New vaccine adoption in lower-middle-income countries

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Accepted 8 March 2012

Objectives Lower-middle-income countries (LMICs) are lagging behind both high-income and low-income countries in new vaccine adoption. Our study involved the following objectives: (1) understand the decision-making processes of LMICs on new vaccine adoption, (2) identify the factors influencing LMIC decisions, (3) obtain the views of vaccine manufacturers about LMIC markets for new vaccines, and (4) make recommendations concerning how to speed up and improve decision making, including proposing mechanisms for implementation of the recommendations.

Methods Collect and analyse qualitative data from participants in decision making in 15 case study countries [12 LMICs and three upper-middle-income countries (UMICs)] and multinational and developing country vaccine manufacturers.

Findings Interviews of actors in decision making indicate that the aspects deemed most important for adoption are: World Health Organization (WHO) recommendations, the existence of local epidemiological data and a set of factors comprising affordability, cost-effectiveness and overall cost of the new vaccine for the programme. National Immunization Technical Advisory Groups (NITAG) have a key role in advising decision-makers, although their resources and capacity vary. Country decision-makers and manufacturers both see advantages in pooled procurement mechanisms for vaccine purchasing. Recommendations for countries and the international community involve assisting with making epidemiological data and vaccine market information accessible to countries, building and reinforcing related analysis capacity, and assisting with purchasing mechanisms and practices such as pooled procurement.

Keywords Immunization, middle income countries, vaccines, GAVI, pooled procurement

KEY MESSAGES

- Of particular importance in new vaccine adoption decisions in lower-middle-income countries (LMICs) are local burden of disease data, vaccine prices and the cost implications of adopting a new vaccine.
- LMICs use a technically-focused decision-making process that places National Immunization Technical Advisory Groups in a key advisory role.
- Recommendations include making epidemiological data and vaccine market information accessible to countries, building and reinforcing related analysis capacity, and promoting more efficient procurement mechanisms such as pooling.
Introduction

Lower-middle-income countries (LMICs) receive little external support for their vaccination programmes, despite representing about 57% of annual global births and a more than commensurate share of the burden of disease. The World Health Organization (WHO) has estimated that there were 8.1 million cases of *Haemophilus influenzae* type b (Hib) worldwide in 2000, before widespread use of vaccines against Hib by other than high-income countries, and that 5.6 million (69%) were in LMICs (WHO 2011a).

Until a recent revision in eligibility in 2011, the GAVI Alliance was assisting 41 lower-income countries and 31 at the lower-income end of the LMIC category. On 18 July 2011, among the World Bank’s countries classified as lower-middle-income, 40 were not GAVI eligible while 16 were deemed to be ‘graduating’ from GAVI support in the coming years, as their per capita Gross National Income (GNI) was above the GAVI threshold of US$1500.

Since 2000, GAVI has assisted the countries it supports for the adoption of new vaccines, such as the pneumococcal conjugate and rotavirus vaccines, through the purchase of vaccines with only a small requirement of co-financing from countries. GAVI eligibility has been associated with accelerated adoption of Hib vaccine (Shearer et al. 2010). Many GAVI eligible countries are currently introducing these new vaccines and a majority of the remainder has submitted applications to do so. New vaccines such as pneumococcal and rotavirus have already been introduced into the immunization schedule of the vast majority of high-income countries. By contrast, very few non-GAVI LMICs have adopted them. For instance, 86% of GAVI-assisted countries (whether low-income or lower-middle-income) had adopted the Hib vaccine in their national immunization programmes by 2010, but only 54% of the non-GAVI LMICs had done so (WHO 2011b). Few of the latter countries had adopted new vaccines such as rotavirus and pneumococcal (see Table 1).

National immunization programmes in non-GAVI-eligible LMICs generally have strong managerial capacity and perform well in delivering basic Expanded Program on Immunization (EPI) vaccines to their birth cohort, although there is some heterogeneity within the group of countries. Coverage rates reported to WHO are high; half of the 24 countries achieve over 90% coverage (WHO 2011b) (see Table 1). The programmes are financially self-sufficient, since all costs are paid from national budgets (Lydon et al. 2008). Thus there is a strong base to build upon, although adding new vaccines would often mean a substantial increase in the vaccine budget.

Non-GAVI-eligible LMICs must fund from their national budgets future purchases of vaccines that they add. A study reported that the average routine immunization expenditures worldwide increased from US$6 to US$18 annually per infant between 2000 and 2010 (Lydon et al. 2008). In the open market, the prices of these vaccines are substantially higher than the traditional EPI vaccines. For example, Morocco obtained prices of US$22 per dose for pneumococcal and US$7 per dose for rotavirus vaccines through international tendering in 2009 vs

### Table 1 Adoption of new vaccines by lower- and upper-middle-income countries (LMICs and UMICs)

<table>
<thead>
<tr>
<th>Country country case studies</th>
<th>Decided to adopt vaccine?</th>
<th>2009 DTP3 coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LMIC country case studies</strong></td>
<td>RepB</td>
<td>Hib</td>
</tr>
<tr>
<td><strong>Country visits</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Armenia*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>China</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Ecuador</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Egypt, Arab Rep.</td>
<td>–</td>
<td>✓</td>
</tr>
<tr>
<td>Indonesia*</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Morocco</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Syrian Arab Republic</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Remote</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cape Verde</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Philippines</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>UMIC country case studies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Country visits</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panama</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Thailand</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Turkey</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Remote</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albania*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>South Africa</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Tunisia</td>
<td>✓</td>
<td>–</td>
</tr>
</tbody>
</table>


Note: ✓ = Yes; – = No.

*Indicates a country that has benefited from GAVI support.
The study used qualitative semi-structured key informant interviews. Additional selected quantitative analysis was performed. An interview guide was developed and pre-tested with 15 countries (all but Singapore) involved in the development of the guide. Interviews were conducted in 2010 with a total of 204 key informants in 15 countries (see Table 2). The interviews were conducted in a face-to-face format, and remote data collection methodology was employed in the six remaining countries. The remote data collection methodology was used to ensure that the interviews were conducted in a confidential and safe environment.

Table 2: Key informants interviewed

<table>
<thead>
<tr>
<th>Type of interviewee</th>
<th>Lower-middle-income countries (LMICs)*</th>
<th>Upper-middle-income countries (UMICs)*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Country visits</td>
<td>Country visits</td>
<td></td>
</tr>
<tr>
<td>National EPI staff</td>
<td>Armenia 1 China 1 Ecuador 1 Egypt 1 Indonesia 1 Morocco 1 Philippines 1 Cape Verde -</td>
<td>Panama 3 Taiwan 1 Turkey 1</td>
<td>23</td>
</tr>
<tr>
<td>NITAG members</td>
<td>Armenia 2 China 2 Ecuador 3 Egypt 3 Indonesia - Morocco - Philippines -</td>
<td>- 4 2 -</td>
<td>21</td>
</tr>
<tr>
<td>Other national government staff</td>
<td>(e.g. MOH, MOF, Parliamentarians)</td>
<td>Armenia 11 China 2 Ecuador 5 Indonesia 2 Morocco 16 Philippines 2</td>
<td>60</td>
</tr>
<tr>
<td>International agency staff (e.g. WHO, UNICEF, CHAI)</td>
<td>Armenia 4 China 1 Ecuador 3 Indonesia 6 Morocco 4 Philippines 2</td>
<td>- 6 -</td>
<td>34</td>
</tr>
<tr>
<td>National organizations (e.g. academics, civil society, professional associations)</td>
<td>Armenia - China 4 Ecuador 3 Indonesia 1 Morocco 8 Philippines -</td>
<td>- 4 -</td>
<td>4</td>
</tr>
<tr>
<td>Sub-national MOH staff</td>
<td>Armenia 1 China 1 Ecuador 2 Indonesia 6 Morocco 13 Philippines -</td>
<td>- 2 -</td>
<td>28</td>
</tr>
<tr>
<td>Others (e.g. pharmaceutical companies)</td>
<td>Armenia - China - Ecuador - Indonesia - Morocco - Philippines -</td>
<td>- 1 -</td>
<td>204</td>
</tr>
</tbody>
</table>

Note: *The LMIC and UMIC classifications here are for 2011. In the 2008 classifications used to select countries for inclusion in the study, Albania, Syria, Thailand and Tunisia were all LMICs.

EPI = Expanded Programme on Immunization; NITAG = National Immunization Technical Advisory Group; MOH = Ministry of Health; MOF = Ministry of Finance; WHO = World Health Organization; UNICEF = United Nation's Children's Fund; CHAI = Clinton Health Access Initiative.
collection (by phone and email) was used in case study countries with smaller populations and in one country (Philippines) for which substantial information was already available through a recent WHO vaccine procurement assessment. The six case studies conducted remotely involved fewer interviews than those using site visits (see Table 2).

All interviews in the visited and remotely studied countries were conducted with the same set of interview guidelines (Results for Development 2011). Interviews were open ended and probed when necessary. The interview guide focused on factors of adoption, constraints and enabling factors concerning vaccine adoption, and the decision-making process in recent vaccine adoptions. It also explored suggestions by key informants on how decision-making processes could be improved. The hypothesized factors explored by interviewers were based on previous studies’ findings (DeRoeck et al. 2003; DeRoeck 2004; Munira and Fritzen 2007; Griffiths and Miners 2009). They included epidemiological information, prices and costs, recommendations by international bodies, experience with vaccines in private markets, the role of the media, procurement options and whether neighbouring countries had adopted. Factors in the decision-making process were classified in five categories: ‘factors reported by interviewees to be critically important’; ‘factors considered to be important’; ‘factors considered a bit important’; ‘factors considered not important’; and factors that were ‘not available or not considered’.

Key informants were selected in consultation with the relevant WHO Regional Office and the local immunization programme manager in each country and also used a snowball methodology. Key informants were informed that individual comments would not be directly attributed.

The country and remote interviews were conducted by teams with skills and experience of working on immunization issues and new vaccine adoption from a multiple disciplinary background, including economics, policy and public health. All teams used the same interview guide and had overlapping membership to ensure adequate consistency of approach, but differed because of language skills required and availability. Interviews took between 30 and 90 minutes each. The interviewers took notes and compiled results, charting data thematically and analysing results on a cross-country basis. On some occasions follow-up emails or phone calls were employed to clarify responses or to fill gaps.

**Findings**

**Decision-making process in lower-middle-income countries**

All countries appear to take a systematic and technical approach in deciding whether or not and when to adopt a new vaccine. Almost all countries have established a National Immunization Technical Advisory Group (NITAG) or equivalent technical body that makes recommendations on the adoption of new vaccines.

“The task force on immunizations (NITAG equivalent) takes up new vaccines that are available, studies the evidence about them, and makes recommendations to the Minister of Health. Once the Minister is convinced, he goes to the Council of Ministers for the final decision.” (Cape Verde national informant on the adoption of Hib and MMR vaccines)

However, this technical approach to decision making often has imperfections. The membership and skills of NITAG members tend to vary as well as the way they operate (see Table 3). Some NITAGs meet only when called upon by the Ministry of Health, while others meet on a regular basis. Some can set the agenda, while others require the Ministry of Health to propose a new vaccine for adoption. Seven of the 15 countries allowed international agencies to be members of the committee, while the remainder does not. Seven included members with some economic analysis skills.

The role of the NITAG or equivalent committee was found to be key in all countries studied, except in two cases where a new vaccine was introduced prior to the set up of the advisory committee (Hib vaccine in Armenia and rotavirus vaccine in Panama) and the decision made was more political.

In all countries studied, the Minister of Health played a critical role, either initiating the decision to take up the new vaccine, for example in Panama and Turkey, or responding to recommendations of the NITAG. In some countries there was support at higher political levels. In Morocco, the first lady of the Kingdom championed HPV vaccine (see Box 1). Ministry of Finance buy-in was deemed important to adoption, since it had to approve overall health budgets, although specific allocations

<table>
<thead>
<tr>
<th>Country</th>
<th>It has resources to gather research and to commission research when local data are not available</th>
<th>It has local cost-effectiveness data and members with economics skills</th>
<th>International organizations, such as WHO and UNICEF, are formal members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Armenia</td>
<td>✓</td>
<td>✓</td>
<td>–</td>
</tr>
<tr>
<td>Cape Verde</td>
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<td>–</td>
<td>✓</td>
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<tr>
<td>China</td>
<td>✓</td>
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<tr>
<td>Ecuador</td>
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<td>✓</td>
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<tr>
<td>Egypt</td>
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<tr>
<td>Indonesia</td>
<td>✓</td>
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<td>Morocco</td>
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<td>South Africa</td>
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<td>Tunisia</td>
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</tr>
<tr>
<td>Turkey</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Key: ✓ The statement applies to the country; – The statement does not apply to the country.
within the health budget usually remained within the Ministry of Health’s decision-making power.

“The major obstacle to increasing the health budget [sufficient to pay for new vaccines] is having good indicators of performance that would enable us to judge programme effectiveness.” (Armenian Ministry of Finance)

Unlike in low-income countries, we found that external partners, such as WHO, UNICEF and bilateral donors, only provide limited support on immunization policy in non-GAVI LMICs, despite global and regional recommendations and advocacy for new vaccines by WHO and others.

“We no longer work on immunizations per se; we are focused on issues around children’s rights.” (International Agency in Egypt)

Other key aspects of the decision-making process involved the development of government multi-year plans and budgets and the enacting of vaccine-related legislation, notably in countries in the Americas that made universal access to immunizations a mandatory obligation of governments (Ecuador, Panama).

### Box 1 Decision-making process in Morocco

The interest of the Moroccan first lady’s Lalla Salma Foundation in cancers in immunizations per se; we are focused on issues around children’s rights.” (International Agency in Egypt)

Other key aspects of the decision-making process involved the development of government multi-year plans and budgets and the enacting of vaccine-related legislation, notably in countries in the Americas that made universal access to immunizations a mandatory obligation of governments (Ecuador, Panama).

### Factors influencing decisions

Our findings on the factors deemed critically important or important in explaining vaccine adoption decision-making will be reported in four categories: those reported by interviewees to be important in every country studied, those important in many countries, those important in a limited number of countries, and those that were hypothesized to be important ex ante but found in fact to be of importance in only a few countries (see Table 4). Key informants reported that the critical drivers in adopting a new vaccine were burden of disease information, the price of the vaccine and funding for the new vaccine. The WHO estimate of burden of disease and related recommendations on use were also deemed important factors in every country studied.

### Burden of disease

Key informants in all countries reported that although WHO recommendations were important, they considered it essential to have their own country-specific burden of disease data. Some give weight to burden information from neighbouring countries, but this is decidedly less valuable than having their own data, particularly for large countries. Availability of burden data had implications for the decision to adopt. For instance, Morocco decided to adopt HPV vaccine in 2015 on condition that the local burden of disease could be demonstrated. In Thailand, an analysis of burden of disease and costs led to the decision not to adopt the Hib vaccine. But only in a few countries were efforts being made to collect data when it was not available. Large countries, such as China, South Africa, Thailand and Turkey, and those with strong academic and research capacity were more likely to have access to country-specific epidemiological studies. In contrast, smaller countries such as Cape Verde tended to rely more on WHO recommendations. Finally, four of the case-study countries saw the epidemiological burden in terms of morbidity rather than mortality level for diseases that are preventable with pneumococcal, rotavirus and Hib vaccines.

### Cost-related drivers

Issues identified as important in final decision making included vaccine price, cost-effectiveness, budget impact and affordability, and available financing. All countries reported in one form or another that financial considerations were very important in the decision-making process, generally after the vaccine had been recommended on epidemiological, safety and effectiveness grounds.

Price of vaccines was cited as an important factor by 9 of the 15 countries. The six countries that did not cite price as an important factor were Albania, China, Ecuador, Indonesia, Panama and Turkey. Among these Indonesia and China rely mainly on domestic vaccine manufacturers and negotiate or set prices for them. Two others, Ecuador and Panama, use the PAHO Revolving Fund.

Value for money was a factor in the majority of the countries studied. Cost-effectiveness was cited by 11 of the 15 countries, although only in two countries could cost-effectiveness studies be sourced. Thailand decided not to adopt Hib-containing vaccine because of an unfavourable cost-effectiveness analysis result. The cost-effectiveness analysis in Tunisia was cited...
### Table 4  Summary of critically important and important factors influencing vaccine adoption

<table>
<thead>
<tr>
<th>Country</th>
<th>Broadly important factors</th>
<th>Factors important in multiple countries</th>
<th>Factors important in a few countries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Epidemiology</td>
<td>Cost-related concerns</td>
<td>WHO BOD ests. &amp; recommendations</td>
</tr>
<tr>
<td></td>
<td>Cost-effectiveness</td>
<td>Budget resources devoted to vaccines</td>
<td>Price</td>
</tr>
<tr>
<td>---------</td>
<td>------------------</td>
<td>--------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Albania</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Armenia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cape Verde</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>China</td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
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<tr>
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<tr>
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<td>Indonesia</td>
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<tr>
<td>Panama</td>
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<td>Philippines</td>
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<td>✓</td>
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<tr>
<td>South Africa</td>
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<td>Syria</td>
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<tr>
<td>Thailand</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Tunisia</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Turkey</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>12</td>
<td>11</td>
</tr>
</tbody>
</table>

by nearly all national respondents as giving a clear priority to
which new vaccines to adopt first, second and third.

In addition, Ecuador performs cost-effectiveness analysis prior
to adopting a new vaccine and, if a favourable ratio is found,
then price is not a key factor in the decision. Turkey also
conducts cost-effectiveness analyses and, further, feels that its
birth cohort size gives it bargaining power on prices. Having
a secure source of funding for vaccines was also reported as
important. Eleven out of 15 countries said having a budget line
for vaccines was a key factor and those that did not have
budget lines specifically for vaccines stated they had concerns
over the sustainability of financing. GAVI graduating countries
indicated that the challenge of raising the resources to add new
vaccines would be particularly difficult, since the increases in
vaccine spending needed to pay for previously GAVI-subsidized
vaccines and for additional new vaccines were so large.

“I don’t know how we will be able to achieve such a big increase
in vaccine funding from the Ministry of Finance once the GAVI
assistance ends.” (Armenian Ministry of Health)

Eleven of the case-study countries indicated that they did not
have a reliable source to go to for vaccine prices and market
conditions. However, PAHO countries such as Panama and
Ecuador felt confident that they could rely on the PAHO
Revolving Fund for price information and, as mentioned above,
China and Indonesia negotiated prices for vaccines from
domestic manufacturers. Interviews showed that there was a
degree of confusion over the prices to be paid for new vaccines.
Countries often cited prices and market conditions that were
incorrect or long out of date. It was often assumed by country
informants that prices would be the same as those paid by
high-income countries or domestic private markets. Impact on
vaccine price of large volume orders or the agreement of
multi-year contracts that include other services bundled (such
as technical assistance) with the vaccine price were often
misunderstood. Finally there was uncertainty and speculation
among key informants on the future level of prices.

“We are unsure whether the price we get this year will be similar to
the prices we’ll get over the next few years.” (Ministry of Health
official, Egypt)

Other decision-making factors
Other less important factors cited by key informants included
the experience of neighbouring countries (7/15), access to
adequate procurement mechanisms (6/15) and the role played
by global/regional bodies to engage countries (5/15).

Those countries with access to pooled procurement (in the
Americas) or UNICEF’s Supply Division services (e.g. Morocco)
 saw this as advantageous. Smaller population countries, such as
Cape Verde and Armenia, expressed worries that they might be
taken advantage of without the benefit of pooled procurement
mechanisms, such as those offered by UNICEF and PAHO.
Panama, which participates in PAHO’s Revolving Fund, had no
such concerns. Some countries expressed an interest in pooling
arrangements, such as respondents in Egypt who expressed
interest in joining a regional pool.

Factors that were found to be important in few countries
included leadership by local champions and advocacy by other
influential parties (4/15); local vaccine production (in countries
with production capacity) (3/15); precipitating local events
(such as outbreaks of vaccine-preventable diseases) (3/15);
perception of vaccine safety (3/15); strength of the existing
routine immunization programme (3/15); insufficient progress
towards Millennium Development Goal (MDG) targets (3/15);
and experience of the private sector vaccine market (2/15).

The role of local vaccine production was deemed important as
a factor for decision making in countries that have local
production. Countries with local production capacity include
Egypt, China, Indonesia and Thailand. To date only China
produces rotavirus vaccine among the new vaccines. While not
explicitly a condition for adoption, the issue of whether local
manufacturers could be suppliers came up in many of the
interviews conducted in these countries.

The capacity to achieve the MDGs was cited by three
countries, and notably by Morocco, whose Ministry of Health
sees the adoption of pneumococcal and rotavirus vaccines as a
key intervention to accelerate progress to reach the goals by
2015.

The strength of the existing routine immunization pro-
gramme was cited by four countries as a factor in their
decision-making process. Some key informants in countries
such as Thailand and Turkey expressed concern that a too rapid
adoption could jeopardize the effectiveness of their
programmes.

Many of the new vaccines are available in the private markets
of all 15 countries (5–10% of birth cohort). A majority
of informants indicated the presence of the vaccines in these
markets, and the perception that they are used safely and
effectively was a positive influence on attitudes of decision-
makers toward national adoption.

Factors of limited importance
Factors that the study found to be of limited importance
(in single countries or mentioned only indirectly in interviews)
included: (1) vaccine characteristics (including presentation,
cold chain and other infrastructure requirements as well as less
traditional characteristics such as injection schedule and loca-
tion of production), and (2) the role of the media. However,
Panama ran into cold chain capacity issues when it began to
implement national use of new vaccines. The case studies found
that several countries use the media to promote new vaccines
and to disseminate information to the public about them, but
in none of them did we hear that there is pressure from the
media to adopt new vaccines.

Manufacturer views
Key informant interviews of multinational and developing
country manufacturers (MNM s and DCM s, respectively)
showed that they view LMICs as attractive markets, although
they market vaccines by geographical zones rather than by
income levels. Manufacturer informants reported that they do
not see a capacity problem in supplying LMICs as long as there
is advance forecasting of when adoption will take place. The
manufacturers noted that GAVI’s success in ‘creating a market’
was based on its strong procurement practices, including
accurate demand forecasting, multi-year contracting and assured funding.

Both groups of manufacturers reported support for pooled procurement by LMICs, despite their responses indicating unhappiness with the PAHO Revolving Fund pooling procurement across its member countries with widely varying levels of per capita income. DCMs see pooled procurement as giving them access to markets (as GAVI’s procurement through UNICEF’s Supply Division has done) and MNMs appreciate the likely reduction of transaction costs, ease of procurement and more-reliable forecasting resulting from pools. MNN respondents said that the ability for individual MNMs to maintain a tiered pricing approach, however, is important to them. Tiered pricing means charging higher prices to countries with higher per capita income (said to allow manufacturers to recover investment costs of developing and increasing capacity for new products) and lower prices to countries with lower per capita income (to make products more accessible).

DCMs view themselves as disadvantaged compared with MNMs in terms of their ability to produce and market the new vaccines. DCMs are reportedly eager to see more technology transfer agreements between themselves and biotechnology companies, public health institutes and MNMs. MNMs said that they, too, are interested in technology transfers with DCMs, provided that the agreements are based on ‘economics’ (both reasonable financial compensation to the MNMs and paying attention to the scale economies of supplying the recipient) and not political factors (e.g. being required to transfer technology as a condition to supply a country). The DCMs also see some LMICs favouring longer-standing relationships with MNMs, even though the DCMs have WHO pre-qualified products to offer.

Some of the larger-population LMICs with vaccine industries, such as China, India and Indonesia, are likely to access new vaccines through various technology transfer arrangements to their local manufacturers. Technology transfers, however, take time, which may delay new vaccine introduction if the countries are unwilling to source vaccines externally in the interim.

Discussion

Our study found that the burden of disease data, vaccine prices and the cost implication of including the new vaccine in the immunization schedule were the most important factors in new vaccine adoption decisions in LMICs. This is consistent with previous studies (DeRoeck et al. 2003; DeRoeck 2004; Walsh and Mitu 2006; Griffiths and Miners 2009; Burchett et al. 2012).

The study showed that NITAGs play an increasingly important role in technically-focused decision-making processes in advising the Ministries of health and finance whether to adopt a new vaccine. This confirms previous findings by Munira and Fritzen (2007), Schoub et al. (2010) and Senouci et al. (2010), although NITAGs or their equivalent remain uneven in their capacity and resources across the 15 countries.

As mentioned previously, LMICs lag behind developed and GAVI-eligible countries in the consideration and adoption of new vaccines such as pneumococcal, rotavirus and HPV. As a result it will be critical to strengthen the current decision-making process to allow these countries to make evidence-based appropriate decisions. This involves the development of local evidence, in line with the perception that local burden of disease is key to the decision-making process. This could involve reinforcing country capacity, increased cooperation between LMICs and additional support from regional or global agencies. A particular emphasis may be placed on promoting the use of cost-effectiveness and economic benefit analysis of vaccination (Bloom 2011), which has been identified as critical in the decision-making process (Walsh and Mitu 2006) and was cited by a clear majority of the countries included in the study as a factor important in decision making. This will also mean that NITAGs are better supported and resourced.

Recommendations by WHO on vaccine adoption are valued by a majority of countries surveyed. However, our study also highlighted the lack of support by international agencies to LMICs. These agencies do not tend to focus on immunizations in LMICs, with studies showing instead that they have been increasingly focused on chronic and non-communicable diseases. This might account for the finding that advocacy was of lesser importance compared with other factors for the countries studied, not because it was not listened to, but because of its absence from the agenda of WHO, UNICEF and others.

A key finding of the study is the lack of understanding by many LMICs of pricing mechanisms for new vaccines, and the lack of procurement mechanisms to ensure affordable and reliable supplies. Our study showed that pooled procurement was viewed as a good strategy to obtain better prices for vaccines, while also economizing on procurement effort by sharing costs. The study concluded from manufacturers’ interviews that LMICs with smaller populations lacked bargaining power and information about prices, suppliers and procurement options. The smaller-population LMICs could be the greatest beneficiaries of joining a pooled procurement mechanism and having access to comprehensive information about vaccine markets, though pooled procurement could also be attractive to larger-population LMICs such as Egypt. Our survey of vaccine manufacturers indicated that they also see certain advantages to pooled procurement. However, pooled procurement raises organizational and political challenges (DeRoeck et al. 2006).

It requires participating countries to agree and co-ordinate on matters including the choice of vaccines, regulation, presentations and, potentially, schedules. This means that countries would give up some sovereignty and renounce individual procurement. Stronger regional or international leadership would be critical to push pooled procurement development forward, with UNICEF being in a good position to procure on behalf of LMICs that would request it.

The study heard from case-study countries that they did not have a reliable source to go to for vaccine prices and market information. Thus, there is a need to organize and maintain a clearinghouse to provide reliable and accurate information to LMICs, possibly based on the further development of the WHO’s Vaccine Product, Price, and Procurement Project.9 This clearinghouse could build on and expand the model of the price information provided by PAHO or by UNICEF’s Supply Division. This would allow countries both to benchmark prices, thus...
gaining useful insight of the marketplace, and to advocate for higher domestic financing. However, a limitation would be that there remain limited incentives for countries to submit procurement and price information to the clearinghouse.

The specific case of countries graduating from GAVI support needs to be highlighted. These countries stressed the challenge of raising additional resources to add new vaccines in the context of having to take over financing from GAVI of the existing vaccines. It remains to be seen whether the termination of external subsidies will cause a lag in new vaccine adoption by GAVI graduates compared with never-GAVI-eligible LMICs that had a similar or lower ability to pay.\(^7\)

We have shown that financial considerations, not surprisingly, are important in decisions on whether to adopt by LMICs. However, this is not a simple question of price per dose or cost per fully immunized child. There are many uncertainties in decision making, such as the affordability of the new vaccine, the overall cost and funding requirements of the immunization programme, the uncertainty about the future level of prices, and the price available depending on different procurement arrangements. Countries need guidance and improved information on how to better address these particular issues. Further discussions with the vaccine manufacturers are needed to address tiered-pricing policy and technology transfer.

**Strengths and limitations**

The strength of this study lies in the high number of LMICs surveyed and in the wide range of decision-makers and key influential actors that were interviewed using a standard research protocol. By drawing on a large set of key informants we were able to satisfactorily triangulate information. Another strength was that the study collected the views of vaccine manufacturers at the national and global levels, allowing recommendations to address both demand and supply issues around new vaccine adoption. However, there are several limitations to the study that we would like to highlight.

A first limitation is that we had a two-tier approach to the research, with some countries being surveyed with field visits and others remotely. This was mitigated by the use of a single protocol. Differing numbers of people were interviewed in each country, reflecting both varying stakeholders’ landscape and availability of interviewees. This is mitigated by taking the country, not the individual respondent, as the unit of analysis. Overall our findings were broadly consistent across countries, although each country has its own specific conditions to address. A second limitation is that although many themes highlighted by the research were common to the 15 countries, the results may not extend to all vaccines and countries. However, we consider that our findings based on a set of diverse countries do provide a valuable contribution to understanding of why LMICs lag behind in new vaccine adoption, and provide recommendations on how some of the current constraints to vaccine adoption can be alleviated.

**Recommendations**

The information produced by the study has led to the formulation of practical recommendations at the country, regional and global levels to assist LMICs in improving the decision-making process for new vaccine adoption. The recommendations formulated by the study team in close consultation with the study’s Advisory Group address four themes: (1) evidence and capacity building, (2) policy and advocacy, (3) financing, and (4) procurement and supply. Table 5 details the study’s highest priority recommendations.

The first set of recommendation calls for LMICs with the support of regional and global agencies to strengthen their capacities in epidemiological and economic analysis so that decisions can be backed by evidence-based analyses. The second and third sets of recommendations address funding for new vaccines. At the country level, recommendations involve improved access to information on prices and possible procurement arrangements to ensure affordable and sustainable supply. Recommendations for global and regional stakeholders

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**Table 5 Lower-middle-income country and new vaccine study: first priority recommendations**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Level</th>
<th>Country</th>
<th>Regional</th>
<th>Global</th>
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</thead>
<tbody>
<tr>
<td>Evidence and capacity building</td>
<td>Strengthen epidemiological and economic analysis capacities</td>
<td>Actively promote and strengthen regional information-sharing and joint research on burden of disease, pricing, cost-effectiveness, etc. (regional clearinghouse)</td>
<td>Create a technical and reliable source for global vaccine market information including vaccine pipeline, vaccine prices, pricing policies, procurement principles and practices</td>
<td></td>
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<tr>
<td>Policy and advocacy</td>
<td>Improve procurement regulation to promote competition, quality and sustainability</td>
<td>Conduct advocacy to strengthen political will and support champions for new vaccines</td>
<td>Conduct advocacy to strengthen political will, regulation and policy development</td>
<td></td>
</tr>
<tr>
<td>Financing</td>
<td>Take steps to increase domestic funding and capacities to negotiate with Ministries of Finance and other potential funders</td>
<td>Increase countries’ and partners’ awareness of the value of vaccination in the broader context of government investment and achievement of the MDGs</td>
<td>Promote transparency and access to comparatively low and affordable vaccine prices with sustainable domestic financing</td>
<td></td>
</tr>
<tr>
<td>Procurement and supply</td>
<td>Consider using or joining a pooled procurement mechanism</td>
<td>Develop inter-country and regional processes for achieving pooled procurement (where desired by countries), vaccine quality, safety and diversified and sustainable base of supply</td>
<td>Support regional and country activities for efficient and effective procurement systems through assessment, and identification of improvement to current practices and policies</td>
<td></td>
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</tbody>
</table>
Conflict of interest

None declared.

Endnotes

1 This study uses the World Bank’s definition of a lower-middle-income country for 2008, GNI per capita of US$976–3855.
2 Specific vaccine coverage surveys sometimes show lower rates than the figures reported to WHO.
3 The quantitative analysis sought to examine the relationship between measurable hypothesized factors (many of those shown in Table 4 of this paper) and the actual adoption decisions of countries for Hepatitis B and Hib vaccines.
4 The 2008 classification of countries was the most recent available when the study began in 2009. Note that four of the 2008 LMICs became UMICs by the 2011 classification (Albania, Syria, Thailand and Tunisia).
6 The World Health Organization’s Vaccine Product, Price, and Procurement Project (VPP) was established in 2011 and took up some of this study’s recommendations before a clearinghouse.
7 Some of the rapidly growing graduating countries now surpass in per capita income some of the countries that never were eligible for GAVI support.

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References


