the following: Hepatitis B, Haemophilus influenza type b [Hib], Pneumococcal conjugate [PCV], Rotavirus, Human Papillomavirus [HPV], Epidemic Meningitis, Japanese Encephalitis [JE], Typhoid and Yellow Fever vaccines.
Against this background the Strategic Advisory Group of Experts on Immunization (SAGE) has requested a session in their April 2010 meeting to discuss the impact of the introduction of new vaccines on immunization and health systems. The background paper for this session provides the following:

- A first and limited overview of the published evidence to date on the impact of new vaccines introduction on immunization and health systems;
- Data sources and gaps in evidence;
- Research needs to help fill the knowledge gap on the critical issues affecting the impact of new vaccines introduction on immunization and health systems - both short term and long-term.

**Health Systems**

Health systems can be defined in many different ways. This paper is based on the definition provided by WHO. A health system can be defined as consisting of all organizations, people and actions whose primary interest is to promote, restore or maintain health. The goals of health systems are improving health and health equity in ways which are responsive, financially fair, and make the best, or most efficient, use of available resources. Intermediate goals include achieving greater access to and coverage of effective health interventions, without compromising efforts to ensure provider quality and safety (WHO 2007).

To achieve these goals the WHO health system framework defines six system building blocks: service delivery; health workforce; information; medical products, vaccines & technologies; financing, and leadership/governance. [See Figure 1 for a diagrammatic presentation]

**Figure 1: The building blocks of the health system: aims and attributes**

![The WHO Health System Framework](source)

The immunization system is an integral part of the overall health system, with its focus on vaccine preventable diseases. The immunization system has been defined as having five elements: víz, vaccine delivery, advocacy and communications, disease surveillance, logistics, and vaccine supply and quality (WHO 2000).

In the early EPI days, immunization systems were largely vertical programmes with limited shared functions with the rest of the health system. However, they have gradually become more integrated and today, immunization systems largely share functions and resources with the overall health system. These include the time of multi-purpose health workers, the health infrastructure, logistical functions and planning and management systems. Nevertheless, there are dedicated parts of the immunization system that are still part of the health system but are not shared with other services, for example central staff at an EPI unit, the cold chain (largely), the vaccines, most immunization campaign functions and the time of single purpose immunization staff (where they exist).

**New Vaccine Introduction and Health Systems**

It is clear that all health interventions have systems level effects in one way or another. The issue of the health system as a platform for the immunization system has long been an important part of the discussion on the implementation of EPI and other focussed interventions. The interrelationships have received more attention with the introduction of new vaccines in countries with weak health systems and with the emergence of additional new vaccines.

From the outset it was realised that a central issue was the need for well-functioning health systems for the effective scaling up of immunization interventions. It was also obvious that health systems in many of the countries planning to introduce new vaccines were weak and some of these weaknesses were exposed as the new interventions began to be implemented. Within the GAVI Alliance, the original focus on the provision of commodities was complemented almost immediately by establishing a window for immunization services support (ISS) – cash support as a reward for extending coverage - and an initial cash grant accompanying the introduction of a new vaccine. One response to the recognition of the weaknesses within the health systems was the offer of financial support of health systems strengthening initiatives such as the new Health System Strengthening [HSS] window.

Both immunization and health systems are dynamic and interacting. Aspects of an immunization system can affect aspects of the overall health system. Existing constraints and any changes in health systems will affect aspects of immunizations systems and their likely impacts. Major changes in an immunization programme are likely to have a bigger impact on weak health systems. At the same time, immunization programmes may have achieved greater coverage where they occur within strong and supportive health systems. The association between the immunization and health systems can therefore be described as complex and non-linear. Important factors which both shape the effects of the introduction of NUVs and be themselves consequences of that introduction include levels of national political commitment, the legislative framework, the organization of health services, staff availability and motivation. On a broader and more societal level, socio-cultural and demographic variations have also been found to affect the capacity and ability of a given immunization and health system to have any significant impacts (Clements 1994; Clements 2006); and these may also be affected by the introduction of the new vaccines. One of the lessons that may be learned from the earlier mass immunization campaigns is that unless the health care systems have also improved, gains in coverage levels may not be sustained (Dietz, 1997).
This report focuses on the impact of the introduction of new vaccines on the immunization systems and where relevant, on the broader health system. It must, however, be noted that most of the available literature on the relationships between the introduction of NUVs, and immunization and broader health system focuses on the factors influencing the progress and success of immunization activities. There is considerably less information on the impacts of the introduction of NUVs on broader health systems, and much of this is speculative and hypothetical. There are several reasons for this: the principal ones are the paucity of impact assessments studies – especially those that permit scientific generalisation, and there remains a continuing dependence on process and output indicators versus outcome indicators in the monitoring frameworks utilised in most countries. An examination of the factors affecting the success of immunization programme implementation is useful because some impacts may be inferred from the analysis of barriers, challenges and constraints. However, it is clear that there remain large and numerous gaps in our knowledge and understanding of impacts.

**New Vaccines: Current Status and Trends**

There is now sufficient data to show that there have been major improvements in immunization coverage with new vaccines and that this has led to decreasing incidence and burden of the diseases and syndromes they target. However, it is important to note that the averages may disguise realities at individual and regional units of analysis. A review of the African and South Asian regions has shown that national averages too frequently mask significant variation and inequalities in coverage that are related to gender, income levels, as geographical location and cultural factors (Mhatre 2009).

*Short versus long-term impacts*

New vaccine introduction is often seen in a short-term perspective. However, a new vaccine eventually becomes an “old” vaccine while even newer vaccines emerge. The effects of a NUV may change over time as illustrated below in Table 1.

<table>
<thead>
<tr>
<th>Table 1: Short and Long Term Effects of NUV Introduction</th>
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<tr>
<td><strong>Short-term</strong></td>
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<td><strong>Cost</strong></td>
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<td><strong>Burden of disease</strong></td>
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<td><strong>Burden on delivery system</strong></td>
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<td><strong>Risk for diversion of human and financial resources</strong></td>
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<td><strong>Cold chain</strong></td>
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<td><strong>Planning &amp; mgmt</strong></td>
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**Delivery modalities**

The way new vaccines are formulated and delivered may have a significant influence on their impact. Of critical importance is the burden that the mode of service delivery places on the existing immunization and health systems; large-scale introduction may be unsustainable because the effort may absorb much of the available funds/resources leaving other areas unattended. The cost-effectiveness of interventions may vary according to the different methods of service delivery. The impact of NUVs therefore depends on whether they are introduced in campaign mode, are integrated into a routine vaccination programme, or are specifically delivered to targeted groups. NUVs with new and different immunization schedules that require separate visits or target different population groups from existing target populations such as HPV, YF, and meningococcal meningitis have potentially stronger effects on the immunization and wider health systems than vaccines that are delivered in the regular routine infant immunization system. At the same time access can be improved through well-executed campaigns that often reach a higher percentage of the target groups than the routine system. Table 2 below illustrates the possible relationships between vaccine characteristics and potential effects.

| Table 2: Characteristics of new vaccines and strength of potential effects |
|-----------------------------------------------|----------------|----------------|----------------|----------------|---------------|---------------|
| New antigens                               | Process         | Output         |                |                |
| In combination vaccine                      | Cold chain      | Planning & mgmt| Demand / social| Work load      | Cost | Access       |
| As separate vaccine                         | - -             | -              | 0              | 0              | -   | + +          |
| Delivered through campaigns                 | - -             | -              | + +            | -              | -   | + + +        |
| For different target groups                 | - -             | -              | + +            | -              | -   | + +          |
| With oral administration                    | -               | -              | + +            | +              | -   | + +          |

+ , ++, +++ = positive effects (different strengths)
- , - -, - -- = negative effects (different strengths)
+ / - = could be positive or negative effect
0 = neutral

Antigens that are delivered as stand-alone vaccines such as rotavirus, PCV and the HBV birth dose require either additional contacts with the clients and/or generate additional work. These new vaccines may not have the immediate large-scale system-level effects that accompany campaigns but as the products are delivered separately they can have specific impacts for example on the workload of health workers.

In contrast, antigens that are delivered as a component in a combination vaccine (e.g. DTP-HepB-Hib) result in fewer repercussions on the immunization and health systems. Their strongest effect is in financing with the additional cost of the new antigen, but there are also effects on managing existing vaccine stock and proper demand forecasting.

The mode of administration (oral or injectable) also has a variable impact on the system: oral vaccines (e.g. polio, rotavirus) may result in less pressure on health care workers. The impacts on the immunization or health systems of the different delivery modalities may vary and there are continuing debates about which service delivery modes are most effective and in which types of environment.
Methodology and Literature Search

Rapid literature researches – using Medline - were conducted by a librarian at CDC, Atlanta and a librarian at PATH, Seattle. In addition, other opportunistic searches were made using the GAVI Knowledge Bank and inputs were sought from recognised experts in the field. The combined searches produced 1543 references.

The CDC literature review was conducted using a search comprised of keyword terms relating to vaccines and freetext terms relating to health planning and health systems. This search produced a total of 1437 references. The PATH literature review was based on a strategy which used keyword terms relating to vaccinations, immunization, immunization programmes, health care facilities manpower and services, access, coverage schedule, data collection, resource use and allocation, disruption, disruptive technologies, cold chain, community involvement, social mobilisation, hepatitis Hib, Haemophilus influenzae type b, Yellow Fever, Japanese Encephalitis, rotavirus, pneumonia, and human papillomavirus. It identified 196 references. In all cases the search was limited to humans. Opportunistic searches were also carried out using the GAVI Knowledge Bank and Academic Search Premier and from experts in the field. These identified 31 additional references.

An ad-hoc group of experts was convened to provide inputs and evidence and develop a framework [See Annex] for assessing the evidence from the literature search and review the background paper. The framework was based on WHO’s health system building blocks. The abstracts and papers were then analysed by group members by drawing out the key messages and issues as categorised according to the framework developed.

Limitations

The searches conducted were preliminary and, given the time constraints, did not attempt to be comprehensive. As such, not all potentially relevant search terms were included, and apart from Medline and Academic Search Premier other databases were not included. Due to time constraints, the group was not able to review full articles from all studies which would have provided more information on detailed results of the studies, and a discussion of the methodology, sample strategy and limitations of the study. Therefore the group was unable to determine the quality of the studies and may have missed some additional data that were not presented in the abstracts.

Cost effectiveness, incidence and disease burden studies were only included if context specific impact or outcome data were used (i.e. not prospective modelling), or if the study provided an explicit reference to the impact on the health care system. There are data from both developed and developing countries.

It must be emphasised that also due to time constraints, only a limited amount of grey literature was examined at this stage of the enquiry. There may therefore be additional information and data that could potentially influence the conclusions of this paper. Further, within the time allotted the review was not able to examine literature focussing on Global Health Initiatives and health systems which could shed additional light on possible effects.
Results

The following discussion is based on the results of the literature search using the framework developed for this exercise. Potential NUV effects on the immunization and health system, for which no references in the published literature were found are not listed here, but are stated in the annexed framework.

Service Delivery

There is evidence that the addition of the NUVs has improved the overall coverage of routine EPI vaccines for persons aged over one year. Establishing new outreach centres and mobile facilities has facilitated greater access by a larger group of persons. The introduction of the new vaccines has also created opportunities for additional contacts with target populations and has enabled greater access to specific groups such as the poor (Valencia-Mendoza 2008), adolescents living in high-risk settings (Tedeschi 2007; Sneller 2008), the elderly (Andrews 2005), prisoners (Sutton 2008), intravenous drug users (Altice 2005; Rogers 2005), and some ethnic minorities in the USA (Zhou 2003).

Through improvements in NUV programme management and the adoption of safe injection practices the immunization system can increase access to its services (Cooley 2004). Where vaccines such as the HBV and DTP-Hib have been shown to be safe and associated with few adverse events the impact on their coverage has been shown to be greater (Martins 2007; Mikaeloff, Caridade 2007; Rouge-Maillart 2007).

However, the effects of NUVs on immunization systems are not always positive and do not always lead to improvements in general access to vaccination. In some countries the introduction of Hepatitis B vaccine had no impact on coverage with other antigens (Chunsuttiwat1997; Ndiritu 2006). In Pakistan overall coverage remained relatively low and there was significant variation between districts (Loevinsohn 2006). NUV introduction has increased inequities as providing access to persons in hard to reach populations proved difficult, given bulky vaccine presentations (de Oliveira 2008).

The introduction and use of combination vaccines has been associated with improved timeliness of the administration of both routine and new vaccines (Aiken 2002; Chunsuttiwat 2002; Breen 2003; Happe 2007; Happe 2009). However, this association does not always occur: in Switzerland for example, only half of infants at risk of HBV infection were immunised correctly and on time; in New York approximately 20% of the physicians who gave PCV delayed administering other vaccines because of concerns about giving four or more vaccines simultaneously (Schaffer 2002).

One possible explanation of the failure to improve access to the immunization system may be related to the socio-cultural acceptability of some of the new vaccines. Vaccines - for example HPV vaccines - may be associated with sexually transmitted infections [STIs] and therefore can encourage stigmatisation. It has been found that the introduction of HPV led to media messages that adversely affected HBV uptake (Watson, Shaw et al. 2009). Similarly, messages need to be more pertinent to the situations of migrant and ethnic minorities (Pulido 2001; Allen 2009; Wong 2009). Opposition from socially conservative groups and ethical considerations have been found to negatively affect the social acceptability of new vaccines (Schneider 2007). Indeed, it has been found that an increase in uptake sometimes required changes in the types of messages provided (Goldstein 2001; Sansom 2001; Salleras 2003; Bigham 2006; Rouge-Maillart 2007; Balinska 2009; Chan 2009; Watson 2009).

An extensive use of social mobilisation initiatives – including local and cultural brokers, and specific advocacy campaigns which sought to correct prevailing perceptions about knowledge levels - were sometimes required to improve acceptability. In most instances these were short term measures but they
do absorb significant financial resources and their impact on the health systems was sometimes underestimated.

The successful introduction of the NUVs can vary significantly with the type of delivery strategy utilised. The principal delivery approaches have been time-bound national strategies to achieve universal coverage, specific targeting, incorporating NUVs into the routine system, and integrating this immunization service with other health programmes.

The evidence on the relationship between delivery modality and increased coverage is mixed. In the Western Pacific region it was found that time-bound supranational Hepatitis B control with universal coverage goals were very effective and strengthened routine immunization. With the introduction of NUVs previously declining trends in routine immunization coverage showed signs of reversal (Rani 2009). The emphasis on attaining universal coverage also helped to induce improved programme management and there was a noticeable increase in equitable access (Cooley 2004). With the universal coverage approach the effort may be more likely seen as a safe and worthwhile investment of public funds (Hay 1987). However, sustained coverage – especially at the peripheral levels - can be challenging as it significantly increases the costs, and requires improvements in staffing, financing and guidelines, as well as in the ability to procure a constant vaccine supply (Fendrick 1999; Van Damme 2002; Griffiths 2005; Milstien 2007; Lauria 2009).

Specific targeted approaches which are especially relevant for example for JE, HPV and typhoid vaccines, have been particularly useful for reaching specific groups such as adolescents in school or people living in high-risk settings. They have been successful in a wide variety of countries. They gave proven to be logistically convenient and feasible, the least disruptive and cost-effective as it is likely to entail small increases in cost, personnel and resources (Cassidy 1998; Di Fabio 2001; Aiken 2002; Morrison 2002; Wilson 2002; Wright 2002; Guay 2003; Zhou 2003; Tung 2005; Yang 2005; Agtini 2006; Vila-Corcoles 2006; Eckrode 2007; Simard 2007; Tedeschi 2007; Schwarz 2008; Sneller 2008; Sutton 2008; Allen 2009). Including NUV in child health days have improved general health-seeking behaviours and increased community organisation (Fiedler 2008). However, in at least one country the targeting of specific groups had different degrees of success suggesting the possible importance of other factors in explaining the actual variations in uptake (Scognamiglio 2009).

With respect to the strategy of integrating NUVs into existing vaccination programmes the intervention compatibility and the strengths of the existing EPI need to be assessed (Wallace 2009). New vaccine formulations can lead to increases in storage volume requirements as well as increased capital and training costs that are not easily borne by the country. Incorporation of NUVs may introduce unworkable burdens on available staff and on the cold chain and storage facilities (Samant 2007; Griffiths 2009; Hessel 2009). Where the administering health workers have concerns about an increased work load, and the scientific merits of a NUV (e.g. HepB), they may not comply with the vaccine recommendations (Siegel 1994; Vaudaux 1998; Keating 2008). Compliance can also be limited if the methods and messages are perceived as challenges to physician’s practice and medical professionalism (Rothman 2009).

However there is an increasing evidence that integration of the NUVs into existing vaccination programmes can be effective, and many studies advocate for substantial strengthening of routine immunization as an important strategy for achieving general and more equitable access to NUVs. This can result in improved coverage of both routine and new vaccines and also improved general immunization safety (Cabezas 1995; Opstelten 2001; Cooley 2004; Cui 2009). Integration provides new opportunities for ensuring access to the NUV, it is likely to be less costly, is convenient, and continuity with other programmes is beneficial. It has also meant the more efficient use of available services (Savage 2000; Woringer 2000; Ward 2001; Khan 2004; Agtini 2006; Freed, Cowan et al. 2006; Happe 2007;
Pollack 2007; Isaacman, 2008; Reeve, De La Rue 2008; Duclos 2009; Happe 2009; Simoens 2009). The application of existing public health system performance norms, standards and regulations have also helped to increase the efficiency and wider delivery of the NUVs (Connors 1998; Faustini 2001; CDC 2003; Coyle 2004; Goldstein 2005; Sokos 2005).

With respect to the benefits of integration or linkages with other health services, there is evidence that the introduction of NUVs has led to the increased uptake of this and other services such as MCH [GAVI Annual Progress Reports - personal communication] and the distribution of insecticide treated bednets. Nevertheless, successful introduction of NUVs may depend on the availability of and compatibility with other services: for example it has been found that birth dose administration of Hep B is highly dependent on community-based pregnancy services and the relationships with maternity practices (Murakami 2008).

In general therefore the introduction of NUVs into existing and routine immigration systems may have either positive or negative consequences. There is continuing debate on what might be the best and most effective type of service modality for a particular set of resource circumstances. There is also insufficient knowledge on the extent to which the utilisation of other services suffers or improves with the addition of NUVs (Pegurri 2005; Ryman 2008).

Health Workforce

In general, NUVs can create a greater workload for on existing health staff, as well as require increases in the human resource requirements. A good immunization system can reduce the administrative burden and allow cost-savings in the immunization system (Bartlett, Washington et al. 2007). The introduction of new combination vaccines may have a small effect here, and there is evidence that the use of existing facilities (e.g. school based clinics) entails relatively small increases in cost, personnel and other resource requirements (Cassidy 1998). However, for new separate vaccine presentations and particularly for vaccines that are delivered through campaigns or to new target groups with different immunization schedules, the additional workload, and the risk of diverting human resources could be significant. In some cases it has been found that even perceived increases in workloads can discourage the delivery of NUVs (Jachuck 1990; Vaudaux 1998; Dexheimer 2006).

There is evidence that the training associated with the introduction of NUVs – especially on-the-job training - tends to be associated with improved vaccine coverage and better overall quality of service (Robinson 2001; Ayaya 2007; Milstien 2007; Wang 2007; Balinska 2009; Kumar 2009). However, some more general questions have emerged about the possible disruptions and distortions that may be caused by the extensive training [in and out of service] that accompanies the introduction of NUVs. While it is clear that skills and knowledge have increased, very little is known about the application of the training received, the utilisation and (re)deployment of the newly trained staff - either within the specific immunization system or the broader health systems. It has been suggested that the increased training can increase a brain-drain out of the health sector, if the training programmes are not accompanied by necessary adjustments to the human resource frameworks and career paths, or to adequate remuneration arrangements (Pfeiffer 2008). In some instances – especially where the levels of financial involvement and commitment by the national governments have been very limited, it may not be possible to sustain the necessary level of effort - with negative outcomes for the longer term sustainability of the immunization programme.

The introduction of NUVs has highlighted the need for and importance of better supervision. There is evidence that there have been significant improvements in the extent and quality of the monitoring and supervisory efforts (Djibuti 2009). At the present time however – and largely because there is little data -
it is difficult to definitively link any improvements in the quality of supervision with improvements in the quality or efficiency of service delivery.

**Information**

The introduction of NUVs - which has also meant higher investments - has led to a heightened awareness of the need for general information systems that support decision-making and enable monitoring and surveillance at central, provincial and district levels. Integrated data collection can facilitate feedback to the lower levels. Good immunization tracking systems can assist the delivery of catch-up vaccines (Groom 2008). A new vaccine usually requires modification of data collection and reporting formats. New vaccines will also require additions and improvements to the surveillance system and will require better vaccine management systems. New Adverse Events following Immunization [AEFI] monitoring / Post-Marketing Evaluation [PME] systems have been established, standards, methods and tools have been developed, and in some cases new surveillance sites may be added to the routine system (Yameogo 2009). However, if a vaccine is given to new target groups this may entail considerable system modifications and additional workload.

Although there have long been discussions on the importance and need for strong and viable health information systems accompanying NUVs and other health interventions, the development of the health information systems [HISs] in many developing countries is still in its infancy. Specific efforts to improve the HISs have occurred in several countries [Review of GAVI proposals - personal communication]; but the monitoring frameworks are still largely inadequate and insufficiently developed, integrated and centralised health information systems are often absent, and there is still insufficient attention to the collection and analysis of outcome and impact measures (Wenger 1999; JSI Research and Training Institute 2009). The undeveloped character of many on-going surveillance systems makes it difficult to assess the impact of NUVs on target diseases and syndromes (CDC 2009).

There are some countries in which evaluations and cost-effective assessments were carried out prior to the introduction of a vaccine; but at the same time there were others where the decisions proceeded without the benefit of these kinds of studies (Welte 2004; Welte 2005; Wisloff 2006). Not much is therefore really known about the extent to which the information systems facilitate decision-making forecasting and planning. The data deficiencies also mean that the causal pathways between intervention, outcome and impact continue to be poorly understood (Alliance for Health Policy and Systems Research 2007). There is a possibility that the dependence on external funds has encouraged health information system fragmentation resulting from the establishment of multiple and stand-alone separate systems for data control and storage.

**Medical Products, Vaccines & Other Technologies**

The costs of medical products, vaccines, equipment and training tend to increasingly make up the largest portion of the financial requirements for NUVs. These requirements sometimes place difficult-to-support burdens on existing EPI systems (Trama 2005). A major effect of new vaccines are the additional cold chain requirements and increasing complexity to handle vaccines with different requirements in terms of temperature stability; some of the new vaccines require significant expansions of cold chain capacity (Griffiths 2009). The risk of freezing some new vaccines may also be significant. There is evidence that the use of auto-disable syringes reduces dangerous waste, is economically worthwhile, promotes injection safety, and improves resource utilisation (Drain 2003; Levin 2007). In other instances, new vaccines require critical infrastructure for vaccine deployment which is not available
The availability of vaccine storage sites then becomes an important determinant of vaccine delivery (Murakami 2008). Related training costs may be expected to increase with the introduction of NUVs.

In general, the selection of the most economical vaccines requires consideration of an array of characteristics (price, number of doses needed, shelf life, cold storage requirements, route of administration, etc). However, the full range of considerations and possible trade-offs are not always examined.

**Financing**

Immunization with traditional EPI antigens is one of the most cost-effective interventions. Ranges in cost-effectiveness estimates are related to differences in coverage level or scale of a programme; unit prices of key inputs; and, the type of delivery system used to provide services (Brenzel 1994; Kaddar 2004). New vaccines have higher cost-effectiveness ratios related to higher unit prices. Countries that introduce the pentavalent vaccine will have a more than a four-fold increase in the average expenditures per infant (Lydon 2008). The costs for a NUV introduction depend not only on the unit price of the vaccine but also on the method of administration and delivery (including cold chain management), the strategies for reducing wastage, distributing and storing vaccines at all levels, and the extent and character of the training and social mobilisation efforts required.

New vaccine introduction has had implications for the costs and long-run affordability of national immunization programs (Poulin 1992; Peltola 1999; Schaffer 2002; Fontanessi 2004; Hutton 2006; Villa-Corcoles 2006; Simoens 2009; Wong 2009). Historically, human resource costs accounted for the largest share of programme cost, but now vaccines are the single largest cost driver of immunization programmes (at least 50% of expenditures). In most countries, government financing of national immunization programmes has increased since 2000. However, in recent years, nearly twenty of the poorest countries have seen a drop in immunization financing by governments that suggest possible substitution in favour of donor financing and greater donor dependency (Lydon 2008).

However, there is also a great deal of evidence from developed and developing countries on the cost-benefits arising from changes in the costs of hospitalisation and treatment resulting from the introduction of NUVs. There are multiple studies which document the reduction in medical visits and hospitalisations for meningitis, pneumonia, diarrhoeal diseases, hepatocellular carcinoma and other diseases and an associated decrease in costs. Historically we have seen the closing of measles and polio wards because of effective vaccine delivery. Further to these, in recent years reduced hospital use has also been reported for Hib-related diseases and rotavirus disease (Bent 1994; Kao 2001; Limcangco 2001; Saadallah 2001; Ray 2002; Asensi 2004; Lee 2005; Harris 2007; Isakbaeva 2007; Shoaib 2007; Madar 2008; Nieto 2008; Prasad 2008; Sangfelt 2008; Zhang 2008; Al Awaidy 2009; Constenla 2009; Flem 2009; Gurgel 2009; Hartwig 2009; Hung 2009; Jeurissen 2009; Milne 2009; Ortega 2009; Tate 2009). At the present time, the management and treatment approach to febrile children has become less conservative in places where PCV and Hib vaccines are in use. The introduction of NUVs has encouraged greater attention to the cost-benefits of different delivery approaches, and has stimulated the more efficient utilisation of existing immunization and other health facilities.

Fiscal space, national budget ceilings and competing priorities may affect affordability of, and the sustained support for new vaccines. There have been increases in the financial commitment of the national governments [comprehensive Multi-Year Plans (cMYP) reviews; GAVI proposal reviews] especially where a demonstration of increased government responsibility and ownership over time is
required for the receipt of external funds. There is evidence that there is a positive relationship between the level of financial commitments by the national government and the levels of coverage rates (Charuvastra 2001; Stokley 2006; Simoens 2009; Tariq 2009). Where a clear indication of the value for money being expected of the proposed new interventions is required, there has also been more careful attention to the development of cMYPs and the costs and benefits associated with NUV. However, in many developing countries the full range of costs – especially those associated with the operationalisation of decentralised systems - are sometimes underestimated with consequences for effective and sustainable implementation and/or later scale-up (Edmunds 2000; Pegurri 2005; Peny 2005; Liu 2008). It has also been suggested that in this kind of environment excessive dependence on external funding has tended to encourage distortions in the health system through the devotion of funds to specific diseases and activities and to short term numerical targets – but at the expense of other sectors of the health system (Garrett 2007); it may also stimulate feelings of local envy and hostility towards the sector receiving the benefits. There is some evidence that there are continuing weaknesses in the immunization and health systems that impede the absorption capacity and prevent sustained gains (Alliance for Health Policy and Systems Research 2007). Given the multiple demands for health resources in low-income countries, the government’s contributions may not be affordable or sustainable (SOWVI, 2010). Considerably more investigation of these possible realities is required.

Leadership and Governance

A new vaccine must be part of the national plans and frameworks, will be included in advocacy efforts, and may become part of integrated disease control efforts. The availability of funding for the introduction of NUVs and for the development of the necessary health system supports has had a direct impact on efforts to improve the overall planning and monitoring systems. In many countries there has also been a general desire to improve availability and supply at the district level, and the governments have sought to reorganise the health systems. In several instances this has been encouraged and supported by HSS funding. Health reform initiatives have included efforts to strengthen the management and planning capabilities at the provincial and even district levels, the introduction of greater decentralisation, increasing the outreach facilities, encouraging greater involvement of health sector stakeholders, and increasing the amount of intersectoral co-ordination especially at the point of implementation [Review of GAVI HSS proposal - personal communication]. Where these occur they have facilitated the introduction of NUVs. Levels of political commitment as well as an enabling legislative environment tend to be associated with higher levels of immunization coverage and effectiveness (Ruocco 1999; Liu 2006; Olshen 2007; Dekker 2008; Maybarduk 2009; Rani 2009).

However, although the importance of leadership and appropriate governance is now well recognised, this has proved to be one of the more difficult areas to address and has received the least attention in most of the funding proposals submitted. [GAVI-HSS Summaries - personal communication]. The Latin American experience with the introduction of the rotavirus vaccine has illustrated the critical need for, and the challenges involved in developing precise plans that will ensure technical, programmatic and financial sustainability (de Oliveira 2008). In many cases, although funds have been requested to support these kinds of activities successive evaluations and progress reports have shown significant delays in their implementation largely because of insufficient attention to the importance and time-consuming character of the political and organisational negotiations and bargaining often required for success or any kind of progress. Too often therefore the country’s “readiness to implement” is not in place when fund disbursements begin (JSI Research and Training Institute 2009), and too much time of the “funded” period is absorbed by the efforts to tackle what is likely to be a complex and difficult business.
Unfortunately there is very little hard data and information on this aspect of the immunization and health systems. It is therefore difficult to specifically identify impacts in either direction.

**Conclusions**

Most of the earlier evidence regarding immunization and health systems has focused on the effects of vertical programmes - such as polio eradication activities [PEI] and measles elimination - on the broader systems and on the factors influencing the successful implementation of vaccination programmes. It has been sometimes easier to identify the negative vs. the positive impacts. The local country context and the strengths and weaknesses of the existing health systems are critical factors in the NUV implementation process. Challenges are greater with weaker health systems. Although the available evidence does not permit definitive answers there are nevertheless areas in which positive trends have been found. These are

- The introduction of NUVs have often resulted in increased access to new and old vaccines in most documented cases; the resultant changes in morbidity and mortality patterns have resulted in necessary changes in the health and medical management practices relating to the targeted groups and syndromes;
- Access to certain special groups is increasing in certain settings and the development of integrated programmes has increased utilisation of other health services;
- Immunization safety has generally improved with the introduction of new products;
- Awareness and demand for immunization may have increased;
- Training appears to have increased to address the necessary skills required for implementation;
- Awareness of the importance of a health information system that can be useful for decision-making has increased, and there are new efforts to introduce the types of systems required. Standard methods and tools have been developed, and new AEFI monitoring / PME systems are being established;
- There has been an increase in domestic resources devoted to immunization and other health sector initiatives. There is also some evidence that financial and political levels of commitment are positively associated with increased levels of coverage, and the longer term sustainability of the interventions;
- Coalitions at the global, national, sub-national and district levels have been established and have been found to have beneficial impacts on intervention impact and success.

**Knowledge Gaps**

There are a number of other areas in which only tentative conclusions may be drawn as the data are based on limited case studies from which generalisations are currently speculative. These are areas in which further data and analyses are required. The following observations are the major and more general findings - which are especially critical for the further advance of NUV programmes.

It is critical to determine the extent and ways in which immunization and health systems may need to be adjusted and changed so as to bring about greater equity in the coverage of the new vaccines, and contribute to the development of sustainable health systems.

- The impacts of NUVs on routine immunization systems are inconclusive, but this review of the experiences to date does show that the impacts can be either positive or negative. The introduction of NUVs may have exposed and highlighted many weaknesses in the existing systems. It has therefore
drawn attention to the importance of better identifying what needs to be done to address the weaknesses and take advantage of the strengths so as to ensure more successful introduction of the NUVs. Better information is required on the relative value and effectiveness of different types of service delivery in different socio-economic and political environments. It is necessary to identify those arrangements that can reduce inequities and meet the needs of both “over-served” and “underserved” populations. It is necessary to better identify those weaknesses that could be addressed prior to the introduction of the NUVs.

- The extent to which external funding for NUVs leads to distortions and disruptions in the existing health system is still unclear and the possible resource drain from other areas of the health sector insufficiently assessed;
- The spill-over effects on the routine immunization system and other health system sectors – e.g. increased uptake, better timeliness in service delivery, greater cost-effectiveness, improved safety practices, reduction in wastage - need to be examined;
- The impacts of increased training programmes on the efficiency and effectiveness of health workforce utilization and deployment require further evaluation;
- The best strategies for the development and utilization of health information systems that can benefit decision-making need to be identified;
- The long-term sustainability of the programmes being implemented; and
- The factors affecting the pursuit of health reforms that increase the capacities of the national governments for effective stewardship, planning and overall management need to be further explored.

**Research Questions**

Several research issues and questions are suggested by this identification of the major knowledge gaps. These are as follows:

1. What type of service delivery modality is most cost-effective and is best suited for effectively meeting the immunization needs of specific populations in an equitable manner? How might these vary according to the types of existing health system and/or particular the socio-economic and cultural situations?
2. How do the different or changes in delivery models positively or negatively affect the other health services?
3. What impact has a move to combination vaccines (e.g., pentavalent and MMR) had on the availability and cost of monovalent presentations of measles, monovalent HepB, and DTP vaccine?
4. Have the social mobilisation activities and the awareness–raising activities for NUVs led to an increased demand for and uptake of immunization and other related health services?
5. To what extent do the increases in skill and human resource capabilities and the provision of work incentives which accompany the introduction of NUVs result in improved service delivery, better quality supervision and improved programme management?
6. What have been the consequences of NUV introduction on the utilization of local infrastructures, and human resources?
7. Has the use of external funding for new vaccines created distortions and disruptions in the existing health delivery system – especially in the deployment of the available financial and human resources?
8. Has the introduction of new vaccines strengthened the development, and use of an integrated HIS that facilitates development of a platform for routine surveillance, programme planning, adjustment, and evaluation?
9. What has been the impact of pooled procurement practices for new vaccines on the costs of vaccinations?

10. Has donor and government funding for new vaccines increased at the expense of financing of routine immunization programmes and strategies?

11. Has new vaccine introduction had greater or lesser positive or negative effects in countries with better governance and co-ordination compared to countries with poorer governance?

12. What are the minimum requirements: leadership, governance, infrastructure, etc required for successful implementation of NUV?
References


## Annex: Framework on New Vaccine Introduction Impact on the Immunization and Health System

<table>
<thead>
<tr>
<th>Building Block</th>
<th>Sub-Area</th>
<th>Effect on Immunization System</th>
<th>Effect on Health System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>ACCESS and COVERAGE:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical and geographical access</td>
<td>Access may be increased to new and traditional vaccines. Access to older age groups (&gt;1 yr) and to some special groups increased.</td>
<td>New vaccines bring opportunity for additional contacts (e.g. adolescent health interventions)</td>
</tr>
<tr>
<td></td>
<td>Social and demographic access</td>
<td>Creation of inequities (e.g. private sector, hard to reach populations) Targeted programmes may reduce inequities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Affordability</td>
<td>Public financing critical for increased and sustained access.</td>
<td>Parental loss of income due to childhood illness reduced.</td>
</tr>
<tr>
<td></td>
<td>Social &amp; cultural acceptability</td>
<td>Non-acceptance of some new vaccines decreases uptake of other vaccines.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>QUALITY OF CARE:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immunization safety</td>
<td>Immunization safety improved with new products.</td>
<td>Positive spill-over to the use of safe injection practices in other services</td>
</tr>
<tr>
<td></td>
<td>Timeliness</td>
<td>Affects timeliness of vaccination</td>
<td>May increase timeliness of other health services.</td>
</tr>
<tr>
<td></td>
<td><strong>DELIVERY MODALITIES:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alternative delivery strategies</td>
<td>Extent of change in service delivery model unclear (fixed facilities and other modalities). Schedules and target age groups may change.</td>
<td>Campaigns impact negatively on other services. Utilization of other services suffers. Changes in delivery models have potential to impact other health services.</td>
</tr>
<tr>
<td></td>
<td>Degree of integration and other intervention add-ons (GAPP, cancer, CAH, IMCI, etc.)</td>
<td>Potential to both improve and harm the immunization programme.</td>
<td>Other health services get renewed interest and expand access to pre-existing prevention and treatment programmes. If immunization is a lead health intervention, other services that are integrated with it will improve. Immunization is a good platform for other services (vitamin A, breastfeeding, ITNs, etc.).</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
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<th>Sub-Area</th>
<th>Effect on Immunization System</th>
<th>Effect on Health System</th>
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</thead>
<tbody>
<tr>
<td><strong>Service Delivery</strong></td>
<td><strong>DEMAND &amp; ACCEPTANCE:</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Social mobilization, advocacy and communication</td>
<td>Awareness and demand for services increase. Mobilization of people increases for vaccinations. Increased publicity and media attention. <em>More complex communication messages.</em></td>
<td>Mobilization of people increase for health services utilization</td>
</tr>
<tr>
<td></td>
<td>Incentives (clients)</td>
<td>Evidence of impact of incentives unclear.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Community and parental acceptance</td>
<td>Accountability of the National Immunization Programme to the population increases. Information, misinformation, and lack of information affect acceptance.</td>
<td></td>
</tr>
<tr>
<td><strong>Health Workforce</strong></td>
<td><strong>AVAILABILITY/DISTRIBUTION OF STAFF:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No. and distribution of staff</td>
<td><em>Increased number of staff required.</em></td>
<td><em>More staff can provide additional services.</em></td>
</tr>
<tr>
<td></td>
<td>Workload</td>
<td><em>Workload increases.</em></td>
<td><em>Mass vaccination activities reduce staff time for other services.</em></td>
</tr>
<tr>
<td><strong>TRAINING AND CAPACITY OF STAFF:</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Pre-service training</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>In-service training</td>
<td><em>More training needed and offered.</em></td>
<td><em>Better trained health staff able to offer other services</em></td>
</tr>
<tr>
<td></td>
<td>Technical capacity</td>
<td>Tools, training materials developed for routine use. <em>Technical capacity increases.</em></td>
<td></td>
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<tr>
<td><strong>REMNUNERATION &amp; SATISFACTION:</strong></td>
<td></td>
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<tr>
<td></td>
<td>Incentives</td>
<td><em>Motivation increases.</em></td>
<td><em>Demand for incentives increases.</em></td>
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<tr>
<td></td>
<td>Wages and career</td>
<td><em>Job satisfaction increases.</em></td>
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<tr>
<td><strong>PERFORMANCE AND SUPERVISION:</strong></td>
<td></td>
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<tr>
<td></td>
<td>Supportive supervision</td>
<td><em>More supervision required.</em> <em>Quality of supervision increases.</em></td>
<td><em>May divert from routine services supervision.</em></td>
</tr>
<tr>
<td>Building Block</td>
<td>Sub-Area</td>
<td>Effect on Immunization System</td>
<td>Effect on Health System</td>
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<td>------------------------</td>
</tr>
<tr>
<td><strong>ROUTINE DATA COLLECTION &amp; REPORTING:</strong></td>
<td>Data quality</td>
<td><em>Increased awareness of the importance of quality data for decision making.</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data collection process</td>
<td><em>Data collection formats and child health cards require modification.</em></td>
<td><em>Over-burdening of health care workers with reporting functions.</em></td>
</tr>
<tr>
<td></td>
<td>Integration with HMIS</td>
<td><em>Possible parallel data collection/reporting.</em></td>
<td><em>Increased emphasis on integrated data collection and feedback to lower level.</em></td>
</tr>
<tr>
<td><strong>SURVEILLANCE:</strong></td>
<td>Surveillance sites and platform</td>
<td><em>New surveillance sites added to routine system (e.g. sentinel)</em></td>
<td><em>Surveillance platforms extended to include other diseases.</em></td>
</tr>
<tr>
<td></td>
<td>Impact monitoring</td>
<td><em>Importance of impact assessment stressed.</em></td>
<td><em>Changes in clinical practice due to reduction of disease burden</em></td>
</tr>
<tr>
<td></td>
<td>Adverse Events Following Immunization (AEFI) / post-marketing evaluation (PME)</td>
<td><em>AEFI reporting becomes more common. New AEFI monitoring and PME systems established.</em></td>
<td><em>Links between AEFI and drug PME established.</em></td>
</tr>
<tr>
<td><strong>USE OF DATA FOR DECISION MAKING:</strong></td>
<td>Data management</td>
<td><em>Standards, methods, tools developed.</em></td>
<td><em>Tools may be useful for other health information systems.</em></td>
</tr>
<tr>
<td><strong>FORECASTING:</strong></td>
<td>Demand and supply forecasting</td>
<td><em>Demand and supply forecasting improved for all vaccines. More precise forecasts prevent overstocking.</em></td>
<td><em>Template for demand and supply forecasting for other medical products.</em></td>
</tr>
<tr>
<td><strong>PROCUREMENT:</strong></td>
<td>Stock management</td>
<td><em>Increased stockouts of both new and traditional EPI vaccines (if in combination). More efficient stock management results in reduced wastage.</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pooled procurement</td>
<td><em>Pooled procurement lowers vaccine prices.</em></td>
<td><em>Example for other pooled procurement mechanisms (e.g. medical products)</em></td>
</tr>
<tr>
<td><strong>COLD CHAIN &amp; LOGISTICS:</strong></td>
<td>Cold chain management</td>
<td><em>Cold chain requirements increase. More emphasis on cold chain management</em></td>
<td><em>Attempts underway to have integrated supply chains.</em></td>
</tr>
</tbody>
</table>

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<th>Effect on Health System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical products, vaccines &amp; technologies</td>
<td>VACCINE MANAGEMENT:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Effective Vaccine Management</td>
<td>Improved vaccine management tools available.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Efficiency and wastage</td>
<td>Cost for wastage increases. Wastage decreases.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Waste disposal</td>
<td>Increased demand on waste disposal system for some NUV. Potentially generates additional sharps waste.</td>
<td></td>
</tr>
<tr>
<td>Financing &amp; Sustainability</td>
<td>AFFORDABILITY:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sustained financing</td>
<td>Long-term sustainability and affordability in poor countries more difficult to achieve.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaccine unit prices</td>
<td>Vaccines are less affordable. Increased price per vaccine dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Healthy markets, fostering developing country manufacturers</td>
<td>Healthy markets bring down vaccine prices and enable vaccine security.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DOMESTIC FINANCING:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fiscal space</td>
<td>Increased allocation of domestic resources. May have lack of operating funds for services in countries with decentralized systems. Costs for cold chain management and improvement increase.</td>
<td>Risk of underfunding other health programmes. Effect on the budget ceiling in countries with Medium Term Expenditure Framework. Mobilization of other resources for integrated functions.</td>
</tr>
<tr>
<td></td>
<td>Fund handling</td>
<td>Resources available to EPI programme make it relatively more powerful.</td>
<td>‘Envy factor’ in relationship to other ministries and programmes.</td>
</tr>
<tr>
<td></td>
<td>EXTERNAL FINANCING:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Budget support</td>
<td>Better financial planning and budgeting processes</td>
<td>Better linking up to health sector planning process.</td>
</tr>
</tbody>
</table>

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### Innovative mechanisms

Funding from GAVI and other sources increased. First AMC as pilot for other vaccine AMCs. Additional resources in short- and long-term are needed.

### Building Block

<table>
<thead>
<tr>
<th>Sub-Area</th>
<th>Effect on Immunization System</th>
<th>Effect on Health System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor pooling (SWAp)</td>
<td>Potential neglect of immunization programme needs.</td>
<td>Better alignment with other health programmes.</td>
</tr>
<tr>
<td>Competing priorities, opportunity costs</td>
<td>May affect quality and funding for other routine EPI efforts.</td>
<td>Increased pressure for access to prevention and care of communicable diseases.</td>
</tr>
<tr>
<td>Treatment and hospitalization costs</td>
<td></td>
<td>Disease management changes. Lower burden of disease reduces treatment costs which can be re-allocated to other uses.</td>
</tr>
</tbody>
</table>

### Financing & Sustainability

#### DISBURSEMENT & RESOURCE ALLOCATION:

- Improved regulatory processes for other medical products.
- Alignment of vaccine and drug regulatory frameworks.

#### Leadership and Governance

#### HEALTH & REGULATORY POLICIES:

- Regulatory policy frameworks established.
- Vaccine prequalification system established.
- More NRAs established or meet requirements for functionality.
- More NITAGs established and capacity for evidence-based decision-making strengthened.
- Preferred product characteristics established including appropriate formulations and presentations for developing countries.
- Legislation requiring vaccination improves access.
- Legislation requiring vaccination improves access.

#### POLITICAL COMMITMENT:

Global immunization networks established.

#### ORGANIZATION, STRUCTURE & REFORM:

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<table>
<thead>
<tr>
<th>Governance &amp; accountability</th>
<th>Improved accountability procedures. Integrated MoH-MoF decision making established.</th>
<th>In considering NVI, countries may choose to implement health system reform. Underestimation of resources for reform.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme planning and management</td>
<td>Better management required and improves other immunization services.</td>
<td>Better management will improve other health services.</td>
</tr>
</tbody>
</table>

**NEGOTIATION, STEWARDSHIP:**

| Inter Agency Coordinating Committees | Sustainable coordinating mechanism established. | Example for coordination in other health sectors. |