

Evaluation of GAVI's Injection Safety Support

TECHNICAL REPORT

Prepared for the GAVI Alliance

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JSI Research & Training Institute, Inc.



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ACRONYMS

AD (syringes)	Auto-disable (syringes)
AFR	African Region
AFRO	WHO Regional Office for Africa
AMR	Americas Region
AMRO	WHO Regional Office for the Americas
APR	Annual Performance Report
BCG	Bacillus Calmette-Guérin (vaccine against tuberculosis)
CADE	Computer Assisted Data Entry
CIDA	Canadian International Development Agency
DFID	United Kingdom Department for International Development
cMYP	country Multi-Year Plan
DTP	Diphtheria Tetanus Pertussis vaccine
EPI	Expanded Program on Immunization
EMR	Eastern Mediterranean Region
EMRO	WHO Regional Office for Eastern Mediterranean
EU	European Union
EUR	European Region
EURO	WHO Regional Office for Europe
FSP	Financial Sustainability Plan
GAVI	GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization)
GDP	Gross Domestic Product
GNI	Gross National Income
HCW	Healthcare Waste
HCWM	Healthcare Waste Management
HIPC	Highly Indebted Poor Countries
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HSS	Health Systems Strengthening
ICC	Inter-agency Coordinating Committee
INS	Injection Safety (in GAVI context)
IRC	International Rescue Committee
IS	Injection Safety
ISPP	Immunization Safety Priority Project
ISS	Immunization Services Support
JICA	Japan International Cooperation Agency
JRF	Joint Reporting Form
JSI R&T	JSI Research & Training Institute, Inc.
MDGs	Millennium Development Goals
MMIS	Making Medical Injections Safer (project)
MoF	Ministry of Finance
MOH	Ministry of Health
NIP	National Immunization Program
NIS	Newly Independent States
NVS	New and underused vaccine support
OLS	Ordinary Least Squares
PAHO	Pan American Health Organization

PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
RFP	Request for Proposal
SB	Safety Box
SC	Steering Committee
SD	Standard Disposable
SD	Supply Division (UNICEF)
SEAR	Southeast Asia Region
SEARO	WHO Regional Office for South East Asia
SIGN	Safe Injection Global Network
TB	Tuberculosis
UNFPA	United Nations Population Fund
TFI	Task Force on Immunization
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund
USAID	U.S. Agency for International Development
VII	Vaccine Independence Initiative
WHO	World Health Organization
WPR	Western Pacific Region
WPRO	WHO Regional Office for Western Pacific

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EXECUTIVE SUMMARY

This report presents the findings of an evaluation commissioned by the GAVI Alliance to analyze the sustainability of its Injection Safety (INS) support. GAVI is an alliance of public and private sector partners dedicated to improving health and saving the lives of children through widespread vaccine use. In 2002, GAVI started providing INS support to national immunization programs to introduce or increase the use of Auto-Disable (AD) syringes. The support came in two forms: 1) in-kind, in the form of AD syringes and safety boxes, and 2) in cash, for those countries that already had a secure, multi-year source of AD syringes and safety boxes, but proposed to use INS support for other injection safety activities.

GAVI contracted JSI Research & Training Institute, Inc. (JSI) in March 2008 to evaluate the INS support window. The evaluation focused on the experience of 58 countries that were awarded INS support during the program's first three years—15 countries in 2002, 22 countries in 2003, and 21 countries in 2004. INS support was time-limited for three years in all cases.¹ Forty-six of the recipient countries received commodities, while the remaining 12 were provided cash to strengthen their injection safety activities. By the end of 2006, GAVI had provided over \$110 million in INS support to the 58 countries that are the focus of this evaluation.

Objectives

The objectives of this evaluation, as stated in the Request for Proposal (RFP), are to:

1. describe the decision-making process regarding the replacement of GAVI INS support;
2. assess how and to what extent countries have replaced GAVI support during the first year (or more) after GAVI INS support ended;
3. determine how countries have replaced GAVI INS support in a sustainable manner;
4. assess the effect of the GAVI INS support on the broader health sector at the country level; and
5. determine how cash funds have supported the implementation of country INS plans of action.

A Steering Committee (SC) established by GAVI and representing several partners and other independent organizations provided guidance to the evaluation team. The SC reviewed and gave feedback on a number of important aspects of the exercise, including the design of the evaluation, content of the interview questionnaires, outline for the final report and earlier drafts of this report.

Approach and methods

The evaluation utilized both quantitative and qualitative methods to determine whether and how participating countries sustained the supply and use of AD syringes after the end of INS support. The quantitative analysis relied on publicly available data, as well

¹ Another 13 countries were provided INS support in 2005 (six), 2006 (five) and 2007 (two). See Annex 3.

as data provided by the GAVI Secretariat, to ascertain program performance before, during and after GAVI support. The qualitative analysis relied on information collected during telephone interviews with National Immunization Program (NIP) managers in the subject countries and WHO/UNICEF immunization focal points.

The evaluation started with a **desk review** of available documentation relating to injection safety and waste management in the 58 INS countries. The documents reviewed for all 58 countries included: GAVI INS applications, Annual Progress Reports (APRs) to GAVI, Interagency Coordinating Committee (ICC) meeting notes, GAVI Independent Review Committee (IRC) Monitoring Reports, WHO/UNICEF Joint Reporting Forms (JRFs), comprehensive Multi-Year Plans (cMYPs) for immunization and Financial Sustainability Plans (FSPs). Additionally, the evaluation reviewed data from the World Bank statistical database, WHO's Vaccine Preventable Diseases Monitoring System, GAVI records showing the annual disbursement of funds by country, and project reports from the Making Medical Injections Safer (MMIS) countries that received INS support. All relevant data were entered into a desk review database. Country data on over 75 variables were collected and included in the analysis.

Once the desk review was completed, **telephone interviews** were conducted with most of the **NIP managers** in the recipient countries; those unable to participate in a personal interview submitted written responses to the questionnaire. The interviews included qualitative and semi-structured questions about the decision-making process leading to a country's replacement or failure to replace INS support; the extent to which GAVI INS support was replaced with government and/or donor funding in each year after a country's INS support ended; and, how INS may have impacted the broader health sector. For the 12 countries receiving cash in lieu of INS commodities, country officials were asked how their cash awards were utilized and about their INS implementation experience.

The GAVI Regional Working Groups, including **regional and sub-regional WHO and UNICEF offices**, were also contacted to solicit their assessments and perspectives on INS performance in the recipient countries. They reviewed, elaborated on or, if necessary, clarified the data received from the country immunization officers in their regions. In addition, the evaluation requested data from the **UNICEF Supply Division** in Copenhagen on syringe and safety box procurement by or on behalf of the 58 countries. By triangulating responses from these different sources, the evaluation team was able to **verify data** collected in desk reviews and interviews and thereby increase confidence in the evaluation's overall findings.

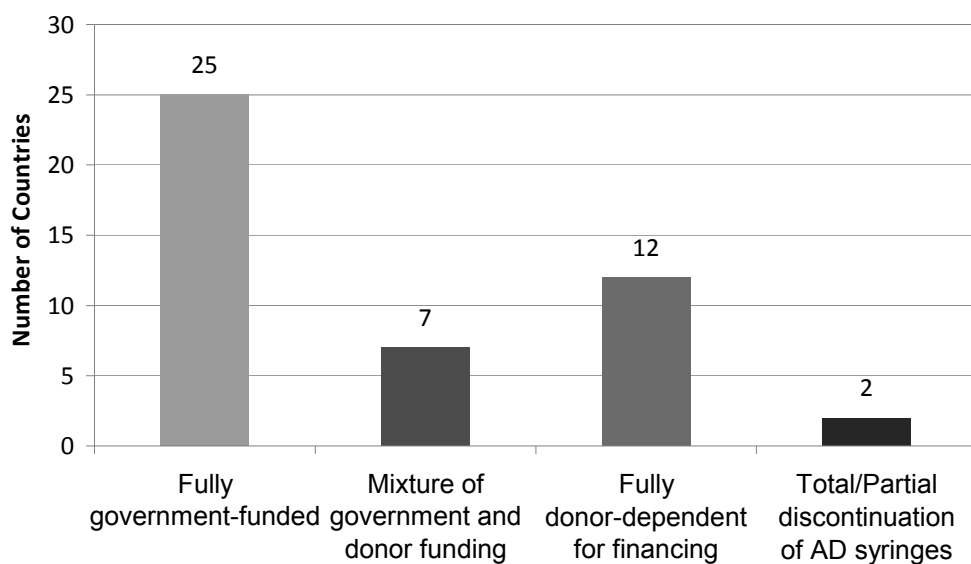
Data **analysis** was structured to answer important questions about country decision making, financial sustainability and changes in NIP and broader health sector injection safety and waste management policies and practices. Factors affecting the replacement and sustainability of injection safety funding in the years after INS support ended, such as injection safety policies and NIP characteristics, were evaluated. Quantitative methods used in the analysis included frequencies, cross-tabulations and a multivariate analysis using the ordinary least squares (OLS) method. Quantitative analyses were supplemented with qualitative information from interviews with NIP managers and WHO and UNICEF regional focal points. Finally, UNICEF procurement data were analyzed to document changes in the pricing, procurement and other aspects of injection safety commodities at the global and regional levels that may be associated with the introduction by the GAVI Alliance of its INS support.

Findings

Analyses were run separately for countries receiving INS commodities (N=46) and those receiving cash grants (N=12). The evaluation also assessed the impact of GAVI INS support on the broader level (i.e., medical sector and global injection safety).

a) Countries receiving commodities: The most important finding of the evaluation is that all but two of the 46 commodity-recipient countries were **able to replace and sustain** the use of AD syringes and safety boxes after the end of their GAVI INS support. By mid 2008, 54 percent of the countries were fully financing their commodities with government support, 15 percent were using a combination of government and donor funding and the remaining 26 percent were donor dependent. Of the two countries that did not continue using AD syringes, Ukraine used locally produced, standard disposable syringes and Uzbekistan used AD syringes in some oblasts and standard disposables in others.

Financial sustainability of AD syringes and safety boxes among 46 commodity-recipient countries (2008)



Countries achieved different levels of financial sustainability that did not change dramatically from year to year. Of thirteen (28%) countries that started procuring commodities with donor support, only one improved its level of financial sustainability over time. Countries in the medium sustainability category were somewhat more likely to improve, but still only two of nine moved into the full government funding category. This finding highlights the importance of working with countries to mobilize government and other resources long before time-limited funding, such as GAVI INS support, is due to end.

In terms of **programmatic problems** faced after INS support ended, 13 countries (28 percent) reported short-term stock-outs of AD syringes or safety boxes, particularly immediately after the transition.

The evaluation found that 78 percent of the **decisions** regarding the replacement of INS support took place in ICCs or similar coordination venues. In 95 percent of the countries, the decision to continue procuring/funding injection safety commodities was made prior to the end of GAVI's INS support. Most countries identified a source of both financing and supply during the decision-making process. Respondents in eight countries emphasized that the three years of INS funding was too short in that they had to hurriedly search for replacement funding when support ended.

West African countries performed better on the financial sustainability indicator than countries in other regions/subregions, possibly because of advocacy by WHO and UNICEF focal points and significant budget support from the European Union for vaccines and essential supplies.

The evaluation found that neither a national immunization **program's strength**, nor the existence of an **injection safety (IS) policy** significantly affected the level of financial sustainability achieved once GAVI INS support ended.

Seventy-four percent of the countries receiving commodities and almost all (34 out of the 35) of the government- and/or partially donor-funded countries had a **budget line item** for the procurement of AD syringes and safety boxes at the time of the evaluation. Ninety-one percent of these budget line items were introduced before the end of the GAVI INS support.

Governments in wealthier countries, countries with pooled funding mechanisms, countries with decentralized health systems, and countries with Vaccine Independence Initiative (VII) and/or the Highly Indebted Poor Countries (HIPC) funding were more likely to be fully funding the procurement of their NIP injection safety supplies after the end of GAVI support.

A **multivariate analysis** was conducted to assess the relative importance of the factors above associated with **financial sustainability**. Despite the small sample size, three factors were found to be statistically significant: 1) an adequate decision-making process, 2) geographic region (West Africa) and 3) GNI per capita.

b) Countries receiving cash: The 12 countries that received cash support used that support in a variety of ways. The evaluation found that nine of the 12 countries invested in injection safety activities, including training, monitoring and waste management (i.e., construction and maintenance of incinerators). Five countries used their INS funding to purchase AD syringes from the local or international markets per agreement with the GAVI Alliance. Although this was not the original intent for cash support, GAVI approved for reasons specific to country circumstance.

All 12 cash-recipient countries **continued to use** AD syringes and safety boxes in their immunization programs in the years following GAVI INS assistance. In 2008, five countries were using only government funds, four were using a combination of government and donor support, and three were fully dependent on donors for their commodities.

c) Broader health sector: The evaluation found that GAVI INS support had a **positive impact** on injection safety practices in the broader health services.

Thirty of the 57 countries (53 percent) that responded to this set of questions fully or partially introduced AD syringes and safety boxes to medical services and programs beyond immunization, e.g., curative care, HIV/AIDS programs, family planning. Of these 30 countries, 20 (67 percent) introduced AD syringes and 5 (17 percent) introduced safety boxes. Two countries also reported using their INS support to improve healthcare waste management. Nine countries (30 percent) introduced AD syringes into other health services before the start of GAVI INS support; 12 countries (40 percent) introduced them during GAVI INS support; and, in the remaining 9 countries (30 percent), introduction took place after INS support ended.

Overall, 90 percent of those responding said that GAVI INS was somewhat influential to very influential in the decision to introduce safe injection policies/practices to the broader health sector. In addition, 85 percent of the NIP managers stated that GAVI INS influenced the development of an **injection safety policy** for their health sectors.

Introduction of AD syringes and safety boxes increased the **health care waste management (HCWM)** burden on countries. The lack of incinerators, their poor maintenance and unsafe disposal of wastes were mentioned as serious concerns by over one third of respondents who stated that GAVI should have done more to prepare them for disposing of the wastes generated by AD syringes. The lack of **storage space** for AD syringes was also mentioned as a problem.

d) Global level: Since the late 1990s, the demand for AD syringes has increased dramatically. As a result, the **price** of AD syringes was reduced by half even before the GAVI INS support project was launched. Increases in demand and the number of manufacturers continued to keep the price reasonable although it did not drop significantly after GAVI INS support began. In recent years, the cost of AD syringes and standard disposable (SD) syringes has narrowed (10-15 percent differential) and there is less to be saved by procuring the latter.

The INS evaluation team found that AD syringe use is considerably **higher in GAVI countries** than in non-GAVI, lower-middle-income countries. Of the 27 non-GAVI countries that were the subject of this study, only 41 percent were using only AD syringes for injectable vaccines. Among the others, 37 percent used a mix of AD and non-AD syringes and 22 percent used only non-AD syringes, e.g. plastic single-use syringes such as a standard disposable. Additionally, several countries in the WHO European Region (EUR) and Americas Region (AMR) maintain that syringe re-use is not a problem in their settings and therefore they do not perceive the use of AD syringes as essential to injection safety.

An analysis of UNICEF Supply Division data supported the finding that non-GAVI-funded procurement of AD syringes and safety boxes (i.e., procurement by countries and others through UNICEF) increased after 2004. The fact that UNICEF data were not disaggregated by GAVI funding window (i.e., no distinction is made between commodities purchased for INS and NVS, or for routine services versus campaigns) precludes a complete analysis. However, the trend in supply of AD syringes for BCG vaccines, which are unique to GAVI INS, provided evidence that INS support was not

only fully replaced, but that the volumes supplied through UNICEF actually increased after INS support ended. Similarly, the evaluation showed that the decrease in volume of GAVI-funded safety boxes was fully compensated by governments and other partners in the years following GAVI support.

Recommendations

GAVI's INS support has improved injection safety practices and almost all recipient countries have found ways to replace and sustain the use of AD syringes and safety boxes. In the course of this evaluation, recommendations for improving GAVI INS support and other similar time-limited interventions came from country and regional respondents and from the evaluation team itself. The evaluation's primary recommendations are:

- 1) GAVI should continue to encourage country-level program managers and external **partners** to be part of the decision-making for introduction and timely replacement of new technologies as they were in West Africa.
- 2) GAVI should promote a close partnership between ministries of health and syringe and safety box manufacturers. Where economically feasible, GAVI should advocate for and facilitate **local production** of new technologies.
- 3) GAVI should advocate and support capacity building for the local authorities who are responsible for procuring syringes and safety boxes in countries with **decentralized procurement**.
- 4) When introducing a new technology, it is suggested that GAVI support a **comprehensive approach**, one that includes the training of health workers and other inputs to ensure that countries are fully prepared.
- 5) GAVI should support assessment, planning and implementation of **healthcare waste management** efforts as a new investment and/or in conjunction with other funding windows, i.e., NVS, Health System Strengthening (HSS), Immunization Services support (ISS), and others.
- 6) GAVI should develop mechanisms to **monitor more closely** the progress of its interventions both during implementation and soon after funding has ended and work through WHO and UNICEF regional offices to obtain regular feedback on program operations and progress towards financial sustainability.
- 7) GAVI should commission the **preparation of a monograph** documenting its experience with the design and implementation of INS support to inform other partners about this successful, time-limited and sustainable approach to the introduction of a new health technology.
- 8) GAVI should consider disaggregating and analyzing the **UNICEF supply data** on procurement of AD syringes and safety boxes by country, source and purpose to determine trends after INS support ends.

1. INTRODUCTION

1.1 GAVI Injection Safety Support

In 2002, the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization) began offering Injection Safety (INS) support to countries that were eligible for this funding window.² Countries that wanted to introduce or increase the use of auto-disable (AD) syringes and safety boxes into their national immunization programs (NIP) were eligible to apply for this assistance. The AD syringe is designed to minimize the inadvertent transmission of a blood-borne disease by a needle and syringe that has been used on more than one person, through a plunger-locking mechanism that disables it after a single use. Once approved, GAVI provided participating countries with sufficient AD syringes and safety boxes (SB) to immunize children and women for a period of three years. Initially, INS support was offered only to countries receiving GAVI Immunization Service Support (ISS), but eligibility was soon broadened to include all GAVI-eligible countries.

In addition to INS support in the form of commodities, GAVI offered cash as an alternative form of support to countries where AD syringes and safety boxes were already being procured. These countries are referred to as *cash-recipients*. Instead of commodities, their national immunization program received funding equivalent to the cost (at prices obtained by UNICEF) of AD syringes and safety boxes for three years. This support was intended for program-strengthening activities related to injection safety in areas such as training, supervision, monitoring, surveillance and healthcare waste disposal.

The injection safety support is one of five windows of funding offered by the GAVI Alliance. By evaluating this mechanism, the GAVI Alliance intends to determine to what extent the INS support objectives have been achieved. Questions which characterize the scope and nature of this evaluation are:

- How did countries that received GAVI INS support, replace it during the first year after support ended? To what extent was the support replaced?
- What were the positive and negative effects of INS support on the broader health sector at the country level?
- For countries that received cash, how did they use the funds to improve injection safety in their immunization programs? Were these improvements sustained?

The evaluation also explored global and country-level policy implications of GAVI INS support particularly as they related to organizational partnerships, decision-making and other factors that affect financial sustainability.

1.2 Objectives of the evaluation

The GAVI Alliance commissioned JSI Research & Training Institute, Inc. (JSI) in March 2008 to carry out an evaluation of its INS support during GAVI phase 1. The purpose, goal and objectives of the evaluation are based on those which were provided in the

² Countries were eligible for GAVI funding if their per capita Gross National Income (GNI) was less than \$1,000 (www.gavialliance.org).

Request for Proposal (RFP). GAVI's goal is "to evaluate how countries have been able to replace, in a sustainable way, GAVI INS support when it ends". INS support introduces a catalytic, one-time type of funding, rather than the more traditional donor funding that is renewed over time. This form of support is based on the premise that the benefits of the technology will be perceived to be worth the transition, and a country will sustain its use after the initial INS support ends. GAVI also assumes that, as necessary, countries will find other sources of financing to ensure that they can continue with the improved technology, i.e., AD syringes and safety boxes.

The stated objectives of the GAVI INS evaluation are to

- describe the decision-making process for replacing GAVI support;
- assess how and to what extent countries have replaced GAVI support during the first year post-GAVI INS;
- assess how countries have sustainably replaced GAVI support;
- assess the effect on the health system (expected and unexpected positive/negative effects) of INS support at the country level;
- assess how cash funds supported the implementation of the country INS plan of action (for countries that received cash instead of supplies).

2. BACKGROUND TO THE INTERVENTION

Concerns about unsafe immunizations and injections pre-date the introduction of GAVI's INS support. Historically, immunization programs have been concerned with safety issues under the universal global health principle of *do no harm*.

At the start of the Expanded Programme on Immunization (EPI) in the late 1970s, a variety of injection technologies were in use in developing countries, including reusable glass syringes that required autoclaving, BCG syringes that required the needle to be passed through a flame, and standard single-use disposable syringes. For the majority of countries that could not afford standard single-use disposable syringes, WHO and UNICEF worked with manufacturers in the early 1980s to develop and introduce portable pressure cookers that could operate on a stove top or a fireplace. These pressure cookers were fitted with internal racks on which used syringes, specially made of high-grade plastic resistant to heat, were hung along with the used needles. After flushing water through them, the syringes and needles were then sterilized under pressurized steam and could be re-used over 100 times.

A combination of technical, logistical, behavioral and financial challenges need to be addressed and overcome for the safe use of any injection technology. Use of steam sterilizers and reusable syringes and needles posed significant challenges to the safety of both health workers and patients. In 1986, in response to growing concerns about the risk of disease transmission through unsafe injections, the World Health Organization (WHO) developed specifications for a disposable vaccination syringe that could be used for only one injection. That device, an auto-disable (AD) syringe, has a mechanism that automatically disables the plunger after the initial activation.

A field evaluation in Pakistan concluded that Soloshot (one of the first AD syringes) could "be introduced into the EPI as a direct replacement for disposable injection devices for intramuscular and subcutaneous injections in countries where reuse of disposables commonly occurs or where sterilization is not practical."³ As a result of this field trial, WHO recommended the supply of Soloshot to immunization programs in developing countries and UNICEF entered into a procurement agreement with the manufacturer. Delivery began in 1992.

Until the mid-1990's, when it was heavily subsidizing the price, UNICEF was supplying only 25 million AD syringes every year to national immunization programs throughout the developing world. By 1997, UNICEF, recognizing that AD syringes were the optimal injection technology available, advocated for procuring ADs over other injectables. That year, although many countries could not afford them, UNICEF supplied 50 million AD syringes to a number of developing countries.

Momentum for the support of AD syringes increased during the second half of the 1990's. Measles and tetanus toxoid campaigns were launched, which were a catalyst for UNICEF, WHO and other members of the donor community to advocate for increased use of AD syringes. The goal of the organizations was to prevent disease

³ Steinglass, R., D. Boyd, M. Grabowsky, AG Laghari, MA Khan, A. Qavi and P. Evans. (1995). "Safety, Effectiveness and Ease of Use of a Non-Reusable Syringe in a Developing Country Immunization Program." Bulletin of the World Health Organization. 73 (1) 57-63

transmission and lower the incidence of unintended effects, such as local skin abscesses. Market forces gained influence as the growing demand for AD syringes increased the number of manufacturers, eventually broadening the selection and making the unit price more competitive.

While more and more countries began using AD syringes in their national immunization programs, universal acceptance remained elusive. Many immunization program managers believed that re-use of single-use injection equipment was not a problem in their countries and there was therefore no incentive to transition to a more expensive device. There was also fear in some circles that single-use injection devices would be re-used inappropriately (i.e., scavenged after being discarded) and that most donor-assisted countries lacked safe disposal practices and technology, and therefore the wide-scale use of AD syringes could result in infectious waste that would soon become an unmanageable problem.⁴

By 1999, AD syringes emerged as the primary device for NIP injection services. Several important events took place that year, including the establishment of the Immunization Safety Priority Project (ISPP), by WHO's Department of Immunizations, Vaccines and Biologicals.⁵ The ISPP was established to ensure that all immunization services given by NIPs were safe, and to prevent, or detect and as quickly as possible respond to, adverse events following immunization. The project was designed to have a life span of four to five years by which time it was anticipated that immunization safety would be a core component of all WHO's immunization activities. The ISPP was informed by a steering committee which provided strategic advice and concluded in 2005.

Three other significant developments occurred in 1999:

1. Citing the risks associated with reuse of disposable syringes, WHO, UNICEF and UNFPA issued a *Joint Statement* in 1999 on the use of AD syringes in immunization services (see Annex 1). The statement noted that AD syringes were widely available and affordable and declared that they should be the device of choice for administering vaccines in both routine services and during campaigns. It also recommended that safety boxes be sent or *bundled* with syringes, that all countries use only AD syringes for immunization by the end of 2003, and that partners assist in supplying bundled AD syringes and safety boxes with vaccines.
2. The second development in 1999 was the formation of the Safe Injection Global Network (SIGN). Dealing with various technical aspects related to immunization, SIGN supported a broader adoption of AD syringe technology by national immunization programs and became an influential advocacy body. SIGN also documented and disseminated information about dangerous injection practices around the world, including one account of a nurse in India giving 150–200 injections in four hours with only ten syringes and 25 needles.⁶
3. The third important event of 1999 was the creation of the Global Alliance for Vaccines and Immunization (now called the GAVI Alliance). Through its Injection

⁴ Ibid.

⁵ World Health Organization website for the Immunization Safety Priority Project

⁶ Reeler, Anne and Lone Simonsen. May 2000. Children's Vaccine Program. *Occasional Paper #2*. Washington, DC: PATH.

Safety Support (INS), GAVI offered eligible countries three years of financing for the procurement of the AD syringes and safety boxes recommended by UNICEF, WHO and UNFPA in the *Joint Statement*. GAVI's INS support, which started flowing to countries in 2002, is the subject of this evaluation.

3. EVALUATION FRAMEWORK

The framework and figures depicted in this section are based upon the evaluation objectives and pertain to GAVI INS support sustainability, decision making, the effects on the health system and how countries used cash in lieu of commodities to improve injection safety in their immunization programs. A map of the countries receiving GAVI INS support and a list of GAVI INS eligible countries appear in Annex 2 and Annex 3 respectively.

3.1 Sustainability of GAVI INS support

The GAVI Alliance defines sustainability as follows:

“Although self-sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity.”⁷

A framework was developed to examine a country's ability to sustain an element of support initially provided by a donor, such as GAVI INS. The framework helps to consider the factors present at the country level that have the potential to affect the viability of donor-driven improvements to a national immunization program. In constructing this framework, the evaluation uses a different definition of sustainability than that above, so that separate levels of government and donor involvement can be distinguished.

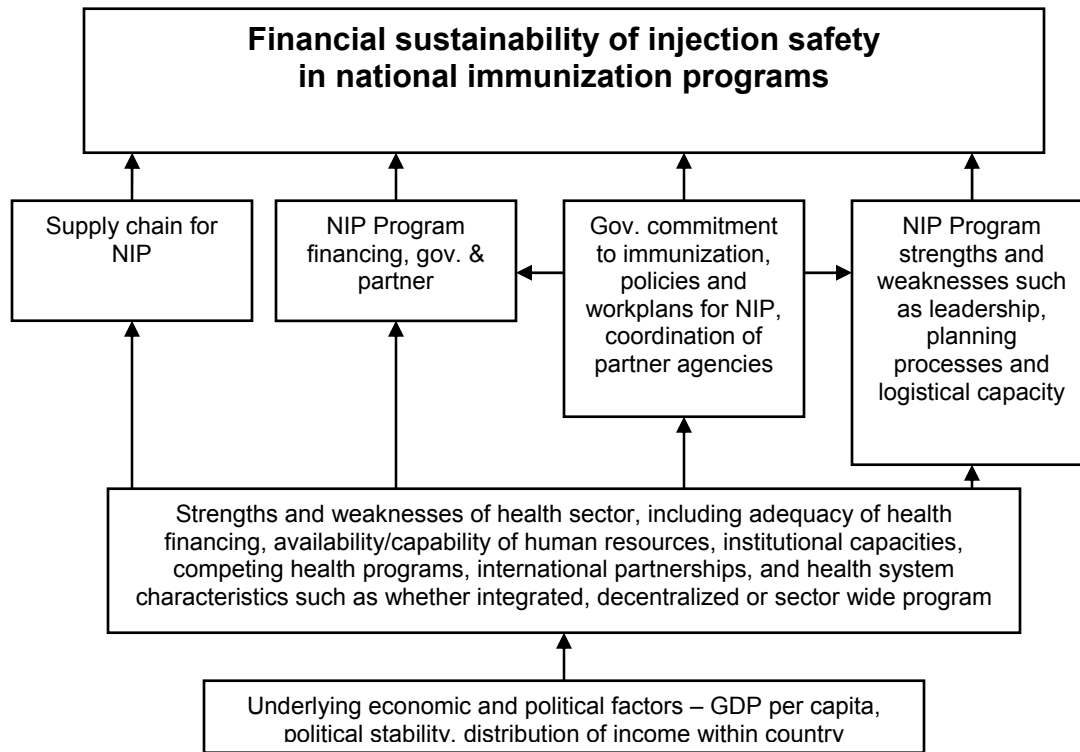
The evaluation examines two aspects of sustainability: *replacement* and *financial sustainability*. *Replacement* is considered to have occurred when a country continues the use of AD syringes and safety boxes after GAVI INS support has ended, irrespective of the source(s) of financing. *Financial sustainability* takes into account the concept of self-sufficiency and is defined as the extent to which GAVI INS support is sustained through the resources of the country itself rather than external partners. Sustainability is further broken out into four levels, which are described in greater detail in the Methodology section (section 4). This categorization incorporates the concept of self-sufficiency and differentiates between levels of government and donor support.

As shown in Figure 1, the financial sustainability of a country's injection safety program is affected by many inter-related factors. At its most fundamental are the underlying macro-economic and political aspects that influence funding for the overall health sector. The GNI per capita, for example, is a leading factor in determining the size of a country's national budget, but a government's support for the health sector may be affected by many other factors including political stability. Similarly underlying economic and political factors affect the health sector's ability to deliver health care. Funding levels, physical infrastructure, institutional capacity, structural reforms and other aspects of a health system are all influenced by a country's economic and political situation, as well as its donors. Is a country integrated or decentralized? Does it have a sector-wide

⁷ http://www.gavialliance.org/about/governance/reports/5th_Board_FTF_update.php

approach or other coordination mechanisms? Is it undergoing health sector reform? These characteristics affect the financial sustainability of a country's immunization program by influencing available program funding, government commitment to immunization, as well as NIP strengths, such as program leadership, logistical capacity and reliability of planning processes. The characteristics of the NIP also affect the level of investment and commitment to injection safety in the program.

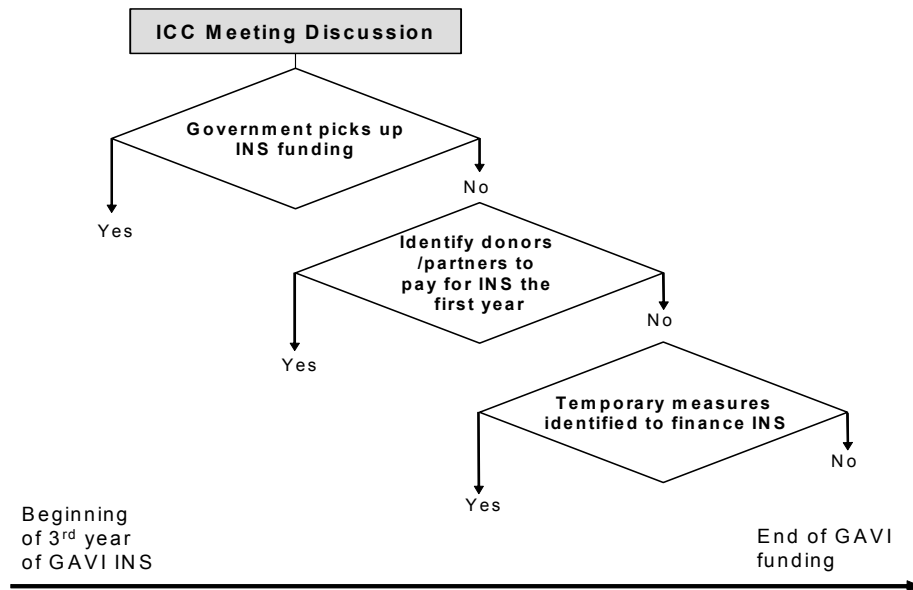
Figure 1. Financial sustainability framework



3.2 Decision-making process for replacing GAVI INS support

The evaluation assessed the extent to which countries replaced GAVI INS support after it ended and examined the decision-making process that was undertaken in recipient countries to replace the support. The common decision-making process is illustrated in Figure 2.

As shown, to ensure an uninterrupted supply of commodities, the identification of replacement funding must occur before GAVI INS support ends. In most countries, the government first determines if it will use its own funds to procure AD syringes and safety boxes. If it cannot fully replace the INS funding, the Interagency Coordinating Committee (ICC) or equivalent body identifies an alternate source or sources of funding for the first year after the GAVI INS support ends. If funding still cannot be identified, the government must find temporary measures to finance the AD syringes and safety boxes or forgo the supply of these commodities. The government and donors must also identify the sources of supply for the AD syringes and safety boxes.

Figure 2. Decision-making process to replace INS support

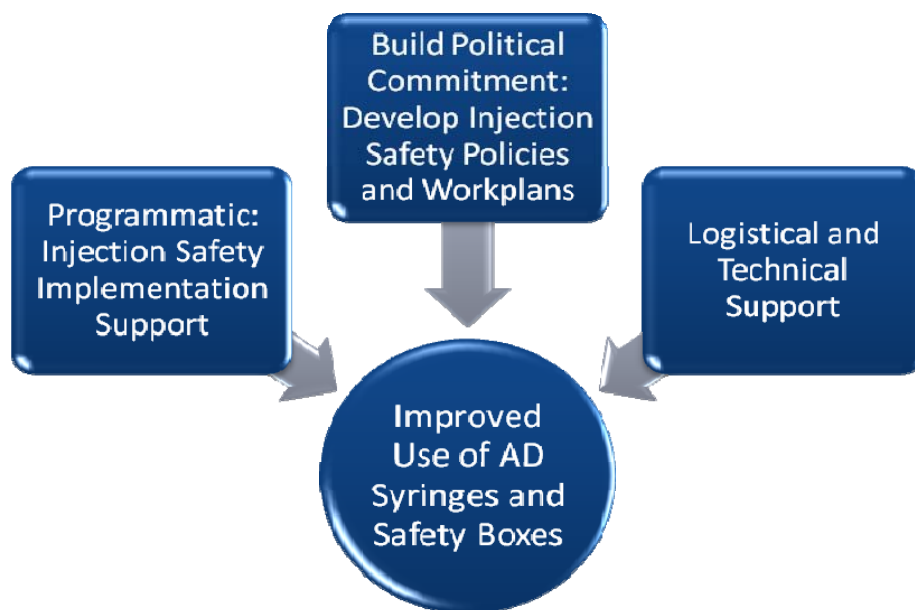
3.3 Effects of GAVI INS on the health system at country level

The evaluation explored the intended and unintended effects of GAVI INS support on country health systems. This included documenting the positive implications and challenges involved in introducing or broadening the use of AD syringes beyond immunization. The evaluation's assumption was that the positive effects might include the wider use of AD syringes and safety boxes in curative and preventive services beyond immunization, policy changes that encourage or facilitate improved injection safety practices, increased attention to waste management, etc. Likewise, the evaluation assumed that the potential negative effects might include the logistical and environmental burden created by increased volumes of single-use devices without a plan for their storage, transport and safe disposal.

3.4 Use of GAVI INS support by cash-recipient countries

For country NIPs that were already using AD syringes and safety boxes funded by the government or partners, GAVI INS support was provided in the form of a cash equivalent of a three-year supply of safe injection commodities. The cash support was intended to improve the use versus the supply of AD syringes and safety boxes (Figure 3). The evaluation considered the various ways in which cash recipients could use this form of support. For example, cash recipients could strengthen programs by improving planning, training and supervising health providers, advocating for political support, improving logistics and technical capacity and/or reinforcing other program components. The evaluation assesses whether the use of INS support by cash-recipient countries fell within these categories.

Figure 3. Use of funding by countries receiving cash support



Section Summary

- ◆ GAVI definition of sustainability is contrasted to the definition used in this evaluation.
- ◆ A distinction is made between the *replacement* and *financial sustainability* of a country's injection safety supplies post-GAVI INS support.
- ◆ The conceptual framework guiding the evaluation's data collection and analysis is introduced.
- ◆ The framework relates economic and political factors as well as government commitment, logistics capacity, effectiveness of the planning process, donor support, and other factors to financial sustainability
- ◆ Contextual factors such as decentralization, integration and other reforms are also considered.
- ◆ The positive and negative effects of GAVI INS support in the broader health system are measured as perceived by those interviewed.
- ◆ The evaluation also documented how countries receiving cash in lieu of supplies used this form of GAVI INS support.

4. METHODOLOGY

In this section, we describe the study sample, data sources, data collection techniques and methods of analysis. The analysis plan developed for this evaluation is attached as background in Annex 4.

4.1 Study sample

The evaluation focuses on the 58 countries that completed their INS support in 2004, 2005 and 2006. Table 1 shows that of the 58 countries, 15 received their final INS support in 2004, 22 received it in 2005, and 21 received it in 2006. Eighty percent (46 countries) received injection safety supplies (AD syringes and safety boxes), while 20 percent (12 countries) received cash support because at the time of application they already had a secure supply of AD syringes and safety boxes.

Half of the countries in the sample are in the Africa Region (AFR). Nine countries (16 percent) are in the Europe Region (EUR), seven (12 percent) are in South East Asia Region (SEAR) and the other thirteen are divided among the Eastern Mediterranean (EMR), Western Pacific (WPR), and Americas (AMR), as shown below.⁸

Table 1. Characteristics of the 58 countries receiving INS support

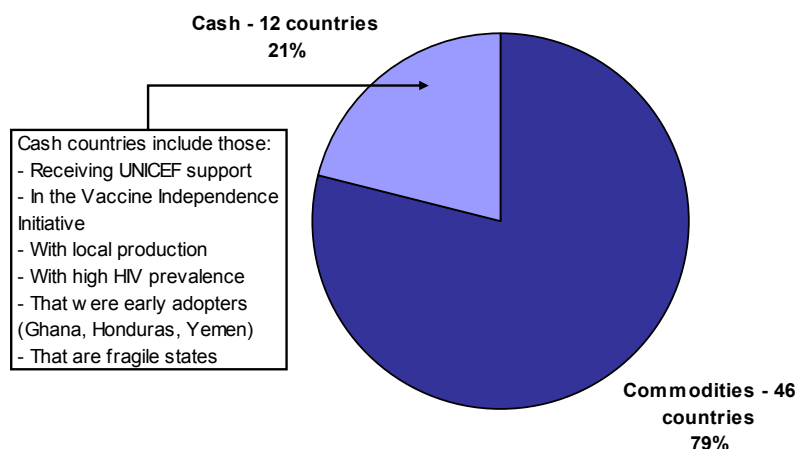
Characteristic	Categories	Number (%)
Year support ended	2004	15 (26)
	2005	22 (38)
	2006	21 (36)
Materials vs. cash	Materials	46 (79)
	Cash	12 (21)
Regions	AFR	29 (50)
	AMR	3 (5)
	EMR	6 (10)
	EUR	9 (16)
	SEAR	7 (12)
	WPR	4 (7)
GNI per capita	≤\$350	14 (24)
	\$350–700	16 (28)
	>\$700	21 (36)
	No data	7 (12)

Source: GAVI INS country application and reporting documents

The twelve countries that received cash rather than supplies are diverse. They include those that used AD syringes sooner than other countries in their region, *fragile countries* that were receiving injection safety support from UNICEF, countries that were participating in the Vaccine Independence Initiative (VII), as well as countries with local production of AD syringes (Figure 4).

⁸ For the sake of consistency, WHO regions are used in this evaluation report.

Figure 4. Percentage of countries receiving commodities or cash



GAVI's total INS investment in these 58 countries from 2002 to 2006 was approximately \$78.4 million. \$52.8 million was spent on injection supplies for the 46 commodity-recipient countries, while \$25.6 million was provided to the 12 cash-recipient countries. The average amount invested in injection safety supplies per commodity-recipient country was \$1.1 million. The average investment per cash-recipient country was higher (\$2.1 million), but this average is skewed by the inclusion of China's cash payment of \$15.9 million. Excluding China, the average grant to cash-recipient countries was approximately \$0.9 million

As shown in Table 2, from 2002-2006, GAVI's total INS investment in the 58 countries was significantly less than its investment in New and Underused Vaccines (\$2.6 billion). It was also much less than the Immunization Services Support (ISS) (\$145 million) GAVI provided to 53 of these countries during the same period. Although this evaluation did not address the countries' ability to replace different types of GAVI funding, by relative measure we can say that INS should have been more affordable and potentially easier for the recipient countries to replace.

Table 2. GAVI INS support compared to GAVI NVS to 58 countries (2002-2006)

Measurements	Injection Safety support (\$000s) to commodity recipients	Injection Safety support (\$000s) to cash recipients	New Vaccine Support (\$000s)
Range	\$22-\$9,854	\$32-\$15,900	\$162-\$89,400
Mean	\$1,148	\$2,131	\$14,333
Median	\$610	\$656	\$1,934
Total	\$52,820	\$25,569	\$2,557,350

Source: GAVI Alliance 12/07

The number of syringes provided and amount of financial support to each of the 46 commodity-recipient countries is shown in Table 3. Table 4 summarizes the total cash support provided for injection safety activities to the other 12 countries.

Table 3. GAVI INS support provided to commodity-recipient countries, 2002-2006

Country	GAVI INS Support	Total AD Syringes	Reconstitution Syringes
Albania	\$109,918	1,373,625	43,290
Angola	\$1,288,651	15,203,889	451,693
Armenia	\$64,942	930,283	33,688
Azerbaijan	\$151,040	1,634,565	79,947
Bangladesh	\$6,740,996	100,466,767	10,744,044
Bhutan	\$31,741	698,282	50,515
Bolivia	\$601,500	25,491,977	138,600
Burkina Faso	\$933,497	9,301,428	544,052
Burundi	\$390,294	5,723,917	119,086
Cambodia	\$587,653	10,587,073	835,172
Cameroon	\$995,838	12,493,816	248,818
Central African Republic	\$119,651	1,812,720	75,821
Chad	\$436,085	6,162,033	104,251
Comoros	\$42,322	432,978	9,667
Congo	\$231,784	3,990,690	88,520
Dem Rep of the Congo	\$2,713,931	54,769,399	952,884
Eritrea	\$146,634	5,153,396	89,264
Ethiopia	\$2,696,697	44,527,576	759,569
Gambia	\$101,184	4,258,175	105,552
Georgia	\$61,451	907,727	18,301
Guinea	\$381,064	9,002,430	259,498
Indonesia	\$9,853,614	77,590,170	3,591,398
Kenya	\$1,142,027	31,677,034	990,044
Korea DR	\$744,499	10,417,764	1,310,804
Kyrgyzstan	\$179,995	1,838,160	95,904
Laos	\$255,505	6,056,782	251,104
Lesotho	\$106,633	1,489,871	44,430
Mali	\$666,222	10,358,977	241,169
Mozambique	\$836,572	19,097,302	532,220
Myanmar	\$2,173,611	30,395,736	567,024
Nepal	\$1,158,189	16,029,881	315,925
Niger	\$951,427	8,140,899	202,070
Pakistan	\$7,577,549	127,104,321	2,144,959
Sao Tome and Principe	\$21,656	117,100	10,700
Senegal	\$619,474	9,820,038	282,036
Sierra Leone	\$272,660	4,127,544	92,748
Sri Lanka	\$742,378	6,833,515	168,210
Sudan	\$1,492,752	24,763,500	3,620,276
Tajikistan	\$343,146	4,045,922	136,527
Togo	\$321,107	4,843,104	90,777
Turkmenistan	\$150,641	2,525,250	119,280
Uganda	\$1,207,299	31,712,968	739,828
Ukraine	\$750,462	6,408,030	272,532

Country	GAVI INS Support	Total AD Syringes	Reconstitution Syringes
Uzbekistan	\$727,012	14,860,125	509,490
Zambia	\$714,786	12,580,462	235,742
Zimbabwe	\$983,891	15,213,490	388,050
TOTAL	\$52,819,980	792,970,691	32,705,479

Table 4. GAVI INS cash support provided to twelve countries, 2002-2006

Country	GAVI INS Cash Support
Afghanistan	\$1,676,500
China	\$15,926,581
Djibouti	\$33,900
Ghana	\$855,300
Haiti	\$397,500
Honduras	\$457,000
Mauritania	\$205,000
Rwanda	\$369,500
Somalia	\$210,140
Tanzania	\$1,016,452
Viet Nam	\$3,226,000
Yemen	\$1,194,757
TOTAL	\$25,568,630

4.2 Data collection

The evaluation team used four methods to collect data on the availability, use, financing and sustainability of AD syringes and safety boxes:

1. desk review of available documentation on injection safety and waste management in the 58 countries where GAVI INS support ended between 2004–2006;
2. interviews with national immunization or MOH program managers;
3. interviews with WHO and UNICEF regional and country focal points, MMIS project directors and other stakeholders;
4. review of UNICEF's Supply Division records on the procurement of AD syringes and safety boxes by GAVI countries after their INS support ended.

A list of persons contacted for this evaluation appears in Annex 9.

In addition to the methods above, the GAVI RFP called for up to six country visits, which the JSI team was prepared to conduct. However, the marginal benefit of this effort was questioned by the Steering Committee. Ultimately, it was agreed that the additional information gathered during country visits would not be worth the extra burden on countries. Data provided through the sources described in the Methodology section of this report were considered to be sufficient for the purposes of this analysis.

4.3 Data collection sources and methods

4.3.1 Desk reviews

The evaluation team conducted a desk review of relevant documents for all 58 GAVI INS-recipient countries. The process is described in detail in Annex 5 of this report.

Data were reviewed from the following sources:

- Country applications for GAVI INS support;
- Country injection safety plans;
- Annual Progress Reports submitted by countries to the GAVI Alliance, which cover the receipt of AD syringes and safety boxes, problems encountered, disposal of sharps, and transition plans;
- ICC minutes describing decision making on the replacement of GAVI INS support;
- GAVI Monitoring and Evaluation Independent Review Committee reports;
- WHO/UNICEF Joint Reporting Form statistics on country immunization coverage, injection safety, immunization program financing and healthcare waste management;
- Country Multi-Year Plans and Financial Sustainability Plans for immunization;
- World Bank country and regional on-line database;
- JSI's Making Medical Injections Safer (MMIS) Project reports (seven countries).

These data were either copied or downloaded into a computer "flat" sheet (Excel spreadsheet) for comparison and analysis.

4.3.2 National immunization program managers

The evaluation team conducted telephone interviews with national immunization program managers in nearly all of the recipient countries. In a few cases, interviews were conducted with others who were familiar with the program when the manager was new or unavailable. Interviews included qualitative and semi-structured questions that focused on:

- the decision-making process leading up to the replacement of INS support;
- how much of the INS support was replaced with government and/or donor funding in each year after it ended;
- the positive and negative effects of INS support on the country's health system;
- where relevant, how cash support provided by GAVI (in lieu of INS commodities) was used.

The questionnaire used during the survey of program managers is attached as Annex 6 to this report.

Interviewers were trained to collect data and use the computer software for data input. Each interview team comprised a lead discussant who conducted the interview and a note-taker who entered the data into a computer software program tailored for the purposes of this study. Care was taken to ensure that interviews were language appropriate. Ultimately, interviews were conducted by trained staff in English, French, Spanish, Russian and Portuguese during the months of May and June 2008.

In the case of eight countries, interviews could not be conducted by phone. For these countries, completed questionnaires were submitted in writing and supplemented with data collected from interviews with WHO and UNICEF focal points. If further clarification was needed on the written responses, the team went back to the respondents by email or telephone to ask for additional information. The countries in this group are: Azerbaijan, Bolivia, China, Haiti, Democratic People's Republic of Korea, People's Democratic Republic of Lao, Myanmar and Turkmenistan.

Most NIP managers (32 of 54 respondents) had been in their positions for more than five years and were knowledgeable about GAVI INS support. When NIP managers had been in their positions for a shorter period of time, they compensated for their own lack of knowledge about GAVI INS by consulting with program deputies and/or previous NIP managers.

The evaluation team developed a computer-assisted data-entry system using Lime Survey. Lime Survey is in the public domain and available at no charge to the user. Note-takers used this program to enter responses into a web-based database as the interviews were conducted. Codes were used to identify countries, and the program was password protected to allow for more than one person to use it simultaneously. Data were stored in the same database and retrieved according to fields specified by the data analyst.

4.3.3 WHO and UNICEF regional focal points

The evaluation team also conducted telephone interviews with members of the GAVI regional working groups that support the GAVI-recipient countries, most of which are led by WHO and UNICEF regional or sub-regional immunization focal points. These interviews solicited their assessments and perspectives on the replacement of GAVI INS support. In addition, they were asked to review and validate information obtained from national program managers about the replacement of GAVI INS support, logistical and financial issues confronting countries and other factors related to sustainability. Focal points also commented on the management of AD syringe and safety box waste disposal by individual countries. A list of questions from the regional focal point interview guide appears as Annex 7.

4.3.4 MMIS country directors

The USAID/CDC-funded Making Medical Injections Safer (MMIS) project is active in seven of the 58 INS-recipient countries. During its annual meeting in mid-July 2008, the evaluation team took advantage of the presence of the country directors from these seven MMIS countries to solicit their input on the program, in general, and how it has been implemented in their respective countries. During a focus group session with this group, a primary topic of discussion was whether and how GAVI INS had affected injection safety policies and practices beyond immunization, in the broader health sector. The list of discussion questions appears in Annex 8.

4.3.5 UNICEF commodity data

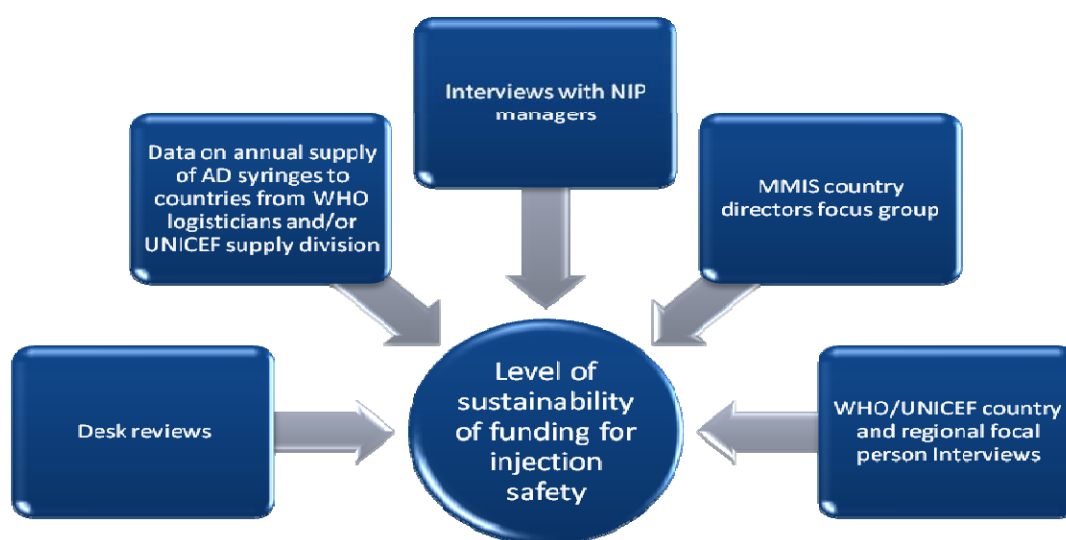
We requested the UNICEF Supply Division to provide data on the procurement of AD syringes and safety boxes, by country, after GAVI funding ended. This information was

used to verify the number and type of syringes that countries had ordered and the sources of support they reported using. UNICEF supply data were also used to examine global trends in the pricing and procurement of AD syringes and safety boxes.

4.3.6 Verification of data

The team reviewed data from various sources on the replacement of GAVI INS support to assess the overall validity of the information collected and used in this analysis. Figure 5 shows that data were obtained from the desk review, national immunization program managers, and WHO/UNICEF country and regional focal points. The responses from each were compared in order to identify any discrepancies in country data. The data requested from UNICEF Supply Division was also used to verify response data about procurement and funding sources. The country summary table template that was used to help verify and to collect further data can be found in Annex 10.

Figure 5. Verification of data



When national manager responses and desk review data were compared with regional and national focal point responses, the team found some variations. The main variation occurred in the reporting on: (1) the sources of funding for AD syringes and safety boxes, (2) the presence of a line item for AD syringes and safety boxes in the health sector budget, and (3) the presence of financial or logistical difficulties at country level. Variation among responses by source is shown in Table 5.

The evaluation established a protocol for treating discrepancies in the data. When there was variation among the data collected, the evaluation ranked the reliability of the data by information source as follows:

- (1) UNICEF Supply Division
- (2) WHO/UNICEF regional and national focal points
- (3) NIP managers

Data from the UNICEF Supply Division on numbers of syringes procured by device, country and year were considered the most reliable data. In the presence of a discrepancy about the source of funding for AD syringes and safety boxes, we used data from the regional and national WHO/UNICEF focal point rather than from the NIP manager.

Table 5. Variation among responses by source of data

Characteristics	Telephone interviews with national manager or desk review	Regional and national WHO/UNICEF focal points/JRF	Number
Source of funding	Government funding	Mixture of government and donors	3
	Mixture of government and donors	Donor dependent	1
Line items	No	Yes	3
Macro-economic status	No instability	Economic instability	1
Financial and logistical difficulties	None	Yes	2

Source: NIP Managers, WHO/UNICEF Regional/National Focal Points, Joint Reporting Forms

4.4 Other aspects of assistance

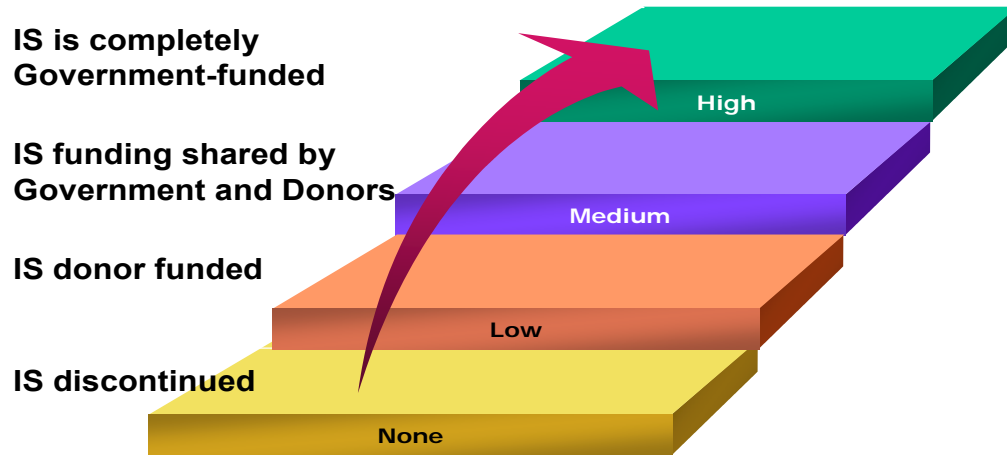
4.4.1 Financial sustainability

We assessed the extent to which various sources of financing replaced GAVI INS support in each year after it ended, through mid 2008 for all 58 countries. To assess the relative sustainability of injection safety commodities in the countries, we created a variable that measures financial sustainability at four levels (Figure 6), as follows:

- (1) None: AD syringes not replaced or partially replaced
- (2) Low: replaced but fully donor dependent
- (3) Medium: replaced with mixed government and donor funding
- (4) High: replaced and fully government funded.

To construct this variable, we collected data on the source or sources of funding countries used to procure AD syringes and safety boxes in each year after GAVI INS support ended. We relied predominantly on NIP managers' reports, but we also verified their responses in interviews with WHO/UNICEF country, regional and subregional immunization focal points. In 2008, because interviews took place in the middle of the year, the accuracy of all country responses was verified through discussions with the relevant regional WHO and UNICEF focal points and in our review of the procurement records provided by the UNICEF Supply Division.

Figure 6. Levels of financial sustainability



The team analyzed factors associated with higher and lower levels of financial sustainability based on the evaluation framework in Figure 1 (section 3). To determine which factors were most influential in achieving high levels of financial sustainability, we ran frequencies, cross-tabulations and a multivariate analysis on the variables described in the framework. The analysis was stratified by the type of support received (commodities or cash), the year funding ended, and geographic region. Multivariate analysis was performed using the ordinary least squares (OLS) method. The analysis is described in greater detail in the Findings section (section 5).

It was hypothesized that the effectiveness or strength of a national immunization program would influence financial sustainability; therefore, a composite variable was created to measure program strength. The factors that comprise this variable appear in Table 6.

Table 6. Components of “program strength” variable

Components	Weighting
1. 2006 DTP3 coverage \geq 80 percent	1
2. Country has national injection safety policy	1
3. NIP manager rated the program logistics as mostly or completely adequate	1
4. Injection safety has a strong advocate in the MOH or a partner organization	1
5. Program maintains a continuous supply of AD syringes and safety boxes	1
Highest score possible	5

Another variable that we assumed would be closely associated with financial sustainability was the existence of a line item for injection safety commodities in the MOH budget. Typically, governments introduce a line item when they intend to finance some or all of the cost of a program. However, whether a line item was introduced before or after a government decided to pay for injection safety supplies was not clear in all cases. Therefore, we ran frequencies and cross-tabulations on this variable and the financial sustainability variable only, and it was not entered into the multivariate analysis.

4.4.2 Impact of INS support on the broader health sector

The impact of GAVI INS on the broader health sector was assessed through a descriptive analysis of the introduction and use of AD syringes and safety boxes beyond national immunization programs. The evaluation determined whether ministries of health had introduced AD syringes, safety boxes, other injection safety or waste management interventions into non-immunization services, and if so, when this had occurred. It also determined whether injection safety and/or healthcare waste management policies had been developed for the broader health services and the role that GAVI INS support may have played in such policy change. Frequencies were also run on the AD syringe disposal methods that were in use during and after the three years of GAVI INS support.

4.4.3 Utilization of cash support

GAVI policy states that:

“Countries that can demonstrate secure and sufficient support to maintain use of auto-disable syringes and safety boxes may apply instead for grants towards injection-safety activities...” (GAVI Alliance website)

The evaluation determined how the twelve cash-recipient countries used their INS support. Furthermore, it assessed whether they continued to meet the criteria above for cash versus commodities during their three years of GAVI INS support. As in the commodity-recipient countries, the evaluation also examined: (1) the decisions countries made in replacing their GAVI INS support, (2) whether the supply of commodities continued once GAVI INS support ended, and (3) whether GAVI INS support had an

impact on the broader health sector. Because of the small number of countries in this subgroup, frequencies and crosstabs were run on most variables, but multivariate analysis was not performed.

4.4.4 Implications of GAVI INS support at global and regional levels

The evaluation assessed whether GAVI INS support affected the use of AD syringes beyond the country level, looking specifically at: (1) the price of AD syringes on the global market and (2) the use of AD syringes and safety boxes in non-GAVI eligible, lower-middle-income countries. Data on pricing of AD syringes and the market for these commodities were examined to determine if GAVI INS influenced their cost.

To determine whether GAVI INS-recipient countries were more or less likely than other developing countries to introduce AD syringes and safety boxes in their immunization programs, the evaluation compared the use of AD syringes and safety boxes in GAVI-eligible countries to their use in all non-GAVI eligible, lower-middle-income countries. Lower-middle-income countries, which include those with a GNI per capita ranging from \$936 to \$3,705, were identified using the World Bank categorization on its website.⁹ In the analysis, we compared Joint Reporting Form (JRF) data on the utilization of injection safety commodities in both categories of countries.

The evaluation also used data provided by UNICEF's Supply Division to assess trends in the volume of injection safety commodities procured and the sources of funding used during the period studied. These data supported the analysis of how and to what extent countries replaced GAVI support during the years after GAVI INS support ended, a key objective of the evaluation. Because UNICEF supply data are by volume and by country, and not by GAVI window of assistance or purpose (i.e., routine immunization versus mass campaign), we used a proxy indicator for GAVI INS commodities—the BCG syringe (0.05 ml), which is one of the syringes that is used almost exclusively by the routine immunization program that GAVI INS supports. Order levels for BCG syringes, as well as for safety boxes were used to describe trends in AD syringe procurement by volume and funding source.

4.4.5 Evaluation limitations

We faced some study limitations in conducting the GAVI INS evaluation because of the type of data collection methods used and the retrospective nature of the study.

Much of the information was obtained through telephone interviews, with uneven quality of phone connections and across linguistic and cultural barriers. While this type of data collection is more efficient and less disruptive than conducting country or regional visits, it does not provide the same depth of information about contextual and enabling factors. It is also more difficult for interviewers to probe and verify responses.

Some of the national program managers interviewed were not in their posts when their country's INS application was written. Others joined since the decision was made to replace GAVI INS support or during the first year after that support ended. Consequently, not all respondents could answer all the questions about their country's

⁹ <http://go.worldbank.org/K2CKM78CC0>

INS support. As a result, many non-responses were recorded during the interviews, which caused variation in the numbers of observations. Some respondents could not recall all the details of the decision-making process regarding replacement of GAVI INS support because it had occurred as long as four years before the interview. Thus, some responses lacked detail and/or interviewees did not respond to all the questions. The way the analysis addressed incomplete and inconsistent data is described in the Methodology section (section 4).

We found that some of the interviewees, usually NIP managers, were not knowledgeable about injection safety practices in the broader health sector. Consequently, they could not respond in detail to the questions on the impact of INS support outside of their own immunization programs.

Over one-third of the countries (21/58) completed their third and final year of GAVI INS support in 2006. All but one of these countries successfully replaced their AD syringes and safety boxes in 2007 and 2008 (see Table 8). However, in terms of exposure, they have needed to replace and sustain funding for their injection safety commodities for a shorter period than have the countries in the sample that received their final GAVI INS support in 2004 or 2005.

Some of the data used in the analysis, such as whether the countries had line items in their MOH budgets for AD syringes and safety boxes, were taken from the Joint Reporting Form (JRF) that countries submit each year to WHO and UNICEF. Although these reports are checked by the WHO and UNICEF country offices before being published, inconsistencies are common. We verified JRF responses to the degree possible during telephone interviews and believe that we were able to correct or clarify most if not all of the noted inconsistencies.

The evaluation analyzed UNICEF Supply Division data to assess trends and verify country reports on the procurement and financing of injection safety commodities. Unfortunately, Supply Division data were available by volume and country only. As such, we were unable to determine which GAVI funding window (i.e., GAVI INS or GAVI New and Underused Vaccine Support) had been used for individual procurements and whether commodities had been purchased for routine immunization services or mass campaigns. This made the analysis of Supply Division data a challenge. As explained above, a proxy indicator (BCG syringes procured per year) was agreed upon and used to verify the responses of NIP managers and other key informants at country level.

Section Summary

- Study sample = 46 countries received commodities and 12 received cash.
- GAVI invested almost \$80 million in the 58 countries included in this sample.
- A desk review of available data and documents was conducted, including GAVI applications, APRs, ICC minutes, JRFs, and cMYPs
- Interviews with 57 NIP managers and 13 WHO and UNICEF regional focal points for immunization were carried out.
- Procurement data from the UNICEF Supply Division were obtained and analyzed to validate country responses and measure trends in the global pricing and markets for AD syringes.
- Data from different sources was triangulated for verification purposes.
- Two new variables were constructed to describe national immunization “program strength” and “level of financial sustainability”.
- Country financial sustainability was ranked as “high” (government funded), “medium” (mix of government and donor funding), and “low” (donor funded).
- The analysis was stratified by the type of support received (commodities or cash), the year funding ended, and geographic region.
- Multivariate analysis was performed using the ordinary least squares (OLS) method.
- The evaluation also investigated the impact of INS support on the broader health sector, how cash support was used and the impact of GAVI INS at regional and global levels.
- Study limitations included the retrospective nature of the evaluation, the limitations of telephone interviewing, lack of NIP manager’s familiarity with the history of GAVI INS support in some cases, and limited time after INS support ended to determine sustainability in the last cohort of countries.

5. FINDINGS

The evaluation's findings are presented separately for INS commodities and cash recipients. Unless otherwise noted, all results are as reported or documented in mid-2008.

5.1 Commodity Support

The characteristics of the 46 countries that received GAVI INS support in the form of AD syringes and safety boxes are displayed in Table 7. Of these countries, one-quarter received their final INS commodities in 2004, while three quarters received them in 2005 or 2006. More than half of the commodity-recipient countries are from the AFR region, followed by EUR and SEAR. The remaining five countries are from EMR, WPR and AMR.

Table 7. Characteristics of the 46 commodity-recipient countries

Characteristic	Categories	Number (%)
Year support ended	2004	13 (28)
	2005	18 (39)
	2006	15 (33)
Regions	AFR	25 (54)
	AMR	1 (2)
	EMR	2 (4)
	EUR	9 (20)
	SEAR	7 (15)
	WPR	2 (4)
GNI per capita	<=\$350	13 (28)
	\$350-700	14 (30)
	>\$700	17 (37)
	No data	2 (4)

Source: GAVI INS country application and reporting documents

Note: No World Bank estimate of per capita GNI is available for DPR Korea and Myanmar.

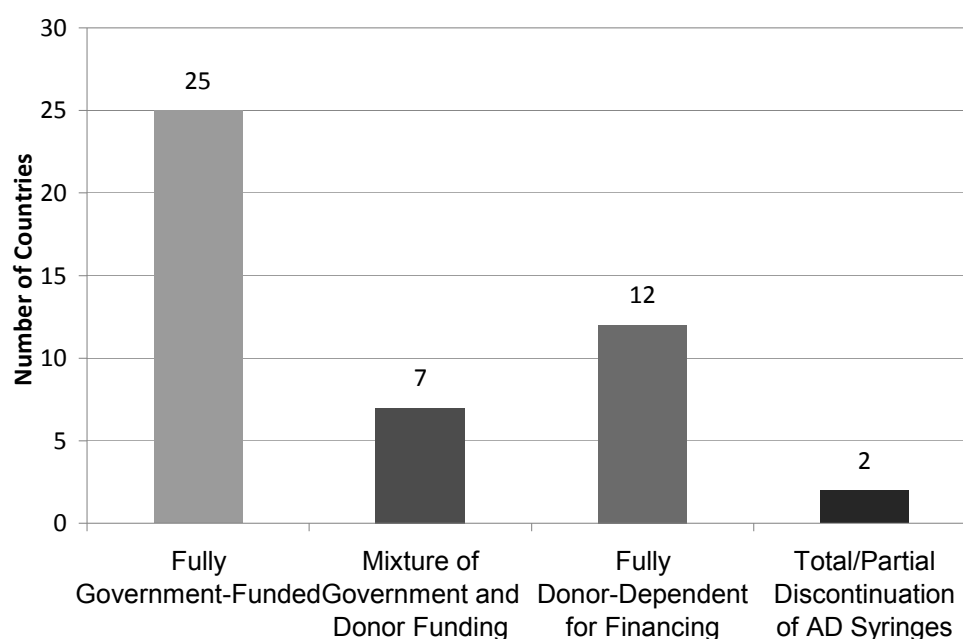
5.1.1 Replacement and financial sustainability

A major finding of this evaluation is that there was almost universal *replacement* of INS funding by the 46 commodity-recipient countries. All but two of these countries (96 percent) continued to use AD syringes and safety boxes after INS ended. By mid 2008, twenty-five (54 percent) were financing the purchase of their own AD syringes and safety boxes completely with government funding and seven (15 percent) were using a mix of government and donor funding. Only 12 countries (26 percent) continued to be totally donor dependent (Table 8 and Figure 7).

Table 8. Financial sustainability of AD syringes and safety boxes (46 commodity countries, 2008)

Level of financial sustainability	Number (%)
None: Total/partial discontinuation of AD syringes	2 (4)
Low: Fully donor-dependent for financing	12 (26)
Medium: Mixture of government and donor funding	7 (15)
High: Fully government funded	25 (54)
Total	46 (100)

Source: Program manager interviews, regional and national WHO/UNICEF focal point interviews

Figure 7. Financial sustainability of AD syringes (46 commodity countries, 2008)

The two countries that discontinued the use of AD syringes and safety boxes were Ukraine and Uzbekistan. Ukraine discontinued use entirely and Uzbekistan continued in only one-quarter of its health facilities. Ukraine is producing standard disposable syringes in country and has chosen to procure this less expensive product instead of imported AD syringes. In Uzbekistan, problems arose when some authorities at the oblast level, who have the authority to procure their own commodities, chose to buy non-AD products (Box 1).

Box 1. Decentralized procurement

At present in Uzbekistan the MOH procures vaccines centrally. Syringes and other supplies such as safety boxes are purchased from local sources. A bidding process takes place at both national and local levels. As a result, many varieties of syringes are being procured and used.

As more countries move toward decentralized procurement, it is a concern to international organizations like GAVI. Partners will need to know how to work within this structure so that program and procurement objectives can be realized. (Source: EURO Interview)

The characteristics of countries that sustained the use of AD syringes and safety boxes are discussed in this and other sections of the evaluation report. A map of GAVI INS-supported countries, indicating assessed level of sustainability, also appears as Annex 11.

5.1.2 Patterns of financial sustainability

Across the countries, minor differences were seen in the financing of AD syringes and safety boxes by mid 2008. Countries ending support in 2004 were more likely (62 percent) by the time of the evaluation to have secured government funding for their AD syringes and safety boxes than countries ending in 2005 (56 percent) or 2006 (47 percent) (Table 9). This may be related to having more time to secure government budget for injection safety supplies, however, the sample size is too small to support this conclusion.

Table 9. Financial sustainability in mid 2008 by the year GAVI INS support ended

Countries ending support in,,,	2004 (%)	2005 (%)	2006 (%)	Total (%)
<i>High:</i> Fully government funded	8 (62)	10 (56)	7 (47)	25 (54)
<i>Medium:</i> Mixture of government and donor funding	1 (8)	2 (11)	4 (27)	7 (15)
<i>Low:</i> Fully donor dependent	4 (31)	5 (28)	3 (20)	12 (26)
<i>None:</i> Total or partial discontinuation of AD syringes	0 (0)	1 (6)	1 (7)	2 (4)
Total	13 (100)	18 (100)	15 (100)	46 (100)

A major evaluation finding is that the level of financial sustainability achieved by the commodity-recipient countries did not change dramatically over time (Table 10). Of the thirteen countries that started procuring commodities with donor support in the first year after their INS support ended, only two had improved their level of financial sustainability by mid 2008. The situation of countries in the medium sustainability category was slightly better. Of the five countries that started in this category in 2005 and 2006, only two remained by mid 2008, the other three having moved into the higher sustainability/government funding category.¹⁰ None of the other countries showed any change in level of financial sustainability, regardless of when their GAVI INS support

¹⁰ Cambodia and Sudan were not able to secure full government funding immediately, but they succeeded in the third year post-INS. One other country, Lesotho, whose support ended in 2005, was not fully government funded until 2007.

ended. This finding--that countries starting at one level of sustainability tend to stay at that same level--highlights the importance of working to mobilize government resources long before time-limited support, such as GAVI INS, is due to end.

Table 10. Country replacement of AD syringes and safety boxes in the years after GAVI INS ends, by level of financial sustainability/source of funding

Countries ending support in 2004								
	Number of Countries				Proportion			
	2005	2006	2007	2008	2005	2006	2007	2008
High: Govt funding	6	6	8	8	46%	46%	62%	62%
Medium: Govt+donor funding	3	3	1	1	23%	23%	8%	8%
Low: Donor funding	4	4	4	4	31%	31%	31%	31%
Total or partial discontinuation	0	0	0	0	0%	0%	0%	0%
Total	13	13	13	13	100%	100%	100%	100%
Countries ending support in 2005								
	Number of Countries				Proportion			
		2006	2007	2008		2006	2007	2008
High: Govt funding		9	9	10		50%	50%	56%
Medium: Govt+donor funding		2	2	2		11%	11%	11%
Low: Donor funding		6	6	5		33%	33%	28%
Total or partial discontinuation		1	1	1		6%	6%	6%
Total		18	18	18		100%	100%	100%
Countries ending support in 2006								
	Number of Countries				Proportion			
			2007	2008			2007	2008
High: Govt funding			7	7			47%	47%
Medium: Govt+donor funding			4	4			27%	27%
Low: Donor funding			3	3			20%	20%
Total or partial discontinuation			1	1			7%	7%
Total			15	15			100%	100%
Total completed GAVI INS	13	31	46	46				

5.1.3 Decision making

Decision making on the replacement of GAVI INS support occurred in most commodity-recipient countries (78 percent) before GAVI INS funding ended. Sixty-three percent of the NIP managers interviewed stated that decision making took place in an Interagency Coordination Committee or similar multi-agency forum. During the decision-making process, 76 percent of the countries reported identifying a source of financing, as well as a source of supply. Most respondents (72 percent) stated that their country's decision-making process was either good or excellent; 21 percent stated that it was somewhat satisfactory or poor. Decision making before funding ends gives countries time to identify both funding and supply sources and minimizes the risk of stock outs or interruption in services.

Table 11. Characteristics of country decision-making on replacement of GAVI INS

Characteristics	Categories	Number (%)
Entities involved	ICC or similar group	29 (63)
	MOH only	5 (11)
	MOH and MOF	2 (4)
	No decision making	1 (2)
	No response	9 (20)
Timing of decision-making	Before funding ended	36 (78)
	After	2 (4)
	Don't know	4 (9)
	No response	4 (9)
Funding sources identified before end of INS	Yes	35 (76)
	No	4 (9)
	No response	7 (15)
Supply source identified before end of INS	Yes	35 (76)
	No	2 (4)
	Don't know	4 (9)
	No response	5 (11)
Perceived adequacy of decision-making	Poor	2 (4)
	Somewhat Satisfactory	8 (17)
	Good	21 (46)
	Excellent	12 (26)
	No response	3 (7)

Source of information: EPI manager interviews

5.1.4 Interruptions in supply of AD syringes after GAVI funding ended

In 13 (28 percent) of the 46 commodity-recipient countries, the supply of AD syringes to the immunization program was interrupted after GAVI support ended (Table 12). In five countries, these interruptions were due to short-term, logistical problems related to transportation or financial disbursement difficulties. For example, Niger's immunization program initially had a problem replacing GAVI INS because release of the national budget was delayed. This problem was resolved after a few months and no further interruption in the supply of AD syringes was reported. Three countries also reported experiencing stock outs of AD BCG syringes during the first year after INS ended.

Table 12. Interruption of supply of AD syringes

Type of Interruption	Number
<i>None</i> : Short-term logistical difficulties	6
<i>Low</i> : Financial difficulties → use of alternative syringes	2
<i>Medium</i> : Stock outs of BCG syringes	3
<i>High</i> : Discontinued AD syringes	2
Total	13

Source: Telephone Interviews, Regional or National WHO or UNICEF Focal Points

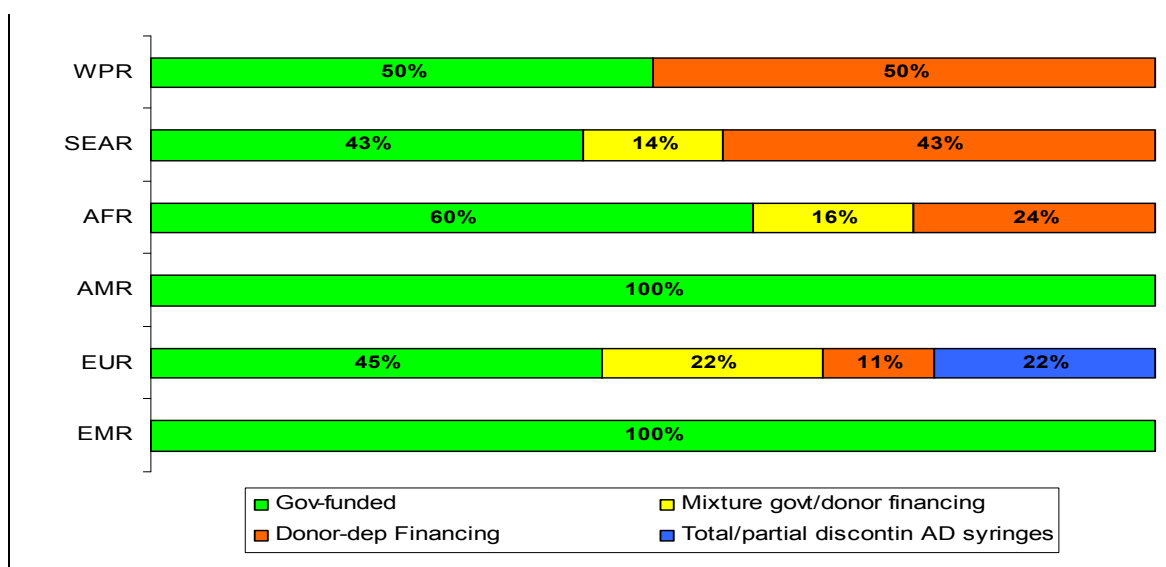
5.1.5 Factors affecting financial sustainability among commodity recipients

The evaluation assessed the influence of various factors on a country's level of financial sustainability. These included geographic region, program strength, existence of an injection safety policy, GNI per capita, and other health system characteristics.

5.1.5.1 Regional variation

The percentage of countries in the evaluation that funded their AD syringes and safety boxes from a government source ranged from 43 percent in the SEAR (three countries) to 100 percent in the AMR (three countries) and EMR (two countries) (Figure 8).

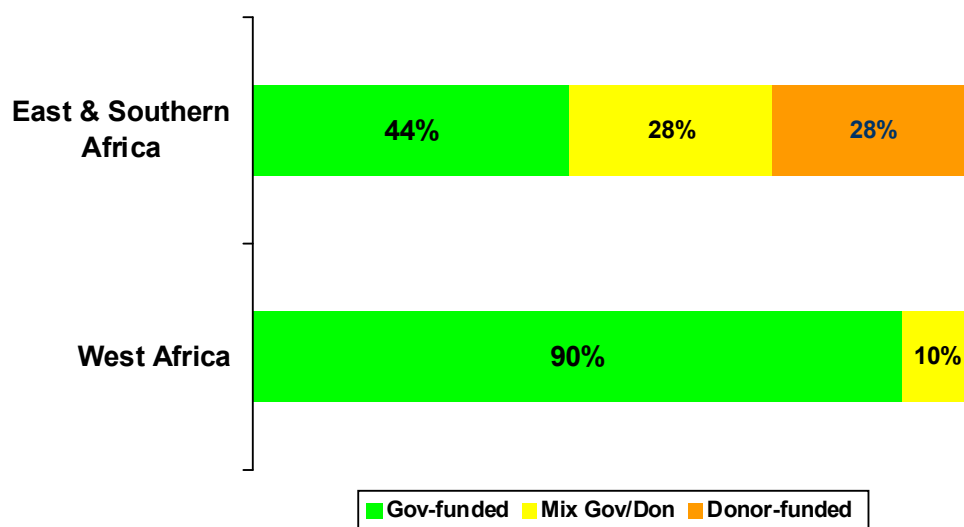
Figure 8. Financial sustainability by region (46 commodity countries, mid 2008)



Although AFR is the most economically disadvantaged region, the team found a high level of financial sustainability (i.e., government funding for AD syringes and safety boxes) (60 percent). When the financial sustainability in AFR was examined closely, intra-regional variation was found. The eleven countries of West Africa¹¹ were found to have a higher level of financial sustainability than countries in other parts of Africa (Figure 9).

¹¹ West Africa includes the following countries: Burkina Faso, Chad, Gambia, Ghana, Guinea, Mali, Mauritania, Niger, Senegal, Sierra Leone and Togo.

Figure 9. Level of financial sustainability in Africa (2008)



Factors that may have contributed to this result in West Africa include:

1. In 2002, the WHO Task Force on Immunization (TFI) in Africa issued a statement recommending the use of AD syringes by national immunization programs. According to WHO/UNICEF focal points in West Africa, this statement was used successfully to achieve a transition to the new technology.
2. WHO and UNICEF focal points in this subregion also reported playing an important advocacy role during EPI reviews and other country planning activities, which they believe had a positive effect on the willingness of countries to continue using AD syringes and safety boxes.
3. The European Union (EU) required countries in West Africa to establish budget line items for vaccines and injection safety commodities when they received EU support. As part of the Vaccine Independence Initiative (VII), the EU also helped countries purchase vaccines and injection safety commodities by guaranteeing their payments.

Other regional variations among commodity-recipient countries were detected, as follows:

The European Region was the only one with countries—Ukraine and Uzbekistan—that did not replace their AD syringes, as explained in section 5.1.1.

In the Southeast Asian Region, two countries (Bangladesh and Indonesia) are producing AD syringes locally. Bangladesh benefited from a WHO-supported evaluation that looked at the transfer of AD syringe technology to local producers and has now been prequalified as a UNICEF supplier (Box 2).

In the Western Pacific region, the regional focal points reported that they initiated discussions on replacement of INS funding with countries in their region. In addition, they held discussions with donors including the Japanese International Cooperating Agency (JICA), who played an important role in replacement by providing financial assistance to countries in the region during the years immediately following the end of GAVI INS.

In the Eastern Mediterranean region, WHO and UNICEF encouraged the two INS commodity-recipient countries to introduce budget line items and to commit the necessary financing for AD syringes and safety boxes after GAVI INS support ended. Both countries are now fully government funded.

Box 2. Technical assistance for local production – Bangladesh

In Bangladesh, a transfer of technology effort was supported by the International Association of Safe Injection Technologies (IASIT). IASIT brought together a manufacturer from the United Kingdom and a Bangladeshi firm seeking to produce AD syringes that met WHO specifications.

Following a 2004 WHO-supported study that looked at technology transfer, investment in the Bangladeshi firm was determined to be a viable way to expand local capacity. As a result, the Bangladeshi manufacturer became a pre-qualified UNICEF supplier, potentially exporting their product, as well as using them in-country. (Source: SEARO interview)

Countries in Central and South America are influenced differently. In this region, PAHO recommends four types of AD syringe, instead of the two that UNICEF and WHO recommend. These syringes are of different sizes and the price per syringe is higher for some than others, which may present a barrier to their procurement. Another factor affecting the use of AD syringes in the region is that PAHO does not have a policy promoting their use. This is due to the perception that re-utilization is not a problem for countries in the region. In addition, some respondents expressed the belief that AD syringes from WHO pre-qualified manufacturers were of lower quality than syringes available to them through other suppliers.

5.1.5.2 Program strength, injection safety policies and sustainability

The relationship between “program strength” and “level of financial sustainability” is shown in Table 13. As described in the Methodology section, national immunization programs were rated as “weak” if their program strength score was 1 or 2, “medium” if it was 3, and “high” if it was 4 or 5. Similarly, a country’s level of financial sustainability was defined according to the source or sources of funding it used to replace INS-supplied AD syringes and safety boxes.

Countries with “high” scores on the program strength variable were able to replace INS support with government funding or a mixture of government and donor funding more often than countries with “medium” or “weak” scores on the same variable. However, it is clear that program strength alone does not account for financial sustainability because three countries with “weak” programs also achieved full government funding for their AD syringes and safety boxes.

Table 13. Financial sustainability by program strength (2008)¹²

Level of Sustainability	Weak Score: 1–2 (%)	Medium Score: 3 (%)	Strong Score: 4–5 (%)	Number of Countries (%)
<i>None</i> : Total or partial discontinuation of AD syringes	0 (0)	0 (0)	2 (9)	2 (5)
<i>Low</i> : Fully donor-dependent	2 (40)	5 (45)	2 (9)	9 (23)
<i>Medium</i> : Mixture of government and donor funding	0 (0)	1 (10)	6(26)	7 (18)
<i>High</i> : Fully government funded	3 (60)	5 (45)	13 (57)	21 (54)
Total	5	11	23	39

Source: Program manager interviews, JRF, WHO/UNICEF Focal Points.
Pearson chi-squared – 15.7, significance = 0.471

No relationship was found between the existence of a national injection safety policy (either at the time of the application to GAVI or after GAVI INS support ended) and level of financial sustainability (Table 14).

Table 14. Financial sustainability by presence of a national immunization injection safety policy (2008)

Level of Sustainability	No IS policy	Policy in Development	National IS Policy
<i>None</i> : Total/partial discontinuation of AD syringes	0	0	2
<i>Low</i> : Fully donor-dependent	7	2	3
<i>Medium</i> : Mixture of government and donor funding	1	0	6
<i>High</i> : Fully government funded	10 (56)	2 (50)	13 (54)
Total	18	4	24

Source: Program manager interviews, JRF, WHO/UNICEF Focal Points.
Pearson chi-squared 7.679, significance = 0.104

5.1.5.3 Per capita income and financial sustainability

Countries with a higher per capita income were more likely to have government funding for AD syringes and safety boxes (Table 15), and less likely to be donor dependent. However, a greater percentage of countries with low per capita income were fully funded

¹² The program strength measure is not available for seven countries due to incomplete respondent data.

by their governments than were middle income countries, possibly due to advocacy efforts as described earlier.

Table 15. Financial sustainability by GNI per capita (2008)

GNI per capita (U.S.\$)	≤\$350 (%)	\$351–\$700 (%)	>\$700 (%)	Total
<i>None</i> : Total/Partial discontinuation of AD syringes	0 (0)	1 (7)	1 (6)	2 (5)
<i>Low</i> : Fully Donor-dependent for Financing	5 (38)	3 (24)	2 (12)	10 (23)
<i>Medium</i> : Mixture of Government and Donor funding	1 (8)	4 (29)	2 (12)	7
<i>High</i> : Fully Government Funded	7 (54)	6 (43)	12 (71)	25
Total	13 (30)	14 (32)	17 (39)	44*

Source: World Bank, NIP managers, WHO/UNICEF focal points

*No published data on per capita income available for two countries.

5.1.5.4 Line item

It was considered to be significant for the purposes of the evaluation to examine when line items for AD syringes and safety boxes were introduced into MOH budgets in relation to GAVI support. The evaluation found that many national immunization programs did not fund syringes from their budgets until they began using AD syringes with GAVI support. In many countries, a budget line item was established once AD syringes replaced what had been used previously, e.g. standard disposables. Table 16 shows that 34 out of 46 commodity-recipient countries currently have a line item for injection safety commodities in their MOH budget. Most (91 percent) of these had been introduced by the end of GAVI INS support, indicating a commitment to pay for AD syringes and safety boxes after GAVI INS ended.

Table 16. Timing of line item introduction into MOH budgets

Years	Before GAVI Funding	During GAVI Funding	After GAVI Funding	Total
2004	6	3	2	11
2005	5	7	1	13
2006	7	3	N/A	10
Total	18	13	3	34

Source: NIP manager interviews

Table 17 shows that countries with a line item in the MOH budget are more likely to partially or fully finance these commodities. However, seven countries that have a line item are not paying for AD syringes and safety boxes for their national immunization programs.

Table 17. Level of financial sustainability and existence of a budget line item for AD syringes (2008)

Level of financial sustainability	Has line item (%)	No line item (%)	Number (%)
<i>High</i> : fully government-funded	23 (70)	2 (17)	25 (54)
<i>Medium</i> : mixture of government and donor funding	4 (12)	3 (25)	7 (15)
<i>Low</i> : fully donor dependent for financing	6 (18)	6 (50)	12 (26)
<i>None</i> : total/partial discontinuation of AD syringes	1 (3)	1 (8)	2 (4)
Total	34 (74)	12 (26)	46

As shown in Table 18, the AFR has the highest percentage of countries (86 percent) with budget line items for injection safety commodities.¹³ The region with the lowest percentage of budget line items is EUR (44 percent). This finding was consistent in the analysis which showed that the AFR also has a higher level of financial sustainability than the EUR.

Table 18. Countries with budget line items for injection safety in 2008 by region

Existence of Line Item	EMR (%)	EUR (%)	AFR (%)	SEAR (%)	WPR (%)	AMR (%)	Number (%)
Yes	2 (100)	4 (44)	21 (84)	5 (71)	1 (50)	1(100)	34 (74)
No	0 (0)	5 (56)	4 (16)	2 (29)	1 (50)	0 (0)	12 (26)
Total	2	9	25	7	2	1	46

Source: JRF 2007

5.1.5.5 Health system financing mechanisms

We also examined whether health system financing mechanisms had an impact on the financial sustainability of AD syringes and safety boxes. Table 19 shows that countries with pooled funds, decentralized health systems, VII and or HIPC (highly indebted poor countries) designation were more likely to be paying for their AD syringes and safety boxes in 2008 than others.

¹³ This excludes the AMR, where there is only one commodity-recipient country.

Table 19. Financial sustainability by financing factors (2008)

Level of Financial Sustainability	Pool Funds	Decentralization	VII	HIPC	No Health Financing Factor	Number (%)
<i>None:</i> Total/partial discontinuation of AD syringes	0	1	0	0	1	2 (4)
<i>Low:</i> Fully Donor-dependent for Financing	0	0	0	0	12	12 (26)
<i>Medium:</i> Mixture of Government and Donor funding	2	1	0	0	4	7 (15)
<i>High:</i> Fully Government Funded	2	7	3	4	9	25 (54)
Total	4 (9)	9 (20)	3 (6)	4 (9)	26 (57)	46 (100)

*Only includes the countries with these health system characteristics.

Source: Program Manager Interviews, Regional/National WHO/UNICEF Focal Points

Box 3. Uganda: Immunization coverage increases with the help of GAVI INS support

In the late 1990s and early 2000s, before GAVI INS had been introduced, mothers in Uganda began fearing that their children would be exposed to HIV/AIDS through vaccination services. The result was a drop in the national immunization coverage rates – from 79% in 1994 to 58% in 2000 (WHO website).

Concerned about the coverage decrease, the Ugandan MOH conducted a survey that identified the problem and the mothers' concerns. In response, the MOH developed a plan to increase coverage that included the introduction of AD syringes, made possible with GAVI INS support. Increased confidence in the immunization program resulted in a corresponding increase in immunization coverage from 61% in 2002 to 84% in 2005. (Source: Uganda interview)

In countries that have local manufacturers of syringes, the data showed that this served either as an enabling factor or a disincentive for continued AD syringe procurement. The one country that used only the locally-produced AD syringes was fully government funded. On the other hand, the one country that produced conventional disposable syringes (Ukraine) rather than AD syringes, discontinued the use of AD syringes in favor of its locally produced standard syringes.

Interviews with NIP managers revealed that high HIV prevalence had a positive effect on the use of AD syringes. However, only two commodity-recipient countries with high HIV prevalence stated that it was important to sustain AD syringe procurement to ensure that injections were safe and that HIV was not spread through immunization services.

5.1.6 Multivariate analysis

A multivariate analysis was conducted to assess the relative importance of various factors for financial sustainability. Because of the small sample size, the number of factors that could be entered into the equation was necessarily limited. Also, one factor was excluded, having a line item for AD syringes and safety boxes in the MOH budget because it was considered to be endogenous. That is, while having a designated line item may affect a country's level of financial sustainability, the government's desire to be

sustainable in its funding for injection safety may have also had an effect on the introduction of the line item in the first place.

Table 20 shows the coefficients of various factors regressed on the level of financial sustainability of the commodity-recipient countries in 2008. Three factors were found to be statistically significant: (1) having an adequate decision-making process, (2) being located in West Africa, and (3) GNI per capita. However, the relationship between financial sustainability and GNI per capita was not very strong. Program strength was not statistically significant when controlling for the other variables.

The interpretation of the coefficients is:

1. the level of financial sustainability increases by 0.45 for each additional level of decision-making;
2. the level of financial sustainability is higher by 0.29 if the country is located in West Africa; and
3. the level of financial sustainability is higher by 0.24 for each additional US\$100 of GNI per capita.

Table 20. OLS coefficients estimating the impact of variables on level of financial sustainability in 2008

Dependent Variable = Level of Financial Sustainability	N=39
Decision-making process	0.454 (0.003**)
West Africa	0.289 (0.05**)
GNI per capita (2006)	0.243 (0.10*)
R ²	0.271

***=p<0.01; **=p<0.05; *= p<.10; R² = amount of variation in the dependent variable explained by the regression.

Section Summary – Commodity Recipients

- Commodity-recipient countries were fairly equally divided between those receiving their final INS support in 2004, 2005 and 2006.
- More than half of the countries were in sub-Saharan Africa.
- More than 75 percent of the countries made a decision on and identified a source or sources of continuation funding prior to the end of GAVI INS.
- 44 of 46 countries (96 percent) continued the use of AD syringes and safety boxes in one way or another.
- By 2008, 25 countries (54 percent) were purchasing injection safety commodities using government resources only; 7 (15 percent) were using a mix of government and donor support; and 12 (26 percent) were entirely donor dependent.
- Two countries (4 percent) did not continue AD syringe use--Ukraine and Uzbekistan.
- Only a few countries experienced any interruption in supplies and those were short term.
- Greatest success in financial sustainability (i.e., government support for the continuation of AD syringes) was found in the West African region.
- Countries starting at one level of sustainability tended to stay at that same level, highlighting the importance of mobilizing government resources BEFORE INS support ends.
- Having a strong national immunization program, a higher per capita GNI, and a line item for immunization commodities were all factors associated with a higher level of financial sustainability, i.e. government financing.
- Multivariate analysis found an adequate decision-making process, regional location (West Africa) and GNI per capita to be statistically significant in explaining financial sustainability.

5.2 Cash support

Twelve countries were using AD syringes in their immunization programs when they applied for INS support. These countries received cash rather than commodities for a three-year period.

5.2.1 Characteristics of countries

Ten of the 12 cash-recipient countries reached the end of the three years of support in 2005 or 2006 (Table 21). Two-thirds are from the EMR and AFR regions, followed by WPR and AMR.

Table 21. Characteristics of 12 cash recipients

Characteristics	Specifics	Number (%)
Year support ended	2004	2 (12)
	2005	4 (33)
	2006	6 (50)
GNI per capita (U.S.\$)	≤\$350	2 (20)
	\$350–700	3 (30)
	>\$700	5 (50)
	N/A	2 (20)
Regions	EMR	4 (33)
	EUR	0 (0)
	AFR	4 (33)
	SEAR	0 (0)
	WPR	2 (17)
	AMR	2 (17)

Source: Desk review

5.2.2 Utilization of cash support

Cash-recipient countries used GAVI funding to support injection safety activities in their programs. Four of the 12 countries used the support to reinforce the use of AD syringes and safety boxes through training, monitoring, supervision and/or evaluation. Three countries used the funding to construct incinerators for disposal of used syringes. Two countries used GAVI INS funding to purchase AD syringes and safety boxes from local manufacturers, per agreement with the GAVI Alliance. Table 22 describes the use of INS cash support by category of activity and country.

Table 22. Utilization of INS cash support by type of activity

How GAVI cash support was used	Number of countries	Comments
Injection safety support activities, including planning, training, supervision, monitoring and others.	4	<i>Afghanistan</i> : Planning, training, production of incinerators, surveillance, IEC and supervision, monitoring and evaluation <i>Djibouti</i> : Training, surveillance, incinerator renovation, medical education <i>Haiti</i> : Training and waste management <i>Honduras</i> : Renovation of vaccination rooms, furniture, portable needle destructors, training, monitoring and supervision
Construction and/or maintenance of incinerators	3	Ghana, Mauritania, Tanzania
Purchase AD syringes and safety boxes from local manufacturers	2	China and Vietnam, the latter used some funding for training, evaluation of trainings, and pilot study on management of used syringes
Purchase AD syringes and safety boxes internationally	3	Rwanda, Somalia, Yemen

Source: Annual Progress Reports, NIP managers' interviews and GAVI secretariate

Nine of the 12 countries used GAVI INS cash support for injection safety activities, such as training, construction of incinerators and local production. In the three countries that used the funding to purchase AD syringes and safety boxes internationally, GAVI made agreements to transfer cash to these countries because of their particular circumstances. In Somalia, for example, an agreement was made with UNICEF to purchase the syringes so that it could continue to provide commodities to a country which is considered "fragile." Another country—Yemen—had been using a World Bank loan to purchase AD syringes and was permitted to use GAVI INS cash support to replace this source of funding.

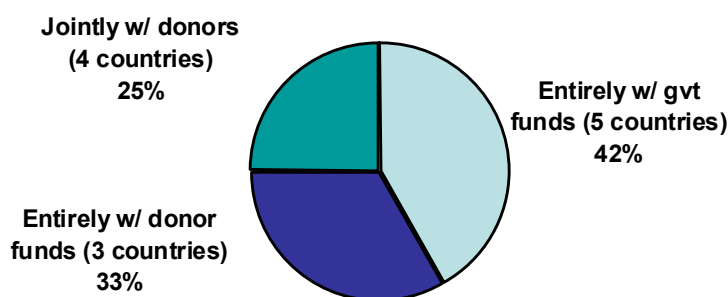
Rwanda's application for cash support stated that it would use the funding for improvements in waste disposal management, i.e., purchase and maintenance of incinerators, and other injection safety activities. However, the Rwandan Government (or its National Regulatory Authority) required the purchase of waste disposal technology that would comply with WHO requirements at that time. Because there was no such affordable technology that would meet those specifications, Rwanda received permission from the GAVI Alliance after its application was approved to use its cash support to purchase AD syringes instead.

5.2.3 Financial sustainability of INS cash support

Following the end of GAVI INS support, the 12 cash recipient countries continued to use AD syringes and safety boxes in their national immunization programs. Of the 12 countries, in 2008 approximately five purchased AD syringes and safety boxes with government funding only, four used a mix of donor and government funding, and three continued to rely exclusively on donor funding for their injection safety supplies (Figure 10).

Among the seven countries using some donor funding, three purchased AD syringes and safety boxes using a combination of government and donor support through a basket funding mechanism. Two of the countries—Vietnam and China—reported purchasing locally produced AD syringes and safety boxes with government funding. The other two are purchasing internationally.

Figure 10. Sources of funding used by cash recipients to procure AD syringes and safety boxes (2008)



Information was not available at the time of this evaluation to determine whether countries that used GAVI cash support for injection safety activities (versus commodity purchases) were able to find additional funding for these types of activities after INS ended.

Section Summary – Cash Recipients

- Half of the cash-recipient countries were in the wealthier (higher GNI per capita) category.
- Resources were used in 9 countries to support injection safety program activities such as training, supervision, health care waste management.
- Two of these countries also purchased AD syringes and safety boxes from local manufacturers.
- The other three countries were allowed to use their GAVI cash support to procure AD syringes and safety boxes internationally because of their particular circumstances.
- After INS funding ended, five of the 12 countries were procuring AD syringes and safety boxes with full government support, three were using a combination of government and donor support, and four were entirely donor dependent.
- Information about the replacement of INS cash support for injection safety activities (versus commodity purchases) was not available.

6. IMPACT ON THE BROADER HEALTH SECTOR

In this section, we present findings from all 58 GAVI INS countries in relation to the effects of INS support on the broader health sector. First, we present the findings on the extent to which injection safety practices were extended to other health services. Then, we discuss the impact of INS support on healthcare waste management and other health program logistics.

6.1 Introduction of injection safety practices into other health services

Forty-six program managers (80 percent) reported that GAVI INS had some influence (a little influence to very influential) on injection safety practices in health services beyond immunization. Seventeen percent said that AD syringes and safety boxes had been introduced into curative services and 34 percent stated that some element of injection safety had been introduced into one or more non-immunization services (Table 23). Health workers were also said to have reacted very positively to the new injection safety technologies (Box 4).

Table 23. Introduction of injection safety into other health services

Other Health Services	Number (%)
Introduction into other health services	
Full introduction into other services	10 (17)
Partial introduction	20 (34)
No introduction	27 (47)
No response	1 (2)
Injection safety component	
AD syringes	20 (67)
Safety boxes	5 (17)
Health care waste management	2 (7)
No information	3 (10)
Timing of introduction into other services	
Before end of INS support	9 (30)
During INS support	12 (40)
After INS support	9 (30)
Influence of GAVI's INS on other services	
Not at all influential	2 (3)
A little influential	3 (5)
Somewhat influential	13 (23)
Influential	13 (23)
Very influential	17 (29)
No response	10 (17)

Source: National program manager interviews

Of the 58 countries in the evaluation, respondents from 30 countries (52 percent) reported that they had used funding from PEPFAR, UNFPA, UNICEF and USAID to

Box 4. Health worker responses to the introduction of AD syringes and safety boxes

The interviews revealed positive reactions to the GAVI INS support by health workers and managers. A few excerpts from NIP manager interviews appear here:

- ◆ Bangladesh: The field workers took it very positively because this reduced their workload (i.e., the need to sterilize syringes and needles) and also ensured safe injection practices.
- ◆ Central African Republic: There was a good reaction from the health workers in the field. They were excited to use these new materials. They did not have to buy kerosene to re-sterilize the injection devices.
- ◆ Chad: The health workers were excited. They knew that with our HIV/AIDS programs how important this kind of training and equipment really was. The injection supplies were systematically used. The health workers were pleasantly surprised. Before, it was necessary to sterilize syringes with kerosene, etc. They were happy to have all of the necessary supplies.
- ◆ Democratic Republic of Congo: The health staff noticed less risk of contamination; it was a relief to have safer practices.
- ◆ Djibouti: The workers were reassured [by the safety boxes]. Before they didn't know what to do with the needles [and used syringes], where to put them.
- ◆ Sudan: A real satisfaction. Before, the health workers had to sterilize syringes and it took time and money for kerosene to sterilize. Also, they were happy to be protected with the new devices.

introduce AD syringes and/or safety boxes into health services, such as HIV/AIDS, family planning and TB services. Twenty-one (70 percent) out of 30 respondents stated that they introduced the AD syringes and/or safety boxes into other services during or after GAVI INS. When asked whether GAVI's INS support influenced the decision to introduce the AD syringes and safety boxes into other health services, 30 of 48 program managers stated that they were influenced or very influenced.

GAVI INS also influenced the development of injection safety policies in the health sector. Of the 39 countries that have a policy or are developing one, 85 percent of program managers stated that GAVI INS influenced the development of this policy. This is shown in Table 24.

Table 24 Influence of GAVI INS on health sector IS policies

Influence on Policy	Number (%)
Injection Safety Policy in Health Sector in 2008	
Has policy	35 (60)
Developing policy	4 (7)
No policy	16 (28)
No information	3 (5)
GAVI INS Influential in Policy Development	
Yes	33 (85)
No	6 (15)

Source: National program manager interviews

6.2 Impact of INS on HCWM and other program logistics

Concern about healthcare waste management (HCWM) is a relatively new phenomenon. Previously countries used steam sterilizers and injection equipment that had to be sterilized. Other countries used standard syringes that were re-usable or were used inappropriately. When AD syringes and safety boxes were introduced into immunization

programs, there was an increased burden on recipient countries to develop mechanisms to dispose of the large volume of used commodities.

Research for this evaluation indicated that most (72 percent) of the countries in the evaluation (42/58) had a policy on HCWM. These policies were reported to range from basic to relatively advanced, and included those that were nationally ratified and those (most) that existed but had not been ratified by the national government. In some countries, the HCWM policy had been developed by an environmental ministry or office other than the MOH. Based on the interviews conducted for this evaluation, countries are currently disposing of their used syringes and safety boxes using incinerators for waste disposal when available (usually, at large medical facilities and/or urban areas). Twenty-nine countries (50 percent) reported burning and burying their used syringes and safety boxes; 17 countries (29 percent) reported burning only; and 2 countries (3 percent) reported using other more advanced technologies (e.g. shredding and sterilizing).

Program managers in a third of the countries (19) stated that HCWM is an unresolved problem for their health systems. Sixteen reported a lack of incinerators, one cited difficulties maintaining incinerators, and two mentioned unsafe disposal of waste. When asked what GAVI could have done better when they introduced INS support, more than a third of the countries (20) stated that GAVI should have done more to prepare them for disposing of the waste generated by the introduction of AD syringes and safety boxes.

Three program managers reported that they were not prepared for the additional storage space requirements of the AD syringes and safety boxes. The managers reported that their warehouses and health facilities did not have adequate storage space for the larger volume presented by the new commodities. Similarly, three program managers had problems arranging transport to deliver the materials to the periphery. In addition, some countries mentioned difficulties accessing adequate transport to send used syringes and safety boxes for disposal to facilities having incinerators.

Eight of 58 program managers (14 percent) suggested that the three-year time period for INS was too short and that the application process was considerable for a three-year provision of support. Furthermore, the limit to three years resulted in a hurried search for sources of financing when GAVI funding was about to end, potentially risking an interruption of health services.

Section Summary

- Two-thirds of INS-recipient countries reported using AD syringes in their broader health services by the end of INS support
- Many EPI managers reported that health providers were introduced to AD syringes through the INS-supported immunization activities
- Most (85 percent) of the 39 countries with injection safety policies or policies under development thought GAVI INS support had influenced the adoption of those policies
- INS support also influenced the development of HCWM policies and raised awareness of HCWM problems/needs
- One-third of countries reported problems with HCWM; a few cited storage and/or transport problems managing the large volume of AD syringes and safety boxes

7. IMPACT AT THE GLOBAL LEVEL

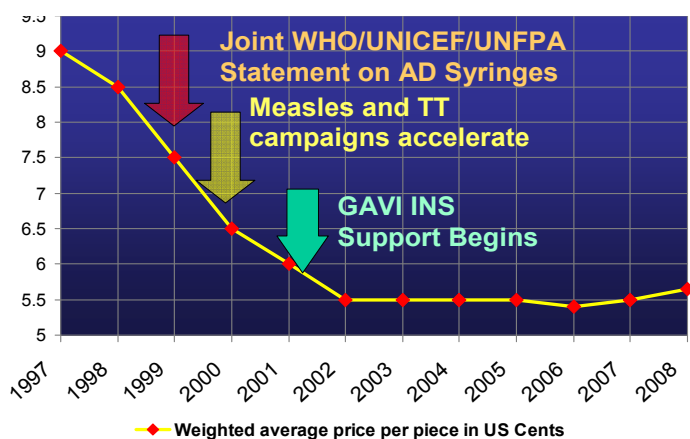
In this section, two issues are examined: (1) did the price of AD syringes decrease in response to the introduction of INS support; and (2) has the uptake of AD syringes and safety boxes been the same in lower-middle-income, non-GAVI countries as it has been in GAVI INS-recipient countries?

7.1 Price of AD syringes

Research for this evaluation revealed that demand for AD syringes has increased considerably since the technology was introduced to NIPs in the early 1990's. As described in the background, the increase was related to several developments within and external to national immunization programs. Two events in particular were very important: (1) the joint statement from WHO/UNICEF/UNFPA encouraging countries to use AD syringes for injections given by NIPs (Annex 1), and (2) the accelerated measles and tetanus toxoid campaigns that started around 2000. As a result of these and other forces, the number of suppliers of AD syringes rose from one supplier in 1992, to five suppliers of 0.5 ml AD syringes, two suppliers of BCG AD syringes, and two suppliers of safety boxes in 2005. The price also dropped during this period as a result of increased demand, as well as increased competition among the growing number of manufacturers.

The evaluation found that the GAVI Alliance's decision to procure and provide INS commodities increased the market for AD syringes and safety boxes worldwide, but had little effect on the price. (GAVI's share of the growing AD syringe and safety box market after 2000 is discussed in section 7.3.) From 1992 to 2001, the weighted average price of an AD syringe decreased from U.S.\$0.13 to U.S.\$0.06 (UNICEF Supply Division presentation). Despite the large increase in demand from the GAVI INS, however, prices have not declined since 2002 (see Figure 11).

Figure 11. Price of AD Syringes



Source: UNICEF Supply Division Procurement Records

7.2 Comparison of use of AD syringes in GAVI INS recipients with non-GAVI lower-middle income countries

The use of AD syringes is higher in GAVI INS-supported countries than in non-GAVI lower-middle-income countries (Table 25)¹⁴. However, it is not only the lack of eligibility for GAVI support that is affecting these countries. Discussions with regional WHO/UNICEF focal points indicate that some middle-income countries in the EUR and AMR do not perceive that AD syringes are necessary for their countries because they do not believe that their health facilities re-use single-use syringes. In EUR, program managers noted that the wealthier countries are not using AD syringes. However, data from this evaluation indicated that health ministry officials expressed interest in continuing to use AD syringes once they had been introduced into their country's immunization programs.

Table 25. Types of syringe used in GAVI INS countries and non-GAVI lower-middle income countries

Type of syringes used in immunization program	GAVI INS recipients	Non-GAVI lower-middle income countries
Fully using AD syringes	56 (96)	11 (41)
Using mixture of AD and non-AD syringes	1 (2)	10 (37)
Fully using non-AD syringes	1 (2)	6 (22)

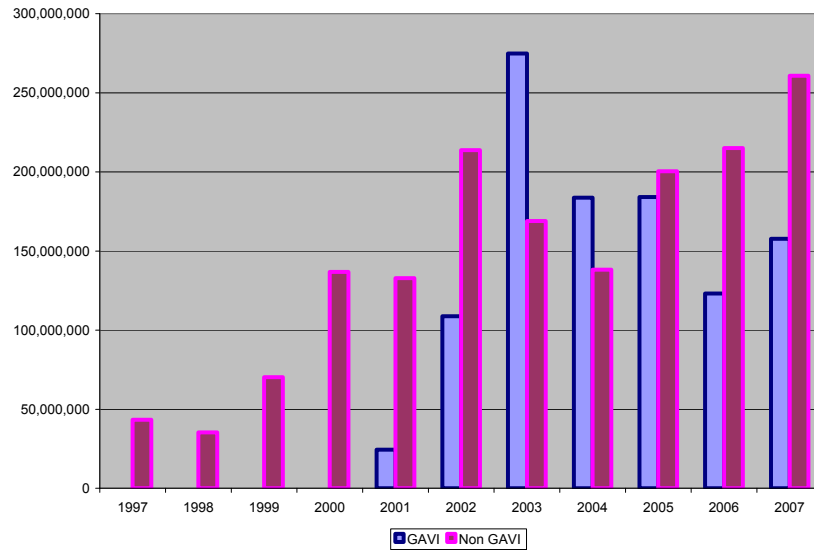
Sources: JRF 2007 and telephone interviews with program managers and WHO and UNICEF staff

7.3 Correlating evaluation findings with UNICEF Supply Division data

Data relating to the most commonly used size of AD syringe in immunization programs (0.5ml) for 51 countries of the 58 GAVI INS countries was provided by the UNICEF Supply Division (SD) and analyzed as part of the evaluation. UNICEF SD data are not disaggregated and do not distinguish between those provided by GAVI INS and GAVI new vaccines initiatives. Moreover, non-GAVI syringes are not divided into those used for routine versus mass campaign. Nonetheless, the data shows that overall non-GAVI supply has continually increased since 2004 (see Figure 12).

¹⁴ Lower-middle-income countries are defined by the World Bank as having per capita income between US\$936-US\$3,705.

Figure 12. 0.5 ml AD syringes for countries beginning support 2002, 2003 or 2004



The following three tables reflect the trends in supply of 0.5 ml AD syringes to the three groups of countries in this evaluation, according to the year that GAVI INS support started.

Figure 13. 0.5 ml AD syringes for countries receiving support in 2002 - 2004

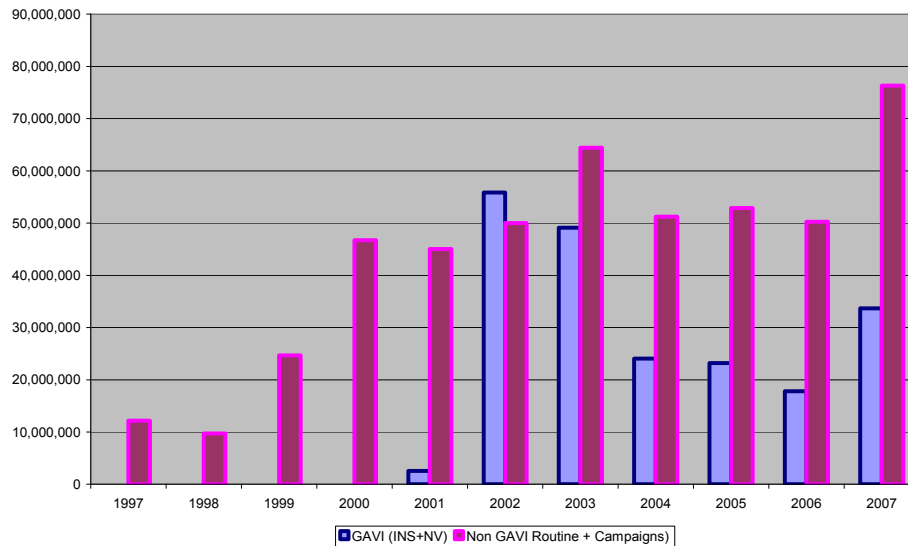


Figure 14. 0.5 ml AD syringes for countries receiving support in 2003 - 2005

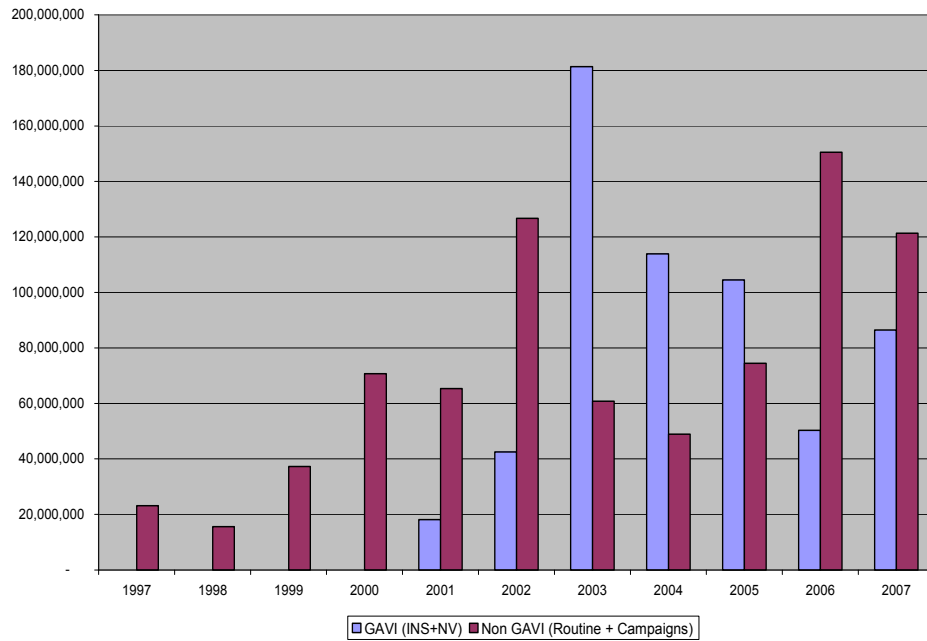
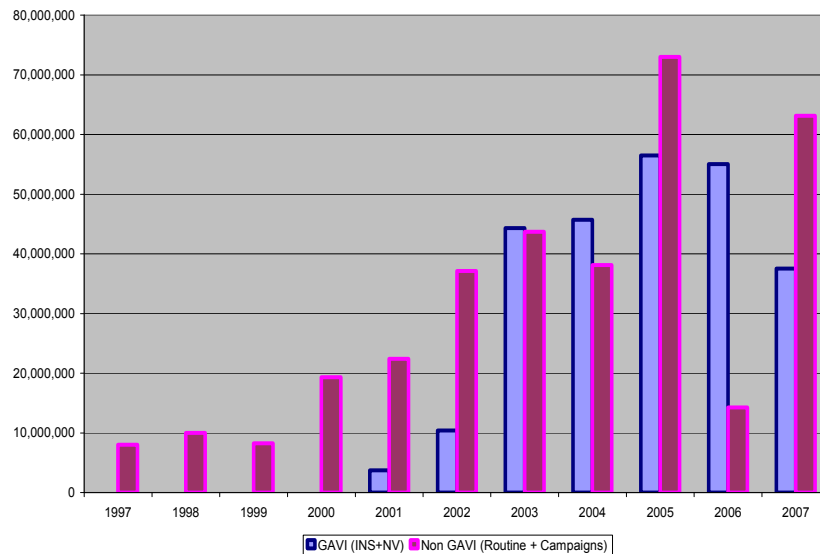


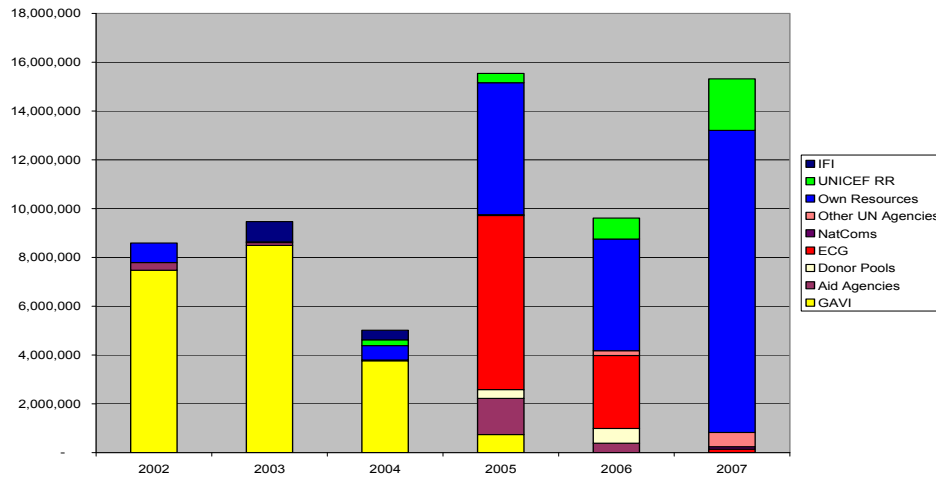
Figure 15. 0.5 ml AD syringes for countries receiving support in 2004 – 2006



It is possible to see the more direct influence of GAVI's INS program by observing the trend for BCG AD syringes, since they are not procured through the GAVI NV funding window or for campaigns. Therefore, it is reasonable to assume that the replacement of

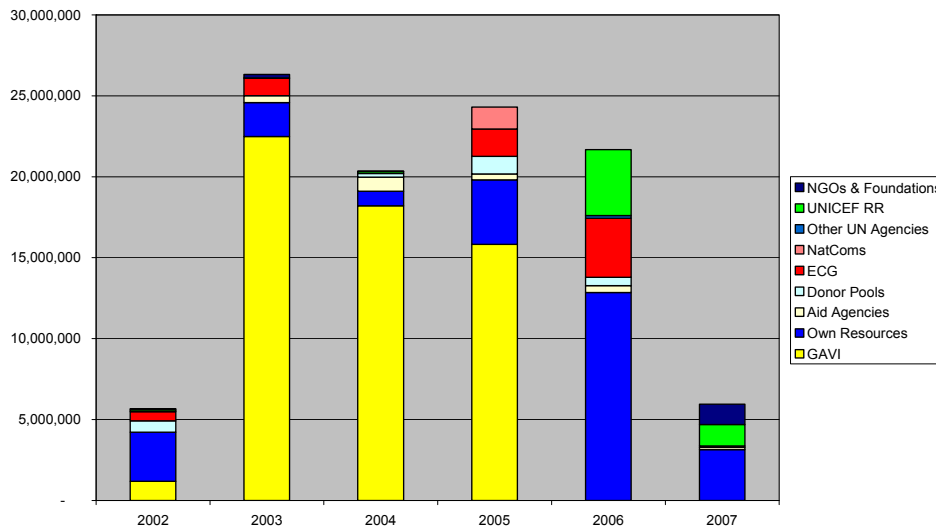
0.5ml syringes is similar to the replacement of BCG syringes, as shown in Figure 16. Fourteen countries out of 15 (data not available for Djibouti, which received cash) that started receiving GAVI INS support in 2002 not only fully replaced the supply but also increased the volume for the three years after the GAVI support ended.

Figure 16. Supplies of BCG AD syringes by source of funding for countries starting INS in 2002



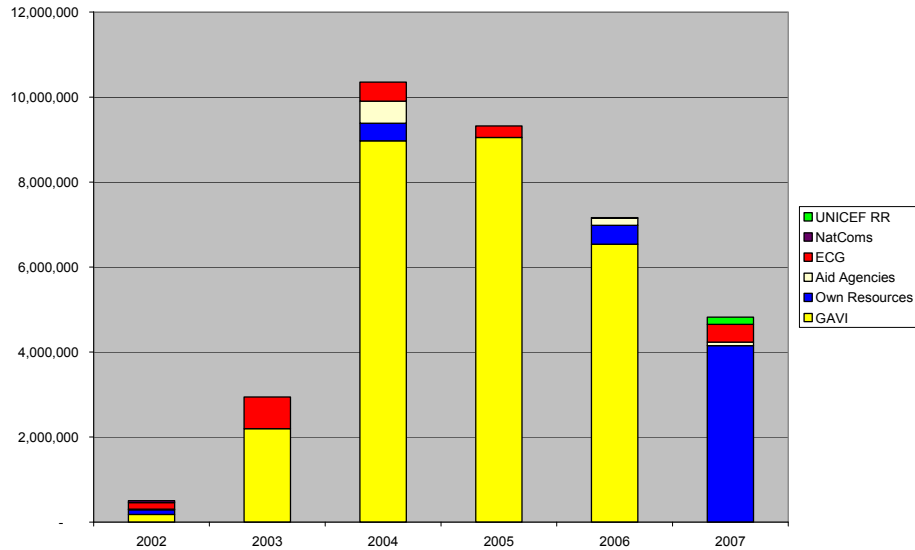
For the second group of countries that started receiving GAVI INS support in 2003, 19 out of 21 countries (data not available for Rwanda and Ghana, which received cash), showed the overall volume increased in 2006, the first year after the end, but decreased in 2007. This decrease may be attributed to incomplete data (see Figure 17).

Figure 17. Supplies of BCG AD syringes by source of funding for countries starting INS in 2003



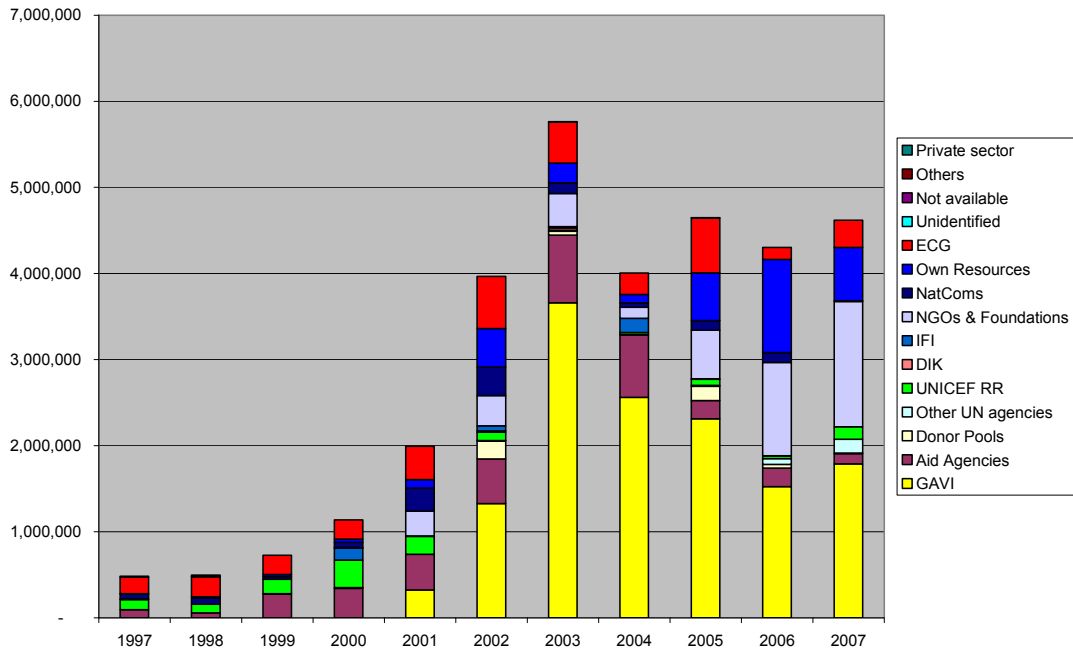
A similar trend of increased government/donor contribution can also be observed for countries where support ended in 2006 (Figure 18).

Figure 18. Supplies of BCG AD syringes by source of funding for countries starting INS in 2004



The volume of safety boxes from all sources has doubled in evaluated countries since the beginning of INS support. For the last four years, the decrease in volume from GAVI (INS and NV) has been compensated by governments and other partner (Figure 19).

Figure 19. Source of funding for Safety boxes for countries that started INS between 2002 and 2004



Section Summary

- The cost of AD syringes decreased prior to the initiation of the GAVI INS support.
- Utilization of AD syringes in immunization programs was found to be higher among INS recipients than among non-GAVI, lower-middle-income countries.
- To cross-check country reports, the evaluation used UNICEF Supply Division data to analyze trends in 0.5 ml and 0.05 ml AD syringes used in immunization programs.
- As the volume of GAVI-funded AD syringes and safety boxes has ended in recent years, the volume purchased from UNICEF SD by non-GAVI sources (i.e., host-country governments and other partners) has increased.

8. DISCUSSION AND RECOMMENDATIONS

GAVI facilitated and accelerated the introduction of a new technology—AD syringes and safety boxes—to resource-constrained countries by providing a window of support for injection safety. GAVI funding came at an opportune time as the new AD technology had been approved by WHO in the early 1990s. Yet, some GAVI-eligible countries were not fully aware of the advantages of the new technology, and there were disincentives that discouraged the introduction of AD syringes, the primary one being higher cost and the need for training of the health workers who had to use them.

There was apprehension among some that because GAVI INS support was limited to three years, some of the recipient countries might not be able to continue financing the AD syringes after GAVI INS ended. Our evaluation of INS sustainability found these fears to be unjustified. The survey showed almost all countries receiving the support (96 percent) continued to procure and utilize AD syringes and safety boxes in the year(s) after the GAVI support came to an end. In addition, more than half of the countries surveyed are fully paying for the AD syringes and safety boxes with government funding.

Some of the reasons why this GAVI program succeeded are: (1) AD syringes are now only slightly more costly than standard disposable syringes; (2) relative to other immunization costs such as vaccines, INS requires significantly less resources; (3) most countries had good decision-making processes in place; and (4) growing recognition of the magnitude of unsafe injections; and (5) global and regional partners (WHO, UNICEF, and the EU) have successfully advocated for the use of AD syringes at meetings and with the countries' MOHs, particularly in the AFR and WPR regions.

Despite the success of the GAVI INS support, the evaluation team identified a number of lessons learned and ways that the INS effort can be built upon and improved by GAVI, and that have relevance for other initiatives that include a dimension of new technology introduction.

1. Broadened Decision-Making – The Evaluation of GAVI's Injection Safety Support found that the countries of West Africa were particularly successful at replacing GAVI support with government funding. Of the 11 countries in the region, nine are purchasing the AD syringes and safety boxes fully with government funding. The remaining two are procuring the supplies with a mixture of government and donor funding for the immunization programs. Some potential explanations for the self-sufficiency of West African countries in purchasing AD syringes and safety boxes include: (1) budget support from the EU and other donors; these donors have urged the MOH to introduce line items in their budgets for vaccines and safe injection safety supplies; (2) strong regional support from WHO and UNICEF to the countries, during their planning process, to continue using AD syringes; and (3) performance-level comparisons among national EPI managers at regional EPI meetings, creating a form of competition and peer pressure.

RECOMMENDATION: GAVI and partners should continue to encourage country-level program managers and external partners to be part of the decision-making for introduction and sustained use of new technologies as they did in the INS support program in West Africa.

2. Local Production - Two countries from the EUR region partially or fully discontinued use of AD syringes and safety boxes because of unique circumstances. One country has local production of non-AD syringes (Ukraine) and preferred to purchase the less costly locally produced disposable syringes when the GAVI funding ended. The situation might have been different had the country been provided technical assistance, allowing them to convert and up-grade the local production facility to manufacture AD syringes. This was done in Bangladesh which is now producing and using the safer AD syringe (see Box 2 for a description of what took place in Bangladesh). The survey of the INS countries indicated a high degree of interest in developing or improving the capability to produce commodities such as safety boxes in-country or regionally.

RECOMMENDATION: GAVI should promote a close partnership between national immunization program managers and syringe manufacturers to advocate for and facilitate local production of new technologies where economically feasible.

3. Decentralization - A second EUR country (Uzbekistan) partially discontinued AD syringes in three-quarters of its health facilities. This country has decentralized procurement and only a limited number of oblasts are purchasing AD syringes. This finding suggests that more advocacy, at both the national and local administrative levels, is required in countries with decentralized procurement. This is a finding that partners should keep in mind as more countries decentralize and local authorities are required to determine how scarce resources are to be expended.

RECOMMENDATION: GAVI should develop strategies to advocate and build capacities for centralized procurement of essential medical supplies and, if needed, build capacities for local authorities that are responsible for procuring commodities (including syringes and safety boxes) in countries committed to decentralized procurement.

4. Comprehensive Approach – It takes a comprehensive approach to introduce a new technology, such as AD syringes, to ensure that countries are fully prepared. It is necessary to anticipate what assistance program managers will require in training, logistics, supervision, monitoring, behavior change, advocacy, and management as well as what additional warehousing, transport or waste disposal may be needed. The GAVI INS support to the commodity recipient countries was limited to the supply of materials. NIP managers had to identify other sources of financing for other expenses associated with the introduction. For example, they had to design and implement trainings for health workers on the use of the new supplies.

Since 2004, the MMIS project in 11 PEPFAR countries has implemented a comprehensive program which includes health worker training, awareness building and behavior change among the public, advocacy, capacity building in procurement and logistic support and health care waste management. This program has been highly successful in introducing new IS technology and practice to the broader medical area. One measure of the project's effectiveness is that countries like Kenya and Uganda have now adopted and are implementing a policy that mandates that only AD syringes can be imported and used in the public health services.

RECOMMENDATION: When introducing a new technology, it is suggested that GAVI consider supporting a more comprehensive approach beyond commodity support to ensure that countries are fully prepared.

5. Waste Management - The Evaluation of GAVI's Injection Safety Support identified considerable demand for financial and technical support in strengthening health care waste management. There was an expressed/felt need by a large portion of national immunization program managers interviewed, as well as many regional WHO/UNICEF focal persons, that waste management was a serious and growing problem that urgently needed addressing. Program managers stated that they were not prepared for the additional waste management requirements imposed by AD syringes. Even though some countries received technical assistance and donor support to construct incinerators through non-GAVI initiatives (such as through disease-specific campaigns), they were too small, constructed with inappropriate materials, over-used, poorly managed, and broke down easily. Most of these are no longer in use.

Some WHO/UNICEF regions and donors have intervened to assist countries with their waste management issues—e.g., WHO/EURO financed interventions in seven countries in the region. Another recent GAVI/WHO initiative is helping 18 countries, mostly in Africa, conduct assessments and develop waste management plans. However, funding is not available to turn these plans into reality. Waste management of AD syringes and safety boxes remains an unresolved issue in the vast majority of countries that participated in the GAVI INS support project.

RECOMMENDATION: In concert with other partners and programs, GAVI should consider developing and launching a stand-alone support project to assess, plan, and implement health care waste management efforts in participating countries.

6. Monitoring Implementation - GAVI INS has been influential in extending injection safety practices and use of AD syringes and safety boxes into the broader health sector, particularly for HIV/AIDS and family planning services and, in many cases, curative care. More than half the GAVI INS recipients have introduced some aspect of injection safety into other health services; 90 percent felt that GAVI INS had influenced this introduction. Many program managers also stated that GAVI INS was an important influence on the development of injection safety policies in the health sector.

The INS evaluation found the regional officers for WHO and UNICEF were very familiar with operations in the countries under their jurisdiction and were invaluable not only in verifying country-level information but also providing deeper insight into what is happening at the country level and why.

Nevertheless, the Evaluation revealed some gaps in GAVI's monitoring of the project. Because GAVI did not follow-up with countries regarding AD syringe and safety box use after INS funding ended (except through the APRs), it was not aware that one country had stopped using the supplies altogether and another had partially stopped. In addition, one of the cash support countries, Rwanda, apparently used the GAVI INS funds to purchase AD syringes and safety boxes internationally, thereby replacing government and/or external partner funding for these commodities which is against GAVI guidelines.

RECOMMENDATION: GAVI should develop mechanisms to monitor more closely the progress of its interventions both during implementation and soon after funding has ended and establish closer links with WHO/UNICEF regional offices for purposes of getting effective feedback on program operations.

7. Documentation - The GAVI INS has been a successful, time-limited mechanism to introduce an important technology, AD syringes and safety boxes, to improve the health of populations in lower-income countries by reducing blood borne pathogen transmission. GAVI and other organizations trying to introduce new technologies can learn some important lessons and best practices from the introduction and implementation of this experience.

RECOMMENDATION: GAVI should commission the preparation of a monograph to document its experience designing and implementing its INS support effort to educate other partners on how to develop sustainable time-limited programs to introduce a new technology at scale.

8. Supply data – Our analysis of the aggregated data provided by the UNICEF Supply Division identified some interesting trends for BCG syringes (used as a proxy indicator for country uptake of GAVI INS support). The review of this data proved to be very revealing and substantiated data collected from other sources. It is possible that similar trends exist if the data were disaggregated and studied.

RECOMMENDATION: It is suggested that if GAVI is interested to know more about procurement of AD syringes post INS support, they arrange for further analysis of the existing UNICEF Supply Division data.

Section Summary

The main recommendations are:

- Country managers and external partners should be part of decision-making process regarding replacement of new technologies.
- Country managers and external donors should advocate for/facilitate local production of new technologies.
- Where decentralization exists, GAVI should build local procurement capacities.
- When introducing a new technology, GAVI should support a comprehensive approach (including training).
- GAVI should consider a stand-alone project to support the health care waste management efforts.
- GAVI should strengthen monitoring mechanisms, including closer collaboration with UNICEF/WHO regional offices.
- GAVI should document lessons learned on how to develop sustainable technology interventions.
- GAVI could consider analyzing disaggregated UNICEF supply data.

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Annex 1: Safety of Injections: WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization

WHO/V&B/99.25
ORIGINAL: ENGLISH
DISTR.: GENERAL

Safety of injections

WHO-UNICEF-UNFPA joint statement* on the use of auto-disable syringes in immunization services

1. The reuse of standard single-use disposable syringes¹ and needles places the general public at high risk of disease and death.
2. The auto-disable syringe, which is now widely available at low cost, presents the lowest risk of person-to-person transmission of blood-borne pathogens (such as Hepatitis B or HIV) because it cannot be reused. The auto-disable syringe is the equipment of choice for administering vaccines, both in routine immunization and mass campaigns.
3. "Safety boxes", puncture-proof containers - for the collection and disposal of used disposable and auto-disable syringes, needles and other injection materials - reduce the risk posed to health staff and the general public by contaminated needles and syringes.
4.
 - WHO, UNICEF and UNFPA reaffirm the current policy that auto-disable syringes, vaccines and safety boxes should continue to be supplied as a "bundle" (see box, page 4) for all elective and emergency campaigns.
 - UNICEF reaffirms its current policy that UNICEF programme funds cannot be used to procure standard disposable syringes for any immunization purpose.
 - UNICEF announces that, as of 1 January 2001, no procurement service contracts² for standard disposable syringes will be entered into.
 - WHO, UNICEF and UNFPA urge that, by the end of 2001, all countries should use only auto-disable syringes or syringes which are designed to be sterilized. Standard disposable syringes should no longer be used for immunization.
 - WHO, UNICEF and UNFPA urge that, by the end of 2003, all countries should use only auto-disable syringes for immunization.
5. All partners of immunization services are requested to finance not only the vaccines, but also the safe administration of vaccines, auto-disable syringes and safe management of waste. Partners should do this by planning and implementing the above strategy, as well as by supporting related training, supervision and sensitization activities.



*This joint policy statement revises and replaces the document *WHO-UNICEF policy statement for mass immunization campaigns*, WHO/EPI/LHIS/97.04 Rev.1. It is issued by the World Health Organization, Geneva, Switzerland (Department of Vaccines and Biologicals), the United Nations Children's Fund (UNICEF Programme Division, New York, USA and UNICEF Supply Division, Copenhagen, Denmark) and the United Nations Population Fund, New York. This policy is also the adopted practice of the International Federation of Red Cross and Red Crescent Societies in their operations.



Background

Information reaching WHO, UNICEF and UNFPA consistently highlights the widespread occurrence of unsterile injection practices and identifies a major cause as insufficient supplies of syringes and needles³. Unsafe injections can result in the transmission of blood-borne pathogens from patient-to-patient, patient-to-health worker and, more rarely, health worker-to-patient. The community at large is also at risk when injection equipment is used and then not safely disposed of. In many instances, used equipment is reused, sold or recycled because of its commercial value. The imperative to improve safety of injections in immunization services is underlined by the publication of articles in the *WHO Bulletin* (October 1999) which show that, although immunization injections are thought to be safer than curative injections, around 30% of immunization injections are still unsafe. Much evidence of reuse of disposable syringes exists and even recent country reviews suggest that sterilization of syringes and maintenance of sterilization equipment is not systematic.

Last year, in the developing world, routine immunization of children under one year and immunization of women of childbearing age with tetanus toxoid (TT) accounted for over one billion injections. In addition to routine immunizations, measles control/elimination activities and disease-outbreak control operations together delivered more than 200 million injections in the same year.

Hepatitis vaccine is now in use in half of the developing countries and Hib, measles-mumps-rubella (MMR) and pentavalent vaccines are already widely used in the Americas. Acceleration of special activities which aim at the elimination of maternal and neonatal tetanus and at better control of measles has begun. And a Global Alliance for Vaccines and Immunization (GAVI) is being formed to assure access to new vaccines for many of the poorest countries where the vaccines are needed most.

These increases of immunization services, including the elimination and control campaigns, offer an opportunity for improvement and make it imperative that injections are made safe for people.

The disease burden associated with unsafe injection practices has been estimated⁴ and the cost implications of treatment of these diseases has been quantified⁵. Each unsafe injection costs governments between three to five times the extra cost of auto-disable syringes (which guarantee a sterile injection), not to mention the toll in terms of human suffering.

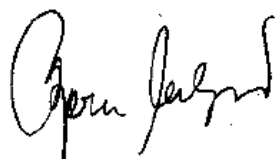
Strategy

Over the past years, WHO, UNICEF and UNFPA have launched a number of initiatives which aim to improve the safety of injections. The most recent was the precursor to this joint statement in 1997⁶ which related to the use of auto-disable syringes and safety boxes in immunization campaigns. That policy has assured the simultaneous budgeting and parallel purchasing and shipping of sufficient syringes and safety boxes for each consignment of vaccines for mass campaigns. Now, with a broad experience of the use of this equipment in the field, is the time to consolidate a policy to cover all administration of vaccine.

WHO and UNICEF have agreed to implement a strategy to ensure that special attention is paid to the safe administration of vaccines, both in routine immunization services and during mass campaigns. The policy statement (*on page 1*) defines the position of WHO and UNICEF and is intended as a guide to other partners of immunization services, including national ministries of health.

In addition to this policy statement, WHO and UNICEF recommend that:

- Countries exert maximum effort to ensure that procedures for injection safety are rigorous -this includes routine use and monitoring of indicators of sterilization while sterilizable equipment is still used. Partner agencies involved in immunization programmes in countries should provide maximum support for the strengthening of safe injection practices.
- Urgent attention be given to develop appropriate tools (current monitoring tools are still insufficient to objectively demonstrate compliance to safe injection practices).
- Agencies supporting immunization services be encouraged to provide time-limited financial support to countries procuring standard disposable syringes for immunization until government-won budgets can be increased to cover the additional cost of auto-disable syringes.
- Agencies supporting immunization services which fund the purchase of locally-manufactured standard disposable syringes for immunization should assist countries with technology transfer to enable them to switch to auto-disable syringes in the shortest possible time.
- Used auto-disable syringes should be deposited in safety boxes without re-capping, burned locally and the remains buried underground - until improved disposal methods are developed. Urgent attention should be given to develop improved means for effective, safe and environmentally-acceptable waste processing and final disposal of auto-disable syringes.



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Cooperation and Development (NSCD),
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& Red Crescent Societies

FOOTNOTES

- ¹ Auto-disable (A-D) syringes conform to the WHO/V&B Performance Specifications E8/DS1 and DS2 and include pre-filled pouch-and-needle injection devices. This statement applies only to available supplies of A-D syringes.
- ² UNICEF procurement service contracts cover the procurement of supplies and equipment by UNICEF as a service to governments and other organizations.
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- ⁶ Safety of Injections: WHO-UNICEF policy statement for mass immunization campaigns, WHO/EPI/LHIS/97.04 Rev.1 – replaced by this statement, WHO/V&B/99.25.

The term “bundling” has been chosen to define the concept of a theoretical “bundle” which must comprise each of the following items:

- Good quality vaccines
- Auto-disable syringes
- Safety boxes

The implication is that none of the component items can be considered alone; each component must be considered as part of a “bundle” which contains the other two. “Bundling” has no physical connotation and does not imply that items must be “packaged” together.

Copies and information may be requested from:

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Department of Vaccines and Biologicals, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Phone: +41 22 791 4374; Fax: +41 22 791 4192; E-mail: vaccines@who.int

United Nations Children's Fund (UNICEF)

3 United Nations Plaza, New York, NY 10017, United States of America
Phone: +1 212 824 6313; Fax: +1 212 824 6460; e-mail: ssakai@unicef.org

United Nations Children's Fund (UNICEF)

Supply Division, Freeport, 2100 Copenhagen Ø, Denmark
Phone: +45 35 27 35 27; Fax: +45 35 26 94 21; E-mail: sdpublications@unicef.dk

United Nations Population Fund (UNFPA)

Technical and Policy Division, 220 East 42nd Street - 17th floor, New York, NY 10017, United States of America
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International Federation of Red Cross and Red Crescent Societies (IFRC)

Case postale 372, CH-1211 Geneva 19, Switzerland
Phone: +41 22 730 42 22; Fax: +41 22 733 0395; e-mail: secretariat@ifrc.org

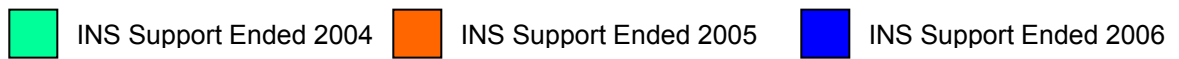
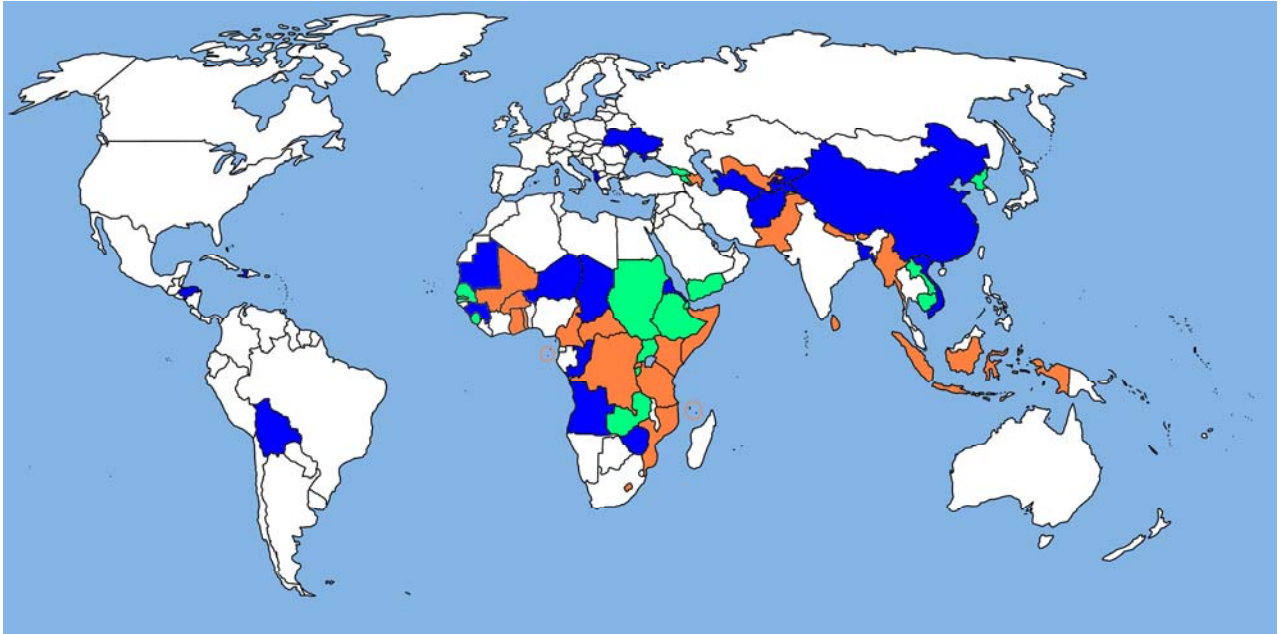
Ordering code: WHO/V&B/99.25. Printed: December 1999

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Annex 2: Map – Countries receiving GAVI INS support



Annex 3: List of countries receiving GAVI INS support (by year)

All GAVI-Eligible Countries

Years of GAVI Injection Safety Support						GAVI-Eligible Countries Not Receiving INS Support
Included in this Evaluation			Not Included in this Evaluation			
2002-2004	2003-2005	2004-2006	2005-2007	2006-2008	2007-2009	
Armenia	Azerbaijan	Afghanistan(cash)	Benin	Bosnia*	Côte d'Ivoire	Guyana
Burundi	Bhutan	Albania*	Guinea Bissau	Cuba	Nigeria	Kiribati
Cambodia	Burkina Faso	Angola	India	Liberia		Papua New Guinea
Djibouti (cash)	Cameroun	Bangladesh	Moldova (cash)	Madagascar		Solomon Islands
Ethiopia	CAR	Bolivia	Mongolia	Malawi		Timor-Leste
Gambia	Comoros	Chad	Nicaragua			
Georgia	Congo DR	China* (cash)				
Korea DPR	Ghana (cash)	Congo				
Lao PDR	Indonesia	Eritrea				
Senegal	Kenya	Guinea				
Sierra Leone	Lesotho	Haiti (cash)				
Sudan	Mali	Honduras (cash)				
Uganda	Mozambique	Kyrgyz Rep				
Yemen (cash)	Myanmar	Mauritania (cash)				
Zambia	Nepal	Niger				
	Pakistan	Sri Lanka				
	Rwanda (cash)	Tajikistan				
	São Tomé	Turkmenistan*				
	Somalia (cash)	Ukraine				
	Tanzania (cash)	Vietnam (cash)				
	Togo	Zimbabwe				
	Uzbekistan					

(*) These countries became ineligible for GAVI Support in 2006.

Annex 4: Analysis plan for GAVI INS Support Evaluation

Analysis Plan for GAVI Injection Safety Support

Introduction

In this analysis, we analyze the extent to which countries were able to replace the GAVI catalytic funding for AD syringes and safety boxes. We also looked at the broader positive and negative impacts of the injection safety support on the entire health sector.

Analysis of Sustainability of Injection Safety Support

To analyze the data collected through the desk review and telephone interviews, a number of variables were examined to determine the sustainability of injection safety support, including—

1. level of sustainability of injection safety support
2. strength of national immunization program planning/logistical capacities and leadership
3. availability/capacity of health workers
4. government commitment to injection safety
5. program financing
6. existence of health system reforms such as sector-wide program, decentralization, and/or integrated system
7. political/economic stability.

Table 1. Sustainability Variables for Injection Safety Support

Score/Range	Level of Sustainability for Injection Safety Support In a Country's National Immunization Program
1	Discontinued use of AD syringes and safety boxes
2	Dependent on donors to finance; short donor commitments
3	Donor(s) are financing AD syringes and safety boxes, medium to long commitment
4	Government is financing a portion of the expenditures
5	Government is financing all AD syringes and safety boxes
	Strength of NIP Planning/Logistical Capacities and Leadership
1-5	Score based on availability of national plan for injection safety and its follow through, adequacy of planning for replacement, adequacy of logistics for injection safety, and champion for injection safety identified
	Availability/Capacity of Health Workers
1-3	Score based on existence of initial training on injection safety, refresher trainings in injection safety, pre-service training on injection safety, and health workers' reaction to introduction of injection safety materials
	Government Commitment to Injection Safety
1-3	Score based on availability of policies for injection safety and waste management; also extent to which government considers injection safety a priority

	National Immunization Program Financing
1-3	Score based on the percentage of NIP that is financed by the government; the number of external donors, other than UNICEF and WHO; adequacy of financing for program
	Existence of Health System Reforms Such as Sector Wide Program, Decentralization, and/or Integrated System
0-1	Indicator of major health system reform/structural factor that is affecting funding available for national immunization program
	Political/Economic Stability
0-1	Indicator of whether country is considered a <i>country in crisis</i> , such as having a civil war or economic crisis

Frequencies were run on the identified variables for the 58 countries. Additionally, countries were stratified according to the following criteria: (1) the year support ended, (2) the level of sustainability as scored according to the variables in table 1, (3) the GNI per capita (GNI per capita < 350 and GNI per capita > 350), (4) by region, and (5) presence of political conflict. Further, countries were analyzed according to whether their support was for materials (46 countries) or in cash (12 countries). Frequencies were run on all of the sub-groups.

We also assessed whether there are statistically significant correlations among variables with a high level of sustainability. For example, if they examined whether the government commitment to injection safety is associated with the level of sustainability of injection safety support. We also ran regression analyses of the sustainability level on selected variables, pending sample size and controlling for other variables.

Analysis of Impact of GAVI Injection Safety Support on the Broader Health Sector

To assess the impact of GAVI Injection Safety Support on a country's broader health sector, frequencies were run on the variables from Section G in the telephone questionnaire (see the questionnaire in the attachments). In some cases, the analysis included relevant documentation from other sources, for example, identify an example or leave this out. The analysis assessed the number of countries that extended their injection safety to other parts of the health sector and determined the number of countries that have introduced AD syringes and safety boxes to health services outside the national immunization program, such as curative care, clinical services, or family planning services. This assessment identified when injection safety measures were extended to other services in order to determine whether GAVI's funding had a catalytic effect on the introduction of a new technology.

The evaluation ran frequencies to examine the extent to which GAVI INS had positive affects on the health sector. For example, we assessed the number of countries that have introduced training on injection safety at various levels within the system through pre-service training, in-service training, and refresher trainings. We also examined the number of countries that have introduced preventive health measures, such as hepatitis B injections for health workers and post-exposure prophylaxis (PEP) procedures for needle stick injuries. Further, our evaluation identified the number of countries that have started producing their own AD syringes and safety boxes, and whether that country's national immunization program uses these products.

The evaluation also identified factors that could be potential constraints to a broader use of AD syringes and safety boxes in the broader health care sector, such as import taxes that made injection safety materials expensive.

Finally, the evaluation examined the extent to which there were negative affects when AD syringes and safety boxes were provided—examples include issues related to health care waste management, as well as feedback related to funding for national immunization programs and not other programs.

Annex 5: Desk review framework

GAVI INS Evaluation Data Collection Phase I: Desk Review

The evaluation team conducted a desk review during the first phase of data collection, drawing from documents provided by the GAVI Secretariat as well as documents available in the public domain. For each country in the evaluation, both qualitative and quantitative data were recorded to provide background information on:

1. *Basic demographic indicators*
2. *The national immunization program, including waste management practices*
3. *The 3 year progression of GAVI INS support*
4. *Financing for immunization and injection safety activities*

The team used the findings of the desk review to become familiar with the injection safety situation in each country before interviewing national EPI managers.

Sources for each country's desk review data included the following, if available:

1. GAVI Injection Safety Support Application
2. Country Injection Safety Plan (if provided with application)
3. WHO/UNICEF Joint Reporting Form (JRF) (2007)
4. Annual Progress Reports beginning the first year of INS support through 2006
5. Minutes of Inter-agency Coordinating Committee (ICC) Meetings
6. Independent Review Committee (IRC) Monitoring Reports
7. Financial Sustainability Plans (FSP); Comprehensive Multi-Year Plans (cMYP)

Other sources consulted included:

1. World Bank Statistics (for demographic data)
2. Country-specific WHO Data (for immunization financing and demographic data)
3. Spreadsheet provided by GAVI Secretariat detailing disbursements of funds by country, type of support, and year
4. Reports from the Making Medical Injections Safer (MMIS) project

For relevant data points, longitudinal data were included for comparison. These points included immunization coverage (since 2003), basic demographic indicators (since 2000), child and infant mortality (by decade since 1960 and by year since 2004), and JRF immunization program indicators (since 2001).

Appearing here in the same order as in the Desk Review Database, the following data points were collected and included for analysis:

Section 1: Application Information
Sources: INS Application, GAVI Disbursement Spreadsheet
Year of INS Application Approval
Year INS Support Began
Date of Last Injection Safety Support
Type of Support received (materials vs. cash)
Amount of Support Received
Years of Immunization Service Support
Years of New Vaccine Support (specify vaccine)
Years of HSS Support

Section 2: Demographic Data
Sources: WHOSIS, WHO Immunization Profile, World Bank Data
Total population (2000-2006)
Live births (2000-2006)
Surviving infants (2000-2006)
Pop. less than 5 years (2000-2006)
Pop. less than 15 years (2000-2006)
Female 15-49 years (2000-2006)
Probability of dying (per 1 000 live births) under five years of age (Child) (1960-2007)
Infant mortality rate (per 1 000 live births) (1960-2007)
GNI per capita, Atlas method (current US\$) (1960-2007)

Section 3: Vaccine Data
Sources: JRF, GAVI Website
Vaccine schedule and whether the vaccine is funded by GAVI (2005-2006)
Immunization coverage by vaccine (2003-2007)

Section 4: Injection Safety Plan and National Policies
Sources: INS Application, Injection Safety Plan
Injection Safety Plan available?
Strategies & Activities Proposed? Includes training? Destruction of Used Injection Equipment?
Secure Required Budget?
What specific performance indicators are included?
Is there a national safe injection policy? (at time of application)
Is there a national waste management policy? (at time of application)

Section 5: APR Data and Waste Management
Sources: Annual Progress Reports
Progression of transition plan for safe injection and safe management of sharps waste
Problems encountered during the implementation of the transitional plan for safe injection and sharps waste (only in 2006)
Statement on use of GAVI Alliance injection safety support (if received in the form of a cash contribution)
Report on how sharps are disposed (only in 2006)
Use of ISS for injection supplies, IS training, etc.

Section 6: Inter-agency Coordinating Committee Information
Sources: ICC Minutes, APR's
of ICC Meetings per year (only in 2006)
Who is part of the ICC? MOH Program Managers? EPI Manager? WHO? UNICEF? DFID? JICA? CIDA?
In ICC minutes, was there discussion of AD syringes and waste management?
Was a plan for continuation of injection safety materials discussed?

Was there discussion of use of INS support?

Section 7: Joint Reporting Form Injection Safety Indicators

Sources: JRF

Was there an activity work plan for (a) immunization injection safety? (Yes/No/NA) (2001-2006)

Was there an activity work plan for (b) waste management? (Yes/No) (2001-2006)

Sterilizable: Type of injection equipment used for routine immunizations (Yes/No) (2001-2006)

AD syringes: Type of injection equipment used for routine immunizations (Yes/No) (2001-2006)

Non AD disposables: Type of injection equipment used for routine immunizations (Yes/No) (2001-2006)

Are safety boxes distributed with all vaccine deliveries (Yes/No) (2001-2006)

National policy regarding disposal: Incineration (Yes/No) (2001-2006)

National policy regarding disposal: Open burning (Yes/No) (2001-2006)

National policy regarding disposal: Burial (Yes/No) (2001-2006)

National policy regarding disposal: Other (Yes/No) (2001-2006)

National policy regarding disposal: No policy (Yes/No) (2001-2006)

Section 8: Independent Review Committee Reports

Source: IRC Reports

Were IRC Reports from 2004, 2005, and 2006 complete and available?

What comments about the sustainability of the INS support were made, if any?

Section 9: Immunization Financing Indicators and System Factors

Sources: JRF, WHO Immunization Financing Website, FSP, cMYP, World Bank Data

Was there a line item in the national budget for purchase of vaccines used in routine immunizations? (Yes/No) (2001-2006)

Was there a line item in the national budget for purchase of injection supplies (syringes, needles, sharp boxes) for routine immunizations? (Yes/No) (2001-2006)

What percentage of routine vaccine costs was financed by the government (including loans) (From 0 to 100%) (2001-2006)

% of immunization spending financed using Government funds (From 0 to 100%) (2001-2006)

Total expenditure on health as percentage of gross domestic product ? (2001-2006)

General government expenditure on health as % of total government expenditure ? (2001-2006)

Per capita government expenditure on health at average exchange rate (US\$) ? (2001-2006)

% of health budget spent on immunization (2001-2006)

Sources of immunization program financing (if possible indicate sources and percent financed by each source) – Government/ UNICEF/ WHO/ DFID/ USAID/ JICA/ GAVI/ Other – Last year of INS support/ First year after/ Second year after

Sources of funding for injection safety materials (if possible indicate sources and percent financed by each source) – Government/ UNICEF/ WHO/ DFID/ USAID/ JICA/ GAVI/ Other – Last year of INS support/ First year after/ Second year after

INS funding planned for in annual plan and cMYP (yes/no)

% of national injection safety needs financed by government

GNP annual growth rate

Trend in % national budget allocated to health sector (if given in document)

Trend in % MOH budget allocated to immunization program (if given in document)

Indicate with an X if country is undergoing any major health reforms or has major economic or political instability: Decentralization/ Sector-wide approach/ Economic instability/ Political instability

Section 10: MMIS Countries Only

Sources: Making Medical Injections Safer Baseline and Preliminary Reports

National Injection Safety Policy highlighting injection safety and waste management submitted to relevant authorities and operational

Number and Proportion of persons who have been trained in safer medical practices

Proportion of facilities with providers trained in injection safety

Proportion of facilities where sharps are observed to be re-used on patients without re-

processing

Proportion of facilities with no stock outs of any size of new sterile standard or safety syringes in prior 6 months

Proportion of facilities that use safety boxes for sharps waste disposal

Proportion of injection providers who have received the vaccine against the Hepatitis B virus

Proportion of facilities in which waste handlers receive the vaccine against the hepatitis B virus

Annex 6: NIP Manager/MOH interview form



GAVI ALLIANCE EPI MANAGER SURVEY V1.1

Telephone Questionnaire

EPI Manager/MOH Representative

Section A. Identifying information

1. Please tell me your name.
2. Please tell me your job title.
3. Please tell me the department in which you work.
4. What is your role with national immunization program?
5. How many years have you been involved with the immunization program?
6. Country represented by respondent.
7. [For Notetaker Only: Please note if this is a routine interview situation, or if it is an outlier. By "outlier," we mean that the interview situation is not the usual or expected one at the outset and should be noted by any reviewer.]

Section B: Application for GAVI Injection Safety Support

1. In what year did your country first apply for GAVI INS support?
2. Were you involved in the process of applying for GAVI injection safety support?
 - a. Could you describe the decision-making process to apply for the GAVI injection safety support?
3. Was the MOH aware that the funding would end after three years?
4. Was there concern about how to fund the AD syringes and safety boxes after GAVI funding ended?

Section C. Utilization of Injection Safety Support & Waste Management

1. Are you knowledgeable about the introduction of GAVI's injection safety support (AD syringes, safety boxes) into the program?
2. Did the program receive AD syringes and safety boxes or cash?
 - a. If the country received cash rather than injection safety materials, how were funds used? (for what?)
3. Please describe the process of how AD syringes and safety boxes were introduced into your country.
4. How did the health workers react to the introduction of the new injection safety materials?
5. Were there any difficulties in introducing AD syringes and safety boxes?
 - a. If yes, what difficulties did you have in introducing AD syringes and safety boxes?
6. Is there a health care waste management policy in your country?
7. If something could have been changed to improve the way that GAVI injection safety support was introduced, what would it have been?
8. Did EPI workers receive any training related to the use of AD syringes and safety boxes?
9. Please describe the training process for EPI workers.
10. Was the introduction of AD syringes and safety boxes staggered across the country or done nationwide at one time?
11. How should immunization waste be disposed according to the policy?
12. Regardless of the policy, what is the most common practice for disposing of immunization waste?

Section D. Decision-making on Replacement of Injection Safety Support

1. Were you involved in the decision making process about the replacement of GAVI INS support?
2. Please describe the decision making process on the replacement of GAVI injection safety support.
3. Was the replacement of AD syringes discussed before GAVI funding ended?
 - a. If "Yes," when and where did the discussions take place?
4. When (if ever) was a source or sources of FINANCING for the AD syringes and safety boxes identified?

5. How accurately was program able to forecast the amount of AD syringes and safety boxes needed?
6. What discussion (if any) about the AD syringes occurred during this period?
7. Did any system factors such as health reform, decentralization, economic instability, or political conflict affect decision-making in this case?
8. In your opinion, how good was the decision-making on replacing GAVI injection safety support?
 - a. Please explain why you chose this rating.
9. When (if ever) was a source or sources of SUPPLY for the AD syringes and safety boxes identified?
 - a. List of source(s).
10. When (if ever) were sources of funding identified?
 - a. List of source(s).

Section E. Replacement during the 1st year after GAVI support ended.

1. In what year did GAVI INS support end? (final year country received cash or INS materials from GAVI)
2. In the first year after GAVI INS support ended, how much of the injection safety support was replaced?
3. If INS support was not fully replaced in the year after GAVI support ended, what were the major factors that caused this?
4. Did the program have any financial or logistical difficulties in replacing the support?
5. Were there any interruptions in supply during which alternative injection devices had to be used?
 - a. Did it affect your coverage levels?
6. What alternative injection devices did you use?
7. How much funding was available for immunization injection safety material in the first year after termination of GAVI support?
8. What were the sources for the funding available for immunization injection safety material in the year after the end of GAVI INS support?
9. What types and amounts of each syringes were procured for immunization injection safety material in the year after the end of GAVI INS support?
10. How many safety boxes did you procure for immunization injection safety material in the year after the end of GAVI INS support?
11. What were your sources for immunization injection safety boxes in the year after the end of GAVI INS support?
12. Was the program required to pay import taxes on syringes in the year following the termination of GAVI support?
 - a. How did this import tax requirement affect the program?
13. How was waste management of AD syringes handled during the 1st year after GAVI support ended?
14. On a scale ranging from poor to excellent, how adequate do you think the replacement of AD syringes and safety boxes was during the 1st year after funding ended?
 - a. Why did you choose this rating?

Section F. Replacement of GAVI support in a Sustainable Manner in Subsequent Years

1. How much financing for injection safety is available during the second (and third if appropriate) years after the termination of GAVI funding?
2. How long is the commitment from these sources for financing for injection safety in future?
3. Which future sources of financing for AD syringes and safety boxes have been identified?
4. Is there a line item for ADs & safety boxes in the MoH budget?

5. Does MOH have the ability to procure or have a procurement agent for AD syringes?
6. Does MOH have the ability to procure or have a procurement agent for safety boxes?
7. Is there a line item for waste management in the MOH budget?
8. If no line item for waste management in MOH budget exists, have other sources of funding been identified?
9. Was the amount of funding budgeted for AD syringes and safety boxes by the MOH actually allocated during each of the subsequent years?
10. Has the program encountered any difficulties in replacing the funding in a sustainable manner?
11. What difficulties has the program encountered in replacing the funding in a sustainable manner?
12. On a scale of poor to excellent, how sustainable do you think the funding for AD syringes and safety boxes is in the immunization program?
 - a. Please tell why you gave this rating.
13. What are the sources of financing for the IS during the second (and third if appropriate) years after the termination of GAVI funding.

Section G. Effect of INS on Health System

1. Has the government introduced AD syringes and safety boxes and/or health care waste management in other services in the health sector?
 - a. Which other services?
 - b. When were they introduced?
 - c. What were the sources of funding?
2. Please tell us the order in which this introduction was made relative to GAVI INS support.
3. Are import taxes a problem in the purchase of AD syringes and safety boxes for use outside the immunization program?
4. Has a national policy for injection safety been developed for health services?
5. What year was (or were) the policy (ies) developed?
6. Do you believe that GAVI injection support was a catalyst/influenced the development of these policies?
7. Has pre-service training on injection safety been introduced outside the immunization program?
8. Has in-service training on injection safety been introduced outside the immunization program?
9. Has provision of Hepatitis B vaccine for health workers been introduced outside the immunization program?
10. Has a post-exposure prophylaxis policy for health workers been introduced outside the immunization program?
11. Has country production of AD syringes been introduced outside the immunization program? If so, are these in use?
12. Has country production of safety boxes been introduced outside the immunization program? If so, are these in use?
13. Has any other injection safety activity been introduced outside the immunization program? If so, what?
14. Has a national policy for waste management been developed for health services?
15. Did MOH program managers have any technical or logistical problems when they introduced injection safety materials into the broader health sector?
 - a. If "Yes," explain:
16. How influential has the introduction of AD syringes and safety boxes into the immunization program been on injection safety in the broader health sector?
 - a. If "Yes", explain.

Section H. Other Questions for EPI Managers/MOH Representatives

1. How adequate was the logistics for the AD syringes and safety boxes when GAVI provided the support?
2. Have the logistics for AD syringes and safety boxes changed since GAVI support ended?
 - a. If "Yes", please describe how the logistics have changed since GAVI funding ended.
 - b. If "Yes," how adequate are the logistics today?
3. Have there been any stock-outs of AD syringes and/or safety boxes in the country since the end of GAVI INS support?
 - a. If "Yes," at what level and how long did they last?
4. Are refresher trainings held on injection safety practices?
 - a. If "Yes," when was the last one held? where? who attended?
5. Does the Ministry of Health consider injection safety a priority for its immunization program?
6. Does the Ministry of Health consider injection safety a priority for the broader health sector?
7. Has anyone in the Ministry of Health or among the external organizations advocated strongly for injection safety in the immunization program and/or broader health sector?
 - a. If "Yes," what is the position of this individual? What are his or her motivations as an advocate?

Section I. Request for further Contacts and Resources

1. Are there other people associated with the immunization program (in the Ministry of Health, Ministry of Finance or partners) who you would recommend that we interview?

Section J. Notepad

1. Notes

Annex 7: WHO/UNICEF EPI Regional Representative interview form

GAVI INS Evaluation Telephone Interview Questionnaire for WHO/UNICEF Regional level Representatives (Word Version).

Background

GAVI awarded John Snow Inc. (JSI) a contract to evaluate the replacement of INS support after GAVI's support ended. The study is to evaluate how countries have been able to replace, in a sustainable way, GAVI support when it ended. The findings can be used to design a better and more sustainable GAVI program in the future. The objectives are to describe the decision-making process for replacing GAVI support, to assess how and to what extent countries replaced GAVI support in the first year and in subsequent years, to assess the positive and negative effects on the country health system, and to assess how cash was used to strengthen country programs (if they received cash in lieu of supplies). Interviews will be confidential.

A. Role of the Regional Representatives

1. When GAVI support for injection safety ends in countries in your region, how do you or your organization assist countries with decision-making on replacement of AD syringes and safety boxes?

B. Replacement of Injection Safety Support

2. Which countries have been able to replace the support during the first year after the support ended? Which countries were not able to replace the support? Why and why not?
 - 2a. What factors affected the ability of countries to replace the support? E.g. economic factors, political factors, logistical factors?
 - 2c. Do the countries in your region have adequate logistics management capacity and how did this affect its ability to replace AD syringes and safety boxes?
 - 2d. Could you also tell us about the use of AD syringes in non-GAVI eligible countries in your region?
3. If something could have been changed to improve the way that GAVI injection safety support was provided and/or ended, what would it be?

C. Waste Management

4. Has the EPI program/MOH introduced waste management into its program? Did you or other external partners need to advocate for introduction of waste management into the program? Describe the process to introduce waste management into the program.

Annex 8: MMIS Country Director focus group discussion questions

GAVI INS Evaluation Focus Group July 16, Wed. 5:00-6:30, MMIS CD Meeting Rm. Questions for MMIS Country Directors

Does the summary sheet for your country reflect reality? What comments/changes would you make? More broadly:

A. How important was the GAVI INS support in your country in introducing and convincing the MOH of the need to sustain AD syringe use in the immunization program?

B. How did AD syringes in the immunization program and GAVI support in your country influence the introduction of ADs into the curative sector?

C. How did the HCWM support by GAVI in your country help orient the MOH to the importance/need for HCWM?

D. What would the situation be like in your country today had there been no GAVI IS & HCWM support?

Annex 9: List of evaluation interview respondents

GAVI Injection Safety Evaluation List of Respondents

On occasion, a group of respondents was interviewed collectively without every member being identified individually. As such, this list may be considered accurate for institutional contacts made during the course of the study, but may not necessarily include all persons who contributed data.

Name	Title	Office/Country	Data Collected
<i>Regional-level Representatives of WHO and UNICEF</i>			
Dragoslav Popovic		UNICEF/CEE/CIS	Regional Rep Interview
Diana Chang Blanc	Regional EPI Focal Point	UNICEF/EAPRO	Regional Rep Interview
Ahmadu Yakubu	Immunization Specialist	UNICEF/ESARO	Regional Rep Interview
Paulo Froes	Social Psychiatry Regional Advisor Child Survival and Immunization	UNICEF/LACRO	Regional Rep Interview
Mahendra Sheth	Regional Health Advisor	UNICEF/MENA	Regional Rep Interview
Pankaj Mehta	Regional EPI Manager	UNICEF/ROSA	Regional Rep Interview
Eugênia Gomes	Immunization Advisor	UNICEF/WCARO	Regional Rep Interview
Celestino Costa	Regional Health/Immunization Advisor	UNICEF/WCARO	Regional Rep Interview
Modibo Dicko		WHO/AFRO (former)	Regional Rep Interview
Ezzeddine Mohsni		WHO/EMRO	Regional Rep Interview
Denis Maire	CDS/Immunization Quality and Safety	WHO/EURO	Regional Rep Interview; Country Summary Edits
Claudia Castillo	EPI Officer	PAHO	Regional Rep Interview; Country Summary Edits
Stephane Guichard	Technical Officer, Vaccine Supply and Quality	WHO/SEARO	Regional Rep Interview
<i>Country-level Representatives of National EPI Programs</i>			
Agha Dost		Afghanistan	NIP Mgr. Interview
Silvia Bino	Head of the Department of Control of Infectious Diseases	Albania	NIP Mgr. Interview
Alda Morais Pedro	Chief of Immunization Section	Angola	NIP Mgr. Interview
Gayane Sahayan	EPI Manager	Armenia	NIP Mgr. Interview
Svetlana Zmitrovich	Deputy Director-General, Republican Center of Hygiene and Epidemiology	Azerbaijan	NIP Mgr. Interview
Tazul Islam	Program Manager, Child Health and Limited Curative Care	Bangladesh	NIP Mgr. Interview
Dr. Akter Hamid	NPO/WHO	Bangladesh	NIP Mgr. Interview
Dr. Aatur Rahman	Health Program Specialist, UNICEF	Bangladesh	NIP Mgr. Interview
Dr. Selina	NPO/WHO	Bangladesh	NIP Mgr. Interview
Karma Tshering	EPI Manager	Bhutan	NIP Mgr. Interview
Javier Flores	EPI Manager	Bolivia	NIP Mgr. Interview
Dr. Ma Ouattara		Burkina Faso	NIP Mgr. Interview (written)

Hillaire Ninteretse	Directeur du PEV	Burundi	NIP Mgr. Interview
Prof. Sann Chan Soeung	EPI Manager	Cambodia	NIP Mgr. Interview
Dr. Emmanuel Nomo	EPI Director - greater program permanent secretary	Cameroon	NIP Mgr. Interview
Dr. Mbary Daba	National Director of Vaccination Program (PEV) (at MOH)	Central African Republic	NIP Mgr. Interview
Emmanuel Nomo	EPI Director	Chad	NIP Mgr. Interview
Dr. Liang Xiaofeng	EPI Program Manager	China	NIP Mgr. Interview
Dr. Sainda Mohamed	Coordinatrice Nationale du PEV	Comoros	NIP Mgr. Interview
Dr. Said Ali Mbae	Health Administrator/WHO	Comoros	NIP Mgr. Interview
Mr. Abdramane Maiga	MPN/OMS	Comoros	NIP Mgr. Interview
Mr Abdou Said Abdallah Mkandzile	National EPI Logistician	Comoros	NIP Mgr. Interview
Edouard Ndinga	Director of PEV	Congo	NIP Mgr. Interview
Dr. Micheline Mabiala	Director of PEV	Congo DR	NIP Mgr. Interview
Dr. Saleh Banoita	General Secretary	Djibouti	NIP Mgr. Interview
Filli Said Fili	EPI Manager	Eritrea	NIP Mgr. Interview
Tesfaye Neghist	Family Health Department Director	Ethiopia	NIP Mgr. Interview
Yamandow Lowe- Jallow	Deputy EPI Manager	Gambia	NIP Mgr. Interview
Baidoshvili Levan	Head of Department	Georgia	NIP Mgr. Interview
Nana Antwi-Agyei	National EPI Manager, Ghana Health Services	Ghana	NIP Mgr. Interview
Dr. Camille Soumah	Coordinator of PEV	Guinea	NIP Mgr. Interview
Dr. Elie Pierre Celestin	Directeur national du Programme Elargi de Vaccination	Haiti	NIP Mgr. Interview (written)
Ida Berenice Molina	EPI manager	Honduras	NIP Mgr. Interview
Dr. Prima Yosephine	Chief of M&E Section for Immunization Program	Indonesia	NIP Mgr. Interview
Tatu Kamau	EPI Manager	Kenya	NIP Mgr. Interview
Joldosh Saparovich Kalilov	Head of Republican Center for Immunoprophylaxis	Kyrgyzstan	NIP Mgr. Interview
Ellen Moshesha	EPI Manager	Lesotho	NIP Mgr. Interview
Dr. Nouhoum Kone	Chef Section of Immunization	Mali	NIP Mgr. Interview
Dr. Idrissa Yalcouye	WHO/Mali	Mali	NIP Mgr. Interview
Dr. Boubacar Guindo	USAID/Mali	Mali	NIP Mgr. Interview
Dr. Ishagh Ould Khalef	Coordinator Nationale du PEV/ National Project Coordonator OMS Mauritania	Mauritania	NIP Mgr. Interview
Manoel Novela	Former EPI manager	Mozambique	NIP Mgr. Interview
Dr. Than Tun Aung	Assistant Director EPI	Myanmar	NIP Mgr. Interview (written)
Shamraj Upreti	Chief of EPI Programme Nepal	Nepal	NIP Mgr. Interview
Dr. Lado Abdoulaye	Director of PEV	Niger	NIP Mgr. Interview
Altaf Bosan	Deputy National EPI Manager	Pakistan	NIP Mgr. Interview
Dr. Fidel Ngabo	EPI Coordinator	Rwanda	NIP Mgr. Interview
Elisabeth Carvalho	Nurse; Chief of Reproductive Health	São Tomé	NIP Mgr. Interview
Dr. Papa Coumba Faye	Director of Medical Prevention	Senegal	NIP Mgr. Interview
Foday Kamara	National Cold Chain Coordinator	Sierra Leone	NIP Mgr. Interview
Dr. John Lebga	EPI Project Officer Health & Nutrition	Somalia	NIP Mgr. Interview
Dr. Sudath Peiris	Epidemiologist/ EPI Manager	Sri Lanka	NIP Mgr. Interview

Nisreen Musa Widaa	EPI National Immunization Advisor/GAVI Advisor	Sudan	NIP Mgr. Interview
Dr. Amani Mustafa,	Deputy Manager EPI Program	Sudan	NIP Mgr. Interview
Dr. Al Sayed	EPI Director for past 7 years, now Director of Mother and Child Health	Sudan	NIP Mgr. Interview
Dr. Salah	WHO EPI Officer	Sudan	NIP Mgr. Interview
Shamsidin Jabirov	General Director of Republican Center for Immunoprophylaxy	Tajikistan	NIP Mgr. Interview
Mary Kitambi	EPI Manager, Program Manager	Tanzania	NIP Mgr. Interview
Dr. Danladi Ibrahim Nassoury	Director of EPI Program	Togo	NIP Mgr. Interview
Annamurat Orazov	Deputy Head of MOH, Head of National Sanitary Epidemiological Service of MOH	Turkmenistan	NIP Mgr. Interview
Powssy Makumbi	Deputy EPI Manager	Uganda	NIP Mgr. Interview
Chinara Aidryalieva	Deputy Director of Immunization for Russian Federation; former Supervisor of Immunization Programs in Belarus, Ukraine, Moldova	Ukraine	NIP Mgr. Interview
Dilorom Alimovna Tursunova	EPI Manager	Uzbekistan	NIP Mgr. Interview
Nguyen Van Cuong	Deputy EPI Manager at National Level	Vietnam	NIP Mgr. Interview (written)
Dr. Eissa Mohammed Eissa	EPI Manager	Yemen	NIP Mgr. Interview
Flint Zulu	EPI Officer, UNICEF	UNICEF/Zambia	NIP Mgr. Interview, Country Summary Edits
Mary Kamupota	EPI Manager	Zimbabwe	NIP Mgr. Interview
<i>Country-level Representatives of WHO and UNICEF</i>			
Toure Hamadassalia		UNICEF/Angola	Country Summary Edits
Sheldon Yett	UNICEF Representative	UNICEF/Armenia	Country Summary Edits
Dénis Karaga	Assistant Health Project Officer	UNICEF/Burkina Faso	Country Summary Edits
Deo Manirakiza		UNICEF/Burundi	Country Summary Edits
Aun Chum	Immunization Officer; Child Survival Section	UNICEF/Cambodia	Country Summary Edits
Achu Lordfred	EPI Specialist	UNICEF/CAR	Country Summary Edits
Granga Daouya		UNICEF/Chad	Country Summary Edits
Lydie Maoungou Minguiel		UNICEF/Congo	Country Summary Edits
Mr Sumaili Bonny	EPI Health Officer	UNICEF/Congo DR	Country Summary Edits
Dr. Hamzaoui Larbi	Medical Officer	WHO/Djibouti	Country Summary Edits
Dr. Tuya Mungun	Health Specialist	UNICEF/DPR Korea	Country Summary Edits
Tariku Berhanu		UNICEF/Ethiopia	Country Summary Edits
Nehemie Mbakuliyemo	EPI Focal Person	WHO/Ethiopia	Country Summary Edits
Debessai Haile		UNICEF/Eritrea	Country Summary Edits
Adama Ouedraogo		UNICEF/Mauritania	Country Summary Edits
Dr. Manoel Novela	Former Chief of Immunization Program	WHO/Mozambique	EPI Manager Interview, Country Summary Edits
Mouhamed Boss Diop		WHO/Senegal	Country Summary Edits
Nuhu Maksha	Immunization Specialist	UNICEF/Sierra Leone	Country Summary Edits

Ayadil Saparbekov	Health & Nutrition Specialist	UNICEF/ Turkmenistan	Country Summary Edits
Ranganai Matema	EPI Officer	UNICEF/ Zimbabwe	Country Summary Edits
<i>Other Persons Contacted</i>			
Dr. Solomon Worku	Country Director	MMIS/Ethiopia	MMIS Interview
Dr. Gerald Lerebours	Country Director	MMIS/Haiti	MMIS Interview
Dr. Jackson Songa	Country Director	MMIS/Kenya	MMIS Interview
Mr. Americo Ubisse	Country Director	MMIS/Mozambique	MMIS Interview
Dr. Mamadou Adama Diallo	Country Director	MMIS/Rwanda	MMIS Interview
Dr. Ernest Chenya	Country Director	MMIS/Tanzania	MMIS Interview
Dr. Victoria Maseembe	Country Director	MMIS/Uganda	MMIS Interview
Dr. Rose Macauley	Former Program Officer for GAVI Programs	WHO/AFRO	Regional Rep Interview
Ms. Annika Salovaara	Contract Manager, Immunization Team	UNICEF/ Copenhagen	Commodity Data
Dr. Edward Hoekstra	Senior Health Specialist, Global Measles Programme & Health Emergencies	UNICEF/New York	Commodity Data

Annex 10: Country Summary Table Template

Country Summary of Findings on GAVI INS Support Replacement Template

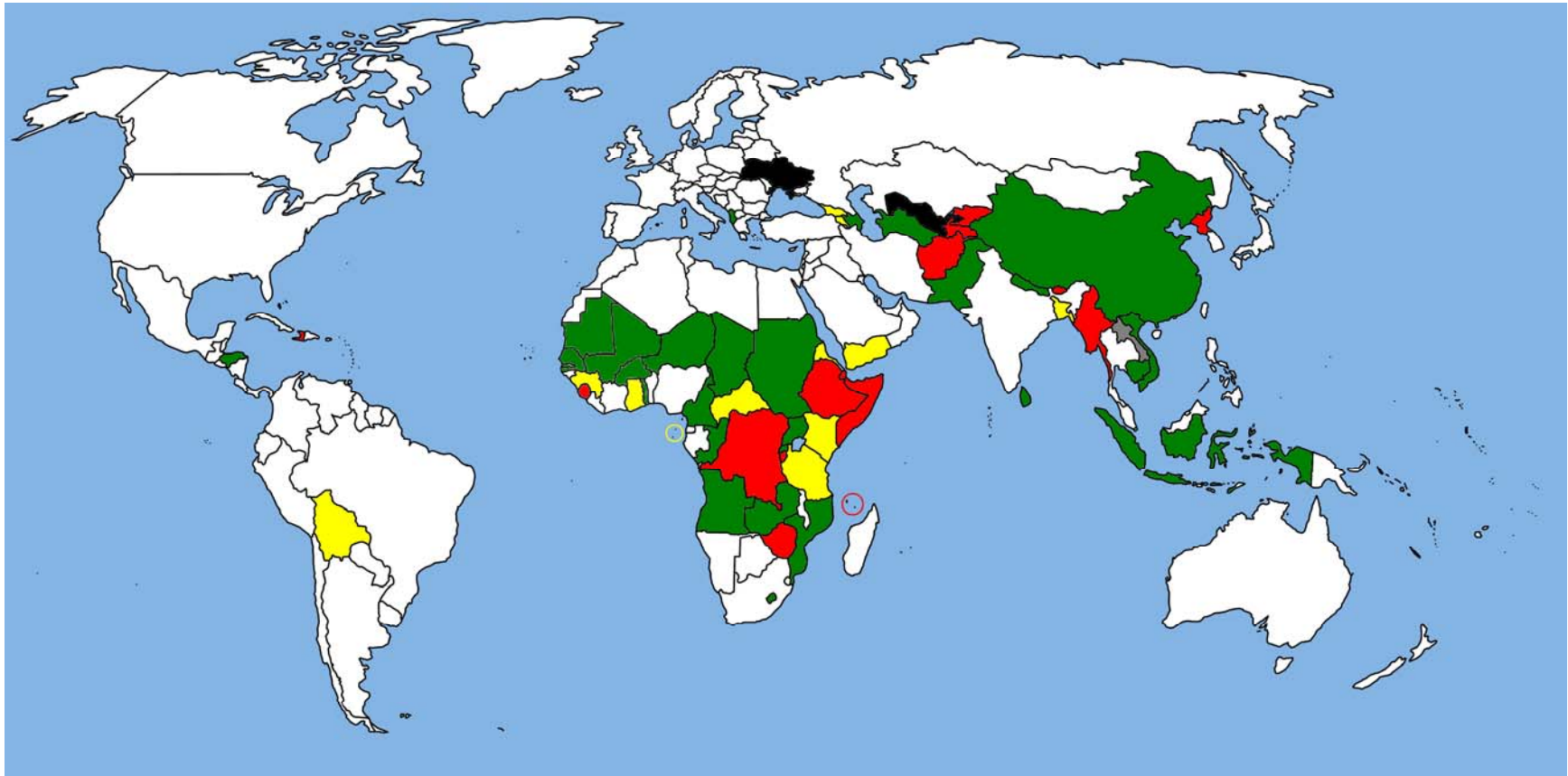
#	Question	Finding	More info (if provided) from Source	Your Comments
1.	Date of Last Injection Safety Support			
2.	Type of support received (materials vs. cash)			
3.	If the country received cash rather than injection safety materials, how were the funds used?			
4.	Were there any difficulties introducing the AD syringes and safety boxes?			
5.	Are refresher trainings held on injection safety practices?			
6.	Please describe the decision making process on the replacement of GAVI injection safety support?			

#	Question	Finding	More info (if provided) from Source	Your Comments
7.	Did system factors such as health reform, decentralization, economic instability, or political conflict can affect decision-making?			
8.	In the first year after GAVI INS ended, how much of the injection safety support was replaced?			
9.	Were the national government, UNICEF, JICA, and/or others identified as a source of funding in the first year after GAVI INS ended?			
10.	Were the national government, UNICEF, JICA, and/or others identified as a source of supplies in the first year after GAVI INS ended?			
11.	Did the program have any financial or logistical difficulties in replacing the support?			
12.	If the support ended in 2004 or 2005, what was the source of financing for the AD syringes and safety boxes in 2007?			

#	Question	Finding	More info (if provided) from Source	Your Comments
13.	How long is the commitment from these sources for financing in the future?			
14.	Has a national policy for injection safety been developed for health services?			
15.	Is there a health care waste management policy in your country?			
16.	Regardless of the policy, what is the most common practice for disposing of immunization waste?			
17.	How was waste management of AD syringes handled during the 1st year after GAVI support ended?			
18.	Do you believe that GAVI injection support was a catalyst/influenced the development of these policies?			
19.	Was there a line item in the national budget for purchase of injection supplies (syringes, needles, sharp boxes) for routine immunization?			

#	Question	Finding	More info (if provided) from Source	Your Comments
20.	Has the government introduced AD syringes and safety boxes and/or health care waste management in other services in the health sector?			

Annex 11: Map – Level of financial sustainability of INS support



■ Government-Supported ■ Mix of Gov't and Donor Support ■ Donor-Dependent ■ Total/Partial Discontinuation of AD