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New Vaccine Adoption: Qualitative Study of National Decision-Making Processes in Seven Low- and Middle-Income Countries

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Running title: National Vaccine Adoption Decision-Making Processes

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 prioritisation 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

Abstract

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-four 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 prioritisation 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 have not always resulted in consideration of all relevant factors. As familiarity with GAVI procedures has 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) bear little resemblance to real-life decisions, which are dominated by domestic politics. Understanding the realities of vaccine policy decision-making is critical for developing strategies to encourage evidence-informed decision-making about new vaccine adoptions. The potential for international initiatives to encourage evidence-informed decision-making should be realised, not assumed.

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 both at country and global levels (Moxon et al., 2011, Mahmoud, 2011, Cunliffe and Nakagomi, 2007).

One of these challenges is how governments decide which vaccines to adopt into their national immunisation 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 ever-more complex (Levine et al., 2011, Andrus 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 calls for the encouragement of more national autonomy (Moxon et al., 2011, Zuber et al., 2011, Mahmoud, 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 coordinating committees (ICCs) to coordinate 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) and GAVI's Accelerated Vaccine Introduction

Initiative) and to support evidence-informed vaccine decision-making (e.g. ProVac, SIVAC, the Hib Initiative) (Levine, 2004, Program for Appropriate Technology in Health (PATH) et al., 2003, Acosta et al., 2004, Andrus et al., 2007, Senouci et al., 2010, Hajjeh 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., 2011).

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 (Burchett et al., 2011, Levine et al., 2010). 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, Piso and Wild, 2009, Munira and Fritzen, 2007). This study aimed to explore the process of vaccine adoption decision-making in 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).

Table 1: Demographic and economic statistics of the case study countries

Country	Population (million)	2009 ¹ Under five mortality rate ¹	2009 ¹ GNI per capita (US\$) ¹	2009 ^{1,2} Total expenditure on health as % of GDP ^{1,2}	2009 ¹ Eligible for GAVI support ³
Cameroon	162	52	580	3.4%	Yes
Ethiopia	19	154	1,190	5.6%	Yes
Guatemala	79*	104	330	4.3%	Yes
Kenya	14	40	2,650	7.1%	No
Mali	40	89	760	4.3%	Yes
South Africa	15**	191	460	5.6%	Yes
Bangladesh	49	62	5,760	8.5%	No

¹ ADDIN EN.CITE <EndNote><Cite><Author>World Bank</Author><Year>2011</Year><RecNum>58</RecNum><DisplayText>(World Bank, 2011)</DisplayText><record><rec-number>58</rec-number><foreign-keys><key app="EN" db-id="fw0tp0r9tertx0e2et452r9tpwpp2z2xfwt">58</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>World Bank,</author></authors></contributors><titles><title>Data: Indicators</title></titles><number>01/07/2011</number><dates><year>2011</year></dates><urls><related-urls><url>http://data.worldbank.org/indicator</url></related-urls></urls></record></Cite></EndNote>(HYPERLINK \l "_ENREF_38" \o "World Bank, 2011 #58" World Bank, 2011) except where stated otherwise

² Total health expenditure is the sum of public and private health expenditure

³ ADDIN EN.CITE <EndNote><Cite><Author>GAVI Alliance</Author><Year>2011</Year><RecNum>62</RecNum><DisplayText>(GAVI Alliance, 2011)</DisplayText><record><rec-number>62</rec-number><foreign-keys><key app="EN" db-id="fw0tp0r9tertx0e2et452r9tpwpp2z2xfwt">62</key></foreign-keys><ref-type name="Web Page">12</ref-

type><contributors><authors><author>GAVI Alliance,</author></authors></contributors><titles><title>Eligible countries</title></titles><number>13th July 2011</number><dates><year>2011</year></dates><urls><related-urls><url>http://www.gavialliance.org/support/who/eligible/index.php</url></related-urls></urls></record></Cite></EndNote>(HYPERLINK \l "_ENREF_11" \o "GAVI Alliance, 2011 #62" GAVI Alliance, 2011)

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In all case study countries the Expanded Programme on Immunisation (EPI) offered vaccination free of charge at the point of delivery. All countries had adopted a new vaccine within the last three 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.

Table 2: Vaccination coverage and recent vaccine introductions

	Country	2010 estimated DTP3 coverage ¹	Rotavirus vaccine introduction ²	Pneumococcal vaccine introduction ²	Hib vaccine introduction ²	Other previous vaccine introductions ²
	Bangladesh	89%	--	Planned 2013	2009	Hepatitis B (2003)

Cameroon	84%	Planned 2013	2011	2009	Yellow fever (2004), Hepatitis B (2005)
Ethiopia	86%	Planned 2012	2011	2007	Hepatitis B (2007)
Guatemala	94%	2010	Planned 2013	2005	Influenza (2007) Hepatitis B birth dose (2010)
Kenya	83%	Planned 2013	2011	2001	Hepatitis B (2001)
Mali	92%	Planned 2012	2011	2005	Meningitis A (2011), Yellow fever (2001), Hepatitis B (2002)
South Africa	91%	2009	2009	1999	Intravenous polio vaccine (2009), Hepatitis B (1995)

¹ ADDIN EN.CITE <EndNote><Cite><Author>World Health Organization</
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 Health Organization, 2011b)

² ADDIN EN.CITE <EndNote><Cite><Author>World Health Organization</
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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 staff, World Health Organisation (WHO) and United National Children fund (UNICEF) country representatives, academics, members of immunisation advisory committees and ICCs and other key stakeholders. In total, 94 key informants were interviewed; 11-15 per country.

The interview topic guide was based on a previously-devised decision-making framework (see table 3) (Burchett et al., 2011). 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 LSHTM team member. Most interviews were conducted in English. In Guatemala, interviews were in Spanish, in French in Mali, in

French and English in Cameroon 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.

Table 3: Framework of New Vaccine Adoption Decision-Making

Category	Criteria
The importance of the health problem	Burden of disease (e.g. prevalence)
	Political priority
	Costs of disease
	Perceptions of importance (e.g. perceived severity)
	Other
Vaccine characteristics	Efficacy/effectiveness
	Vaccine safety
	Delivery issues (e.g. vaccine schedule)
	Other characteristics
Programmatic considerations	Feasibility
	Vaccine supply
Acceptability	Acceptability of vaccine
Accessibility, equity and ethics	Accessibility, equity and ethics
Financial/ economic issues	Economic evaluation
	Incremental costs
	Funding sources
	Vaccine price
	Financial sustainability
	Other (including affordability)

Ethical approval was obtained in each country and from LSHTM. Framework analysis was used to explore the data (Ritchie and Spencer, 1994). An initial, broad coding framework was drawn up based on a preliminary assessment of the interview transcripts and the previously-developed decision-making

framework (Burchett et al., 2011). 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 refining the coding framework. The revised framework was subsequently applied to the transcripts by charting and mapping the codes, first by country and then across countries. The software 'Open Code' was used (Umea University, 2011).

Findings

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.

In Guatemala and South Africa, smaller groups than in the GAVI-eligible countries were directly involved in decision-making. In these two countries, interviewees noted that recent adoption decisions (for rotavirus vaccine and pneumococcal and rotavirus 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 both countries, the EPI

teams within the Ministry of Health were not involved in the decision-making.

This contrasted starkly to 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.

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.

"The minister is extremely supportive of the vaccination programme. The events ...which mobilise the minister most are to do with EPI....therefore at political level, it is clearly important." 004, Cameroon

Despite being considered good practice, only South Africa had an active technical advisory committee for immunisation. Their National Advisory Group on Immunisation (NAGI) was a strong and influential group of prominent academics and clinicians. Although influential in the build-up of the evidence, it was not directly involved throughout the decision-making process. In Guatemala, the National Advisory Committee on Immunisation Practices (ACIP) had been inactive for several years and did not participate in the rotavirus

vaccine adoption decision. In GAVI-eligible countries, no advisory committees were operational in the run-up to the decisions studied.

WHO was considered an important stakeholder, particularly in GAVI-eligible countries, providing information about future vaccine developments, technical support, financing surveillance and organising workshops to assist the preparation of GAVI applications.

Ministry of Finance involvement in decisions to apply for GAVI funding was not always clear. Some stated that finance officials were not involved, whilst others felt that they had been consulted. It was unclear at what stage they were brought into the decision-making process and whether they had any influence or were merely there to sign the GAVI application. In some countries, discussions with the Ministry of Finance commenced after GAVI funding had been approved. South Africa was unique in that interviewees reported the critical involvement and leadership of a Ministry of Finance health official (with a public health background). In no other country was Treasury pushing for the adoption of new vaccines.

Researchers and clinicians (notably paediatricians and National Paediatric Societies) were involved in advocacy in many countries, although their influence varied. National actors with global links seemed to have more influence than those without international involvement.

Sub-national actors were not involved in national vaccine adoption decision-making in any of the countries.

Pharmaceutical companies played a key role in GAVI non-eligible countries,

with interviewees reporting that their lobbying influenced decision-making. In GAVI-eligible 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 it 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 cue to action for its adoption, with the organisation 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 led to 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 three 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, 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 2006-7, 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 was less discussion as the need for the vaccine was well accepted. Although the ICC could be a forum for discussions, it mostly remained a technical body that was not the locus of the decision.

In Bangladesh the National Committee on Immunisation 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 involving a wider range of actors than seemed to be the case in reality.

Despite the establishment of clearer decision-making structures (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) appear to be faster than that for the earlier Hib vaccine, where only Kenya applied as soon as the possibility arose (see Table 2). Compared to 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.

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 recognised. 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, 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 or cost-effectiveness studies 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 prioritisation 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 prioritisation was arguably more influential. Immunisation 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) as well as 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 only noted as affecting which pneumococcal vaccine to adopt, rather than the decision to adopt per se.

Acceptability

The acceptability of vaccination 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 in the study, 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, 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 to 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, 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, 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 particularly mentioned 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 vaccines' 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 to being 'pushed' by non-governmental sources. This enhanced the appeal of a pneumococcal vaccine.

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

The strength of this study lies in its comparison of decision-making across seven countries, drawing on interviews with 94 key informants, and in its clear analytical framework. A possible limitation was 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, it was possible to triangulate and identify areas particularly vulnerable to acquiescence bias or idealistic assumptions.

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 non GAVI- as well as GAVI-eligible countries. Other studies have also highlighted the importance of political factors in vaccine adoption decisions (Bryson et al., 2010, Haas et al., 2009, Druce et al., 2006, Brooks et al., 1999). 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 (Druce et al., 2006, Munira and Fritzen, 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 been reported elsewhere, both for vaccine decision-making and other areas of health policy (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. In the GAVI-eligible countries, the decision-

making process appeared to be speeding up, with less consideration of whether to adopt compared to earlier vaccine adoptions (World Health Organization, 2008, Lairumbi et al., 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 to earlier GAVI-funded adoptions (Gordon et al., 2011, Weber, 2004). This is a particular concern given increasing immunisation budgets and more costly new vaccines (Lydon et al., 2008, Zuber et al., 2011, McQuestion 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., 2011, Jauregui et al., 2011).

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, Druce et al., 2006, Lairumbi et al., 2008, Weber, 2004).

In summary, the main drivers influencing vaccine adoption decisions were the

availability of funding, political prioritisation 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). 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.

Conclusion

Decisions to adopt new vaccines are, by nature, political. However, it is clearly important that evidence is used to inform these decisions and the feasibility and sustainability of new vaccine introductions are considered. Although GAVI procedures have established more formality in decision-making, they have not resulted in consideration of all relevant factors. It seems that, as GAVI-eligible countries became familiar with GAVI procedures, so their questioning about whether they should apply for funding diminished. The lack of consideration of financial factors and the feasibility of vaccine adoption is concerning. They have 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 they 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 evidence-informed decision-making about new vaccine adoptions. The potential for international initiatives to encourage evidence-informed decision-making should be realised, not assumed.

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