Report of the Hib Task Force

The Hib Task Force was established by the GAVI Board in July 2004 to explore how GAVI can best support countries make evidence-based decisions on the introduction and/or continued use of Hib vaccination. Since July, the Hib Task Force has conducted a situation analysis, undertaken a major country consultation process, and has explored program, supply, and financing issues specifically associated with Hib vaccination.

Hib status in GAVI/Vaccine Fund eligible countries

Of the 74 GAVI/Vaccine Fund eligible countries, 15 countries have been approved for and have or are about to introduce Hib vaccine; 22 countries are considered eligible for Hib vaccine but have not yet applied; 26 countries (which together constitute the largest number of children in the world) are considered to have unclear disease burden; 8 countries are considered to have high disease burden but are ineligible due to weak immunization systems (DTP3 coverage less than 50% (with the exception of Nigeria)); and 4 countries are ineligible having already introduced Hib prior to GAVI. (Annex 1 – Map of countries eligible for GAVI/VF support for Hib vaccine.)

Feedback from the country consultation process

The Hib Task Force commissioned the consortium of the Euro Health Group and the Liverpool Associates in Tropical Health (EHG/LATH) to engage in a detailed and intensive country consultation process around Hib introduction with three groups of countries: (1) those countries that have or are about to introduce Hib vaccine (Kenya, Ghana, Malaysia*, Mongolia); (2) those countries that are eligible for Hib but have not applied (Cameroon, Mozambique); and (3) those countries considered to have an unclear disease burden (Bangladesh, Uzbekistan). Among the key general findings from the country consultation process:

(1) There is a poor understanding of Hib burden of disease and epidemiology

In contrast to a high level of understanding of Hepatitis B burden of disease and epidemiology, the importance of Hib disease is not well understood in 7/8 of the countries visited (Malaysia- a non-GAVI/VF eligible country being the exception). Misconceptions of Hib disease are common within both the national and donor communities in countries. For the most part, the decision to introduce Hib was not based on careful analysis and information on burden of disease; rather, Hib introduction appears to have largely been a “tag-along” to Hepatitis B vaccine introduction.

(2) Information sharing and communication around Hib is poor

The EHG/LATH group found that information-sharing related to Hib vaccine and introduction is poor within and between countries. Countries were somewhat aware of regional data, but there was little national data available or shared with decision-makers at the time of introduction. Furthermore, for those countries that have introduced Hib vaccine, good surveillance data is rarely available and when available, is not widely shared. To date, few countries have conducted analyses that will permit them to determine the impact of Hib vaccine introduction. Additionally, in countries eligible to introduce Hib vaccine, there appears to be a strong disparity between country and partner perspectives on Hib, with countries seeming to be more enthusiastic about the possibility of Hib introduction than donor partners. Overall, however, the level of understanding of Hib disease and issues was deemed to be poor.

(3) Future financing of Hib vaccine is highly vulnerable

For those GAVI countries that have introduced Hib vaccine, this decision was made without detailed analyses of costs and benefits of Hib vaccine introduction. Given current vaccine prices and the limited appreciation of the impact of Hib vaccine introduction, the future financing challenges are felt to be almost insurmountable without additional transitional support from GAVI. Little or no cost and financing information related to the introduction of Hib vaccine was available at the outset and the Ministry of Finance and other financing bodies were not engaged at the time of decision to introduce Hib. There is general consensus that the Financial Sustainability Planning process, while largely valuable, came too late in the process to inform decision making.

Program, supply and financing considerations associated with Hib vaccine

In parallel with, and informed by the country consultation process, the three sub-groups of program, supply, and financing explored issues specific to Hib vaccine. Among their key findings and needs assessments:

Program

Documenting Hib burden of disease and the impact of the vaccine is difficult because Hib is not associated with a single clinical syndrome, laboratory confirmation is limited by sensitivity of available methods, and in many areas there is a widespread use of antibiotics prior to the collection of specimens.

For countries that have already introduced Hib vaccine, the core challenge is to document whether the vaccine accomplishes the public health objective of reducing Hib disease. Although there are data from several industrialized countries as well as from The Gambia and South Africa, little local data exists from other parts of the world.

For countries considered to have a high disease burden but have not yet introduced Hib-containing vaccines, the core issues are to obtain disease burden and cost-effectiveness data and to communicate existing information more effectively.

In countries with unclear disease burden, the main challenge is to establish disease burden and cost-effectiveness of Hib immunization. While the gold standard for establishing disease burden is a vaccine probe study, the Hib Task Force does not consider vaccine probe studies to be appropriate for most GAVI/VF-eligible countries as there are other less costly options including Hib Rapid Assessments, enhanced surveillance, and case control studies which can serve to the document burden of disease and thereby facilitate country-decision making. However, the Hib Task Force does recognize that a vaccine probe study is both appropriate and essential to documenting Hib disease in Asia. Indeed, large countries such as India and China, consider vaccine probe studies to be imperative to documenting disease burden and determining whether to introduce a new vaccine into their immunization program. Information from a vaccine probe study would greatly facilitate decision-making in countries in Asia.

Supply

Among key findings and conclusions: (a) pentavalent vaccine continues to be the vaccine of choice of countries seeking to introduce Hib vaccine; (b) based on current uptake as indicated by WHO, there is anticipated to be an excess of supply over demand by end of 2005; (c) two new suppliers of pentavalent vaccine are expected to enter the market by 2007 raising the total number of suppliers to three; (d) without significant increased uptake of Hib, and despite anticipated competition, prices will only decline moderately; (e) it is anticipated that additional antigens will be added to current pentavalent vaccine in the future; (f) UNICEF SD is anticipating continuing on three year procurement cycles because of the changing composition of combination vaccines and to allow easy access of new entrants; at the same time it is evaluating the procurement approach to support the demand and to meet long-term objectives of Hib vaccine implementation , The supply sub-group has noted that bridge financing can act to suppress demand unless only very modest cost sharing is required of governments, based on a general assessment of affordability.

Financing

The GAVI Financing Task Force is exploring two bridge financing options to transitionally support countries that have adopted new vaccines, including Hib-containing products

Option 1: Phased national contributions according to a preset schedule for gradual and step-wise increases in national and partner contributions, whereby countries and national partners contribute an increasing percent of vaccine costs on an annual or bi-annual basis over a 5 or 10 year period (time to be determined); and,

Option 2: Fixed co-payment whereby countries and national partners provide a fixed co-payment for vaccines and the Vaccine Fund assumes responsibility for the difference between the fixed co-payment and the market price over a 5 or 10 year period (time to be determined).

Among the key considerations: eligibility, time frame, and defining increasing percent contribution in Option 1, and level of the co-payment under Option 2. The immediate next steps are:

1) per GAVI Board Agenda Item XX, request the Board to adopt US$ XXX as a working number for a resource ceiling under different scenarios;
2) analyze the potential advantages and disadvantages of current options with regard to ability to provide an incentive for increased government commitments to immunization program; and minimize transaction costs;
3) systematically consult with decision makers in Vaccine Fund recipient countries and other GAVI partners (particularly vaccine manufacturers) as to the advantages and disadvantages of each of the options; and
4) present findings to GAVI Board for decision at their next meeting.

RECOMMENDATIONS

Based on the feedback from the country consultation process and the work of the three subgroups – program, supply, and financing – it is evident that, given competing health priorities many countries lack the required information to make evidence-based decisions whether to sustain or introduce the Hib vaccine to their immunization programs. At the same time and at the global level, there is a cycle of low demand contributing to limited supply and competition leading to high prices which, in turn, contribute to low demand.

Recognizing that countries face different and sometimes multiple rate-limiting steps towards determining the relevance of Hib for their immunization program, it is the consensus of the Hib Task Force that efforts be mobilized immediately to support countries make informed and well-grounded decisions regarding the introduction and continuation of Hib vaccine in their immunization programs. ***The overall goal is not to convince countries to adopt and/or sustain Hib, but rather to ensure that countries have the information they need to make evidence-based decisions whether or not to introduce (and sustain) Hib vaccine in their immunization program given their particular country context.*** In this regard, the Hib Task Force recommends that the GAVI Board consider the following two options:

OPTION 1: Comprehensive program (includes vaccine probe study)
The GAVI Board approve an overall envelope of $37 million to be awarded through a competitive tender either to a single entity or to a consortium of partners working together over a four (4) year period to support those countries wishing to sustain Hib vaccine and those countries wishing to explore whether the introduction of Hib vaccine is a priority for their immunization program/health system.

The funds will be used to coordinate the contributions of multiple groups to support country requests in the following activity areas: assessment and monitoring of burden of disease, surveillance, information sharing, costing and financing, and global and country-level communication strategies. This recommendation includes specific support for a vaccine probe study in India (estimated cost $9 million). It is the considered opinion of the Hib Task Force that a vaccine probe study in India is essential to unequivocally documenting the burden of Hib disease in Asia.
The Government of India has indicated that is interested in a Hib vaccine probe study and would be willing to both detail personnel and co-finance such an effort.

OPTION 2: Basic Program (excludes vaccine probe study)
The GAVI Board approve an overall envelope of $27.5 million over a four -year period to be awarded to either a single entity or to a consortium of partners to provide support to GAVI/Vaccine Fund-eligible countries at their request in the following areas: assessment and monitoring of burden of disease, surveillance, information sharing, and global and country-level communication strategies. Under this recommendation, there is no provision for a vaccine probe study in India, which is deemed essential to unequivocally documenting Hib burden of disease in Asia.

Competitive process
Entities wishing to submit proposals –either individually or preferably in partnership --would require 30 days to respond to an RFP. The Hib Task Force recommends that an Independent Review Group be established to review proposals and make a final recommendation to the GAVI Board.

Oversight
The Hib Task Force further recommends that given the many similarities and parallels between Pneumococcal and Hib disease issues, the membership of the ADIP Management Committee be revised to include the required skills for oversight management to the Hib work.

Illustrative Budget (including funds for one vaccine probe study)

The following budget is illustrative for purposes of establishing an overall funding ceiling. It is anticipated that a detailed budget would be developed by the grant recipient(s) based on preliminary consultations with countries.

Item	Annual Cost ($)	Total Cost ($) over 4 years
Hib management team (staff and operations)	1,500,000	6,000,000
Regional and country support for Hib assessment and monitoring	2,750,000	11,000,000
Pilot projects (e.g. syndromic surveillance for meningitis and pneumonia)	1,250,000	5,000,000
Strengthening surveillance networks	1,125,000	4,500,000
Communication (both global and country communication)	500,000	2,000,000
Vaccine probe study	2,250,000	9,000,000
Total		$37,000,000

In parallel and pending the selection of the entity/entities through a competitive tender, the Hib Task Force recommends the following activities be undertaken by the Hib Task Force sub-groups before March 2005.

The Hib Task Force Supply Group will (a) explore the potential of developing guaranteed multiyear price and volume agreements for the pentavalent vaccines in the near-term; and, (b) consult with emerging new manufacturers to determine what they require to accelerate the development and licensure of combination products for use in the developing world.

The Hib Financing Group will continue to work with the GAVI Financing Task Force on bridge financing options and will report back to the GAVI Board in March 2005 for final approval of the bridge funding mechanism, with the intent to implement immediately upon approval. (For more information please see Board Agenda Item on Bridge financing.)