Introduction
The following is a summary of the main themes and findings obtained from a review requested by the SAGE on the impact of new vaccine introduction on immunization and health systems. The research encompassed a range of data sources: 1) a review of the published literature; 2) a review of the grey literature; 3) an in-depth study of 3 countries; 4) interviews with key informants from countries and regions; and 5) a multivariate analysis examining impact of new vaccine introduction on DTP3 coverage. The purpose of this summary document is to extract cross-cutting themes and to highlight gaps in understanding the impact of vaccine introduction on immunization and health systems across these various resources.

Health systems may be characterized by a set of activities encompassing: service delivery; health workforce; information; medical products, vaccines and technologies; financing and sustainability; and leadership and governance. The WHO Health System Framework\(^1\) of building blocks was used to organize the analysis of potential areas of impact of new vaccine introduction on health systems. The figure below presents this framework in detail.

Methods
Each of the 5 data sources were developed using different methods. The following paragraphs briefly describe the approach used for each data source (further details may be found in the executive summary of each of the 5 data sources; SAGE members also have access to longer reports for each data source).

Published literature review: For the published literature review (Hyde T, et al., 2012), six publication databases (Medline, Embase, Nursing Update, West African Journal of Nursing, CINAHL, Web of Science and Global Health) were searched using 104 terms encompassing vaccines, immunization systems, and health systems themes. The search, completed on September 29, 2010 and not limited to a beginning year, yielded an initial 24,768 articles. After abstraction, 130 articles were found to be relevant and included in the analysis. A standardized abstraction form, based on the WHO Health Systems Framework of building blocks, was developed to systematically collect information on the study setting, methodology, relevance and impact on immunization and health system. Most of the articles analyzed in the review pertained to experiences in high-income countries.

Grey literature review: A systematic search of the grey literature (Favin M, et al. 2012) included hard- or soft-copy documents that were not peer-reviewed or published commercially, written between January 2000 and October 2010. The following databases were searched using a mix of free text and MESH terms: Popline, PubMed, Cochrane Library, ELDIS, System for Information on Grey Literature in Europe (SIGLE), CAB Abstracts, and WHO regional office databases. In addition, internet searches of agencies working on immunization and new vaccine introduction also were searched, and documents were found through networking. From the hundreds of documents examined, the MCHIP team included 61 that contained information on the impact of new vaccine introduction on immunization programs and, in a few cases, the broader health system. The grey literature review focused on low- and middle-income countries.

In-depth study of 3 countries: In order to understand the impact of new vaccine introduction on the EPI and health systems, field-work was conducted by the London School of Hygiene and Tropical Medicine (Burchett H, et al., 2012) in Guatemala (on the rotavirus vaccine introduction in February 2010), Kenya (on the PCV10 introduction in February 2011) and Mali (on the Meningococcal A [MenA] vaccine introduced between September 2010 and November 2011). Semi-structured interviews were conducted with key informants to assess the impact on the health system of the new vaccine introduction. One hundred and sixteen interviews were conducted with national, regional and district staff stakeholders. Questionnaires were completed with staff from 87 facilities in the selected districts. Selected routine data were collected at health facility level, including number vaccinated and number receiving antenatal care services before and after the introduction of the new vaccine.

Interviews with country and regional informants: Semi-structured interviews were conducted with nine national immunization and health officials and seven WHO regional office staff during the annual New and Under-utilized Vaccine Implementation (NUVI) meeting in June 2011 to gain their perspectives on the impact of recent vaccine introductions on immunization and health systems. Informants were also asked about their views on
possible tools to guide countries on minimizing potential negative effects and maximizing positive effects of introducing a new vaccine.

**Analysis of impact on DTP3 coverage:** A multivariate, cross-national, mixed-effect longitudinal model was developed to evaluate the effect of new vaccine introduction on DTP3 coverage in 176 countries during 1999-2009 (Shearer J et al., 2012). DTP3 vaccine coverage from the UNICEF/WHO Joint Reports was measured for the year following introduction of new vaccines, and regressed against income variables, female literacy rate, health expenditures per capita, GAVI Alliance support, outpatient visits per capita, as well as antenatal care coverage, among other variables.

**Summary of Findings Identified Across the Five Data Sources, by the Six WHO Health System Framework Building Blocks** *(Further details may be found in the Annex.)*

1. **Service Delivery**
   Review of the data found the following:
   - For immunization systems, new vaccine introduction appears to have mixed effects on service delivery:
     - There appear to be no positive or negative impacts on routine vaccination coverage over the long-term.
     - There is a perception of short-term improvement in coverage for routine vaccines, particularly when introducing new vaccines that target highly visible diseases.
     - With campaigns, there were short-term negative effects on coverage for routine vaccines and on other health services.
     - Generally, new vaccines increased acceptance of EPI activities by households and were viewed positively by health workers. However, occasional exceptions were related to anti-vaccination movements.
     - There was a positive impact due to increased use of safe injection practices and improved quality of services.
   - For health systems, there was little evidence of impact on service delivery.

2. **Health Workforce**
   Review of the data found the following:
   - For immunization systems, new vaccine introduction appears to have mixed effects on the health workforce:
     - There were positive impacts on health worker skills associated with the training accompanying vaccine introduction and with short-term increased supervision.
     - In a number of countries, health worker motivation increased due to the ability to offer clients an additional effective health intervention.
     - There was at least a temporary increase in staff workload with vaccine introduction. However, countries did not expand the workforce except for campaigns or some alternative delivery strategies (e.g., school-based delivery).
   - For health systems, there is no evidence concerning the impact of new vaccine introduction on the health workforce.
3. Information
Review of the data found the following:

- For immunization systems, new vaccine introduction appears to have mostly positive effects on information:
  - Disease surveillance systems (at health facility and laboratory levels) have shown improvement in several countries as a result of improvements in surveillance for diseases prevented by new vaccines.
  - Improved awareness and reporting for AEFIs has occurred as a result of vaccine introduction in a number of countries.

- For health systems, there is limited evidence of positive impact on health information systems:
  - Improvements in surveillance related to new vaccine introduction led to some improvement in surveillance for other diseases.

4. Supply Management (Medical Products, Vaccines, and Technologies)
Review of the data found the following:

- For immunization systems, new vaccine introduction resulted in mixed effects on supply management:
  - Assessment and expansion of cold chain infrastructure took place at the central level but cold chain infrastructure commonly remained inadequate at the periphery.
  - Introductions of combination vaccines placed less stress on immunization systems than introductions of non-combination vaccines.
  - The supply and use of safe injection equipment (AD syringes and safety boxes) has greatly increased due to new vaccine introductions.
  - Existing weaknesses in vaccine forecasting and stock management were amplified with the introduction of vaccines.
  - There was no significant improvement in waste disposal, despite increased needs.

- For health systems, there was some limited evidence of positive impact on supply management
  - In several countries, use of safe injection equipment for newly introduced vaccines (AD syringes and safety boxes) led to their use for other health services.

5. Financing and Sustainability
Review of the data found the following:

- For immunization systems, new vaccine introduction appears to have mixed effects on financing and sustainability:
  - There were substantial increases in costs.
  - Collateral expenses related to introducing a vaccine were not adequately anticipated or budgeted.
  - Vaccine introductions led to diversification of financing mechanisms and funding sources, including greater government co-financing and innovative global financing mechanisms.
  - Vaccine introduction led to concerns of donor dependency by countries and uncertainty about long-term sustainability of financing for the new vaccines.
Most countries have been able to sustain funding for safe injection equipment.

- For health systems, there was evidence of positive impact on financing:
  - New vaccine introduction led to reduction in outpatient visits and hospitalizations, implying reductions in the costs of treating diseases and of responding to outbreaks.

### 6. Leadership and Governance

Review of the data found the following:

- For immunization systems, new vaccine introduction appears to have positive effects on leadership and governance:
  - Prompted by decisions related to vaccine introductions, NITAGs were established or strengthened in a number of countries and there was increased recognition of the importance of NRAs.

- For health systems, there was evidence of positive impact on leadership and governance:
  - New vaccine introduction led to improved coordination between the Ministry of Health and other government ministries, especially with expansion of vaccination to new target age groups (school-age children, adults).

### Conclusions

- The WHO Health Systems Framework of Building Blocks provided a useful framework for analyzing data from a variety of studies.
- Despite different methodological approaches, the major findings and themes were quite similar across the five studies.
- Future introductions should explicitly consider the impact of vaccine introduction on broader health systems.
- Communities and health workers generally welcomed the introduction of vaccines, particularly vaccines that have large, well-recognized disease burdens.
- Where positive effects occurred following vaccine introduction (e.g., increased central cold chain, enhanced NITAG decision-making, improved AEFI monitoring, strengthened disease surveillance, increased training and supervision of health workers, improved injection safety, better intersectoral planning), these outcomes were often in areas where detailed technical guidance or tools, plus adequate financing, were available.
- The introduction of new vaccines did not commonly occur in tandem with greater integration, coordination or synergies with other health services.
- Weakness in planning for human resource and supply needs emerged as a significant gap in preparing for vaccine introduction.

### Discussion

Following review of the findings from the 5 data sources, we considered the implications of this review with regards to missed opportunities for improving immunization and health systems with new vaccine introduction, observations related to planning for introduction, and gaps in knowledge.
Missed Opportunities
With new vaccine introductions, there may be missed opportunities for improving immunization and health systems. These included opportunities to:
- more broadly strengthen laboratory surveillance and health information management systems;
- provide more supportive supervision;
- improve timeliness of vaccination, identify and reach hard-to-reach populations, and track defaulters to improve coverage;
- explore and implement joint vaccine delivery of vaccine with other appropriate disease prevention and control efforts; and
- strengthen waste management.

Observations Related to Planning for Vaccine Introduction
The delivery of vaccines through campaigns may be effective in reaching particular geographic segments or age-groups in the population in a timely fashion, but this strategy can potentially harm routine vaccine coverage and other primary health care services. This needs to be carefully considered and mitigated during the planning process.

Planning should explicitly take into account the anti-vaccine lobby and ensure appropriate social mobilization to address rumours, misinformation, and misperceptions.

Health ministries and EPI programmes frequently do not adequately consider and plan for all the requirements of vaccine introduction (funding, human resources, supplies, coordination) or the collateral non-vaccine costs of vaccine introduction. More technical and financial support is needed to assist countries prior to vaccine introductions to improve the planning phase and address these requirements.

Delayed or inadequate funding can severely compromise proper planning and all aspects of implementing a new vaccine introduction.

All the steps necessary to properly plan and prepare for successful vaccine introduction will support the strengthening of immunization and health systems, so vaccine introduction can have broader health system benefits.

Highlighting Gaps in Knowledge
The following gaps in knowledge should be noted and considered for future investigation.

- What are the most appropriate health interventions to incorporate with the delivery of immunizations, under what circumstances should integrated delivery take place, and what additional resources are needed to ensure that joint delivery of services is done effectively?

- What funding sources are countries using for co-financing? Are resources from other health programmes being re-directed to co-financing for new vaccines or do co-financing funds come from new resources?
- Does the document, “Principles and considerations for adding a vaccine to a national immunization program” provide helpful advice to facilitate new vaccine introductions that also strengthen the immunization and health systems?

- What can be done to improve equity of access and health benefits when a vaccine is being introduced? Underserved populations in countries with weak health systems particularly need to be reached with new vaccines to avoid magnifying health disparities.

- What specific measures can be incorporated into policy and programme architecture to enhance accountability?

- How can the success of a vaccine introduction be appropriately measured? What are the health system determinants of successful vaccine introductions?

- What are the true costs of vaccine introductions on the peripheral health workforce and infrastructure?

- Does current donor and partner support to countries facilitate country efforts to prepare for the introduction of a new vaccine? If not, how can this support be improved?
The following tables present the main findings of each of the data sources, by the 6 building blocks of the WHO Health Systems Framework. Findings are presented relative to immunization system impact or health system impact of new vaccine introduction.

### 1. Service Delivery Building Block

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Impact on Immunization Systems</th>
<th>Impact on Health Systems</th>
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<tbody>
<tr>
<td>Published literature</td>
<td>- In general, coverage of existing vaccines remained the same or increased.</td>
<td>Lack of evidence</td>
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<tr>
<td>review</td>
<td>- Removal of inequities of vaccine distribution were seen when the vaccine was offered for free.</td>
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<td>- Vaccine introduction led to and used school-based programmes to reach different target audiences beyond the routine infant immunization programmes. Additional efforts were needed to reach those who were missed through school-based delivery strategies.</td>
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<td>- Increased communication and social mobilization efforts were generally part of new vaccine introduction.</td>
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<tr>
<td>Grey literature review</td>
<td>- Introductions of HepB and Hib, the most common vaccines studied in this review, generally had little impact on service delivery modes and the vaccination schedule (except in the case of HepB birth dose).</td>
<td>Lack of evidence</td>
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<td>- Vaccine introduction did not significantly affect coverage of other routine EPI vaccines, although health staff in many countries had the impression of increased vaccination. In some countries, coverage temporarily decreased because of supply problems of the new vaccines.</td>
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<td>Study of 3 countries</td>
<td>- There were several reports that new vaccine introduction created more positive attitudes towards the EPI, particularly during the introduction period.</td>
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<td>- In a few countries, strong anti-vaccine movements took advantage of vaccine introduction to publicize the “dangers” of immunization.</td>
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<td>- There was some confusion, re: eligibility, during the switch from old to new vaccines.</td>
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<td>- Vaccine introduction contributed to improvements in safe immunization practices.</td>
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<tr>
<td>Study of 3 countries</td>
<td>- Mixed picture of whether vaccine introductions increased demand for other vaccines and services.</td>
<td>No reported change in provision or utilization of health care services, except in Mali where routine health services (e.g., ANC) were temporarily reduced during the MenA campaign.</td>
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<td>- In Mali, routine and outreach vaccination were interrupted due to the Men A campaign.</td>
<td>- No change in the co-delivery of other interventions with vaccine introduction.</td>
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<td>- Vaccine introductions increased public trust and confidence in the immunization program.</td>
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<tr>
<td>Study of 3 countries</td>
<td>- High profile social mobilization led to better awareness of benefits of vaccination (PCV-10, MenA).</td>
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<tr>
<td>Study of 3 countries</td>
<td>- Vaccine introduction had an unclear impact on quality of services.</td>
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<tr>
<td>Study of 3 countries</td>
<td>- There was a shift in services from an epidemic response to prevention (MenA), but no other changes reported in delivery modalities.</td>
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</table>
| Interviews with country and regional informants | - Impression was that vaccine introduction increased coverage of routine vaccines (especially ones against highly visible diseases, e.g., meningitis, pneumonia).  
- The introduction of vaccines and the AD syringes that usually came with them were seen to have contributed to improved injection safety.  
- Some EPI reviews reported a change to an earlier vaccination schedule.  
- Combination vaccines and ones that resulted in fewer injections per visit reportedly increased mothers’ acceptance of vaccination. | - Vaccine introduction did not lead to greater integration with other health programs or services in most cases. |
| Analysis of impact on DTP3 coverage | - After controlling for other determinants of coverage in multivariable models, adding new vaccines did not negatively or positively affect DTP3 coverage. | n/a |
### 2. Health Workforce Building Block

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<th>Data Source</th>
<th>Impact on Immunization Systems</th>
<th>Impact on Health Systems</th>
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| **Published Literature**          | - There was generally minimal sustained impact on workload of immunization program staff when new vaccines were introduced using regularly scheduled clinics.  
- Increased staffing was needed for school-based programmes.  
- Training was required to increase awareness and handling of adverse reactions and to address parental concerns.                                                                                     | Lack of evidence               |
| **Grey Literature**               | - Health staff in a few countries noted added workload.  
- There were positive impacts of training and capacity building, but not sufficient to improve weak health planning and management skills (forecasting, etc.).  
- Funding that accompanied new vaccine introduction facilitated increased supervision for a limited time period in various countries.                                                                 | Lack of evidence               |
| **Study of 3 countries**          | - Vaccine introduction had no effect on the number and distribution of health staff.  
- Workload for health workers was mostly unaffected beyond the introduction period.  
- Training for introduction of new vaccines enhanced skills and provided a general refresher for routine immunization services.  
- No ongoing changes in supervision were reported.  
- Motivation may have improved because of the perceived positive effect of the vaccine introduction on population health.                                                                 | - Training may have marginally contributed to absence of essential health staff from facilities in the countries studied. |
| **Interviews with country and regional informants** | - Vaccine introductions did not lead to an increase in the number of EPI or frontline workers in any country discussed.  
- In some countries, the addition of more vaccines has reportedly increased the workload and this has negatively affected health worker motivation.  
- Refresher training was one of the most important positive effects of vaccine introduction on EPI that was reported by nearly all informants.  
- Having a new intervention (a new vaccine) increased motivation of health workers.  
- Short-term increase in supervision visits were reported for a few countries.                                                                                   | Lack of evidence               |
3. Information Building Block

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<thead>
<tr>
<th>Data Source</th>
<th>Impact on Immunization Systems</th>
<th>Impact on Health Systems</th>
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| Published Literature | - Vaccine introduction often strengthened the use of immunization-related information for policy development, programme advocacy, and impact assessment.  
- Vaccine introduction stimulated development of new surveillance or vaccine registry systems. | Lack of evidence               |
| Grey Literature      | - Some countries strengthened disease and AEFI surveillance, although systems as a whole remained weak in poor countries. | Lack of evidence               |
| Study of 3 countries | - No change was identified in data quality or in timeliness of reporting.  
- Vaccine introduction resulted in a positive impact on awareness of AEFI at health facility level but no increase in routine reporting of AEFI. | - Vaccine introduction enhanced sentinel laboratory based surveillance. |
| Interviews with country and regional informants | - Vaccine introduction led to improvements in AEFI surveillance and reporting.  
- Vaccine introduction led to development of a defaulter tracking system for both the new vaccine (pentavalent) and measles (1 country).  
- Due to training for new vaccine introduction, routine data collection and verification improved (1 country). | - Surveillance for new VPDs had a positive impact on surveillance of other diseases (e.g., TB, malaria, hospital infection control).  
- Surveillance for VPDs re-established disease surveillance systems in several post-conflict countries. |
### 4. Supply Management (Medical Products, Vaccines, and Technologies) Building Block

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<tr>
<th>Data Source</th>
<th>Impact on Immunization Systems</th>
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<tbody>
<tr>
<td><strong>Published Literature</strong></td>
<td>- AD syringes were introduced due to new vaccine introduction and were used for all vaccines.</td>
<td><em>Lack of evidence</em></td>
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<td>- Cold chain capacity was increased on the basis of assessments conducted.</td>
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<td>- Increased availability of combination vaccines with vaccine introduction reduced the need for injection supplies and potentially also reduced administrative costs.</td>
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<td><strong>Grey Literature</strong></td>
<td>- Vaccine introduction was associated with procurement and installation of cold rooms and cold chain equipment in many low- and middle-income countries.</td>
<td><em>Vaccine introduction contributed to the availability of AD syringes in non-immunization services.</em></td>
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<td>- There were a few indications that vaccine introduction strengthened forecasting at the national level, but this remained a weak area.</td>
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<td>- Some stock-outs of combination vaccines resulted in shortages of traditional antigens.</td>
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<td>- Bulky new vaccines created significant, somewhat unanticipated, needs for frequent, high-volume, transport in various countries.</td>
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<td>- The increased expense of newer vaccines resulted in decreased vaccine wastage but also may have created missed opportunities for administering traditional antigens.</td>
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<td>- There were some improvements in waste disposal but it remained inadequate in most settings.</td>
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<tr>
<td><strong>Study of 3 countries</strong></td>
<td>- Cold chain capacity increased at national and regional levels but less at delivery levels, resulting in the need for more frequent re-stocking in the periphery.</td>
<td><em>Lack of evidence</em></td>
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<td>- Stockouts of new vaccines negatively affected perceived availability of all vaccines.</td>
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<td></td>
<td>- There was no expansion in waste disposal, despite the increase in biomedical waste with new vaccine introduction.</td>
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<tr>
<td><strong>Interviews with country and regional informants</strong></td>
<td>- Inadequate cold storage to accommodate the increased volume of the new vaccines led to increased frequency of vaccine deliveries in several countries. This also eventually led to expansion of the cold chain systems.</td>
<td><em>In a few countries, planning of cold chain expansion for vaccines took into consideration cold chain expansion needed for other medical products</em></td>
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<td>- Vaccine introduction led to increased awareness of weaknesses in current forecasting and stock management practices.</td>
<td>- Vaccine introduction led to use of AD syringes for other health services.</td>
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<td>- New vaccines caused serious waste disposal problems in several countries.</td>
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### 5. Financing and Sustainability Building Block

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<tr>
<th>Data Source</th>
<th>Impact on Immunization Systems</th>
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| **Published Literature**     | - Global innovative financing mechanisms have become available.  
- With new vaccines, the cost per infant for vaccination increased 2-4 fold, resulting in significant funding gaps and programme interruptions. | - Fewer ambulatory consultations and hospitalizations from illness can potentially reduce costs. |
| **Grey Literature**          | - Costs of routine immunization programmes increased substantially, increasing donor dependence.  
- Funding mechanisms have diversified.  
- Collateral costs of introducing new vaccines were not taken into consideration in many countries.  
- Need for co-financing may have increased government financing of immunization programme.  
- Most countries were able to sustain use of AD syringes at the end of GAVI support.  
- Modest improvements in financial and service planning through cMYPs were reported. | *Lack of evidence*                                                                                     |
| **Study of 3 countries**     | - Vaccine introduction resulted in an increase in co-financing in GAVI-eligible countries with no reports of problems in mobilizing funds.  
- There was no evidence of funds being diverted for new vaccines but there were perceptions that stock-outs may have been associated with fund diversion.  
- The cost of routine vaccine collection and delivery increased in some cases with no corresponding increase in funding  
- Vaccine introduction led to increased government financing of cold chain.  
- Vaccine introduction resulted in additional donor financing.  
- In GAVI-eligible countries, vaccine introduction led to concerns about long-term financial sustainability.  
- GAVI co-financing increased country ownership of new vaccines. | - There was potential freeing-up of resources that had previously been used to treat disease outbreaks.  
- Health service disruption due to campaigns reduced fee-for-service revenue generation in health facilities.  
- New vaccines enhanced equity by providing access to free vaccine (in contrast to curative services that require payment by clients). |
| **Interviews with country and regional informants** | - Vaccine introduction led to an increase in government contributions and commitment to EPI for some countries, but led to declines in others as donors picked up costs.  
- Stock-outs of OPV in one country were attributed to funds being used for the country’s co-financing contribution.  
- Donor dependency in some countries is potentially increasing, as they consider asking donors for support for new, expensive vaccines.  
- There are significant concerns for long-term financial sustainability in GAVI-eligible countries. | - Impressions were that co-financing has either led to reductions in funding for other priority programs (e.g., TB, malaria control), or had no impact. |
### 6. Leadership and Governance Building Block

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<tr>
<th>Data Source</th>
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<th>Impact on Health Systems</th>
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</thead>
<tbody>
<tr>
<td><strong>Published Literature</strong></td>
<td>- Public-private partnerships were formed.</td>
<td>- New vaccine introduction led to changes in fever management guidelines and in the antibiotic treatment policy for vaccinated children.</td>
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<td></td>
<td>- There was increased participation by NITAGs and NRAs for policy-making.</td>
<td>- Intersectoral coordination with non-health ministries occurred as part of vaccine introduction planning (e.g., Education, Defense).</td>
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<td>- Political benefits accrued to authorities as a result of vaccine introductions.</td>
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<tr>
<td><strong>Grey Literature</strong></td>
<td>- There were several mentions that vaccine introduction at least temporarily activated the role of ICCs.</td>
<td>- Vaccine introduction led to increased interest in integrated disease prevention and control programmes.</td>
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<tr>
<td><strong>Study of 3 countries</strong></td>
<td>- Evidence informed more structured decision-making process and communication strategies.</td>
<td>- Vaccine introduction resulted in greater involvment of civil society organization in the preparation and implementation of introduction.</td>
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<td>- The AEFI committee was activated in one country with new vaccine introduction.</td>
<td>- Collaboration among government departments and partners was strengthened during introduction.</td>
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<td>- The regulatory framework was bypassed in order to introduce MenA.</td>
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<tr>
<td><strong>Interviews with country and regional informants</strong></td>
<td>- New vaccine introduction has been a catalyst for the establishment or strengthening of NITAGs in many countries.</td>
<td>Lack of evidence</td>
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<td>- New vaccines have improved evidence-based decision-making processes in several countries, including analysis of new types of data (e.g., cost-effectiveness).</td>
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<td>- Vaccine introduction was a catalyst for developing or improving the NRA in a few countries.</td>
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<td>- The cMYP has had a positive influence on planning in some countries, with limited ownership of the plans in others.</td>
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