

Executive Summary for April 2012 SAGE Meeting: In-depth study of 3 countries

Impact of vaccine introduction on EPI and health systems: Preliminary findings from three countries

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Introduction

Staff of LSHTM and local collaborators conducted a study to assess the impact of three new vaccines on the vaccination programmes and health systems in Guatemala (Rotavirus vaccine), Kenya (PCV10) and Mali (Meningococcal A “MenA” vaccine) (see Table 1). While rotavirus and PCV were added to the routine schedule, the MenA vaccine in Mali was introduced through a three phase vaccination campaign. It is currently planned that the MenA vaccine will be introduced into the routine programme in 2015.

There were a number of coincidental events at the time the new vaccines were launched. In Mali, the MenA vaccine was introduced through a campaign¹ that occurred in the same year when the new PCV13 was gradually phased in across the country.² Both Kenya and Mali switched from a 1 to a 10 dose vial pentavalent vaccine at the time of new vaccine introduction. Finally, new staff were recruited as part of the Economic Stimulus Programme in Kenya ahead of the introduction, and this could have had an effect on staff workload.

Table.1 New vaccine introduction country study

	Guatemala	Kenya	Mali
Vaccine	Rotavirus	PCV10	Men A
Income	Middle-income	Low-income	Low-income
Delivery strategy	Infant schedule	Infant schedule	Campaign (2 main phases-2010 and 2011)
Target population	Routine child immunisation schedule	Routine child immunisation schedule	1-29 years old (10 million people)
Date of introduction	Feb 2010	Feb 2011	Dec 2010 and Nov 2011
Funding	Self financing	GAVI +co-financing	GAVI + co-financing

¹ In Mali, there were a total of 14 campaigns in 2010 (9 were vaccination campaigns) and 14 campaigns in 2011 (11 were vaccination campaigns).

² The LSHTM will conduct a separate evaluation of the effects of PCV13 on health systems.

Methods

The study was undertaken in three regions in Guatemala and Kenya and in two regions in Mali. 116 semi-structured interviews were conducted with national, regional and district staff stakeholders. In addition questionnaires were completed with staff from 87 facilities in the selected districts. Routine data was collected at health facility level in all countries including number vaccinated and number receiving antenatal care services before and after the introduction of the vaccine.

Limitations

Our study only involved three countries, two of which were in Sub Saharan Africa and GAVI eligible, and it focused on three different vaccines. This may affect the generalisability of the findings to other countries.

Results

Service Delivery

Access & Utilisation

In Kenya and to a lesser extent in Guatemala, there was a sense that new vaccine introduction had contributed to an increase in coverage for other vaccines through defaulters' catch-up and increased demand. But this was not supported by routine data on the number of children vaccinated in the health facilities. In Mali, although the Men A campaign had a positive effect on the perceived credibility of the vaccination programme, implementation had a negative effect on the availability and utilisation of routine vaccination services and to a lesser extent on other health care services (as with other vaccination campaigns). In Mali, the majority of health care facilities reported that they were closed for routine vaccination during the campaign and half of the facilities reduced other services, such as antenatal care.

Overall, there was no reported change in the provision of health care services in the months following the introduction of the new vaccines.

Quality of Care

There were no reported changes reported in the quality of immunisation services associated with the introduction of the new vaccines.

Delivery Modalities

No changes were reported in the methods for vaccine delivery, such as the number and timing of sessions. No change was reported in the frequency and type of the interventions normally co-delivered with vaccination, such as vitamin A. The MenA campaign, which targeted a population of 10 million people, was not used as an opportunity to deliver other interventions alongside.

Demand & Acceptance

High demand for the newly introduced vaccines was reported. Resistance towards the new vaccines was rare and exceptional. In Guatemala, and to some extent in Mali, it was reported that some mothers had complained and felt discriminated against because their children were not age-eligible to receive the vaccine. In Kenya and Mali, social mobilisation was high and generated strong demand.

There was general agreement among respondents in the three countries that the vaccine introduction had increased public trust in the programme and reinforced the population's confidence in immunisation. Staff were also overwhelmingly positive about the new vaccines because of the expected impact on disease incidence, some of which could already be observed (e.g., meningitis in Mali).

Health Workforce

Availability/Distribution of staff

In Kenya and Guatemala, no respondents stated that changes had been made in the availability and distribution of health care staff due to the vaccine introduction. However, since the introduction in Mali was implemented through a campaign, additional staff were hired for the duration of the campaign only.

Some staff at facility level reported that their workload had increased, but others noted that the increase in workload was only marginal. The rise in workload seemed to reduce after the initial months following the introduction in Kenya and Guatemala. The increase in workload was associated both with the time taken to administer the vaccine and the additional reporting tasks. Workload was high during the MenA vaccination campaign, but only lasted the duration of the campaign.

Training and capacity of staff

Training on the new vaccine was provided to most staff, but duration tended to vary from one week to a few hours, depending on the vaccine and the type of staff.

Independent of the duration of the training, facility staff and interviewees at all levels were overwhelmingly positive about the training. It was noted that it enhanced skills beyond those required for the specific vaccine introduced, acting as a general refresher on vaccination. Interviewees in Kenya and Mali explained that there were otherwise usually few opportunities for vaccine-specific training.

While some district level interviewees stated that routine services may have been negatively affected on the day they were away for training, most felt that this was not the case. The facilities where this was considered an issue were often operated with one nurse only.

Motivation

A majority of respondents stated that staff were motivated to deliver the new vaccine because of their dedication to the programme and of the positive perceived effect of the vaccine on population health.

Remuneration

Financial incentives were given to health staff in Mali, as in other vaccination campaigns. In Guatemala and Kenya, there was no change in salaries and no incentives.

Performance & Supervision

There were no changes reported by any respondents in the quantity and quality of supervision.

Information

Routine Data Collection, reporting and use of data for decision-making

Respondents reported no fundamental changes to the information system. The only change was the inclusion of the new vaccine in newly-printed child health cards and facility registries. However, these changes were not necessarily made prior to the introduction, but in the following months.

Time required to complete documentation was reported to have increased in Kenya, but it was unclear whether this had changed in Guatemala. Timeliness and completeness of reporting was not reported to have changed after the new vaccine was introduced.

Surveillance

The introduction did not affect the routine passive disease surveillance system. However, additional sentinel laboratory based surveillance sites established ahead of the introduction strengthened surveillance, including for other diseases than those targeted by the new vaccines.

In all three countries, emphasis was placed on AEFI surveillance during the introduction itself, including strengthening the skills of health workers to recognise and report AEFI. Especially in Mali it was felt that the MenA vaccine introduction had strengthened the surveillance systems for AEFI and enhanced capacity of institutions such as the AEFI surveillance national committee. However, no increase in routine AEFI reporting was noted in any of the countries.

Supply Management

Forecasting

No changes to stock management were reported by any of the respondents. Vaccines were still being ordered with the same frequency as before the new

vaccine introduction. However, a minority of health facilities in Kenya reported an increased frequency of vaccine orders.

Procurement

In Guatemala, there were several successive changes in the procurement strategy of the rotavirus vaccine, but no effects on procurement were reported in the two other countries.

Vaccine stock-outs of the new vaccine and other vaccines were reported in Kenya and Guatemala during the period of the vaccine introduction, but the stock-outs could not be attributed to the new vaccine.

There was no reported effect of the vaccine introduction on wastage rates of other vaccines.

Cold Chain Management, Logistics & Waste Disposal

There was limited increase in cold chain capacity prior to the new vaccine introduction in Kenya and Mali. In Mali, however, the cold chain had been strengthened in four regions in the run-up to introduction of the PCV13 vaccine, which also took place in 2011. There was no increase in cold chain capacity in Guatemala where problems due to lack of space during and after introduction were reported. The vaccine manufacturer provided storage space at the national level and transported the rotavirus vaccine to the regions. None of the health facilities reported a significant increase in cold chain capacity, with the exception of the provision of vaccine carriers in Mali. The simultaneous switch from a single dose vial to a ten dose vial pentavalent vaccine in Kenya and Mali was reported to have substantially eased the need for increased cold chain capacity.

In Kenya and Guatemala there was a perception that the facilities had started to collect vaccines more frequently.

The vaccination campaign in Mali provided an opportunity to install or rehabilitate some waste disposal equipment, but in the two other countries no changes were reported on the waste disposal system for sharps and contaminated materials.

Financing & Sustainability

Affordability

Co-financing increased in the two GAVI-eligible countries following the new vaccine introduction but interviewees did not report difficulties securing funds for these new commitments.

Domestic Resource Allocation

At national level, it was generally reported that the introduction of the new vaccines did not divert funds from other priority areas. However, in Guatemala, the fact that the rotavirus vaccine costs had not been included in the original yearly vaccine budget, while accounting for 40% of total vaccine costs, led some to speculate that

the vaccines stock-outs during December-January 2010 could have been associated with rotavirus vaccine procurement.

At sub-national level, there was generally limited reported effect on operational costs, with the exception of additional transport costs associated with increased frequency of vaccine delivery in Kenya and Guatemala. In Guatemala, some added logistical costs were borne by the vaccine supplier. In Mali, the campaign was adequately budgeted for with the exception of some outreach transport and communication costs which had to be financed by the local community. However, there was reduced fee-for-service revenue generation in health facilities in Mali because of health service disruption due to the campaign.

External financing

In Mali, additional unanticipated external financing was leveraged for the introduction of the MenA vaccine. However, concerns about the sustainability of GAVI funding were expressed in both Mali and Kenya.

Leadership & Governance

Regulatory policies

The only mention of an effect on regulation was in Mali, where interviewees reported that regulatory norms and standards had been updated with the MenA vaccine introduction. These included national guidelines for vaccines and training modules. In particular, the institutional set up for post-marketing surveillance of pharmaceuticals was strengthened and operationalised, including the surveillance of AEFI. A negative effect was that, because of time pressure, the MenA vaccine approval process did not comply with regulatory mechanisms. Instead of going through the country's routine regulatory approval process, it was approved through an exceptional letter from the Minister of Health.

Political commitment

In the two GAVI countries, the requirements for GAVI funding applications led to a more structured and evidence based decision-making process. Both Kenya and Mali reported using local evidence to support their introduction decision.

There was high political commitment to support the new vaccine introduction. Heightened collaboration between partners and government departments during the introduction of the new vaccines was reported in Kenya and Mali. However, only in Mali was this collaboration between some agencies perceived to be beneficial beyond the time of preparation for the introduction.

In GAVI-eligible countries, domestic co-financing reportedly increased Kenya's country ownership of the new vaccine.

Organisation, Structure, Reform, Negotiation, Stewardship

At national level, there was no reported effect on overall organisation and management. However, in Guatemala, unlike in Kenya and Mali, there was no vaccine introduction plan in place and little or no time to accommodate the introduction activities. Planning for the vaccine was generally not perceived to have had an impact on other planning activities, although a few interviewees in Mali felt that some other activities would have been postponed. Finally, the introduction of the Men A vaccine enabled a shift from costly and disruptive outbreak response to a preventative strategy that would be beneficial to the population as well as the system.

Comments

Evidence from three countries shows that the introduction of vaccines provided an opportunity to strengthen staff skills. High demand for the newly introduced vaccine was reported in all countries, and associated with a perceived increased in demand for other vaccines, although this was not confirmed by analysis of routine facility data. Possible negative effects reported related to an increase in workload, primarily at the time of introduction. Vaccine supply management issues included an increase in the frequency of delivery of vaccines. Stock-outs were reported in two countries, but could not be attributed to the newly introduced vaccines.

Long-term positive effects included enhanced staff capacity; institutional strengthening such as the AEFI surveillance system; enhanced disease control and the freeing of resources previously used for epidemic outbreak response and improved perceived equity.

The campaign had more immediate negative effects on other routine services. Overall, the addition of a vaccine to the routine immunisation schedule was smooth, notably when the introduction had been effectively planned. However, in all countries the study showed that there had not been a deliberate strategy to use the vaccine introduction to change and improve the way in which other vaccines or health services were delivered.