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NOTE FROM THE DIRECTOR

The first quarter of this year saw a flurry of events that have helped to accelerate the introduction of Hib and other vaccines in developing countries. GAVI recently published revised guidelines that determined lower co-financing levels for previously available vaccines, in addition to adding pneumococcal and rotavirus vaccines to the list of offered vaccines. A few countries submitted applications for the January deadline for pentavalent vaccines, and many more are preparing to submit their applications for the April deadline. The Hib Initiative will be supporting multiple studies in Africa and Asia in order to strengthen surveillance systems, which in turn will help to demonstrate the impact of these vaccines. The Hib Initiative and PneumoADIP recently supported a large meeting for investigators in Bangkok, bringing together many experts on bacterial meningitis and pneumonia to discuss ways of improving country capacity to conduct such studies. Ethiopia, the country with the 6th largest birth cohort in the world, launched its nationwide introduction of the newly available fully liquid pentavalent vaccine. With all the currently available opportunities, children in developing countries now have better chances than ever at having access to all these vaccines, and it's our responsibility to provide the evidence and facilitate the political commitment needed to make these decisions happen.

Rana A. Hajjeh, MD



Events

April 23-25
EPI Managers Meeting: EURO
Dubrovnik, Croatia

May 12
GAVI Board Meeting

May 12-23
World Health Assembly
Geneva, Switzerland

May 28-31
EPI Managers Meeting: EMRO
Tunis, Tunisia

April 17-20
Partnership for Maternal,
Newborn & Child Health
Meeting
Dar es Salaam, Tanzania

June 18-20
New and Under-Utilized
Vaccine Introduction Meeting
Geneva, Switzerland

June 19-22
EPI Managers Meeting: WPRO
Location TBD

Announcements

GAVI deadlines:

New proposals for support should be sent to the GAVI secretariat by the following deadline: **20 April** (see article on page 3).

New customizable Pneumonia and Meningitis Advocacy presentation now available: the Hib Initiative and PneumoADIP project have created a pneumonia and meningitis presentation and fact sheets. To request an advance copy, please contact Layla Lavasani at llavasani@jhsph.edu

ETHIOPIA LAUNCH OF PENTAVALENT VACCINE

Introduction of *Haemophilus influenzae* type b and Hepatitis B vaccines into routine immunization in Ethiopia

The Federal Democratic Republic of Ethiopia is committed to protecting the lives of Ethiopian children and has accelerated its commitment to Millennium Development Goals on child health and infectious diseases. On March 23, 2007, Dr Kebede Worku, State Minister for Health in Ethiopia announced the launch of a new childhood vaccine, DTP-HepB-Hib, which combines the benefits of the previous diphtheria, tetanus and pertussis vaccine and adds protection against two additional deadly killers: *Haemophilus Influenzae* type B (Hib) and Hepatitis B. Month-long launch activities began with the announcement of the new vaccine in the Somali region, an area where historically routine immunization has been low, underlining the government's commitment to protecting its children.



Dr. Tesfanesh Belay, MoH, Family Health Department Head vaccinates the first baby girl, Mieraj Siek Umer, with the new vaccine

“We are proud to invest in life-saving vaccines for our country’s children. We estimate that Hib vaccine can potentially save 1 of every 25 children that are currently dying or suffering life-long disability and prevent many from developing chronic liver disease and death caused by Hepatitis B,” said Dr Kebede Worku, State Minister for Health, Ethiopia.

“Ethiopia is demonstrating, through its sustainable introduction of life-saving vaccines, its clear commitment to reaching the Millennium Development Goals in health,” said Julian Lob-Levyt, Executive Secretary of the GAVI Alliance.

Although the pentavalent vaccine is initially more expensive than alternative formulations, the long-term benefits in terms of vaccine administration effectiveness and reduced non-vaccine costs out-weigh the marginally increased vaccine price. With support from the GAVI Alliance and The Vaccine Fund, the Ethiopian government has worked to ensure it met the criteria for GAVI support including increasing its national EPI coverage.

With the 6th largest birth cohort (2.9 million) in the world, Ethiopia has been working for some time toward the possibility of introducing new vaccines like HepB and Hib-containing vaccines. In collaboration with partners, the Government of Ethiopia (GoE) reached consensus concerning vaccine introduction—with the first choice being a pentavalent formulation (DTP-HepB-Hib). Once the decision was made, the GoE began preparation for introduction of the pentavalent vaccine along with partners including WHO,

Other Hib Related Activities

Country visits

- . Vietnam
- . Bhutan
- . Cambodia
- . Ukraine
- . Ethiopia
- . Burkina Faso
- . India

Meetings Attended

- . Global Action Plan for Pneumonia - Geneva
- . AFRO EPI - Harare
- . AFRO EPI - Burkina Faso
- . Asia Pacific Congress of Pediatrics – Colombo
- . All Party Parliamentary Group: Pneumococcal Vaccine – London
- . GAVI Advocacy Group Meeting – London
- . Bangkok Surveillance and Investigators Meeting - Thailand



UNICEF, and the GAVI Alliance. Preparations included development and distribution of guidelines for vaccine introduction, training of health care workers; development of materials for parents and health care workers; introduction of strategies to reduce vaccine wastage; and upgrading the cold chain including transport and storage. Health Extension Workers in rural communities were trained on the pentavalent vaccine to ensure scale up

The introduction of the pentavalent vaccine into the routine EPI will make a significant long-term contribution to reducing the overall non-vaccine cost of immunization. This will include lower costs for health staff, injection equipment, waste disposal, transportation and outreach.

immunization service delivery for optimal impact.

“The introduction of this vaccine, which has been demonstrated to be safe and highly effective under a wide variety of conditions, is such an important step forward in reducing child mortality and disease,” said Dr. Rana Hajjeh, Director of the Hib Initiative. “Now that the vaccine is available in Ethiopia, we hope that even more parents will fully immunize their children, reducing the threat from serious disease.”

Ethiopia: assessment of burden of *Haemophilus influenzae* type b

The Hib Initiative recently visited Ethiopia to assist with a Hib Rapid Assessment (RAT) in order to estimate the local burden of the Hib disease where population-based surveillance has not been established. Two new sites will be added the PBM network, one in Addis Abba and one rural site. The data will support a future vaccine impact study.

GAVI Phase 2 funding to allow the introduction of Hib vaccine and others at an even more affordable price

GAVI recently published revised guidelines that provided lower co-financing levels for previously available vaccines, in addition to adding pneumococcal and rotavirus vaccines to the list of offered vaccines. The new levels of co-financing will allow countries to introduce additional vaccines affordably. Co-payments for the pentavalent (DTP-HepB-Hib) vaccine range from US \$0.10 to \$0.30/dose, depending on country grouping. Importantly, Monovalent and combination vaccines require the same co-payment.

Countries will be able to select single antigen vaccines or any combination vaccines at the prescribed co-financing levels. For the first vaccine, countries will be requested to contribute a set price according to the country grouping (see chart below). The co-financing fee for each additional vaccine will cost an additional US\$ 0.15 cents (regardless of country grouping) with the exception of

Hib Focus newsletter

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We would like to hear from you

What topics would you like us to address in this newsletter? We appreciate your feedback, questions or suggestions. Please contact: Layla Lavasani at llavasani@jhsph.edu

Thanks

Photos courtesy of Photoshare and WHO/MOH Ethiopia

The Hib Initiative

unites experts from Johns Hopkins Bloomberg School of Public Health, the London School of Hygiene and Tropical Medicine, the U.S. Centers for Disease Control and Prevention and the World Health Organization to advance evidence-informed decision-making regarding the introduction and use of Hib vaccination in the developing world.

the forth vaccine which will cost from US \$0.10 to \$ 0.15 cents.

The levels indicated in the table below are minimum levels. Least poor countries are expected to scale up co-financing by 15% annually. Remaining countries can maintain levels indicated up to 2010 when they will be revised upwards gradually.

Inclusion of two new vaccines

The GAVI Alliance Board has approved the inclusion of rotavirus and pneumococcal vaccines in the portfolio of vaccines offered to countries.

An optimal co-financing model for a more simplified approach

The rotavirus and pneumococcal vaccines are anticipated to be more widely available to GAVI countries after 2009. Two vaccine formulations for rotavirus diarrhoea have demonstrated efficacy in Latin America and Europe. Efficacy studies are also underway for Africa and Asia, the results of which will determine the availability of the vaccine. For pneumococcal disease, one 7-valent conjugate vaccine, a vaccine proven effective in Africa and Asia, is currently available in limited supplies and will be available between now and 2010 for countries interested in becoming early introducers. Two additional pneumococcal vaccines that protect against additional serotypes of the disease are in the pipeline for licensure between 2009 and 2011. Increased quantities will then become available to GAVI-eligible countries.

The GAVI Secretariat will soon consult with all eligible countries to determine demand for both of these vaccines; applications for support will be requested thereafter.

Revised co-financing levels

		Price USD cents per dose by country grouping			
Vaccine	Examples	Poorest	Intermediate	Least Poor	Fragile States
1	1st vaccine single antigen vaccine or any combination vaccine	\$0.20	\$0.30	\$0.30	\$0.10
2	2nd additional vaccine single or combination	\$0.15	\$0.15	\$0.15	\$0.15
3	3rd additional vaccine single or combination	\$0.15	\$0.15	\$0.15	\$0.15
4	4th additional vaccine single or combination	\$0.10 to \$0.15	\$0.10 to \$0.15	\$0.10 to \$0.15	\$0.10 to \$0.15

Deadline for Applications: 20th April & 28th September 2007

New proposals for support should be sent to the GAVI secretariat by the deadlines above. Proposals should be prepared according to the latest version of the “*Guidelines and Application form for country proposals: phase 2.*” The form is available on the GAVI Web site at: www.gavialliance.org/Support_to_Country/Forms/index.php

Vaccine Hunters, BBC World documentary series

28 million children in developing countries do not have access to routine immunization and 2.5 million children die needlessly of vaccine preventable diseases each year.

Vaccine Hunters, a four-part documentary series, examines the science of modern vaccines, what it takes to deliver them to the most needy, and the challenges ahead. In February, BBC World aired the series comprised of four episodes:

- . An Injection of Hope
- . The Price of Life
- . Incredible Journeys
- . A Cure for Poverty?

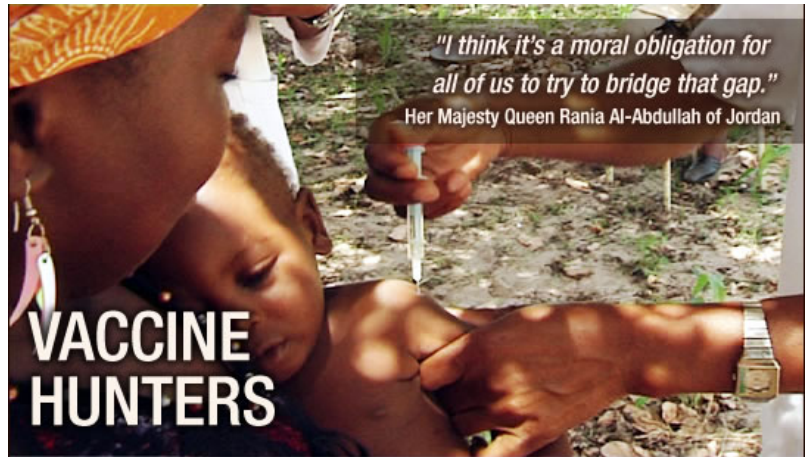
Episodes feature such topics as the real-world challenges of delivering life-saving vaccines to children in the developing world; the benefits of prevention vs. treatment; making the new vaccines accessible and affordable to developing nations; new economic models to offer vaccines at a lower cost; the challenges of delivery; the potential for new technologies in the industry such as thermostable vaccines and vaccine nasal sprays; and the impact of the new vaccines and herd immunization.

Dr. Julian Lob-Levyt, executive secretary of the GAVI Alliance; Dr. Ciro de Quadros, president of the Sabin Vaccine Institute; Vivienne Perry, UK Vaccination Committee; Queen Rania Al-Abdullah of Jordan; and Dr. Ripley Ballou of GlaxoSmithKline describe the challenges of making vaccines affordable and accessible to the countries where they are needed most.

The series provides a first hand look at the challenges of delivery. Medical staff trek on foot over precarious rope-bridges to get vaccine supplies from the distributor to the clinics in rural Kenya. Dr. Lob-Levyt visits clinics in Kenya and talks with staff about delivery of vaccines and cold storage. Queen Rania Al-Abdullah of Jordan is seen visiting clinics in India to promote the benefits of vaccination, part of her personal interest in the global immunization program.

Acknowledging that partnerships are critical for success, the series features the efforts of the GAVI Alliance as well as the Hib Initiative, The Rotavirus Vaccine Program at PATH, and the Pneumococcal Accelerated Introduction and Development Plan.

The *Vaccine Hunters* documentary is available on CD through the Hib Initiative. Please email Latia Brinkley at lbrinkle@jhsph.edu.



“If we have instruments that can avoid disease, avoid death and contribute to economic development which will in turn get people out of poverty, it would be immoral if the world leaders from all countries don’t take action.

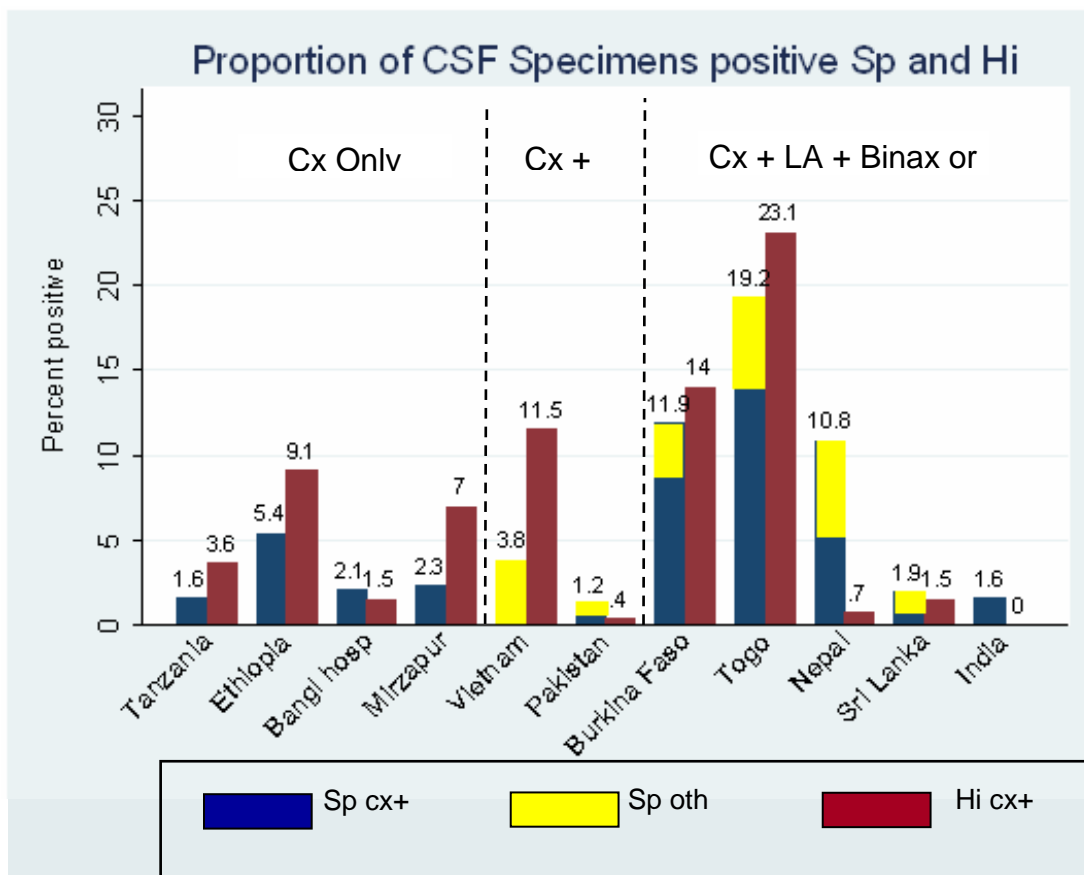
Action should be taken today.”

- Dr. Ciro de Quadros, president of the Albert B. Sabin Vaccine Institute

Pneumococcal and Hib Surveillance Network Investigators Meeting in Bangkok, Thailand, March 28-30

The 4th Pneumococcal and Hib Surveillance Network Investigators meeting was sponsored by the World Health Organization, GAVI's PneumoADIP and the Hib Initiative which brought together experts from a number of countries including Bangladesh, India, Pakistan, Indonesia, Republic of Korea, Mongolia, Nepal, Sri Lanka, Thailand, Viet Nam, Kenya, Mali and Mozambique.

Dr. Maria Knoll, Director of Vaccine Research - Pneumo ADIP, presented surveillance results from networks in both Africa and Asia. Although sites differed by age distribution (some collected data for children under 5 only, while others reported all ages); distribution of pneumonia versus meningitis; blood versus CSF samples; severity of pneumonia detected and laboratory methods (culture only, culture plus latex agglutination, +/- PCR or Binax); certain comparisons could still be made: in all cases, the number of specimens positive for *S. pneumoniae* was positively correlated to the addition of detection methods (see figure below). Hib was the most commonly isolated pathogen in CSF, but results varied, depending on whether samples were taken from children under 5 or all ages.



The urgent need for a sustained effort to accelerate the prevention of meningitis and pneumonia formed the core of discussions among leading researchers. Experts reviewed progress in each surveillance network and discussed future directions for networks and collaborators. Representatives from WHO, the Hib Initiative and PneumoADIP each gave presentations on a number of topics including a summary of surveillance projects, cost effectiveness analysis, GAVI funding opportunities, as well as presentations on communication and advocacy efforts. Successful case studies showing how data were successfully used to raise awareness about the

for child survival efforts and advocate for Hib and pneumococcal vaccines were presented by Dr. Fred Were (Kenya) and Dr. Samir Saha (Bangladesh).

In a press conference held during the meeting, Dr. Jean-Marie Okwo-Bele, Director, Department of Immunization Vaccines and Biologicals, WHO, commented, "Effective surveillance of meningitis and pneumonia has helped us to better understand the magnitude of the problem and help evaluate the impact of available vaccines." During the conference, reporters had the opportunity to discuss country experiences with Dr. Supamit Chunsuttivat, Ministry of Health, Thailand, Dr. Samir Saha, Professor of Microbiology of Institute of Child Health, Dhaka Shishu Hospital and Dr. Anita Zaidi, Aga Khan University, generating in-depth coverage of the meeting in leading papers in Thailand, Bangladesh and Pakistan.

WHO Regional Office for Africa (AFRO) Meeting in Brazzaville, DRC, January 17-18



The World Health Organization and the Hib Initiative brought together more than 100 of Africa's decision makers and leaders in immunization and child health from over 21 African nations to chart a course for the prevention of childhood pneumonia through vaccination. This meeting is the last in a series of five regional forums developed to increase awareness about meningitis and pneumonia.

The challenges to introduction of new vaccines in African nations are surmountable. New co-financing mechanisms will provide funding mechanisms to support introduction. To date, 18 GAVI-eligible countries in Africa have introduced or have been approved to introduce Hib-containing vaccines. It is the political will of nations that must make the introduction of these vaccines a national priority. Participants developed plans while at the meeting to either take advantage of the political will to introduce Hib vaccine or to develop a strategy to build support for new vaccine introductions.

Request for Proposals

The Hib Initiative Request for Proposals (RFP) process began in August 2006 in order to fund activities that assist with decision-making concerning the Hib vaccine in countries that are GAVI eligible. Expressions of interest were sought from groups that were able to design and implement studies that will contribute to the understanding of the burden of Hib disease. The Hib Initiative received 28 expressions of interest from a number of regions including South Asia, South East Asia, Western Pacific, Newly Independent States, Africa and non-GAVI eligible countries. After an extensive internal and external review in February, the Hib Initiative has made a preliminary decision regarding the proposals that will be funded. Announcements will be made in the near future.

RECENT ARTICLE

The epidemiology of pneumococcal, meningococcal, and Haemophilus disease in the Middle East and North Africa (MENA) region—current status and needs

Worldwide, three bacterial pathogens are responsible for over 80% of bacterial meningitis among children, *Streptococcus pneumoniae*, *Haemophilus influenzae* type b (Hib), and *Neisseria meningitidis*¹. *S. pneumoniae* and *H. influenzae* type b also represent major causes of bacteraemia, pneumonia and acute otitis media in children under 5 years of age.

This paper is one of the first published by the MENA (Middle East & North African) Vaccine-Preventable Diseases Regional Advisory Group, formed in 2003 by local experts in vaccine-preventable diseases, experts from Algeria, Egypt, Jordan, Lebanon, Oman, Pakistan, Qatar, Saudi Arabia, and Tunisia. The paper focuses on the epidemiology of bacterial meningitis and other invasive diseases caused by *S. pneumoniae*, Hib, and *Neisseria meningitidis*. It describes both published data and local data compiled from a number of sources and aims to inform healthcare decision makers as they assess the potential benefits of introducing new vaccines into regional and national vaccination programmes.

The paper provides a background of the three bacterial pathogens including a description of disease, mortality and incidence rates, and prevention and control strategies including conjugate and polysaccharide vaccines. The review of published and unpublished data, when available, is provided for each country and highlights the wide variability in the quantity and amount of data available. Where investigated, Hib and *S. pneumoniae* represent the major bacterial pathogens responsible for endemic meningitis (and *N. meningitidis* as well, particularly in outbreak situations). Evidence suggests that where Hib conjugate vaccines have been introduced in the region, there has been a marked decline in the occurrence of Hib disease. Along with the most likely low reporting of rates of disease, much of the data fall short in helping understand the absolute burden of disease. Given the availability of new vaccines that are highly effective in the youngest age groups, it becomes especially urgent to understand the true burden of disease in the Eastern Mediterranean Region.



In certain cases, decisions to introduce a well-proven vaccine may not necessarily need to wait for additional studies. There is significant evidence suggesting a moderate to high burden of Hib disease in the region where studies have been conducted as well as in separate analyses using the WHO Hib Rapid Assessment Tool. With this in mind and the recommendation from the WHO Scientific Advisory Group of Experts (SAGE)² that advocates for implementation of the Hib vaccine, the authors of this paper suggest that even in the absence of detailed local information, MENA countries carefully take into account the regional data in their national Hib vaccination decisions.

Reference: Hausdorff, W., Hajjeh, R., Al-Mazrou, A., Shibl, A., Soriano-Gabarro, M. (2007). The epidemiology of pneumococcal, meningococcal, and Haemophilus disease in the Middle East and North Africa (MENA) region—current status and needs. *Vaccine*, doi:10.1016/j.vaccine.2006.11.018.

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