

New Products into Old Systems

The Global Alliance for Vaccines and Immunization (GAVI)
from a country perspective

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Save the Children

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Abbreviations

A-D	Auto-Destruct/Disable (syringe)	Hib	Haemophilus influenzae type b
AFP	Acute Flaccid Paralysis	HIPC	Heavily Indebted Poor Country
AFRO	African Regional Office (WHO)	HIV/AIDS	Human Immunodeficiency Virus/Auto-Immune Deficiency Syndrome
BASICS	Basic Support for Institutionalizing Child Survival	HSA	Health Service Area (Lesotho)
BCG	Bacille Calmette-Guerin (vaccine for tuberculosis)	ICC	Inter-Agency Co-ordinating Committee
CHAL	Christian Health Association of Lesotho	JICA	Japanese International Co-operation Agency
DANIDA	Danish Agency for Development Assistance	JPPI	Joint Public-Private Initiative
DFID	Department for International Development (UK)	JSI	John Snow International
DHS	Demographic Health Survey	MCH	Maternal and Child Health
DQA	Data Quality Audit	MoH	Ministry of Health
DTP1	First dose of Diphtheria-Tetanus-Pertussis Vaccine	MTEF	Medium Term Expenditure Framework
DTP3	Complete course of three doses of Diphtheria-Tetanus-Pertussis Vaccine	NIDs	National Immunization Days
EPI	Expanded Programme on Immunization	SC UK	Save The Children UK
EU	European Union	SDC	Swiss Development Co-operation
GAVI	Global Alliance for Vaccines and Immunization	SWAp	Sector Wide Approach
GDP	Gross Domestic Product	UNCRC	United Nations Convention on the Rights of the Child
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria	UNFPA	United Nations Population Fund
GTZ	German Organisation for Technical Co-operation	UNICEF	United Nations Children's Fund
HbsAg	Hepatitis B surface Antigen	US	United States
HepB	Hepatitis B	USAID	United States Agency for International Development
		WB	World Bank
		WHO	World Health Organization

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Glossary

- Numerator:** ‘the upper portion of a fraction used to calculate a rate or ratio’; in this case the number of children already immunised or the number are planned to be immunised.
- Denominator:** ‘the lower portion of a fraction used to calculate a rate or ratio’; in this case the number of children that need to be immunised.
- Pentavalent:** a pentavalent vaccine combines 5 different vaccine antigens that can be given as a single shot; in this case it is the addition of Hepatitis B vaccine and Haemophilus influenzae type b vaccine to the existing Diphtheria-Tetanus-Pertussis (DTP) vaccine.
- Quadravalent:** a quadravalent vaccine combines 4 different vaccine antigens that can be given as a single shot; in this case it is the addition of Hepatitis B vaccine to the existing Diphtheria-Tetanus-Pertussis (DTP) vaccine.
- Cold chain:** ‘the equipment and the people that keep vaccines cold, from the manufacturer to the child’; important equipment includes vaccine refrigerators and vaccine carriers. A cold chain failure, where vaccines have not been kept at specified temperature, can result in vaccines losing their potency.
- Coverage:** ‘a measure of the extent to which the services provided cover the potential need for these services in a community’; in this case, an immunisation coverage of 76% means that 76 out of every 100 children who need the vaccine have received it.
- Census:** enumeration of a country’s population, which usually counts the numbers of people by geographical distribution, age and sex. Typically, countries conduct a national census every 5 or 10 years.
- Fixed facilities:** health facilities – for example hospitals, health centres or health posts – where services are provided; here it usually means that immunisations are provided at these facilities on a daily basis, or one day per week, or at some other interval.
- Outreach:** health workers, who are based at a ‘fixed facility’, travel to other areas where they provide services on an agreed day or date; typically, health workers will provide immunisations at these outreach points at regular intervals, for example weekly, monthly or less frequently

Executive Summary

This report describes the country-level experiences of applying for support from the Global Alliance for Vaccines and Immunization (GAVI) in Tanzania, Mozambique, Ghana and Lesotho; as well as early implementation experiences in the first three countries. The aim of the initiative is to raise immunisation coverage and introduce new and underutilised vaccines.

The renewed focus on immunisations, strengthening of country immunisation co-ordination committees, introduction of Hepatitis B vaccine with safe injection equipment, and flexible systems support funding were all welcomed. All countries experienced the pace of the application process as too rapid, which contrasted with delays in the arrival of the vaccines. Support around technical issues, both within countries and from GAVI, was generally appreciated. However, donors – especially those committed to sector-wide approaches – believed that the initiative took insufficient account of agreed mechanisms for country planning and prioritisation.

The success of GAVI will be heavily dependent on the strength of existing systems delivering routine infant immunisations. In most of the study countries, fieldwork revealed serious systems weaknesses. These included low staffing levels, insufficient transport and fuel, poorly functioning cold chains and infrequent supervision. The low levels of systems support funding provided by GAVI to countries were unlikely to solve these problems. Inherently weak routine information systems in some of the countries will undermine GAVI's ability to monitor and reward improvements in immunisation systems.

It is unlikely that recipient countries could sustain the relatively high cost of the new vaccines, if GAVI funding ceases at the end of the five-year commitment, unless other sources of support are mobilised. Donor country-level advisers were much less optimistic than were ministries of health that such support would be forthcoming.

Section I: Introduction

I.1 Background and purpose

The context in which public health needs are being pursued at the start of the twenty-first century is rapidly changing. Pharmaceutical companies are coming under mounting pressure to develop appropriate products for developing countries and to price their products fairly. New kinds of donor are emerging, with private foundations and the commercial private sector increasingly offering to make donations to public health efforts¹. Donations are administered through what are known as ‘public-private partnerships’: these new private donors form joint initiatives with public bodies at both international level, allied to offices of UN bodies, and at national level, with government departments and sometimes NGOs.

The Global Alliance for Vaccines and Immunization (GAVI) was one of the first of a number of such joint public-private initiatives (JPPIs) established in the last five years. Launched in late 1999 after a decade of falling immunisation coverage in many developing countries, GAVI aims to expand the use of underutilised vaccines in 74 developing countries, and, in addition, to support the development of new vaccines.

Save the Children UK (SC UK) has witnessed the growth of JPPIs with interest, and has been keen to explore their implications for the realisation of children’s right to “the enjoyment of the highest attainable standard of health” (UNCRC article 24). After more than 20 years of health sector experience, SC UK has concluded that this right is most effectively and equitably achieved over the

long term by strengthening health systems to provide appropriate healthcare for all. SC UK began to explore many of the salient issues around JPPIs and children’s right to health in an Analysis Briefing² published in May 2001.

With these issues in mind, SC UK wanted to investigate the emerging implications of one selected JPPI at national and sub-national level by looking at its impact on country priorities and public health systems. GAVI was selected for the following reasons:

- Save the Children’s experience of immunisation programmes over the past 20 years, in particular the Expanded Programme on Immunization (EPI) and polio eradication initiative
- Independent evaluation of GAVI’s operation at country level is limited, yet interest in its impact has been mounting
- GAVI is being seen as a model for new initiatives such as the Global Fund to fight AIDS, tuberculosis and malaria (GFATM)
- GAVI is one of the largest global health initiatives, funded among others by the largest private donor.

To undertake this study, SC UK approached the London School of Hygiene and Tropical Medicine, given its research interests in JPPIs. The study was funded by SC UK, and Save the Children policy advisers also formed a steering committee for the study with staff at the London School³. This report is the result of six months’ research undertaken between May and October

2001 to describe and learn lessons from the early experiences of a few selected countries that had applied for GAVI support.

The purpose of the work was to:

- describe recipient countries' experiences and perspectives of the process of applying for support from GAVI
- evaluate the initial and likely future impact of the GAVI initiative on country health systems.

1.2 Objectives and scope

The study aimed to describe and evaluate the application process from a country-level perspective, identifying which aspects worked well and which less well. The perspective was that of senior staff of the Ministry of Health (MoH), donor agencies and any country Inter-Agency Coordinating Committee (ICC) or advisory group. Further, it aimed to report any subsequent country-level GAVI-related activities, where a country had received funding approval; and specifically, what the country-level players anticipated would be the likely impact of the introduction of new vaccines and GAVI funds, given the current state of the health systems in the selected countries.

Case studies were undertaken in three countries that made successful applications to GAVI in the first round of applications, July 2000 (Ghana, Mozambique and Tanzania); and in one country that was initially unsuccessful (Lesotho). The selection was primarily so as to include countries

that had early successful applications, where vaccines and financial support were more likely to have arrived at country level. Another consideration was the possibility of support from Save the Children country programmes to help with contacts, meetings and providing logistical support. Some countries were specifically excluded at the request of GAVI because they were being considered for evaluation in a separate exercise initiated by GAVI itself, funded by USAID⁴.

1.3 Methodology

Data collection consisted of a review of information posted on the official GAVI website, and of unpublished GAVI reports. Although senior GAVI staff were informed early on about the study, since the work focused on country-level perspectives and experiences, contact with GAVI staff at the global and regional level was minimal, being largely to identify or confirm some of the more rapidly changing processes.

Between July and September 2001, in-country interviews were conducted with key policy-makers in the respective health ministries, and with representatives of the relevant donor and international agencies, mainly those who were GAVI partners at the national level (Appendix A). A checklist of issues and questions was used to guide the interviews (Appendix B), and the responses were written up afterwards. Unpublished documents, minutes of meetings and official Government reports were obtained and reviewed wherever possible; these are listed in Appendix C.

Additionally, a rapid assessment was conducted at a sample of facilities, including vaccine stores, cold chain equipment and fixed site immunisation facilities at the regional and peripheral level in Tanzania, Mozambique (one week in each) and Lesotho. Where possible, the choice of facilities focused on the more remote areas, and/or those with low coverage rates. One regional and two district visits, including one facility assessment, were conducted in Ghana. In all, 25 fixed immunisation facilities were visited in the four countries. Visits also sought to obtain the perspectives of managers and public health staff involved in the planning and implementation of immunisation services. Although visits to facilities in Ghana were more restricted, a great deal of informal and formal national-level information was made available.

There were a number of limitations to the study. In Tanzania and Lesotho some key informants were unavailable (on annual leave, attending workshops, or participating in sub-national immunisation activities) and could not be interviewed. Interviews with staff at the periphery were sometimes in local languages, requiring the assistance of translators, which may have resulted in some moderation in the reporting and recording of responses. The application process for three of the countries had started about 18 months earlier, and therefore relied on respondents' ability to recall events. Not everyone involved in the different stages of the application process was available for interview; and it was not always possible to confirm respondents' recall of events, using minutes of meetings or other documents. Wherever possible, attempts were made to verify and check perceptions and

opinions. Where there were divergent opinions, either within or between different categories of respondents, these have been reported.

1.4 Structure of the report

Drawing on largely web-based information and some published and unpublished reports, Section II outlines developments in the progression of GAVI as a global initiative, emphasising the evolving nature of its structures and processes, and summarising levels of support committed to countries to date. Section III outlines the study country contexts, focusing particularly on factors influencing immunisation.

Drawing on responses from key informants and local documentation, sections IV and V describe country experiences of applying for GAVI support and the initial impact of introducing new vaccines and support for their health systems. Section VI highlights and discusses some of the key issues that emerged, in relation to the application process and the capacity of health systems to benefit from the initiative, and around future sustainability. Section VII concludes with outstanding questions and some recommendations with regard to the introduction of new and underused vaccines into routine immunisation programmes. It also considers possible lessons for the wider debate around the Global Fund to fight AIDS, Tuberculosis and Malaria, and the introduction of new health products – drugs and vaccines – into the health systems of poor countries.

Section II: GAVI – a new alliance for immunisation⁵

2.1 Background

Immunisations have been the single greatest success in improving child survival in the last three decades. Through raising coverage from about 5 per cent in the mid-1970s to 80 per cent by 1990, the Expanded Programme on Immunization (EPI) – which provides vaccines to protect against diphtheria, tetanus and pertussis (DTP), measles, polio and tuberculosis – has prevented about three million deaths each year in children. However, in spite of a number of global initiatives, immunisation coverage over the past decade has fallen. About 25 million of the 30 million children who do not get vaccinated live in low income countries, among whom there are still about 1.6 million deaths every year from measles, tetanus or pertussis.

The Global Alliance for Vaccines and Immunization (GAVI) was founded in late 1999, following a substantial donation from the Bill and Melinda Gates Foundation. It provided a new co-ordinating mechanism for partner organisations to revitalise international support for the control of vaccine-preventable diseases.

2.2 GAVI aims and objectives

Overall, GAVI aims to reduce the global burden of vaccine-preventable diseases by facilitating extensive improvements in and expansion of country-level immunisation programmes. Acknowledging that immunisation plays a critical role in overall health and economic development, GAVI states that immunisation is “...an essential step to protecting children’s health and allowing

each child to reach his or her greatest physical and intellectual potential” and aims to protect “...children of all nations and of all socio-economic levels ...”. In order to achieve this, GAVI has developed and refined five key strategic objectives, outlined in Box 1.

BOX 1: GAVI OBJECTIVES

1. Improve access to sustainable immunisation services
2. Expand the use of all existing, safe and cost-effective vaccines where they address a public health problem and promote delivery of other appropriate interventions at immunisation contacts
3. Accelerate the development and introduction of new vaccines and technologies
4. Accelerate R&D efforts for vaccines needed primarily in developing countries
5. Make immunisation coverage a centrepiece in international development efforts

Source: GAVI website

At the GAVI Board Meeting in June 2001, a sixth objective was added: “To support the national and

international accelerated disease control targets for vaccine-preventable diseases.”

Key milestones for the achievement of these strategic objectives include:

- 80 per cent of developing countries will have routine immunisation coverage of at least 80 per cent in all districts by 2005
- 80 per cent of countries with adequate delivery systems will introduce Hepatitis B (HepB) vaccine by 2002, and all countries by 2007
- 50 per cent of the poorest countries with high burdens of disease and adequate delivery systems will have introduced Haemophilus influenzae type b (Hib) vaccine by 2005.

Strategies for achieving these objectives are outlined in Box 2.

2.3 Mechanisms for governance

As a relatively recent partnership, GAVI structures and processes, laid down at inception, continue to evolve. The following two subsections outline the major instruments in relation to country-level activities, as at October 2001.

2.3.1 GAVI structures

Figure 1 outlines schematically the key GAVI structures at the global, regional and country levels.

The GAVI Board establishes principles and makes recommendations on fund allocation. Meetings occur approximately every four to six months – the sixth Board Meeting took place in Ottawa in October 2001. The Board is comprised of 15 seats, four of which are occupied by permanent representatives: the Bill and Melinda Gates Foundation (which is the biggest benefactor to the Vaccine Fund), the World Health Organisation (WHO), the United Nations Children’s Fund (UNICEF) and the World Bank. UNICEF currently occupies the Chair. In addition, there are 11 rotating seats⁶ with representatives of different constituencies (current members in italics):

- Developing countries (2): Mali, Bhutan
- Developed countries (3): The Netherlands, Norway, United Kingdom
- Non-Governmental Organisation (1): Gates’ Children’s Vaccine Programme at PATH
- Industry in developing countries (1): Centre for Genetic Engineering and Biotechnology
- Industry in developed countries (1): Aventis Pasteur
- Foundation (1) UN Foundation
- Technical Health Institute (1): US Center for Disease Control (CDC)
- Research and academia (1): Institut Pasteur

BOX 2: GAVI STRATEGIES

- Improving donor collaboration to ensure effective use of immunisation funding and developing sustainable financing instruments for vaccine procurement
- Working with individual countries to strengthen national immunisation services through enhanced coordination among governments and development partners
- Working with global vaccine industry partners to continue to provide the highest quality vaccines at the lowest appropriate pricing and exploring a competitive negotiation mechanism to help bring new vaccines to the poorest populations at the earliest possible time
- Seeking to achieve a balance between three vaccine procurement objectives: prices that are affordable to governments; adequate investment in capacity to supply global needs; and private investment in research and development of high-priority vaccines for developing countries
- The newly created Vaccine Fund is one of the financial tools available for GAVI to purchase under-utilized and new vaccines and to provide resources to strengthen immunisation infrastructure. It will also support research for developing new vaccines – against diseases such as malaria, AIDS or tuberculosis – needed primarily in the developing world...

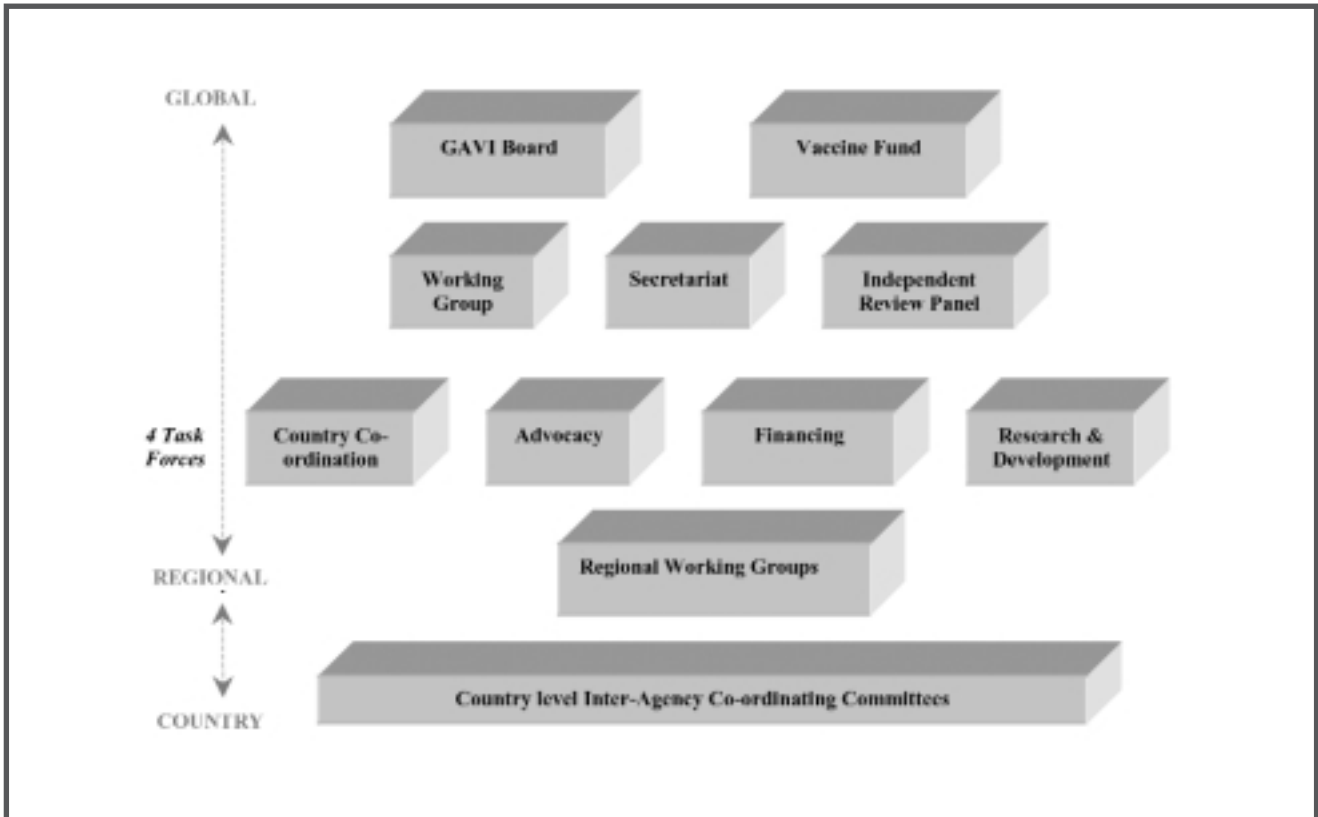
Source: GAVI website

All Board members, excepting developing countries, have contributed to GAVI funds, from relatively small to very large amounts (US\$300,000 to \$750 million).

Alongside the Board, financing the partnership is the Vaccine Fund, an independent charitable foundation. A US statute, whereby charitable donations from US-based organisations and individuals are tax-exempt, governs the Fund. The Fund has a separate Board of Directors with

11 members who are supported by a staff of 11 (www.vaccinefund.org). A five-member Fund Executive is responsible for the allocation of funds, which are based on Board recommendations (*interviews, GAVI*). The Fund has three sub-accounts, two of which are currently active: the first provides funds to recipient countries to strengthen immunisation systems and services; the second finances the purchase and provision of new and underused vaccines and safe injection equipment⁷.

Figure 1: GAVI Structures and Instruments



Source: compiled from information on the GAVI website

To date, donations sufficient for the ‘initial period’ of the Alliance, 2001-05, are in excess of US\$1 billion. Almost three-quarters is from the initial grant from the Bill and Melinda Gates Foundation. The remaining contributions are from developed country governments, notably the United States, Norway, the Netherlands, Canada and the United Kingdom. According to GAVI, further contributions will be necessary to extend this initial five-year time frame, and to reach those children currently outside the 80 per cent coverage milestone.

Supporting the Board is a small Secretariat, based at UNICEF, Geneva. The Secretariat is also responsible for managing country applications to the Vaccine Fund, which are assessed and scored by an Independent Review Panel.

A nine-member Working Group, composed mainly of representatives from partner organisations, is responsible for policy implementation⁸. Additionally, encompassing four key policy areas, there are four GAVI Task Forces: Country Co-ordination, Advocacy, Financing, and Research and Development. These are composed of representatives of partner agencies, industry and governments. Task force

members meet regularly or conduct conference calls to address specific issues. As examples of GAVI outputs, the Financing Task Force and an ad hoc Baltimore Working Group on injection safety, have commissioned substantial working papers that feed into policy and strategy development.

At the regional level – mirroring WHO regional structures – GAVI regional working groups are in place, which act as a link between the global and country levels. Finally, country-level Inter-Agency Co-ordinating Committees (ICCs), originally established to support and co-ordinate polio eradication efforts, provide the mechanism for co-ordinating national immunisation programmes. ICCs are responsible for supporting countries through the GAVI application and implementation processes.

2.3.2 GAVI processes

2.3.2.1 Applications

Four preconditions apply to countries submitting proposals for consideration for GAVI support, namely:

- Annual Gross Domestic Product (GDP) per capita of less than US\$1000; currently 74 countries are eligible
- Inclusion of a recent review (within three years) of national immunisation service provision
- Submission of a multi-year immunisation plan, including mechanisms for sustainable

financing of the enhanced immunisation programmes, once support from the Fund ceases; and plans for improving injection safety if required

- An existing national-level mechanism to co-ordinate donor and MoH inputs to immunisation activities, for example through providing evidence of a functioning ICC or similar committee. The ICC is responsible for developing, monitoring and updating a multi-year plan for immunisation, resource mobilisation, and ensuring that partner inputs meet country requirements.

In most cases, governments of eligible countries submit a proposal through the GAVI Secretariat to GAVI and the Vaccine Fund, using a proposal format provided by the Secretariat. The members of the ICC must endorse the application. There is a special provision for states in conflict or transition: approved non-governmental agencies, such as UNICEF, may apply on behalf of governments, with the proviso that the approved agency accepts responsibility for implementation of the plan.

The Independent Review Panel, made up of eight health and immunisation experts predominantly from developing countries⁹, assesses each application using defined criteria. Based on feedback from earlier rounds, revisions to the application format came into effect for the most recent tranche of proposals.

The GAVI Board reviews the Panel's findings and makes recommendations to the Vaccine Fund

Executive for final approval. Countries receive official notification of the outcome via the Secretariat. At the time of writing, four rounds of proposals had been completed and applications to the fifth round were under consideration.

2.3.2.2 Support available to countries

The national coverage rate for the full infant course of diphtheria, tetanus and pertussis (DTP3) determines country eligibility for both GAVI vaccines and systems support. As illustrated in Figure 2, until recently, countries with less than 50 per cent DTP3 coverage could only apply for systems support, while those with 50-80 per cent could apply for both GAVI vaccines and systems support. Countries with more than 80 per cent DTP3 coverage could only apply for vaccines.

Figure 2: Eligibility for type of GAVI support

	Baseline DTP3 <50%	Baseline DTP3 50-80%	Baseline DTP3 >80%
Systems support	Yes	Yes	No
Vaccines	No	Yes	Yes

Source: GAVI website

However, the June 2001 meeting of the GAVI Board approved a retroactive once-off systems support payment of US\$100,000 to all countries with DTP3 coverage in excess of 80 per cent, in recognition of the start-up costs associated with new vaccine introduction. The Board also decided to cap the level of support to some vaccine-producing nations with large birth

cohorts (Indonesia, China and India). Each will now receive a maximum of US\$40m within the five years of the initiative.

To date, the provision or promise of new or underutilised vaccines has been limited to Hepatitis B (HepB), *Haemophilus influenzae* type b (Hib) and yellow fever, together with safe injection equipment. Various combinations of the antigens are in production or currently available, for example DTP combined with HepB (quadravalent vaccine); and DTP-HepB-Hib (pentavalent vaccine). However, there were delays in the supplies of the combination vaccines in 2001, requiring some countries, which requested DTP-HepB vaccines to either accept the monovalent HepB, or delay until one or other of the combination vaccines became available. Moreover, there have been worldwide shortages of yellow fever vaccines during 2001, necessitating limiting supplies to high-risk epidemic areas (*interviews, GAVI*).

The value of actual or promised GAVI support to individual countries (vaccines and systems support) has depended on the size of the birth cohort, ie, the target population, and the country's own estimate of the expected increase in immunisation coverage. The total value of awards has been heavily dependent on the type and combination of vaccines requested, as there are significant differences in their unit costs (see Section V).

GAVI has not funded the provision of the six core EPI vaccines – diphtheria-tetanus-pertussis (DTP), oral polio, BCG and measles, unless DTP is combined with HepB or Hib. Until mid-2001,

GAVI only funded auto-destruct (A-D) solo-shot needles, syringes and disposal boxes for GAVI vaccines. The new Board policy then stated that three years' supply of A-D syringes and disposal boxes for all routine EPI vaccines would be provided to all GAVI applicants, irrespective of the type of support requested.

Departing from the more traditional donor support mechanisms, GAVI – using the Vaccine Fund systems support sub-account – has indicated that it will reward improved EPI outputs. An initial share allocation divided in two equal instalments, 12 months apart, is meant to cover both initial transaction costs associated with the introduction of new vaccines and to stimulate improved performance.

The first instalment has been upfront with the second to follow within one year. The level of the initial allocation or 'share value' has been determined by the target of additional numbers of children to be immunised, measured against a baseline of DTP3 coverage as stipulated by the country in the initial GAVI application. A share is the value of one additional child immunised, currently US\$20 per child for countries with between 50 and 80 per cent baseline DTP3 coverage.

Subsequent monies for systems support in future years are currently based on the number of additional children immunised annually. Countries that have set higher targets for increased numbers of immunised infants have received greater initial share amounts than those with lower targets. There have been no conditions attached to how countries would use

systems support money, providing it contributed to the overall goal of raising EPI coverage and was not used to support recurrent cost expenditure.

GAVI indicated that there would be independent monitoring of the integrity of routine immunisation data, which would be used to measure performance. It therefore commissioned a consortium to conduct externally assessed data quality audits (DQAs) at country level, based on tools developed by WHO. The first phase of pilot DQAs was completed by October 2001, with data from eight countries including Tanzania collected and analysed. From the pilot evaluations (LATH Consortium, 2001), the DQA report outlined a need to focus on a number of key areas in the future, including:

- Development and inclusion of qualitative measures so as not to rely only on quantitative assessment of EPI performance
- Uniform use of denominators and targets within countries
- Improved data management
- Training and better supervision to improve standard operating procedures such as the completing of tally sheets so as to minimise over- and under-reporting.

2.4 Summary of support to countries

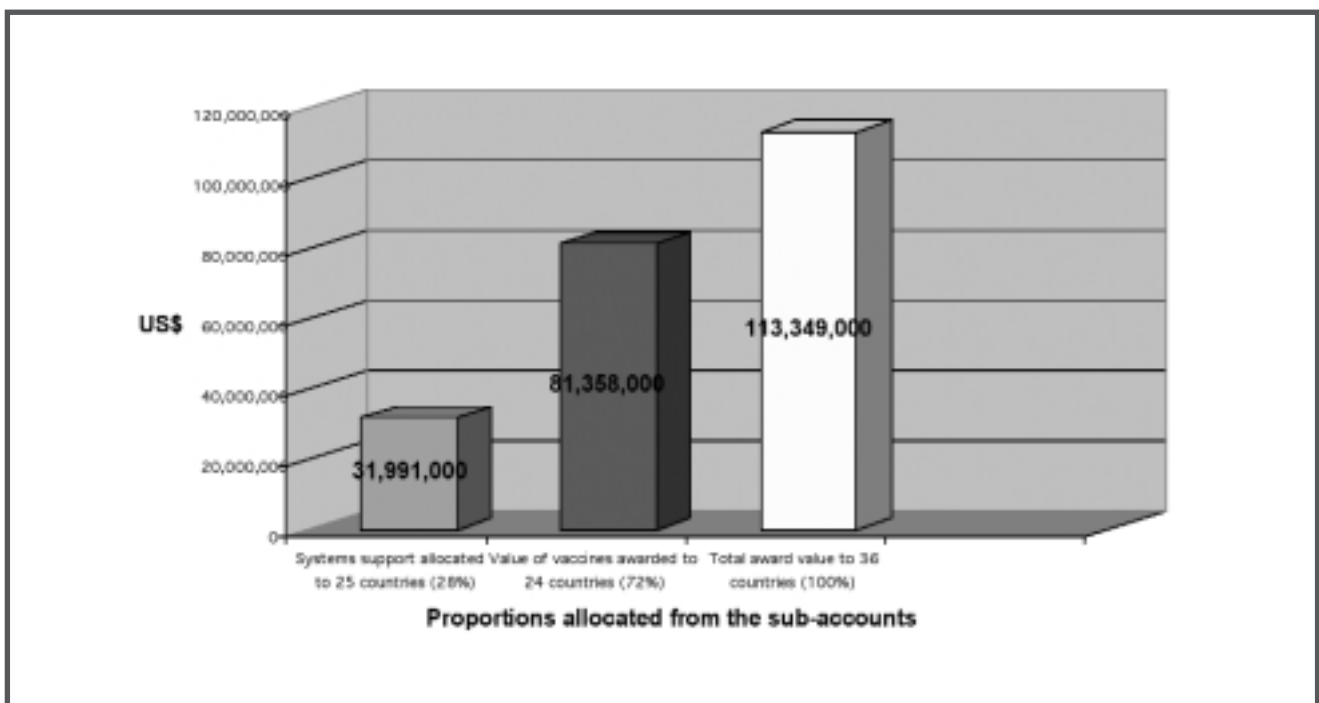
By October 2001, following four completed rounds of submitted and reviewed proposals, some 90 applications (between the two accounts)

from 54 countries had been reviewed. There had been 51 approved applications from 36 countries – almost half of those eligible for GAVI support (some with clarifications required). For a minority of countries the support had been deferred until 2003. In some cases, this was due to vaccine shortages and in others at the request of the countries. Total awards amounted to US\$113,349,000, with \$81,358,000 allocated to vaccines and \$31,991,000 (28 per cent of the total award) to support strengthening of immunisation delivery systems. This is summarised in Figure 3.

GAVI had noted that countries with more robust health systems and higher coverage rates were among the earlier successful applicants. GAVI also recognised that, as additional countries applied and qualified for support, it was likely that the proportion allocated to systems support would increase.

At the time this report was being finalised, awards for the fifth round were under review. The proportion allocated to systems support and to the purchase of vaccines was likely to change, as seven countries had applied for systems support and only six for new vaccines. In addition, 21 countries that were among the earlier successful

Figure 3: Awards allocated to the 36 successful countries after 4 tranches of reviews



Source: GAVI website

applicants had applied for the new injection safety equipment. Thirteen countries, which were unsuccessful in earlier rounds, were resubmitting applications¹⁰.

Section III: Study country profiles

The countries differ most markedly in population size, ranging from 32 million in Tanzania to 2 million in Lesotho. In many other respects the indicators illustrated in Table 1 are relatively similar. Ghana has the best performing health system of the four countries, according to WHO's composite measure, although there has been controversy surrounding these rankings and doubts raised about the data on which they were

based (Navarro 2000, Williams 2001). The DTP3 coverage estimates suggest that the immunisation systems performed well or improved in Ghana, Mozambique and Tanzania during the 1990s. However, there are doubts about the accuracy of the data, as will be discussed later. Lesotho had a fall in immunisation coverage during this period.

Table 1: Comparative indicators for the four countries

	Total pop 1999 ⁽¹⁾	Health exp pc US\$ ^(1,2)	Total health exp as % GDP ⁽¹⁾	Overall health system performance ^(1,3)	DTP3 1999 (1990) ⁽⁴⁾	BCG 1999 (1990) ⁽⁴⁾
Ghana	19,678	11	3.1	135	72% (50%)	88% (71%)
Lesotho	2,108	28	5.6	183	64% (69%) ⁽⁵⁾	68% (78%)
Mozambique	19,286	5	5.8	184	81% (46%)	100% (59%)
Tanzania	32,793	12	4.8	156	82% (78%)	93% (85%)

Source:

- (1) WHO Health Report, 2000, Geneva.
- (2) Total expenditure (all sources) at official exchange rate.
- (3) Ranking according to composite measure of achievement in level of health, the distribution of health, the level of responsiveness, the distribution of responsiveness and fairness of financial contribution for 191 member states – higher numbers indicate poorer overall performance.
- (4) WHO data www.WHO.int/vaccines/surveillance/StatsandGraphs.htm (coverage time series).
- (5) 1991

3.1 Ghana country profile¹¹

Table 2: Select health service indicators for Ghana

	1980	1996
Infant mortality (per 1000 live births)	100	71
Under 5 mortality (per 1000 live births)	157	110
Total fertility rate	6.5	5.0
Life expectancy at birth (years)	NA	57M/61F
Overseas Development Assistance as % of GNP	NA	10.5

Source: World Bank Development Report 1998/9

Ghana’s health system has undergone significant reforms over the past decade. It is organised into national, regional and district, sub-district and community levels. At the national level, the Ministry of Health (MoH) is responsible for sector-wide policy formulation and monitoring of progress in reaching objectives. The service arm of the MoH is responsible for allocating resources and creating partnerships with the private sector and communities. Ghana has adopted a sector wide approach (SWAp), whereby the MoH and pooling donors jointly agree health sector priorities, plans and programmes of work¹².

The EPI began in 1985, using mass campaigns, shifting to routine services from 1991. Immunisation delivery is through a combination of fixed facilities (daily, weekly or monthly immunisations), outreach, mass campaigns, National Immunization Days (NIDs) for polio

eradication, and utilisation of missed opportunities (immunising infants and children who are brought to health facilities for other reasons). Home visits by community health nurses to immunise children is now MoH policy but is not yet a widespread practice.

3.2 Lesotho country profile¹³

Table 3: Select health service indicators for Lesotho

	1980	1996
Infant mortality (per 1000 live births)	108	74
Under 5 mortality (per 1000 live births)	NA	113
Total fertility rate	5.6	4.6
Life expectancy at birth (years)	NA	57M/60F
Overseas Development Assistance as % of GNP	NA	8.7

Source: World Bank Development Report 1998/9

Due to its climate, malaria and many other ‘tropical’ diseases are of low prevalence or absent in Lesotho. However, HIV/AIDS is a particular concern: in 1999, HIV prevalence in the 15-49 age range was estimated at 24 per cent. ‘AIDS orphans’ are a growing problem. Chronically high unemployment has been aggravated by the continued retrenchment of Basotho migrant workers in the South African mining sector, and skilled health professionals continue to seek work overseas, exacerbating staff shortages. Lesotho has experienced a steady decline in external assistance

since the mid-1980s, and also a decline in technical support from donors. For example, overall aid as a share of GDP almost halved between 1992 and 1997.

Facilities including hospitals, in its 18 geographical health areas, are owned, administered and managed by a combination of government and church providers. The latter are required to charge for some under-fives healthcare. The health sector is in the midst of reforms, based on the provision of a basic district health package and decentralisation of services. Immunisation services are delivered by a combination of fixed facilities and limited outreach, supplemented by NID campaigns for polio and measles. Its EPI has weakened in the past five years, which is reflected in the drop in immunisation coverage. Volunteer community health workers support health staff in service delivery, but are not permitted to give injections.

3.3 Mozambique country profile¹⁴

Table 4: Select health service indicators for Mozambique

	1980	1996
Infant mortality (per 1000 live births)	155	123
Under 5 mortality (per 1000 live births)	285	214
Total fertility rate	6.5	6.1
Life expectancy at birth (years)	NA	44M/46F
Overseas Development Assistance as % of GNP	NA	59.8

Source: World Bank Development Report 1998/9

Mozambique has seen rapid economic improvement in recent years, but remains one of the world's poorest nations. In Mozambique, HIV/AIDS prevalence is an emerging health priority and increasingly burdening a fragile health system. HIV prevalence in 1998 exceeded 14 per cent, and current estimates are higher. The country remains heavily dependent on external assistance, much more so than the other countries in this study; more than half of total budgetary expenditure is funded from external sources.

Healthcare provision is predominantly by government providers, with some 1,037 health units supplying services to approximately 40 per cent of the population. Gains achieved in the early years after independence were eroded as health staff and facilities became targets in the South African-backed civil war. This exacerbated existing shortages of skilled professionals, necessitating an expensive reconstruction programme after 1992.

Immunisation services are delivered by a combination of fixed facilities and outreach, although recent improvements in reported national coverage rates have resulted in the suspension of NID-associated activities. Mozambique is in the early stages of developing a SWAp.

3.4 Tanzania country profile¹⁵

Table 5: Select health service indicators for Tanzania

	1980	1996
Infant mortality (per 1000 live births)	108	86
Under 5 mortality (per 1000 live births)	176	144
Total fertility rate	6.7	5.6
Life expectancy at birth (years)	NA	49M/52F
Overseas Development Assistance as % of GNP	NA	15.6

Source: World Bank Development Report 1998/9

Following an economic downturn in the 1980s, Tanzania's economic situation is slowly improving, with annual growth forecast at 4 per cent.

Health service delivery on the mainland is organised in 20 administrative regions, which support facilities and staff in 117 health districts. The health sector is in the midst of wide-ranging and extensive reforms, which include the development of a SWAp. The reforms differ from those in Ghana in that devolution of funds, budgetary management and responsibility for planning is taking place at the local government level. Technical support through country-level donors and consultants has also been more predominant.

Immunisations are delivered through a combination of fixed facilities, outreach and NIDs for polio eradication as well as sub-national campaigns for measles.

Section IV: Applying for GAVI support

4.1 Country time frames and overview of country-level perceptions

All of the study countries initiated preparation of applications for systems support and new vaccines soon after GAVI invited expressions of interest from countries on 20 January 2000. Ghana, Mozambique and Tanzania submitted proposals for the first round deadline of 1 July 2000. All three countries received responses from the GAVI Secretariat within one month, informing them that their applications had been approved and they would receive support for immunisation services and new and underused vaccines for the year 2001, pending clarification on certain data. Lesotho submitted its first application in October 2000 for the second round of applications. This was unsuccessful and, at the time of writing, was currently awaiting a decision on its resubmission made in October 2001, as part of the fifth round of applications. Table 6 summarises the type of support applied for and the value of the award.

The level of detail in responses from interviewees regarding the application process varied, largely dependent upon whether the individual respondents and/or their organisations had been involved in the original application. A comprehensive paper trail of ICC minutes, memos and responses from GAVI was available for Ghana. This was either missing or could not be accessed for the other countries. As respondents were being asked about a process that had been initiated 18 months previously, limitations in the data collection included possible recall bias and changes in personnel.

Country-level perceptions regarding the overall application process varied. However, there were some common perspectives across countries. Some of the perceived benefits of the GAVI application expressed by national MoH staff, and country donor and multilateral agency representatives were that the process provided an opportunity to address weaknesses in EPI

Table 6: Awards to successful study countries

Study country	Surviving infants to 2001	Award for systems support US\$	Requests for vaccines	Value of vaccines	Total value of support
Ghana	709,000	530,000	DTP-HepB-Hib, yellow fever	11,037,000	11,567,000
Tanzania	1,279,000	1,214,000	DTP-HepB	8,282,000	9,496,000
Mozambique	725,000	462,000	DTP-HepB	4,708,000	5,170,000

Source: GAVI website (October 2001)

performance, raise the profile of EPI on the policy agenda and revitalise country ICCs. The most frequently voiced criticism was that of the sheer pace of the application process, which did not allow countries sufficient time to collect data and consider and prepare responses to requests from GAVI. These issues are examined in more detail in the following subsections.

4.2 Choice of vaccine support

Although all of the study countries applied for support from the new and underused vaccines sub-account, the process of decision-making and the outcomes differed in the four countries.

Ghana, Mozambique, Tanzania, and initially Lesotho, all applied for the quadravalent vaccine (DTP-HepB), based on pre-existing concerns that Hepatitis B was a significant contributor to the burden of disease in their adult populations.

Tanzania's Assessment of Immunisation Services (2000) included a review of a sample of patient records and mortality data. The Tanzanian GAVI application stated a 5-15 per cent prevalence for Hepatitis B surface Antigen (HbsAg), a marker of previous infection.

In interviews, MoH staff in Mozambique indicated that assessments on burden of disease had been done at tertiary facilities in Maputo. The Mozambique application to GAVI stated a 10 per cent prevalence for HbsAg.

An undated (circa 1997) report prepared by Ghana's EPI Manager outlined the case for

including HepB vaccine in the EPI schedule. It reviewed 11 studies from Ghana, including seven that showed HbsAg prevalences ranging from 5 to 20 per cent in blood donors. Additionally, Ghana requested yellow fever vaccine.

None of the countries requested the pentavalent (DTP-HepB-Hib) combination vaccine, although Ghana requested support to determine the disease burden from *Haemophilus influenzae* type b (Hib), envisaging that this vaccine would be added to its EPI programme if the Hib disease burden was established.

Following the successful awards to Ghana, Tanzania and Mozambique, countries learned that there were worldwide shortages of the quadravalent vaccines. In interviews, both Mozambique and Tanzania national-level staff in the MoH (supported by findings in ICC minutes) reported pressure from GAVI to accept the monovalent HepB, as an alternative:

“We didn't *want* monovalent HepB – the logistics would be too difficult. I felt sorry for other countries, but we stuck to our guns” (*Tanzania, MoH*).

Mozambique similarly insisted on the quadravalent format. During the course of the fieldwork, there were no indications that Tanzania had expressed interest in assessing the need for introducing the Hib vaccine, and all the available minutes of ICC meetings refer only to the quadravalent presentation. However, the September 2001 edition of the GAVI Update indicates that a GAVI-led assessment team was scheduled to make a rapid assessment of Hib burden of disease in Tanzania.

Ghana reported having been offered three alternatives, without undue pressure to agree to any one of them. These were monovalent HepB, available in the second quarter of 2001, pentavalent (DTP-HepB-Hib) vaccine in the third quarter of 2001, or a further delay for the quadravalent vaccine. The ICC in Ghana was presented with a tight deadline in January 2001, having been informed by a multilateral agency representative that GAVI required a decision within ten days. Ghana chose the pentavalent vaccine, which necessitated a revision of its cold chain and storage requirements. Reflecting on the process, one ministry official commented on the time frame for deciding between the available options:

“this was not fair – we should have resisted”
(*Ghana, MoH*).

Reservations about introducing Hib vaccine were expressed at the ICC:

“a member raised the following concerns: (1) sustainability not certain, (2) little knowledge about disease burden of Hib; Hib meningitis low except pneumonia, (3) most costly of the three. Hib rapid assessment survey is to be carried out with technical support from WHO. However, if this is done and the burden of disease found to be low, the country would already have committed itself” (*Ghana, ICC minutes*).

A rapid assessment of Hib burden of disease was later conducted in July 2001, supported by GAVI. This appeared to confirm that Hib was an important cause of meningitis in Ghana, with a

district estimate of “16 probable cases of Hib meningitis between June 2000 and May 2001 . . . (or) 72 per 100,000 children under five years of age, a rate consistent with literature from the region” (*Ghana trip report, 2001*). However, the methodology had some limitations: it was a retrospective record review that appeared to estimate Hib meningitis incidence by exclusion of meningococcal causes, and was based on a small sample size (95 per cent confidence intervals of 41-117 for an estimate of 72 per 100,000). The sample was from a single district hospital, which could have resulted in selection biases. The pentavalent combination, with the addition of a further (and more costly) antigen, increased the value of Ghana’s award considerably. This is discussed in more detail in Section V.

Of the three countries studied, Mozambique is the only one to have received its vaccines to date (April 2001), as originally requested. Supplies for both Tanzania and Ghana were due before the end of 2001. Ghana, which had planned a national launch for October 2001, was advised of a delay and rescheduled its launch for January 2002; it was then advised not to announce a launch date until the vaccines had arrived. Any further slippages in timing would cause Tanzania in particular difficulties in supply, since according to a bilateral representative involved in procurement of vaccines, after several estimated dates for delivery, there are only sufficient quantities of DTP stocks until the end of 2001.

4.3 Role and performance of co-ordinating partners

Each country must have a functioning ICC to qualify for GAVI support. Originally established to co-ordinate polio eradication, which predates the GAVI initiative, ICCs were in place in all of the countries visited. These address key issues in immunisation, such as the planning of National Immunization Days (NIDs) for polio eradication, measles immunisation campaigns and neonatal tetanus control, as well as the routine EPI. The fieldwork indicated considerable variation between the countries in terms of frequency of meetings, membership and attendance at key meetings, and level of documented discussion and inputs to the GAVI application process.

The frequency of ICC meetings in Ghana and Tanzania was regular, with an average of one meeting every six weeks from the start of the application until the time of the fieldwork. Minutes in both countries were available. Although limited in Tanzania, those from Ghana provided particularly clear and detailed accounts of the sequence of discussions and subsequent decisions around both GAVI-related and broader immunisation issues throughout the period.

Mozambique and Lesotho presented a contrasting picture. In Mozambique, respondents from the MoH and multilateral and bilateral donors could remember only two meetings of the ICC in the 18 months prior to the fieldwork: the first was to sign the GAVI application in June 2000 and the second in April 2001 was to co-ordinate arrangements for the visit of a high-level international team from GAVI. This visit was the

‘launch’ of the new vaccines in Africa. No ICC minutes were available for review. Towards the end of the fieldwork, in September 2001, the core terms of reference for the group were revisited and a formal secretariat established.

The situation in Lesotho differed, as the GAVI Review Panel had cited the lack of a functioning ICC as one of the reasons for the refusal of the initial application. Since December 2000, there had been more frequent meetings, but several respondents from a broad range of agencies were of the opinion that the frequency was driven mainly by a need to demonstrate regular attendance for the forthcoming application:

“Meetings have increased due to application hoop-jumping.” “Meetings are almost weekly these days to get the evidence for the GAVI application” (*donor*).

There were significant differences in the ICC membership, attendance at meetings and involvement in the GAVI process, in the four countries, which is captured in Figure 4.

Figure 4: ICC membership and attendance

	Ghana	Mozambique	Tanzania	Lesotho
Chair	Director P/Health	National Director of Health	Director of Preventative Services**	Director General/Principal Secretary**
Secretary	EPI Manager**	EPI Manager	EPI Manager**	EPI Manager**
MoH	Dep/Director General; Dep/Directors P/Health**; Head Disease Control	Pharmaceutical Dept; IEC Unit; Epidemiology Dept; Maintenance Dept; Family Health Dept; Planning Dept; Supply Unit	Medical Stores Dept**; Food and Nutrition Centre; EPI staff	Director Health Planning; Statistics Unit
Multilateral	WHO**; UNICEF**	UNICEF; WHO; EU; WB; UNFPA	UNICEF**; WHO**; WB	UNICEF**; WHO**
Bilateral	JICA; USAID**; DFID	Dutch Cooperation; Irish Cooperation; Swiss Cooperation; DFID; GTZ; USAID	DANIDA**; Ireland Aid; DFID; JICA	Ireland Aid**
NGOs	Rotary	Rotary	Rotary; AMREF	CHAL; Rotary
Other	Paediatric Society of Ghana; Director Noguchi Memorial Institute for Medical Research			Maseru City Council

Source: GAVI application forms and interviews

**Regular attendees, according to ICC minutes/interviews

In Ghana and Tanzania, the ICCs have been composed of representatives of a broad range of stakeholders involved in immunisation, including multilateral agencies, bilateral donors and, in the case of Tanzania, NGOs, chaired by senior staff from the MoH.

In the three countries with sector-wide approach (SWAp) mechanisms in place – Ghana, Mozambique and Tanzania – there was to varying

extents little involvement of pooling and other bilateral donors in the ICC and application process, although these were funders of vaccine procurement and immunisation activities. In Tanzania, MoH respondents perceived that this was due to the relatively rapid rate of agency staff turnover. In Ghana, there was intermittent involvement of one pooling donor (DFID) and regular involvement from one non-pooling donor (USAID). Low involvement of pooling donors

was not seen by any respondents as a deliberate policy to exclude them. Instead, donors cited excessive numbers of meetings and workload as the main reason for their infrequent attendance.

In Mozambique and Lesotho, the links with GAVI Regional Working Groups and thus links to the GAVI Board tended to be through multilateral agency members of the ICC. For example, either UNICEF or WHO offices usually passed letters and memos from GAVI to the MoH. In Ghana and Tanzania, this was also sometimes the case. In Ghana, the MoH EPI Manager attended a number of GAVI-related meetings outside of the country and was the main point of contact for visiting consultants. Country perspectives on the level and quality of support from GAVI in preparing their applications are reported in the next section (4.4).

Perceptions of the performance of the ICCs in the GAVI application process varied both within and between countries. In **Tanzania**, the ICC was actively chaired and led by the MoH, and was generally seen by all respondents as up-to-date on key immunisation issues. ICC meetings facilitated important discussions around critical areas such as long-term sustainability and injection safety. However, the available minutes provided limited information.

In **Ghana**, the MoH perceived that the ICC had worked well, playing a useful technical support role. Key MoH decision-makers and additional experts attended meetings when important decisions needed to be taken. Some of the donors were more critical of the scope and expertise of the ICC. They saw the minimal involvement of

pooling donors as a weakness, in that mainly project-oriented donors dominated the ICC. One recommendation from a regular participant was that involvement of pooling donors might have been facilitated if those most centrally involved – selected donors and MoH staff – had produced summaries of the initiative and key issues involved for distribution to the other donors. He believed that pooling partners would then have been able to engage better in considering the implications of GAVI within an integrated approach to planning and delivering services.

While bilateral donors faulted the ICC for not addressing the issue of integration of the initiative into the MoH Plan of Work, the MoH respondents were less concerned about this. An observation by one regular ICC attendant was that meetings were themselves overloaded:

“ICC meeting agendas overwhelm the participants who can only raise a few strong concerns, eg, around financial or technical issues. The pressure on participants is to get to the end of a large agenda so as to get back to their offices to deal with other commitments” (*Ghana donor*).

The same donor commented that transaction costs associated with the application were both too high and not high enough – the latter in that more systems-focused people were not sufficiently involved.

In **Mozambique**, the limited number of meetings (only two) and the absence of minutes made an accurate assessment of ICC performance difficult. The local UNICEF office played a key role in the

application preparation and submission. Most donor respondents felt that the ICC had not performed as well as it could have, reflecting what they perceived to be the currently poor working relationships between the individual multilateral agencies, and also between them and some of the bilateral donors.

Lesotho's ICC was seen by informants as having been much improved during the preparation of the second application. However, as previously indicated, key inputs from the Christian Health Association of Lesotho (CHAL) who provide and manage half the Health Service Areas (HSAs) in the country were often absent and some informants commented on the poor working relationship between multilateral agencies involved in the ICC. Given that the core group is smaller than in the other countries, absence or issues of rapport may have a greater impact. In Lesotho, one multilateral adviser stated that the initiative was driven by head office, without taking into account the

“...thinness of local technical assistance to support the process”.

4.4 External support to countries

All study countries received external technical support during the application process, either directly from GAVI or arranged and funded by it, although the extent of support varied considerably. From the perspective of the MoH respondents, all of the countries judged the quality of technical input from external advisers as reasonable and appropriate, in view of the newness of the initiative.

In both Ghana and Tanzania, the application process was firmly led by the MoH. Much of the technical work was delegated to the EPI Manager and the MoH took the lead in filling out the application proposal documents and preparing necessary information. Both countries received support from WHO African Regional Office (AFRO) and GAVI Regional Groups at workshops and meetings; each had short one or two-week visits from GAVI consultants and other occasional inputs, for example from experts from the Center for Disease Control, Atlanta, to assist with the collation of information. In both countries, most of the technical support was given via the EPI Manager. In Tanzania, the constant checking of required information was seen as a great deal of work, which not infrequently displaced other activities. However, in both countries the quality and balance of technical inputs were viewed very positively.

One criticism in **Ghana**, apart from the pace of the process, was that communication channels between the MoH and GAVI could have been better: announcements of modifications to GAVI were made at meetings or through informal communications, but were not later confirmed in writing. Donors were more critical of the technical support provided by GAVI in terms of issues like financial sustainability. Lack of data on the cost and cost breakdown of Ghana's overall immunisation programme and on the additional costs to the system of introducing new vaccines, later made available through the report by Levin et al. (2001), impeded proper discussion and analysis of sustainability issues.

“Technical briefing on these issues was needed. GAVI should have given better guidance. The only guidance to the ICC was the GAVI proposal format. GAVI needs to produce a guide for ICCs to bring them through the process and implications of the initiative, especially for dealing with sticky issues” (*Ghana donor*).

“It forced a review of EPI, confirming anecdotal evidence and bringing EPI to a wider audience” (*multilateral adviser*).

In **Mozambique**, the local UNICEF office, with short-term technical assistance from WHO and BASICS, was largely responsible for completing the application.

Mozambique’s EPI review had taken place in 1998 co-ordinated by UNICEF, who also wrote the multi-year plan, 2000-04, with minimal input from senior staff at the MoH. Lesotho did not submit either a recent EPI review or comprehensive multi-year plan with the first application. However, the subsequent application, which was being finalised during the GAVI fieldwork, was going to be accompanied by an EPI review and a five-year plan, written with support from external WHO consultants.

In **Lesotho**, external support to the MoH for the initial unsuccessful application came from the local offices of WHO and UNICEF, with minimal outside assistance. For the current application, Lesotho has obtained external short-term consultancy advice from WHO AFRO, in particular from a consultant who was involved in a successful application for the pentavalent vaccine in Malawi.

In addition to recent reviews and plans, countries were expected to provide a list of documents to accompany the submission, for example health policies and strategies, terms of reference and recent minutes of the ICC. Countries had to indicate how they would fill unmet needs or funding gaps and propose strategies for sustainability. The countries found the process of collating information difficult or, as in the case of Ghana, subject to unreasonable time pressure. The level of detail required for the application was often uncertain, necessitating GAVI consultants to frequently check with Geneva as to what would be acceptable.

4.5 Information requirements for proposals

Countries were expected to submit comprehensive reviews of EPI provision, prepared within the previous three years, and multi-year plans with each application. In Mozambique and Ghana the MoH had reviewed EPI in 1998, thus much of the information to inform the application process was already prepared. In Tanzania, the necessity to prepare the application documents was seen as definitely positive, providing an opportunity to review key areas of concern such as injection safety.

4.6 Immunisation coverage

The GAVI application required each country to submit immunisation coverage rates (reported rates and those measured by survey, where available) for the previous two years. It also asked

for the numbers of reported cases of vaccine-preventable diseases and ratios of cases to deaths in the same period. Table 7 shows coverage rates for the four countries, with variations within countries, dependent on the source of data¹⁶.

The original national coverage estimate of 80 per cent for DTP3 in 1999 was included in the initial application, which would have precluded Mozambique from qualifying for GAVI systems support. However, a footnote in the application

Table 7: Study country national immunisation coverage

% Coverage	GHANA			TANZANIA			MOZAMBIQUE			LESOTHO
	MoH 1998	MoH 1999	DHS Survey 1998 (1)	MoH 1998	MoH 1999	TRCHS Survey 1999 (2)	MoH 1998	MoH 1999	DHS Survey 1997 (3)	MoH 2000
BCG	77.4	84.9	87.8	85	87	93	99	100	78	51
DTP3	68	73	72.2	74	76(74)	82	77	80(76)	60	56
Measles	67.0	71.4	72.6	72	72	79	87	89	58	59
All EPI vaccines	-	-	50.5	-	-	-	-	-	47	-

Source:

- (1) Demographic Health Survey 1998
- (2) Tanzania Reproductive and Child Health Survey 1999
- (3) Demographic Health Survey 1997

4.6.1 National immunisation coverage trends and explanatory factors

Mozambique demonstrated a steady rise in immunisation coverage during the 1990s, with an increase in DTP3 rates from approximately 50 per cent in 1993 to 80 per cent in 1999 (estimated from a graph summarising coverage for all EPI immunisations from 1981-98, in the MoH, Five-Year Plan 2000-2004 and 1999 national coverage rates). The greatest increase has been in the more remote northern and central regions. As a result, the MoH decided to halt NID activities in 1999 and incorporate all activities into the routine immunisation programme.

indicated that the MoH believed that a more accurate DTP3 estimate was in the range of 60-65 per cent. Feedback from GAVI included a recalculation of the coverage, based on the numerators and denominators submitted, indicating a DTP3 coverage of 71 per cent. The final DTP3 estimate, on which the award was approved following discussions with GAVI, was 76 per cent.

A number of respondents from both the MoH and multilateral organisations questioned the reliability of reported information, in that measles outbreaks had occurred in high-coverage areas during 1998 and 1999. The Demographic

Health Survey (DHS) of 1997 revealed that only 60 per cent of Mozambican children aged 12-23 months had received DTP3. Moreover, outreach activities were limited, often conducted from the district hospital and not from other district facilities; and the cold chain extended to only 54 per cent of health facilities (*interviews MoH*). Therefore, survey as well as coverage estimates may overestimate the proportion of the target population that is protected. The 1997 DHS showed a wide discrepancy between rural and urban populations: in urban areas, 85 per cent of children received a full EPI course compared with 36 per cent in rural areas. Low coverage in rural areas suggests the potential and the need to improve performance in these areas. However, uncertainties around the actual reported coverage may be problematic in setting targets and monitoring performance.

Field visits to Zambezia Provincial Health Department indicated wide variations in district coverage estimates for 1998-2000. For example, the range of reported 1999 DTP3 coverage by district, as recorded at the provincial level, ranged from 32 to 236 per cent, with a provincial average of 83 per cent. These data included numerators and denominators and were not due to incorrectly calculated percentages. Similarly wide coverage ranges were reported for other vaccines: for example, 1999 BCG coverage of 386 per cent was recorded in one district. The three districts visited showed less variation in 1999 DTP3 rates, at 129 per cent (Mopeia), 68 per cent (Morrumbala) and 75 per cent (Maganja da Costa). Calculation of coverage takes place at

district, rather than health facility level and is aggregated at provincial statistics departments before submission to the national level.

MoH interviewees at district and national level cited several factors that could account for the wide range of estimates, mainly related to incorrect target population sizes: the 1997 census may have underestimated the true denominator in some areas¹⁷; there may have been recent population increases in some areas due to an influx of displaced refugees following the recent flooding; and/or target children might have been immunised more than once. For Zambezia, there was no observed difference between provincial and national data for 1999. Although GAVI performance targets are based on numbers of additional children immunised, not on coverage rates, wide variations in target population size make it difficult for ministries to set realistic performance targets. This is discussed in more detail in the following section.

EPI coverage levels in **Ghana** have shown a steady upward trend since the beginning of the 1990s, from a low of 23 per cent for DTP3 in 1989. Reported DTP3 coverage rose from 68 per cent in 1998 to 73 per cent in 1999, while the 1998 DHS showed a coverage of 72 per cent. Numbers of reported measles cases, which should be a good impact indicator for EPI performance, were around 30,000 to 40,000 annually for most of the 1990s; these dropped to 23,335 in 1998 and 15,895 in 1999 (Adjei and Cofie 2000). The recent 2000 national census has shown a lower target population than previously estimated, so

that some districts (including one in Ashanti) have reported DTP3 rates over 100 per cent.

Some districts have also reported higher DTP3 than DTP1 levels. According to MoH respondents, several factors could account for this: DTP3 was already a district and sectoral performance indicator before GAVI, so health workers might be exaggerating performance; however, respondents believed that unintended recording and reporting errors were a bigger problem, more than any deliberate overestimations of coverage achieved. Taking into account the revised national target estimates, current coverage may be higher than previously estimated, making further increases more difficult to achieve. Reasons for believing that coverage estimates for 1999 and 2000 have been high, possibly around 70-80 per cent for DTP3, include:

- 1998 DHS survey estimates were higher than reported estimates, based on projections from the 1984 census¹⁸
- The fall by 1999 in the number of measles cases to about 40 per cent of the 1997 level
- The numbers of wild polio isolates among acute flaccid paralysis (AFP) cases – though fluctuating – have averaged less than ten annually since 1997, with only three isolates from 108 AFP cases in 1999 (Adjei and Cofie, 2000).

Field visits to Ashanti Region supported the overall trend, as reported at the national level:

DTP3 aggregate coverage, based on projections from the 1984 census, was around 60 per cent (1997-9) and rose to 73 per cent in 2000, with a similar trend reported from all districts in the region.

In **Tanzania**, reported coverage has declined slowly in the past ten years, albeit from a relatively high baseline. The EPI Strategic Planning document for 2000-04, reported a gradual reduction in immunisation rates from a baseline of just above 80 per cent in 1992 to 76 per cent in 1999.

However, there have also been overall reductions in the number of measles cases from around 27,000 in 1991 to around 5,000 in 1999. Two considerations point to possible explanations for this apparent contradiction. Firstly, as in other countries, the distribution of coverage is uneven. For instance, the 1999 Tanzania Reproductive and Child Health Survey (TRCHS) shows that 81 per cent of urban children receive all EPI vaccines versus 66 per cent of rural children. Secondly, the DTP3 estimate from the 1999 population survey was notably higher (82 per cent) than the reported estimates for that year (76 per cent by MoH and 74 per cent in the final GAVI application).

There are two types of reported coverage data available at the national level: firstly, coverage percentages are calculated at the facility level and reported in the Health Management Information System; secondly, the numbers of children immunised, which are recorded on EPI tally

sheets, are reported from health facilities to districts and then to regions.

At an annual nationwide EPI meeting, the coverage rates are then adjusted at the central level, taking into account projected changes in population since the last census in 1988. This adjustment is to the denominator only and takes no account of possible inaccuracies in recording and reporting the numerator, ie, the number of children immunised (*interviews, MoH*)⁹.

Visits within Lindi Rural District in Lindi Region revealed differences in coverage estimates between the national and regional/district levels. Data from the regional headquarters showed regional DTP3 coverage for 1999 at 70.8 per cent compared with a regional estimate of 57 per cent at the national level. For Lindi Rural District the 1999 figure reported at the district level was 63 per cent for DTP3 compared with a district coverage of 41 per cent recorded at the national level. The MoH used the latter national estimates for the GAVI application. There were no discrepancies noted between regional and district estimates for district coverage. Staff interviewed at regional and district level stated that they were unaware of these adjustments to the coverage estimates being made at the national level.

Staff in one of five immunisation facilities visited were unable to calculate coverage rates, although facility records included coverage rate estimates. Reasons attributed by health facility staff for difficulties in computing coverage rates included that the training on how to use the new

management information had preceded the roll-out of the forms by some eight years. All district staff interviewed considered the available population denominators to be a significant underestimate of the true values, but reported using them to calculate coverage. Adjustments downwards at the national level, as revealed for Lindi Region, suggests that the national level may also be concluding that target population is larger than the denominators used at lower levels, based on projections from a census conducted 13 years previously. Uncertainties as to the actual coverage rates raise a number of questions around the implications for measuring the impact of new initiatives and setting local as well as national milestones and targets for improving coverage.

Immunisation coverage has shown a dramatic decline in **Lesotho** in the past years, from about 80 per cent for DTP3 in the early 1990s (estimated from bar chart in the EPI Five-Year Plan of Action 2002-06, MoH 2001) to 56 per cent in 2000. During the fieldwork, it was not possible to review national coverage data, as staff who could have provided access to the data were busy with the ongoing GAVI application. However, it was possible to detect some variations in reported DTP3 coverage between different areas of the country, which ranged from 43 per cent to 129 per cent in two Health Service Areas (HSAs). Both the EPI review and the five-year plan outline a number of factors that may have contributed to the decline, in particular:

- lack of good quality central and local supervision

- demotivated health facility staff
- lack of transport resulting in cancelled outreach and supervisory visits.

Field visits to the health facility level in two HSAs, Scott and Leribe, indicated that outreach at most of the sites was limited by a lack of staff, transport or unfavourable weather.

4.7 Feedback from GAVI following application

From the perspective of senior staff in the ministries of health in all four countries, feedback from GAVI on the country applications was seen as prompt, constructive and fair. Conditional approval of the applications was communicated to Ghana and Tanzania by the end of July 2000, within one month of submission. The MoH in both countries were able to quickly respond to queries from GAVI, clarifying outstanding uncertainties about the census data, numerators and denominators, resulting in full GAVI approval being communicated to them by early September. Senior MoH staff in Lesotho were also impressed with the reasonable and helpful feedback on the (unsuccessful) first application, acknowledging that

“We knew we would fail, but we decided to put in the application anyway” (*MoH*).

Section V: Supporting country health systems

5.1 Extent and planned use of funds for systems support

All three of the study countries with approved applications had already received GAVI funds for systems support at the time of the fieldwork. Awards have been based on incremental targets set by the individual countries, representing the numbers of additional children expected to be vaccinated each year, for the five years of the initiative. Initially, there is an upfront award of US\$20 per additional child vaccinated. For example, starting from a 1999 base of 567,197 children vaccinated with DTP3 (73 per cent coverage), Ghana planned to vaccinate 594,028 children in 2000, representing a 4.7 per cent increase. This qualified Ghana for an initial award of almost US\$530,000 (see Table 8).

The first of two equal instalments arrived in the three countries in December 2000 and the second was due for disbursement in October 2001 (*interviews MoH and internal memos/minutes of the ICCs*). The intention has been that subsequent awards would act as a reward for increased coverage performance. However, continued delays in distribution of the combination vaccine to both Ghana and Tanzania may lead to reductions in DTP3 coverage, thereby also jeopardising the incentive. Table 8 summarises the level of GAVI systems support, expressed as a percentage of actual or projected government health expenditure.

The levels of systems support allocated to each country have been relatively small in relation to total country health expenditure, in the range of 0.3 per cent (Mozambique) to 1.7 per cent

(Tanzania) of estimated annual health expenditure in the first two years of the initiative²⁰. Expenditure plans and perceptions as to the adequacy of the support differed between the countries.

In **Ghana**, the initial US\$264,500 arrived in December 2000 and the country was due to receive a further US\$264,500 in October 2001. In line with advice from the senior MoH staff, it was planned that additional systems support funds would only be used for one-off activities. These would include staff training for the introduction of new vaccines and the purchase of items such as computers. They would not be used to fund recurrent costs such as additional outreach activities or to pay incentives to staff. Additional cold chain support, such as freezers, fridges and vaccine carriers, were provided by JICA and USAID. The Ghana MoH decided to spend much of the GAVI systems support money at the central MoH level, to fund activities - most of which would take place at the regional and district levels although some funds were reserved for planning activities in low performing districts.

Table 8: Level of GAVI systems support

	MOZAMBIQUE	GHANA	TANZANIA
Annual health budget or projected health expenditure in US\$m	165 ⁽¹⁾	142 ⁽²⁾	71.8 ⁽³⁾ (86.3) ⁽⁴⁾
Initial GAVI systems support in US\$	460,000	529,000	1,214,000
Initial GAVI systems support as a % of annual health budget	0.28	0.37	1.69 (1.41)
Year 1 instalment of initial GAVI systems support as a % of annual budget	0.14	0.19	0.84 (0.7)

Source:

- (1) Projected 2001 total (recurrent and capital) expenditure, from MTEF June 2001. Exchange rate: 21,387 meticals = 1US\$
- (2) Actual 1999 total (recurrent and capital) expenditure (Levin et al. 2001)
- (3) Projected 2001/02 total (recurrent and capital) expenditure, based on verbal information from MoH during fieldwork, sourced from the 2001/02 Budget Summary from the Plan of Action. Exchange rate: 865 shillings = 1US\$
- (4) Projected 2001/02 total (recurrent and capital) expenditure, based on presentation by MoH during Joint MoH/Partners Annual Review of the Health Sector, March 2001

All informants were of the opinion that the amount of additional money for systems support was relatively small and would not have much impact. Most, including MoH staff, believed that the low level of the performance share was a 'blessing in disguise', in that there was less risk of distortion to the existing programme, due to the lower level of 'incentives' associated with the modest targets set. There was also general approval of the flexibility attached to the support, with the MoH free to decide how to use it. One local immunisation expert and ICC member commented that such a low level of support would probably be inadequate in other countries, which had weaker health systems. All regions and one-third of districts nationally, including the two visited, had received training in the new initiative

during 2001. Field visits to two districts in Ashanti Region confirmed that sub-district staff had been briefed; and additional cold chain equipment (vaccine carriers and fridges) had already reached districts and had been disbursed to sub-district facilities.

In **Tanzania**, according to interviews with MoH staff and a review of internal memos, US\$611,000 was received in December 2000²¹. In contrast with the other two countries where it was decided to allocate funds to general systems strengthening, 17 districts in 10 regions (10 per cent of all districts on the mainland) had been targeted to receive additional support. MoH staff reported that the selection was based on population size and overall poorer performance in coverage according to routine data. If Tanzania

meets all of the targets, an additional 219,000 children will have been vaccinated by 2005.

According to interviewees from the MoH, GAVI objected to the modest targets set by Tanzania, but the MoH insisted that they did not want to set unachievable targets in the selected districts.

Plans for disbursement of systems funds included training for EPI staff on GAVI-related issues and replacement of the fuel source for the cold chain. In addition, improved supervision, as well as monitoring and evaluation of the GAVI initiative was planned. The majority of the budget was reserved for unspecified district activities. At the time of the district field visits in Lindi Region in July/August 2001, cascade training for staff had begun, although district-level staff knew little about additional planned activities. District respondents were unaware of the total amount of support allocated to their districts or that the central MoH had set a target of raising DTP3 coverage from 41 per cent to 50 per cent by 2004 in Lindi district.

MoH and WHO staff reported that the funds would be disbursed via a special fund at WHO similar to that created for the NIDs budget. MoH staff and some bilateral donors indicated that a possible reason for not channelling the funds via the SWAp basket funding mechanism was because this would result in delays in disbursement and in accessing pooled funds at the district level. In general, the MoH and donors agreed that the award was relatively small and

“...not enough to expand outreach in remote areas” (*multilateral adviser*).

However, some donors expressed concerns about the potential for distorting reported coverage if performance was linked to cash rewards:

“It is human nature to exaggerate coverage levels if money is an incentive, but field visits from ICC members act as a check on the system” (*multilateral adviser*).

In **Mozambique**, US\$230,000, which was the first of the two instalments of systems support funds, arrived in December 2000. According to respondents in the MoH, it was planned to disburse funds to the Provincial Health Departments in all 11 provinces, with allocations weighted by population size. Funding would bypass the normal disbursement channels, which are via the provincial offices of the Ministry of Finance, as budget access through normal channels was considered to be too slow.

At the time of the fieldwork, MoH plans and a provisional budget indicated that most of the money would be spent on recurrent costs: employing additional EPI staff on temporary contracts, additional outreach activities, and on monitoring and supervision. MoH respondents were adamant that local targets would not be set and rewarded through systems support money, as

“they [the targets] would immediately be achieved” (*MoH*).

At the time of provincial and district visits to Zambezia, monies had not yet arrived and staff at provincial level were unsure as to the amount of support expected.

5.2 Initial impact of GAVI on current country systems

In terms of initial and likely impact of the GAVI initiative, the four study countries presented a divergent picture²². The following subsections present results on: a) the impact of GAVI on country-level prioritising and planning; b) cold chain maintenance; and c) safe disposal of ‘sharps’ (ie, needles, syringes, lancets, etc). The issue of financial sustainability is examined in some detail in the final subsection.

5.2.1 Prioritising and planning

In **Ghana**, all respondents agreed that EPI was a priority for the country, but there was some divergence of views about the impact of GAVI. The MoH tended to view GAVI as fitting in with its priorities (though wanting better evidence on the cost-effectiveness of introducing new vaccines); or as fitting in but producing some distortion in the timing of taking on new immunisation challenges (measles control being a greater priority). Donors and especially pooling donors saw it as distorting the EPI programme, so that expansion of coverage to include hard-to-reach populations might suffer. The possibility that the introduction of new vaccines could have a negative effect on efforts to extend coverage to hard-to-reach groups (ie, negative effects on equity) was raised by two respondents – one donor and one local ICC expert.

Bilateral donors, generally, were more concerned that GAVI was not yet being integrated or mainstreamed into the general planning process and annual plans of action, where most of the

pooling donor inputs and influence was exercised. However, bilateral donors also recognised that the joint planning forums were already overcrowded with issues. The MoH was generally less concerned about lack of integration and saw GAVI as providing a much needed boost and focusing of efforts on improving the EPI programme. Its view was that all new initiatives start in a vertical way and gradually get incorporated into the Programme of Work and that GAVI was less problematic than many other donor-led vertical initiatives. National MoH staff had been instructed not to talk about GAVI at the district level, but to announce this as a new national initiative to incorporate new vaccines into Ghana’s EPI schedule. There was a definite sense of country ownership of the initiative among MoH respondents; they also believed that they could handle problems of integration, in that GAVI had given them a fairly free hand.

Many respondents in **Tanzania** perceived that EPI was a top priority for the MoH, and that the GAVI initiative was providing positive motivation. A particular benefit was that it broadened the focus of immunisation issues discussed at the ICC and stimulated a systematic review of service provision. MoH informants were adamant that GAVI supported country priorities, especially in terms of the introduction of new vaccines, in spite of the reservations expressed about the format of vaccines. There were some reservations expressed by MoH staff about the opportunity costs of the application, in that it diverted them from other activities; but, on balance, they felt that this was worthwhile. They also felt that the level of systems support money would have limited impact. Overall, on a positive

note, the MoH viewed the initiative as a catalyst to attract a greater proportion of government budget to the EPI programme, which had been steadily increasing in recent years.

Donors, in general, were more sceptical, expressing reservations about the uncertainties of sustainability, while acknowledging that higher volume distribution of new products should force down their unit costs over time. Donors involved in vaccine procurement were critical of the delays in shipment and the impact on planning processes. All donor respondents noted the high level of ownership and leadership demonstrated by the MoH, particularly in relation to managing the process and associated decision-making.

In **Mozambique**, MoH respondents reported that the GAVI initiative was supporting country priorities, through introducing new vaccines and supporting EPI, which was a priority for the MoH.

Donor views varied. Some perceived EPI performance to have been improving since the early 1990s. However, most external advisers interviewed felt that overall, leadership at the central level was weak, and that Mozambique's EPI capacity was low, or even that

“EPI is the weakest programme in the MoH” (*bilateral donor*).

Three donor respondents attributed this to the historical placement by donors of short-term technical advisers within EPI. This was not addressing the problem of low capacity within the MoH, or encouraging senior staff to accept

responsibility for their departments. An additional factor, as reported by two respondents – one donor and one MoH – was that there were no promotion opportunities for MoH staff within the EPI programme.

Both donors and staff at EPI central level reported that recent staff turnover and a chronic shortage of staff had resulted in poor institutional memory. The central EPI team had only eight staff, three of whom were support staff. Overall, a broad range of donors interviewed perceived UNICEF, rather than the MoH, as leading the GAVI initiative in-country. One respondent, however, acknowledged that the MoH had displayed some leadership. In describing the MoH response to pressure from GAVI to accept monovalent HepB, he stated:

“...under pressure, the MoH defended its position well” (*multilateral adviser*).

Concerning the actual impact of GAVI to date in Mozambique, donor views were more critical than those of the MoH. For example, one multilateral adviser stated that (they)

“...were not sure if Mozambique was capable of handling new initiatives as measles is yet to be conquered, so why start something new”.

Bilateral donors involved in training and initial introduction of the new vaccines were highly critical of both the transaction costs and the opportunity costs associated with training. Training of 1,297 of the MoH's staff, countrywide, was implemented in only 28 days. Costs incurred by one bilateral donor included

US\$228,000 for training and logistics, and \$111,000 for introduction of the new reporting card²³. As another bilateral adviser noted:

“although GAVI is integrated into routine immunization, it comes with a vertical training programme. . . Donors encourage global initiatives that run counter to a systems approach and do not build capacity in governments...GAVI runs the risk of being too much about commodities and supply, with insufficient emphasis on systems”.

In **Lesotho**, donor and MoH respondents perceived the impact of the GAVI application process on country priorities as largely positive. The MoH, and particularly the EPI Manager, was viewed as being in the driving seat, using the GAVI initiative to capitalise on the higher profile created for EPI. One donor however, commented that the GAVI initiative had minimal impact due to other pressing national health priorities:

“EPI is no longer on anyone’s radar screen – it has been eclipsed by HIV/AIDS”.

Donors also felt that insufficient time had been allowed for the preparation of the second application despite the initial unsuccessful application, and had been left until very close to the deadline to complete:

“there is a sense of panic to get it right this time. The deadline isn’t far away and it’s still a blank sheet of paper” (*bilateral donor*).

5.2.2 Maintaining the cold chain

In order to assess the likely initial impact of GAVI at the peripheral level, facility assessments were conducted at central, regional and a range of peripheral, health facilities in Tanzania, Mozambique and Lesotho. In **Ghana**, one region and two districts in the region were visited, which included an assessment of the vaccine storage facilities in one district. There, a sufficient stock of vaccines under the correct storage conditions was found.

In **Tanzania**, a 1998 cold chain review, as reported in the 2000 Assessment of Immunization Services, highlighted a number of issues concerning the adequate maintenance of the cold chain. In particular, there was a lack of transport for EPI supplies, leading to frequent stock-outs, shortages of kerosene and of spare parts for the maintenance of fridges. MoH interviewees reported that two recent policy changes had the potential to improve aspects of cold chain management. Firstly, there was the reopening of regional vaccine stores to improve stock levels in the regions during the rainy season; and secondly, the directive that cold chain officers and MCH co-ordinators must participate in supervisory district visits.

As part of the fieldwork, brief visits were made to the central vaccine stores in Dar-es-Salaam as well as the regional and district stores in Lindi Region. Vaccines were found to be stored correctly at each location, within expiry dates and at the correct temperature. Additional visits to six remote health facilities in Lindi Rural District were made, including a mix of Government and Church

providers. In three of the facilities, the kerosene refrigerators had no functioning thermostat or were broken. In one facility, twice-daily recordings of temperatures were consistently maintained within the correct range, yet the fridge had no external thermostat and the internal gauge had broken. At another site the vaccines were stored in the wrong positions within the fridges, with potential implications for the efficacy of the vaccines.

In all of the remote facilities, staff reported frequent shortages of spare parts, in particular in the supply of wicks. Some of the facility staff reported using gauze bandages as replacement wicks, with the result that excessive amounts of kerosene were used so supplies ran out, necessitating vaccines to be discarded. Staff at one facility reported that the decision to withdraw replacement supplies of wicks and burners had been taken at central level in advance of a planned national conversion to liquid paraffin gas (LPG). Staff at district level attributed the shortfall in spare parts and fuel for routine supervision to lack of access to district basket funds. If this is the case then the supplies of LPG to the newly converted fridges are likely to be insufficient, due to transport constraints.

Although sufficient mobile vaccine carriers were observed, staff in all facilities visited lacked the resources required to conduct outreach services, notably bicycles and allowances for overnight stays in outlying villages.

In **Mozambique**, cold chain facility visits and assessments were carried out at central, provincial and district levels. At the central level, the cold

room had adequate storage space and functioning fridges, with vaccines correctly stored.

Multilateral advisers reported an average of six-month delays at customs for replacement refrigerators supplied by UNICEF, due to non-payment of advances on import taxes required by Central Government for non-emergency supplies. There were similar delays in the customs clearance of boxes of needles and syringes and disposal boxes for GAVI vaccines. Interviewees from bilateral donors involved in vaccination stated that the recent release of Heavily Indebted Poor Country (HIPC) funds had part-funded the procurement of unstable vaccines that had already been rejected by a neighbouring country. Fortunately, the batch of vaccines had been detected as faulty by central EPI staff, prior to distribution.

Airfreight is often the only option, given the distances for transporting vaccines to the north of the country, especially during the rainy season or in emergencies. One bilateral adviser reported that the MoH had not kept up payments to the monopoly national carrier, resulting in suspension of flights for all vaccines to provinces. In order for the first batch of GAVI vaccines to reach the provincial stores in July 2001, the donor had to pick up the costs of air transport. Moreover, for airfreight within the country, vaccines must be brought from the cold room to the airport, where they are kept without refrigeration while a freight invoice is prepared and issued. They are then transported back to the EPI cold store to await shipment, often some weeks later.

One visit was made to the vaccine stores in the provincial capital of Zambezia Province. The purpose-built warehouse, built with assistance from the European Union (EU), had plenty of space and all the vaccines were stored correctly. Additional visits were made to nine health facilities, including the headquarters in three districts in remote south-west Zambezia. Refrigerators in many facilities were new, but had ceased to function after as little as 30 days' use. Staff reported that one make of refrigerator was particularly unreliable and appeared to require a higher quality of kerosene than was available locally. Subsequently, interviews with senior MoH staff revealed that an investigation had been requested, because this make was identical to the 600 replacement fridges recently procured by UNICEF to replace the cold chain.

Several respondents at national and district level reported that routine cold chain maintenance at all levels was minimal, although staff were aware of basic procedures for reporting faults; and that spare parts for fridges were difficult to obtain. Staff stated that solar power was the most appropriate energy source in remote areas, yet only one health facility used solar fridges.

In general, vaccines were stored correctly, but low staffing levels evident at all of the facilities visited and a general lack of transport and fuel precluded outreach. The exceptions were those few districts supported by Save the Children UK and UNICEF, where the recent provision of motorbikes meant that staff were in a position to increase coverage. However, the cost of extending this initiative countrywide may be prohibitive, thus limiting further improvements in outreach in rural areas.

In **Lesotho**, visits were conducted to central and HSA vaccine stores and to eight health facilities providing mostly fixed site immunisations. These were combined with occasional outreach services, if transport from local residents could be obtained and paid for from clinic funds. The EPI review of 2001 indicated some storage constraints at central level, which could limit the importation and storage of additional new vaccines. Otherwise, central and HSA stores were in good condition with sufficient supplies and vaccines stored at the correct temperature. The EPI Manager reported that both Ireland Aid and JICA were supporting cold chain replacement.

In general, the building infrastructure was better than in the other countries, and facilities were well maintained and clean. Only one refrigerator in the eight health facilities assessed was found to be faulty, with a recorded temperature of 15 degrees centigrade. Staff reported that supplies of gas were obtained locally. However, unlike in government facilities, both the Christian Health Association of Lesotho (CHAL) and private providers were required to purchase supplies from their own funds. As a result, these facilities levied a nominal charge to patients for vaccination/child health screening. One multilateral adviser commented that even nominal charges could act as an obstacle to increasing immunisation coverage, given the high unemployment rates and the rising incidence of AIDS orphans. They would also have a negative impact on equity of access to health provision.

All of the facilities reported low levels of supervision of peripheral health workers, which could hamper the smooth introduction of a new initiative; and the new vaccine carriers observed at

facility level were rarely used by staff due to insufficient staffing levels or lack of transport for outreach provision.

5.2.3 Sterilisation and safe disposal of injection materials

As part of the fieldwork at facility level in Tanzania, Mozambique and Lesotho a rapid assessment of sterilisation equipment and the disposal of 'sharps' was undertaken.

According to **Tanzanian** MoH interviewees, a recent WHO report on injection safety in Tanzania found more than 80 per cent of all injections to be unsafe²⁴. In interviews, MoH respondents were supportive of the forthcoming introduction of auto-destruct (A-D) syringes, saying that parents were concerned about the reuse of needles due to the possibility of HIV transmission. Additionally, the recent 2000 Assessment of Immunization Services highlighted the lack of kits for immunisation and inadequacy of sterilisation equipment, with an associated increase in the numbers of injection abscesses.

In Lindi Rural District, all of the staff interviewed were familiar with the use of A-D syringes, as these were the syringe of choice for sub-NIDs programmes. The syringes were popular with staff, as time was saved during immunisation schedules, as well as in preparation and cleaning. However, the routine EPI currently utilises reusable equipment, which requires sterilisation. On inspection, most of the sterilisers were old, and at two facilities the thermostat was broken.

Staff at all the clinics reported shortages of kerosene and replacement parts for sterilisers.

Shortages of needles and syringes at many facilities were also a problem, and staff stated that insufficient supplies meant that reusable needles were not always sharp. In one clinic, disposable needles were not discarded and were observed soaking, presumably for reuse.

The disposal practices for sharp items including disposable needles, ends of intravenous giving sets and old vaccine vials were of variable quality in Tanzania. Each of the health facilities had a disposal area approximately 50m from the clinic. All but two were too shallow and most had accumulated clinical waste that was several days old, had not been incinerated and was scattered around the disposal site. There are major implications here for the adequate disposal of these new products when introduced. The GAVI vaccines are distributed in packs that include A-D syringes and disposal boxes. If the GAVI policy on providing A-D syringes were implemented, all EPI vaccines would use A-D syringes and disposal methods. This would increase the need for safe disposal facilities. Interviews with one bilateral adviser indicated that WHO had been working on prototype incinerators for the past year, but at the time of the fieldwork no decisions had been made on potential sources of funding.

At two of the clinics, large numbers of partially used vaccine vials were discarded but staff were not calculating rates of wastage. Only one clinic was seen to be observing an open vial policy, namely that unused vaccines may be kept for subsequent days and not discarded on the day of opening. This raises questions around wastage calculation rates in costing the introduction of new, more costly, vaccines such as DTP-HepB. Cold chain weaknesses themselves, as outlined in

5.2.2, call into question the safety of widespread use of an open vial policy.

Mozambique was the only study country visited that had already received supplies of GAVI A-D syringes and disposal boxes. At central and provincial level, supplies of the boxes and syringes were available. One multilateral adviser commented that

“the most positive thing about GAVI in Mozambique is the introduction of A-D syringes (due to HIV prevalence); however, disposal is problematic”.

At provincial level one senior member of staff stated that he had already submitted a proposal for incinerators to the MoH for consideration. At facility level in Zambezia, all staff reported using A-D syringes for the quadravalent GAVI vaccines and for other EPI vaccines apart from BCG, and a mixture of sterilised and disposable syringes for other injections. The A-D format was popular with staff because of ease of use. Sterilisers were all functioning, although in one facility disposable needles were observed soaking in solution.

Disposal of GAVI boxes varied at the sites visited, but in general was inadequate. Many of the disposal pits were too shallow, with incompletely burned waste, including the GAVI boxes, which are paraffin impregnated for ease of combustion. Due to the volume of waste at district hospitals, including many other syringes from general wards, waste including sharps was scattered around the pits at all of the sites. Staff reported that they were therefore unwilling to get too close to the pit and threw waste from a distance, thus

adding to the debris. Further, staff viewed waste disposal as a non-clinical duty, and claimed that shortages of support/cleaning staff exacerbated the problem. There are implications here for the quality of supervision, not just disposal of sharps. All levels reported that supervision was infrequent, due to lack of staff, and all facilities reported no supervision in the previous year. A recent, but undated, report²⁵ on the management of health services in a neighbouring province, Nampula, supports this finding of insufficient supervision.

In **Lesotho**, staff at facility level generally used disposable syringes. Inspection of sterilisers found reasonably new, functioning equipment. The majority of facilities used purpose-built brick incinerators for disposal of all clinical waste, which staff reported worked very well. Only two clinics were without an incinerator; the staff reported that used disposable needles were put in the staff pit latrine. Staff in CHAL and private facilities reported that when supplies of needles not infrequently ran out, more had to be purchased utilising clinic funds. Along with the purchase of gas and other disposable items, as discussed in previous sections, these additional immunisation costs were likely to be passed on to patients, discouraging attendance especially among the poor.

5.2.4 Sustainable financing of new vaccines and products

As part of GAVI support, successful countries must submit a proposal for sustainable financing in the second year. Raising the issue of the financial sustainability of the GAVI initiative

elicited differing views, not only between countries but also between Government and donors (to varying degrees) in each of the four countries.

In **Ghana**, a 2001 study, which reviewed the financing of immunisations and considered options for increasing EPI cost-effectiveness, had been commissioned and conducted after Ghana had agreed to the expensive pentavalent vaccines (Levin et al. 2001).

Based on Levin et al.'s *Ghana Immunization Financing Study* (2001), the estimated total cost of the existing national immunisation programme, including NIDs and surveillance, was about US\$8 million in 2000 (routine EPI \$3.7m and NIDs \$3.9m), \$0.41 per dose, and \$16.63 per fully-immunised child. With the proposed introduction of the DTP-HepB-Hib vaccine (unit cost \$3.25 per dose), additional annual costs of the vaccine would be about \$7.1 million. This would result in an additional annual funding gap of between \$9.2 and \$11.6 million, which would be mostly filled by GAVI during the five years of the commitment.

“If it was to be funded by Ghana, the US\$8 million marginal cost of this vaccine would be equivalent to 40 per cent of the total funds contributed to the Donor Pool during 2000” (*bilateral donor*)

This would more than double the annual cost of the national immunisation programme. This is illustrated in Table 9.

Table 9: Estimated annual expenditures required in Ghana for Hepatitis B vaccines, by presentation: 2001

	Monovalent Hepatitis B	DTP-Hepatitis B	DTP-Hepatitis B-Hib
Unit Cost	\$0.28	\$1.10	\$3.25
Target Pop	736,490	736,490	736,490
Wastage	25%	25%	15%
Desired Coverage	85%	85%	85%
Sub-Total	\$699,386	\$2,747,586	\$7,202,320
Syringes	\$173,996		
Minus Cost of DTP		\$103,674	\$103,674
Cost of reconstitution needles	\$8,545	\$8,545	\$42,726
Grand Total	\$881,927	\$2,652,457	\$7,141,372

From: Levin et al., Ghana Immunization Financing Study, 2001

Regarding future financing of the combination vaccine if GAVI financing ceases at the end of five years, there was a divergence of opinion between MoH and donor respondents. The MoH interviewees took their lead from a senior MoH interviewee, who stated that donors make too big an issue of sustainability. He argued that GAVI is the first donor to give a five-year commitment – no other donor had given a commitment as long as this. Second, Ghana would continue to be dependent on external resources for the immediate future, whether this was donor support, HIPC or other support. Third, Ghana's relationship was with GAVI, not with the Vaccine Fund; and fourth, sustainability could not be separated from the issue of Ghana's priorities. The issue was not about resources allocated to support particular initiatives or programmes, it was about accessing sufficient resources to support the health system. If it were a priority for the country, then the funding would have to follow.

The MoH believed that there would be a moral imperative on wealthy countries to bridge the funding gap, and that GAVI was a 'good buy'. From a technical perspective, the MoH recognised that it would be possible to revert from the pentavalent to a quadravalent vaccine – reducing vaccine costs from about US\$7.2 million to \$2.7 million, by current estimates – but that this would be politically undesirable.

All respondents agreed that it was not possible to predict what would happen at the end of the five-year GAVI commitment. However, donors were more sceptical, both about GAVI and about long-term aid levels.

“The MoH may be making an unwarranted assumption that there will be funding support from this donor for GAVI-related immunization activities in the future” (*donor*).

A non-pooling donor recommended that the Ghana MoH and its partners should advocate for vertical donors to commit to picking up such costs. He reported that at the country level, there was currently neither consensus nor clarity about the future sustainability of the GAVI initiative.

“What is required is not [just] a plan but a consultation and consensus building process that involves a larger group of donors. Lay the startling facts on the table – Ghana has five years to come up with a sustainable way of paying an extra US\$8 million per year for vaccines” (*bilateral donor*).

In **Tanzania**, the issue of sustainability was less of a concern to both donors and MoH respondents. On the one hand, MoH staff were of the view that budgeted expenditure for EPI was improving: the Ministry was increasing the EPI budget year-on-year, gradually raising the proportion of internal versus external funding. Additionally, MoH interviewees commented that donors were also increasing pledges and expenditure.

However, donors generally expressed more concern than the MoH around the sustainability of the initiative. One bilateral donor commented:

“vaccines are a small proportion of the total budget, the main concern is the replacement of A-D syringes after five years, although if demand increases worldwide, unit costs will drop”.

All the other donor representatives supported this concern about the future financing of syringes. One staff member at a peripheral health facility also raised concerns about the problem of

consistent availability of A-D syringes if reusable syringes were discontinued.

It was not possible to review all the necessary documentation on vaccine costs in Tanzania; however, the 2000 EPI strategic plan has estimated that EPI vaccine costs, with the inclusion of the GAVI quadravalent vaccine, will rise from US\$2.2m in 2000 to \$9.9m in 2004, with the inclusion of DTP-HepB.

In **Mozambique**, MoH staff were of the opinion that the money would be found to continue to purchase the new vaccines, if/when GAVI funding ceased, because Hepatitis B was a country priority. Donors were less optimistic. One multilateral donor was hopeful that the market price of underutilised vaccines and syringes would drop with a worldwide increase in demand. A bilateral adviser expressed the opinion that GAVI support will have to be extended, as it would be

“politically unacceptable to cut off support after five years”.

Many staff at peripheral level voiced concerns about the supply of boxes and syringes, claiming that no vaccines, not just GAVI vaccines, could be given without an uninterrupted supply of A-D syringes, if current supplies of disposable needles were withdrawn. The Mozambique MoH (undated) EPI strategic plan projected an annual rise in vaccine costs from US\$1.9m to \$3.8m between 2000 and 2004.

In **Lesotho**, as the application process for GAVI support was ongoing, the issue of future sustainability was not explored in the same detail

with MoH staff. However, the EPI Manager reported that in 2001 the MoH had made its first contribution to the procurement of imported vaccines by contributing some 15 per cent towards the cost of BCG. Two external advisers who regularly attended ICC meetings commented that the issue of sustainability had not yet been discussed at the ICC. One commented:

“the Government does not consider issues of sustainability, as donors will always provide. For example, the EPI review raised many issues but no donor has yet been approached for funding” (*donor*).

Section VI: Discussion

GAVI is a new initiative, about 18 months in existence when fieldwork for this study was started in mid-2001. It has developed at a remarkable pace, and continues to evolve. Both international and national players have been grappling with new and changing processes, working within tight time frames. This has been particularly true for early applicants, like those included in this study: Mozambique, Tanzania, Ghana and Lesotho.

This study has highlighted a number of important issues, which have implications for efforts to support countries to provide effective immunisation services and increase coverage. Evidence is mainly based on the perceptions of country-level participants – senior MoH staff and multilateral and bilateral donor representatives, as well as facility-based staff. While these were supported by a review of available documents and peripheral-level facility assessments, the findings are time-limited, based on the views of national-level players and cannot constitute comprehensive assessments of the countries' health systems or GAVI's impact on countries. However, the different sources of information showed fairly consistent patterns within the four countries, and some common issues and concerns across the countries.

Important differences emerged between the four countries in terms of the respective MoH's ownership of the GAVI initiative, its capacity to undertake leadership of the application process, and in the underlying functioning or 'health' of the health systems. The early evidence suggests these factors will have a major bearing on the success of GAVI (and other global initiatives) in

different countries. In this section we highlight some of the main questions which were raised in relation to these issues and the GAVI initiative.

COUNTRY PRIORITIES

GAVI was generally seen as a positive development in all four countries. The renewed focus on EPI was welcomed, in that vaccine-preventable diseases had dropped down the policy priority list and the GAVI announcement coincided and accorded with countries' own wishes to re-focus attention on EPI. There were differences: Ghana had begun to review its EPI and was preparing a multi-year plan at the time of the announcement. In Tanzania, concerns had already been expressed at the national level about falling immunisation coverage rates. In Mozambique the MoH respondents reported that EPI was a national priority, although the general view of donors was that EPI had been a low priority within the Mozambique health sector, and that GAVI had given a much needed boost to the immunisation programme. In Lesotho, there was general recognition that its EPI was deteriorating, with HIV/AIDS for instance having become a much higher priority than vaccine-preventable diseases.

In terms of the main features of the GAVI initiative, countries particularly welcomed the fact that systems support money was on offer, giving them freedom to spend it as they wished, without significant conditionalities. Respondents contrasted this with previous experiences of aid to the health sector where donors had been much more controlling of how money was to be spent. A second welcomed feature was the proposal to

provide Hepatitis B vaccine to countries for incorporation into their EPI schedules, as this was seen as a priority that countries had not previously been able to fund. It will be some decades, however, before the major population benefits of this vaccine will be felt by countries, assuming that high coverage can be sustained.

More contentious in some cases was the type of vaccine combination offered to countries, as in the case of Ghana's acceptance of the pentavalent vaccine, when informed of delays in the availability of the quadravalent vaccine. This suggests that the type of new combination vaccines introduced to countries can be supply- rather than demand-led. Respondents (both MoH and donors) in Tanzania and Mozambique expressed the view that there had been some pressure on them from GAVI to accept the monovalent HepB vaccine, probably because of worldwide shortages of the quadravalent vaccine. However, in both cases, they were able to resist GAVI pressure, actual or perceived, and hold out for the quadravalent vaccine. It is notable that national-level respondents in these three countries did believe that their choices were ultimately respected. However, concerns remained among some ICC members about the adequacy of the evidence for introducing Hib vaccine in Ghana.

THE PACE OF THE APPLICATION PROCESS

One striking finding in the study, from all four countries, was that they experienced pressure to make rapid decisions, and in some cases were subject to what they felt were unreasonably tight deadlines in the application process. An example of this was where the Ghana MoH was informed

that it needed to make a decision within ten days about acceptance of the expensive pentavalent vaccine, in the absence of Hib burden of disease evidence or adequate time and guidance to analyse the implications for future sustainability.

The pace of the application process was most marked in the first six months, leading up to submission of applications. However, subsequently the pace of the process slowed considerably, particularly with regard to the delivery of vaccines. Initial systems support awards were made in December 2000 but Mozambique received its first shipment of quadravalent vaccines in April 2001. However, Tanzania and Ghana had not yet received supplies of vaccines at the time of the fieldwork (August 2001), although plans were in place to change over from DTP to the new vaccines.

National-level respondents were concerned about the consequences of delays in the arrival of the quadravalent vaccine. In Tanzania prolonged delays were raising concerns about exhausting the remaining supplies of DTP, which would seriously undermine its routine EPI. If delays were prolonged, avoidance of shortfalls in essential EPI vaccines would require co-ordinated emergency action, involving bilateral donors (who have traditionally been the funders of EPI) and possibly vaccine producers. Planning would be difficult for all concerned, if uncertainties about the timing and volume of combination vaccines persisted.

New initiatives have to fit alongside pre-existing commitments and priorities. MoH staff are also unable to make immediate changes to systems at

the delivery level, such as reporting mechanisms (for example, new record cards need to be printed and distributed); and refresher courses or retraining of staff takes time. These were possible reasons for the fact that, in spite of the timely arrival of the systems support monies from GAVI, both Tanzania and Mozambique had only spent a small proportion of the total by August 2001.

Delays in vaccine availability will also prevent GAVI reaching its global milestones on time, such as the introduction of HepB vaccine by 80 per cent of countries with adequate systems by 2002. This will require GAVI to review its targets.

COUNTRY CO-ORDINATION AND EXTERNAL SUPPORT

Donor and MoH staff whose main interest was in EPI dominated membership of ICCs. In some cases they may have lacked sufficient awareness of wider systems issues and their implications for the initiative. For example, to different extents in the four countries, most of the work of the ICC was carried out by a core group of MoH and key multilateral advisers. They focused on GAVI criteria and were less concerned about how GAVI would fit into wider programmes of work, within SWAp processes. In countries where the MoH did not take the leading role in the functioning of the ICC, other members – UNICEF for example – played a strong role. This may have compromised opportunities for capacity building and promoting country ownership of the process. In those countries where ICC meetings have been infrequent, as in the case of Mozambique, or limited to a smaller core group of donors, as in Lesotho, there is a risk of not meeting GAVI's

aims of building a broad constituency to mobilise further political and financial resources for immunisation.

All four countries had significant technical assistance from outside. Technical inputs from GAVI were generally seen as appropriate, helpful and timely; although GAVI consultants appeared to country-level respondents as unsure about some of the requirements of the application process. In some cases the timing of external guidance was problematic, for example, the Levin et al. (2001) financing report and Hib burden of disease assessment were produced after Ghana had decided to accept the expensive pentavalent vaccine.

The evolutionary nature of the initiative can be seen as positive, in that GAVI appeared to be getting feedback and learning from country-level experiences, using these to modify and improve practices. An example was the decision to provide A-D syringes for all EPI vaccinations, not just for the new vaccines. Another was the introduction of retroactive payments to countries only previously eligible for vaccine support, recognising the transaction costs associated with the introduction of new products. However, the decision by the GAVI Board to cap funding to countries with large birth cohorts has implications for inter-country equity within this initiative.

IMPACT OF GAVI ON COUNTRY SYSTEMS

The GAVI initiative has been intensive and demanding, with significant transaction and opportunity costs on MoH and/or donor staff in all countries in the six months leading up to

submission of the application. In terms of GAVI's initial impact on country systems, the respective MoH staff, especially those with a remit for EPI, viewed the benefits – raising the profile of EPI and seizing an opportunity for additional external inputs and new vaccines to strengthen the programme – as outweighing the costs. The provision of A-D syringes for all EPI vaccines was seen as a clearly positive component, more so as mothers were reported as fearing that reusable syringes were placing their infants at risk from HIV.

Multilateral agency staff usually held a similar view of the initiative. Bilateral donor representatives, especially those committed to SWAp mechanisms, were sometimes more sceptical. Reasons cited were that GAVI was producing a lot of activity for a relatively small amount of money, its benefits might be short-lived, it was re-verticalising donor support to health; and it was overextending limited capacity, both that of MoH and donor counterparts.

Systems support money was being channelled in different ways and was going to be spent on different activities in the three successful countries. In all cases, the money was to be earmarked for EPI-GAVI-related activities, rather than pooled. Ghana, by making decisions at the central level on what district activities to fund, could be said to have been undermining district-level planning and decision-making. However, this did avoid placing an additional burden on districts for what would have been a relatively small amount of money. In Tanzania most of the money was being reserved for unspecified activities in 17 low coverage districts. In

Mozambique it was to be disbursed to provinces. Earmarking and bypassing of common pooling mechanisms has potential advantages (greater flexibility and more rapid disbursement), and disadvantages (districts have to manage parallel financial monitoring and reporting mechanisms).

Of much greater concern for the sustainability of the initiative was the decision of some countries to use the money to fund recurrent activities, contravening an important condition set by GAVI. The funding of supervision in Tanzania and Mozambique – and of additional outreach and temporary contract staff in Mozambique – indicates that MoHs recognise that these essential aspects of health systems are seriously underfunded.

THE CAPACITY OF COUNTRY SYSTEMS TO IMPLEMENT GAVI

Given that countries are incorporating the new GAVI vaccines into routine EPI services, rather than through mass campaigns such as NIDs, the likely impact of the initiative will be highly dependent on the capacity and performance of the current health systems. Even in Ghana, where the circumstantial and reported evidence indicates that immunisation coverage is already relatively high and holding up, there were concerns about the ability of the system to reach the additional children required to increase coverage.

The EPI reviews and field visits in most of the countries revealed structural and systemic constraints and weaknesses that were having a significant impact on coverage rates and programme effectiveness. These were probably

the result of chronic underinvestment in recurrent costs over many years. Immunisation is highly dependent on a complex network of inputs. The shortcomings that were revealed during fieldwork (although in a small number of facilities, purposively selected for their low coverage or remoteness) have serious implications for the overall effectiveness of the EPI programme, not just for the GAVI initiative.

Inability to provide and fuel transport for outreach and for delivery of EPI supplies has implications for both raising coverage and ensuring adequate supervision and maintenance of an effective cold chain. If cold chain weaknesses (non-functioning fridges and thermostats, and vaccines exposed to ambient temperature) are widespread, especially in rural areas, reductions in vaccine efficacy will seriously undermine immunisation and preventative health services generally. While the introduction of A-D syringes has been welcomed, insufficient attention has been paid to planning their disposal, especially in the light of A-D syringes being made available for all EPI vaccines in the near future.

Moreover, whereas the above constraints could be at least temporarily addressed through additional funding, serious staff shortages were revealed in some of the countries, in particular Mozambique and Lesotho. This may explain the decision in Mozambique to use systems support to fund temporary contract staff to conduct outreach. However, these short-term solutions and improvements will not be sustainable, unless additional support is mobilised beyond the time frame of GAVI. In addition, GAVI systems support money is unlikely to be able to address all

of these issues even in the short term, in that the amount of funding is a very small percentage of total health budgets. The deep-seated systems weaknesses in some countries call for a more substantial response, not just from GAVI but from the wider international community.

MONITORING AND REWARDING PERFORMANCE

There is an opportunity to capitalise on the momentum and political profile of the GAVI initiative to address wider systems issues. For example, one of the findings in Tanzania and Mozambique, where district-level assessments were conducted, is that they have major difficulties in recording and reporting valid and reliable data. Both at the national and lower levels there was uncertainty around current immunisation coverage, with different district estimates computed at different levels of the system. There was a lack of confidence in estimates of target population size, which probably accounted for the wide range of district estimates revealed in the fieldwork. This was also reflected in adjustments made to national coverage estimates during the application process.

The fieldwork, however, did not attempt to assess the accuracy and completeness of reporting of numbers of children immunised. Therefore, reports of measles outbreaks in high-coverage areas in Mozambique could have been due to a combination of factors: over-reporting of numbers of children immunised, underestimations of the target population, and cold chain failures leading to loss of vaccine efficacy.

Increased performance in terms of coverage is one of the GAVI milestones and achievement of locally set targets attracts a performance award. There is the risk that this places excess emphasis on reporting and monitoring of quantitative data, which could be manipulated so as to increase rewards. Both district and national-level respondents reported this possibility. In Ghana, DTP3 levels, already used for sectoral monitoring, were higher than DTP1 levels in some districts. The DQA pilot evaluation report also recognises, from the authors' interaction with "some very sharp and motivated local counterparts" (LATH Consortium 2001), the risk of data being manipulated, even if audit systems are introduced. It therefore advises against relying solely on quantitative measures. These findings raise major questions for target setting and reward systems for global health and development initiatives more generally, including poverty reduction strategies and the new Global Fund.

The current reward system may also encourage countries to use funds to raise overall coverage, rather than to address some of the inequities within countries. Only Tanzania has taken the opportunity to allocate systems support funds to address in-country inequities, by targeting it towards low coverage districts. Further, the extent to which reported coverage based on uncertain data determines the type of support countries can apply for (hence the importance of Mozambique's downward adjustment of its baseline DTP3 from 80 per cent to 76 per cent) raises questions about the equity of such quantitative cut-offs for countries applying for GAVI support.

SUSTAINABILITY OF THE GAVI INITIATIVE

In terms of future financing of the initiative beyond the five-year time frame, the lack of consensus between donor representatives and national staff at country level is stark. On the one hand, it is hardly surprising to find that MoHs, for so long dependent on external support, remain pragmatic in anticipating that funds will eventually follow the plans and priorities of the sector. Similarly, given the more usual time frames of donor commitments (often one-year actual and a further two-year indicative commitments), the fact that they welcome a five-year commitment is understandable.

However, the costs of sustaining such new initiatives beyond the initial donation present challenges to the health sector and the international community, especially given that at country level there appears to be an assumption by MoHs that costs will be picked up by donors or international organisations. This may prove to be the case and, as GAVI has pointed out, continued success will be dependent on further future financing at local level from partner organisations.

However, there is little specific evidence yet of individual agencies indicating that these costs will be covered in the future, particularly as some countries may have greatly increased the future cost base by opting for more costly combination vaccines. In the case of Ghana, the annual cost of its routine EPI (currently US\$3.7 million) will almost triple, with the introduction of the pentavalent vaccine. The lack of discussion and co-ordination around future financing, involving

the major donors at the country level, was a notable finding of this study.

There is a risk that withdrawing expensive combination vaccines and A-D syringes from immunisation programmes in the future may prove to be too politically sensitive for governments. In which case, if the additional funding is not forthcoming, other, and possibly greater, priorities might suffer. The scenario of funding and managing a series of competing country priorities could be further compounded by future global initiatives, seeking to introduce other new products including drugs and vaccines into what continue to be underfunded health systems. Co-ordination and a greater resource commitment from international players, so as to minimise costs and ensure countries' systems are strengthened to incorporate these products in a sustainable way, will be essential.

Section VII: Conclusions and recommendations

Representing a new approach to public health, GAVI is being used as a model for the administration of donor funds. The purpose of such a partnership between public and private sectors should be to pool resources and capacities so as to enhance countries' access to necessary products. Co-ordination within the wider international community will be necessary to sustain the initiative. While this study has clearly found enthusiasm for aspects of the initiative, a number of concerns and reservations have also emerged. These are around country processes, impact on systems, monitoring, sustainability and governance. It is on the basis of these that the recommendations in Box 3 are made.

- Overall, countries viewed the initiative as an opportunity to mobilise additional resources, access new vaccines, fund DTP and raise the profile of EPI as a programme.
- Countries were concerned about the overall pace of the application process, whose rapidity was in direct contrast to the comparative delays experienced in receiving vaccines. Donors currently funding vaccine procurement were critical that combination vaccine presentations were supply-driven and were also critical of the impact of delays on planning for EPI procurement.
- The mechanism of the ICC provided opportunities to broaden the number of stakeholders in the GAVI initiative, and to mobilise effort for immunisation. However, perceptions about the effectiveness of ICCs varied among the different stakeholders. MoH ownership and drive was questioned in some cases and concerns were expressed

that ICCs and GAVI focused on introducing GAVI vaccines and injection equipment, without sufficiently addressing broader immunisation and systems issues.

- Long-standing structural and systemic constraints reflecting chronic underinvestment over many years were apparent in three of the countries, although to differing degrees. These include low staffing levels, insufficient transport and fuel, poorly functioning cold chains and infrequent supervision.
- The GAVI systems support funds will not be sufficient to redress current weaknesses, especially in countries with an inadequate or non-existent cold chain, for example much of rural Mozambique. Save the Children UK is also concerned that the GAVI initiative is creating additional transaction and subsequent recurrent costs. These include costs of additional training, administration, setting up of reporting systems, and staff salaries associated with these. Much greater support will need to be mobilised, from GAVI and/or from other sources, to sustain these activities and improve coverage, especially in countries with weak health systems.
- There have been discussions around the provision of incinerators to assist in the management of the extra waste generated by the use of A-D syringes. Where these are not yet in place, guidelines on waste management need to be strengthened and enforced in advance of their introduction.

- The weaknesses in country reporting and monitoring systems throw into question the reliance on quantitative assessments for rewarding improved immunisation performance, especially where current coverage estimates appear to be highly unreliable.
- MoHs were not particularly concerned about the long-term sustainability of the GAVI initiative, feeling that if support did not come from GAVI other donors could be mobilised to provide financial or vaccine assistance. Donors, however, were concerned about this, especially in Ghana where the cost of the new, combined pentavalent vaccine was so high.
- Given donor concerns, there appeared to be a disjunction between the GAVI initiative and the countries' SWAp programmes. This is surprising, in that both country priorities and health systems funding are increasingly being channelled through these mechanisms.
- From this study of the GAVI experience comes a number of implications for other global initiatives such as the Global Fund to fight AIDS, Tuberculosis and Malaria:
 - Critical path analyses will be required, which take into account both the existing pressures on country-level staff and product availability, so as to optimise the co-ordination and timing of inputs and processes.
 - The transaction costs for both countries and donors in going through the application process, should access to the GFATM be based on such a process, will be more complex and difficult. This will require a realistic level of funding as well as well-informed technical expertise, on systems as well as disease-specific issues, at an early stage.
 - There will also be opportunity costs and trade-offs. Indeed, country-level implementation of the GAVI initiative may suffer as limited national capacity and expertise is diverted into AIDS, tuberculosis and malaria.
 - Although global-level mechanisms and instruments may be put in place relatively quickly, country-level mechanisms and processes will take much longer, and will need significant strengthening of health systems. This is a critical point. For example, considerable funds need to go into improving health worker morale, service delivery and information systems, if the new Fund is to have an impact.
 - If 'reward systems' such as the GAVI country shares are introduced, reliable information systems will need to be in place. However, both the LATH study and this report throw into doubt the advisability of target-linked performance rewards.

BOX 3: RECOMMENDATIONS

- The pace of the GAVI application process should be geared to the capacity of countries to make well-informed decisions, especially when they may involve significant increases in future recurrent expenditure.
- GAVI needs to take steps to ensure that the introduction of new products does not unduly distort immunisation priorities in countries applying for support.
- Before countries are encouraged to accept expensive new vaccines, those with weaker health systems will require additional resources. Sufficient systems support is essential, for example, to effectively implement routine EPI programmes, manage information systems, and make provision for the safe disposal of clinical waste.
- Quantitative performance monitoring and reward systems need to be complemented by a range of other indicators of systems strengthening. These could include, for example, evidence of effective cold chain coverage, regular and effective supervision, safe injection practices and waste disposal, and indicators of staff motivation.
- Bilateral, including pooling, donors should be involved from the inception of the initiative at the country level, so as to ensure co-ordination with existing national processes, widen the constituency of support, ensure that ICCs continue to oversee the implementation process, and address those aspects of systems that are failing prior to the introduction of new products.
- If GAVI is to contribute to genuine, sustainable development in poor countries, all partners – countries, GAVI, bilateral and multilateral partners – should work together to produce country plans for future financing of the initiative, especially where expensive new vaccines have been adopted.

Endnotes

- 1 The Bill and Melinda Gates Foundation earmarked US\$1.44 billion for world health in 2000, 300 million more than the US government.
- 2 Heaton, A., (2001), Joint Public Private Initiatives: meeting children's right to health? Save the Children, UK.
- 3 Regina Keith, Annie Heaton, Gill Walt, Ruairi Brugha, Peter Poore and Fiona King.
- 4 As of October 2001, only data from two countries had been collected.
- 5 All information and quotations in this section are from the official GAVI website as at 12 October 2001, www.vaccinealliance.org, unless otherwise stated.
- 6 Rotating Board seat tenure is currently for one or two years only. There have been three new members since inception.
- 7 A third sub-account, not yet active, is to support research and development of new vaccines.
- 8 WHO, UNICEF, GAVI Secretariat, Vaccine Fund, USAID, Tanzania, Wyeth-Ayers Laboratories.
- 9 Members are drawn from Thailand (Chair), Ghana, Tanzania, Tunisia, The Philippines, The Bahamas, Slovenia, Mali and the US.
- 10 GAVI Update Oct 2001.
- 11 Information is partly based on Adjei and Cofie (2000).
- 12 In a SWAp, participating donors (mainly bilaterals) put a proportion of their development aid for health into a 'common pool', which the MoH draws on to fund agreed activities.
- 13 Information for this section comes from a combination of two sources: a) the Kingdom of Lesotho EPI Five-Year Plan of Action 2002-06, MoH, 2001 and b) the Common Country Assessment for Lesotho, United Nations, 2000.
- 14 Information from this section is obtained from a combination of sources: a) Republic of Mozambique Health Sector Profile, MOH, 1998; b) Republic of Mozambique MoH National Evaluation of the Expanded Vaccination Programme, UNICEF/WHO/SDC/USAID-BASICS, 1998; and c) Country Profile: Mozambique, Economist Intelligence Unit, 2001.

- 15 Information for this section is sourced from a) the United Republic of Tanzania Assessment of Immunization Services, MoH, undated; b) the United Republic of Tanzania EPI Strategic Planning 2000-2004, MoH undated; and c) Tanzania Reproductive and Child Health Survey, National Bureau of Statistics, 1999.
- 16 Survey coverage rates are from population surveys, usually national Demographic and Health Surveys (DHS). Rates, based on numbers of vaccinations reported as performed, showed some variation between reported data provided by the country MoH during the fieldwork and rates included in the applications to GAVI. Where there were differences in reported rates, those included in the GAVI application are included in brackets.
- 17 The 1997 census was widely reported by respondents as an underestimate of actual population, especially in opposition-dominated areas, such as Zambezia, where access for government officials was partially restricted.
- 18 Normally, reported estimates, based on numbers of antigens given, overestimate coverage rates as measured in population surveys.
- 19 Note: in the fieldwork for this study, we did not attempt to verify if the numbers of children immunised were being correctly reported up from facility through district and region to national level. However, such an exercise was being conducted as part of a data quality audit (DQA) in nine countries including Tanzania during 2001, commissioned by GAVI.
20. Projected budget expenditure may differ from actual expenditure in some cases, which would affect the proportion of systems support against annual budget.
- 21 This contrasts with the amount reported on the GAVI website of two instalments of US\$607,000.
- 22 In assessing views from Lesotho, respondents at the central level were occupied with the current application, and less information was available on country priorities, although district visits helped to complete the picture.
- 23 Many of the health facilities at district level in Zambezia Province had run out of record cards after only two months, with implications for record keeping.
- 24 The report was not made available for review.
- 25 Study of health services and management situation at the Provincial Health Direction, Nampula. Undated, but the fieldwork was undertaken in 1996, unofficial translation from original in Portuguese.
- 26 Deloitte Touche Tohmatsu Emerging Markets, Euro Health Group, Liverpool Associates in Tropical Health.

Appendix A: List of people interviewed

INTERNATIONAL LEVEL:

GAVI Alliance

Steven Landry

USAID Representative, Working Group

Lisa Jacobs

Communications Officer, GAVI Secretariat

Academia

William Muraskin

Professor of Urban Studies, Queens College, New York

Felicity Cutts

Professor, London School of Hygiene & Tropical Medicine

DFID UK

Catriona Waddington

Health Adviser: GAVI, until June 2001

COUNTRY LEVEL:

GHANA

National-level informants

Dr Sam Adjei

Deputy Director (MoH)

Professor Francis Nkrumah

Noguchi Medical Institute

Dr George Amofah

(Acting) Director, Public Health (MoH)

Dr Victor Ankrah

Project Officer (UNICEF)

Dr Mercy Essel Ahun

National EPI Manager (MoH)

Bob Pond

Programme Officer (USAID)

Tony Seddoh

Policy Co-ordinator (MoH)

Patsy Sterling

Programme Officer (DFID)

Dr Victor Bampoh

Programme Officer (DFID)

Regional/district-level informants, Ashanti Region

Dr Sadik Kyei Faried

Regional Senior Medical Officer, Public Health (SMO PH)

Mr Douglas Brenya

Regional Disease Control Head

Mr Yaw Fobi

Regional EPI Co-ordinator

Dr Hussein

District Director of Health Services (DDHS), BAK

Peter Solaga

Secretary to District Health Management Team (DHMT),
Mampong

TANZANIA**National-level informants**

Paul Smithson	Adviser, DFID, Tanzania
Dr Suleiman Kimatta	Project Officer, Health, UNICEF
Dr Caroline Akim	Manager, EPI, MoH
Dr David Manyanga	Medical Officer, EPI
Mr Jergen Johannsen	HSPS Adviser, DANIDA
Dr Hingora	Director, HSR project, MoH
Dr Cornelia Atsyor	EPI Epidemiologist, WHO
Mr Ben Mkasa	Director of Distribution and Sales, Medical Stores Department

Regional and District level:**Lindi Region**

Mr Fredoline Mchopa	Acting Regional Administrative Secretary
Dr Ali Mohammed	Regional Medical Officer
Mr Simon Malulu	Regional Health Officer
Mr Said Kichukwi	Assistant Regional Health Officer
Mrs Faith Nipwapwacha	Regional MCH co-ordinator

Lindi Rural

Dr Francis Anga	District Medical Officer
Mr Joseph Ndijuye	District Cold Chain Officer
Mr C. Malunde	Acting DED Director, Manpower Management Office
Mr William Kazungu	Assistant Chief Accountant, DED Office
Mrs Rahema Malenzi	MCH Aid, Mchingnga I Dispensary
Mrs Maryanne Likumbo	Nurse Assistant, Rondo I Dispensary
Mrs Alice Monjesa	Nurse Assistant, Rondo I Dispensary
Frederick Ng'ombo	Nurse Assistant, Rondo II Dispensary
Christopher Makota	Clinical Assistant, Rondo II Dispensary
Mrs Meckytildis Amlima	MCH Aid, Rondo III Dispensary
Village Chief	Mihima Village

MOZAMBIQUE**National-level informants**

Dr Alejandro Gonzalez-Richmond	Health Officer, UNICEF
Dr Martinho Dgedge	Deputy Director of Community Health, MoH

Mr Manuel Horacio	Deputy Chief of EPI, MoH
Mr Inacio Mario	Procurement Assessor, Medical Stores Department, MoH
Dr Vivian Van Steirteghem	Health & Nutrition Officer, UNICEF
Mr Manuel Mattosse	Former Chief of EPI, MoH
Mr Noel Kulemaka	Social Sector Adviser, World Bank
Dr Enrico Pavignani	Independent Consultant
Dr Theo Pas	Health Sector Specialist, Dutch Cooperation
Ms Caroline Compper-Runhaar	Health Project Manager, Dutch Cooperation
Dr Ilka Esquivel	Child Survival & Reproductive Health Results Team Leader, USAID
Dr Charles Paluka	Epidemiologist, WHO
Dr Allison Beattie	Health and Education Adviser, DFID
Ms Josiane Risacher	Health Officer, NORAD
Dr Milton Valdez	Epidemiologist, JSI
Dr Arturo Sanabira	Field Officer, JSI
Dr Jorge Barreto	Head of Immunology, National Institute of Health, MoH
Provincial level Zambezia	
Mr Alfredo Da Costa Azevedo	Preventative and Community Health Technician
Mr Anntonio Lorenzo	Head of Statistics
Dr Leonardo Chavane	Provincial Medical Officer
Mr Jose Ambrosio	Preventative Medicine Assistant, Provincial Vaccine Stores
Mopeia District	
Mr Sousa Mwamuamua	Medical Assistant Lua-Lua Health Post
Mr Luis Chipuanha	Nurse, Chimuaru Health Post
Mr Aandrs Paiva	Chief of EPI, Mopeia District
Mrs Isabella Nova	Assistant for Preventative Medicine, Mopeia District
Dr Celestine Pedro	Hospital Director, District Health Director, Mopeia
Morrumbala District	
Mr Juma Simba	Medical Assistant, Megaza Health Post
Mr Edmundo Cuprino	Hospital Director, District Director of Health
Mr Manuel Cancao	Nurse, Gurisa Health Post
Maganja Da Costa District	
Mr Eufrazio Candido	Chief of EPI, Maganja District Hospital

Mr Orlando Campel	Preventative Medicine Asst., Maganja District Hospital
Mr Ricardo Gregory	Hospital Director, District Director of Health
Mr Virgil Mwanupwana	Medical Asst, Nante Health Post
Ms Isabel Zacarius	MCH Nurse, Nante Health Post

LESOTHO

National-level respondents

Dr Kelello Lerotholi	Programme Officer, Ireland Aid
Dr M. Mapatano	Epidemiologist, WHO
Mrs Kimberley Gamble-Payne	Representative, UNICEF
Mrs Agnes Kalaka	Project Officer, Health, UNICEF
Ms Anne-Marie Fonseca	Social Policy and Planning Officer, UNICEF
Mrs Lois Fergusson	Primary Healthcare Co-ordinator, CHAL
Mrs Anne Taole-Petlane	EPI Manager, MoH

Scott Health Service Area (CHAL)

Mrs Hocane	Matron, Scott Hospital
Mrs Ella Ramatla	Health Centre Co-ordinator
Mrs Khasaake	Chief of Under-fives Clinic
Sister Maliche	Matelite Health Centre
Nurse Assistant Lemphane	Matelite Health Centre
Sister Letompa	Ribanaeng Health Centre
Nurse Assistant Lala	Ribanaeng Health Centre
Nurse Assistant Thamane	Ribanaeng Health Centre
Staff Nurse Pitikoe	Masemouse Health Centre
Nurse Assistant Masitha	Masemouse Health Centre
Nurse Clinician Manyo	Malealea Health Centre
Nurse Assistant Muloinyane	Malealea Health Centre

Leribe Health Service Area (Government)

Ms Mohakala	Assistant, Public Health Team
Sister Masiu	Matlameng Health Centre
Mrs Matsela	Ramapepe Private Clinic
Sister Nthinya	Mahobong Health Centre

Appendix B: Country-level checklist of questions

Country level: MoH, multilateral, bilateral and NGO advisers

- ◆ *To what extent is health systems planning co-ordinated within an overall sector-wide approach? How does EPI fit in terms of vertical/horizontal mix, eg, is EPI/immunisation planning a discrete programme or co-ordinated within the health sector programme and are there designated staff for EPI/polio eradication at each level?*

have been independent of ICC, or where there was no ICC involved.)

- ◆ *What, if at all, was the technical consultancy input at the country level (disciplinary background? Agency background? Agenda/accountability and perceived quality of consultancy input? How long were they in-country/familiar with context)?*
- ◆ *What was the quality of the feedback from GAVI/Independent Review Committee on the initial application? How has this altered subsequent applications?*

Application process

- ◆ *Who from the country was involved in preparing the application (MoH? Other ministries? At what levels of seniority)? How much input from senior staff was required? What kinds of opportunity costs and transaction costs were involved? Did it take senior staff from other areas of work? Were the information systems able to provide sufficiently accurate data for application? Was it necessary to collect new information/establish new systems to satisfy GAVI application rules?*
- ◆ *How, if at all, was the ICC involved (composition of the ICC? Remit and expertise of the ICC – this may be around the ICC having been constituted to support polio eradication)? Perceptions of the quality of ICC input? Were the ICC members seen as neutral players supporting the country, or were some or all seen as coming with their own agendas? What are the structural relationships with the Regional Working Groups? (Similar issues can be explored for bilateral donor and multilateral agency involvement, which might*

- ◆ *Could the application process have been improved to facilitate countries applying for GAVI funds? How? How did the country-level players perceive the ‘conduct’ of GAVI (focus on ‘code of conduct’ and ‘governance principles’ issues). What is the perceived balance of ‘ownership’ of GAVI between the country, the donors and the central GAVI structures? How has decision-making taken place?*
- ◆ *What are the GAVI priorities and objectives? Are GAVI priorities well understood? How did the country-level players perceive the objectives and priorities of GAVI, and did they experience any pressure to alter their priorities, around:*
 - ◇ *strengthening of routine services*
 - ◇ *prioritisation of different programmes*
 - ◇ *incorporation of HepB into routine immunisation programmes*

- ◇ *incorporation of Hib into routine immunisation programmes?*
- ◆ *If so, where did the pressure come from?*
- ◆ *Was the balance of proposed funding allocation to vaccines and to systems support in line with what the country applied for? If not, in what way was it different?*
- ◆ *Have other initiatives from the international level been considered? Are MoH officials currently negotiating with any other JPPIs? What has been the impact in terms of opportunity and transaction costs?*
- ◆ *How are country interests represented?*

How GAVI funds will be utilised, including capacity issues

- ◆ *What funds for system strengthening have reached the country? Have there been delays? Where have these occurred? Are the levels of funds different to what was promised?*
- ◆ *Where are the funds located? Who has control over them and who will decide how they are used? Will money be channelled down to support district service delivery? How? (EPI-specific? MoH? Local Government?) Will it be possible to track the spending of GAVI funds separately in the financial management reporting system (eg, will it be within or outside a common financing pool)? Does GAVI require an independent financial monitoring system?*
- ◆ *How is it proposed to spend the systems support money? Which districts and why?*

Have plans been developed? (Get copies and, if possible, get budget allocation to different activities.) Is there systems mapping in place to support options appraisal for capacity building?

- ◆ *Are there processes in place (eg, within the ministry and perhaps involving external experts/consultants) for advising on how to strengthen systems? What input is there from GAVI to advising on systems strengthening? Too much, too little, the wrong kind?*
- ◆ *What degree of flexibility does the country have in deciding how to spend the systems strengthening funds? Performance-related shares?*
- ◆ *What activities have been planned/are taking place to increase existing immunisation coverage? Are new fixed immunisation points planned? Are new immunisation outreach visits planned? How are these to be resourced? Are the additional resources sufficient to implement such plans?*

Vaccine support

- ◆ *Which vaccines were promised? Have these arrived? Have there been delays? What were the original time –lines? Where were the delays and what were the reasons given? Have the other necessary supplies arrived or are they easily accessed (safe syringes, cold chain integrity, etc)? Is the proportion breakdown between vaccines and systems support in line with what was agreed?*

- ◆ *What impact will new vaccines (HepB, Hib) have on the existing system? Will new training and support be needed? How long will it take to undertake these? What positive and/or negative impact will the introduction of new vaccines have on other services?*
- ◆ *What activities have been planned/are taking place to introduce new vaccines within existing programmes? Will there need to be trade-offs between using systems support money to increase current coverage and using it to introduce new vaccines? How will these trade-offs be made?*

Impact on country health sector planning and prioritisation

- ◆ *How does application for GAVI support sit within the overall reform environment and policy context of reforms? Impact on structures and policy planning process? Does it fit within the country's existing planning cycle? Has the planning for use of GAVI funds been integrated into existing planning systems? Has it involved planning in parallel, outside of existing planning processes and cycles?*
- ◆ *How has the promise/arrival of GAVI funds influenced country-level prioritisation? Has there been any distortion of country-level prioritisation? If so, in what way?*
- ◆ *Will GAVI funds have any effect on other sources and levels of funding? Will it attract additional funds? Will it substitute for existing (donor or MoH) funding?*

- ◆ *Has the timing of arrival/non-arrival of funds and vaccine had any effect on the planning and implementation processes?*

Implementation of a GAVI strategy

- ◆ *Is it proposed to introduce GAVI activities countrywide or to roll them out selectively? Mass campaigns or through existing structures? Are there likely to be inequities in service delivery (eg, will it be possible to only introduce new vaccines in certain areas of the country)?*

Systems monitoring and evaluation

- ◆ *Are there local targets? What are they and who set them? What is the likelihood of reaching the agreed targets? Are they realistic? Is the baseline accurate? What factors will determine whether the targets will be met? What positive and/or negative impact will the targets have on EPI service delivery? Will trying to achieve these targets have positive and/or negative impacts on other services – which? What are the implications of not achieving the targets? Is there any evidence to suggest concerns about possible distortion of data to achieve targets/incentives?*
- ◆ *Has the MoH been informed by GAVI on how it wants improvements in immunisation coverage monitored? Have you heard of the immunisation data quality assessment (IDQA) tool? What national input has there been to developing the IDQA instruments?*

Sustainability

- ◆ *The current GAVI commitment is for five years only, with one year already elapsed. What will happen at the end of the five-year commitment (vaccines, support and A-D syringes)? Will the country be able to continue funding the systems support? Will it be able to carry the cost of the additional vaccines? Have donors indicated a willingness to continue supporting the initiative?*

Peripheral level: regional and district managers and immunisation staff

Awareness of GAVI

- ◆ *Have you heard of the GAVI initiative? (Explore what they know.) If yes, what was the involvement of staff at the periphery in the application process, degree of input and consultation, feedback on application response? Where did the information/communication come from – MoH, NGO, other agency?*
- ◆ *(If not) have you heard of a new programme that will provide your district with additional support to improve immunisation coverage and introduce new vaccines? (Explore what they know.)*
- ◆ *Give the informant a brief summary of what is proposed under GAVI – additional resources to strengthen EPI service delivery, a new Hepatitis B vaccine and new syringes.*

Current EPI programme (district)

- ◆ *Explore current district EPI strategies and performance: overall coverage, coverage by sub-districts, areas of high and low coverage; numbers of fixed facilities (govt, mission); immunisation outreach activities (govt, mission): get current coverage data. Explore how it is measured (WHO population surveys/cluster or household/no. of vaccines given/vaccines used?) An EPI situation analysis, based on interviews and review of district EPI records, will assist in determining the feasibility of achieving GAVI objectives at the district level. NB tendency to over report.*

Current status of GAVI (district)

- ◆ *What new EPI support money has reached are you expecting to reach the district? How much? Is the money earmarked for EPI support? Is the amount of money in line with what you expected? What new vaccines have reached the district? What other supplies? What conditions have been/will be attached to new systems support and vaccines? What targets (if any) have you been set for increasing immunisation coverage and incorporation of new vaccines? (Get copies of all directives, memos, etc, received from national/regional levels.)*

How GAVI funds will be utilised, including capacity issues

- ◆ *How will/would you utilise additional EPI support funding? (Explore plans around setting up new fixed immunisation delivery sites; expansion of coverage at existing sites; new outreach visits.)*

- ◆ *What additional resources will you need to implement these plans: transport (four-wheel drives, motorbikes, bicycles); fuel; staff (redeployment of existing staff, better use of existing staff, use of dedicated polio staff)? What will it take to increase coverage by xx per cent?*
- ◆ *Explore about planned health worker training programmes.*
- ◆ *Explore about planned community mobilisation activities.*
- ◆ *Where are the funds located? Who has control over them and who will decide how they are used? Will it be possible to track the spending of GAVI funds separately in the financial management reporting system (eg, will it be within or outside a common financing pool)? Will GAVI require an independent financial monitoring system?*
- ◆ *Are there processes in place (eg, within the ministry and perhaps involving external experts/consultants) for advising on how to strengthen systems? What input is there from GAVI at district level to advising on systems strengthening? Too much, too little, the wrong kind?*
- ◆ *What degree of flexibility does the district have in deciding how to spend the systems strengthening funds?*

Vaccine support

- ◆ *Which vaccines were promised? Have these arrived? Have there been delays? What were*

the original time lines? Where were the delays and what were the reasons given? Have the other necessary supplies arrived or are they easily accessed (safe syringes, disposal methods, cold chain, etc)? Is the proportion breakdown between vaccines and systems support in line with what was agreed?

- ◆ *What impact will new vaccines (HepB, Hib) have on the existing system? Will new training and support be needed? How long will it take to undertake these? What positive and/or negative impact will the introduction of new vaccines have on other services?*

Impact on district health sector planning and prioritisation

- ◆ *How would/will additional GAVI funds affect current district planning? Has the planning for use of GAVI funds been integrated into existing planning systems? Has it involved planning in parallel, outside of existing planning processes and cycles?*
- ◆ *How has the promise/arrival of GAVI funds influenced district-level prioritisation? Has there been any distortion of district-level prioritisation? If so, in what way?*
- ◆ *Will GAVI funds have any effect on other sources and levels of funding at local level? Will it attract additional funds? Will it substitute for existing (donor or MoH) funding?*
- ◆ *Has the timing of arrival/non-arrival of funds and vaccine had any effect on the planning and implementation processes?*

- ◆ *Is it proposed to introduce GAVI activities district-wide or to roll them out selectively? Mass campaigns or through existing structures? Are there likely to be inequities in service delivery (eg, will it be possible to only introduce new vaccines in certain areas)?*

Systems monitoring and evaluation

- ◆ *What is the likelihood of reaching the agreed targets? Are they realistic? What factors will determine whether the targets will be met? What positive and/or negative impact will the targets have on EPI service delivery? Will trying to achieve these targets have positive and/or negative impacts on other services – which? What are the implications of not achieving the targets? Is there any evidence to suggest concerns about possible distortion of data to achieve targets/incentives?*
- ◆ *How will the MoH assess that it is meeting performance-related targets? What monitoring systems will it use at local level? Will these be part of the routine monitoring, or will it require setting up new monitoring systems? Have you heard of the immunisation data quality assessment (IDQA) tool? – explore.*

Sustainability

- ◆ *The current GAVI commitment is for five years only, with one year already elapsed. What will happen at the end of the five-year commitment (vaccines, support and A-D syringes)?*

- ◆ *Will your district be able to sustain additional EPI activities if the support to districts ends in three to four years?*

Resource check

- ◆ *At selected centres check fridges, sterilizers, fuel/solar supply, thermostats, outreach vaccine carriers and ice supply and disposal of sharp items, etc.*

Documentation check

- ◆ *EPI records from district HQ/hospital. Map of outreach/fixd sites. Local constraints on coverage. Evidence of local evaluation and points forward, monitoring of cold chain integrity: thermostats/ defrosting/ maintenance/fuel supply.*

Appendix C: References

- GAVI Update on country-level GAVI and Vaccine Fund-related activities; complete set to October 2001
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Navarro, V., "Assessment of the World Health Report 2000", *Lancet* 2000; 356: 1598-601
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Ghana

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Hib Disease Burden Rapid Assessment, Ghana trip report (27.07.01)
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Inception Report to GAVI (draft September 2001) for countries receiving support in 2001: Ghana
Levin, A. et al., (2001) Ghana Immunization Financing Study

Tanzania

- Annual reported EPI coverage rates for central OK, Lindi Region and Lindi Rural District, 1998, 1999 and 2000, Ministry of Health
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Tanzania Reproductive and Child Health Survey Summary Findings (1999), National Bureau of Statistics

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Republic of Mozambique Health Sector Profile, MoH, 1998

Republic of Mozambique Expanded Vaccination Programme, Five-Year Plan 2000-2004 (undated) MoH

Republic of Mozambique National Evaluation of the Expanded Vaccination Programme, UNICEF/WHO/SDC/USAID-BASICS, 1998

Lesotho

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Common Country Assessment for Lesotho, United Nations, 2000

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Kingdom of Lesotho Report of a Review of the Expanded Programme on Immunization, Draft July 2001, MoH/WHO/UNICEF/DoH South Africa

Response from GAVI to Lesotho MoH following initial application, November 2000

