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Synthesis Report: New Vaccine Adoption In Lower-Middle-Income Countries

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Executive Summary

Lower-middle-income countries (LMICs) receive little external support for their vaccination programs, despite a birth cohort of nearly 80 million and the burden of disease from vaccine-preventable diseases, such as *Haemophilus influenzae* type B (Hib) of which LMICs have 5.6 million cases out of 8.1 million cases worldwide.¹ The GAVI Alliance (Global Alliance for Vaccines and Immunization) assists 41 low-income countries (LIC), as well as some (31) at the lower-income end of the LMIC category.² As of 2010, most (86%) of the GAVI-assisted countries (whether LIC or LMIC) had adopted the Hib vaccine in their national immunization programs, but only 54% of the non-GAVI LMICs had done so. Two factors are set to exacerbate the divide between GAVI-supported countries on the one hand and most LMICs on the other. First, countries will begin to graduate from GAVI support as their gross national incomes (GNIs) per capita exceed the reassessed threshold of US\$1,500. When the new policy took hold on January 1, 2011, 16 countries began the process of graduating from GAVI support. Graduating countries will continue to receive support from GAVI's existing commitments for 5 years, though they will be required to fund all purchases of new vaccines from their national resources. Second, additional new vaccines are now on hand, and the countries that GAVI assists have the necessary help to adopt them; however, no such assistance is available for LMICs. For example, GAVI is offering support for the adoption of pneumococcal conjugate and rotavirus vaccines, and yet very few non-GAVI LMICs have adopted these vaccines. All of these vaccines are widely used by upper-middle-income countries (UMICs) and high-income countries. Thus children in LMICs have already fallen behind the rest of the world in their protection from vaccine-preventable diseases and are at risk of falling further behind.

Nevertheless, national immunization programs (NIPs) in non-GAVI LMICs perform well in delivering basic Expanded Program on Immunization vaccines to their birth cohorts. Coverage rates are high, with half of the 24 countries having coverage rates of greater than 90%. The programs are financially self-sufficient, since all costs are paid from national budgets. Thus there is a strong base to build upon.

In 2008, both the World Health Organization's (WHO) World Health Assembly and the Strategic Advisory Group of Experts on Immunization noted that little had been documented concerning the obstacles faced by LMICs in adopting new vaccines. They also acknowledged the importance of vaccinations in LMICs to reach global health goals and recommended that WHO investigate obstacles and mobilize resources for low- and middle-income country adoption of new vaccines.^{3,4}

In response, the Bill and Melinda Gates Foundation funded and cochaired (along with WHO) the Advisory Group for this study in order to address these concerns. The Results for Development Institute implemented the study, which analyzed decision making concerning new vaccines, identified and classified factors that influence the decision-making process, and gathered information from vaccine manufacturers and global experts in immunization programs. The study focused primarily on vaccines for Hib, pneumococcal conjugate, rotavirus, and human papilloma virus. With its findings, the study identified practical interventions at three levels—global, regional, and country—to address the issues uncovered.

Methods

The study employed both qualitative and quantitative analyses and benefited from the participation of stakeholders at the global, regional, and country levels. Data collection included semistructured in-depth interviews with 20 global vaccine experts; 23 representatives of 10 vaccine manufacturers (5 multinational corporations [MNCs] and 5 developing country manufacturers [DCMs]); and key informants from the public, private, and nonprofit sectors in 15 case-study countries (11 LMICs and 4 UMICs). The study's quantitative component analyzed the effects of quantitatively measurable factors on the historical adoption of the hepatitis B (Hep B) and Hib vaccines among LMICs and UMICs (see Section 2 and Annexes A, B, and D for more on the study's methods).

¹ World Health Organization (WHO). Immunization surveillance, assessment, and monitoring: Under five Hib and pneumococcal deaths and cases by country [year] excel file [xls 265kb]. http://www.who.int/immunization_monitoring/burden/Pneumo_hib_estimates/en/index1.htmlhttp://www.who.int/immunization_monitoring/burden/Pneumo_hib_estimates/en/index1.html. Accessed August 19, 2010.

² GAVI now assists 40 low-income countries (LICs) and 16 lower-middle-income countries (LMICs).

³ WHO. Sixty-first World Health Assembly: Global Immunization Strategy (May 24, 2008). http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R15-en.pdf. Accessed January 12, 2011.

⁴ WHO. SAGE tracking sheet. http://www.who.int/immunization/sage/2_Tracking_report.pdf. Published October 22, 2010. Accessed January 12, 2011.

Decision-Making Process in LMICs

Overall, LMICs try to take a systematic approach to deciding whether and when to adopt a new vaccine, but there are holes and weaknesses in their systems. Nearly every country studied has a National Immunization Technical Advisory Group (NITAG) or an equivalent body of national vaccine and vaccination experts that recommends vaccines for adoption, with the ministries of health (MoH) and finance (MoF) making final decisions, including budgetary allocations to ensure sustainability.

The deliberations often begin by noting the WHO recommendation concerning a vaccine. They then focus on the efficacy, cost, safety, and applicability of the vaccines to the burden of disease (BOD) in the specific country. Weaknesses to the approach include uneven access to national BOD data; variable ability to accurately interpret epidemiological data, including global estimates of BOD; and lack of skills and data to estimate and interpret cost-effectiveness ratios.

Once the NITAGs recommend a new vaccine for adoption, the decision of whether to accept the recommendation is also subject to difficulties. MoHs must balance the new vaccines against other priorities, which often involve a growing burden and visibility of noncommunicable diseases; a perception that high child mortality has already been solved; and health system issues, such as increased coverage by health insurance schemes. In addition, the consideration that MoHs and MoFs must give to costs and financing is beset by imperfections in the available information concerning prices, sources of supply, procurement options, and market dynamics for new vaccines.

The external partners (such as WHO and bilateral donors) that assist LICs with these issues through their in-country offices often do not focus on immunizations in non-GAVI LMICs. Thus they are of limited help, despite global and regional recommendations and advocacy for new vaccines by WHO and others.

The result of the systematic decision-making approach is a good intention to account for vaccine characteristics as compared with national BOD, cost-effectiveness relative to alternative uses of resources, and consideration for long-term financial sustainability. Unfortunately, flawed implementation of this intent often has the consequence of delays or misinformed decisions concerning adoption.

Factors Influencing Decisions

The study collected data in the case-study countries on factors that have been hypothesized to influence vaccine decision making. The results fell into four categories: (1) factors important in every country studied, (2) factors important in many countries, (3) factors important in a limited number of countries, and (4) factors that were hypothesized to be important *ex ante* but found to be of limited importance.

As would be expected given the decision-making processes described previously, the study team found that BOD information, cost considerations (including price, cost-effectiveness, etc.), and WHO estimations of BOD and recommendations for use were important factors in every country studied (Section 4.1).

Other factors important in many countries (Section 4.2) included the following:

- Policies and engagement of global or regional bodies
- Procurement mechanisms
- Experiences of neighboring countries
- Strength of the existing routine immunization program

Factors that the study found to be important in a limited number of countries (Section 4.3) included the following:

- Local vaccine production (in countries with production capacity)
- Precipitating local events (such as outbreaks of vaccine-preventable diseases)
- Perception of vaccine safety
- Leadership by local champions and advocacy by other influential parties
- Experience of the private-sector vaccine market
- Progress toward the Millennium Development Goals

Factors that the study found to be of limited importance (Section 4.4) included the following:

- Vaccine characteristics (including presentation, cold chain, and other infrastructure requirements, as well as less traditional characteristics, including the injection schedule and location of production)
- Media influence

In addition to the information collected in the case-study countries, an analysis of the influence of variables that could be measured quantitatively regarding the adoption of Hep B and Hib showed the following to be positive influences in multiple analyses (see Annex D for details):

- Adoption by neighboring countries (Hep B adoption)
- Stronger basic NIPs (higher coverage)
- Being in the Americas Region
- Being in the Western Pacific Region (Hep B and Hib)

Other positive influences indicated in the quantitative analysis, but only in single analyses, were the following:

- GNI per capita (Hep B)
- Having a budget line item for vaccination (Hep B)
- Being in the Eastern Mediterranean Region (Hib)

Manufacturer Views

The interviews conducted with vaccine manufacturers revealed some not-surprising and other apparently new attitudes concerning LMICs as markets. Manufacturers view LMICs as attractive markets, though manufacturers are organized to target marketing by geography rather than by income levels. Although the size of the LMIC market makes them attractive, manufacturers do not see a capacity problem in supplying them, as long as there is advance forecasting of when adoption will take place. According to the manufacturers, GAVI’s success in “creating a market”

is based in its strong procurement practices, including accurate demand forecasting, multiyear contracting, and assured funding.

An apparently new attitude is the support by manufacturers for pooled procurement by LMICs. DCMs see pooled procurement as giving them access to markets (just as GAVI’s procurement through the UNICEF [United Nations Children’s Fund] Supply Division has done), and MNCs appreciate the likely ease of procurement and forecasting that results from pools, as well as the ability for MNCs to maintain their tiered pricing approach. DCMs view themselves as disadvantaged when compared with MNCs in terms of the ability to produce and market new vaccines. DCMs are eager to see more technology-transfer agreements between themselves and biotechnology companies (biotechs), public health institutes, and MNCs. In addition, MNCs are interested in technology transfers with DCMs, provided that the agreements are based on “economics” (in terms of both a financial advantage to the MNCs and paying attention to the recipient’s scale economics) and not on political factors (such as being required to transfer technology as a condition to supply a country). DCMs also see some LMICs discriminating against them in procurement by favoring longer-standing relationships with MNCs, even though the DCMs offer WHO-prequalified products.

Table 1. Highest Priority Recommendations by Theme and Level

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

The study team concluded from the manufacturer interviews that smaller-population LMICs are particularly structurally disadvantaged in their relations with manufacturers, since they lack bargaining power and information about prices, suppliers, and procurement options. Thus the smaller-population LMICs would be the greatest beneficiaries of joining a pooled procurement mechanism and having access to comprehensive information about vaccine markets, though pooled procurement would also be attractive to larger-population LMICs.

Many of the larger-population LMICs that have vaccine industries are likely to access new vaccines through technology-transfer arrangements with their local manufacturers. A disadvantage to technology transfers is that they take time that may delay new vaccine introduction if the countries are unwilling to source vaccines externally in the interim.

Recommendations

The information gathered and analyzed by the study resulted in the identification of practical actions that could be taken at the country, regional, and global levels to assist LMIC immunization programs perform to their full potential. The recommendations fell into four themes: (1) evidence and capacity building, (2) policy and advocacy, (3) financing, and (4) procurement and supply. The first theme addresses weaknesses in the NITAGs' technical assessment of the need for vaccines and in the availability of information concerning vaccine prices and markets

as provided by MoHs and MoFs. The second and third themes address the priority given to immunizations at all levels and, in particular, to finding funding for them. The fourth theme takes up pooled procurement to enhance the ability of LMICs (in particular small-population LMICs) to operate in vaccine markets and to provide manufacturers with stable, predictable markets. Table 1 shows the highest-priority recommendations at each level in each theme area (see Section 7 for more information on these recommendations and for additional recommendations arising from the study). It is essential to note that funding must be provided for the implementation of all the recommendations, with external funding required particularly at the regional and global levels. Furthermore, an overall condition for the adoption of new vaccines is to ensure the basic strength of national immunization programs, thus ensuring that high coverage is attained with existing vaccines before taking on new ones.

Recommended Mechanisms for Intervention

Among actors external to LMICs, WHO's stature and authority on health policy issues generally make it a natural key player in coordinating all three levels (country, regional, and global) of intervention, as well as in implementing many of the regional and global interventions. However, WHO should take advantage of the other actors that have comparative advantages in particular areas. Thus the study recommended that WHO facilitate and coordinate implementation through a partnership, network, or consortium of the actors best positioned to act. Most notably, individual MoHs should lead the country-level interventions. See Section 8 for detailed suggestions of implementers for each recommendation.

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