New vaccine adoption and decision making in Ethiopia: Qualitative study of national decision-making processes for the introduction of PCV 10

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Abstract

Background: Although vaccines are proven to protect communities from infectious disease, in countries with several competing health problems prioritizing health interventions is important. This study assessed the decision-making process in adopting new vaccines -specifically pneumococcal conjugate vaccine (PCV 10) in Ethiopia.

Methods: We conducted in-depth interviews with 16 purposively selected key informants in Addis Ababa. Informants from Ministry of Health, Ministry of Finance, UN agencies, bilateral organizations, civic societies, universities and professional associations participated in the study. A team of researchers, two from Ethiopia and one from the London School of Hygiene and Tropical Medicine, conducted the interviews.

Findings: Few actors were involved in the decision-making process, with the then Minister, a former GAVI board member, playing a key role. Availability of GAVI funding was the most prominent cue to action although discussion about pneumococcal vaccines preceded the GAVI invitation for funding applications. The political prioritization of immunization and a desire to meet MDG 4 (reducing child mortality) were other key drivers of the decision.

The role of the Ministry of Finance was minimal although the government was committed to allocate a cost sharing approach, as requested by GAVI.

Conclusion: The decision-making process was dominated by only few actors at a central level and was mostly politically driven by the availability of GAVI funding. Though small, cost-sharing indicates the commitment of the government. The involvement of the Ministry of Finance should be encouraged for the sustainability of the program as more new vaccines are introduced into the health system. [*Ethiop. J. Health Dev.*2015; Special Issue 1:17-22]

Introduction

There is an increased interest in decreasing child mortality as stated in the Millennium Development Goals, among which MDG4 aims at decreasing child mortality by 2/3 between 1990 and 2015 (1). This has motivated countries and relevant international agencies to study the most important illnesses that cause child morbidity and mortality. A study assessing the epidemiology and aetiology of childhood pneumonia indicated that pneumonia is one of the major causes of under-five child mortality and morbidity worldwide with more than 95% of the burden concentrated in developing countries (2). To offset this, new and advanced vaccines are being developed and their introduction is promoted by international stakeholders, because vaccines are known to decrease the burden of infectious diseases (3,4). Consequently, many countries are adopting new vaccines (5).

Ethiopia started the extended program of immunisation (EPI) against six communicable diseases (Diphtheria, Pertussis, Tetanus, TB, Polio and Measles) among children under the age of five in the early 1980s (6). In 2007, it introduced two additional vaccines: *haemophilus influenzae* type b (Hib) and hepatitis B (HepB), taking the number of antigens to eight. Information about the decision-making process in the introduction of new vaccines helps to understand why new vaccines are adopted or not (7, 8).

In countries where a number of competing health problems exists, it is common to set priorities. However, how these priorities are translated into decisions especially when it comes to introducing new vaccines has not been assessed in Ethiopia. This study investigated the decision-making process of the new pneumococcal conjugate vaccine PCV 10.

Methods

***Study Design*:**

The study was qualitative. Interviews were conducted with policy makers and partners at the national level (because sub-national levels were not involved in the decision making process).

***Study Area*:**

This study was part of a multi-country study which included both GAVI eligible and non-illegible countries (Bangladesh, Cameroon, Ethiopia, Guatemala, Kenya, Mali and South Africa). Ethiopia is a GAVI-eligible country with low immunisation coverage. We collected data at a central level in Addis Ababa. Addis Ababa is the capital city of Ethiopia where all ministries, one regional bureau (Ormiya Regional Bureau), UN agencies, bilateral organisations, NGOs and civic societies are located.

***Sampling and data collection*:** We purposively selected individuals who were involved in, or were knowledgeable about, the process of vaccine adoption

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decision-making. Interviewees included EPI officers, other relevant Ministry of Health staff, staff from the World Health Organisation (WHO), United Nation Children's Fund (UNICEF), academia, members of the Inter-Agency Coordinating Committee (ICC) and other key stakeholders. In total, 16 key informants were interviewed (Table -1).

Table-1: **Organization affiliation of individuals participated in the study, March 2011**

Informant	Organization affiliation
E001	Core group
E002	Ministry of Finance
E003	World Health Organization
E004	World Health Organization
E005	World Health Organization
E006	Ministry of Health
E007	Clinton Health Access Imitative
E008	Ministry of Health
E009	United nation Children's Fund
E010	United Nation Children's Fund
E011	Medical Faculty, Addis Ababa University
E012	(World Health Organization)
E013	(Integrated Family Health Program)
E014a	Oromiya Regional Health Bureau
E014b	Oromiya Regional Health Bureau
E015	The Ethiopian Paediatric Society

The interview topic guide was prepared by the London School of Hygiene and Tropical Medicine (LSHTM) and focused on questions regarding how the decision to adopt the new vaccines was made; who was involved; what were the drivers of decisions (e.g. disease burden, funding, political priority); programmatic considerations; acceptability, equity and access; financial considerations, and vaccine availability. Interviews focused on the recent decision to adopt PCV10.

Interviews were conducted between February and March 2011, by a team of researchers: one from LSHTM and two (School of Public Health Addis Ababa University and an independent consultant) from Ethiopia. Most interviews were conducted in English except one interview which was conducted in Amharic. All interviews were recorded and then transcribed. The Amharic transcript was then translated into English.

***Analysis and Interpretation*:**
Framework analysis was used to explore the data (9). An initial, broad coding framework was drawn up based on a preliminary assessment of the interview transcripts and a previously-developed decision-making framework (10) which was applied to the seven country study. A meeting was held at LSHTM in 2012 where collaborators from all study countries identified key issues arising from the data and further refined the coding framework. The revised framework was subsequently applied to the transcripts by charting and mapping the codes. We used 'Open Code' software for data analysis (11).

Ethical approval was obtained from the Ethiopian Public Health Association (EPHA) and from LSHTM. Prior to interviews, the aim of the study was explained and an information sheet provided for each informant. After discussing any questions or concerns, interviewees signed a consent form.

Findings
Timeline:
The decision to introduce PCV occurred after a detailed process, with initial discussions leading to a decision to apply for GAVI funding, followed by the completion of the GAVI application process.

Discussions around preventing pneumonia and about PCV developments began in 2007 in the ICC (interagency coordination committee). Several meetings were conducted within the ICC forum, after which the MOH expressed interest in introducing the new pneumococcal vaccine with GAVI's support in 2008. In 2009, a decision was taken to apply for GAVI funding. An application was submitted in September 2009 for a planned introduction the PCV vaccine in January 2010. However, the process became more protracted with GAVI Board approval for January 2010 later changed to January 2011, and finally introduced even latter in September 2011.

Some countries had already introduced PCV 7, but when Ethiopia applied, PCV 10 and 13 had become available. Then the discussion focused on the introduction of PCV 10 versus PCV 13. However, as there was a supply shortage of PCV 13, weighing up the advantages of the additional strains against the delay that choosing PCV13 would cause to the introduction, the decision to adopt PCV10 was taken. It was argued that more lives would be saved by introducing PCV10 vaccine earlier. An informant from WHO described the situation as follows:

> *"....At that time it was only PCV 7 and 10 that were available, and the country applied for the 10 valent vaccine. Well the 10 valent was more attractive because of the wider sero coverage ... At that point there was no offer about PCV 13 but of course the wish is that if you have wider vaccine that protects against more serotypes that would be the preferred option, but what was available was PCV 10 and PCV 7 and 10 was the more attractive option." (E003)*

Status of EPI:
The participants in this study indicated the EPI was one of the strongest programs run by the Ministry of Health (MOH) as a vertical program. In the Health Sector Development Program (HSDP) of the country, EPI was identified as one of the main strategies, under maternal and child health (MCH), employed to decrease child mortality and morbidity. Several different vaccination strategies are used by the government, including static (provided at health facilities), outreach (provided at a community level), mobile (services provided to the mobile population) and, at times, supplementary immunization activities (SIAs) for some antigens.

Different participants in this study indicated the strength of the program as follows:

> *"Yes, very strong. We have some very good coverages, for example.... by the third quarter of 2010, this is from HMIS of the government, we have about 89% coverage for DTP3 and measles about 84% coverage. So I mean relatively by other standards, it's very strong... I would say strong, yeah, [even] related [compared] to other countries." (E004)*

However, some participants indicated their concern that the attention to child health in general was being diluted as there was no focal person in the Ministry for MCH or EPI at the time of the study. This role has been replaced by directorates with a rural, pastoralist and urban focus rather than one oriented around programs. Professional associations were strong advocates of the EPI program as they promoted boosting immunisation coverage and also strengthening the EPI programme.

> *"We were also advocating about boosting the immunization coverage; we cannot just introduce vaccines over vaccines without obtaining a high coverage of immunizations. Whenever we introduce a new thing, we have to strengthen the existing …." (E015)*

Actors Involved:

Few actors were directly involved in decision-making of PCV 10 introduction in Ethiopia. Officials from the Ministry of Health, especially the then Minster (who had previously been a GAVI board member), played a central role. Apart from pneumococcal vaccine, the Minister insisted that the country apply to introduce the rotavirus vaccine earlier than the technical team had planned.

In Ethiopia, like many GAVI-eligible countries, no technical immunisation advisory committee was operational in the run-up to the decisions studied. Instead the ICC was responsible for the application process after several meetings. The WHO played an important role in providing information about future vaccine developments, technical support, financing surveillance and organising workshops to assist in the preparation of GAVI applications.

The role of the Ministry of Finance (MoF) in the decision to apply for GAVI funds, or the application process itself, was negligible.

Many actors were interested to assist the program as the introduction process progressed. One example was the Clinton Foundation which was providing technical assistance to facilitate the introduction, as mentioned by the informants.

The National Paediatric Society of Ethiopia played a major role as an advocate of the introduction of the vaccine. In consultation with the WHO, it had been providing training for civil society, university teachers and health professionals about the importance of vaccines and also on Mid-Level EPI management. In addition, they held a symposium to learn more about the new vaccines, inviting pharmaceutical giants like GSK and Pfizer to facilitate the introduction.

> *"….We continued to remind WHO and UNICEF about the new vaccine introduction frequently asking them when will be the new vaccine introduced and we also asked them to let us give trainings .... as a result, we trained university teachers, and professionals in order to make them ready for the new vaccine introduction...." (E015)*

Cues to Action:

Study participants indicated that discussions about the pneumococcal vaccine preceded the GAVI call. However, the GAVI call for application also played an important role in the introduction of pneumococcal vaccine in Ethiopia. Participants of this study indicated that there were a lot of instances to learn about the availability of the new vaccine from different sources, as indicated in the following selected quotes:

> "*We started talking about it in ICC meetings and we learned that some countries have already introduced PCV. For example, PCV7 was introduced in Rwanda and other countries.... based on this information we started to write an application and contacted GAVI and started to develop a proposal to introduce it in 2010." (E001,)*

> *"Scientific publications … like the Lancet are good sources of information ... if you come to my office you can get many of them, they inform us which vaccines are in which country and when ...(E004)*

International and national meetings (e.g. World Health Assemblies and WHO regional meetings) were often noted as key events, briefing country stakeholders about new vaccine developments and providing lobbying opportunities. Advocacy activities by international agencies such as the WHO played a key role in setting the agenda at country level and in supporting the decision-making process.

> *"I do not remember who exactly brought the agenda at ICC meetings ... it is someone from WHO or UNICEF; we were in international meeting ... I myself with the MoH officials attended the TFI meetings (Task force for Immunisation in Africa)...." (E001)*

The burden of disease was also mentioned as a cue to action for introduction by some. Though there were not comprehensive biomedical studies based on local surveillance data, assessment of the burden of disease in the country and health facility routine morbidity reports identified pneumonia as one of the major health problems in the country.

> *"The government was using records from health facilities and WHO sentinel sites and*

was trying to decrease the distress caused by pneumonia .... Even before the introduction of the vaccine the government allowed local health workers to treat pneumonia, and of course now we have the vaccine" (E003).

Procedures:
In Ethiopia, the requirements for GAVI funding applications led to more structured decision-making procedures. Before writing the application, there were several discussions (e.g. during ICC meetings) about the pneumococcal vaccine prior to the expression of interest in applying for funding. Among the participants of this study, those who participated in the GAVI application process reported that there were several consultative meetings while writing the application, which they believed also, helped to introduce them to the application process. This made the subsequent application process for rotavirus vaccine easier, because they understood better the GAVI application system.

"T*here were workshops ... paediatric society, UNICEF and focal persons from MOH were part of it, we discussed about introducing both pneumococcal vaccine and Rota."(E004)*

The ICC played an important role in leading the application process, with several meetings held to review the application.

"... here, the ICC is strong to me, especially the technical groups, we had frequent meetings, whenever there is an issue ... and we assigned people to develop the proposal. After all the ICC groups commented back and forth discussing on the issues it was finally submitted to the Government, we are not directing it to GAVI, it is the Government (the Minister) signed and submitted it to GAVI." (E001)

A sequence of preparation was in place to maintain the cold-chain capacity. UNICEF (which had the mandate to work on cold chain capacity) ensured the cold-chain capacity was considered during the decision process to apply for GAVI.

Evidence:
As mentioned in the previous paragraph, there was no biomedical evidence to support the vaccine adoption decision except the burden of the disease mostly established from morbidity and mortality reports of the MoH. However, evidence from neighbouring countries like Kenya was used for this purpose.

"There are capacity limitations of conducting such a [local] study and you should not wait, really, to have such a study for introduction of these vaccines. I mean regional data are more or less similar, and other evidences are also similar." (007)

Drivers:
The importance of the health problem: The burden of disease was one of the main reasons mentioned by the informants in this study, as well as the political prioritisation of vaccine-preventable disease in order to meet MDG4. Availability of GAVI funding was also a very important factor in the decision.

"W*ell this has been discussed before 2007 ... the strategies for each major cause of under five deaths has been discussed, so I think, pneumonia accounts for 3 to 8% deaths of under five in Ethiopia. And pneumococcal is one of the leading causes of under five deaths. We can see from the 2000 country estimators, WHO country estimators and also from regional data for Africa. So that has been known and been discussed, but clearly, officially in 2007 that a letter of interest has been written to GAVI…" (E012)*

Financial/Economic Issues:
The availability of GAVI funding was a major driver of vaccine adoption decisions. What seemed important for the policy makers and stakeholders was not to miss the opportunity offered by the GAVI funding to introduce the vaccine as early as possible. There was less concern about future sustainability implications, although this was mentioned by a few interviewees. Whether the country would shoulder the expenses for introducing so many new vaccines was not reported to have been considered.

From this study we found that the involvement of the Ministry of Finance in vaccine adoption decision-making was limited. However, the informant from Ministry of Education indicated that donor money is considered as a component of the development budget and suggested that there was always a back-up budget to ascertain sustainability of the vaccination program.

This was also reinforced by the fact that the Government had covered the money for the co-financing which is a requirement to all countries who receive GAVI funding.

"This is not the issue of the MoF or MoH, it is also the issue of the Ministry of Women Youth and Children .... we have to ensure sustainability of the health sector .... once the government is engaged on such thing it has to continue ..." (MoF)

Informants indicated that the government had a strong commitment towards and was ready to co-finance the immunisation program.

"….government already showed its commitment by reserving some amount of money from its annual budget by declaring to, in the name of Ministry of Health. So that means already I know that's going to be implemented for the cost sharing purpose …." (E006)

Some of the informants who were closely working in the EPI program said that when it comes to vaccine acquisition, the government co-finances or covers 100% of vaccines costs.

> *"The government is committed towards the immunisation program and has been covering 100% of the costs of some of the vaccines like BCG, TT and 59% of polio..." (E012)*

Acceptability of the Program:
In Ethiopia, the introduction of PCV was supported by all stakeholders. Pneumonia was perceived as a priority health problem among children under 5 years of age. Informants indicated that they did not foresee any opposition to the introduction.

The general acceptability of vaccines by the community was almost 100% according to interviewees. Health care professionals and program managers would teach the community about the new vaccines generally and acceptance was easy as the health problems addressed by vaccination were common in the community.

> *".... when we teach the community about pentavalent we inform the community its protection from hepatitis and haemophilus influenza, they have accepted it as hepatitis is common in the country" (E001)*

Accessibility, Equity and Ethics
In Ethiopia vaccination is provided free of charge in all health facilities including the private sector, which only charged some administrative fees. Vaccines are not imported by the private sector as the MoH is the responsible body which also provide vaccines to the private free of charge to increase coverage. Inequity is not an issue.

Consideration of Alternative Interventions:
In Ethiopia, some interviewees noted that Ministry of Health staff were initially resistant to the introduction of community-based pneumonia treatment, an intervention perceived as being 'pushed' by non-governmental sources. This enhanced the appeal of a pneumococcal vaccine.

Other Drivers:
Some informants indicated that advocacy activities by international agencies, such as the WHO, as well as new vaccine introductions in neighbouring countries such as Kenya, helped to promote adoption in their country.

Discussion
This study suggested that only a few actors were involved in the decision to adopt a new vaccine, specifically PCV10. The main drivers of this decision were political commitment towards the attainment of the Millennium Development Goals, burden of disease and availability of GAVI funding. The fact that EPI was a strong health program in the country facilitated the adoption of the new vaccine. Lack of biomedical evidence in the country, and unavailability of vaccines with more strains were reported as the principal challenges faced during the decision-making process.

The burden of disease is one of the major cues to the introduction of the vaccine in Ethiopia. Many actors including the paediatric society emphasised community level pneumonia treatment and pneumonia conjugate vaccine introduction. Estimating the lives that could be saved by introducing PCV 10 rather than waiting for a vaccine that covers more strains like PCV 13, the MoH decided and introduced PCV 10 to decrease morbidity and mortality due to pneumonia. Other studies indicated that vaccine introduction in many countries was guided by burden of disease (12) while some documented the efficacy of the vaccine in preventing pneumonia among young children (13).

The adoption of PCV was considered and was a point of discussion in the ICC meetings before the GAVI call for applications for funding. However, the GAVI invitation for funding was the main driver for the vaccine adoption process and was seen as an opportunity for the country to accelerate the decrease in child mortality and achieve MDG 4. Therefore, the decision to adopt the new PCV vaccine may be seen as driven by both financial and political factors. Studies in other countries also indicated the importance of these factors in vaccine adoption decisions (14). The fact that few actors were involved in the decision making process could suggest that key decision-making is concentrated centrally. This is also in line with findings from other countries which had experienced a similar process (8,14).

The immunisation program in Ethiopia is heavily donor dependant. It is therefore understandable that a critical cue for action in deciding to adopt PCV was the desire not to miss the opportunity offered by the GAVI funding (14). However, whether the country would shoulder the vaccine cost when GAVI support ceased should be a point that needs serious attention. The fact that the Ethiopian Government is committed to pay the cost sharing - which is a requirement for GAVI funding - is reassuring. The GAVI model of cost sharing reflects and promotes the country's ownership of its immunisation programme, and may indicate that funding will continue after GAVI support has ended even though the programme currently seems highly donor dependent (15, 16). However, non-vaccine costs have now outweighed vaccine costs, especially when it comes to new vaccines including storage, running costs and program expansion. Globally new vaccine introduction has almost doubled countries' expenditure in non-vaccine costs (17, 18).

Furthermore, the fact that the Ethiopian government covers only 21% of health care financing compared to 39% by bilateral and multilateral agencies suggests that the country is far behind in efforts to cover total vaccine costs and will need much effort and commitment to sustain the program (19).

Conclusion:
Availability of GAVI funding was an opportunity and driver for new vaccine adoption although the decision was also politically driven. Though biomedical evidence was lacking, data from MoH reports and evidence from neighbouring countries were used. As new and improved vaccines are introduced, the cost implications and sustainability of the programme should be considered.

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