

Immunisation for All?

A critical look at the first GAVI partners meeting

by Anita Hardonⁱ

The road to GAVI

The global effort to immunise the world's children is a remarkable success story. Building on the gains of the global smallpox eradication programme, the World Health Organization (WHO) launched the Expanded Programme on Immunisation (EPI) in 1974. At the time less than 5% of the world's children were immunised against the six main target diseases, diphtheria, tetanus, whooping cough, polio, measles and tuberculosis, though vaccines for them were inexpensive. The EPI effort was accelerated when the Universal Childhood Immunisation (UCI) campaign was adopted. At the 1990 World Summit for Children, the United Nations Children's Fund (UNICEF) declared that the UCI target of 80% had been achieved.ⁱⁱ When this success was announced in 1990, the main actors initially planned to continue the effort to reach the 10%-20% of the population still lacking vaccine coverage. As the then assistant Director-General of WHO stated:

Vaccination coverage does not only need to be sustained, ... it needs to be increased. The reason for setting a goal of 90% coverage by the year 2000 is that this requires extending vaccination to the currently unreached. These are the poorest of the poor, and those to whom vaccination especially benefits, as they are at special risk from disability and death from vaccine preventable diseases.ⁱⁱⁱ

Instead, the thirty year effort to immunise children and adults began to break apart in the 1990s. The change happened for a number of reasons including war, new diseases (such as HIV/AIDS), donor fatigue and a change of leadership at WHO. (Dr Hiroshi Nakajima of Japan became the organisation's new Director General, replacing Dr. Halfdan Mahler, a staunch advocate of "Health for All"^{iv}) These changes influenced international agencies involved in immunisation programmes and caused them to decrease their emphasis on reaching out to under-served populations. In the 1990s, agencies followed more selective approaches, including the eradication of polio and the development and introduction of new and improved vaccines.

The results of immunisation efforts in the 1990s were dismal. Immunisation coverage deteriorated in most of the world's poorest countries. By 2000, global coverage for the six traditional vaccines had dropped to 75%.^v More disturbing still, UNICEF identified 19 countries, mainly in Africa, where diphtheria, tetanus and polio (DTP3) coverage dropped below 50%. In another 22 countries, fewer than 75% of children receive DTP3 immunisation. Some countries were hit even more

severely: Nigeria's overall coverage went from 80% in 1990 to 27% in 1998; the Democratic Republic of Congo's immunisation rate dropped from 46% to 25% for the same period, while Togo went from 100% coverage to little more than half of that (54%).^{vi} The result is an estimated 3 million unnecessary vaccine preventable deaths per year.^{vii}

How GAVI works

This deterioration of immunisation services is now being addressed by a multi-million dollar Global Fund for Children's Vaccines launched by the Global Alliance for Vaccines and Immunization (GAVI), a public-private venture formally launched at the World Economic Forum in Davos in January 2000. GAVI's strategy involves improving access to sustainable immunisation services, expanding the use of all cost-effective vaccines, accelerating the introduction of new vaccines, speeding up efforts to create new vaccines and making immunisation a central part of assessing international development efforts.^{viii} Its founding partners include the WHO, UNICEF, the World Bank, The Bill and Melinda Gates Children's Vaccine Program, the Rockefeller Foundation, the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA) and some national governments.

The Global Fund and GAVI were created when the Bill and Melinda Gates Foundation made a US\$750 million donation to reach a "simple" goal: "to fulfill the right of every child to be protected against vaccine-preventable diseases of public health concern"^{ix}. Since this initial donation, the Fund has received commitments from the governments of the US (\$US50 million), Norway (US\$125 million), the United Kingdom (\$US5 million) and The Netherlands (US\$100 million). This massive monetary support to the Fund has revitalised global immunisation efforts.

GAVI documents state that the Global Fund's Board decides on the allocation of resources to projects and programmes that GAVI has recommended. The Fund is not obliged to follow GAVI's recommendations. Responding to queries on the composition of the Global Fund's Board, a communication officer for the Bill and Melinda Gates Vaccines Programme explained that, at present, it had renewable and rotating members (see appendix).

A first assessment of GAVI

The Global Fund's operations and the GAVI were discussed at the first biannual meeting of GAVI partners held in Noordwijk, The Netherlands from 20-21st November 2000. At the meeting, members of GAVI's Board and its task forces presented summaries of the progress made during the past year. Through an independent review process, GAVI's Board has recommended to the Global Fund that 23 countries receive support to strengthen their national immunisation plans. Thirteen countries were selected in September. An additional ten were chosen during the Board meeting preceding the GAVI partners meeting.

Details of the first round of approvals reveal that a total of US\$150 million in vaccines and funding^x is to be given to the 13 countries already involved over a period of five years^{xi}. Details on the first disbursements (2000/2001) reveal that approximately 10% of these funds are earmarked to strengthen immunisation services, while 90% will go towards introducing new vaccines, mainly hepatitis B.^{xii} GAVI policy encourages the use of the newly developed DTP-hepatitis B vaccine, especially in countries with a weak immunisation programme. The emphasis on the introduction of

new and under-used vaccines in GAVI reflects a more general shift away from equity towards technological innovation and disease eradication in global health programmes. This appears to indicate a fundamental move in vaccine policy from the values of the Post Alma-Ata (Primary Health Care era). The dominant themes in international health at that time included community participation, the right to health, and equitable distribution of health resources. Now in the opening days of the new millennium, international health policy makers involved in immunisation programmes seem to view developing countries no longer primarily as recipients of internationally procured essential vaccines, but rather, as markets for new ones.

By spending such a large amount of its resources on new vaccines, GAVI and the Global Fund run the risk of compounding health inequities in the poorest countries which they have prioritised for support. In nine of the countries selected for support in the first round, immunisation coverage remains below 75%. However, under new arrangements, the remaining 25% or more are likely to remain “unserved”. By introducing a hepatitis B vaccination in these countries, children who are already being immunised with the traditional EPI vaccines will be protected against yet another disease. The under-reached children are most likely to be those living in the worst poverty. Another concern, acknowledged at the Noordwijk meeting by a spokesperson from the Vaccines Supply Division of UNICEF, is that the rapid increase in demand for the hepatitis B-DTP combination vaccine cannot be met.

GAVI’s appeal for industry

The emphasis on the introduction of new vaccines makes GAVI an alliance in which industry is willing to participate. The GAVI Board’s seats includes two for industry – one for an Organization of Economic Cooperation and Development (OECD) industry representative and one for an industry representative from a developing country. Jean Stephenne, president of SmithKline Biologicals (a company producing the combination DTP-hepatitis B combination which is now in great demand) outlined in one of the meeting’s keynote speeches the conditions for industry participation in the Alliance. This included a guarantee for “reasonable prices”, support for a credible and sustainable market, respect for international property rights, a tiered pricing system including safeguards against re-export of products back from developing countries to high-priced markets, and a prohibition on compulsory licensing^{xiii}. In plenary discussions and breakout sessions in Noordwijk, industry representatives involved in vaccine development stressed the need to rely on research-based companies to develop the needed new vaccines, and said that they opposed technology transfer proposals. They stressed that vaccine development is too complex for public research institutes and local producers in developing countries. “Push and pull” mechanisms to accelerate vaccine development were proposed, involving public sector subsidies to companies to conduct clinical trials and set up manufacturing plants.

The GAVI partners appeared unconcerned about some possible conflict of interest between the large research-based companies’ interest in markets for new products and the public health objective of preventing childhood mortality in developing countries. In what is proposed as the “win-win-win” paradigm, there is little room for critical questions.

Asking critical questions

The problem with the new ideology governing public/private interactions is the firm conviction that everyone benefits and no one loses. In the programmes approved by GAVI, developing country governments will join hands with multilateral and bilateral agencies to increase the number of children reached by the services who receive new, expensive and under-used vaccines. Those children not reached by current immunisation programmes will probably lose out again. As inequity in access to vaccines increases, they remain the losers.

While many developing countries have seemed eager to benefit from the Alliance's support, some lone voices of dissent could be found in Noordwijk. "We know what needs to be done," said Dr. Muga, a representative of the Kenyan Ministry of Health, during the meeting's open forum. "GAVI partners don't take the time to find out why we don't do what we should be doing." He stressed the need to support local systems and enable people at country level to perform.

GAVI's effects on the UN

Have public/private interactions, such as GAVI, weakened or strengthened the role of UN agencies including the WHO and UNICEF? This question must be asked remembering that they achieved near universal immunisation coverage by 1990. Other important questions arise from the fact that, in GAVI, UN agencies are partners, and no longer the leaders. WHO's Director General has been appointed the Board's chair for its first two years and she will be followed by Carol Bellamy, UNICEF's Executive Director for another two years. But it is unclear who will lead the initiative after that. GAVI's structure also includes no clear mechanisms for accountability nor is there transparency in its decision-making. Decisions are made by the board which is dominated by donors and Northern representatives (including the Gates Foundation and representatives from the industrialised country governments which have contributed to the Global Fund).

In Noordwijk, the GAVI Board first met with other partners and made a number of key decisions including which diseases would be the focus of the vaccine research and development programme. The first GAVI partners meeting felt somewhat like a public relations event: partners were told what was happening, but given little opportunity to contribute to strategy development and decision-making. By contrast, in the UN system, there are some mechanisms for accountability, e.g. during General Assemblies. And importantly, in the UN structure, developing countries rather than donor countries and agencies, hold the majority vote.

Further concerns involve the lack of sustainability. From 1990, in the era of donor fatigue, developing country governments started to develop mechanisms to become more independent in vaccine needs. They were supported in this by the UNICEF Vaccine Independence Initiative. Under GAVI, donor dependence for the procurement of vaccines is being reinforced. What will happen in five years' time when the Gates Foundation donation has been spent? Will the necessary global, political will still exist to support immunisation programmes in the poorest countries? Or will these countries be left to find resources for the expanded, and more expensive, immunisation programmes that GAVI brings? As William Muraskin, a writer who has studied the politics of public health commented on the Gates initiative: "They are as bright as hell, and I'm very impressed with the Gates people, but it doesn't answer the question of sustainability." He continued, "Bandwagons can stop as well as go."^{xiv}

It is difficult to criticise a vaccine initiative. No one is against increased immunisation coverage. That isn't the real issue. Rather, what needs to be examined and discussed openly is the question of who is going to direct these important efforts and make sure that they reach the people who most need them. Who will ensure that public health needs are addressed before the private sector agenda or that of the research-based industry? Can private foundations, providing the overwhelming majority of funds for such efforts, be held accountable in the way that governments or UN agencies can? And is it really their role to provide the financial support to vaccinate the world's children? What responsibility do national governments have to continue their commitment to reach this crucial goal? As Jeffrey Sachs, an international economist at Harvard University and chair of the WHO's Commission on Macroeconomics and Health has said, "It's not a year or two of help that we need, but it's 20 years of help. What Gates has done is fantastic. But Gates by himself can't carry the world on this."^{xv}

Appendix

GAVI Board Members as of March 2001

Renewable Members:

<i>Member</i>	<i>Represented by</i>
Bill and Melinda Gates Foundation	Mr. William H. Gates, Sr., Co-chair and CEO
UNICEF	Ms. Carol Bellamy, Executive Director [ex officio member; will serve as Chair July 2001 through July 2003 Dr. Suomi Sakai, Senior Health Advisor, Immunization Health Section
The World Bank Group	Mr. James Wolfensohn, President [ex officio member] Mr. Christopher Lovelace, Director, Health Nutrition and Population
WHO	Dr. Gro Harlem Brundtland, Director-General [Chair through July 2001] Dr. Yasuhiro Suzuki, Executive Director, Health Technology and Pharmaceuticals

Rotating Members

<i>Constituency</i>	<i>Member Term of office</i>	<i>Represented by</i>
Foundation	Rockefeller Foundation July 99 – July 01	Dr. Tim Evans, Team Director, Health Sciences Division
Government- Developing country	Bhutan Jan 00 – Jan 02	Mr Lyonpo Sangay Ngedup Minister of Health and Education
	Mali Jan 01 – Jan 03	Dr. Fatoumata Nafu-Traore Minister of Health
Government- OECD country	Canada July 99 – July 01	Dr. Yves Bergevin, Senior Health Specialist, Canadian International Development Agency (CIDA)
	The Netherlands Jan 00 – Jan 02	Dr. E. Borst-Eilers, Deputy Prime Minister and Minister for Health, Welfare and Sport
	Norway Jan 01 - Jan 03	Dr. Sigrun Mogedal, State Secretary
Industry- Developing country	Center for Genetic Engin- eering and Biotechnology Jan 01 – Jan 03	Dr. Luis Saturnino Herrera Martinez, Director-General
Industry- OECD country	Aventis Pasteur Jan 00 – Jan 03	Mr. Jean-Jacques Bertrand Chairman and CEO
NGO	Bill and Melinda Gates Children’s Vaccine Program	Dr. Mark Kane, Director
Research Institute	US National Institutes of Health (NIH) July 99 – July 01	Dr. John LaMontague, Deputy Director, National Institute of Allergy and Infectious Diseases
Technical Health Institute	US Centers for Disease Control Jan 01 – Jan 03	Dr. David Fleming, Deputy Director for Science and Public Health

References

ⁱ Anita Hardon is an Associate Professor at the University of Amsterdam, where she directs the Medical Anthropology Unit. She led the transnational team “Global Immunization Policy and Technology Development” of the Social Science and Immunization project (1994-1998), and has also conducted policy-oriented research in other fields of international health, including extensive field research on the use and distribution of medicines in diverse health systems, and studies on gender and reproductive health. She chairs the HAI Europe Foundation Board.

ⁱⁱ The achievement is a global estimate: in many countries coverage rates had not yet reached 80%; and within countries there were also still disparities in immunisation coverage.

ⁱⁱⁱ Henderson, 1994. P. 9.

^{iv} The Health for All concept started in 1977 when the World Health Assembly determined that the main social target for governments and WHO should be “the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life”, otherwise known as Health for all by the year 2000” (resolution WHA30.43) taken from Implementation of the Global Strategy for Health for All by the year 2000, Eighth report on the world health situation, Vol. 1, WHO, Geneva.

^v The State of the World’s Children 2001, UNICEF. <http://www.unicef.org/sowc01/tables/table3.htm>

^{vi} Donnelly, J. Immunizations plummet in poorest nations wars, funding cuts blamed for decline, The Boston Globe, 13 Nov 2000, p. A1.

^{vii} Brundtland, GH, Statement at GAVI symposium, Oslo, Norway, 13 June 2000., http://www.who.int/director-general/speeches/2000/20000613_oslo.html.

^{viii} Summary of GAVI strategy from its webpage: <http://www.unicef.org/gavi>

^{ix} GAVI information, 26 Jan 2001, <http://www.who.int/vaccines/aboutus/gavi.htm>

^x Global vaccine fund commits US\$150 million in vaccines and funding over five years to 13 developing countries, press release, WHO, 20 Sept 2000, <http://www.who.int/inf-pr-2000/en/pr2000-GAVI13.html>

^{xi} The initial 13 countries include: Cambodia, Cote d’Ivoire, Ghana, Guyana, Kenya, the Kyrgyz Republic, Laos, Madagascar, Malawi, Mali, Mozambique, Rwanda, and Tanzania.

^{xii} See GAVI, October 2000. Detail of first disbursement from the Global Fund for Children’s Vaccine. <http://www.vaccinealliance.org/reference/1stdisburs.html>.

The Global Fund will provide three sub-accounts for:

1. the development of immunisation services as part of the health system
2. introduction of new and under-used vaccines and associated safe injection equipment
3. research and development of vaccines for diseases which are prevalent in developing countries.

The last account is not yet operational. The first two sub-accounts are only open for the 74 countries with per capita income below US\$1,000/year. Countries with an immunisation coverage below 50% can only request support from the first sub-account – they are not entitled to funds for new and under-used vaccines.

^{xiii} Compulsory licensing is a provision in the global trade agreement on intellectual property rights (TRIPs) that can help address the negative effect of patent monopolies. Compulsory licensing is the granting of a license to a third party without the consent of the patent holder. It can be issued on various grounds including public health. The patent holder receive remuneration for the license. Compulsory licensing is a legal option within the TRIPs agreement.

^{xiv} Donnelly, J. 2000.

^{xv} Ibid.