Introduction of PCV-10 in Ethiopia: Effects on the health system

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Abstract

Background: Pneumonia is a leading cause of death for children under the age of five in Ethiopia. An important tool in the fight against the disease, the pneumococcal-conjugate vaccine (PCV-10), was introduced into the routine immunisation schedule in 2011. This study, which was part of a larger, six-country research project, aimed to understand the effects of the introduction on the Expanded Programme for Immunisation (EPI) and the wider health system.

Methods: Our study design and analysis were based on the World Health Organisation's health systems building blocks theoretical framework. A mixed-methods approach was used. Twenty-three key semi-structured interviews were carried out at the national, regional and district levels and questionnaires were completed by staff at 26 health facilities. Data on routine service activity were collected at 25 facilities.

Results: There were minor or no effects to the majority of components of the health system. Positive effects were seen in training and capacity-building, an increase in health worker motivation, as well as in improved collaborations between government actors and greater political commitment towards the immunisation programme. Negative effects were found in increased workload for health facility staff, both immediately after introduction and in the medium-term. Mixed effects were found on data collection and reporting, adverse effect following immunisation (AEFI) surveillance, cold chain management and financing.

Conclusion: Our study found that PCV-10 integrated smoothly into the EPI and the wider health system. However, questions remain about longer-term capacities and limits of the programme. [*Ethiop. J. Health Dev.* 2015; Special Issue 1:08-16]

Introduction

The pneumococcal-conjugate vaccine (PCV) has been proven to be an important tool in the fight against pneumonia (1), a disease that kills over half a million children in sub-Saharan Africa each year (2). Ethiopia, where pneumonia is one of the leading causes of death for children under the age of five (3), introduced PCV-10 (which protects against ten serotypes of the bacteria). The vaccine, which is financially supported by the GAVI Alliance, was added to the Expanded Programme for Immunisations (EPI) in its routine vaccination schedule.

Although the epidemiological consequences of introducing the vaccine in a country with high incidence of pneumonia among children, such as Ethiopia, are likely to be positive, questions remain about the effects of the introduction of new vaccines on the health system. Some studies have looked at health systems effects of other vertical disease control programmes (4-6), but limited evidence exists on routine vaccine introductions so far. A recent literature review found that health system impacts were rarely the main focus of vaccine-related studies and existing evidence focuses largely on high-income countries (7). In low- and middle-income countries, the majority of studies have focused on operational issues, particularly as part of post introduction evaluations (PIE) (8).

Beyond the effects that a new vaccine introduction can have on health systems in low-income settings, the introduction of PCV-10 in Ethiopia poses important questions. Although the country's health systems have been strengthened in recent decades (9-10), Ethiopia faces considerable challenges with regard to human resources for health. With large remote areas and pastoral populations, vaccination coverage in some regions remains dismally low (11).

PCV-10 was introduced in November 2011 throughout the country. The vaccine is delivered to children at 6, 10 and 14 weeks of age alongside two other antigens: the DPT-HepB-Hib (or 'pentavalent') vaccine and the oral polio vaccine (OPV) (12). An initial catch-up strategy to vaccinate all children under the age of one, irrespective of their pentavalent vaccination status, was implemented.

The aim of this study was therefore to evaluate the impact of the PCV-10 introduction on the Expanded Program on Immunisation (EPI) and on the broader health systems in Ethiopia. This study was part of a six-country research project looking at the effect of the introduction of new vaccines on EPIs and health systems in Africa and Latin America (13).

Methods

The study design and analysis were carried out using the World Health Organisation (WHO) health systems building blocks framework (see Figure 1) (14). The WHO building blocks were sub-divided into vaccination-specific components (see Table 1) (15).

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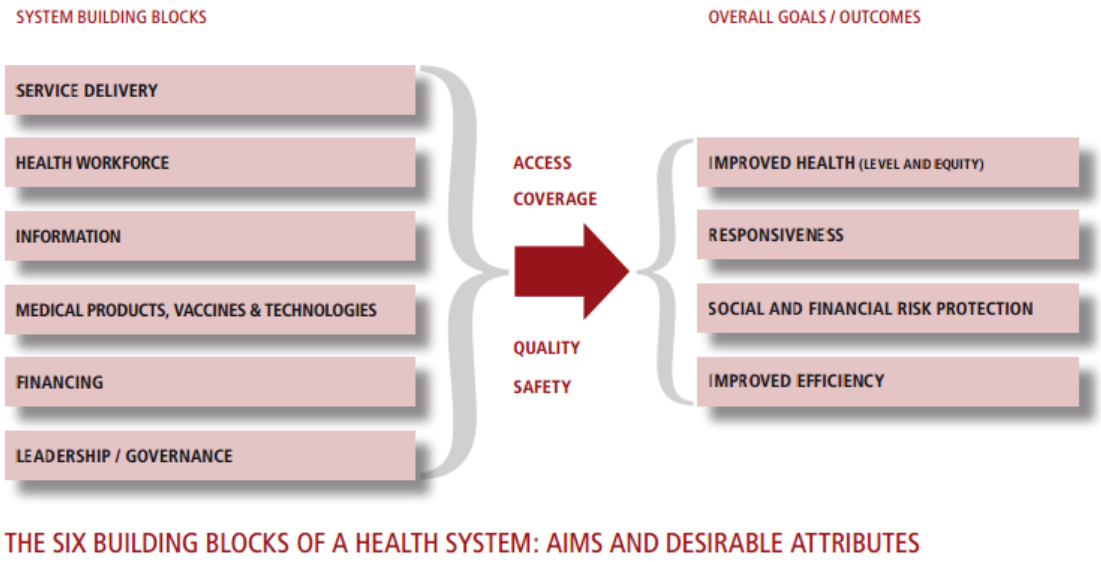

Figure 1: **The WHO health system building blocks framework (14)**

Table 1: **Study framework for assessing the health systems impact of new vaccine introductions**

Health system building block	Vaccination-specific components
Service delivery	▪ Access and utilisation ▪ Delivery modalities ▪ Demand and acceptance ▪ Quality of care
Health workforce	▪ Availability and distribution of staff ▪ Training and capacity of staff ▪ Remuneration and satisfaction ▪ Performance and supervision
Health information system	▪ Routine data collection and reporting ▪ Disease surveillance
Medical products, vaccines and technologies	▪ Forecasting of vaccines and injection supplies ▪ Procurement and stock management ▪ Cold chain management and waste disposal
Financing and sustainability	▪ Affordability ▪ Domestic financing ▪ External financing
Leadership/governance	▪ Regulatory policy ▪ Political commitment ▪ Organisation, structure, reform, negotiation, stewardship

Site Locations:

Three regional states (Oromia, Amhara and Afar) and one city administration (Addis Ababa) were selected for the study. These four areas were chosen to reflect urban, rural and pastoral disparities in different geographical settings, as well as a range of vaccination coverage rates, from 47% coverage of the third dose of the diphtheria-tetanus-pertussis vaccine (DTP3) in Afar to 84% in Addis Ababa (11). In each regional state and in Addis Ababa, three districts (or sub-cities) were purposely chosen to reflect a range of vaccination coverage rates, as well as varying profiles of urbanisation. In Afar, a pastoralist area, only two districts were chosen due to distance and safety concerns.

A total of 26 health facilities were selected across the 11 districts. Two to three health facilities were chosen per district, except for a remote district in Afar where only one facility was selected as explained above (see Table 2). A wide range of types of facilities were sampled: public and private; hospitals, health centres and health posts.

Table 2: **Health facilities included in survey according to *district***

Region	*District/Sub-city*	Number of facilities
	EluGelan	3
Oromia	Dendi	3
	Ambo	3
	Hageremariam	3
Amhara	Antsokiya	2
	DebreBerham	3
	Addis Ketema	2
Addis Ababa	Kirkos	2
	Lideta	2
	Asayta	2
Afar	Logia	1
Total		**26**

Data Collection:

Data were collected at national, regional and district levels from the providers' perspective using three methods: 1) semi-structured interviews with key informants at the national, regional and district levels; 2) researcher-administered questionnaires with health facility staff; and 3) routine patient data collection at the district and health facility levels.

A total of 23 key informants were interviewed at national, regional and district level (Table 3). At the national level, five interviewees were from the Ministry of Health, two from United Nations agencies, and one from a non-governmental organisation. In the regions, health bureau heads were interviewed. In the districts, the heads of health offices or, alternatively, staff responsible for vaccination services, were interviewed. At the facility-level, one staff member directly involved in vaccination responded to the researcher-administer questionnaire. Of the 26 who participated, 17 were nurses, 7 health extension workers and 2 health officers. Monthly routine data were collected on the number of children vaccinated with PCV-10 and pentavalent vaccine. Data were collected for ten of the 11 districts visited (one district's data were unavailable at the time of visit).

Ethical Considerations:

Ethical approval was obtained from the London School of Hygiene and Topical Medicine and the Ethical Review Committee of the Ethiopian Public Health Association.

Table 3: **Number of interviewees at each level of the health system**

Level	Number of people interviewed
National	8
Amhara Region	1
Hagere Mariam	1
Antsokiya	1
Debre Berhan	1
Oromia Region	1
Elu Gelan	1
Dendi	1
Ambo	1
Addis Ababa Region	1
Addis Ketema Sub-city	2
Kirkos Sub-city	1
Lideta Sub-city	1
Afar Region	1
Asayta	1
Total	**23**

Prior to data collection, the research project was described to all interviewees and facility respondents, information sheets on the project were distributed and questions were answered. Written consent was obtained from all interviewees and facility respondents. Data collection teams were fluent in English and Amharic, as well as in pertinent regional languages (such as Oromifa). Key informants and respondents were asked in which language they preferred to be interviewed. Data were collected in December 2012, 13 months after the introduction of PCV-10.

The semi-structured interviews with key informants were recorded, transcribed and, when necessary, translated. When key informants preferred to not have their interviews recorded, notes were taken and typed soon after. A coding outline was developed based on the WHO health system building blocks framework. Transcripts were coded using the software 'Open Code' (16). Data from the health facility questionnaires and the routine data were analysed in SPSS. Segmented regression analysis was conducted on the health facility and district level routine data.

Results

PCV-10 was generally well integrated into EPI. No or minor effect were reported for most health systems components. Negative effects were only reported in terms of staff workload (see Table 4).

Table 4: **Summary of effects of PCV-10 introduction per health system building block and component.**

Health System Building Block	Positive effect	Negative effect	No or minor effect	Mixed effect
Service delivery			-Access and utilisation -Delivery modalities -Demand and acceptance -Quality of care	
Health workforce	-Training and capacity of staff -Remuneration and satisfaction	-Availability and distribution of staff	-Performance and supervision	
Health information system				-Routine data collection and reporting -Surveillance system
Medical products, vaccines and technologies			-Forecasting, procurement and stock management	-Cold chain management and waste disposal
Financing and sustainability			-Affordability -Domestic Financing	-External Financing
Leadership/governance	-Organisation, structure, reform, negotiation, stewardship		-Regulatory policy -Political Commitment	

Positive Effects:

Training and capacity of staff: Many key informants and a majority of facility respondents (18/26) stated that training helped refresh their general knowledge about EPI and strengthen particular skills such as injection safety, vaccination schedule, cold chain and waste management. Training guidelines printed and distributed in preparation for the PCV-10 introduction also covered broader topics such as pneumonia prevention techniques. No major interruptions to regular services were reported as a result of training activities.

In terms of disease control strategy, a national integrated management of childhood illnesses (IMCI) training of health workers and Health Extension Workers (HEWs) was reported to have been carried out a few months before the PCV-10 introduction. Although the training did not explicitly cover PCV-10, it did cover issues related to respiratory illness prevention, such as exclusive breastfeeding and hand washing. According to relevant key informants at the national level, since the PCV-10 introduction there was more collaboration between EPI and IMCI staff. It was noted that the IMCI training manual, which was updated a year prior to the PCV-10 introduction, contained information about PCV-10.

Remuneration and satisfaction: Several key informants mentioned that participating in the introduction of the vaccine gave healthcare staff a boost in morale because respiratory illness is among the most common causes of death for children under the age of five.

> *"They were not only motivated, but were also happy and satisfied to give this vaccine — but they didn't like the workload."* [E_6, District level interviewee]

Organization, structure, reform, negotiation, stewardship: There was a strong political commitment to support the new vaccine introduction. The Inter-agency Coordinating Committee (ICC), convened by the state minister, as well as a technical ICC led by the Health Promotion and Disease Prevention Directorate participated in the planning of the introduction.

Members from the Ministry of Health, such as the Maternal and Child Health (MCH) department, Health Management Information System, Pharmaceutical Funds and Supply Agency and the IMCI programme, were involved, as well as representatives from other government departments, such as the Ministry of Finance, partners including UN agencies (WHO and UNICEF) and non-governmental organisations such as CORE group. Several interviewees stated that the process of working together within the technical ICC strengthened relations between different actors.

The technical ICC's working groups oversaw components of the introduction process such as cold chain logistics, sensitisation and information systems. Some respondents felt these subcommittees were so effective that at one point during the PCV-10 introduction planning process it was proposed that all immunisation activities be brought under their remit. Regions also had their own working groups which met regularly. There were some reports that taskforces were also established for the introduction of PCV-10 in at least one district., Even after the introduction period passed, these remained in place in order to support routine EPI activities as well as the Enhanced Outreach Strategy. Some stated that the PCV-10 introduction planning process was seen as an example to follow by taskforces planning other interventions.

> *"Political commitment was provided by the government and as a result resources were allocated and health professionals also provided the attention, strong attention, to the introduction of the vaccine. That is why [the introduction] was successfully conducted."* [E_22, National level interviewee]

No or Minor Effects:

Access and utilisation: Key informants at the regional and district levels, as well as a majority of health facility staff (16/26) stated that the PCV-10 introduction had led to an increase in demand for other vaccines. However, segmented regression analysis (n=24 facilities) showed that the introduction of the PCV-10 vaccine had no impact on the number of children vaccinated with the pentavalent vaccine (see Figure 2).

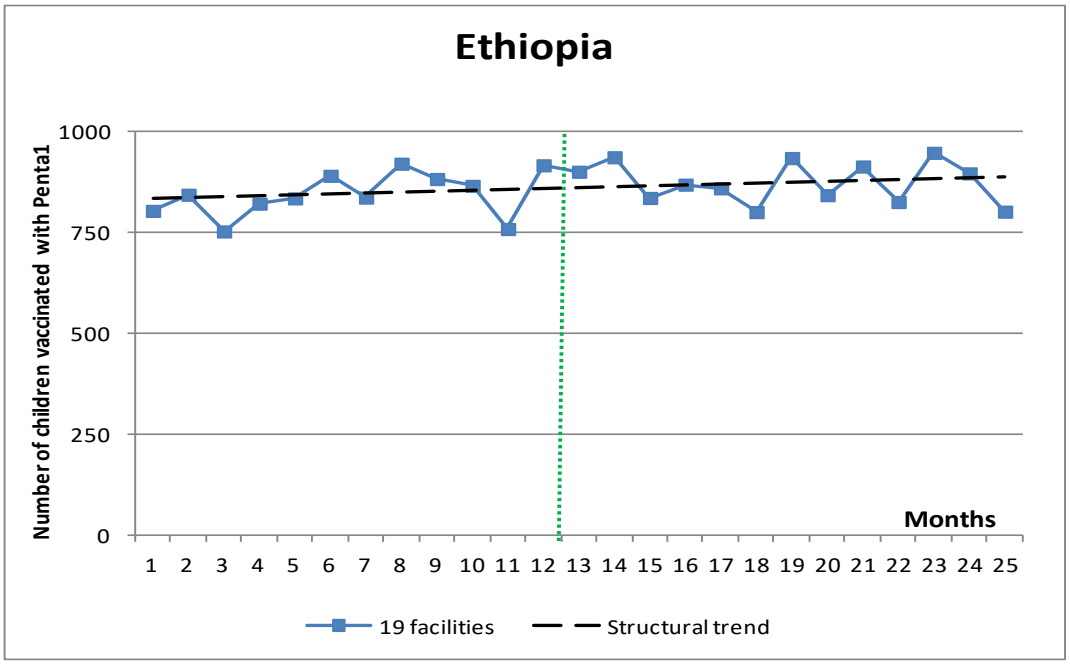

Figure 2: **Monthly number of children vaccinated in Ethiopia before and after the introduction of PCV-10**

	Co-efficient	Standard Error	P-value
Constant β_0	805.30***	24.50	0.000
Secular trend β_1	5.99**	3.34	0.088
Change in level β_2	-2.07	33.37	0.951
Change in trend β_3	-5.15	4.63	0.279

Note: ***P<0.001, **P<0.05, *P<0.01

Delivery modalities: No changes were reported to frequency or duration of routine and outreach vaccination sessions, or to co-delivery of other interventions. A small minority (5/26) of health facility staff reported a decrease in demand for curative services.

Demand and acceptance: Although by most accounts social mobilisation efforts for PCV-10 were highly visible, they tended to focus almost entirely on the new antigen instead of on general EPI topics. Some key informants stated that the high visibility of the introduction contributed to increased visibility of EPI in general. No major resistance to the vaccine was noted by key informants or facility respondents, although there were some reports about mothers not wanting their children to be injected twice in one day (PCV-10 and pentavalent vaccine).

> *"It was good because pneumonia is a well-known disease. The society was really happy. They have known it for a very long time because they saw it practically when their children got infected... [The vaccine] has strengthened the programme to some extent. It also created awareness on both the community and the health extension [workers]. As a result, it has helped us in tracing defaulters and we hope to decrease child mortality."* [E_12, Regional level interviewee]

Quality of care: Key informants reported no changes in injection safety practices. Only 8/26 facility respondents stated making changes to their injection safety practices following the introduction of PCV.

Performance and supervision: The frequency and the integrated nature of supervision did not change following the introduction of the PCV-10 according to most key informants and facility respondents.

Forecasting, procurement and stock management: According to most key informants and respondents, the procurement mechanisms for PCV-10 were the same ones followed for other vaccines. No substantial alterations in frequency or method of procurement were reported as a result of the introduction; only 2/26 of facility respondents reported changes. No stock-outs of other vaccines were reported as a result of the vaccine introduction at any level of the health system. Some difficulties in stock management of PCV-10 were reported at regional level due to an unexpectedly high demand and miscalculation of the number of children in the vaccination catch-up age range. Some key informants said that this led to an increase in buffer stock of the new vaccine from 10% to 25% in one of the regions. However, this increase did not affect cold chain and storage capacity for other vaccines.

Regulatory policy: No changes were reported.

Affordability: Most key informants agreed that a budget
was made available for the purposes of training and social mobilisation. A minority of key informants reported temporary increases in operational costs, mostly to do with transportation costs, which were absorbed by the regional authorities. No substantial changes in revenue caused indirectly (e.g. by increased update of other services) were reported by key informants or by the majority of facility respondents (24/26).

Domestic Financing: No trade-offs in domestic finance were reported to accommodate the financing of the new vaccine introduction.

Political Commitment: Key informants stated that the PCV-10 introduction enjoyed strong support from members of the Ministry of Health because it was thought that it would support routine immunisation activities. Given that pneumonia was one of the top causes of death for children under the age of five, the introduction of PCV-10 was seen as a way to substantially reduce the rate of infant mortality.

Negative Effects:

Availability and distribution of staff: Several key informants, as well as a sizeable number of facility respondents (12/26) including nearly all of those in Oromia, felt that workload had increased during the month following the introduction of PCV-10. Five of them felt the increased workload continued a month after introduction. Some key informants attributed the increases in workload to the time spent on catch-up activities (finding children within the eligible age range but who had already received the three doses of the pentavalent vaccine). Workload was also said to have increased for the Health Development Army, a group of female community volunteers who act as health champions in their community and work closely with health facilities. Other than a national coordinator, no key informants or respondents reported new hires relating to the new vaccine. However, many key informants stated that some staff normally working in other activities (such as antenatal care and maternal and child health) were temporarily assigned EPI duties to help in the introduction effort. The shift in duties was said to last between a few days and a few months.

> *"When there [is] much workload there is a system where we bring additional staff from other services to cover the gap for the time being ... For the first three months the workload was intensive."* [E_6, District level interviewee]

Mixed Effects:

Routine data collection and reporting: Registries, vaccination cards, tally sheets and other documents were updated in preparation for the introduction. However, many key informants and facility respondents stated that distribution of data collection tools were often greatly delayed or altogether absent. This led to some districts having to print forms using their own budget, or having to manually introduce extra columns to the existing formats. A large number of key informants and facility respondents (14/26 in reference to the vaccine register, and 13/26 to vaccination cards) reported increases in the time needed to fill out data collection forms. However, some key informants felt that the accuracy of data reported had improved as a result of the training that took place prior to introduction.

Surveillance system: No changes to disease surveillance or laboratory capacity were reported as a result of the introduction of the PCV-10 vaccine. However, there was a discrepancy in perceptions about the effects of the introduction on AEFI surveillance. Key informants stated that improvements to AEFI surveillance were carried out as a result of the introduction, particularly given that PCV-10 is preservative-free. Four active surveillance sites (where every vaccinated child would be monitored 24 and 72 hours after vaccination) were said to have been set up for a year to monitor adverse effects in different parts of the country. Key informants added that the PCV-10 introduction gave a boost of energy to the AEFI surveillance system that had been described as previously nearly non-existent. However, the facility respondents largely did not feel that the AEFI surveillance system had been strengthened; the majority of them (15/26) reported not having any operational guidance for monitoring and reporting AEFIs.

Cold chain management and waste disposal: Perceptions about changes in cold chain management were varied. Some key informants stated that cold chain capacity was increased in preparation for both the PCV-10 introduction, as well as for the rotavirus vaccine introduction, planned for 2013. Others stated not having received additional cold chain support, which led to difficulties with reduced space capacity. A minority of facility respondents (6/26) reported having received additional cold chain capacity in preparation for the new vaccine introduction. No changes to waste disposal methods or capacity were reported.

External Financing: According to a key informant at the national level, the Ethiopian government paid USD 0.20 for each dose of the vaccine, which totalled about USD 2.1 million per year. The GAVI Alliance provided the remaining USD 7 to pay for each dose of the vaccine. Generally, informants stated that the decision to co-finance the PCV-10 vaccine was appropriate given that pneumonia was one of the main causes of death for children under the age of five. Several highlighted the importance of government co-financing the vaccine as a way to create a sense of national ownership. Informants linked this sense of ownership to a better and more careful management of the vaccine at all levels. According to the 2011-2015 country Multi-Year Plan for immunisations, the total cost of the PCV-10 and rotavirus vaccines for the 5-year period was USD 414 million, which was nearly two-thirds of the expected costs of routine vaccination (11). However, some key informants expressed concern about issues of long-term financial sustainability of new vaccine introductions.

"Financing creates a sense of ownership. So this kind of [co-]financing is very important to create a continued support. Mainly receiving from others will not create a sense of ownership. If you provide something, even though it's very little, it will give a sense of ownership. It will improve the handling of the vaccine. So that is important." [E_15, National level interviewee]

Discussion

This study found that there were limited effects to the EPI and wider health system from the introduction of PCV-10. For most components of the health system, the introduction was carried out with no or minor effects. Some positive effects, particularly in the areas of training, worker satisfaction and higher-level planning were found.

Negative effects from the PCV-10 introduction were only found in relation to staff workload. For some respondents the increased workload was felt only in the short-term; for others it lasted for over a month following the introduction. Although limited, these negatives effects should be examined further, particularly as some evidence suggests that the mean time of immunising a child in Ethiopia may be longer than in other countries (17). The crisis in human resources for health has been widely debated in academic and policy spheres for the last decade (18, 19). Although low-income countries like Ethiopia have broadened the health staff base through the training HEWs (34,000 by 2010) reservations remain about their knowledge and performance (20, 21). It is in light of these challenges that greater attention needs to be paid to increases in staff workload following introduction of new services, with closer study through observational methods in order to better understand the great gaps in MCH services (17, 22).

The findings regarding AEFIs show the strengths of carrying out research simultaneously across all levels of the health system. Whereas key informants at the national level stated that the introduction of the preservative-free PCV-10 gave a much-needed boost to AEFI monitoring, facility respondents largely did not feel that AEFI monitoring had improved and stated that they had not received guidance for monitoring and reporting AEFIs. Examining both bottom-up and top-down approaches provides a richer understanding of implementation failure.

One of the more significant findings from this study was the increased collaboration between EPI and the IMCI programme relating to the introduction of PCV-10, particularly around prevention of respiratory illness activities such as exclusive breastfeeding and hand washing. Given the multi-pronged approach needed for pneumonia prevention, as stipulated in the Global Action Plan for the Prevention and Control of Pneumonia (23), this is an encouraging finding and one that was not observed in other countries in our larger study on introducing PCV (13).

This study suggests that the effects of the PCV-10 introduction in Ethiopia had no or minor effects on most health system components. However, a larger question about longer-term EPI and health system capacities and limits (particularly on already weak components such as data collection and reporting) goes unanswered, which is particularly relevant if the pace of GAVI-funded introduction increases in the coming years. Further research to better understand possible breaking points within EPI and across the health system at large is needed.

Limitations:

Although great effort was devoted to sampling a wide range of districts and health facilities, the sample chosen is small and may not be representative of the country at large. Remoteness and safety concerns prevented the research team from accessing certain areas. Routine data was incomplete or lacking in some of the facilities sampled. Due to a generally positive perception about the impacts of vaccines on children's health, health facility workers may not have reported negative effects (due to conscious or unconscious acquiescence bias). As in other retrospective studies, recall bias may have affected some health facility workers' responses. Furthermore, it is important to acknowledge that this study used a provider-focused health systems definition. A key missing element is therefore the users' perspective. Exploring changes to user perceptions, satisfaction and confidence in the health system following the introduction of new services is an important area of research that requires further work.

Conclusion:

The PCV-10 vaccine was generally well-integrated into the EPI. There was little or no impact in most components of the health system. Positive effects were seen on training, worker satisfaction and higher-level planning. Negative effects on health facility workers' workload, particularly those that continue after the introduction period, should be studied more closely.

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