

Executive Summary for April 2012 SAGE Meeting: Grey Literature Review

Impact of New Vaccine Introduction on Developing Country Immunization Programs and Health Systems

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Introduction:

At the request of WHO's working group on the impact of new vaccine introduction, a systematic search was conducted of hard- or soft-copy documents, written from 1999 to 2010, that were not peer-reviewed or published commercially. 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 vaccine introduction were searched.

From the hundreds of documents examined, the USAID/MCHIP team selected 61 that contained information on the impact of new vaccine introduction (NUVI) on immunization programs and, in a few cases, the broader health system. Most of the documents were Post-Introduction Evaluations (PIEs), PIE summaries, meeting reports and presentations, and consultant reports. Most dealt with one NUVI but a few covered multiple country experiences (one summarized 16 PIEs, another seven). Country experiences reviewed were mostly from low-income African countries and concerned introductions of HepB and Hib, although there were several cases from middle-income countries, other continents, and rotavirus, pneumococcal vaccines, and human papillomavirus vaccines (RV, PCV, and HPV). To summarize relevant information, MCHIP used a format based on the WHO health systems components, with separate columns for impact on the EPI and health system.

Limitations:

- ▶ Most documents about EPI, but not about NUVI specifically, failed to mention the effects of NUVI on the EPI or health system; most documents on NUVI focused on the preparation and introduction, or the EPI status shortly after the introduction.
- ▶ PIEs and other NUVI assessments report on a particular point in time, which may fail to capture the changing effects of NUVI over time.
- ▶ In many cases only PIE summaries from WHO were available rather than full documents, and they sometimes contained contradictory or incomplete information.
- ▶ It was difficult to separate the effects of NUVI from the effects of donor funding that often accompanied NUVI.
- ▶ Because introductions of PCV, RV, and HPV into developing countries began only a few years ago, there was limited information on their impact, so the review may not

have fully captured some potential effects (e.g. due to RV's age requirements or HPV's particular target group).

Results:

Service Delivery: Health officials commonly suggested that NUVIs helped improve coverage, but overall evidence was mixed. Global or national shortages of new vaccines temporarily harmed coverage in several countries and, at least initially, RV coverage lagged behind DTP in Latin America. In contrast, there were a few reports that the fear of pneumonia and meningitis led to increased service utilization for both vaccination and other services. The 2004 evaluation of GAVI Immunization System Support (ISS) funding found that “countries generally did not undertake any special effort to target the ‘hard to reach,’ except to the extent that a significant portion of funding supported outreach efforts.”

Most new vaccines did not require significant changes in vaccination schedules. Exceptions were HPV, which targets adolescent or pre-adolescent girls, the birth dose of HepB, and the challenge of the strict age range for RV. Wastage of new vaccines appeared to be low, especially when they came in one-or-two-dose presentations, and health staff reported being motivated to avoid wasting expensive vaccines. Immediately after introduction in several countries, there was confusion among both health staff and the public regarding which children were eligible to receive the new vaccine. Some parents were unhappy if their child was denied the new vaccine.

In some cases NUVI reduced the number of recommended vaccinations and in others it increased the number. In a few countries the issue of multiple injections in one visit concerned health workers and the public.

Public acceptance of new vaccines was strong in most countries, regardless of the extent or quality of social mobilization/communication activities. In general even when mothers knew nothing about the new vaccine, there were no acceptance problems if the public had previously been well-disposed to the immunization program. There were a few reports that vaccine introductions improved the image or perceived importance of the EPI among the public and within the ministry of health (MOH). In a small number of countries, anti-vaccine or anti-government movements vocally opposed new vaccines and the EPI. Overall, vaccine introductions appear to have had little impact, positive or negative, on community involvement in immunization.

The GAVI Alliance's new vaccine and injection safety (INS) funding improved the availability of auto-disable (AD) syringes for injection safety in immunization. Moreover, almost all countries that received such support were able to sustain the availability of AD syringes and safety boxes, and around one-third of countries receiving INS support improved injection safety in non-immunization services. PIEs indicate that NUVI training

on injection safety improved practices but that practices such as recapping continued in many countries.

Health Workforce: Many countries took advantage of NUVI to provide additional training and support materials to health staff. Although useful, particularly in preparing staff to manage the new vaccine, these actions did not sufficiently address deficiencies in vaccine management and in collection and use of data. Health workers in various countries complained that training was too short, rushed, and that the new vaccine, diluent, or AD syringes were not available for practice. However, in a few countries training was reported to have been innovative and effective.

In a several countries, staff complained about the extra work that the vaccine introduction brought.

Funding that accompanied vaccine introduction enabled increased supervision in many countries, usually for a limited initial period. Various PIEs reported that supervision was not systematic (with no checklists) and that supervisors left no documentation of findings and recommendations at facilities.

Information: Generally, changes in forms, registers, and vaccination cards were anticipated and completed before introduction, but in several cases health workers had to use a temporary method to record doses of the new vaccine. Many PIEs reported that weak collection, manipulation, analysis, interpretation, and use of data persisted post-introduction in many countries.

Some countries (a few in Africa, many in Latin America) strengthened surveillance for the particular diseases addressed by new vaccines, although systems as a whole remained weak in the poorest countries. There was no specific evidence of NUVI impact on wider surveillance systems. According to PIEs, most countries had some, but not all, elements of well-functioning AEFI system.

Medical Products, Vaccines and Technologies:

NUVI was responsible for the purchase and installation of much cold chain equipment and storage capacity needed for new vaccines. Although there was inadequate cold storage capacity at some levels in some countries, it was generally adequate by the time of introduction. However, cold chain and logistics management skills remained deficient in many countries. Even in several strong, well-managed programs, small-dose vials and high-volume presentations and packaging commonly led to significantly increased frequency and volume of immunization materials distributed and a shortage of dry-storage capacity. In Turkey, which introduced several vaccines over a few years, the volume of vaccine per fully immunized child was 21 times higher in 2008 than 2005; and the number of intermediate cold rooms increased from five to 90+ in the same

period. Lack of bundling of AD syringes and diluents with vaccine was commonly reported in PIEs.

There were some indications that NUVis strengthened forecasting at national level, but this remained a weak area at local levels post-introduction in many countries. Stock-outs that occurred during or after the introductory period were commonly related to the bulky new vaccine temporarily overwhelming vaccine distribution capabilities and temporary global and national shortages of the particular vaccine or formulation introduced (mostly penta). In Kenya the high demand for PCV led to stock-outs of other vaccines. Intermittent vaccine stock-outs and local over-stocking followed the Hib introduction in Ukraine.

There were several mentions that wastage was lower for the new vaccines because they came in one- or two-dose presentations and staff were motivated to avoid wasting such expensive vaccine. There were also reports that, to avoid opening a 10-dose penta vial for only one or two children, staff reduced the number of sessions.

Many PIEs noted improvements in waste disposal at the time of NUVI but also acknowledged serious deficiencies in both incinerators and health worker practices.

Financing and Sustainability

Despite the high cost of many new vaccines, in most cases short-term vaccine costs were usually anticipated and covered predominantly by donors (the GAVI Alliance, bilaterals, and manufacturers). However, some countries did not plan for collateral costs such as continued expansion of cold and dry storage capacity; much more frequent and higher-volume distribution of vaccines and related supplies; fuel to run the cold chain (often in local budgets); and a significantly higher volume of waste to safely dispose. A few countries that had almost reached the end date of donor financing had no solution for how new vaccine costs would continue to be paid.

Latin American and Caribbean countries covered almost all of their vaccine costs, but UNICEF recently estimated that low-income countries paid 15 percent of their vaccine costs. The 15 countries included in the Sabin Vaccine Institute's Sustainable Immunization Financing (SIF) Program contributed from less than 5% of the immunization program costs to as much as 55%. National contributions tended to rise in years that donor contributions fell and vice versa.

The report from a recent Africa regional workshop indicated that in some countries the high costs of new vaccines and gradually increasing country co-financing obligations may have stimulated improved financial planning, increased national contributions to EPI, and collaboration between ministries of health and finance, and legislatures. It appears that the GAVI Alliance requirement for countries to prepare Financial

Sustainability Plan (FSPs)/ comprehensive Multi Year Plan (cMYPs) had stimulated improved planning and budgeting.

Pooled procurement via UNICEF and regional revolving funds have enabled many countries to purchase vaccine and supplies at lower cost, and the GAVI Alliance has spurred innovative mechanisms for vaccine financing such as the AMC, the IFFIm, and IDA Buy-Downs. However, despite the substantial international attention, and some positive steps such as co-financing and reduced PCV prices for GAVI-eligible countries, the cost of new vaccines (plus their distribution and storage) remained unaffordable to many governments without donor support. Countries not GAVI-eligible do not benefit from some price-reduction mechanisms, and consequently many face significant financial barriers to NUVI. One had to increase its vaccine allocations by a factor of 6.8 from 2004-8. Long-term financing of new vaccines and their impact on national health budgets remain critical issues.

Leadership and Governance:

Outside of Latin America, there were few firm indications that NUVI has strengthened political commitment to immunization, although by 2004 in Ghana, DPT3/penta 3 (introduced in 2002) had been selected as a major indicator for monitoring the district assemblies' performance. Planning for and monitoring NUVI served to activate ICCs for a time, but it was unclear if ICCs stayed energized.

New vaccine introduction does appear to have resulted in some countries taking steps towards better financial planning and expanded links between the MOH and other ministries.

Comments:

In most cases, NUVI did not have major, lasting impacts on EPIs or health systems. There was generally little impact on coverage; with some decreases (due to stock-outs) or modest increases. New vaccines were generally well accepted, except in a minority of countries where anti-vaccine movements caused problems. A common area of stress was unanticipated costs. In many cases, not all planned assessments and preparatory actions were completed, because of insufficient time, a lack of appreciation of the complexity of good preparations, and too strong a focus on the launch. There is an untapped potential for wider partnerships and strategies within the MOH for diarrheal disease and pneumonia control.

While the analysis of results did not systematically test hypotheses, it appeared that important determinants of smooth or disruptive introductions were the choice of a vaccine, presentation, formulation, and packaging as well as the quality and thoroughness of pre-introduction planning and actions. Although country wealth and the strength of the pre-introduction EPI components were no doubt important, there were

several instances when even middle-income countries with strong EPIs encountered high stress from NUVIs.

The likelihood that NUVI will *strengthen* EPI and health system components appears to be related to specific planning for these outcomes and to taking a long-term view to system strengthening, although there were few examples of this in the grey literature.