Impact of new vaccine introduction on the Vaccine Programme and Health Systems

Preliminary findings from 3 countries

Guatemala, Kenya and Mali

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

Brief summary

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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 campaign\(^1\) 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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Guatemala</th>
<th>Kenya</th>
<th>Mali</th>
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<tr>
<td>Income</td>
<td>Middle-income</td>
<td>Low-income</td>
<td>Low-income</td>
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<tr>
<td>Delivery strategy</td>
<td>Infant schedule</td>
<td>Infant schedule</td>
<td>Campaign (2 main phases-2010 and 2011)</td>
</tr>
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<td>Target population</td>
<td>Routine child immunisation schedule</td>
<td>Routine child immunisation schedule</td>
<td>1-29 years old (10 million people)</td>
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<td>Date of introduction</td>
<td>Feb 2010</td>
<td>Feb 2011</td>
<td>Dec 2010 and Nov 2011</td>
</tr>
<tr>
<td>Funding</td>
<td>Self financing</td>
<td>GAVI +co-financing</td>
<td>GAVI + co-financing</td>
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\(^1\) In 2010 there were a total of 14 campaigns in Mali (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 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. on 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 show 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.
Impact of rotavirus vaccine introduction on EPI and Health Systems

Preliminary Findings from Guatemala

Introduction

Rotavirus vaccine was introduced in Guatemala in February 2010. The decision to introduce was taken for the most part unilaterally by the Minister of Health without significant involvement of the EPI programme. For this reason only limited preparations for vaccine introduction were implemented. Moreover, during the first year of introduction, several vaccine procurement problems were encountered. As shown in the timeline of events in Figure 1, the vaccine that was introduced first was RotaTeq™, but when stocks of this vaccine ran out, Rotarix™ was temporarily procured through the PAHO Revolving Fund procurement system. After a few months, RotaTeq™ was re-introduced in February 2011.

Figure 1: Timeline of rotavirus vaccine introduction in Guatemala
Methods
Semi-structured interviews were conducted with 41 key informants to assess the impact on the health system of the introduction of this new vaccine. Eleven interviews were conducted at national level and the remaining 30 were carried out with regional and district staff responsible for vaccine management, delivery or logistics. The study was undertaken in nine districts in the provinces of Chimaltenango, Santa Rosa and Suchitepéquez. Questionnaires were completed with staff from 26 facilities in the nine selected districts. Routine data were collected at facility level before and after introduction.

Results
Service Delivery
Access & Utilisation
During December 2010, the country experienced a nationwide stock out of pentavalent, rotavirus and OPV vaccines. Respondents with involvement of vaccine procurement stated that the stock out was caused by a government cash-flow problem. There was no evidence that the rotavirus vaccine introduction directly caused the stock out.

Overall, there was no reported change the provision of health care services or change in utilisation of these services following the rotavirus vaccine introduction. Only one facility staff reported a change access to health services for hard-to-reach groups. In this facility, it was reported that coverage had decreased because of the additional work associated with rotavirus vaccine introduction, so that eligible children were not vaccinated, especially after stock outs during December/January 2010. The health worker commented that she felt pressured to increase immunization coverage and spent more time in outreach activities, including house by house visits, resulting in the Health Post being left unattended.

Quality of Care
There were no reported changes reported in the quality of immunization services associated with the introduction of this new vaccine.

Delivery Modalities
No changes were reported with regard to methods for vaccine delivery, such as the number and timing of sessions, associated with the introduction of this new vaccine.

Demand & Acceptance
A range of responses was received on the question whether the introduction of the new vaccine had lead to increased demand for vaccination services; nine respondents stated that demand had increased and 12 respondents said that there
was no change. No respondents said that demand for health services other than vaccination had increased.

There was general agreement among respondents that the vaccine had been well accepted by the population, but some negative observations were reported with regard to the recommended age limits for vaccine administration. It was stated that some mothers had complained and felt that they experienced discrimination because their children were not eligible to receive the vaccine. There was general agreement among respondents that the vaccine introduction had increased public trust in the programme and reinforced the population’s confidence in immunization. Staff were overwhelmingly positive about the vaccine because of the expected impact on childhood diarrhoeal disease rates.

Announcements were given in the national media about the new vaccine introduction, but there was no specific social mobilization campaign organised from central level. Instead, each health facility was responsible for providing health education to mothers about the new vaccine. The quality of activities varied among the facilities; some facilities organised media events, but others did not organise any specific activities to promote the new vaccine.

Health Workforce

Availability/Distribution of staff

No respondents stated that any changes had been made in the availability and distribution of health staff due to rotavirus vaccine introduction. There were contradictory responses about whether the workload of health workers had increased with the new vaccine. 21 respondents stated that there was no increase or only a very marginal increase in the workload. However, 11 respondents stated that the workload had increased due to the new tasks of administering an additional vaccine and filling in the additional paperwork. Health workers in one facility had measured the extra time it takes to administer the new vaccine and found that it took 24 minutes to vaccinate a child whereas before rotavirus it took 17 minutes. The increased duration was attributed to additional time required for the child to swallow the vaccine. Some respondents mentioned the extra workload involved was due to the switch between rotateq™ and rotarix™.

Training and capacity of staff

Training was given to staff in 20 (74%) of the 27 facilities visited. Training was reported to have focused primarily on operational guidelines for the new vaccine and was financed by the vaccine supplier. There were mixed responses to whether the training had been focused completely on rotavirus vaccine introduction or whether other aspects of the programme were also included. There was limited report that the training had been linked to diarrhoea management. The type and length of training varied among facilities.
Remuneration & Satisfaction

No financial incentives were given to any health staff in relation to rotavirus vaccine introduction. There was no change in salaries. Almost all respondents stated that staff were motivated to deliver the new vaccine because of their dedication to the programme and knowledge of the importance of the vaccine in terms of preventing diarrhoeal disease.

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

There were no fundamental changes to the information system reported by any of the respondents. The only change was the inclusion of the new vaccine in newly-printed child health cards and facility registries. However, these changes were not made in preparation for the introduction, but only after the vaccine had already been introduced. Of the 27 facilities visited, all except four had received new child health cards at the time of the interview. In these four facilities, the old cards were used by adding doses administered in the "Others" section.

There was no consistent answer to the question about whether it took more time to fill in the forms after the introduction of the new vaccine. About half of the respondents said it was faster while the other half said it was more time-consuming after the new vaccine was introduced.

Surveillance

All respondents stated that the introduction had not affected the national disease surveillance system nor the AEFI reporting system. Sentinel rotavirus surveillance to assess the baseline rotavirus disease burden and evaluate impact of rotavirus vaccine was established at two hospitals in Santa Rosa in collaboration with CDC and the EPI programme.

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 rotavirus vaccine introduction.
Procurement

A limited number of our respondents were knowledgeable about vaccine procurement. It was reported that RotaTeq™ was procured differently than other vaccines, which are procured through the PAHO Revolving Fund. RotaTeq™ was instead procured through a local purchase directly at the central level outside of the EPI programme.

Cold Chain Management, Logistics & Waste Disposal

There was no systematic evaluation of the need for cold chain expansion in preparation for the introduction. There was not enough space at national level in the National Biological Center to store rotavirus vaccine, so it is being stored at the local stores of the commercial distributor of RotaTeq™ vaccine. Many district warehouses and facilities did not have adequate space to store the new vaccine. Additional equipment was requested and delivered in a piecemeal fashion, primarily from the regional level.

At the time of the data collection in July 2011, the local commercial distributor was responsible for collecting RotaTeq™ at the airport and also distributed the vaccine from the national level to all regions once a month. Hence, while regions collected the other vaccines, Rotateq was distributed to regions in a separate distribution system. Most facilities collect vaccines on a monthly basis from district warehouses and according to respondents at the facilities, this had not changed. However, there was a perception at higher levels that the facilities may have started to collect vaccines more frequently than once a month.

No changes were reported on the waste disposal system for contaminated vaccination materials, but this was to be expected given that rotavirus vaccine is an oral product requiring no syringe and needle.

Financing & Sustainability

Domestic Resource Allocation

The cost of purchase of rotavirus vaccine was not included in the vaccine budget for the year it was introduced.

At facility, district and regional levels there were no direct effects on costs and budgets were reported. The general perception was that they had not perceived any change in operating costs and continued to work under the same conditions. However, 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.
Leadership & Governance

Regulatory policies

No respondents reported any change in regulatory policies as a result of the introduction of rotavirus vaccine.

Organization, Structure, Reform, Negotiation, Stewardship

There was no vaccine introduction plan in place. Furthermore, since the rotavirus vaccine was introduced relatively rapidly in Guatemala, there was no time to update routine programme guidelines prior to vaccine launch.

Conclusion

Rotavirus vaccine introduction was implemented without adequate time for normal preparations in Guatemala, so there was not adequate time to assess the need for and implement the necessary cold chain expansion, social mobilization and training activities. However, in spite of these constraints the health facilities managed to introduce the vaccine with minimal interruption to health services. The present study did not reveal any evidence that the introduction had negatively affected other services. Health care staff were generally positive about the introduction of rotavirus vaccine. The majority of staff at health facilities reported that demand for routine vaccines increased at the time of introduction. However, there was no evidence of increase in vaccine coverage rates compared to the year before the introduction.
Impact of the PCV-10 introduction on EPI and Health Systems
Preliminary Findings from Kenya

Introduction
Kenya officially launched the PCV10 vaccine in February 2011. The initial impact of this introduction on the immunisation programme and broader health system was explored in July-August 2011.

There were a number of simultaneous policies, programmes and health issues that occurred around the same time as the introduction (e.g. additional nurse recruitment through the Economic Stimulus Programme, numbers of districts, facilities and immunisation providers were increasing, health professional trainings were run, there was a measles outbreak and polio campaign). These may have influenced the extent to which the new vaccine introduction affected the immunisation programme and health system.

Methods
Semi-structured interviews were conducted with 46 key informants at the national, regional and district levels. Interviews at regional and district level were conducted in three regions: Nairobi, Rift Valley and Western and three districts within each of these regions. Questionnaires were completed with staff from 43 facilities in the nine selected districts. Routine data were collected at facility level before and after introduction.

Results
Service Delivery
Access & Utilisation
There was an overwhelming sense that the PCV introduction had increased coverage of other vaccines, because caregivers were bringing children who either would not normally attend immunisation services or had missed previous routine vaccinations (defaulters) and these could then be ‘captured’ to offer them those they had missed. However it is interesting to note that the routine data collected from facilities did not support this. A minority of interviewees and facility respondents noted that the perceived increase was particularly, or only, during the first few months following the PCV introduction.

Quality of Care
Only a small minority of facility respondents said that they had made changes to their injection safety practices. Most did not report receiving a new injection safety job aid/tool.

**Delivery Modalities**

Opinions varied regarding whether the introduction had affected the time spent on immunisation activities or the frequency and duration of immunisation sessions. No changes were reported in outreach activities or the co-delivery of other services (e.g. vitamin A supplementation) alongside immunisation.

**Demand & Acceptance**

High demand for the PCV vaccine was universally reported. Only a small number of facilities reported experiencing any resistance from the community regarding the new vaccine. Approximately one third of facilities reported that fewer mothers refused other vaccines for their children since the PCV10 introduction.

The social mobilisation around the PCV introduction was very high profile, including a presidential launch. Interviewees were positive about the advocacy and social mobilisation efforts. Some interviewees described the mobilisation as covering not only PCV but vaccination more broadly, whilst a minority reported that it covered other broader health services and behaviours such as family planning and hand washing.

**Health Workforce**

**Availability/Distribution of staff**

The Economic Stimulus Programme had led to a recent increase in the numbers of nurses hired to work in facilities. Several interviewees felt that without these additions, there would have been challenges during the introduction. However some did note that there were staff shortages prior to the introduction.

Almost all interviewees and facility staff felt that staff workload had increased since the introduction, although some reported that this was only for the initial months after the introduction.

**Training and capacity of staff**

Most facilities reported that there was training, lasting one day or less, prior to the introduction. Facility staff and interviewees at all levels were overwhelmingly positive about the training. It was noted that it enhanced skills beyond knowing about PCV10 specifically, acting as a general refresher regarding EPI and immunisation. Some interviewees explained that there were usually few opportunities for EPI-specific training. Some interviewees and facility staff commented that they would have like more people trained, or ongoing training (e.g. because of staff turnover issues).
Most district-level interviewees felt that the training had not affected usual facility services offered. However some conceded that they may have been affected on the day of the training, particularly in facilities with only one nurse.

**Remuneration & Satisfaction**

Interviewees generally felt that the introduction had motivated staff, either through the outcome of reduced child morbidity and mortality, or because the associated training was itself motivating.

**Performance & Supervision**

Most participants felt there had not been changes to supervision following the introduction.

**Information**

**Routine Data Collection, Reporting & Use of Data for Decision Making**

Although data collection tools had been revised, almost all facility staff and interviewees felt that the quality of the data had not changed as a result of the introduction. However the majority of facility respondents felt that the time required to complete documentation had increased.

**Surveillance**

The introduction was not felt to have affected the surveillance system at local level.

Some interviewees felt that the introduction had boosted AEFI monitoring and reporting, with increased attention to the issue. However others felt that there had been no change, or any effect had been for the few months following the introduction. AEFIs were rare and the numbers reported were not felt to have increased since the introduction.

**Supply Management**

**Forecasting**

A minority of health facility respondents said that they had changed the way they ordered vaccines following the PCV introduction, either increasing the frequency or volume ordered. Some of these noted that these changes were only in the initial introduction phase and had since stabilised.

**Procurement**

There were widespread PCV stock-outs, particularly in the initial months due to the high demand for the vaccine and the fact that there was a catch-up period for all under one year olds (leading to a larger cohort than for the other routine vaccines). A
few interviewees explained that the implications of stock-outs went beyond the use of that particular vaccine, as word spread in the community that there was a vaccine stock-out, without specifying that it related to only one vaccine.

At sub-national levels, supply challenges led to either stock-outs of PCV itself or reduced quantities received which resulted in more frequent deliveries or collections of vaccine supplies. Generally, the PCV introduction was not felt to have affected stock-outs of other vaccines, with interviewees either reporting no stock-outs or explaining that those that occurred did so for reasons other than the new vaccine introduction.

The majority of respondents reported that the introduction had not had any effects on wastage rates. A minority of facilities reported changing the way they administered vaccines to prevent wastage of PCV (e.g. by limiting access to certain days or when sufficient clients were present).

**Cold Chain Management, Logistics & Waste Disposal**

Several national level interviewees stated that cold chain capacity had been increased, either at the national and regional levels or at all levels. However in contrast, at regional-, district- and facility-level, most reported that cold chain capacity had not been increased. There were mixed views among interviewees regarding whether there was a need for increased cold chain capacity, with some feeling it was required whilst others reported having sufficient space. Most facilities reported that there was no change in cold chain capacity for other vaccines and that there were no particular problems with cold chain since the introduction.

Some interviewees reported dealing with the effect on the cold chain by holding less stock of each vaccine. For some this did not lead to challenges because they weren’t able to get the maximum stock levels they required. Others said that it meant restocking more frequently. A few interviewees noted that the pack size for the pentavalent vaccine had reduced, which released space which the old formulation had used up. A few felt that stock management had become more efficient, with closer monitoring of stocks and ensuring that the precise amount required was needed.

No changes to the waste disposal system were reported following the introduction, although a minority noted increased amounts of waste or problems with their waste disposal.

**Financing & Sustainability**

**Affordability**

Some national and regional interviewees noted that costs of vaccine collection or delivery increased. However no district-level interviewees mentioned financial implications of an increased frequency of vaccine delivery and only one facility surveyed noted increased costs relating to vaccine delivery.
Domestic Resource Allocation

National level interviewees reported that the new vaccine received additional funds and so did not draw funding away from other immunisation activities. Most regional interviewees either did not know the funding situation or felt that there was no change. A small minority reported that there had been no additional funds except for training. At district level, interviewees either reported no effect or no change in funding, however this may be because they do not handle budgets at that level.

Only a minority of facilities reported that changes in the use of the facility had had an impact on their financial revenues. However it is important to note that immunisation is officially free in Kenya, with only a small minority of facilities admitting to charging. Some facilities also reported that child curative services were also free.

External Financing

Domestic co-financing was reported to have increased country ownership of new vaccine. However some interviewees expressed concerns for the long term sustainability of the external funding.

Leadership & Governance

Health & Regulatory Policies

No changes to regulatory norms or standards were reported at the national level. However it should be noted that the vaccine was already licensed and available in the private sector prior to the introduction in the public sector.

Political Commitment

There had been collaboration with partners and other government departments during previous introductions; there was no evidence that this had changed with the current introduction.

Organization, Structure, Reform, Negotiation, Stewardship

Decision-making process was structured by the GAVI application process and was informed by evidence, notably local evidence and this was felt to be positive. But other than that no clear effect on governance, planning or management was identified from the interviews or facility questionnaires.

Conclusion

There were positive effects derived from the introduction of the new PCV-10 vaccine on the immunization system in Kenya, notably strengthening EPI skills through training. At sub-national level, alongside the high demand for PCV-10, there was a strong perception that the PCV-10 introduction had increased coverage of other
vaccines through improved catch-up of defaulters and possibly other health service benefits although this was not confirmed by analysis of health facility data.

Overall, there was no or limited impact of the new vaccine on the building blocks of the health systems. Possible negative effects reported related to an increase in workload and vaccine supply management issues, with some facilities commenting that cold chain capacity was reduced and that frequency or volume of delivery had to be altered.

The introduction of the vaccine did not lead to a deliberate change in either how the EPI or other health services were delivered.
Impact of the Meningococcal A Vaccine Introduction on EPI and Health Systems

Preliminary Findings from Mali

Introduction

Mali introduced the new meningococcal vaccine Menafrivac vaccine through mass immunisation over 3 separate campaigns targeting the population aged 1-29 years old, over the period September 2010 to November 2011.

Mali officially launched the Menafrivac (MenA) vaccine in September 2010 in two districts (Phase 1). In a second phase, all Malians aged between 1 and 29 were vaccinated in the regions of Bamako, Koulikoro and Segou (14 to 23 December 2010). A third phase took place from 15 to 24 November 2011, during which the population 1-29 years old in all the 6 remaining regions of Mali was vaccinated. Over 10 million people were vaccinated during all phases of the MenA campaigns with a coverage rate of 95%.

During the period when the three Menafrivac campaigns were organised, Mali also introduced pneumococcal vaccine (PCV-13) in March 2011, although comprehensive coverage across the country was only achieved in December 2011. A high number of public health campaigns including many polio vaccination campaigns were also carried out over this period, including 14 campaigns in 2010 (9 vaccination campaigns including 7 National Immunisation Day (NID)) and 14 campaigns in 2011 (11 vaccination campaigns including 9 polio NID and 1 measles campaign). Finally Médecins sans Frontières (MSF) implemented the MenA campaign in several districts including in the Kati district which was one of the surveyed districts. These may have influenced the extent to which the new vaccine introduction affected the immunisation programme and health system.

Methods

Semi-structured interviews were conducted with 32 key informants at the national, regional and district levels. Interviews at regional and district level were conducted in two regions - Bamako and Koulikoro - and three districts within each of these regions. Questionnaires were completed with staff from 18 facilities in the six selected districts. Routine data were collected at facility level before and after the MenA campaign.

3 Based on WHO evaluation coverage survey of phase 1 and 2 of the vaccination campaign
The assessment of the impact of the MenA introduction campaigns on the immunisation programme and broader health system was explored in July-August 2011. Additional interviews at national level were conducted in January 2012.

**Results**

**Service Delivery**

**Access & Utilisation**

The MenA campaign drew large number of people because of its wide target population. According to interviewees, MenA led to a better awareness of the benefits of vaccination and a higher credibility of the vaccination programme (fostered by the absence of meningitis cases during 2011).

However, the negative effect of the MenA campaign was that in the large majority of facilities surveyed, routine vaccination was stopped during the 10 days of the campaign (12/15), even in many of those which were well staffed. Likewise outreach vaccination services were mostly discontinued during the campaign. There was a contrast between the view held by national and regional stakeholders who thought that routine vaccination continued during the campaign and evidence collected on the ground that showed that broadly it did not.

Impact of the campaign on other health services was lower than for routine vaccination, with one third of facilities reporting a reduction in services. In total, half of the facilities reported that antenatal care (ANC) had been reduced or closed during the campaign, or had no entry on the registry. An analysis by region showed most of the facilities that reported a reduction in ANC and outpatient services were situated in Koulikoro where staffing levels were lower.

Of note was the regular discontinuation of routine services during the multiple campaigns organised during the year – a point raised as a major issue by many interviewees.

Interviewees did not report a change in health service utilisation after the campaign was completed. However, a third of the facilities reported an increase in children coming for vaccination after the campaign. Routine vaccination data in the week following the campaign showed in a number of health facilities a comparatively higher level of routine vaccination that could be interpreted as the catch-up of missed vaccinations during the campaign.

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4 In the 3 other facilities of the Kati district, the campaign was carried out by MSF with no involvement of the local health facilities so there was more limited impact on routine health services.
Disease control

All interviewees commented that a major impact of the new vaccine on health systems had been the absence of disease. In 2011, there was no reported case of MenA in Mali (apart from 3 cases in non-vaccinated individuals).

Several interviewees noted that the introduction of MenA had enabled to shift from an epidemic response to prevention, which was seen as an effective and cost-effective approach. It was noted that epidemic responses in the past mobilized significant resources, both in terms of finances and human resources, also having a negative impact on routine services. The freeing of resources previously used for meningitis outbreaks for other purposes was also mentioned (staff on standby to take care of meningitis at district level, pre-positioned stockpiles of antibiotics in regions).

Beyond the benefits to the health system, several interviewees commented that the new vaccine improved equity (eg free access to vaccination versus paid treatment) for patients. This enhanced equity was deemed particularly important in some specific groups such as people affected by sickle cell anaemia, who are more prone to infections (12% of Mali’s population).

Quality of Care

No impact noted.

Delivery Modalities

The campaign was organised similarly to other vaccination campaigns with fixed vaccination posts, and outreach and mobile vaccination teams. However, more staff had to be drawn in as the target population was large.

The MenA campaign did not involve any co-delivery of other interventions (eg Vitamin A, de-worming). Some interviewees suggested that a more integrated approach with other services might have been positive while others commented that the high resulting workload would have made co-delivery of other services not feasible.

Overall the MenA campaign was not used to catch up defaulters or conduct interpersonal communication, because of a perceived shortage of time (interviewees reported high influx of people and a long period of time taken to fill in vaccination cards). These were mentioned by several interviewees as missed opportunities for EPI.

There was no change reported in outreach activities or the co-delivery of other services alongside immunisation, once the campaign had been completed.

Demand & Acceptance
High demand for the MenA vaccine was universally reported. Negative rumours about the new vaccine emerged in two regions but these were quickly curbed thanks to rapidly organised community meetings. No facility reported changes in the refusals of other vaccines once the campaign had been completed.

The social mobilisation around the MenA vaccine introduction was very high profile, notably in phases 1 and 2. In phase one, an innovative community mobilisation strategy was designed, with strong involvement of local leaders and journalists. Information collected during this exercise was said to have allowed a better understanding of communication aspects of vaccination and was used to strengthen EPI communication strategies.

Interviewees were very positive about the advocacy and social mobilisation efforts. However facilities reported that the communication primarily focused on the new vaccine and the disease it was preventing.

**Health Workforce**

*Availability/Distribution of staff*

As in other campaign additional staff were mobilised for the duration of the campaign including volunteers, medical and nursing students, and unemployed staff. Once the campaign was over, the use of additional staff was discontinued. During the campaign, the level of staff dedicated to outreach activities increased, allowing access to areas with traditionally few contacts with health services.

Because of the high number of campaigns implemented in recent years, the vaccination campaign was generally viewed as a routine activity, although it imposed an increased temporary workload. Workload during the campaign was reported to be high, particularly for supervisory and management positions. The vast majority of facilities reported that workload was higher than usual, with the exception of facilities supported by MSF. It was mentioned in particular that the workload impact was substantial in remote regions.

*Training and capacity of staff*

All facilities reported that there was training, lasting 5 to 6 days for the head doctor and usually a few hours for other facility staff, immediately prior to introduction. Facility staff and interviewees at all levels were very positive about the training.

The training was considered a general refresher of EPI and immunisation. Some interviewees explained that there were usually few opportunities for EPI-specific training. They commented that particular emphasis was laid on the management of AEFI as well as waste management, surveillance and social mobilisation. Some noted that this would improve the implementation of other campaigns.

A large majority of facilities reported that the training was primarily focused on the new vaccine but all reported that it helped strengthen their EPI related skills.
Most district-level interviewees and facilities felt that the training had not affected the usual facility services offered. However, some conceded that the absence of the head doctor for several days had led in some cases to the cancellation of outpatient activities.

**Remuneration & Satisfaction**

Interviewees generally felt that the introduction had motivated staff, either through the outcome of reduced child morbidity and mortality, or because the campaign was associated with the payment of a per diem. In some districts the per diem was below expectations and interviewees reported a lack of motivation during the campaign.

**Performance & Supervision**

There were campaign related supervisions which focused essentially on monitoring campaign performance and results. However in some cases supervisory visits were reported to be used for feedback on other vaccination or health services issues (eg. in remote regions).

Most participants felt there had not been changes to supervision following introduction (apart from additional supervision focused on (Event Following Immunisation (AEFI) monitoring). However one district official conceded that the high number of campaigns meant that routine supervisory visits had often to be suspended or postponed.

**Information**

**Routine Data Collection, Reporting & Use of Data for Decision Making**

The MenA campaign had no reported effect on the routine information system. Data collection during the campaign was conducted on a daily basis and exclusively focused on MenA results (coverage, stocks). A dedicated card that was provided to vaccinees was printed but leftovers were used in subsequent campaigns (eg. measles). Most interviewees said that the campaign did not result in a change in completeness and timeliness of other reported routine data.

**Surveillance**

The introduction had a positive effect on the surveillance system, both in terms of disease surveillance and surveillance of AEFI.

The introduction of case-based surveillance for meningitis in 2010 provided information on other infections than MenA (eg W135, Hib, and Pneumococcus) which was felt to be positive. An improved and more systematic notification of meningitis was also mentioned, thus contributing to strengthening the surveillance system. Capacity was strengthened notably at district level where staff had been trained to conduct lumbar punctures, and also in laboratories.
A majority of interviewees felt that the introduction of the MenA vaccine had strengthened AEFI surveillance capacity, notably through the re-energization and consolidation of the post-marketing surveillance national and sub-national committees. It was mentioned that the national Committee would now be used for other vaccines and drugs. Staff involved in special surveillance studies of AEFI also mentioned improved skills.

Although facility health workers reported a better understanding of AEFI reporting processes, national and regional interviewees commented that there had not been any significant change in the passive reporting of AEFI for other vaccines than MenA.

**Supply Management**

*Forecasting*

There was no identified impact on forecasting.

*Procurement and stock management*

Only rare stock-outs of the MenA vaccines were reported during the campaign and when these happened, they were solved quickly. No interviewee reported stock-outs of other routine vaccines during the campaign. The fact that routine vaccination was not conducted in a large majority of facilities may explain why cold chain capacity during the campaign did not appear to be a problem. When stock-outs were reported for EPI vaccines, they were not attributed to the MenA campaign.

At sub-national level, no change was reported in the ordering of vaccines - before or during the campaign. However, 4/18 facilities reported that they had reduced or cancelled vaccine orders during the campaign.

**Cold Chain Management, Logistics & Waste Disposal**

The cold chain was strengthened in 4 regions in 2010 in the run-up to new vaccines introduction (MenA and PCV-13) with support of JICA. There was no reinforcement of the cold chain in phase 2 but in phase 3, four additional vaccine carriers were provided to all 1,050 health facilities as well as 5 vaccine carriers for each district. This additional cold chain equipment was financed by the Government. In addition in phase 3, two new cold rooms were installed at national level. Finally MSF donated a 9m3 cold chain to the national EPI programme and 5 new incinerators in one district in which they carried out the campaign. Some interviewees mentioned that the new vaccine carriers had been already used in other vaccination campaigns.

Overall cold chain capacity was deemed sufficient to handle the campaign. This was explained by a discontinuation of routine vaccination, existing sufficient capacity, the temporary relocation of routine vaccine in other places (regional and district level,
other facilities), the use of the veterinarian cold chain capacity, and the provision of temporary cold chain capacity by MSF.

Limited changes to the waste disposal system were reported during the campaigns with two incinerators per district which were set up or rehabilitated in phase two. Interviewees noted that all waste had been disposed of using existing equipment although in one case it had taken over a month to complete the work.

Strengthening of waste management skills was often mentioned by interviewees as a positive outcome of the campaign.

**Financing & Sustainability**

*Affordability*

Views on affordability varied. Overall, interviewees commented that the funds needed to conduct the three phases of the MenA campaign were raised within the expected timeframe, despite an initial gap in funding in the run-up to phase 3 of the campaign. This gap was closed with additional funds from the Canadian development aid programme ($1 million). However a few interviewees noted that the introduction of two new vaccines in the same year may have had some impact on the funding available for the overall programme.

It was felt by a majority of interviewees and facilities that the funds planned for the implementation of the campaign were sufficient to cover its costs. Only a few interviewees noted that additional funds drawn from the routine budget were used to pay for transport, fuel and communication costs and in one district to supplement the level of per diem. A few facilities (5/18) reported that routine operational funds had been used for purchasing fuel, communication and small equipment.

*Domestic Resource Allocation*

Mali introduced both MenA and PCV-13 in 2011, resulting in significant additional costs for the Government. The domestic contribution for the MenA campaign out of a total cost of $9.3 million was reported to be $600,000 (300 million FCFA), excluding shared costs. No informant reported that money for the MenA campaign had diverted funding from other activities. However some noted that it was easier to mobilise funds for vaccination than other health activities.

Interviewees at district level and some facilities reported the cancellation or reduction in routine activities during the campaign had in some cases caused a reduction in fee-for-service revenues. They commented that this was not specific to the MenA campaign but made worse by the high number of vaccination campaigns in recent years. Interviewees said that there was a need for the state to financially support health care facilities which could not raise sufficient revenues from fees.

In terms of financial processes, it was reported that the disbursement of funds for communication and social mobilisation activities in phase 2 of the campaign had
been more efficient than in other vaccination campaigns (eg polio) and had permitted these activities to take place in a more timely and effective manner.

**External Financing**

Additional funding was mobilised by several donors to finance the campaign. $1 million (472 million FCFA) was provided by Canada to the Government of Mali through targeted budget support. It was confirmed that these funds were additional to the regular Canadian contribution to budget support.

**Leadership & Governance**

*Health & Regulatory Policies*

Interviewees commented that some regulatory norms and standards had been updated in preparation of the introduction of MenA. These included standards on surveillance of AEFI, such as guidelines and training modules. The MenA introduction was used as an opportunity to re-activate the national and sub-national committee on AEFI that had not been previously operational. It was noted that the committee was planned to be used for future vaccine introductions such as for the forthcoming rotavirus vaccine and post-marketing surveillance of other medical products.

Because of time pressure, the MenA vaccine did not go through regular regulatory process (licensure approval) and was authorized with a letter from the Ministry of health. This was considered a negative consequence by the regulatory agency.

*Political Commitment*

Interviewees commented on the uniqueness and the innovative character of the collaboration that underpinned the introduction of the MenA vaccine, including the critical role of the WHO. They also noted that the Government had been very committed to delivering the introduction.

*Organization, Structure, Reform, Negotiation, Stewardship*

Although the ICC met more frequently in the run-up to the introduction of the new vaccines, this did not have any reported effect on its organisation or effectiveness. The steering group overseeing the MenA introduction was wider in terms of its membership than for other vaccination campaigns and this was felt to have been positive.

New collaborations were established or strengthened during the preparatory phases of the MenA introduction. These involved increased fruitful collaboration between the Centre for Social Mobilisation and the Centre for Vaccine Development. This collaboration led to a better understanding and the use of a more evidence based communication strategy, during and after the MenA campaign. Other new
collaborations also involved the set up of multi-disciplinary teams in hospital surveillance studies.

Collaboration with various partners including the Ministry of Education also improved the understanding of the emergence of rumours against vaccines. Collaboration between health services and local NGOs was felt to be positive, but did not really differ from other campaigns.

Planning for the MenA campaign followed a similar pathway than for other campaigns, although there was more involvement of the WHO than for other campaigns. There was also more emphasis on specific issues such as planning for AEFI surveillance and waste management. Planning activities related to MenA were reported by some interviewees to have in some cases displaced other activities at national and regional levels.

There was no involvement of other services of the MoH in the planning for the MenA campaign and no discussion on the possible combination of other services with the MenA vaccine. This was felt to be a missed opportunity by several interviewees in charge of maternal and child health interventions.

Conclusion

There were many positive effects of the new vaccine on the various building blocks of the health systems, notably governance and collaboration, communication and social mobilisation, surveillance, and the strengthening of skills, in particular EPI skills, such as AEFI surveillance and waste management. Furthermore a widely perceived positive effect was the reduction of disease, and recognition that equity had been improved at population level. This also improved service planning and freeing up of resources, as previously costly and disruptive outbreak responses could potentially be avoided.

Negative effects identified involved the discontinuation or sharp reduction in routine vaccination services and to a lesser extent the reduction of other health services availability during the 10 days of the campaign. Although it was noted that these effects were short term as they lasted the duration of the campaign, interviewees stressed that the repetition of vaccination campaigns had an adverse effect on the availability and credibility of routine health services.

Overall the impact of the new vaccine was stronger on the vaccination programme than on the wider health systems.