New vaccine adoption: qualitative study of national decision-making processes in seven low- and middle-income countries

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Accepted 16 February 2012

As more new and improved vaccines become available, decisions on which to adopt into routine programmes become more frequent and complex. This qualitative study aimed to explore processes of national decision-making around new vaccine adoption and to understand the factors affecting these decisions.

Ninety-five key informant interviews were conducted in seven low- and middle-income countries: Bangladesh, Cameroon, Ethiopia, Guatemala, Kenya, Mali and South Africa. Framework analysis was used to explore issues both within and between countries.

The underlying driver for adoption decisions in GAVI-eligible countries was the desire to seize GAVI windows of opportunity for funding. By contrast, in South Africa and Guatemala, non-GAVI-eligible countries, the decision-making process was more rooted in internal and political dynamics.

Decisions to adopt new vaccines are, by nature, political. The main drivers influencing decisions were the availability of funding, political prioritization of vaccination or the vaccine-preventable disease and the burden of disease. Other factors, such as financial sustainability and feasibility of introduction, were not as influential. Although GAVI procedures have established more formality in decision-making, they did not always result in consideration of all relevant factors. As familiarity with GAVI procedures increased, questioning by decision-makers about whether a country should apply for funding appeared to have diminished.

This is one of the first studies to empirically investigate national processes of new vaccine adoption decision-making using rigorous methods. Our findings show that previous decision-making frameworks (developed to guide or study national decision-making) bore little resemblance to real-life decisions, which were dominated by domestic politics. Understanding the realities of vaccine policy decision-making is critical for developing strategies to encourage improved
Evidence-informed decision-making about new vaccine adoptions. The potential for international initiatives to encourage evidence-informed decision-making should be realised, not assumed.

**KEY MESSAGES**

- Decisions to adopt new vaccines are, by nature, political.
- The main drivers influencing decisions to adopt new vaccines were the availability of funding, political prioritization of vaccination (or the vaccine-preventable disease) and burden of disease.
- There was little consideration of the financial implications of adopting a new vaccine, nor the feasibility of introduction, prior to the decision.
- The desire to seize donor funding opportunities may inhibit evidence-informed decision-making.

**Introduction**

The beginning of the Decade of Vaccines is an exciting time, following unprecedented pledged funding to the GAVI Alliance and the ever-increasing pace of development of new vaccines (Moszynski 2011; Moxon and Siegrist 2011). However it is also a time for reflection about the challenges ahead and problems faced at both the country and the global level (Cunliffe and Nakagomi 2007; Mahmoud 2011; Moxon et al. 2011).

One of these challenges is how governments decide which vaccines to adopt into their national immunization programme. As new and improved vaccines become available, governments must make these decisions more frequently. New vaccines are more expensive than traditional ones and some have particular logistical or delivery issues, making adoption decisions evermore complex (Andrus et al. 2011; Levine et al. 2011). At the same time, the role of funding institutions such as the GAVI Alliance (GAVI) has led to criticism that decisions are taken out of national governments’ hands and to calls for the encouragement of more national autonomy (Mahmoud 2011; Moxon et al. 2011; Zuber et al. 2011).

Over the past decade, GAVI has become instrumental in providing financial support to low- and middle-income countries to introduce new vaccines. Once GAVI announces a call for funding proposals, countries wishing to apply must express their interest. GAVI requires that countries set up inter-agency co-ordinating committees (ICCs) to co-ordinate funding applications and introduction plans.

Several initiatives aim to encourage countries to adopt new vaccines, to generate evidence to support adoption decisions [e.g. Diseases of the Most Impoverished project (DOMI), GAVI’s Accelerated Vaccine Introduction Initiative, the PneumoADIP and the Rotavirus Vaccine Program] and to support evidence-informed vaccine decision-making (e.g. ProVac, SIVAC, the Hib Initiative) (Program For Appropriate Technology in Health et al. 2003; Acosta et al. 2004; Levine 2004; Andrus et al. 2007; Widdowson et al. 2009; Hajjeh et al. 2010; Senouci et al. 2010). However, a recent systematic review concluded that little was known about decision-making processes, since few studies had explored them and those that did tended to be methodologically weak (Burchett et al. 2012).

Numerous frameworks have been developed to either support or study decision-making processes; a recent systematic review identified 21 unique frameworks, with more published since then (Levine et al. 2010; Burchett et al. 2012). Most frameworks lack information about how they have been developed or whether they have been tested or validated, making it difficult to assess their quality. There is a need to improve our understanding of how adoption decisions are made, in order to better support countries in making the right decisions for their own situation (Wenger et al. 1999; Munira and Fritzen 2007; Piso and Wild 2009). This study aimed to explore the process of vaccine adoption decision-making in seven low- and middle-income countries and to understand which factors are most critical.

**Methods**

This qualitative study involved semi-structured interviews with key informants in seven low- and middle-income countries: Bangladesh, Cameroon, Ethiopia, Guatemala, Kenya, Mali and South Africa. Countries were purposively selected to cover both GAVI-eligible and non-GAVI-eligible (as donors may influence decision-making processes), different health system strengths, various speeds of vaccine adoption and different geographical regions (Table 1).

In all case study countries, the Expanded Programme on Immunization (EPI) offered vaccination free of charge at the point of delivery. All countries had adopted a new vaccine within the last 3 years. Table 2 shows vaccine coverage rates and dates of new vaccine introductions. Some countries were early adopters, while others had more mixed patterns. All countries, apart from South Africa, had a specific line item in their national health budget for vaccines.

Interviewees were purposively selected if they were involved in, or knowledgeable about, the process of vaccine adoption decision-making. Interviewees included EPI officers, Ministry of
Health (MoH) staff, World Health Organization (WHO) and United Nation’s Children Fund (UNICEF) country representatives, academics, members of immunization advisory committees and ICCs and other key stakeholders (see Table 3). In total, 95 key informants were interviewed, 11–15 per country.

The interview topic guide was based on a previously-devised decision-making framework (see Table 4) (Burchett et al. 2012).

The interviews included several questions on each of the following topics:

- Current role and immunization experience
- Government prioritization of vaccination
- Decision-making process
- Stakeholders involved in introduction decision-making
- Factors influencing decisions.

The questions were open-ended, with probes used to explore points raised by interviewees, or for clarification if more information was required. Interviews focused on the most recent adoptions or those expected in the near future: mainly pneumococcal and rotavirus vaccines, but also *haemophilus influenzae* type b (Hib), human papillomavirus (HPV), measles second dose, rubella, hepatitis B birth dose and meningococcal A vaccines. Interviews were conducted between October 2010 and March 2011, mostly by a national researcher and an LSHTM team member. Most interviews were conducted in English. In Guatemala, interviews were in Spanish; in Mali, they were in French; in Cameroon, French and English; and one interview was conducted in Amharic in Ethiopia. Prior to interviews, the aim of the study was explained and an information sheet provided. After discussing any questions or concerns, interviewees signed a consent form. Where permitted and possible, interviews were recorded, transcribed and, if necessary, translated into English. When they were not recorded, notes were taken and typed up in detail afterwards.

Ethical approval was obtained in each country and from the LSHTM. Framework Analysis was used to explore the data (Ritchie and Spencer 1994). An initial, broad coding framework (see Table 4) (Burchett et al. 2012). These codes were applied to each country’s data. A meeting was held where all collaborators identified key issues arising from the data and further refined the coding framework. The revised framework was subsequently applied to the transcripts by charting the codes (i.e. each point from each interview relating to a code was summarized in an excel file) and

<table>
<thead>
<tr>
<th>Country</th>
<th>Population (million) 2009</th>
<th>Under-five mortality rate 2009</th>
<th>GNI per capita (US$) 2009</th>
<th>Total expenditure on health as % of GDP 2009</th>
<th>Eligible for GAVI support 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>162</td>
<td>52</td>
<td>580</td>
<td>3.4%</td>
<td>Yes</td>
</tr>
<tr>
<td>Cameroon</td>
<td>19</td>
<td>154</td>
<td>1190</td>
<td>5.6%</td>
<td>Yes</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>79</td>
<td>104</td>
<td>330</td>
<td>4.3%</td>
<td>Yes</td>
</tr>
<tr>
<td>Guatemala</td>
<td>14</td>
<td>40</td>
<td>2650</td>
<td>7.1%</td>
<td>No</td>
</tr>
<tr>
<td>Kenya</td>
<td>40</td>
<td>89</td>
<td>760</td>
<td>4.3%</td>
<td>Yes</td>
</tr>
<tr>
<td>Mali</td>
<td>15</td>
<td>191</td>
<td>460</td>
<td>5.6%</td>
<td>Yes</td>
</tr>
<tr>
<td>South Africa</td>
<td>49</td>
<td>62</td>
<td>5760</td>
<td>8.5%</td>
<td>No</td>
</tr>
</tbody>
</table>


*Total health expenditure is the sum of public and private health expenditure.

<table>
<thead>
<tr>
<th>Country</th>
<th>2010 estimated DTP3 coverage</th>
<th>Rotavirus vaccine introduction</th>
<th>Pneumococcal vaccine introduction</th>
<th>Hib vaccine introduction</th>
<th>Other previous vaccine introductions</th>
</tr>
</thead>
</table>

had previously been a GAVI board member) insisted that the appeal for political reasons. In Ethiopia, the Minister (who their gender (female); others simply because vaccination because of their professional background (e.g. paediatrics) or passion for child health and vaccination.

In all countries, only a small number of actors were directly involved in decisions to adopt new vaccines. As would be expected, national Ministry of Health officials played a central role in all countries.

In Guatemala and South Africa, smaller groups than in the GAVI-eligible countries were directly involved in decision-making. In these two countries, many interviewees who would generally have been considered central to the decision-making process noted that recent adoption decisions (for rotavirus and pneumococcal vaccines, respectively) came as a surprise, highlighting the fact that many officials were unaware of discussions around the decision until it was announced. The Minister of Health was particularly central to these decisions, along with one or two advisors. In neither country were the EPI teams within the Ministry of Health involved in the decision-making. This contrasted starkly with the situation in the GAVI-eligible countries, where EPI managers and their staff played a central role.

Ministers of Health also had influence in GAVI-eligible countries, with many interviewees noting their support or passion for child health and vaccination.

“The Minister is extremely supportive of the vaccination programme. The events ... which mobilize the Minister most are to do with EPI ... therefore at political level, it is clearly important.” (004, national MoH staff, Cameroon)

Some Ministers were perceived as championing vaccination because of their professional background (e.g. paediatrics) or their gender (female); others simply because vaccination appealed for political reasons. In Ethiopia, the Minister (who had previously been a GAVI board member) insisted that the country apply to introduce the rotavirus vaccine earlier than the technical team had planned, whilst in Kenya interviewees reported that the Minister had been lobbying at global levels for access to vaccines at reduced prices.

Decision-making process
Actors involved
In all countries, only a small number of actors were directly involved in decisions to adopt new vaccines. As would be expected, national Ministry of Health officials played a central role in all countries.

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Findings
A summary of the findings is presented in Table 4.

Table 3 Interviewees

<table>
<thead>
<tr>
<th>Type of interviewee</th>
<th>Bangladesh</th>
<th>Cameroon</th>
<th>Ethiopia</th>
<th>Guatemala</th>
<th>Kenya</th>
<th>Mali</th>
<th>South Africa</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>National EPI staff</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Other national government staff (e.g. Ministry of Health, Ministry of Finance)</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>International agency staff (e.g. WHO, UNICEF, pharmaceutical companies)</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>21</td>
</tr>
<tr>
<td>National organizations (e.g. academics, civil society, professional associations)</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Sub-national Ministry of Health staff</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Others (e.g. clinicians)</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>TOTAL</td>
<td>13</td>
<td>11</td>
<td>16</td>
<td>12</td>
<td>15</td>
<td>15</td>
<td>13</td>
<td>95</td>
</tr>
<tr>
<td>Category</td>
<td>Criteria</td>
<td>Finding</td>
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<td></td>
<td>Burden of disease (e.g. prevalence)</td>
<td>Generally considered important</td>
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<tr>
<td></td>
<td>The importance of the health problem</td>
<td>Reducing child mortality generally considered important—particularly with reference to achieving Millennium Development Goal 4. Political factors (particularly in non-GAVI countries) influential e.g. upcoming elections; pressure to 'improve image' of Minister or Ministry of Health.</td>
<td></td>
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<tr>
<td></td>
<td>Political priority</td>
<td>Political factors (particularly in non-GAVI countries) influential e.g. upcoming elections; pressure to 'improve image' of Minister or Ministry of Health.</td>
<td></td>
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<td></td>
<td>Costs of disease</td>
<td>Perceptions of importance (e.g. in terms of perceived severity or vulnerability)</td>
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<tr>
<td></td>
<td>Other</td>
<td>Rarely mentioned</td>
<td></td>
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<tr>
<td>Vaccine characteristics</td>
<td>New vaccine developed</td>
<td>Not mentioned often—only in Kenya (after their pentavalent introduction they were watching developments of a pneumonia vaccine). A small number of interviewees from Ethiopia and Cameroon also mentioned it.</td>
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<tr>
<td></td>
<td>Efficacy/effectiveness</td>
<td>Only mentioned very occasionally</td>
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<tr>
<td></td>
<td>Vaccine safety</td>
<td>Mentioned occasionally, but did not appear to be drivers of the decision to adopt</td>
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<td></td>
<td>Presentation/delivery issues (e.g. vaccine schedule)</td>
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<td></td>
<td>Other characteristics</td>
<td>Disease burden appeared to be a key factor in choosing between pneumococcal and rotavirus vaccines. Choosing between different pneumococcal vaccines seemed to depend primarily on GAVI availability.</td>
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<td>Programmatic considerations</td>
<td>Feasibility</td>
<td>Seemed to delay introductions rather than influence decisions outright</td>
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<tr>
<td></td>
<td>Vaccine supply</td>
<td>Not a concern</td>
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<tr>
<td>Acceptability</td>
<td>Acceptability of vaccine</td>
<td>Acceptability to public generally high, so not really an issue</td>
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<tr>
<td>Accessibility, equity and ethics</td>
<td>Accessibility, equity and ethics</td>
<td>Not a concern, except in South Africa</td>
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<tr>
<td></td>
<td>Economic evaluation</td>
<td>Only really mentioned in Kenya. A few others mentioned considering 'value for money' judgements, rather than formal, rigorous cost-effectiveness studies.</td>
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<td></td>
<td>Systems costs</td>
<td>Rarely mentioned</td>
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<tr>
<td>Financial/economic issues</td>
<td>Availability of GAVI funding was a major driver in all the eligible countries.</td>
<td>Consideration of co-financing (e.g. whether introduction was affordable) appeared to diminish with each GAVI-funded introduction, as countries became used to that requirement. Some expressed concern that countries jump at opportunities without considering consequences. Some implied that decisions were made before the co-financing arrangement had been agreed with the Ministry of Finance. Guatemala—financial issues were not a consideration. South Africa—Ministry of Finance had money available for new vaccine.</td>
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<tr>
<td></td>
<td>Funding sources</td>
<td>Some implied that decisions were made before the co-financing arrangement had been agreed with the Ministry of Finance. Guatemala—financial issues were not a consideration. South Africa—Ministry of Finance had money available for new vaccine.</td>
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<tr>
<td></td>
<td>Vaccine price</td>
<td>Not a major concern either in GAVI- and non-GAVI-eligible countries.</td>
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<tr>
<td></td>
<td>Financial sustainability</td>
<td>Not mentioned in Guatemala/South Africa Mixed opinions about whether it was a concern, or was discussed, prior to the decision to apply for GAVI funding. A few mentioned a hope that prices will fall, although some also noted that this was expected of pentavalent but prices did not come down as much as anticipated.</td>
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<tr>
<td></td>
<td>Other (including affordability)</td>
<td>Affordability was occasionally mentioned</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

(continued)
### Table 4 Continued

<table>
<thead>
<tr>
<th>Category</th>
<th>Criteria</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of vaccination</td>
<td>Impact on health outcomes</td>
<td>Frequently mentioned. Particularly cited in Ethiopia and South Africa in relation to reaching MDG4 or explicitly stating to reduce child mortality/morbidity.</td>
</tr>
<tr>
<td></td>
<td>Impact on non-health outcomes</td>
<td>Rarely mentioned</td>
</tr>
<tr>
<td></td>
<td>Effect of co-administration</td>
<td>Only mentioned as a concern during introduction planning, not as factor influencing decisions</td>
</tr>
<tr>
<td></td>
<td>Risks of serotype replacement</td>
<td>Rarely mentioned</td>
</tr>
<tr>
<td></td>
<td>Other impact</td>
<td>None mentioned</td>
</tr>
<tr>
<td>Consideration of alternative interventions</td>
<td>Cost-effectiveness of alternatives</td>
<td>Only occasionally mentioned</td>
</tr>
<tr>
<td></td>
<td>Effectiveness of alternatives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other considerations</td>
<td></td>
</tr>
<tr>
<td>Evidence sources/quality of evidence</td>
<td>All considered evidence to be important—particularly disease burden data.</td>
<td>Opinions about the necessity of local data varied—notably depending on whether local data were available.</td>
</tr>
<tr>
<td>Actors involved</td>
<td>Ministry of Health central in all countries.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHO (and to a lesser extent, UNICEF)</td>
<td>appeared important in all of the GAVI countries.</td>
</tr>
<tr>
<td></td>
<td>ICC—or a technical sub-committee</td>
<td>charged with writing the proposal—played a role in all GAVI countries.</td>
</tr>
<tr>
<td></td>
<td>Only South Africa had an active immunization technical advisory group (ITAG) at the time of the decision.</td>
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<tr>
<td></td>
<td>Sub-national levels did not appear to be involved—national decision in all cases.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The perception of the level and timing of involvement of the Ministry of Finance was not always clear—some stated that they were merely there to sign the GAVI proposal.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Researchers were considered influential in most countries, although not necessarily directly involved in decision-making (e.g. taking on an advocacy or advisory role).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Professional associations such as Paediatric Society were also noted as taking on an advocacy role in some countries.</td>
<td></td>
</tr>
<tr>
<td>Decision-making process</td>
<td>South Africa &amp; Guatemala—decision-making deviated from formal expected processes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GAVI countries—more structured decision-making process, although this did not automatically mean more thorough consideration of the issues in deciding whether to apply for funding to adopt.</td>
<td></td>
</tr>
<tr>
<td>Procedures</td>
<td>GAVI calls for expressions of interest were a key cue to action for eligible countries (although in Kenya, Ethiopia and Mali they noted that discussions preceded this, as a key trigger was the pentavalent introduction).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disease outbreaks in both South Africa and Guatemala gained a lot of media attention and were influential.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other cues were:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Research or disease burden data</td>
<td></td>
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<td>- International meetings (e.g. World Health Assemblies and WHO regional meetings)</td>
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<td>- International information/pressure</td>
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<td>- Advocacy efforts particularly by paediatricians and academics</td>
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### Cues to action (e.g. disease outbreaks)

| Neighbours | Few interviewees considered neighbouring countries’ introductions to have much influence |
| Other       | International influence noted in South Africa and Kenya |

*Source: Burchett et al. (2012).*
countries, although some interviewees mentioned contact with pharmaceutical companies, these were not felt to have influenced decisions.

Cues to action
For GAVI-eligible countries, GAVI funding calls were, understandably, a key cue. However, this was by no means the only factor triggering the decision-making process. In Kenya, Ethiopia and Mali, discussions about the pneumococcal vaccine preceded the GAVI call, with the adoption of the pentavalent vaccine leading to consideration of additional ways to reduce childhood pneumonia. In Bangladesh, advocacy by the Hib Initiative (a GAVI-funded consortium with the mandate of accelerating evidence-based decision-making for Hib vaccine) was cited as a catalyst for action for its adoption, with the organization of a regional workshop and a national consultative meeting. A question about the pneumococcal vaccine was posed by a visiting British member of parliament to their Bangladeshi counterpart, who subsequently raised the topic in parliament. This parliamentary debate raised awareness about the vaccine and may have influenced Bangladesh’s GAVI application for pneumococcal vaccine in May 2011.

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.

National advocacy activities also helped to get new vaccines onto the decision-making agenda. For example in Mali, the directors of two research institutions—the Malian research institute, the Centre for Vaccine Development (CVD), and the US CVD—met the president of the Republic to present disease burden evidence and lobby for the introduction of the Hib vaccine, leading to his executive decision to adopt the vaccine.

In both Guatemala and South Africa, diarrhoea outbreaks were key triggers for rotavirus vaccine adoption decisions. In both cases the outbreaks gained substantial media attention, leading to pressure on the Minister of Health to be seen to take action. In South Africa, pivotal vaccine efficacy studies had been conducted which, combined with subsequent advocacy from academics, were considered the starting point of discussions about pneumococcal and rotavirus vaccine adoption.

Procedures
In both South Africa and Guatemala, the decision-making process for recent adoptions deviated from their formal processes. In South Africa, only the first two stages of the process happened as expected. The advisory group (NAGI) reviewed evidence for pneumococcal and rotavirus vaccines in 2007 and made a recommendation to the Department of Health. The EPI team then made a submission to the Minister to adopt the pneumococcal vaccine only, with plans to introduce it in 2010. Normally, the submission would then go to the National Health Council who would decide whether to approve the adoption. In reality, it seems that following a period with no developments, ad hoc meetings were held by the Minister, her advisors, the Ministry of Finance health official and the chair of the NAGI. A few months later, at the World Health Assembly in 2008, the Minister announced plans to adopt both pneumococcal and rotavirus vaccines within 3 months.

“It appeared to come from nowhere…and it really took everyone by surprise because…certain people were talking about it, thinking about it but the consensus was that it was something that we would like to do but that it was just too costly at that stage and then…it was announced by the Minister in Geneva at the WHA…and basically took everyone by surprise…” (004, national MoH staff, South Africa)

In Guatemala, the decision to introduce rotavirus vaccine was also a surprise to interviewees and was generally considered to be a ‘quick’ decision. Although in 2006–07 (before it became inactive), the advisory committee (ACIP) had started discussing the vaccine, this was postponed with the launch of a measles and rubella catch-up campaign. In July 2009, EPI staff were asked to submit a funding request but declined, as they felt the programme was not ready for an introduction. However, in December 2009, they were told that the vaccine would shortly be introduced. The normal process, where the EPI team meets with technical experts to discuss the advantages and disadvantages of adopting a new vaccine, was not followed.

In the GAVI-eligible countries, the requirements for GAVI funding applications led to more structured decision-making procedures. In some (e.g. Ethiopia) there were several discussions (e.g. during ICC meetings) about the pneumococcal vaccine prior to the expression of interest in applying for funding. However, in others (e.g. Cameroon, Kenya and Bangladesh) there appeared to be less discussion as the need for the vaccine was well accepted. Although the ICC could be a forum for discussions, it mostly remained a co-ordinating body that was not the locus of the decision.

In Bangladesh, the National Committee on Immunization Practices (NCIP) had a decision-making function and several interviewees assumed this committee had discussed whether new vaccines should be adopted. However, when committee members were interviewed, they did not report participating in meetings or discussions. In all countries, actors peripheral to the decision-making process often assumed that the process was more formal, structured and evidence-based, and involved a wider range of actors than seemed to be the case in reality.

Despite the establishment of clearer decision-making structures in GAVI-eligible countries (due to GAVI requirements), procedures were not necessarily more thorough. The decision-making process for more recent GAVI-funded vaccines (e.g. pneumococcal and rotavirus) appeared to be faster, with less thorough consideration of the issues, than that for the earlier Hib vaccine, where only Kenya applied as soon as the possibility arose (see Table 2). Compared with the deliberations about whether to apply for Hib vaccine funding, there were often fewer discussions about whether or not to apply for these more recent vaccines. It seemed that as the GAVI system became better understood and countries gained experience in developing applications, the decision to apply became more automatic.
“In general, there is no discussion [about whether or when to make an application to GAVI], as it is something that we see very well that it will help us to reduce morbidity and mortality, so everyone is entirely in agreement...what we do is try to get information on the dates of the application and prepare applications...” (C005, international agency staff, Cameroon)

“I think it’s difficult to pinpoint the moment when the decision was made because there is an obvious international influence on the decision process here. So if we already know that there is a source of funding from GAVI, it can speed up the decision to make the introduction happen. So we can basically say that application comes after the decision but it’s as well because of funding that the decision is taken. Therefore it’s iterative and sometimes a bit circular.” (M003, international agency staff, Mali)

The adoption of the meningococcal vaccine in Mali differed from other GAVI-supported vaccines. It involved the establishment of a partnership to support the development of the vaccine and required African Ministers of Health from meningitis-belt countries to commit to fast-track its adoption. In Mali, WHO was viewed as taking the lead in providing evidence of the safety and efficacy of the new vaccine and planning the introduction through region-wide vaccination campaigns.

Evidence

The importance of evidence—particularly of the incidence or burden of disease—was universally recognized. In countries with sufficient capacity to conduct their own studies, local findings were considered critical. Indeed, interviewees from several countries (Mali, Kenya and Bangladesh) reported that new vaccines would not be adopted unless local disease burden data were available. These tended to be countries with substantial epidemiological surveillance capacity. Countries lacking capacity were more willing to look at evidence from elsewhere.

“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, international agency staff, Ethiopia)

WHO often played a key role in providing technical assistance and financing the collection of local surveillance data.

Although most discussions of evidence focused on disease burden data, some interviewees also mentioned impact studies, particularly from previous vaccine introductions such as Hib vaccine. These were felt to provide evidence of the usefulness of vaccines generally, thus supporting decisions to adopt new vaccines. In countries where efficacy studies had taken place (e.g. South Africa), these were considered influential in getting the vaccine onto the decision-making agenda.

South Africa, Mali and Kenya reported conducting economic evaluations to support their decisions. In South Africa, ‘rough’ analyses, rather than ‘rigorous, academic’ studies were done. In Guatemala, there was disagreement among interviewees about whether an economic evaluation had been conducted for the rotavirus vaccine and simply not communicated, or whether it had not been finished, or even started. Nevertheless, there was consensus that economic evidence had not informed the decision.

Drivers

The importance of the health problem

The burden of disease and the political prioritization of the vaccine-preventable disease were two key drivers influencing adoption decisions.

Disease burden was universally considered to be an important driver of decisions to adopt new vaccines. It also helped in selecting which vaccine to apply for, when, for example, GAVI offered more than one (e.g. pneumococcal and rotavirus vaccines). In Bangladesh, a number of disease burden studies were conducted before Hib vaccine was adopted; interviewees suggested that doubts about disease burden were one cause of the adoption delay.

Some interviewees felt that where the disease was highly visible (e.g. pneumococcal in Kenya or meningococcal in Mali), there was less debate around whether to adopt the vaccine.

Although the burden of disease was clearly necessary for adoption decisions, it was not generally sufficient; political prioritization was also very influential. Immunization was generally considered a high government priority; indeed in several countries (e.g. Mali and Cameroon) coverage was one of the National Health Strategy’s performance targets and in Kenya it was one of the President’s performance targets. Achieving the Millennium Development Goal (MDG) 4 (reducing child mortality) was noted as a key driver by interviewees in almost all countries.

In both Guatemala and South Africa, interviewees reported political pressure on the Ministers of Health for a ‘good news’ story. In South Africa, lack of progress towards the MDGs (largely due to HIV, which the Minister would not address) and upcoming elections were considered major incentives for the Minister to decide to adopt two vaccines at once.

Interim government and parliamentary elections were other major factors cited as delaying the Hib adoption decision in Bangladesh.

Other criteria within the ‘importance of the health problem’ (e.g. ‘costs of the disease’) were rarely mentioned.

Vaccine characteristics

Criteria such as vaccine efficacy or safety were mentioned only occasionally. A few interviewees mentioned the development of new vaccines as a driver of decision-making. In Kenya, interviewees explained that after the introduction of Hib vaccine, they were watching developments of a pneumococcal vaccine (as they believed that this would have a greater impact on pneumonia than Hib vaccination).

Programmatic considerations

Programmatic issues, such as whether adoption was feasible, seemed to delay introductions rather than influence adoption decisions. Cold chain capacity issues were particularly noted. Several countries (e.g. Cameroon) upgraded their cold chain in preparation for GAVI applications or as part of introduction plans. Vaccine supply issues were noted as affecting only which
pneumococcal vaccine to adopt, rather than the decision to adopt per se.

Acceptability
The acceptability of vaccination to the public was high in all countries and therefore not mentioned as an influential factor affecting decisions. Although acceptability issues were raised by some stakeholders in Mali and Cameroon, they did not influence decisions.

Accessibility, equity and ethics
Accessibility and equity were not mentioned as a concern, except in South Africa where the government was felt to be particularly sensitive to issues of inequalities. In this country, the availability of the vaccines in the private sector raised concerns about social inequity.

Financial/economic issues
There were four main financial/economic issues: the availability of funding, co-financing, financial sustainability and cost-effectiveness or affordability.

In all five GAVI-eligible countries, the availability of GAVI funding was a major—possibly the major—driver of adoption decisions. Many interviewees stated explicitly that without GAVI funding, the adoption of new vaccines would not be possible.

In Bangladesh, it seemed clear that GAVI’s funding priorities trumped the national priorities of rubella and hepatitis B birth dose, so pneumococcal and measles (second dose) became the next candidates for adoption (applied for in 2011).

In Guatemala, interviewees did not believe financial considerations influenced the rotavirus vaccine decision. In South Africa, the fact that the Ministry of Finance had money available that they were willing to spend on new vaccines was a key driver of the decision. Financial sustainability was not considered as a hindrance in either of these countries.

In order to receive GAVI funding, countries are required to co-finance a proportion of the costs, some with annual increments. Interviewees gave a sense that the importance of co-financing arrangements, as a disincentive to adoption, had diminished as more GAVI-funded introductions occurred. It appeared that as countries became accustomed to the co-financing requirement, there was less concern and discussion about whether the adoption would be affordable. Some felt that co-financing was not a major concern since the amount required was small compared with the overall cost.

“...because in terms of cost, when they look at it, the vaccine cost, it’s about $30 if not more, it should be more than $30 per dose, yeah. So, and say in Europe or North America that’s the cost, so when you are being asked to pay $0.15 per dose, it’s just like peanuts.” (003, international agency staff, Kenya)

As mentioned above, in some cases interviewees implied that the decision to apply for GAVI funding was made before the co-financing arrangement had been agreed with the Ministry of Finance. However, in several countries (e.g. Bangladesh) the Ministry of Health had authority over its own budget, so approval from the Ministry of Finance was perceived as a formality only.

Among the GAVI-eligible countries, there were mixed opinions about whether financial sustainability was a concern, or whether it had been discussed prior to the decision to apply for GAVI funding. Although there were hopes that vaccine prices would fall over time, several noted that the anticipated decline in the pentavalent vaccine price had been less than expected. Some interviewees worried that countries were ‘grabbing’ funding opportunities without considering the long-term consequences, particularly as the number of vaccines being co-financed increased.

“If the WHO—and it’s often GAVI, but they’re all the same to me because they work together—make an offer, all countries jump on it but without really considering all the consequences.” (010, national Ministry of Health staff, Mali)

In Bangladesh, interviewees were clear that they did not view financial sustainability in terms of government contributions. Instead they considered where external funding could be obtained in future.

Although some interviewees did mention considering the vaccines’ value for money, they rarely used economic evaluations to estimate this. A minority mentioned the issue of the vaccine’s affordability, price or systems costs. Where systems costs were mentioned, discussions were generally held after the decision to apply for GAVI funding, rather than as an issue influencing the decision.

Impact of vaccination
The potential impact of the new vaccine on health outcomes (notably child mortality) was mentioned particularly by interviewees in Cameroon, Ethiopia, Mali and South Africa. However, it was difficult to differentiate comments about the political priority of achieving MDG4, or reducing child mortality, and comments about the health impact; there seemed to be substantial overlap between these two criteria.

Other impact criteria, such as the impact on non-health outcomes, effect of co-administration or risks of serotype replacement, were only occasionally mentioned. They were more often considered during introduction planning, after the decision to adopt had been made.

Consideration of alternative interventions
Alternative interventions were rarely mentioned. 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.

Unsurprisingly, when they were discussed, the issues raised depended on the disease/vaccine being considered. With regards to rotavirus, occasionally the issue of improvements in hygiene, water supply and sanitation were raised as an alternative to vaccination, but these did not appear to have been a significant consideration.
Other drivers
Countries reported that 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.

A few interviewees felt that new vaccine introductions in other (often neighbouring) countries helped to promote adoption in their country, although most felt that this had little influential effect.

The availability of the new vaccine in the private health sector was not considered influential, since such a small proportion of the population could access these services. The only exception was in South Africa, as mentioned above.

Discussion
It was clear from the study that the underlying driver for adoption decisions in GAVI-eligible countries was the desire to seize windows of opportunity for funding. By contrast, in South Africa and Guatemala, the decision-making process appeared to be more rooted in internal and political dynamics.

Our results confirm that vaccination is a political issue in both non-GAVI-eligible and GAVI-eligible countries. Other studies have also highlighted the importance of political factors in vaccine adoption decisions (Brooks et al. 1999; Druce et al. 2006; Haas et al. 2009; Bryson et al. 2010). In our study we found that ‘political rationality’ was often more important in the decision-making process than ‘technical rationality’ (Liu 2003). Hence, deciding to adopt a new vaccine is not simply a technical, evidence-informed decision but rather an example of the craft of policy-making (Shiffman and Smith 2007).

Consistent with previous findings, the burden of disease was another important factor (DeRoeck et al. 2005; Druce et al. 2006; Munira and Fritzzen 2007). Although local evidence was considered critical for decision-making in countries where it was available, those lacking local data accepted the need to rely on evidence from elsewhere. A preference for local evidence has also been reported elsewhere, both for vaccine decision-making and other areas of health policy (DeRoeck et al. 2003; Woelk et al. 2009; Burchett 2010).

There appears to have been a very effective global advocacy strategy focused particularly on Ministers. This may have influenced the extent to which policy decisions were evidence-informed within countries. In the GAVI-eligible countries, the decision-making process appeared to be speeding up, with less consideration of whether to adopt compared with earlier vaccine adoptions (Lairumbi et al. 2008; World Health Organization 2008; Shearer et al. 2010; Levine et al. 2011). This may be because understandings of and confidence in GAVI have increased following earlier experiences. It also suggests that, whilst GAVI has led to the establishment of more formal national procedures, at the same time it may have diminished the thoroughness of the decision-making process. There appeared to be little consideration of the financial implications of adoption (both in terms of co-financing and financial sustainability), particularly when compared with earlier GAVI-funded adoptions (Weber 2004; Gordon et al. 2012). This is a particular concern given increasing immunization budgets and more costly new vaccines (Lydon et al. 2008; McQuestion et al. 2011; Zuber et al. 2011). Other studies have noted a lack of capacity to conduct and interpret economic evaluations in low- and middle-income countries, which may also help explain the lack of consideration of financial and economic issues (Gordon et al. 2012; Jauregui et al. 2012).

The fact that the desire to seize the opportunity of GAVI funding may stifle a thorough consideration of the advantages and disadvantages of new vaccine adoption supports arguments made in other studies, that donors risk ‘taking over’ decision-making (Brooks et al. 1999; Weber 2004; Druce et al. 2006; Lairumbi et al. 2008). It is interesting to note that a previous study conducted in five low- and middle-income countries (none of which were included in our study) found that awareness about rotavirus was ‘extremely low’ (Simpson et al. 2007). Data had been collected in 2006; in November of that year GAVI announced funding for rotavirus vaccines. Given that there was a clear awareness of rotavirus among all our study participants, it is possible that the availability of funding from GAVI had helped to increase awareness.

In summary, the main drivers influencing vaccine adoption decisions were the availability of funding, political prioritization of vaccination or the vaccine-preventable disease and the burden of disease. Other factors did not appear to be influential, and if they were considered, it was generally once the decision had been made. The fact that programmatic issues were not key factors in the adoption process raises questions about the capacity of the vaccination programme to absorb the new vaccine(s). Also the fact that few interviewees noted the importance of vaccine efficacy or safety may be because countries rely on WHO recommendations, rather than in-country evidence of efficacy or safety. This contradicts earlier work exploring the perceptions of decision-makers regarding hypothetical new vaccines, which suggested that in-country data on safety, effectiveness and impact were increasingly important (DeRoeck 2004).

Finally, the current study found that the framework developed from existing published decision-making frameworks was more comprehensive than the actual factors that influenced vaccine adoption decision-making in the study countries.

Strengths and limitations
The strength of this study lies in its comparison of decision-making across seven countries, drawing on interviews with 95 key informants, and in its clear analytical framework. However, a limitation, which may affect the generalizability of the findings to other countries, is that it was based on only seven case study countries, most of which were GAVI-eligible and based in sub-Saharan Africa. The findings may also not be generalizable to all vaccines and diseases. However, the value in our study of the rigorous analysis, based on an existing framework, is that future studies will be able to build on this work to explore similar issues in other countries and through similar studies of other vaccines. This will help develop a more comprehensive evidence-base around new vaccine decision-making.

Another possible limitation is that the sensitive nature of decision-making may have led to some acquiescence bias and assumptions about the process. However, many interviewees were honest about shortcomings in the decision-making
process, and by interviewing a range of key informants from several countries, it was possible to triangulate and identify areas particularly vulnerable to acquiescence bias or idealistic assumptions.

**Conclusion**

Decisions to adopt new vaccines are, by nature, political. However, it is clearly important that evidence is used to inform these decisions and that the feasibility and sustainability of new vaccine introductions are considered. Although GAVI procedures have established more formality in decision-making, they do not appear to have resulted in consideration of all relevant factors. It seems that as GAVI-eligible countries became more familiar with GAVI procedures, so their questioning diminished about whether they should apply for funding. There was a lack of consideration of financial factors and the feasibility of vaccine adoption. This has implications not only for GAVI, but also for other international initiatives, in terms of how they engage with national decision-making processes and the extent to which international initiatives encourage evidence-informed decision-making.

This study provides much needed evidence about the nature of vaccine decision-making processes and particularly challenges assumptions held about them (e.g. that they are formal, technical and consultative). Understanding these processes is critical for developing strategies to encourage improved evidence-informed decision-making about new vaccine adoptions. The potential for international initiatives to encourage evidence-informed decision-making should be realised, not assumed.

**Funding**

Funding was received from the Bill & Melinda Gates Foundation (Grant number OPP51822).

**Conflict of interest**

None declared.

**References**

Acosta CJ, Galindo CM, Ochiai RL et al. 2004. The role of epidemiology in the introduction of Vi polysaccharide typhoid fever vaccines in Asia. (Special Issue on a New Research Agenda for Introducing New Vaccines in Developing Countries: Translational Research). Journal of Health, Population and Nutrition


DeRoeck D. 2004. The importance of engaging policy-makers at the outset to guide research on and introduction of vaccines: the use of policy-maker surveys. (Special Issue on a New Research Agenda for Introducing New Vaccines in Developing Countries: Translational Research). Journal of Health, Population and Nutrition


DeRoeck D, Clemens JD, Nyamete A, Mahoney RT. 2005. Policymakers’ views regarding the introduction of new-generation vaccines against typhoid fever, shigellosis and cholera in Asia. Vaccine

23: 2762–74.

DeRoeck D, Deen J, Clemens JD. 2003. Policymakers’ views on dengue fever/dengue haemorrhagic fever and the need for dengue vaccines in four southeast Asian countries. Vaccine


Burchett HED. 2004. The role of epidemiology in the introduction of new vaccines in the Americas: PAHO’s ProVac initiative. Vaccine


28: S6–12.


20(3): 1104–12.

ADDENDUM

Vaccine


20(3): 1104–12.

ADDENDUM

Vaccine


