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**STUDY ON  
COMPARATIVE EFFICIENCIES  
IN  
VACCINE PROCUREMENT  
MECHANISMS**

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## List of Acronyms

<b>Acronym</b>	<b>Definition</b>
AEFI	Adverse Events Following Immunization
BCG	Bacille Calmette-Guérin (Vaccine against Tuberculosis)
CIDA	Canadian International Development Agency
CMS	Central Medical Store
CMSD	Central Medical Supply Department (Bangladesh)
DFID	UK Department for International Development
DRU	Drug Registration Unit (Botswana)
DQA	Data Quality Audit
DTP	Diphtheria Tetanus Pertussis
EPI	Expanded Program of Immunization
GAVI	Global Alliance for Vaccines and Immunizations
GCC	Gulf Cooperation Council
HepB	Hepatitis B
HNP	Health Nutrition and Population (Bangladesh)
HPPP	Health and Population Program Project (Bangladesh)
IACC	Inter-Agency Coordination Committee
ICB	International Competitive Bidding
ICDDR,B	International Center for Diarrhoeal Diseases, Bangladesh
JICA	Japanese International Cooperation Agency
LDC	Least Developed Countries
LGA	Local Government Authority (Nigeria)
LTA	Long Term Agreement
NID	National Immunization Day
NIH	National Institute of Health
NPHCDA	National Primary Health Care Development Agency (Nigeria)
NPI	National Program on Immunization (Nigeria)
NRA	National Regulatory Authority
OPCS	Operations Policy and Country Service
OPV	Oral Polio Vaccine
PAHO	Pan American Health Organization
PPRA	Pakistan Procurement Regulatory Authority
PMA	Pakistan Medical Association
PPADB	Public Procurement and Asset Disposal Board (Botswana)
SADC	Southern African Development Community
SCMS	Supply Chain Management Services (Botswana)
TT	Tetanus toxoid
UN	United Nations
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VII	Vaccine Independence Initiative
VVM	Vaccine Vial Monitors
WHO	World Health Organization

## 1. Executive Summary

Vaccinations are amongst the most cost-effective public health interventions. The World Bank is involved in the financing of vaccines through its loans, grants, and IDA buy-down programs. Governments use this funding to procure vaccines in a variety of methods, the most common of which are self-procurement and procurement through UNICEF.

Vaccine procurement is a complex issue that interweaves the domains of public health, commodity security, ethics, and procurement. Its cross-disciplinary nature means that neither a straightforward analysis stemming from just one discipline nor a cookie-cutter application of World Bank procurement principles of economy, efficiency, equal opportunity, promoting domestic contracting and transparency will lead to an optimal solution. A more holistic approach is required. The World Bank has therefore historically considered vaccine procurement as “special” and has allowed for exceptions from its guidelines for World Bank funded vaccine procurement.

In general, five core principles should apply in some form to World Bank financed vaccine procurement. They are:

- a) The vaccine market is extremely fragile and so World Bank actions should work to strengthen this market, not weaken it. In 2000-2001, the traditional EPI vaccine market crashed. Two factors restabilized the market. The United Nations Children’s Fund (UNICEF), the largest procurement agent, moved from awarding competitive tenders to one lowest-cost manufacturer to a longer-term, more partnership-oriented approach. The Global Alliance for Vaccines and Immunizations (GAVI) entered the marketplace, providing developing countries with significant funding in 2000. These two factors restabilized the market because it created incentives large enough to keep vaccine manufacturers interested in this market. The World Bank should consider the impacts of World Bank funded procurement decisions on the market and adopt vaccine security friendly policies into its procurement decisions. The World Bank should encourage procurement situations where multiple manufacturers win tenders, where price is important but not the ultimate focus, and where country risk is spread.
- b) The Paris Declaration states that all multilateral institutions should work to improve country capacity, including procurement. Thus, World Bank supported procurement should contribute towards building national capacity to procure vaccines and not towards dependence.
- c) Quality procurement systems should be used. The World Bank should consider the country’s National Regulatory Authority (NRA) skills and capacity, the country’s forecasting abilities, the skills and capacities of the procurement cell, and the country’s ability to arrange finances. Other considerations include corruption and local agents’ political influence. Quality procurement should predominate because the worst case scenario would be to procure a low quality vaccine which could harm a healthy child.

- d) The World Bank funding should be used to procure the highest quality vaccines at the lowest reasonable price. Due to its procurement volumes and relationships with multiple manufacturers, UNICEF usually obtains the lowest prices. A country will most likely not be able to match these prices. Furthermore, UNICEF procurement policies work to keep multiple manufacturers in the marketplace, leading to healthier competition and lower prices for all.
- e) Procurement must be economical and efficient, provide equal opportunity for all bidders to compete, encourage local contracting, and be transparent.

These five core objectives provide a challenge because, while not mutually exclusive, there is clearly some tension amongst them. While some core objectives would promote measured competition, others would promote unfettered International Competitive Bidding (ICB). For example, factors one, three, and four indicate that the World Bank should favor procurement mechanisms such as UNICEF. Factors two and five indicate that the World Bank should favor procurement mechanisms such as government self-procurement. Therefore, a case by case decision is necessary for vaccine procurement.

While all factors are important, the World Bank should place high importance on vaccine security, the fragility of the market, the low prices offered by UNICEF procurement channels and the challenges highlighted in the four surveyed countries' experiences with regards to vaccine procurement. With this in mind, the World Bank should shift from putting the burden of proof on country teams for explaining why it would like to work with UNICEF for procurement to putting the burden of proof on country teams to explain why it would like to work through national procurement systems.

If the World Bank determines that a national country's procurement systems do not have the capacity to act as an effective channel, the World Bank should work to strengthen procurement and quality control institutions. A high priority for technical assistance should go to NRA capacity building and this should be in place before procurement cells are activated.

Countries with adequate procurement and quality control capacity have fewer procurement challenges, but will most likely not be able to provide as low-cost of a procurement option as UNICEF is able to. UNICEF will most likely always provide a lower price due to its large volume and greater competition among manufacturers bidding on orders. Furthermore, individual country self-procurement decisions may negatively impact global vaccine security unless countries incorporate these principles into their procurement decisions. Finally, the decision to move from UNICEF procurement to government self-procurement can be driven by local private sector interests and not increased efficiency and effectiveness of procurement. Therefore, caution should still be exerted when moving from UNICEF procurement to self-procurement in countries that have full procurement and quality control capacity.

## 2. Objective

We carried out a multi country comparative assessment of vaccine procurement issues with regards to country capacity, agencies used, and procurement methods followed. The study was designed to provide strong operational recommendations for issues such as efficiency, price, quality control, and logistic management. This study is intended mainly for internal purposes to facilitate discussions with Operations Policy and Country Service (OPCS) regarding refining the World Bank's position on procurement or supply of vaccine through UNICEF.

## 3. Methods

The study was undertaken between November 2007 and May 2008. It included:

- a) A desk review of vaccine procurement practices in developing countries with a focus on costs, procurement agent, and efficiency and the determinants for these variables.
- b) A review of vaccine procurement practices in four countries, Bangladesh, Botswana, Nigeria, and Pakistan. This assessment reviewed:
  - ③ The procurement method, procurement agent, prices and quality obtained and logistic management.
  - ③ The procurement capacity of public authorities for vaccines and pharmaceuticals including their capacity for pre-qualification.
  - ③ Reliability of national procurement capacity, including timely planning, handling and distribution of the products.
  - ③ The supply chain effectiveness with a focus on vaccines.
- c) A review of the global vaccine procurement situation, including consultation with UNICEF, WHO, and GAVI.

## 4. Overview

Vaccine procurement is a complex issue that interweaves the domains of public health, commodity security, ethics, and procurement. In general, five principles should apply in some form to all vaccine procurement, including if World Bank financed:

- a) The vaccine market is extremely fragile and so procurement actions should work to strengthen this market, not weaken it;
- b) The Paris Declaration states that all multilateral institutions should work to improve country capacity, including procurement. Thus, World Bank activities should lead towards building government capacity to procure vaccines and not towards dependence;
- c) Quality procurement systems should be used. Quality control issues should predominate because the worst case scenario would be to procure a low quality vaccine. Other considerations include the procurement team's capacity and skills, corruption, and local agents' political influence;
- d) The World Bank should try and procure the highest quality vaccines at the lowest reasonable price;

e) World Bank procurement standards should apply.

Each of these core objectives is discussed in more detail in the following sections.

## 5. Vaccine Market Fragility

In 2000, the global vaccine market for low cost traditional EPI vaccines crashed due to manufacturers withdrawing from the market. This crash caused shortages serious enough to jeopardize immunization programs for children in developing countries.

To understand the extent of this crash, the United Nations Children's Fund (UNICEF) procurement numbers can be used. As Figure 1 shows, in 1999, UN agencies procured the majority of vaccines globally, especially when the industrialized country markets are removed. Thus the manufacturer's withdrawal from UNICEF vaccine procurement market can be used as a proxy for the withdrawal from manufacturers from the general developing country vaccine market. Figure 2 shows the quantities of vaccines manufacturers were willing to sell to UNICEF over time.

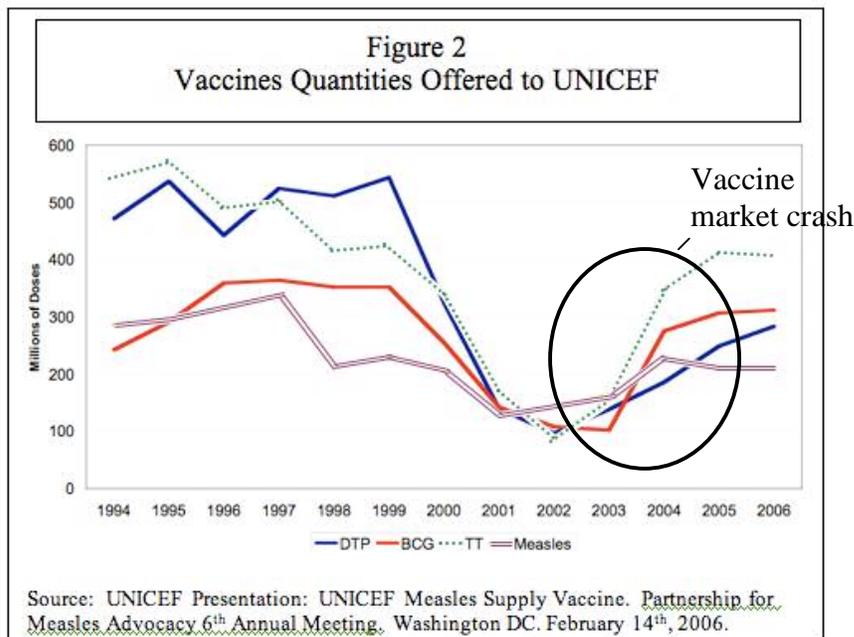
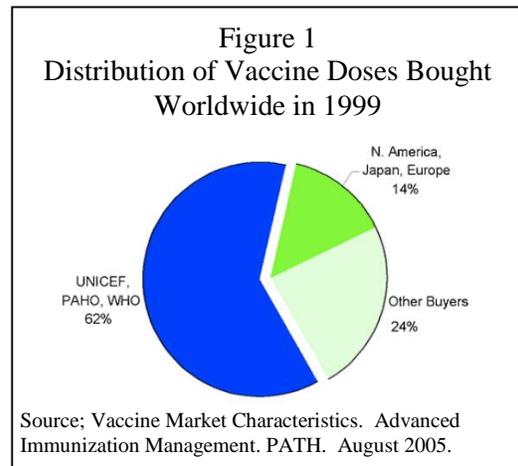
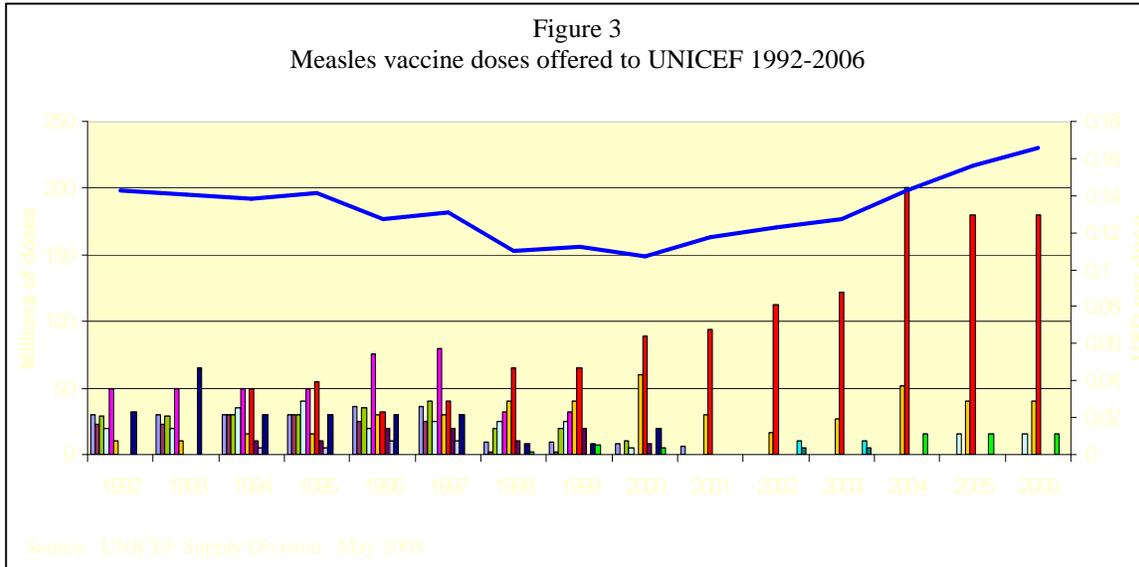


Figure 3 shows the market for measles vaccines. The blue horizontal line represents the total number of doses that manufacturers offered for sale to UNICEF. Each vertical line represents the total quantity offered to UNICEF by a single manufacturer. While multiple vaccine manufacturers competed before 2000, most of the vaccine manufacturers left the market, leaving UNICEF increasingly dependent on one manufacturer to supply the world's required measles doses.



### 5.1. Why did the traditional EPI vaccine market crash?

In general, vaccine manufacturing is a high start-up and fixed cost, high risk, and lower sales price proposition. These challenging business economics for vaccines result in limited profit potential and hence limited interest from the private sector.

#### *High costs*

- a) ***Strict technical and regulatory requirements:*** Vaccines are derived from a biological entity and thus each vaccine differs slightly. In order to produce high quality and consistently safe vaccines, manufacturers must make significant investments in technology, processes, and oversight. The vaccine control process is also much more challenging than for pharmaceuticals. Whereas pharmaceuticals can be chemically analyzed to determine identity, composition, potency, or dosage, vaccines require lot-by-lot release of the product to ensure product consistency.<sup>i</sup>
- b) ***Significant batch failure risk:*** Vaccine manufacturing is a technically challenging process based on live biologicals. Batch failure rates vary based on product, facility, and year but range from under 5% up to 30%. When a batch fails, the manufacturer must start again, resulting in lost costs and delayed orders.<sup>ii</sup>

- c) **Limited shelf life:** Due to a vaccine's perishable nature, manufacturers cannot stock excess capacity but must sell or dispose of all stock, leaving little margin for error. Low profit margins mean manufacturers must be conservative in production capacity to minimize waste.<sup>iii</sup>

### **High risk**

- d) **Production versus sales timing risk:** Stringent safety rules mean that vaccine manufacturers need approximately six to twenty four months to produce a dose, three years to expand existing capacity and five to seven years to build new capacity.<sup>iv</sup> While production lead times are long, countries will often place orders 3-6 months in advance and provide funding either upon arrival of goods or upon order placement. This timing risk increases the risk to the capital invested and hence its cost.
- e) **Product failure risk:** Vaccines are one of the few drugs that are given to healthy children. Thus, the consequences of an adverse reaction are extremely high, often involving significant humanitarian and possibly legal and financial ramifications.

### **Low revenue**

- f) **Consolidated buyers reduce sales price:** A few large buyers such as the Pan American Health Organization (PAHO), and UNICEF purchase large quantities and can exert downward price pressure on manufacturers. Public sector sales account for about 80% of the total vaccine production volume but less than 20% of the revenue.<sup>v</sup> This reduces vaccine manufacturer's profit potential and thus interest in investing in this field.
- g) **Geographic segmentation and diverging markets:** The vaccine market started to bifurcate in the 1980s. Industrialized countries migrated to new more sophisticated and expensive vaccines which remained unaffordable to developing countries. Until this point, children in both developing and industrialized countries received the same vaccines and manufacturers could recoup costs in developed markets. Between 1998 and 2001, ten of fourteen manufacturers partially or totally stopped production of the traditional less expensive vaccines.<sup>vi</sup>

### **Other**

- h) **Significant economies of scale:** In general, industries with high start-up costs and high fixed costs tend to consolidate to few manufacturers. Vaccine production requires advanced technical facilities and highly trained personnel due to its biological nature (more so than pharmaceuticals which are chemical by nature). This leads to high fixed costs: 60% of costs are fixed and 25% are semi-fixed for each batch produced, regardless of how many are produced.<sup>vii</sup> In these situations, manufacturers tend to lower prices aggressively to increase sales volume because a large sales volume leads to allocating these large fixed costs across a greater number

of units. Smaller producers cannot compete and a “winner takes all” effect takes hold.

- i) ***Pharmaceutical firm ownership:*** Global pharmaceutical entities have acquired major vaccine manufacturers. Vaccines must now compete internally against potential blockbuster drugs for money and attention. With lower profit margins and longer production lead times, vaccines do not return as much for the shareholder’s invested capital and hence pharmaceutical firms do not see them as attractive as blockbuster drugs.

## **5.2. What helped the market restabilize?**

Following the 2000 vaccine crisis, two moves helped restabilize the traditional EPI vaccine market. The first is a set of actions by UNICEF to improve vaccine security. It met with vaccine manufacturers, donor governments, procurement officers, and other parties to determine why the vaccine manufacturers were leaving the market. Vaccine manufacturers reported that UNICEF procured vaccines as if they were commodities with too short timelines and too focused on price.<sup>viii</sup>

As a result, UNICEF changed its procurement practices from a one year Invitation to Bid tender process based on accepting the lowest price to a more flexible procurement instrument that incorporated vaccine security principles. UNICEF transitioned to a three year Long Term Agreement (LTA) with manufacturers. The LTAs establish forecasts between UNICEF and a manufacturer on quantities to be produced and procured over a time period. Hard orders are then placed as needed.<sup>ix</sup> UNICEF also adopted the following procurement principles in order to ensure a healthy market:<sup>x</sup>

- a) ***A healthy industry is vital to ensure an uninterrupted and sustainable supply of vaccines.***
- b) ***UNICEF procures from multiple suppliers for each vaccine presentation.*** Multiple suppliers encourage multiple manufacturers to stay in the market. Due to long lead times in setting up vaccine manufacturing facilities and high entrance costs, once a manufacturer leaves a market, that decision tends to be permanent and not easily rectifiable. Vaccine prices tend to decline over time when multiple manufacturers compete. Also, vaccine production is challenging with occasional batch failures. Relationships with multiple manufacturers leave multiple options for procurement when a batch failure occurs.<sup>xi</sup>
- c) ***UNICEF procures from manufacturers in developing countries and industrialized countries.*** UNICEF prefers to have vaccine manufacturers in multiple countries to reduce risk. The higher cost of industrialized manufacturers could be considered the price of vaccine security. For example, the World Health Organization (WHO) continuously evaluates national NRAs and has in the past partially suspended countries’ NRAs for not meeting safety and quality standards. If UNICEF concentrates all its procurement in a country whose NRA becomes suspended, it

opens itself to risk because UNICEF can only procure from WHO pre-qualified manufacturers and one of a manufacturer's requirement for WHO pre-qualification is to reside in a country with a WHO certified NRA.

- d) ***UNICEF pays a price that is affordable to Governments and Donors and a price that reasonably covers manufacturers minimum requirements***
- e) ***UNICEF provides manufacturers long term accurate forecasting.*** Manufacturers provide accurate production plans and governments provide accurate immunization forecasts. The forecast provides the foundation of vaccine security because all production quantities and funding requirements are based upon it. It also helps manufacturers address their timing risks.
- f) ***As a public buyer, providing grants to manufacturers is not the most effective method of obtaining capacity increases.*** In the late 1990s, UNICEF gave a grant to a DTP manufacturer to help it build capacity, but found that this had minimal impact in scaling up production. UNICEF has found that offering LTAs is a much more effective mechanism to encourage manufacturers to stay in the market.<sup>xii</sup>
- g) ***The option to quote tiered pricing should be given to manufacturers in accordance with the World Bank classification.*** Because UNICEF Supply Division mostly procures on behalf of the lowest income countries, it asks manufacturers for their lowest prices. UNICEF does sometimes procure on behalf of middle income countries who need assistance with the procurement function (e.g. Equatorial Guinea) and so will sometimes offer manufacturers the option to give differential pricing for these countries.<sup>xiii</sup>

The second stabilizing factor was the Global Alliance for Vaccines and Immunizations (GAVI)'s entrance into the marketplace in 2000. GAVI has committed \$3.5 billion in multi-year grants to more than 70 of the world's poorest countries for vaccine purchases from 2000-2015.<sup>xiv</sup> GAVI's advent provides developing countries the opportunity to start incorporating newer combination (tetraivalent and pentavalent) vaccines into their immunization schedules through shared GAVI and national government funding of these vaccines. Without GAVI funding, the countries could not order the vaccines and the manufacturers would not have an incentive to build manufacturing to scale.

Many countries prefer combination vaccines because they require fewer inoculations per child and reduce vaccine wastage. On the other hand, they are significantly more expensive than the older single purpose or trivalent vaccines and require some changes to the vaccination schedules.

GAVI's entrance encouraged manufacturers to produce newer vaccines for developing markets through providing a market for these products. When developing countries procure more newer vaccines and fewer older, single-purpose or trivalent vaccines purchases, this impacts global manufacturing decisions. Each vaccine that a manufacturer produces, be it an older EPI vaccine or a newer combination vaccine is a

semi-independent endeavor requiring its own production capacity and certification processes. Manufacturers therefore make long-term commitments to a specific vaccine, not just the area of vaccinations. Also, the technology behind the combination vaccines is much more challenging, raising the technical skills and investments that manufacturers must have in order to participate in the vaccine market.

In 2000, GAVI started support for HepB, Hib, and Yellow Fever vaccines. In 2008, GAVI is expecting to start support for PCV and Rotavirus.<sup>xv</sup>

UNICEF procures all GAVI-funded vaccines and devices, \$135 million in 2006.<sup>xvi</sup> In December 2005, the GAVI Alliance Board received a detailed analysis of the supply activities to date and recommended that UNICEF continue as procurement provider for the existing combination products.<sup>xvii</sup>

While these two factors have significantly restabilized the vaccine market, it does remain fragile. The number of traditional vaccine manufacturers has stabilized and more manufacturers are pursuing WHO pre-qualification for new vaccines. Table 1 shows that the market remains relatively stable yet still fragile with few manufacturers supplying each vaccine.

Table 1: Number of vaccine manufacturers awarded a tender by UNICEF by vaccine

Vaccine Group	Number of Manufacturers awarded in 2001-2003	Number of Manufacturers awarded in 2004-2006	Number of Manufacturers awarded in 2007-2009
BCG	5	4	4
DTP	5	4	3
Measles	5	5	3
TT	7	4	3 (+1)
tOPV	4	5	5
mOPV1	0	1	5
mOPV3	0	1	3
DTP+Hib	0	0	1
DTP-HepB+Hib	1	1	2
DTP-HepB	1	1	3
HepB	4	5	6
YF	3	3	3
Meningitis	1	1	1
MMR	3	3	2
MR	1	1	2
DT/Td	3	2	2

Source: Vaccine Security. UNICEF Vaccine Procurement Overview. Rob Matthews, UNICEF Supply Division. UNICEF Supply Division Vaccine Manufacturers Meeting. April 3-4, 2008.

With UNICEF now procuring such a large percentage of the vaccines for developing countries, concerns have been raised over a monopoly in vaccine procurement going forward. Examining the risk of such a large percentage of global procurement capacity existing in one institution is an important question, but goes far beyond the intended scope of this study.

## 6. Paris Declaration Support of Self-Procurement

The World Bank, along with many donor countries, developing countries and multilateral institutions signed the Paris Declaration on Aid Effectiveness on March 2, 2005. Excerpts from this document that specifically refer to procurement are:<sup>xviii</sup>

*Art 17. Using a country's own institutions and systems, where these provide assurance that aid will be used for agreed purposes, increases aid effectiveness by strengthening the partner country's sustainable capacity to develop, implement*

*and account for its policies to its citizens and parliament. Country systems and procedures typically include, but are not restricted to, national arrangements and procedures for public financial management, accounting, auditing, procurement, results frameworks and monitoring.*

*Art 28. Partner countries and donors jointly commit to:*

- *Use mutually agreed standards and processes to carry out diagnostics, develop sustainable reforms and monitor implementation.*
- *Commit sufficient resources to support and sustain medium and long-term procurement reforms and capacity development.*
- *Share feedback at the country level on recommended approaches so they can be improved over time.*

*Partner countries commit to take leadership and implement the procurement reform process.*

*Art 30. Donors commit to:*

- *Progressively rely on partner country systems for procurement when the country has implemented mutually agreed standards and processes.*
- *Adopt harmonized approaches when national systems do not meet mutually agreed levels of performance or donors do not use them.*

As a signatory to the Paris Declaration, the World Bank has a responsibility to work with and strengthen national systems and assist to define measures of standards and accountability for procurement. If a country does not meet these standards, the World Bank should work to bring a country up to these standards. At the same time, donors have a responsibility to ascertain with how items are being procured with their finances.

## 7. Procurement systems

### 7.1. Options

A government has several options for vaccine procurement: government self-procurement, semi-autonomous or parastatal procurement, pooled procurement, use of UNICEF or PAHO procurement services, procurement through a commercial agent, and procurement with the assistance of another country's procurement staff. This study does not investigate commercial agent procurement as it is out of scope. Each government must decide the best route for its country based on the vaccine amount and type purchased, cost/quantity factors, foreign currency availability, restrictions on the use of funds, country NRA capability for vaccine quality assessment, corruption levels, and the procurement staff's experience and skills.<sup>xix</sup>

***Pooled procurement:*** Pooled procurement may offer lower prices than self-procurement, but it must be properly managed to be efficient. The Gulf Cooperation Council (GCC) acts as a pooled procurement agent for six countries in the Middle East. Table 2 on the next page shows that GCC pricing is up to 46% less than what one of its states received

from the same producers for the same vaccines.

**Table 2**  
**2003/2004 GCC and Member State Vaccine Prices in USD**

Vaccine	Price per dose one member state received through local tender	GCC price per dose	Percent decrease
MMR	5.15	2.79	46%
IPV	5.36	4.75	13%
DTwP	0.27	0.20	25%
DT	0.24	0.17	29%
TT	0.19	0.14	26%
OPV	0.15	0.12	25%
Rubella	1.61	1.32	18%

Source: Vaccine Market Characteristics. AIM (Advanced Immunization Management). PATH (Program for the Appropriate Use of Technology). August 2005.

**UN procurement:** UNICEF, PAHO, and WHO offer procurement services to many low- and middle-income countries that have the means to pay for their own requirements but lack the skill and/or infrastructure required for obtaining safe and effective vaccines from the international marketplace.<sup>xx</sup> These UN agencies also offer several other procurement-related services such as technical assistance for forecasting, cold chain management, and quality control. Whether or not a UN agency functions as a procurement agent does not impact receiving these other forms of technical assistance as the technical assistance is part of their mandate.

- **WHO:** WHO can act as a procurement agent for non-standard vaccines. WHO charges a 3% fee and requires payments in advance.<sup>xxi</sup>
- **PAHO:** PAHO purchases for countries in Latin American and the Caribbean with a revolving fund that allows countries to pay after delivery in local currency. PAHO has one price for all.
- **UNICEF:** UNICEF will procure either with a revolving fund through its Vaccine Independence Initiative (VII) or through direct payments made in advance. UNICEF can accept local currency for vaccine procurement within the program expenditure ceiling. UNICEF utilizes tiered pricing (i.e. manufacturers offer relatively cheaper prices to LDCs). UNICEF awards to multiple manufacturers and focuses not only on price in order to promote healthy markets and vaccine security. UNICEF's procurement system in itself is a high quality asset that a country cannot easily replicate on its own. More information on UNICEF can be found in Annex 1.

**Self-procurement and parastatal procurement:** This works well in countries with a well functioning NRA and vaccine procurement system, adequate currency to enter directly into international tender markets, a well-trained staff, and few corruption issues. Government procurement staff should know about international and local procurement procedures, product specifications, inspection procedures, regulatory and financial requirements, international shipping and trade documentation, international and local vaccine sources, and price levels.<sup>xxii</sup> Self-procurement incurs additional costs to support a procurement cell and incremental NRA capacities.

When evaluating a country's national procurement system, the following should be taken into account:

- a) The country's NRA's (National Regulatory Authority) implementation of six critical functions to ensure the quality of vaccines procured.
- b) The country's ability to forecast demands to provide sufficient quantity of vaccines to avoid shortages and program disruptions.
- c) Adequate capacity, knowledge, and processes in place for preparing bidding documents.
- d) Adequate capacity and processes in place for realizing the tender and selecting the supplier.
- e) Adequate processes in place for arranging finances.

A more in depth analysis of these five areas follows, including references to case studies. Detailed case studies can be found in Annexes 2 through 5. The goal of the case studies is to learn about factors that affect procurement options and to understand how donor funds can best be used in various procurement scenarios. The case studies can also provide some guidance for countries on issues to consider when navigating a fragile vaccine marketplace. Similarly, all these aspects are important for the World Bank to consider when it decides to support vaccine procurement.

## 7.2. The NRA's implementation of six critical functions

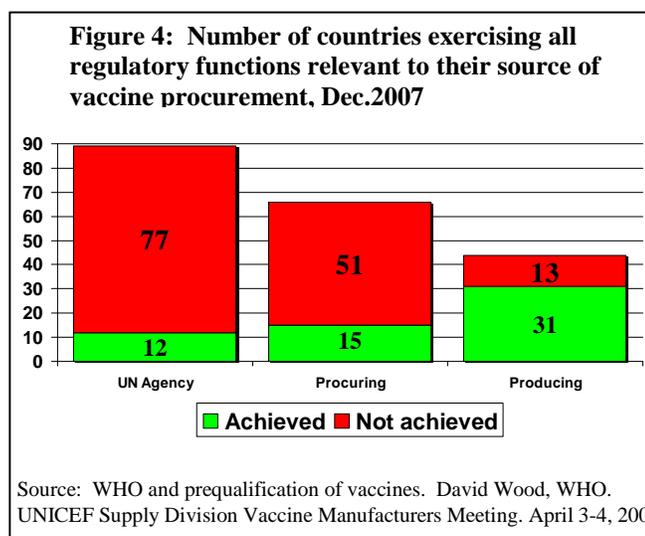
Many countries often overlook quality control issues for vaccines when considering procurement mechanisms. The UN has mandated the WHO to review country NRAs technical capabilities. WHO has identified the need to have an independent NRA that can perform six critical functions. Table 3 shows that a country should implement two, four, or six of these functions, depending on the procurement vehicle used.

Function	Definition	Required If		
		UN Procures	Government Procures	Local Production
Independent NRA	A country must have an independent national regulatory system	x	x	x
1. Licensing	A published set of requirements for licensing (of products and manufacturers)	x	x	x
2. Post-Marketing Surveillance	A system to survey vaccine field performance (safety and efficacy) and post-marketing surveillance including Adverse Events Following Immunization (AEFI)	x	x	x
3. Lot Release	The receiving country's NRA should conduct lot releasing. Lot releasing requires reviewing the summary lot protocols, which describe the production process in detail and must be included by the producer in each lot. This is separate from		x	x

	any testing that happens in vaccine producing countries.			
4. Laboratory Access for Testing	Access to a laboratory with testing abilities for vaccines in order to respond to reported adverse events. If countries do not have their own qualified laboratory, they should obtain access to a laboratory outside the country, such as a WHO reference laboratory.		X	X
5. Good Manufacturing Practice Inspections	Regular manufacturer inspections for Good Manufacturing Practices			X
6. Clinical Evaluation	Evaluation of clinical performance through authorized clinical trials			X

Source: Vaccine Market Characteristics. Advanced Immunization Management. PATH. August 2005.

Procuring countries cannot just rely on WHO pre-qualification of vaccines in the producing country because some functions, such as post-market surveillance, requires domestic government oversight. Also, a 2007 WHO review of the NRA in vaccine producing countries, shown in Figure 4, revealed that only 70% adequately performed the six regulatory functions that WHO deems critical. Furthermore, in-depth assessments of some countries revealed that NRAs who do perform these functions may not be performing them to a depth sufficient to assure vaccine quality.<sup>xxiii</sup>



Gaps in a country's NRA compromise the country's ability to ensure that it procures and receives only quality vaccines. Quality control at all stages of vaccine procurement and distribution must be monitored. When adverse effects following immunization happens, it is quite serious.

**Case study: Measles vaccine in India**

On Wednesday April 23<sup>rd</sup> 2008, four children died in Tamil Nadu, India within one hour of receiving a measles vaccination at two separate sites. Possible causes include:

- **Improper vaccination practices:**
  - Measles vaccine comes in a powder form that needs to be reconstituted by mixing with liquid diluents. Once reconstituted it needs to be used immediately because within three to five hours, harmful bacteria can grow.
  - Measles vaccine is very sensitive to cold chain practices. If not properly stored, it can easily deactivate.

- **Syringe issues:** Non-sterile syringes and needles can also cause bacterial problems.
- **Vaccine diluent issues:** The diluent itself could have been compromised or incorrectly used.
- **Vaccine issues:** A defective vaccine batch could have caused this.

The Government of India immediately sent a team to investigate. They autopsied the children and sent vaccine, vial, and diluents samples for testing. The Government of India suspended 45M doses of the measles vaccine made by the manufacturer. On May 5<sup>th</sup> 2008, the Government of India laboratory results indicated that the vaccine was safe. The Government of India concluded that toxic shock syndrome from improper vaccination practices killed the children.<sup>xxiv</sup>

### **7.3. The country's ability to forecast demands to provide sufficient quantity of vaccines to avoid shortages and program disruptions.**

Without an accurate forecast, a country cannot hope to have the appropriate amount of vaccines delivered to a country. Forecasting provides the foundation of vaccine procurement. Forecasting is independent of procurement in that the procurement mechanism chosen should not impact how a country forecasts. However, if a country's forecasts are off, this impacts its procurement decisions, e.g. inadequate forecasting will result in more emergency procurement.

#### **Case study: Botswana**

The Central Medical Store (CMS) in Botswana's Ministry of Health is responsible for vaccine procurement in Botswana. In the past year, they have had vaccine stock-outs, mostly due to tender processing issues and forecasting issues. The CMS team does the vaccine forecasting without much input from the Expanded Program on Immunizations (EPI) team. CMS has chosen to use a historical forecasting method whereby the previous year's vaccine quantities used form the foundation of the upcoming year's forecast. This approach is not in alignment with international best practices because, for example, a stockout would lead to lower forecasted needs in the following years. A much more accurate approach would be to base a forecast on a target population analysis.

### **7.4. Adequate capacity, knowledge, and processes in place for preparing bidding documents.**

How a government crafts a tender dictates a large part of the response it will receive from the market. Many governments choose to include WHO pre-qualification as a tender requirement because it provides an indication of quality. This does limit potential respondents - by 2001, 48 countries produced vaccines,<sup>xxv</sup> but only twenty four manufacturers in fourteen industrialized and six developing countries had achieved WHO pre-qualification.<sup>xxvi</sup>

If governments self-procure vaccines, they must remain vigilant against pressure from private manufacturers and fillers in their countries who are not WHO-prequalified yet would like to participate in a tender and can bear sometimes significant political pressure.

### **Case Study: Pakistan**

In 2007, the Government of Pakistan switched from UNICEF procurement to self-procurement and launched its first tender. Clause 2.1 of this first tender issued in October 2007 states: “This invitation for bids is open to all original manufacturers within Pakistan and abroad and their authorized agents / importers / suppliers subject to the conditions that:

- a. In the case of foreign manufacturers, they must offer the product pre-qualified by the World Health Organization (WHO).
- b. In case of local manufacturer of vaccines, they will qualify only if they are using concentrates from a manufacturer duly pre-qualified by WHO.
- c. In the case of authorized agents / importers / suppliers, they must quote such products which are pre-qualified by WHO.<sup>xxvii</sup>

Due to Clause 2.1.b, Amson Vaccines and Pharma Limited, a Pakistani pharmaceutical manufacturing company, qualified for the tender by proposing to import WHO pre-qualified vaccine concentrate and locally add the diluents and do the packaging. This dilution process impacts overall product quality and is an important step. Amson itself is not WHO pre-qualified. Amson ended up winning the tender to deliver 979,500 doses of TT vaccine.<sup>xxviii</sup> WHO does not consider this product to be WHO pre-qualified.<sup>xxix</sup>

## **7. 5. Adequate capacity and processes in place for realizing the tender and selecting the supplier.**

When a government procures vaccines, they must comply with the wider government procurement rules to ensure public moneys are well spent. Sometimes rules designed to help the overall country can make vaccine procurement more challenging.

### **Case study: Botswana**

In 2006, Botswana established the Public Procurement and Asset Disposal Board (PPADB) to guide all government procurement. Its new procurement regulations, largely based on World Bank and other international guidelines, have significantly altered vaccine procurement requirements in the past and changes are likely to continue for some time while processes are developed to meet the new regulations.

These changes have caused significant tender delays for the Central Medical Store (CMS), the part of the government responsible for vaccine procurement. In fact, CMS could not obtain a positive outcome from the PPADB on documentation submitted and could not launch a tender for vaccines in 2006. They therefore had to conduct direct purchases on an ad hoc basis once CMS stock levels had depleted. This resulted in rationing to the districts and stock out issues. In 2007, CMS launched a temporary "stop-gap" tender to supply vaccines through the end of March 2009.<sup>xxx</sup> The two areas causing CMS the most problems are:

- The 2004 Civil Empowerment Directive states that if a resident of Botswana can respond to a government procurement tender with a product of equal quality and within 10% of international prices, the tender must go to the Botswanan party. CMS does not currently intend to use the Citizens Empowerment Directive because there are no local human vaccine manufacturers. CMS would prefer to work directly with an international manufacturer than with a local agent because the government procurement rules do not give them the authority to monitor and enforce local agent's cold chain supply.<sup>xxxi</sup> Due to the Civil Empowerment Directive, CMS has not been able to develop a tender document template that PPADB accepts and so CMS must submit each tender of greater than 100,000 Botswana Pula (approximately \$16,000) through the Ministry of Health Clinical Services cost centre and central Ministry of Health finance to the PPADB.<sup>xxxii</sup>

The updated regulations invalidated how CMS had historically pre-qualified all suppliers so they have had to re-qualify all suppliers. CMS estimates that, as of May 2008, they are approximately 80% through this process.<sup>xxxiii</sup>

Realizing a tender is also a time-consuming, paperwork-intensive process that can be subject to corruption, delays, and other challenges. Governments must have adequate capacity and skills in place to successfully manage a tender.

#### **Case study: Bangladesh**

The EPI team in Bangladesh prefers to procure vaccines with UNICEF due to concerns regarding the procurement capacity of the Central Medical Supply Department (CMSD). While Bangladesh's procurement rules are clearly laid out, their application and interpretation often lacks. Since 2000, both the US government through USAID and the World Bank have supported government procurement, improving the Government of Bangladesh's ability to procure. However, due to government staff turnover, these gains are not permanent and must be continually reinforced.<sup>xxxiv</sup>

In 2002, the World Bank conducted an assessment of the Government of Bangladesh's procurement capacities. It found that actual implementation of procurement to be "quite uneven" and "far from satisfactory." Some unsatisfactory features were:<sup>xxxv</sup>

- Procurement delays - These were the single most serious malady found. It should take the government 180 to 330 days to successfully complete an international tender.<sup>xxxvi</sup> However, some contracts have been in process for over 1100 days.
- Poor advertisement
- A short bidding period
- Poor specifications
- Nondisclosure of selection criteria
- Award of contract by lottery
- One-sided contract documents
- Negotiation with all bidders
- Rebidding without adequate grounds
- Other miscellaneous irregularities
- Possible corruption and outside influence.

In 2005, the World Bank commissioned an Independent Procurement Review of World Bank financed projects in Bangladesh where the government was responsible for procurement. This review focused on a total of 75 contracts within four World Bank projects. The review audited 29 contracts valued at \$11.3M in the Health and Population Program Project (HPPP) and 6 contracts valued at \$6.3M in the HIV/AIDS Prevention Project. The review found that the procurement in the HPPP project was "highly insufficient" while procurement in the HIV/AIDS project was "insufficient." Specific areas of issue included:

- Filing and transparency
- Indications of collusion between bidders
- Insufficient World Bank supervision
- Untimely project execution
- Payment delays

Government procurement, however, is gradually taking on more functions successfully. For example, UNFPA used to procure \$40-\$50M of condoms annually for Bangladesh with a 5-6% procurement fee. In 2000-2001, the Government of Bangladesh switched to self-procurement for condoms. As a result, the government now successfully procures condoms without paying up front (UNFPA requirement) and without the procurement fee. It also found that they could procure the condoms for a lower price than UNFPA.<sup>xxxvii</sup>

Different cadres of health workers may differ in motivation. For example, in Ghana, a World Bank process mapping study discovered that the behaviors and motivation driving people working in the EPI program differed significantly from that of essential drugs or family planning. Higher levels of commitment often exist in vaccine procurement as supply chain staff internalize the mission that if they did not do their job right, then a child would die.<sup>xxxviii</sup>

## 7.6. Adequate processes in place for arranging finances.

Once the government awards a tender, it must release financing. Table 4 shows that globally, the greatest historical reasons for vaccine stockouts are delays in release of funding.

Funding issues often have nothing to do with the Ministry of Health or procurement capacity or procurement agent used. These issues can be caused by a lack of sustained flow of funds for vaccines.

Aggregated causes	COUNTRY	No. of Vaccines
<b>Forecast &amp; stock management issues</b>		
	Burundi	1
	East Timor	1
	Guinea-Conakry	1
	Haiti	1
<b>Funding issues</b>		
	Bhutan	1
	Bosnia-Herzegovina	2
	Equatorial Guinea	4
	Lao PDR	3
	Niger	4
	Nigeria	7
	Senegal	3
	Somalia	2
	Swaziland	1
	Tanzania	5
<b>Procurement process issues</b>		
	Indonesia	4
	Nepal	1
<b>Quality issues</b>		
	Albania	1
<b>Shipping</b>		
	Georgia	1
	Madagascar	2
	Rwanda	1
<b>Other</b>		
	West Bank & Gaza	1

Source: Vaccine Security. UNICEF Vaccine Procurement Overview. Rob Matthews, UNICEF Supply Division. UNICEF Supply Division Vaccine Manufacturers Meeting.

### ***Case study: Nigeria***

In 2004, Nigeria's National Population Commission reported that Nigeria's national coverage for full immunization was less than 13%, one of the lowest in the world. Vaccine stock-outs significantly impeded vaccination campaigns. A 2003 UNICEF-WHO Joint Vaccine Security Mission highlighted that all routine vaccines were out of stock, that the Government of Nigeria had last released funds for vaccine procurement in April 2001, and that no basic EPI vaccines except for OPV had entered the country since Q3 of 2001.<sup>xxxix</sup>

The EPI managers successfully conducted international tenders, but they could not then award a contract to the chosen vendor due to the Ministry of Finance not releasing the funds.<sup>xl</sup> For example, although the Ministry of Finance released 60% of the initial 2001 budget for vaccines, they released no funds in 2002, and as of March 2003, the funding cycle has only reached the budget approval stage. The Ministry of Finance also released the 2001 funds late (April 2001) forcing the government to buy vaccine on the spot market, at inflated prices, with uncertain availability, and potentially with less shelf life.<sup>xli</sup>

This non-release of funds has multiple impacts ranging from current vaccination campaigns to future campaigns to global vaccine security. When a country issues a tender and initiates negotiations with distributors or agents, manufacturers initiate production plans to meet the demand, which in Nigeria's case is substantial. (Due to its large size, Nigeria has a significant impact on DTP, HepB, and Yellow Fever Markets). By not continuing to an order, a country loses credibility with manufacturers, which can lead to fewer bidders for future tenders. Also, manufacturers can incorporate risk factor charges going forward in the vaccine prices offered to that country. And from an international supply point of view, this situation could encourage more manufacturers to exit the market, leading to even further global vaccine scarcity and further increases in cost price.

## **8. Procuring the highest quality vaccines at a reasonable price**

To compare which procurement channel, UNICEF procurement or government self-procurement, is less expensive, all costs must be considered. This includes:

### ***UNICEF procurement:***

- UNICEF-procured vaccine cost.
- UNICEF overhead cost.

### ***Government self-procurement:***

- Government procured vaccine cost.
- Government procurement cell. Cost as a percentage of order will vary depending on country size, procurement cell efficiency, and depth of service the procurement cell offers.
- The cost of the two incremental NRA critical functions.

It is extremely challenging to compare vaccine prices. Vaccine manufacturers offer different prices for each vaccine to each customer and in each contract. Elements affecting price include:<sup>xlii</sup>

- Quality and WHO-certification
- The order size
- The number of shipments anticipated

- When the shipments are needed
- Shipping distance
- Currency of payment
- Payment terms
- Product specification including special labeling, packaging and handling requirement
- Risk (e.g. risk of non-payment, of currency devaluation, etc)
- The number of producers
- The market size
- Tiered country pricing for vaccines
- Patents, intellectual property rights and know-how
- Manufacturer inventory positions
- Competition in marketplace

Final country vaccine prices may also include shipping insurance, inspection, testing, custom duties, clearance fees, procurement agent fees, handling fees, licensing and quality control costs. Most countries waive custom duties and taxes on vaccines.

The final factor, competition in the marketplace, is a significant driver of price over the long term. The amount of manufacturer competition for a tender is impacted by two factors:

- a) ***Vaccine manufacturer competition:*** Vaccine prices tend to fall when more manufacturers enter the market and can compete for business. For example,<sup>xliii</sup>
- The world price of plasma-derived hepatitis B vaccine fell from \$15-\$30 per dose to less than \$1 per dose in 1987 when two Korean manufacturers responded to an international tender for hepatitis B. Up to that time, only two firms produced the vaccine.
  - PAHO's price for measles and hepatitis B vaccines fell in the 1990s when producers from Asia submitted bids for the first time and were awarded contracts.

The manufacturing level of competition is the primary driver of global vaccine prices. The World Bank should therefore focus on increasing competition at the manufacturer level.

- b) ***Procurement agent competition:*** The type of procurement mechanism can impact how many manufacturers respond to a tender. Because the number of manufacturers responding to a tender is the key driver in competition and lower prices, sometimes a sole source procurement agent decision will actually maximize competition. For example, UNICEF has historically worked to maximize the number of manufacturers involved in a tender. A self-procuring country sometimes does not have the size to interest many manufacturers to bid or institutes registration requirements which limit how many manufacturers will respond to a tender and thus have less competition on the manufacturing level. Registration requirements can impact a tender process in the following manners:

- *European manufacturers:* In general, if an EPI tender requires significant

investment, European manufacturers will most likely not bid because they are more focused on advanced combination vaccines. With the exception of their commitment to polio eradication, they are moving out of the older EPI vaccines that many developing countries rely on and so will not make significant investments (such as local operational capacity) in a developing country in order to sell these products there.

- *Developing country manufacturers:* These manufacturers tend to focus more on the traditional EPI vaccines and are more willing to meet local registration and operation requirements, depending on country size.
- *Domestic firms:* Domestic firms can either manufacture the vaccine directly (if the firm and the country’s NRA have passed WHO pre-qualification) or can import the vaccine from a WHO pre-qualified international manufacturer. If domestic procurement agents are the prime tender respondents, these agents can be the limiting factor for competition in the country because each domestic firm will usually respond to a tender with just one international manufacturing partner.

#### Case Study: Pakistan

Since Pakistan moved from UNICEF procurement to self-procurement, it has launched three tenders. Each has received a small number of respondents, as shown in Table 5.

Table 5  
Number of Respondents to Pakistani tenders

Tender	Product	Respondents	Pass Technical Qualifications	Tender Awarded?
January 2008	BCG	Two	One	Yes
January 2008	TT	Two	One	Yes
January 2008	OPV	Two	Two	Yes
January 2008	Measles	One	One	Yes
March 2008	mOPV1	Three	One	No
March 2008	mOPV3	Two	Zero	No
March 2008	tOPV	Four	One	Yes
April 2008	mOPV1	One	One	Yes
April 2008	mOPV3	One	One	Yes

Source: Tender evaluation documentation. Ministry of Health. Government of Pakistan. 2008.

Two March tenders had to be relaunched, impacting polio vaccination campaigns. While 71M trivalent OPV doses intended for a June 3<sup>rd</sup> Sub-National Immunization Day were delivered in March, the mOPV1 and mOPV3 vaccines will not be delivered in time for distribution because the government did not enter into a contract for these until mid-May. Thus, this polio immunization campaign is being delayed.

Possible reasons for small number of manufacturers responding to these tenders include:

- UNICEF will not respond to an open tender because this could potentially put it in a conflict of interest situation with the vaccine manufacturers who supply UNICEF under the Long Term Agreements. UNICEF did notify their manufacturers that Pakistan would be moving to self-procurement and asked them to release quantities dedicated to UNICEF for Pakistan.<sup>xliv</sup>
- Few international vaccine manufacturers can respond to a Pakistani tender due to two tender clauses:
  - Clause 2.4: “The bidder should have operational office(s) in Pakistan...”<sup>xliv</sup> Only Glaxo Smith Kline has an operational office in Pakistan.

- Clause 3.2: “In case of vaccines, besides WHO pre-qualification, these must: (a) be registered with the Ministry of Health, Government of Pakistan.”<sup>xlvi</sup> One of the Registration Board’s requirements is, according to Form 5A, “For import purpose a sole agent in Pakistan is required to be nominated by the principal / manufacturer abroad.”<sup>xlvii</sup>
  - The Government of Pakistan is restricted from purchasing any products from either Israel or India. Because India is one of the largest suppliers of vaccines, this provides a challenge, but waivers can and have been obtained.
  - Four domestic firms responded to the tender, each time proposing to import a vaccine from one international manufacturing partner. The four firms are:<sup>xlviii</sup>
    - Amson Vaccine & Pharma responded to six tenders. They proposed to import from Japan BCG Lab, Shantha Biotechnics, Novartis, and Panacea Biotec.
    - Hospital Sales and Services responded to two tenders, always proposing to import from Serum Institute.
    - Sind Medical Stores responded to three tenders, always proposing to import from Sanofi Pasteur.
    - Majeed Sons responded to two tenders, always proposing to import from Novartis.
- In this case, the fact that Amson Vaccines & Pharma has relationships with so many manufacturers but will only propose one manufacturer per tender can limit competition.

It is impossible to say which procurement channel offers the lowest vaccine price in every single circumstance because each order receives a different price due to the large number of potential factors impacting price. A 1996 USAID/BASICS/PATH study found that, “in terms of price, UNICEF and PAHO receive substantial discounts from manufacturers since they are high-volume purchasers, but the addition of an administrative fee, e.g. 6-8% for UNICEF, has frequently bought the total cost up to, or beyond, the lowest vaccine prices offered directly to public-sector markets.”<sup>xlix</sup> In April 2007, after significant criticism over their fees, UNICEF reduced fees globally. UNICEF now charges all Least Developed Countries (LDCs) a handling fee of 4% for EPI vaccines and immunization devices, 3% for new vaccines, and 8% for cold chain equipment. UNICEF charges non-LDCs 4.5% for EPI vaccines and immunization devices, 3.5% for new vaccines, and 8.5% for cold chain equipment.<sup>1</sup> UNICEF also adds an inspection fee. These fees are standard for countries regardless of order size.

A vaccine price less than UNICEF’s prices is rarely seen on the marketplace. Clause 4.33 in UNICEF procurement contracts states: “If at any time during the validity period of the Long Term Agreement [to purchase vaccines], the awarded supplier offers to sell the vaccine at a price lower than the price effective under the Long Term Agreement, the awarded supplier shall offer the same price to UNICEF for the remaining validity period of the Long Term Agreement.” UNICEF has in the past enforced this clause with suppliers but with some exceptions. Cases where UNICEF did not enforce the clause usually revolve around extenuating circumstances with e.g. a vaccine oversupply or a government pressuring a state-owned or a domestic manufacturer to sell its vaccines at below cost.<sup>li</sup>

Three of the countries surveyed offered vaccine pricing comparisons between UNICEF-procured prices and self-procured prices. In all cases, UNICEF procurement channels offered significantly lower prices.

Table 6 on the next page shows that Government of Botswana, which procured by itself, obtained pricing anywhere from 25% to 114% higher than the UNICEF World Average prices. This is most likely at least partially due to Botswana's small purchase volume.

**Table 6**  
**Botswana vaccine procurement 2008: Price comparison with UNICEF**

Product	Quantity	Price Paid		Total Price in Dollars <sup>1</sup>	Unit Price in Dollars	UNICEF 2008 World Average Price <sup>2</sup>	Price premium	Price Premium in dollars
		Amount	Currency					
Polio	8,113	38.00	USD	308,294	0.19	0.15	25%	62,430
BCG	2,600	1.45	EUR	5,858	0.23	n/a <sup>3</sup>	-	-
DTP	6,920	1.60	EUR	17,203	0.25	0.18	42%	5,054
DT	3,900	1.25	EUR	7,575	0.19	0.11	77%	3,295
HepB	34,200	3.00	EUR	159,416	0.47	0.22	112%	84,364
Measles	14,100	1.90	EUR	41,625	0.30	0.23	27%	8,915
TT	5,200	1.15	EUR	9,291	0.18	0.08	114%	4,944
<b>Total</b>	<b>75,033</b>			<b>\$ 549,262</b>			<b>45%</b>	<b>\$ 169,002</b>

Source: Interview with Mr. Kgosiemang, Chief Pharmacist, Central Medical Stores, Ministry of Health, Government of Botswana, April 2008. Compared with UNICEF World Average Prices at [http://www.unicef.org/supply/index\\_7991.html](http://www.unicef.org/supply/index_7991.html)

Nigeria has a substantial vaccine volume but, as shown in Table 7, received prices ranging from 8% to 248% higher than UNICEF prices. This is most likely due to a lower purchase volume than UNICEF and short purchase timeframes leading to ad hoc tenders on the spot market in 2002.

**Table 7: UNICEF's average 2003 prices compared to prices offered to Nigeria in its 2002 tender<sup>4</sup>**

Product	Latest Nigeria tender price 2002 (USD/dose)	UNICEF World Average Price 2003 (USD/dose) <sup>5</sup>	Percent increase in price
BCG 20 d	0.135	0.063	116%
DPT 20 d	0.180	0.085	112%
Measles 10 d	0.220	0.131	67%
TT 20 d	0.140	0.040	248%
YF 10 d	0.430	0.398	8%

Source: Personal communication with UNICEF – Copenhagen. April 2008.

Table 8 on the next page shows the prices that the Government of Pakistan received on the global market. Their prices are also higher than UNICEF even though Pakistan has a substantial volume. Factors increasing their price include lower purchase volumes than UNICEF, limited competition for tenders, additional cost of local agents, more favorable tender terms, and shorter tender timeframes. Annex 5 details these more fully.

<sup>1</sup> Currency converted in May 2008 to USD at rate of 1.55376

<sup>2</sup> UNICEF procures from a number of different manufacturers with different prices. The actual price countries receive would vary depending on availability. Price includes 4.5% procurement fee.

<sup>3</sup> UNICEF does not buy BCG in the 10 dose vial presentation that Botswana procures.

<sup>4</sup> All prices are cost prices, i.e. freight, insurance and clearance cost should be added to both tender prices and UNICEF prices.

<sup>5</sup> Includes a 6 % handling fee. As UNICEF procures from a number of different manufacturers with different prices, the actual price countries receive would vary depending on availability. In 2003, UNICEF was in the process of tendering for its 2004-2006 demand and so their manufacturer price increased from 0-36% starting in 2004.

**Table 8**  
**Government of Pakistan self-procurement vaccine prices, 2008**

<b>Date</b>	<b>Vaccine</b>	<b>Quantity</b>	<b>Agent</b>	<b>Mnf</b>	<b>Cost/ unit incl. freight<sup>6</sup></b>	<b>UNICEF 2008 adjusted cost/unit<sup>7</sup></b>	<b>Increase in price: percent</b>	<b>Increase in price: total dollars</b>
Jan-08	BCG	792,000	Amson	Japan BCG	0.161	0.117	38%	35,128
Jan-08	TT	979,500	Amson	Shantha Biotech	0.061	0.059	4%	2,273
Jan-08	tOPV	2,765,500	Sind	Sanofi Pasteur	0.198	0.170	16%	77,066
Jan-08	Measles	2,644,500	Amson	Serum Insti	0.325	0.260	25%	171,139
Mar-08	tOPV	71,111,100	GSK	GSK	0.174	0.170	3%	323,943
May-08	mOPV1	20,000,000	Sind	Sanofi Pasteur	0.203	0.164	24%	779,248
May-08	mOPV3	20,000,000	GSK	GSK	0.223	0.176	27%	950,818
<b>Total</b>		<b>118,292,600</b>					<b>12%</b>	<b>2,339,614</b>

Source: Government of Pakistan tender documentation. May 2008.

Please note that the above price analyses do not include the cost of a government procurement cell nor the cost of the two required incremental NRA functions required for government self-procurement. These are traditionally accounted for elsewhere within government financing. A full analysis would include these and increase government self-procurement costs accordingly.

<sup>6</sup> Tender costs based in Pakistani rupee and converted at January 2008 rate of 0.01601281, March 2008 rate of 0.016334275 and May 2008 rate of 0.014488633.

<sup>7</sup> Based on UNICEF 2008 published World Average Prices with the following adjustments: 1). 10% added to UNICEF price due to the fact that Pakistan prefers not to purchase from Indian manufacturers. UNICEF has historically procured vaccines for Pakistan from European manufacturers who have been 0-50% higher than the UNICEF World Average Price, depending on the order. Pakistan has obtained waivers to procure from India but the majority of their procurement came from Europe. 2). 4.5% UNICEF handling and inspection fee added. 3). 1.832% freight fee added. UNICEF does not include freight. Average UNICEF freight costs varies based on quantity ordered, but do not vary much based on port of origin as most UNICEF vaccines for Pakistan ship from Europe. For the 39 orders placed under the \$42M World Bank IDA buy-down fund implemented in July to December 2007, freight charges were 1.826% of vaccine costs. For the 18 orders placed with \$21M of the \$74M of the second IDA buy-down spent in December 2007 and January 2008, freight were 1.838% of vaccine costs. For this analysis, an average of these freight costs was used.

## 9. World Bank procurement standards and UNICEF

Four considerations inform the World Bank guidelines for procurement under IBRD loans and IDA credits:<sup>lii</sup>

- ③ The need for economy and efficiency in project implementation, including the procurement of the goods and works involved.
- ③ The Bank's interest in giving all eligible bidders from developed and developing countries the same information and equal opportunity to compete in providing goods and works financed by the Bank.
- ③ The Bank's interest in encouraging the development of domestic contracting and manufacturing industries in the borrowing country.
- ③ The importance of transparency in the procurement process.

Historically, UNICEF and the World Bank have had some challenges in partnering for vaccine procurement, mostly focused around the following areas:

- a) **Sole source:** The World Bank considers UNICEF as a sole source supplier. World Bank procurement guideline Clause 3.10 indicates that when a UN agency acts as a procurement agent, the UN should follow all Bank procurement guidelines for its procurement which includes open competitive bidding.<sup>liii</sup>

However, while open competition remains the basis for efficient public procurement, the guidelines instruct borrowers to select the most appropriate method for the specific procurement. Clause 3.9 indicates that “procurement directly from specialized agencies of the United Nations, acting as *suppliers*, pursuant to their own procedures, may be the most appropriate way of procuring ... specialized products where the number of suppliers is limited such as for vaccines or drugs.”

- b) **Audit:** World Bank procurement guideline 1.11 instructs the Bank “to review the borrower's procurement procedures, documents, bid evaluations, award recommendations, and contracts to ensure the procurement process is carried out in accordance with the agreed procedures but offers flexibilities in the extent to which the review procedures applies to different categories of goods and works to be financed.” The guidelines also stipulate that the World Bank has the right to inspect the accounts, records, and documents relating to the bid submission and contract performance and to have them audited by auditors appointed by the Bank.

UNICEF, as a specialized agency of the United Nations, follows UN regulations which provide internal oversight through UNICEF Financial Rules and Regulations, UNICEF Procurement Procedures, Ethical Code, Contracts Review Committee (independent from contracting staff), and Procurement Training and Certification of contracting staff. External oversight is provided from UN External Audit (French audit in mid-2004 focused on vaccine procurement; no major findings) and UNICEF Internal Audit.<sup>liv</sup> UN policy does not allow for third party audits.

UNICEF procurement contracts with governments stipulate that:<sup>lv</sup>

- “The parties recall that UNICEF’s financial books and records are routinely audited in accordance with the internal and external auditing procedures laid down in UNICEF’s Financial Rules and Regulation.”
  - “The Parties acknowledge that in accordance with the Financing Agreement, the Government has an obligation to deliver to the Association an annual audit certificate in respect of the funds provided pursuant to that agreement. In order to enable the Government to discharge this obligation, UNICEF will on request respond to all reasonable information requests from the Government and provide all assistance, as may be agreed, between the Parties.”
- c) **Liability:** When UNICEF acts as a procurement agent or supplier for a country, it does not take legal liability for the products delivered. This rests with the manufacturer from whom UNICEF procured. While UNICEF has in the past worked with the country and the manufacturer to resolve issues, their contracts do not bind UNICEF to do so.
- d) **Payment terms:** World Bank guidelines stipulate that payment shall be made upon delivery of goods whereas UNICEF financial regulations require payment in UNICEF’s account before it can place an order.

These four challenges have led to long delays under Bank supported procurement using the services of UNICEF as they require extra clearances and waivers to World Bank procurement guidelines at the highest level in the Bank. The World Bank has waived audit and liability clauses in Agreements between Governments and UNICEF which it finances, as it considers these risks low.

At the time of the writing of this report, discussions between UNICEF and the World Bank at the institutional level are ongoing to come to a mutually satisfactory arrangement.

## 10. Conclusion

An analysis of the five core principles that should apply to World Bank financed vaccine procurement decisions does not provide a clear-cut rule for which type of procurement mechanism the World Bank should support in all cases. This is because vaccine procurement is a complex issue that interweaves the domains of public health, market dynamics, commodity security, ethics, and procurement capacity. Its cross-disciplinary nature means that neither a straightforward analysis stemming from just one discipline nor a cookie-cutter application of World Bank procurement principles of economy, efficiency, equal opportunity, promoting domestic contracting and transparency will lead to an optimal solution. In fact, the general application of such procurement principles without considerations for other factors such as vaccine security led to the vaccine market crash in 1999 in the first place.

The World Bank has therefore historically considered vaccine procurement as “special” and has waived for it the strict application of its procurement guidelines.

Going forward, the World Bank should give highest priority to the considerations of vaccine security and the fragility of the market. When this is combined with the lower total vaccine procurement cost most likely achieved through UNICEF procurement channels and the challenges developing countries face with regards to vaccine procurement, as illustrated by the case studies, the World Bank should shift from putting the burden of proof on country teams for explaining why they would like to work with UNICEF for procurement of vaccines to putting the burden of proof on country teams to explain why they would like to work with country procurement systems.

If the World Bank determines that a national country’s procurement systems do not have the capacity to act as an effective agent, the World Bank should work to strengthen procurement and quality control institutions. High priority should be given to technical assistance should for NRA capacity building and this capacity should be in place before national procurement cells are activated and used.

Countries with adequate procurement and quality control capacity have fewer procurement challenges, but will most likely not be able to provide as low-cost of a procurement option as UNICEF is able to. UNICEF will most likely always provide a lower price due to its larger volumes and resulting greater competition among manufacturers bidding on UNICEF orders. Furthermore, individual country self-procurement decisions may negatively impact global vaccine security unless countries incorporate these principles into their procurement decisions. Finally, the decision to move from UNICEF procurement to government self-procurement can be driven by local private sector interests and not by concern for increased efficiency and effectiveness of procurement. Therefore, caution should still be exerted when moving from UNICEF procurement to self-procurement. Therefore, caution should still be exerted when moving from UNICEF procurement to self-procurement in countries that have full procurement and quality control capacity.

## Annex 1: UNICEF Procurement Services

UNICEF is not just a procurement agent but is actively involved in almost all facets of vaccinations. Some of UNICEF's programs regarding vaccines include:<sup>lvi</sup>

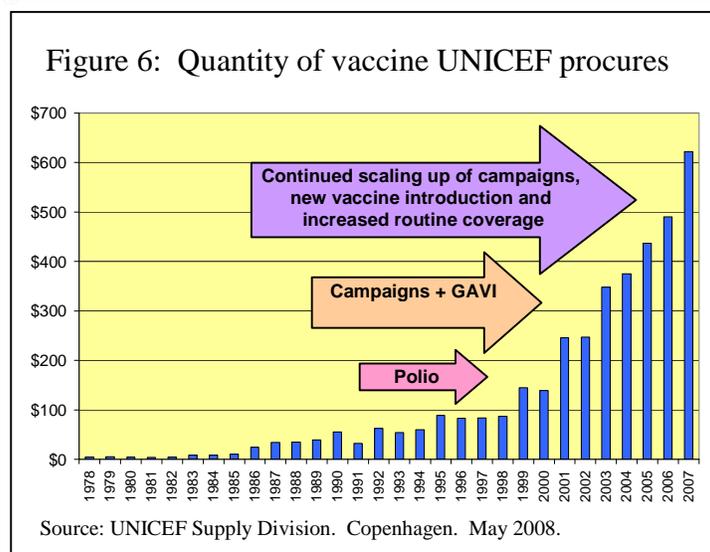
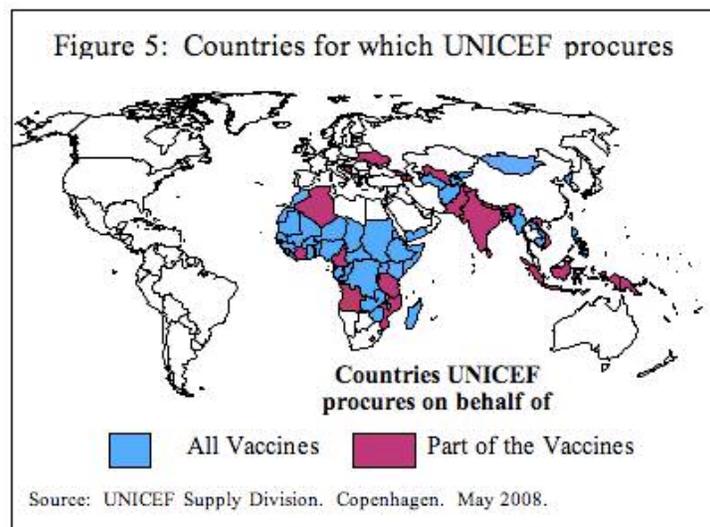
- Working with manufacturers to ensure an adequate supply is available.
- Working with countries to accurately forecast demand.
- Working with countries, donors, and recipient partners to secure funding.
- Purchasing and transporting vaccines.
- Training health workers.
- Galvanizing local communities to bring children to vaccination campaigns.

Countries do not have to work with UNICEF as a procurement agent in order to receive UNICEF technical assistance in these areas.

In-country UNICEF supply staff work locally with the government during the vaccine procurement process to ensure adequate document preparation and delivery assistance. The local UNICEF office does not receive any of the procurement handling fees directly.

Figure 5 shows which countries work with UNICEF for vaccine procurement. Individual countries can significantly impact UNICEF's procurement. The top ten countries constitute 66% of total demand in terms of dollars. In 2007, the largest countries in terms of UNICEF volume were India, then Pakistan, then Bangladesh. UNICEF uses this capacity to reallocate demand and supply between countries and suppliers to avert crisis and reduce the impact of demand and supply fluctuations.<sup>lvii</sup> If a large country drops from UNICEF procurement, this limits UNICEF's ability to manage demand and shift suppliers.

Figure 6 shows how the dollar amounts of UNICEF vaccines purchases increased. In 2007, UNICEF procured vaccines for



approximately 30% of the world's children for routine immunizations and when supplemental polio and measles vaccines are included, it procures about 40% of the total vaccines doses or over 3 billion doses, worth approximately \$617 million (2.4 billion of those doses were for polio.)<sup>lviii</sup> UNICEF procures on behalf of 84% of children in low income countries (excluding the self-producing countries of India, China, and Indonesia).<sup>lix</sup>

### ***UNICEF Funding and Tender Process***

UNICEF invites all manufacturers to apply for multi-year tenders and only WHO pre-qualified manufacturers to compete for single-year tenders. Before a tender, UNICEF weights the importance of the following factors: past on-time delivery performance, price, delivery schedule, future production plans, Vaccine Vial Monitors, shelf-life, ability to maintain buffer stock, timeline for emergency response (packaging), and shipping performance. During a tender, it then chooses a manufacturer for an LTA based upon a quantitative and qualitative review of these factors. For example, in 2003, UNICEF awarded LTAs for HepB. This is a small tender with decreasing annual demand tender due to the rise of combination doses. At the time of the tender, there were five WHO pre-qualified manufacturers, many of whom had production capacities greater than the annual 20-40M dose demand. UNICEF used their methodology to award all five manufacturers, with those offering the lowest price and best historical performance receiving the largest quantities.<sup>lx</sup>

If a manufacturer is not WHO pre-qualified at time of tender, their proposal must include a detailed plan on the timeline to obtain WHO pre-qualification. Upon obtaining WHO pre-qualification, UNICEF will consider re-allocating quantity to the manufacturer if UNICEF is facing a monopoly or near-monopoly situation, there is a lack of performance of current manufacturers or insufficient supply from current manufacturers.<sup>lxi</sup>

UNICEF procures for approximately 100 countries, each one having 3-7 funding sources. UNICEF's financial rules and regulations require payment in advance. Because UNICEF relies on external funding, it cannot make a firm purchase order without having internal committed commensurate funding in place. In general, 95% of funding for over 2 billion doses of vaccines arrives 1-3 months prior to delivery. UNICEF is cautious to make major changes that will set precedent or expectations that cannot be applied to all vaccines or may not be sustainable.<sup>lxii</sup>

UNICEF designed its tendering process to lessen a manufacturer's timing risk. For example, UNICEF's process for the 2007-2009 period was as follows:<sup>lxiii</sup>

- June 2005: UNICEF internal review of tender documents based on vaccine forecasts for 2007-09 period.
- December 2005: UNICEF and vaccine manufacturers meet
- January 2006: UNICEF issues tender
- March 2006: Tender closes
- July 2006: Tender awards made

Countries' processes, usually driven by an annual budgeting cycle, are much shorter. For example, Botswana started its April 2006 - March 2007 tendering process in April 2006.

***Manufacturers who supply UNICEF***

UNICEF procures from both developed and developing countries. Since the 1990s, new manufacturers from developing countries have started to fill the supply gap in traditional vaccines. Table 9, on the next page, shows that UNICEF increased both the dollar amounts of vaccines purchases from 2000 to 2006 by 538% and increased the percentage of total vaccine purchases from developing countries from 34% in 2000 to 37% by 2006. This represents a \$167M increase for manufacturers from developing countries.

Table 9  
UNICEF Vaccine Procurement Sources 2000 and 2006

Country	Company	2006		2000		Change
		Value	Percent	Value	Percent	
<b>Developed Countries</b>						
Australia	CSL Limited	\$378,385	0.08%	\$285,000	0.20%	133%
Belgium	GlaxoSmithKline	\$171,469,155	34.92%	\$32,397,032	23.14%	529%
Canada	Intervax	\$1,122,711	0.23%	\$2,463,959	1.76%	46%
	Aventis Pastuer			\$113,150	0.08%	
Denmark	Statens Serum Institut	\$4,163,414	0.85%	\$2,519,205	1.80%	165%
France	Aventis Pasteur			\$15,589,249	11.14%	
Germany	Chiron Behring			\$19,198,668	13.71%	
Italy	Novartis	\$21,964,330	4.47%			
Israel	Sarel	\$114,905	0.02%			
Japan	Eisai Co			\$637,365	0.46%	
	BCG Laboratory	\$4,058,780	0.83%	\$1,420,281	1.01%	286%
Netherlands	NVI	\$132,090	0.03%			
Russian Federation	State Unitary Enterprise			\$264,600	0.19%	
Sweden	SBL Vaccin	\$130,000	0.03%			
Switzerland	Berna Biotech	\$19,561,981	3.98%			
	Swiss Serum & Vaccine Institute			\$830,390	0.59%	
USA	Merck	\$1,261,552	0.26%	\$136,500	0.10%	924%
<b>Other orders less than \$100,000</b>		<b>\$84,446,073</b>	<b>17.18%</b>	<b>\$16,308,640</b>	<b>11.65%</b>	<b>518%</b>
<b>Subtotal</b>		<b>\$224,242,398</b>	<b>45.6%</b>	<b>\$75,855,399</b>	<b>54.18%</b>	<b>296%</b>
<b>Developing Countries</b>						
Brazil	FIOTEC	\$955,500	0.19%			
China	MoH			\$1,619,996	1.16%	
Cuba	Heber Biotec	\$240,500	0.05%			
India	Haffkine	\$620,880	0.13%	\$9,940,000	7.10%	6%
	Panacea Biotec	\$124,281,631	25.31%	\$20,653,209	14.75%	602%
	Serum Institute	\$38,171,454	7.77%	\$10,995,811	7.85%	351%
	Shantha Biotechnics	\$5,667,721	1.15%			
Indonesia	P.T. Bio Farma	\$3,565,240	0.73%	\$879,159	0.63%	406%
Republic of Korea	Cheil Jedang Corp			\$210,440	0.15%	
	Green Cross Vaccine			\$2,737,660	1.96%	
	LG Life Sciences	\$8,598,603	1.75%	\$157,590	0.11%	5456%
Senegal	Inst. Pasteur de Dakar	\$210,000	0.04%	\$642,096	0.46%	33%
<b>Subtotal</b>		<b>\$182,311,529</b>	<b>37.13%</b>	<b>\$15,489,480</b>	<b>34.17%</b>	<b>1177%</b>
<b>Other orders less than \$100,000</b>		<b>\$84,446,073</b>	<b>17.18%</b>	<b>\$16,308,640</b>	<b>11.65%</b>	<b>518%</b>
<b>Total</b>		<b>\$491,000,000</b>	<b>100%</b>	<b>\$140,000,000</b>	<b>100%</b>	<b>538%</b>

Source: UNICEF Supply Division Annual Report 2006 and 2000.

## Annex 2: Vaccine Procurement in Bangladesh

Bangladesh has large vaccination needs with a population of 150 million. In March 2006, Bangladesh had its first polio case since 2000 and responded with significant polio vaccination campaigns, further increasing its vaccine procurement requirements. Table 10, below, shows Bangladesh's vaccine procurement volume. OPV, measles and TT annual variations follow supply for campaign activities. The 2006 volume represents 8-10% of the total UNICEF vaccine global purchase volume for 2006.<sup>lxiv</sup>

Table 10  
Vaccine doses procured - Bangladesh

Vaccine	2001	2002	2003	2004	2005	2006	Total
BCG	25,000,000	19,856,000	31,640,000	17,632,000	25,100,000	29,442,000	148,670,000
DTP	12,000,000	18,465,500	18,848,000	19,000,000	20,000,000	19,162,000	107,465,500
HepB	1,001,000	1,681,000	6,083,000	4,777,800	17,518,000	10,468,700	41,529,500
Measles	17,500,000	13,368,000	19,800,000	7,637,600	57,965,000	12,796,000	129,067,400
OPV	95,708,000	76,533,000	123,424,000	3,033,000	24,601,000	249,600,000	572,919,000
TT	21,600,000	37,745,000	16,748,000	19,616,500	45,327,500	21,419,000	162,456,000
Other						15,750	15,750
Total	172,809,000	167,648,500	216,543,000	71,696,900	190,511,500	342,903,450	1,162,123,150

Source: Personal correspondence with Thomas Sorenson, UNICEF Supply Division, Copenhagen. October 2007.

Table 11, below, shows immunization coverage rates in Bangladesh.

Table 11<sup>8</sup>  
WHO-UNICEF Reported Immunization Coverage for Bangladesh

	2006	2005	2004	2003	2002	2001	2000
BCG	96	96	96	95	95	94	95
DTP – first dose	96	96	96	93	95	94	93
DTP – third dose	88	88	88	81	83	85	83
HepB – third dose	88	62	10	5			
Measles	81	81	81	76	75	77	76
TT – second dose							
Polio – third dose	88	88	88	82	83	85	83
Government of Bangladesh Reported Immunization Coverage for Bangladesh							
	2006	2005	2004	2003	2002	2001	2000
BCG	98	96	92	95	95	94	95
DTP – first dose	97	95	97	91	86	87	88
DTP – third dose	84	78	96	72	69	65	68
HepB – third dose	84	84	59	5			
Measles	84	78	96	69	65	64	61
TT – second dose	94	88	41	89	89	90	89
Polio – third dose	92	84	96	72	70	66	68

Source: WHO website: <http://www.who.int/vaccines/globalsummary/immunization/countryprofileselect.cfm>. Accessed April 2008.

<sup>8</sup> Government estimates are the official country estimates. UNICEF / WHO estimates are based on government estimates but adjusted to take into account program strength, Independent National Immunization Coverage Survey figures, and population denominator figures.

GAVI is currently reviewing the Government of Bangladesh's application for pentavalent HepB and will make a decision in June 2008. If approved, it will be introduced in 2009. GAVI has an Inter-Agency Coordination Committee (IACC) for vaccines in Bangladesh to improve coordination among partners. It includes UNICEF, WHO, Japanese International Cooperation Agency (JICA), UK Department for International Development (DFID), World Bank, United States Agency for International Development (USAID), Rotary International, Canadian International Development Agency (CIDA), Ministry of Health, Ministry of Finance, Ministry of Forestry, local government agencies, BRAC, and International Center for Diarrhoeal Diseases, Bangladesh (ICDDR,B).<sup>lxv</sup>

### ***Vaccine Procurement***

UNICEF procured all vaccines in Bangladesh except for a negligible amount used in private hospitals. Therefore, while there are significant EPI skills in Bangladesh, there are very few vaccine procurement skills in Bangladesh.

The Government of Bangladesh currently has a multi-year plan for immunization that includes costing for the years 2008-2012. The national budget has a line item for vaccines.<sup>lxvi</sup>

Either World Bank IDA financing or a consortium of donors who pool funds that the World Bank then manages financed \$42.8M for vaccines in 2006. The funds passed directly from the World Bank to UNICEF Copenhagen. In 2006, UNICEF charged 6% for their procurement services (fee subsequently lowered to 4%), resulting in \$2.57M in calculated procurement fees (or almost \$600,000 excluding polio vaccines).

The Government of Bangladesh has applied for GAVI assistance for pentavalent vaccines.

All parties interviewed in Dhaka feel that UNICEF is doing a very good job with vaccine procurement. The Expanded Program on Immunizations (EPI), the part of the Government of Bangladesh responsible for vaccinations, receives the vaccines on time and the process works smoothly. UNICEF will procure and deliver vaccines in about three months time. EPI prefers that UNICEF manages vaccine procurement as opposed to the Central Medical Supply Department (CMSD) in the Government of Bangladesh because it has concerns regarding CMSD procurement capabilities and has historically been pleased with the service it has received from UNICEF.<sup>lxvii</sup> UNICEF and EPI have a working relationship with high levels of trust. UNICEF often goes above and beyond what is contractually required.

In 2002, the World Bank conducted an assessment of the Government of Bangladesh's procurement capacities. It found that actual implementation of procurement to be "quite uneven" and "far from satisfactory." Some unsatisfactory features were:<sup>lxviii</sup>

- Procurement delays - These were the single most serious malady found. It should take the government 180 to 330 days to successfully complete an international tender.<sup>lxix</sup> However, some contracts have been in process for over 1100 days.

- Poor advertisement
- A short bidding period
- Poor specifications
- Nondisclosure of selection criteria
- Award of contract by lottery
- One-sided contract documents
- Negotiation with all bidders
- Rebidding without adequate grounds
- Other miscellaneous irregularities
- Possible corruption and outside influence.

In 2005, the World Bank commissioned an Independent Procurement Review of World Bank financed projects in Bangladesh where the government was responsible for procurement. This review focused on a total of 75 contracts within four World Bank projects. The review audited 29 contracts valued at \$11.3M in the Health and Population Program Project (HPPP) and 6 contracts valued at \$6.3M in the HIV/AIDS Prevention Project. The review found that the procurement in the HPPP project was “highly insufficient” while procurement in the HIV/AIDS project was “insufficient.” Specific areas of issue included:

- Filing and transparency
- Indications of collusion between bidders
- Insufficient World Bank supervision
- Untimely project execution
- Payment delays

Government procurement, however, is gradually taking on more functions successfully. For example, UNFPA used to procure \$40-\$50M of condoms annually for Bangladesh with a 5-6% procurement fee. In 2000-2001, the Government of Bangladesh switched to self-procurement for condoms. As a result, the government now successfully procures condoms without paying up front (UNFPA requirement) and without the procurement fee. It also found that they could procure the condoms for a lower price than UNFPA.<sup>lxx</sup>

## Annex 3: Vaccine Procurement in Botswana

Botswana is a middle-income country (2006 GNI per capita of \$5,950<sup>lxxi</sup>) with a small population of approximately 1.7 million and a birth cohort of approximately 43,000.<sup>lxxii</sup> Botswana self-finances vaccine purchases with no donor assistance. The government self-procures vaccines and then provides vaccines and vaccination services free of charge to the population. The World Bank does not have operations currently in Botswana.

Historically, Botswana has prioritized vaccines and has achieved very good coverage rates, as shown in Table 12 below. In 2004 and 2006, the Government of Botswana made changes to their procurement rules which caused significant problems for vaccine procurement. As a result, Botswana had polio, measles, HepB, BCG, diluents and syringes stock-outs in the past year. The immunization coverage rate impact is, as of yet, unknown because 2007 coverage rates has not yet been fully reported. However, in February 2007, a national EPI coverage survey identified that 5040 children were not vaccinated. 70.8% of these children were not vaccinated because the vaccine was not available.<sup>lxxiii</sup>

Table 12<sup>9</sup>  
WHO-UNICEF Reported Immunization Coverage for Botswana

	2006	2005	2004	2003	2002	2001	2000
BCG	99	99	99	99	99	99	99
DTP – first dose	98	98	98	98	98	98	98
DTP – third dose	97	97	97	97	97	97	97
HepB – third dose	85	85	85	85	85	85	85
Measles	90	90	90	90	90	90	90
TT – second dose	84	83	76	75	71	69	68
Polio – third dose	97	97	97	97	97	97	97
Government of Botswana Reported Immunization Coverage for Botswana							
	2006	2005	2004	2003	2002	2001	2000
BCG	99	99	93	92	77	72	73
DTP – first dose	99	99	98	99	99	82	9
DTP – third dose	99	99	89	93	87	74	85
HepB – third dose	99	99	79	78	46	64	73
Measles	99	99	86	90	79	77	84
TT – second dose	71	72	55	55	49	46	45
Polio – third dose	99	99	88	91	85	75	85

Source: WHO website: <http://www.who.int/vaccines/globalsummary/immunization/countryprofileselect.cfm>. Accessed Oct. 2007.

Botswana is not procuring tetravalent or pentavalent vaccines. The National Standing Committee on Drugs (NASCOD), comprised of public health professionals and doctors within and outside the Ministry of Health, is responsible for determining which vaccines Botswana should procure. The EPI team in the Ministry of Health supplies evidence to NASCOD as well. EPI does not feel that Botswana has a large enough need to require

<sup>9</sup> Government estimates are the official country estimates. UNICEF / WHO estimates are based on government estimates but adjusted to take into account program strength, Independent National Immunization Coverage Survey figures, and population denominator figures.

Hib vaccines. EPI is considering doing a study to evaluate the need for pentavalent vaccines<sup>lxxiv</sup> and is currently not recommending tetravalent vaccines due to the changes this would require in the current vaccination schedule.<sup>lxxv</sup>

### ***Vaccine Procurement***

Vaccine procurement, as with many health functions in Botswana, is centralized at the federal level. Vaccines and pharmaceuticals are included under the same vote in the government budget and share a line item. The Principle Financial Officer of the MoH indicated a strong reticence to separating the budget line for vaccines or for other health programs<sup>lxxvi</sup> and the Central Medical Stores (CMS) reported that there has always been enough money for all required vaccine purchases, even with escalating antiretroviral purchases.<sup>lxxvii</sup> Corruption is very low in Botswana and does not play a significant factor in vaccine procurement.

CMS, a unit under the control of the Department of Clinical Services within the Ministry of Health, forecasts, procures and distributes all vaccines, pharmaceuticals and medical devices for Botswana. Historically, vaccines were tendered once every two years and supplied on an annual basis. CMS would like to move towards four procurement cycles a year. Once delivered to CMS, CMS distributes the vaccines to all 24 districts based on the pull method, whereby the district submits a requisition to CMS approximately every three months. CMS adjusts the requisition based on past orders and CMS stock availability.

The CMS also reports through the Ministry of Health to the Public Procurement and Asset Disposal Board (PPADB). The PPADB, established under the Public Procurement and Asset Disposal Regulations 2006, guides all government procurements. Its new procurement regulations, largely based on World Bank and other international guidelines, have significantly altered vaccine procurement requirements in the past and changes are likely to continue for some time while processes are developed to meet the new regulations.

### ***Vaccine Procurement Challenges in Botswana***

Several vaccine stock-outs have occurred in Botswana in recent years. The main causes are tender delays and improper forecasting but all the following reasons contribute:

1. ***Tender delays:*** CMS has had significant difficulties complying with the new PPADB regulations. CMS could not obtain a positive outcome from the PPADB on documentation submitted and could not launch a tender for vaccines in 2006. They therefore had to conduct direct purchases on an ad hoc basis once CMS stock levels had depleted. This resulted in rationing to the districts and stock out issues. In 2007, CMS launched a temporary "stop-gap" tender to supply vaccines through the end of March 2009.<sup>lxxviii</sup> The two areas causing CMS the most problems are:

- The 2004 Civil Empowerment Directive states that if a resident of Botswana can respond to a government procurement tender with a product of equal quality and

within 10% of international prices, the tender must go to the Botswanan party. CMS does not currently intend to use the Citizens Empowerment Directive because there are no local human vaccine manufacturers. CMS would prefer to work directly with an international manufacturer than with a local agent because the government procurement rules do not give them the authority to monitor and enforce local agent's cold chain supply.<sup>lxxxix</sup> International manufacturers have to register in Botswana to qualify for a tender, but do not have to have operational offices. Due to the Civil Empowerment Directive, CMS has not been able to develop a tender document template that PPADB accepts and so CMS must submit each tender of greater than 100,000 Botswana Pula (approximately \$16,000) through the Ministry of Health Clinical Services cost centre and central Ministry of Health finance to the PPADB.<sup>lxxx</sup>

- The updated regulations invalidated how CMS had historically pre-qualified all suppliers so they have had to re-qualify all suppliers. CMS estimates that, as of May 2008, they are approximately 80% through this process.<sup>lxxxii</sup>

2. **Forecasting:** CMS forecasts vaccine needs every two years based on past consumption. This forecast is then adjusted in the second year based on the consumption from the first year. This process is not in line with international best practices because, for example, a stock out in a district would lead to lower consumption and hence lower future ordering requirements. EPI, a unit within the Public Health Directorate of Ministry of Health, would prefer to use target population as a baseline for forecasting but does not feel it is their position to do the forecast because CMS is responsible for procurement. EPI is not involved in forecasting and must alert CMS if activities are planned which would increase needs. In an effort to improve forecasting and communication, EPI and CMS have bi-monthly meetings regarding stock levels and operational matters. However, communication remains weak and EPI has little involvement in the procurement process.

3. **CMS Standard Operating Procedures:** CMS does not have documented procurement procedures nor Standard Operating Procedures for its activities. They rely heavily on current staff knowledge which is a challenge due to high staff turnover rates. Supply Chain Management Services (SCMS), led by Booz Allen Hamilton, recently reviewed CMS in order to help develop a Quality Manual for CMS along with appropriate Standard Operating Procedures for its activities. While SCMS focused this review on anti-retroviral procurement, it did cover all CMS operational areas. The SCMS local office indicated that the four largest areas of weakness for CMS were<sup>lxxxii</sup>:

- 1) Low collaboration between CMS and other entities procuring health consumables such as laboratory supplies
- 2) Low communication between CMS and the 24 districts
- 3) Inadequate procurement procedures, including tendering, and low level of staff training and human resource capacity
- 4) Inadequate IT systems.

4. **Quality Control:** While all vaccines supplied to Botswana are required to be WHO pre-qualified, Botswana does not have the current required government capacity to ensure

quality. As Botswana self-procures vaccines, it should have four of the six WHO critical functions implemented. Table 13, below, provides an informal summary of the current status of these items.

Table 13  
NRA Capacity in Botswana

Function	Status	Required?	Botswana Capacity
Independent NRA	The Drug Registration Unit (DRU), a unit of Clinical Services within the Ministry of Health, acts as Botswana's National Regulatory Authority.	Y	Y
1. Licensing	The DRU licenses pharmaceuticals and vaccines supplied in Botswana. DRU reviews are submitted to the Drug Advisory Board and the National Standing Committee on Drugs (NASCOD) for technical assessment as well. The same procedure, used for both vaccines and pharmaceuticals, has remained unchanged since 1992. Both WHO and SCMS have reviewed the licensing system in 2007 but the report findings have not yet been made public. <sup>lxxxiii</sup>	Y	Y
2. Post-Marketing Surveillance	DRU is not involved in post marketing surveillance. Active AEFI testing is not done in Botswana but there is adverse drug reporting. Pharmacovigilance, a part of the Health Inspectorate Unit does some random and systematic sampling but notes this is the responsibility of the DRU. <sup>lxxxiv</sup>	Y	N
3. Lot Release	DRU does not have the capability to do lot by lot release. <sup>lxxxv</sup>	Y	N
4. Laboratory Access for Testing	The National Quality Control laboratory is currently able to do some quality testing on solid dose form pharmaceuticals but is not equipped to perform testing on biological products and vaccines. CMS receipt procedures involve a physical examination of contents. <sup>lxxxvi</sup>	Y	N

5. **Tender Specification:** CMS works with NASCOD to prepare vaccine tender specifications. Botswana has experienced difficulty in providing tenders with full technical specifications (including strains required and packaging) that do not limiting the possible suppliers too much. Also some physical specifications, particularly packaging, have not been compliant with international recommendations. CMS has also included the compulsory supply of Vaccine Vial Monitors (VVM) with all vaccines however it has not always been supplied.<sup>lxxxvii</sup> The Government of Botswana recognized that their small size means that it does not get priority attention from manufacturers.

6. **Vaccine Stock Information Management:** Information on vaccine stock levels at the district is weak and an adequate stock management system needs to be developed and implemented. District vaccine requisitions do not include information on usage, wastage or current stock levels so CMS has little visibility into district stock levels when determining how much vaccines to send. The districts also do not report back to CMS if they received the vaccines in good order but the transporters must supply evidence of delivery.<sup>lxxxviii</sup>

7. **Budget Cycle:** The budget cycle is challenging for vaccine procurement. Botswana's fiscal year goes from April to March. The government starts to prepare the budget in January and should allocate funds in April. The vaccine tender process cannot commence until funding is allocated. The PPADB process is challenging and can require 2-3 months to clear a tender. Thus, CMS has limited time to run a tender, receive the vaccines, and then pay the suppliers yet still remain in the fiscal year.<sup>lxxxix</sup> Furthermore, sometimes the government does not allocate and release budgeted vaccine funds immediately in April.<sup>xc</sup>

### **Vaccine Pricing**

Table 14, below, shows the pricing the Government of Botswana received for its most recent tender.

Table 14  
Government of Botswana vaccine prices 2008: Comparison with UNICEF

Product	Quantity	Manufacturer	Total Price in Dollars	Unit Price in Dollars <sup>10</sup>	UNICEF 2008 World Average Price	Price premium	Total Price Premium in dollars
Polio	8,113	Sanofi Pastuer	308,294	0.19	0.145	25%	62,430
BCG	2,600	Serum Institute India	5,858	0.23	n/a <sup>11</sup>	-	-
DTP	6,920	Serum Institute India	17,203	0.25	0.168	42%	5,054
DT	3,900	Serum Institute India	7,575	0.19	0.105	77%	3,295
HepB	34,200	Serum Institute India	159,416	0.47	0.32	112%	84,364
Measles	14,100	Serum Institute India	41,625	0.30	0.222	27%	8,915
TT	5,200	Serum Institute India	9,291	0.18	0.080	114%	4,944
<b>Total</b>	<b>75,033</b>		<b>\$ 549,262</b>			<b>45%</b>	<b>\$ 169,002</b>

Source: Interview with Mr. Kgosiemang, Chief Pharmacist, Central Medical Stores, Ministry of Health, Government of Botswana, April 2008.

### **Other Procurement Possibilities**

Botswana has investigated pooled procurement via the Southern African Development Community (SADC). However, government interest fell after a comparative price analysis for antiretroviral drugs revealed that Botswana received good prices on their own.

<sup>10</sup> Currency converted in May 2008 to USD

<sup>11</sup> UNICEF does not buy BCG in the 10 dose vial presentation that Botswana procures.

UNICEF and the Government of Botswana have discussed UNICEF assistance for procurement. In 2004, the Government of Botswana and UNICEF signed a Memorandum of Understanding which offers UNICEF's procurement services for standard and non-standard supplies including vaccines. Although some members of the Government of Botswana expressed a desire to work with UNICEF on all vaccine procurement, the current procurement legislation in Botswana requires payment via a Letter of Credit and UNICEF requires prepayment. There are government flexibilities which allow a waiver for prepayment, but in general the Government of Botswana remains committed to the Letter of Credit method and waivers are time-consuming to acquire.<sup>xci</sup> UNICEF did procure vaccines for a 2004 measles campaign because Botswana needed large quantities and recognized the price advantage of working with UNICEF. For this procurement, the Ministry of Health received a waiver and did prepayment.<sup>xcii</sup>

## Annex 4: Vaccine Procurement in Nigeria

Nigeria is one of a very few countries in Africa that fully funds the cost of its EPI vaccines from its own resources. It's large population, 135M, one of the largest in Africa, means procuring and distributing vaccines is a complex challenge. Nigeria has been making step by step progress and has dramatically improved vaccine procurement over the past five years.

In 2004, Nigeria's National Population Commission reported that Nigeria's national coverage for full immunization was less than 13%, one of the lowest in the world. Some states in northern Nigeria had coverage rates below 1%, and the average for the whole North West Zone was 4%. Nigeria's immunization program was also one of the most expensive among developing countries. According to the 2004-2008 Five Year National Strategic Plan, the National Program on Immunization (NPI) budgets \$28 per child under one. However, if this budget is set against the internationally accepted denominator of children fully immunized before their first birthday, it amounts to \$226 per fully immunized child. In a 2003 National Immunization Coverage Survey, parents and caregivers indicated that "vaccine not available" as by far the most important reason as to why children were not fully immunized.<sup>xciii</sup> Table 15, below, summarizes vaccine coverage rates from 2000-2006.

Table 15<sup>12</sup>  
Government of Nigeria Reported Immunization Coverage for Nigeria

	2006	2005	2004	2003	2002	2001	2000
BCG	42	49	55		63		34
DTP – first dose	87	45	49				48
DTP – third dose	72	38	38				3
HepB – third dose	36	27	8				
Measles	99	38	40				30
TT – second dose	60	52	30				
Polio – third dose	67	32	37				38
WHO-UNICEF Reported Immunization Coverage for Nigeria							
	2006	2005	2004	2003	2002	2001	2000
BCG	69	69	62	55	48	46	45
DTP – first dose	72	72	62	53	43	42	42
DTP – third dose	54	54	44	35	25	24	24
HepB – third dose	41	41					
Measles	62	62	53	45	36	35	35
TT – second dose	53	51	51	48	46	44	51
Polio – third dose	61	61	54	46	39	32	26

Source: WHO website: <http://www.who.int/vaccines/globalsummary/immunization/countryprofileselect.cfm>. Accessed Oct 2007.

<sup>12</sup> Government estimates are the official country estimates. UNICEF / WHO estimates are based on government estimates but adjusted to take into account program strength, Independent National Immunization Coverage Survey figures, and population denominator figures.

Nigeria bases its national health care system on a three-tier system of primary, secondary and tertiary care provided by the local, state and federal governments respectively. The Federal Ministry of Health has the responsibility to develop policies, strategies, guidelines, plans and programs that provide the overall direction for the national health care delivery system.<sup>xciv</sup> For vaccines, the federal level is responsible for procurement, cold chain support, policy, and coordination.<sup>xcv</sup> The State Ministries of Health provide secondary level of care and technical advice as well as supervision to the Local Government Authorities (LGAs). The LGAs are the implementers of the primary health care services including immunization.<sup>xcvi</sup> For vaccines, the state and LGA levels are responsible for implementation. The National Primary Health Care Development Agency (NPHCDA), a federal level parastatal formed in 1992, is responsible for the delivery of primary health care services, the construction of the new health centers and the establishment and training of local development committees to manage local health care. Recently, the National Program on Immunization (NPI) was rolled into NPHCDA because vaccinations should support primary health care.

Currently, Nigeria does not have domestic vaccine production capabilities. Until approximately 1998, the Government of Nigeria used to manufacture Yellow Fever vaccines in Lagos. The Government of Nigeria is currently considering possibilities for public private partnerships to manufacture vaccines.

### ***Vaccine Procurement Challenges***

Vaccine procurement has steadily improved over the past decade with the successive removal of the following historical roadblocks:

1. Non-release of funds: issue resolved in 2003.
2. Lack of data for forecasting: issue started to resolve in 2005.
3. Distribution at state and Local Government Areas (LGA) level: issue remains a current challenge.

#### ***1. Non-release of funds***

The root cause of the 2002-2003 vaccine shortages was the non-release of funds by the Ministry of Finance. Thus, the EPI managers successfully conducted international tenders, but they could not then award a contract to the chosen vendor due to the Ministry of Finance not releasing the funds.<sup>xcvii</sup> For example, although the Ministry of Finance released 60% of the initial 2001 budget, they released no funds in 2002, and as of March 2003, the funding cycle has only reached the budget approval stage. The Ministry of Finance also released the 2001 funds late (April 2001) forcing the government to procure vaccine on the spot market at inflated prices, with uncertain availability and potentially with less shelf life.<sup>xcviii</sup>

A 2003 UNICEF-WHO Joint Vaccine Security Mission report highlighted that all routine vaccines were out of stock, that the Government of Nigeria had last released funds for vaccine procurement in April 2001, that no basic EPI vaccines except for OPV had

entered the country since Q3 of 2001, and that Nigeria paid more for their vaccines than UNICEF's prices, as shown in Table 16, below.

Table 16: UNICEF's average 2003 prices compared to prices offered to Nigeria in its 2002 tender<sup>13</sup>

Product	Latest Nigeria tender price 2002 (USD/dose)	UNICEF World Average Price 2003 (USD/dose) <sup>14</sup>	Percent increase in price
BCG 20 d	0.135	0.063	116%
DPT 20 d	0.180	0.085	112%
Measles 10 d	0.220	0.131	67%
TT 20 d	0.140	0.040	248%
YF 10 d	0.430	0.398	8%

Source: Personal communication with UNICEF – Copenhagen. April 2008.

Following this assessment, the Government of Nigeria took two steps:

- It committed to a timely release of funds
- It signed a Procurement Service Agreement with UNICEF which remains in force to this day. UNICEF procurement started in the last quarter of 2003.

Vaccine procurement improved remarkably with no report of a stock-out at the national level since the last quarter of 2003. In 2004 and 2005, the Government of Nigeria released 95% and 97% of the provisional plan/budget submitted by UNICEF Supply Division responding to the annual forecast exercise. The 3<sup>rd</sup> and 4<sup>th</sup> quarter 2007 funds were received late, however, due to a presidential election and the mergers occurring within the Ministry of Health.<sup>xcix</sup> Furthermore, part of the funding was used for campaign requirements (meningitis in December 2004 and measles in February 2005) that were not originally included in the budget.<sup>c</sup>

## 2. *Lack of data for forecasting*

Nigeria has historically struggled with forecasting. For example, Nigeria submitted only one annual report to WHO on immunization coverage between 1999 and 2005, despite the requirement to do this annually. Within the routine data reporting system there was evidence of systematic falsification of data at the local level in order to meet centrally set targets. Audit teams from EC and the World Bank have noted serious flaws with NPI's financial reporting.<sup>ci</sup> Furthermore, UNICEF sometimes could not get stock balance figures from NPI and so assumed zero stock at national level for all vaccines when doing forecasts.

<sup>13</sup> All prices are cost prices, i.e. freight, insurance and clearance cost should be added to both tender prices and UNICEF prices.

<sup>14</sup> Includes a 6 % handling fee. As UNICEF procures from a number of different manufacturers with different prices, the actual price countries receive would vary depending on availability. In 2003, UNICEF was in the process of tendering for its 2004-2006 demand and so their manufacturer price increased from 0-36% starting in 2004.

Table 17 shows Nigeria's routine vaccine forecasted and actual order quantities for 2004-2007.

Table 17  
Accuracy of vaccine forecasting in Nigeria –Forecast and actual doses by year

		2004	2005	2006	2007
BCG	Forecast	7,766,060	8,561,080	8,774,800	9,023,140
	Actual	6,093,000	4,275,000	7,130,000	4,388,000
	Percent Over	-22%	-50%	-19%	-51%
DTP	Forecast	15,532,124	17,122,164	17,549,600	18,046,300
	Actual	12,163,000	14,212,000	23,770,000	13,753,000
	Percent Over	-22%	-17%	35%	-24%
HepB	Forecast	12,602,488	17,122,166	17,549,600	18,046,300
	Actual	11,428,500	12,792,500	13,130,500	13,287,900
	Percent Over	-9%	-25%	-25%	-26%
Measles (routine)	Forecast	4,853,788	6,115,056	6,267,700	6,445,100
	Actual	5,112,500	4,559,000	4,368,000	
	Percent Over	5%	-25%	-30%	
Measles (campaign)	Forecast	5,000,000	7,069,560	32,540,400	
	Actual	648,000	46,764,000	39,600,000	
	Percent Over	-87%	561%	22%	
OPV (routine)	Forecast	19,415,153	22,829,555	23,399,500	24,061,680
	Actual	4,844,000	7,852,000	13,238,000	5,836,000
	Percent Over	-75%	-66%	-43%	-76%
OPV (campaign)	Forecast	139,370,000	222,840,780	276,000,000	288,000,000
	Actual	193,246,000	200,404,000	168,324,200	168,161,700
	Percent Over	39%	-10%	-39%	-42%
TT	Forecast	12,943,436	14,222,180	14,624,700	15,038,600
	Actual	13,584,000	12,249,000	6,497,000	11,926,050
	Percent Over	5%	-14%	-56%	-21%

Source: UNICEF Supply Division. May 2008.

Today, NPHCDA, UNICEF, and WHO report working together quite well and transparently on vaccine forecasting.<sup>cii</sup> Forecasting is currently done two quarters in advance and is based on the target population.

### 3. *Distribution at State and Local Government Authority (LGA) level*

Nigeria uses the “push and pull” vaccine distribution system. Once the Federal Government of Nigeria receives vaccines, it sends them to the central cold store storage facility. From here it goes to one of six NPI-operated zonal cold storage units and then to a 36 state cold storage unit and then to one of 774 LGA storage unit and then to a health facility. The national level "pushes" vaccines and supplies to zonal and to State stores and the LGAs and health facilities "pull" to their levels. Several factors including limited State and LGA program ownership and commitment and limited State and LGA financial and human resources have contributed to the breakdown in the distribution chain at the lower levels and the poor program performance.<sup>ciii</sup>

## Annex 5: Vaccine Procurement in Pakistan

Pakistan has a large population of 169M and a large polio eradication campaign. The combination of these two requires extensive financial resources for vaccine procurements to ensure coverage. Pakistan has drawn upon multiple financing sources to purchase vaccines from domestic and international manufacturers/agents and used multiple procurement methods, often all at the same time.

Table 18, below, summarizes vaccine coverage rates from 2000-2006.

Table 18<sup>15</sup>  
Government of Pakistan Reported Immunization Coverage for Pakistan

	2006	2005	2004	2003	2002	2001	2000
BCG	89	82	80	82	82	93	94
DTP – first dose	90	82	75	77	77	86	88
DTP – third dose	83	80	65	67	68	76	78
HepB – third dose	83	73	65	63			
Measles	80	78	67	61	63	75	75
TT – second dose	50	46	45	57	56	51	51
Polio – third dose	83	81	65	69	71	74	80
WHO-UNICEF Reported Immunization Coverage for Nigeria							
	2006	2005	2004	2003	2002	2001	2000
BCG	89	82	80	82	67	67	66
DTP – first dose	90	82	75	77	77	71	70
DTP – third dose	83	80	65	67	68	63	61
HepB – third dose	83	73	65	63			
Measles	80	78	67	61	63	57	56
TT – second dose							
Polio – third dose	83	81	65	69	71	63	61

Source: WHO website: <http://www.who.int/vaccines/globalsummary/immunization/countryprofileselect.cfm>. Accessed in May 2008.

While there have been no stockouts at the federal level, there have been forecasting issues. For example, differences in census and survey data related to fertility rate have made accurate forecasting a challenge.

The Government of Pakistan's public health system is very decentralized. While the federal level remains responsible for vaccine financing, procurement and policy, the district level is responsible for staff funding and vaccination campaigns. The 124 Pakistani districts also individually forecast needs which the federal level then consolidates into annual forecasts.

Although there are no WHO pre-qualified vaccine manufacturers in Pakistan, the following domestic entities are involved in vaccine manufacturing:

<sup>15</sup> Government estimates are the official country estimates. UNICEF / WHO estimates are based on government estimates but adjusted to take into account program strength, Independent National Immunization Coverage Survey figures, and population denominator figures.

- The National Institute of Health (NIH) has manufactured vaccines since the late 1960s. It currently produces OPV, measles, and TT vaccines based on imported concentrate for a small percentage of Pakistan’s annual requirements. The NIH also manufactures snake venom and anti-rabies vaccines.
- Sind Medical Stores produces some vaccines based on imported concentrate and acts as an importing agent. They produce yellow fever for government and army purposes and MMR for the private sector (MMR is not a part of the EPI vaccination schedule).
- Amson Pharmaceuticals produces some vaccines based on imported concentrates and act as an importing agent for many other vaccines.

### *History of vaccine financing in Pakistan*

Pakistan has used multiple financing and procurement mechanisms, as shown in Table 19, below.

Table 19  
Financing Sources and Procurement Mechanisms for Vaccines in Pakistan

Year	Financing Source	Vaccines	Procurement Method	Amount	Percent of total
2004	GoP	routine	UNICEF	7,847,000	6%
	World Bank	OPV	UNICEF	120,384,000	86%
	Other donors		UNICEF	12,535,000	9%
2005	GoP	routine	UNICEF	63,000,000	26%
	World Bank	OPV	UNICEF	172,774,000	71%
	UNICEF		UNICEF	1,900,000	1%
	GAVI	HepB	UNICEF		0%
	Other donors		UNICEF	6,148,300	3%
2006	GoP	routine	UNICEF	8,100,000	3%
	World Bank	OPV	UNICEF	213,710,200	77%
	GAVI	tetravalent	UNICEF		0%
	Other donors		UNICEF	56,776,000	20%
2007	GoP	routine	UNICEF	11,070,000	4%
	World Bank	OPV	UNICEF	243,304,000	87%
	GAVI	tetravalent	UNICEF		0%
	Other donors		UNICEF	26,092,000	9%
2008 To Date	GoP	routine + OPV	GoP	44,174,982	38%
	World Bank	OPV	UNICEF	50,182,000	43%
	GAVI	tetra and penta	UNICEF		0%
	Other donors		UNICEF	22,695,000	19%

Source: Numbers consolidated from World Bank, UNICEF, and Government of Pakistan. May 2008.

The World Bank has provided two rounds of funding through the IDA buy-down program. The first \$42M round was approved in 2003 and has been successfully used and converted into grants. The second \$74M round was approved in 2006 and is almost finished. It is expected that this one will also successfully be converted into a grant. UNICEF procures these vaccines.

DFID has also provided budgetary support to the Government of Pakistan.

### ***History of vaccine procurement in Pakistan***

From 1978 until the mid 1990s, UNICEF procured all vaccines, primarily with USAID funds. In 1995/96, Pakistan self-procured vaccines for one year with very poor results including corruption allegations and vaccines non-shipment issues. In 1997, the Government of Pakistan returned to UNICEF procurement with both government and donor funds financing vaccines. In 2001, the Government of Pakistan took over all vaccine financing except some campaign vaccines.

GAVI started providing support for vaccines in Pakistan in 2001. HepB was introduced in 2002 and used until it was replaced with tetravalent in 2006/2007. Pakistan received 26M combination vaccine doses in 2006/2007. The Government of Pakistan contributes \$0.3 / dose under the co-financing mechanism. GAVI approved \$1.8M for pentavalent vaccine for introduction in Pakistan in July 2008. This agreement runs until 2010.<sup>civ</sup>

In 2004 the Pakistan Procurement Regulatory Authority (PPRA) adopted new procurement regulations based on open competitive bidding procedures and international best practices. The EPI team, concerned about global vaccine market complexities and the influence of local vaccine producers, obtained a waiver allowing them to continue with UNICEF as a procurement agent.

In 2006, the Pakistan Medical Association (PMA), encouraged by local manufacturing interests, filed a court case with the High Court in Lahore. They argued that the Government of Pakistan should self-procure vaccines because the current system did not allow the local market to participate, violated PPRA rules, and denied the government tax revenue because UNICEF does not pay income tax. The PMA won this case and the MoH did not appeal to the Supreme Court so starting in June 2007, the Government of Pakistan moved to self-procurement.

The Government of Pakistan has done quite well in vaccine procurement. Having not procured vaccines for ten years, it successfully tendered and procured over 118 million doses valued at \$44M.

EPI launched its first tender for TT, OPV, BCG, and measles vaccines in October 2007. The EPI team required more time than anticipated going forward to launch this tender because it had to develop and obtain PPRA approval for their tender document. In December 2007, EPI announced the tender winners and signed contracts in January 2008. The government has received approximately 70% of the OPV, measles, and BCG vaccine from this tender, but the TT installments have just started arriving due to the tender winner having some difficulties (lacked facilities to process the imported concentrate and issues with customs).

## *Vaccine Procurement Challenges in Pakistan*

1. ***Inadequate quality supervision:*** When Pakistan moved from UNICEF to self-procurement, the Government of Pakistan became responsible for implementing an additional two critical NRA functions. WHO assessed Pakistan's NRA in 2003, 2004, 2005, and will complete a further assessment in May 2008. WHO considers a score of 50% or more to be functional. Results are shown in Table 20.

Table 20  
Pakistani NRA status for WHO six critical functions

Function	Status	Required?	WHO Assessment		
			2003	2004	2005
Independent NRA	The Drugs Act of 1976 names the Drugs Control Organization, MoH as the NRA for vaccines. It consists of five field offices and the National Control Laboratories.	Y	Y	Y	Y
1. Licensing	SRO 691 of the Drug Act of 1976 guides licensing requirements. Guidelines need to be updated to reflect fast-changing science and technology.	Y	77	61	77
2. Post-Marketing Surveillance	Post-marketing surveillance is conducted through the ADR reporting system for drugs. EPI is responsible for implementing AEFI tracking.	Y	6	19	31
3. Lot Release	Due to the change of procurement mechanisms, NRA has had to develop infrastructure for lot by lot release.	Y	50	62	75
4. Laboratory Access for Testing	The National Control Laboratory has implemented most WHO recommendations	Y	21	50	66
System Pass			No	No	No

Source: National Regulatory System: Review of Vaccines Regulation In Pakistan. World Health Organization. September 2004 and December 2005.

Thus, Pakistan's NRA is considered not functional because it does not meet requirement two, Post-Marketing Surveillance. Both UNICEF procurement and self-procurement require this function, so the change in procurement mechanisms did not involve a change in Pakistan's NRA status.

2. ***Lack of capacity in the EPI team for procurement.*** The Government of Pakistan moved from no vaccine procurement to full procurement very rapidly. The EPI team has not had time to build a procurement cell and so relies on one consultant with minimal

previous experience in vaccine procurement. The EPI staff depends heavily on consultants in general which provides continuity challenges. If the Ministry of Health chooses to continue to self-procure, government EPI vaccine procurement capacity must be built.

**3. Pressure to include non-WHO pre-qualified manufacturers:** Clause 2.1 of this first tender issued in October 2007 states: “This invitation for bids is open to all original manufacturers within Pakistan and abroad and their authorized agents / importers / suppliers subject to the conditions that:

- a. In the case of foreign manufacturers, they must offer the product pre-qualified by the World Health Organization (WHO).
- b. In case of local manufacturer of vaccines, they will qualify only if they are using concentrates from a manufacturer duly pre-qualified by WHO.
- c. In the case of authorized agents / importers / suppliers, they must quote such products which are pre-qualified by WHO.”<sup>cv</sup>

Due to Clause 2.1.b, Amson Vaccines and Pharma Limited, a Pakistani pharmaceutical manufacturing company, qualified for the tender by proposing to import WHO pre-qualified vaccine concentrate from Shanthi in India and locally adding the diluents and packaging. Amson itself is not WHO pre-qualified (Amson is not eligible for WHO pre-qualification because the first requirement is that the NRA of the country in which a manufacturer resides must be WHO certified. Because Pakistan’s NRA has not achieved this, no manufacturer in Pakistan can apply for WHO pre-qualification).

**4. Lack of respondents to tenders.** Since Pakistan moved from UNICEF procurement to self-procurement, it has launched three tenders. Each has received a small number of respondents, as shown in Table 21.

Table 21  
Number of Respondents to Pakistani tenders

Tender	Product	Respondents	Pass Technical Qualifications	Tender Awarded?
January 2008	BCG	Two	One	Yes
January 2008	TT	Two	One	Yes
January 2008	OPV	Two	Two	Yes
January 2008	Measles	One	One	Yes
March 2008	mOPV1	Three	One	No
March 2008	mOPV3	Two	Zero	No
March 2008	tOPV	Four	One	Yes
April 2008	mOPV1	One	One	Yes
April 2008	mOPV3	One	One	Yes

Source: Tender evaluation documentation. Ministry of Health. Government of Pakistan. 2008.

The delays caused by relaunching the tender are impacting polio vaccination campaigns. While 71M trivalent OPV doses intended for a June 3<sup>rd</sup> Sub-National Immunization Day were delivered in March, the mOPV1 and mOPV3 vaccines will not be delivered in time

for distribution because the government did not enter into a contract for these until mid-May. Thus, this polio immunization campaign is being delayed.

Possible reasons for small number of manufacturers responding to these tenders include:

- UNICEF will not respond to an open tender because this could potentially put it in a conflict of interest situation with the vaccine manufacturers who supply UNICEF under the Long Term Agreements. UNICEF did notify their manufacturers that Pakistan would be moving to self-procurement and asked them to release quantities dedicated to UNICEF for Pakistan.<sup>cvi</sup>
- Few international vaccine manufacturers can respond to a Pakistani tender due to two tender clauses:
  - Clause 2.4: “The bidder should have operational office(s) in Pakistan...”<sup>cvii</sup>  
Only Glaxo Smith Kline has an operational office in Pakistan.
  - Clause 3.2: “In case of vaccines, besides WHO pre-qualification, these must: (a) be registered with the Ministry of Health, Government of Pakistan.”<sup>cviii</sup>  
One of the Registration Board’s requirements is, according to Form 5A, “For import purpose a sole agent in Pakistan is required to be nominated by the principal / manufacturer abroad.”<sup>cix</sup>
- The Government of Pakistan is restricted from purchasing any products from either Israel or India. Because India is one of the largest suppliers of vaccines, this provides a challenge, but waivers can and have been obtained.
- Four domestic firms responded to the tender, each time proposing to import a vaccine from one international manufacturing partner. The four firms are:<sup>cx</sup>
  - Amson Vaccine & Pharma responded to six tenders. They proposed to import from Japan BCG Lab, Shantha Biotechnics, Novartis, and Panacea Biotec.
  - Hospital Sales and Services responded to two tenders, always proposing to import from Serum Institute.
  - Sind Medical Stores responded to three tenders, always proposing to import from Sanofi Pasteur.
  - Majeed Sons responded to two tenders, always proposing to import from Novartis.

In this case, the fact that Amson Vaccines & Pharma has relationships with so many manufacturers but will only propose one manufacturer per tender limits the competition.

**5. Time allotted to complete vaccine tender.** Vaccine procurement usually entails long lead times yet the EPI team must respect annual budget cycles. EPI did not release the first tender until October 2007 due to the time required to secure PPRA approval. Thus, the procurement time available was compressed further. Without a buffer stock, Pakistan is in a vulnerable procurement position. Furthermore, local agents report challenges in meeting the short tender timeframes. Short tender timeframes results in higher final prices because the local agent must pay more for concentrate supplies in a tight vaccine marketplace.

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**6. Higher cost:** Table 22 shows that the Government of Pakistan paid 4% to 38% more than it would have if it had used UNICEF procurement. This amounts to over \$2.3M in the first six months of 2008.

Table 22  
Government of Pakistan self-procurement vaccine prices, 2008

Date	Vaccine	Quantity	Agent	Mnf	Cost/ unit incl. freight <sup>16</sup>	UNICEF 2008 adjusted cost/unit <sup>17</sup>	Increase in price: percent	Increase in price: total dollars
Jan-08	BCG	792,000	Amson	Japan BCG	0.161	0.117	38%	35,128
Jan-08	TT	979,500	Amson	Shantha Biotech	0.061	0.059	4%	2,273
Jan-08	tOPV	2,765,500	Sind	Sanofi Pasteur	0.198	0.170	16%	77,066
Jan-08	Measles	2,644,500	Amson	Serum Insti	0.325	0.260	25%	171,139
Mar-08	tOPV	71,111,100	GSK	GSK	0.174	0.170	3%	323,943
May-08	mOPV1	20,000,000	Sind	Sanofi Pasteur	0.203	0.164	24%	779,248
May-08	mOPV3	20,000,000	GSK	GSK	0.223	0.176	27%	950,818
<b>Total</b>		<b>118,292,600</b>					<b>12%</b>	<b>2,339,614</b>

Source: Tender data from Government of Pakistan. May 2008.

Causes for the price increase include:

- Pakistan orders smaller quantities than UNICEF.
- Pakistan works with local agents who add cost to their tender.
- Limited respondents to tender did not offer Pakistan full competition.
- Shorter tender timeframes which cause local agents to pay higher price for imported concentrates
- The tender requirements that EPI proposed differ significantly from UNICEF's standard tenders, as shown below in Table 23. In general, the tender is much more

<sup>16</sup> Tender costs based in Pakistani rupee and converted at January 2008 rate of 0.01601281, March 2008 rate of 0.016334275 and May 2008 rate of 0.014488633.

<sup>17</sup> Based on UNICEF 2008 published World Average Prices with the following adjustments: 1). 10% added to UNICEF price due to the fact that Pakistan prefers not to purchase from Indian manufacturers and, if they had stayed with UNICEF, would have procured from European manufacturers. European manufacturers tend to be 10-15% higher than the World Average Price, depending on the product. 2). 4.5% UNICEF handling and inspection fee added. 3). 1.832% freight fee added. UNICEF does not include freight. Average UNICEF freight costs varies based on quantity ordered, but do not vary much based on port of origin as most UNICEF vaccines for Pakistan ship from Europe.<sup>17</sup> For the 39 orders placed under the \$42M World Bank IDA buy-down fund implemented in July to December 2007, freight charges were 1.826% of vaccine costs. For the 18 orders placed with \$21M of the \$74M of the second IDA buy-down spent in December 2007 and January 2008, freight were 1.838% of vaccine costs. For this analysis, an average of these freight costs was used.

favorable to the Government of Pakistan but does require incremental government infrastructure and pose some vaccine security challenges.

Table 23  
Tender differences between UNICEF and Government of Pakistan

	UNICEF tender	Government of Pakistan tender
<b>Contract Terms</b>		
• Responsibility for problems with vaccine	Manufacturer from whom UNICEF procured vaccine – not UNICEF	Tender winner
• Freight	Not included	Included in price
• Insurance in transit	Included	Included in price
• Handling fee	Yes	No
• Penalty for late delivery	No	Yes
• Performance Security Bond: Tender awardee gives 10% performance guarantee in advance	No	Yes
<b>Payment Requirements</b>		
• Prepayment	Yes	No
• Currency of payment	Dollars / Rupees	Rupees
• Currency risk	GoP	Tender winner
<b>Vaccine Security</b>		
• Awardees per bid	Multiple	One
<b>Taxes</b>		
• Custom Duties	No custom duties are required on vaccines	
• Company income tax	No	Yes
<b>Quality Insurance</b>		
• Responsible party	UNICEF	GoP
• NRA lab testing required	No	Yes
• Manufacturer registered in Pakistan	No	Yes
• Government must do lot by lot inspection	No	Yes
<b>Legal Jurisdiction</b>		
• Governed by	UN	Laws of Pakistan

Source: Meeting with Government of Pakistan, Ministry of Health EPI team. Dr. Hussain Baksh Memon, National EPI Program Manager. Mr. Younis Khokar, EPI Procurement. May 2008. Compared with UNICEF procurement documentation.

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