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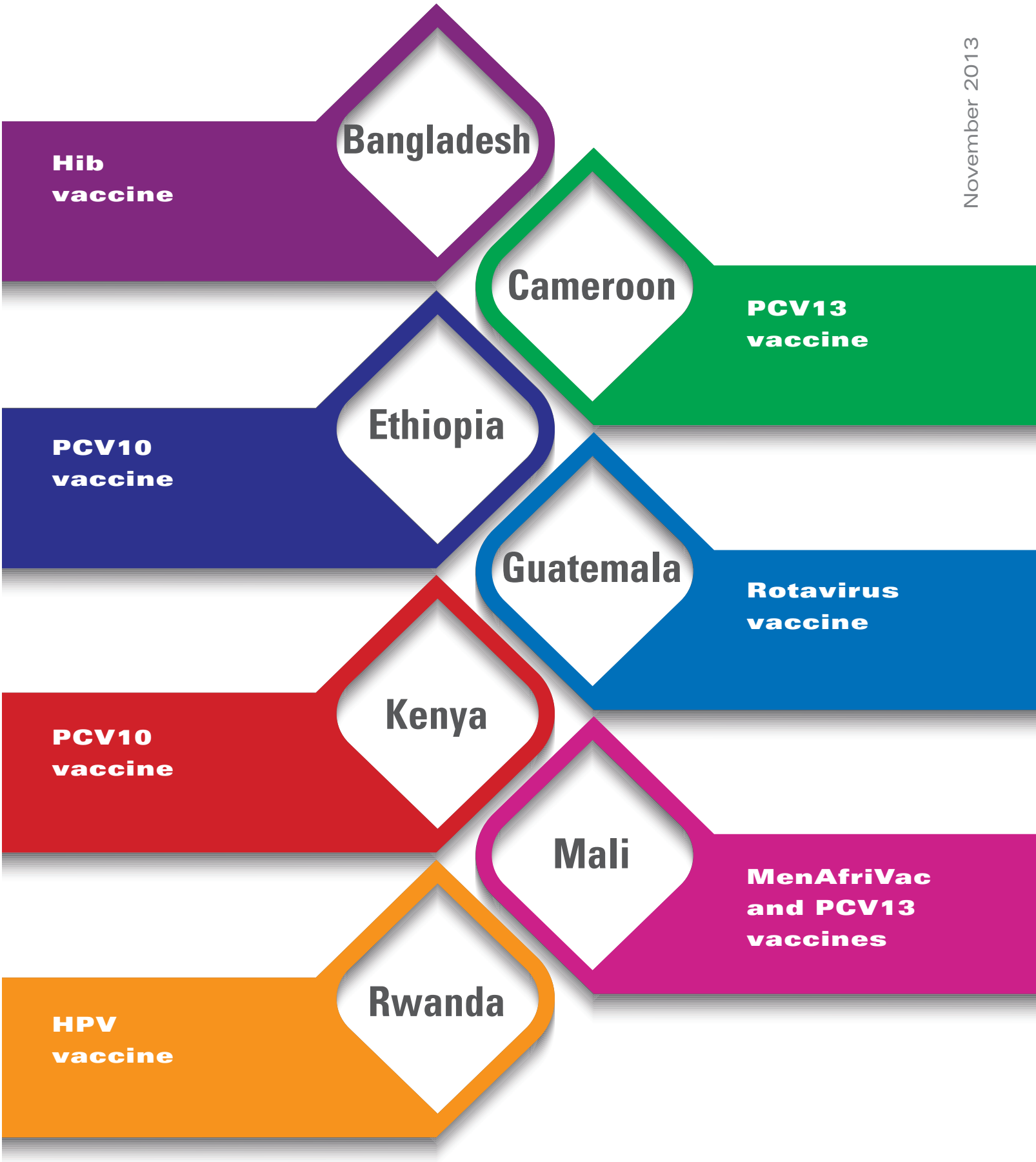


New vaccines: from decision to introduction

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

BILL & MELINDA GATES foundation

Vaccination has been shown to be one of the most effective public health interventions, saving millions of lives across the world. Based on the emerging success of smallpox eradication, the Expanded Programme on Immunization (EPI) was established in 1974, to ensure that all children could benefit from life-saving vaccines. In 2000, the Global Alliance for Vaccines and Immunisation (GAVI) was established, offering Hepatitis B and haemophilus influenzae type b (Hib) vaccines free to 75 low-income countries for five years. In the past ten years, many new vaccines have become available and organisations, such as GAVI, have assisted developing countries with their introduction.

However, there is a lack of research on the impact of new vaccine introductions on countries' EPIs and broader health systems, particularly for in low-income countries. The London School of Hygiene & Tropical Medicine carried out two studies in low- and middle-income countries, in collaboration with country partners, one exploring national decision-making processes around new vaccine adoption and another on the impact of new vaccines on country health systems. Preliminary results from the LSHTM study on the impact of new vaccines on the health system were shared with the World Health Organization ad hoc working group that had been set up in 2010 to explore this specific topic. Two LSHTM staff became members of the WHO working group over the two years that it was active.

Study 1
Decision-making

As more vaccines become available, decisions on which to introduce into immunisation schedules become more complex. This qualitative study investigated processes of national decision-making for new vaccine adoption and sought to understand the factors affecting those decisions.

Ninety-four key informants from the following countries were interviewed to explore national decision-making processes around new vaccine adoption: Bangladesh, Cameroon, Ethiopia, Guatemala, Kenya, Mali and South Africa. Most interviews were conducted between October 2010 and March 2011. Framework analysis was used to explore the issues. Countries were selected to include both GAVI-eligible and non-eligible, different geographical regions and different health system strengths.

Photo: Gates Foundation

Findings

Actors involved

Only a small number of actors were involved in the decision to adopt new vaccines in all countries studied; National Ministry of Health officials played key roles. In the two countries not eligible for GAVI support, Guatemala and South Africa, fewer people were involved in decision-making and interviewees reported that recent decisions to adopt new vaccines came as a surprise. In both countries, the EPI teams within the Ministry of Health were not involved in decision-making, in contrast to the countries eligible for GAVI support, where EPI teams played a central role. Generally the Ministers of Health were influential in all countries studied, with some championing vaccination. South Africa was the only country in the study to have a technical advisory committee for immunisation, the National Advisory Group on Immunisation. The WHO was considered an important stakeholder in GAVI-eligible countries, providing information and support. National actors with global links were influential, researchers and clinicians involved in advocacy had varying degrees of influence. In non-GAVI-eligible countries, the pharmaceutical industry was a key actor.

Cues to action

GAVI funding calls were a key cue in GAVI-eligible countries. In Kenya, Ethiopia and Mali, however, decisions to introduce the pneumococcal vaccine preceded the GAVI call. International and national meetings were instrumental in providing lobbying opportunities and briefing country stakeholders on new vaccine developments. National advocacy activities were also important in getting new vaccines on the agenda. Disease outbreaks were key triggers for some new vaccine adoption i.e. diarrhoea outbreaks in Guatemala and South Africa triggered rotavirus vaccine adoption.

Procedures

In the non-GAVI-eligible countries studied, decision-making processes for recent vaccine adoptions deviated from normal procedures; with decision being more politically driven and introductions expedited in both South Africa and Guatemala. In GAVI-eligible countries, the requirement for funding applications led to more structured decision-making procedures, although these procedures were not necessarily more thorough and in fact tended to become more automatic.

Evidence

The importance of evidence was universally recognised, particularly the incidence and burden of disease. In countries with sufficient capacity to conduct their own studies, local findings were considered critical. Indeed, interviewees from Mali, Kenya and Bangladesh reported that new vaccines would not be adopted unless local disease burden data were available.

Drivers

In countries eligible for GAVI support, the principal driver for new vaccine adoption was the desire to seize the opportunity for GAVI funding. In non-GAVI eligible countries, although the burden of disease was considered a key factor, the decision was primarily driven by internal political dynamics. Overall, decisions to adopt new vaccines were found to always be political. The main drivers influencing adoption decisions were the availability of funding, the burden of disease and political prioritisation of the vaccine or vaccine-preventable disease. There was often little consideration for programmatic feasibility and financial sustainability issues.

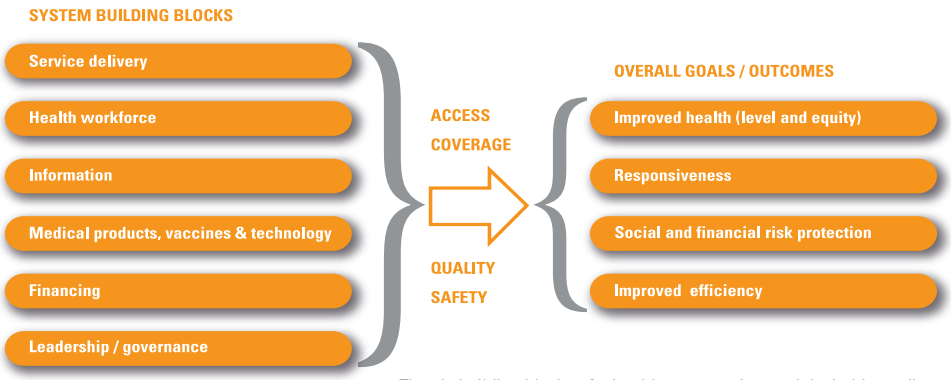
CONCLUSION: Decisions to adopt new vaccines are, by nature, political. The main drivers influencing decisions were the availability of funding, political prioritisation of vaccination or the vaccine-preventable disease and the burden of disease.

Study 2
Exploring the impact of new vaccine introductions on health systems

It is often hoped that introducing additional vaccines will help to strengthen the immunisation programme and the health system, more broadly. There are also concerns, however, that such additions may prove to be an added stressor.
The second study evaluated the impact of seven new vaccine introductions on immunisation programmes and health systems in Cameroon, Ethiopia, Guatemala, Kenya, Mali and Rwanda. The countries were selected to cover a range of vaccines, delivery strategies and financing mechanisms – introductions also needed to have taken place between 2010 and 2011. In each country, two to four regions were selected based on vaccination coverage, two to three districts were selected within each region and one to five health facilities were selected per district. Data collection consisted of semi-structured interviews at national, regional and district levels, structured questionnaires with health facility staff and routine health service use data. Data collection tools and data analysis were structured using the WHO health system building blocks framework.

Country	Vaccine	Date of introduction	Date of data collection	Source of financing
Cameroon	PCV13	July 2011	May–June 2012	GAVI and National government
Ethiopia	PCV10	November 2011	December 2012–January 2013	GAVI and National government
Guatemala	Rotavirus	February 2010	July 2011	National government
Kenya	PCV10	February 2011	July–August 2011 and March–April 2012	GAVI and National government
Mali	MenA	September 2010–December 2011	July–August 2011 and January 2012	GAVI and National government
	PCV13	March–December 2011	January 2012 and March–June 2012	GAVI and National government
Rwanda	HPV	April 2011	August 2012	Pharmaceutical company and National government

A total of 277 semi-structured interviews were conducted with national, regional and district-level key informants. Questionnaires were completed at 196 health facilities.



The six building blocks of a health system: aims and desirable attributes

Findings

The new vaccines integrated well into existing country health systems and had no impact on many of the elements of the building blocks framework. Most effects that were reported were within the vaccination programme rather than the health system. Some effects, such as increased workload, were temporary.

No impact

Utilisation: Although many informants reported increased coverage of other vaccines as a result of new vaccine introductions, routine data showed that they had no impact.

Cold chain: The new vaccine introductions did not generally affect cold chain capacity for other vaccines. GAVI-eligible countries carried out cold chain assessments prior to new vaccine introductions, as this was a requirement of the application process. Guatemala was the only country in the study not to carry out a cold chain assessment prior to introduction. The cold chain in some countries benefited from the coincidental change to a less voluminous presentation of other vaccines.

Supervision: In most countries no changes in supervision were reported.

Regulatory policy: Most countries reported no effect on regulatory policies.

Inter-agency co-ordinating committees: In most countries the new vaccines did not affect the functioning of inter-agency coordinating committees.

Positive impacts

The new vaccine introductions were essentially viewed as inherently positive.

Training: Staff training in preparation for the new vaccines was overwhelmingly viewed as positive, allowing staff to refresh and update their skills.

AEFI awareness: The focus on adverse events following immunisation in several study countries led to increased safety awareness; however, this did not affect reporting of AEFIs.

Financing: The impact of new vaccines on domestic and external financing was seen to be positive; domestic funding for vaccines increased – because co-financing was a requirement for countries to be eligible for GAVI support.

Collaborations: There was generally no change in collaborations, although there were a few cases where new vaccines led to new collaborations, for example in Rwanda, a school-based delivery strategy led to new links with the Ministry of Education being made.

Negative impacts

The negative impacts that were reported were generally short-lived.

Workload: The majority of health facility respondents reported that staff workload increased at the time of, or just after, introduction of the new vaccine. This varied between countries.

Stockouts: Stockouts of all vaccines introduced through routine immunisation programmes were reported, although they were more common in some countries than others and in many cases either occurred in the post-introduction period only, or had also occurred prior to the introduction.

Photo: Sergio Torres-Rueda

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CONCLUSIONS: As far as we know, this is the first study to specifically explore the impact of new vaccine introductions on the broader health system in low- and middle-income countries. We found that new vaccine introductions were generally well-integrated into the EPI and either had no or limited impact on the building blocks of the health system. The most surprising finding was the conflict between the perceived increase in coverage of other vaccines and the results of routine data analysis showing no impact. The study also found that negative impacts of new vaccine introductions were minimal, particularly for issues such as cold chain capacity and those that did occur, such as increased workload at time of introduction, were short-lived. However, the role of planning should not be discounted. Overall, new vaccine introductions were intrinsically viewed as positive, although they had no major impacts on the health system.

"Overall everything went well, which demonstrates the system's capacity to absorb new interventions"

National interviewee, Cameroon, PCV13

"We were able even to get children who...were not immunised with other vaccines because, as you know, in Kenya, pneumonia is feared"

District interviewee, Kenya, PCV10

Policy recommendations for countries

- **Reinforce the positive effects of new vaccine introductions by using the opportunity to:**
  - develop a strategy for the identification and catch up of defaulters
  - promote and provide other services alongside the new vaccine
  - invite collaboration with stakeholders involved in related activities
  - use training to fill specific knowledge gaps
  - develop strategies to ensure training reaches all immunisation staff including those recruited after the introduction
  - take the opportunity to revise aspects of the immunisation programme e.g. reporting forms
  - Develop social mobilisation strategy that go beyond a specific new vaccine introduction

- **Limit the negative effects of new vaccine introductions by:**
  - monitoring routine health service activities during vaccination campaigns to ensure that the delivery of services is not disrupted during campaigns
  - monitoring changes in operational costs at the facility level
  - ensuring sufficient time and resources to plan introductions (e.g. assessment of cold chain capacity/requirements)
  - ensuring stable and sufficient supply of new vaccines and other products (recognise the need for additional supplies during the introduction period, if employing a catch up strategy)
  - incorporate strategies in introduction plans to minimise the temporary increased workload burden on health workers

- **Policy recommendations for WHO/partners:**
  - WHO and partners to use new vaccines as an opportunity to strengthen EPI and health systems
  - Develop guidance on strategies for identifying and capturing vaccine defaulters when introducing a new vaccine
  - Funders to incorporate/incentivise health system strengthening activities into funding applications

"The introduction of this new vaccine strengthened us, in relation to the expectations of the populations of what the Ministry has to offer for the protection of their children. It has strengthened the immunisation programme, considerably because... this vaccine...is...increasing the populations trust in the Ministry"

National interviewee, Guatemala, rotavirus vaccine

"I wish we would have been associated with the new vaccine activities...the spirit of integration is not always well understood because each service think they can achieve their results separately"

National Interviewee, Mali, MenAfriVac

Photo: Sergio Torres-Rueda