Immunization Focus

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GAVI

GAVI is a partnership of public and private organizations dedicated to increasing children's access worldwide to immunization against killer diseases.

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Inside this issue

NEWS

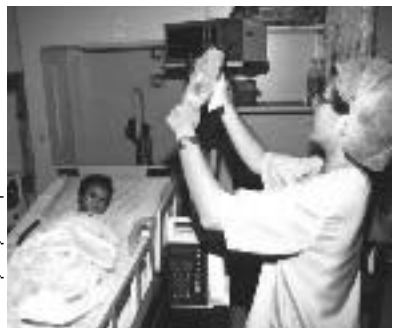
Malaria vaccine moves ahead

A CANDIDATE vaccine that provides partial protection against malaria is to start trials in children in Mozambique next year. The announcement, from the international Malaria Vaccine Initiative at PATH(1) and the vaccine's developer GlaxoSmithKline, came this month as researchers reported that the vaccine reduced rates of infection in a group of adults in a trial in The Gambia(2).

Although the protection is incomplete and shortlived, the evidence so far suggests the vaccine is more promising than most previous candidates, say researchers. "This is the first vaccine that has showed convincingly that you can protect people against malaria," says Adrian Hill of the University of Oxford, a member of the team involved in the Gambian trials. But the vaccine, called RTS,S/AS02, needs to be modified to make it longer-lasting and more powerful, he says.

Nevertheless scientists and public health officials believe that trials of the vaccine in children are justified, because it might offer more benefit to children than to adults. Children make up some 90% of the estimated one million people who die of malaria each year. Young children tend to suffer from more severe episodes of malaria than adults, because they have not yet built up an immune response to the parasite. If a vaccine provides even partial protection, it might allow children to build up some natural immunity while experiencing fewer, and milder, episodes of infection.

Malaria vaccines are notoriously difficult to develop, partly because the malaria parasite, *Plasmodium falciparum*, has a complex life cycle and presents different faces to the immune system. For malaria-endemic areas, scientists believe it will be important for vaccines to block infection by the parasite rather than merely reducing the symptoms of the disease. To do this, a vaccine needs to target the immature form of the parasite, the sporozoite, which enters the bloodstream from the bite of an infected mosquito. RTS,S/AS02 is made with a protein from the sporozoite, fused to the harmless surface antigen from the hepatitis B virus. In The Gambia, the vaccine protected 71% of men from infection in the first nine weeks after it was given, although protection waned to zero by sixteen weeks. Overall, the vaccine's efficacy over the period of the trial was 34%. The MVI project aims to increase the duration of protection and the efficacy of the vaccine.



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One of the lucky few: a child in Thailand is treated for severe malaria. Many children never get to hospital

Although GAVI will support some research and development, malaria vaccines are not currently receiving Alliance support because other players are funding them. The Alliance will instead focus its R&D resources on a limited number of products and technologies that are very close to market, such as vaccines against meningitis A, pneumococcus and rotavirus. But the Alliance considers the development of malaria vaccines to be a high priority for global health and its partners have welcomed the international support for the Mozambique trials of RTS,S/AS02. ■

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More combination vaccines needed

Faced with a bigger than expected shortfall in supplies of some vaccines, countries must make choices. Phyllida Brown reports

WHEN governments began to set out their immunization plans in their proposals to GAVI last year, most said they wanted to use new combination vaccines—those that immunize a child against four or five diseases in one shot—rather than have two or three separate vaccines. The benefits are obvious—fewer needles, fewer procedures, fewer demands on staff, children and parents. The challenge at the end of 2001 is that the supply of these vaccines is still far short of the demand, and that it will be perhaps three more years before all countries that want them will receive them.

This is frustrating for immunization programme managers and all those they serve—and for the Alliance as a whole. GAVI policy clearly states a preference for combination vaccines where possible(1). At issue are two key combinations: diphtheria, tetanus and pertussis plus hepatitis B (DTPHepB) and a five-antigen (pentavalent) combination that also includes *Haemophilus influenzae* Type B (DTPHepBHib). Last year, the Alliance had been told that there would be some 30 million doses in total of these two vaccines by 2002. Now the manufacturer, Glaxo SmithKline, has told GAVI that the true figure will be closer to 20 million. "This has created a big challenge for us," says Tore Godal, Executive Secretary of GAVI.

Already, last year, the Alliance had advised countries that there were too few doses of these relatively new vaccines for everyone who wanted them(see 2), and the GAVI Board had agreed a policy to allocate the available vaccines. Countries were allocated vaccine on the basis of need, giving priority to countries with the most fragile immunization systems and the lowest routine coverage. It was argued that the more fragile the immunization system, the greater the difficulties in introducing separate additional antigens. However, in addition, the Board ruled out Pakistan and Bangladesh because the large populations of these two countries alone could have used up the entire supply.

Even though the manufacturer has almost doubled its production in a year, its output has not grown as fast as expected. As a result, the 12 countries that have already received some supplies of these combination vaccines (see Table) will continue to receive them, but no new countries will join the list in 2002 or 2003. GSK says it will be up and running with significantly increased production by early 2004, but it will probably be 2005 before every country gets what it wants.

Wary producers

So what happened? First, it appears that the manufacturer was wary of putting its full investment into scaling up the production of the vaccines until it had firm evidence of the amounts of vaccine that GAVI would buy. It can take three to five years to scale up production of a vaccine, including adapting the manufacturing plant. But scale-up will only happen when the manufacturer is sure that the buyers are there. The combination vaccines had first been released on the market in 1996, but, says Walter Vandersmissen of GSK, there had been little demand for them until 1999. "The response at first was zero," he says. Surprised, the company sat tight, wondering if there would ever be any customers. Then, in 1999, the Revolving Fund of the Pan American Health Organization (PAHO) started to buy the pentavalent DTPHepBHib combination. "Until then, obviously, we had not stepped up production," says Vandersmissen.

In 2000 and 2001, GSK has been making as much of the two combination vaccines as it can: "We are at the limit of our capacity," says Vandersmissen. The company's estimate that it would have 30 million doses available for GAVI by 2002 was thus vulnerable to any quirk, however small, in production.

Countries needing more time

Vandersmissen points out that GAVI itself has—perhaps inevitably—been slower in approving countries for receiving the vaccines than the ambitious original timetable it originally set itself. Although the GAVI process has been faster than traditional funding mechanisms, its independent review committee has had to request further information from some countries before approving their proposals, and some countries found that they needed more time to gather the information. As a result, says Steve Jarrett of UNICEF, which buys the vaccines on behalf of countries with approvals from GAVI and funding from the Vaccine Fund, "The amount [of vaccine] that we have bought this year is relatively low compared with what we thought we would buy… as there has been a slow uptake by countries." This appears to have made GSK wary of committing itself to immediate full-speed scale-up.

Originally, says Jarrett, UNICEF planned to buy 24 million doses of the two combinations in 2001, but deliveries to most of the approved countries did not start until the autumn. This was due, he says, to ◗

Table 1: The countries that already get the combination vaccines

Countries receiving DTP+HepB:
Cambodia, Cote d'Ivoire, Eritrea, Laos PDR, Madagascar, Mozambique, Tanzania

Countries receiving DTP+HepB+Hib:
Ghana, Kenya, Malawi, Rwanda, Uganda

combination vaccine not being readily available until the second half of the year, as well as some countries' desire to start deliveries late in the year to allow prior preparation.

GSK's own business decisions may also have played a role. In deciding how to allocate antigens between the manufacture of each of the two combination vaccines, the company appears to have chosen to make relatively more of the DTPHepBHib (pentavalent) vaccine, for which initial demand from countries was more modest, than the DTPHepB (tetravalent) vaccine, for which demand was much greater. Each dose of pentavalent vaccine is priced at above $3, compared with around $1 for the tetravalent vaccine. "It is difficult to understand why there was this huge offer of pentavalent vaccine when both the UNICEF tender and the [GAVI] forecasting group projections of demand were much lower," says Julie Milstien in the WHO Department of Vaccines and Biologicals.

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Join the line: vaccine production must be planned months or years ahead

Vandersmissen at GSK admits that the higher-priced pentavalent vaccine is more attractive for the company to make. "There is a difference in price and clearly that makes it more interesting to us to have the newer product added to our output," he says. But he stresses that the prices of the two products are not directly comparable because the tetravalent vaccine is packed in 10-dose vials whereas the pentavalent vaccine is in two-dose vials.

Nor is profit the sole consideration, he says. First, the company had been told that demand for the pentavalent vaccine was likely to rise further in future, he says. Second, the Hib component of the pentavalent vaccine must be freeze-dried, and competition for freeze-drying capacity in the plant creates a "severe bottle neck," says Vandersmissen. Having committed a significant part of that capacity to Hib, the company was not about to waste it. "If you have a scarce resource you must put it to the best use," he says.

While the shortfall continues, there are alternatives. There are plentiful supplies of hepatitis B vaccine available in monovalent form, and, given the delay until the combined vaccine will be fully available, most countries may choose to use it alongside DTP. So far, countries have been "very pragmatic" about the shortfall between demand and supply, says Godal, and he is optimistic that the impact of the delays will be small.

In the medium term, an alternative combination vaccine could become available from 2002. A liquid-form tetravalent vaccine combining DTP and Hib, made by Chiron Vaccines, is expected to be prequalified by WHO shortly and a freeze-dried combination of the same four antigens has been put forward to WHO for approval. Some countries might choose to use one of these together with monovalent hepatitis B vaccine, although the available quantities are not yet known.

Despite the new money available for vaccine purchase, the overall system is still in need of improvement, says Klaus Friederich, head of government and international institutional policy for Chiron Vaccines in Marburg. Industry needs earlier decisions from the public sector on the number of doses of each vaccine it needs, and firmer commitment to buy, he says. He has been told to wait for a final decision on the amount of the liquid DTPHib that UNICEF will buy from Chiron for delivery from September 2002 onwards. "But the lead time to produce the product is more than 50 weeks," he says. "What do I tell the production guys?"

But Milstien at WHO points out that the vaccine is still not prequalified, with WHO awaiting "minor" information from Chiron. "It's a bit of a catch-22." Everyone, it seems, is waiting for someone else. "We are asking countries to consider what substitute they want," says Godal. "We will be seeking to make decisions in early February."

All players can suggest ways to improve the process. Friederich is puzzled that the public sector purchasers cannot commit themselves earlier to buy vaccines whose shelf life is more than a year. Public-sector representatives point out, in turn, that since the formation of GAVI there have been forecasting meetings at which the industry has always been present, giving them knowledge of further demand.

Ultimately, the small number of players in the vaccine industry creates a seller's market for certain products, which some observers feel is inappropriate. For example, says Friederich, PAHO is shortly to tell Chiron how much of the DTPHib vaccine it wants, effectively coming forward as a customer before UNICEF. With a limited amount of vaccine available, Friederich does not believe it should be left to a company to decide which public-sector buyers should get the vaccine.

"The system has to be fine-tuned"

"Everyone is trying very hard, and this is a mutual challenge," he says. "But the system really has to be fine-tuned." ■

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The new global fund and GAVI: similar approaches or different?

Nine months after the first announcements of the Global Fund to Fight AIDS, Tuberculosis and Malaria, Lisa Jacobs assesses progress and compares the experiences of GAVI and the new initiative

THE progress of GAVI and The Vaccine Fund have been watched by many in the field of international public health. Some of the most keen observers are those involved in setting up the new Global Fund to Fight AIDS, Tuberculosis and Malaria.

The team that has been developing the framework for the new Global Fund is meeting for the third and last time this month and is expected to make some key decisions about how the fund will work. Meanwhile, discussions at previous meetings and negotiations have pointed to a basic outline for the fund's operations and priorities. A number of the strategies developed by the GAVI partners to provide money and new vaccines to countries' immunization systems are being analysed and modified to fit the needs of the new Global Fund.

Background to the initiative

The seeds for the new fund were planted at the G8 Summit in Okinawa in July 2000, when the idea for a global partnership to mobilize significant new resources to fight the three major infectious disease killers first emerged. In April 2001, UN Secretary General Kofi Annan issued a challenge to the world for an "AIDS war chest" at the OAU AIDS summit in Abuja. This challenge was accepted by world leaders in June 2001 at the first UN General Assembly to focus on AIDS, and one month later at the G8 Summit in Genoa.

Since then, a Transitional Working Group, a body of nearly 40 representatives of governments of developing and donor countries, nongovernmental organizations, the private sector and UN agencies, has been formed to build the foundations and working principles of the fund. Supported by a temporary secretariat in Brussels, by December 2001 the group will have organised six regional and thematic consultations with developing country health officials, NGOs, and academia, to develop strategy and options papers on how this fund should operate.

The GAVI "model" has been cited in a number of these discussions and documents that are helping to frame the development of the new disease fund. And as the fund moves closer to reality, a number of its elements will be familiar to those who have been involved with GAVI.

Lean structure

"No new bureaucracy", could be considered a rallying cry amongst those involved in setting up the fund. While basic decisions on the GAVI structure and its policy-making systems were made even before the Vaccine Fund was created, its aims of operating leanly and efficiently are considered equally appropriate for the Global Fund to Fight AIDS, Tuberculosis and Malaria.

The fine details are still being hammered out, but it has become clear that policies for the new fund will be decided by a small board with 18 members, the administrative functions will be carried out by a small secretariat, and options for policy and technical issues will be explored by task forces or working groups, for consideration by the Board. A larger partnership forum that meets every other year, such as those employed by GAVI, Roll Back Malaria, and the Stop TB Initiative, will provide the opportunity for a wide range of stakeholders to contribute to discussions on how the fund will work.

Independent review of proposals

For GAVI, the Independent Review Committee is considered to be an important component of the proposal process. It is intended to provide neutral, consistent advice to the GAVI Board about which country proposals are ready for approval and which countries need more technical assistance before funding and vaccines should be delivered. The new global fund will most likely develop similar arrangements, although it will need to closely monitor the review committee's workload, considering the potential number of proposals being submitted to address the three diseases.

Country level partnerships

Country inter-agency coordinating committees (ICCs) that were first developed to support polio eradication and then broadened to focus on improving routine immunization systems and prepare and implement proposals to GAVI and the Vaccine Fund, have proven to be a robust mechanism for increasing collaboration with national partners and ensuring that each country has full ownership of its immunization plans. The global fund will encourage similar partnerships, so that governments, NGOs, private sector organizations, bilateral and UN agencies involved in fighting the three diseases will work together to develop proposals, implement programmes and monitor results.

Performance counts

The GAVI "share" system—investing in plans to increase immunization coverage and rewarding countries for results achieved—is being closely examined as a method for disbursing funds from the new global fund. The details are still at the early stage of development, but options are being explored to fund programmes that measure indicators such as the percentage of children who sleep under bednets to protect them from malaria, the number of adults who have access to quality voluntary ◗

HIV testing and counselling programmes, and the proportion of people with TB infection that complete DOTS therapy. HIV incidence rates may also be used as an indicator.

Representative board

The structure of the board will be somewhat different from that currently set up for GAVI. Country delegations will make up the majority of the board—14 seats, with 7 seats each from developing and industrialized countries. Civil society rounds out the Board with 2 seats for NGO representatives and 1 each for foundation and private sector donors. The global fund board will include UN agencies—likely to be WHO, UNAIDS and The World Bank—but as *ex officio*, non voting members. One *ex officio* seat would also be held by a person living with HIV/AIDS or from a community living with TB or malaria. Constituencies will develop their own processes for selecting board representatives from among their members, with the option to rotate or renew members.

Focused priorities

In order to move fast to reduce the devastating impact and suffering caused by these diseases, the new disease fund will focus funding efforts on scaling up and increasing coverage of proven and effective interventions. The fund will seek—especially in its earliest phase—to maintain a focus on outcomes. However, past experience has shown that in order to promote sustainability, focused efforts must never lose sight of the broader context. The fund will therefore encourage programmes that build on, complement, and co-ordinate with existing regional and national programmes, policies, priorities and partnerships, including poverty reduction strategies and sector-wide approaches.

"Quick-start" funding

Many consider the start-up of GAVI and the Vaccine Fund to have been extremely fast. Political pressure on the Global Fund to Fight AIDS, Tuberculosis and Malaria is pushing it to move even faster. At its final meeting this month, the transitional working group will be exploring strategies for disbursing money quickly—possibly by identifying programmes that are ready for implementation but lack resources, or providing seed money to projects that look promising and will deliver rapid, measurable results. With millions of people's health in the balance, the choices will be watched with intense interest. ■

GAVI Communications Officer Lisa Jacobs has been advising and assisting the temporary secretariat of the Global Fund to Fight AIDS, Tuberculosis and Malaria, working on a part-time basis.

UPDATE

A year of reckoning for Hib

New tools to measure the burden of a killer microbe are delivering results fast, as Phyllida Brown discovers

DESPITE claiming the lives of some 400,000 children a year, *Haemophilus influenzae* Type B (Hib) was for years barely acknowledged as a health threat in many countries. As recently as last year, *Immunization Focus* reported that some governments were unwilling to introduce a Hib vaccine because they lacked data to show the burdens of pneumonia and meningitis caused by the microbe in their populations(1).

Today, all that has changed. Officials at WHO report a sharp upsurge during 2001 in the number of countries in Africa and the Middle East that are keen to measure the burden of Hib nationally and act to control the disease. "It's catching on like wildfire," says Chris Nelson, an epidemiologist in WHO's Department of Vaccines and Biologicals.

The reasons for the sudden growth of interest in Hib are probably twofold. First, there is the obvious attraction of new resources for Hib immunization through GAVI and the Vaccine Fund. But equally important, major practical initiatives have been launched to enable countries to assess their own Hib disease burden, raise awareness of the problem and build national surveillance systems.

> **"Just six months after the first training session, we can see success"**

Hib is one of the leading causes of pneumonia and meningitis in young children, but because diagnosis is difficult and can be confirmed only where hospital and laboratory facilities are adequate, it often goes unidentified, lumped together with the other causes of pneumonia and meningitis in the countries where the burden of childhood diseases is heaviest. In this way, it has kept a disproportionately low profile for a major killer.

No longer. Starting in 1999, WHO and its collaborators had begun to develop and introduce a tool for rapidly assessing the local burden of Hib disease which, after field testing and refinement, is now published and downloadable from the WHO web(2). And this year, WHO also launched a network for laboratory-based surveillance of bacterial meningitis in children, starting with Sub-Saharan Africa. The initiative, which is investing US$14,000 per country for training and equipment, is funded by the Gates Children's Vaccine Program at PATH and the US Agency for International Development.

The rapid assessment tool can be used to produce estimates of disease burden within about 10 days. It uses two separate methods to estimate this burden. Because pneumonia surveillance is difficult, the first method focuses on identifying cases of meningitis. To do this, officials select an area within their country whose population is well defined and search all clinical records for cases of meningitis that occurred among young children during the preceding year. These data are then used ◗

together with information on the outcome of each patient's illness and laboratory data to calculate a local estimate of Hib-related cases and deaths. The estimates are made not only for meningitis, but also for the much more widespread Hib pneumonia: using existing data, researchers estimate that there are about five cases of Hib pneumonia for every case of Hib meningitis. After conducting this exercise in several districts, national estimates are extrapolated.

Asia and the Pacific next

The tool's second method is used where clinical and laboratory records are not sufficiently complete; it is also used to complement the first method where possible. Using data for deaths in under-fives, officials identify what percentage of those deaths are due to acute respiratory infections (ARI), and then use the existing data to estimate what proportion of the ARI deaths are Hib-related. In turn, this allows an estimate of the number of Hib meningitis cases.

Countries have already moved fast to implement the tool: in Sub-Saharan Africa, Ghana, Tanzania and Uganda have conducted assessments, while in WHO's Eastern Mediterranean region, Egypt, Iran, Jordan, Oman and Yemen have also completed their assessments. Next year, Zimbabwe, Lebanon, Libya and Pakistan are among those countries planning to go ahead, and activities are also expected to spread to south Asia and the Pacific with assessments planned in Bangladesh, Malaysia, the Maldives and Thailand.

Meanwhile, the network for surveillance of paediatric bacterial meningitis has already conducted training sessions for paediatricians, microbiologists and data managers drawn from the largest hospital in the capital city of each of 27 countries in Sub-Saharan Africa, together with immunization officials from each health ministry.

New equipment

"Bringing together all members of the surveillance team at one time has contributed to the early success of the programme and has helped to raise awareness," says Nelson. The training covers surveillance activities in the clinic and lab, and, under a regional coordinator, the initiative is providing each country with a manual(3), laboratory reagents, and laptop computers for data management and reporting.

In Addis Ababa, Ethiopia, earlier this month, Dr Themba Mhlanga, coordinator of the network in Sub-Saharan Africa, gave an upbeat assessment of progress. "Just six months after the first training session we can already see the success of this programme, with half of all countries reporting surveillance data on a monthly basis," he told the Ninth Meeting of the African Task Force on Immunization in Africa. Next year, the surveillance network is expected to expand to the Eastern Mediterranean region.

So far, only Ghana, Kenya, Malawi, Rwanda and Uganda have been allocated Hib vaccines (in combination form) by GAVI and the Vaccine Fund. Additional countries are not likely to receive Hib vaccine until next year at the earliest, because of a shortfall in the supply of the existing combinations (see article in this issue, page 2). But, judging from the experiences of countries in Latin America, Europe and North America, the impact of the vaccine is likely to be dramatic once it is introduced: Hib could be facing virtual elimination within years in the countries where immunization is fully implemented. For now, however, the onus is on countries to establish paediatric bacterial meningitis surveillance and measure their Hib burden. So far, from the commitment shown by the first round of countries, there is every sign of rapid progress towards this end. ■

Phyllida Brown

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(3)*The WHO/AFRO Hib-Paediatric Bacterial Meningitis (Hib-PBM) Surveillance Network: Surveillance Manual. Field Test Version,* July 2001.

Note

Management guidelines for the introduction of Hib vaccine are also available from WHO, including information for health workers and parents (WHO/V&B/00.05).
A fact sheet on Hib is also available (WHO/V&B/01.29) at http://www.who.int/vaccines-documents/DoxGen/H3DoxNew.htm.

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