Regional group purchasing of vaccines: review of the Pan American Health Organization EPI revolving fund and the Gulf Cooperation Council group purchasing program

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SUMMARY

This paper reviews the key design features, accomplishments of and lessons learned from two regional group procurement mechanisms dealing with vaccines that have been in operation for more than 25 years. The Pan American Health Organization (PAHO) EPI Revolving Fund purchases vaccines and immunization supplies on behalf of more than 35 countries in the Latin American and Caribbean region. Based on a ‘central contracting’ model, the program handles most aspects of procurement—from tendering to contracting with and paying producers—using a common fund to pay producers before being reimbursed by countries once goods are received in-country. The Gulf Cooperation Council (GCC) Group Purchasing Program among seven Persian Gulf States issues joint tenders for vaccines, as well as drugs and other medical goods. Through this ‘group contracting’ program, countries are responsible for contracting with and paying producers on their own, once the group has selected winning bids. Both programs have experienced substantial growth in the past two decades and are considered to have contributed to or accelerated achievements of immunization programs in both regions, including the introduction of new vaccines. The paper identifies several features of both programs—both those designed to attract country participation and those designed to ensure the programs’ financial viability—which help explain their success and longevity. Copyright © 2006 John Wiley & Sons, Ltd.

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INTRODUCTION

Procuring and purchasing pharmaceuticals, vaccines and other health commodities is a considerable and growing challenge, particularly for low- and middle-income countries. The situation with vaccine procurement is especially acute. More countries, such as those in the former Soviet Union and Central and Eastern Europe, are dealing directly with the global vaccine market, while they once depended heavily on one source (e.g., Russia) for their vaccine supply. At the same time, there are fewer vaccine producers from industrialized countries than there were 10 or 15 years ago, due in part to mergers and acquisitions by multi-national pharmaceutical companies. This decrease in producers can result in reduced competition for a country’s vaccine market and the consequent problems of high or unpredictable prices and irregular supplies from manufacturers. Concurrently, there are more producers from developing and transitional economies selling vaccines on the international market, but countries are not always certain of their quality or reliability.

In addition to these market challenges, national immunization programs must often cope with such internal problems as the irregular release of government funds for vaccines, budget shortfalls, limited in-country capabilities in vaccine procurement and management, and long and complicated or non-transparent procurement practices. These challenges in vaccine procurement are likely to grow in the near future, as more new vaccines come onto the market against such diseases as rotavirus diarrhea, pneumococcal pneumonia, meningitis, malaria, and HIV/AIDS.

One way that countries can address these challenges is to join a regional group procurement mechanism. There have been several efforts over the years to develop group purchasing schemes for pharmaceuticals in different regions. Some have met with considerable success, notably the Eastern Caribbean Drug Service (ECDS), which involves nine small island countries purchasing all their public sector pharmaceutical needs as a group (Huff-Rousselle and Burnett, 1996). Others, such as a program among Maghrebian countries in North Africa and the ACAME program in West Africa for the purchase of generic essential drugs, have had difficulties getting established or have seen a decline in membership (Clark and Moore, 2000). More recently, the concept of international group purchasing for pharmaceuticals or vaccines has sparked renewed interest (Clark and Moore, 2000; World Health Organization, 2002; Barraclough, 2003). The establishment of group procurement schemes for selected essential drugs is currently being explored in Africa and in the South/Southeast Asian region (World Health Organization, 2002; Barraclough, 2003). A study of the feasibility of group procurement of vaccines among self-procuring Central and Eastern European countries has also recently been conducted (DeRoeck, 2003).

Group procurement is viewed as a potential means of increasing competition among suppliers; reducing prices; increasing equity by offering all member countries the same prices, regardless of their market size or level of development; increasing transparency in the procurement process; ensuring quality; and improving the regularity of supply of essential commodities to countries. Via price reductions, accomplished in part through economies of scale, group purchasing can also
potentially enable countries to sustainably introduce newer, more expensive products, such as *Haemophilus influenzae* type B (Hib) vaccine, anti-retroviral drugs and newer generation antibiotics, at an earlier stage than they would otherwise be able to.

Given the growing interest in group procurement, this is an opportune time to review the key design features, accomplishments of, and lessons learned from two regional group procurement schemes that have been in operation for the past 25 years. These are the Pan American Health Organization (PAHO) Expanded Program on Immunization (EPI) Revolving Fund, which purchases vaccines and immunization supplies on behalf of countries in the Latin American and Caribbean region; and the Gulf Cooperation Council (GCC) Group Purchasing Program in the Persian Gulf. While the GCC program deals with a range of health commodities, including drugs and medical supplies, this paper will focus on its experience with vaccine procurement.

We chose to describe these two mechanisms because of their success—as evidenced by their longevity and growth in purchases over the years. This paper is not a comprehensive evaluation of these programs. Rather it is a review of the design, operation and achievements of these programs, based on data from the programs themselves, supplemented by some interviews with country-level participants, and published and unpublished documents. This review attempts to answer three main questions: (1) how do these mechanisms work?; (2) how successful have they been in meeting key objectives; and (3) what lessons can be learned from them for organizations or regions contemplating group procurement?

HOW THESE MECHANISMS WORK

The **PAHO EPI revolving fund**

The Pan American Health Organization—the regional office for the Americas of the World Health Organization (WHO)—began operating the Revolving Fund in 1979 as part of its strategy to improve immunization programs in the Americas. The stated purpose of the program is to assure the continuous flow of high-quality vaccines and related supplies at affordable prices to enable countries to buy sufficient quantities for their public sector immunization programs (PAHO, 2001). The Fund utilizes a ‘central contracting’ model (Barraclough, 2003), in which participating countries delegate to PAHO the authority to conduct, on their behalf, most aspects of vaccine procurement—from issuing tenders to contracting with and paying suppliers. The mechanism involves a common, revolving fund that allows PAHO to pay producers before countries reimburse the Fund—sometimes in local currency—after acceptance of goods in-country. By eliminating the need to pay in advance and in hard currency, the Revolving Fund overcomes two major procurement obstacles that developing countries often face as individual purchasers in the international open

1While UNICEF manages the world’s largest bulk purchasing mechanism for vaccines—much of which are donated to the poorest countries—this paper deals with two regional mechanisms that primarily serve countries that finance their own vaccine supply.
The Fund was launched with an initial sum of money (‘capitalization’) of $1 million from PAHO, to which the United States, the Netherlands, PAHO and UNICEF and several countries in the region later contributed an additional $3.5 million.

How the revolving fund operates

In the third quarter of each year, participating countries submit a forecast of their vaccine requirements for the following year, broken down by quarter, to PAHO headquarters in Washington, DC, USA (Figure 1). These requirements are then consolidated and a single bid solicitation document is sent to all producers of vaccines pre-qualified by WHO. A Contract Review Committee made up of PAHO technical, procurement and financial staff, conducts the tender preparation, opening, and award process. The committee selects the lowest priced vaccines among bids meeting all technical specifications submitted by producers with a proven track record of timely delivery of vaccines. As with standard international tender procedures, bids are sealed and no negotiations can take place. PAHO tries, as much as possible, to select two or three companies per vaccine to help the market maintain as many high-quality producers as possible and to have other producers to call on in case of production failures. Successful bidders are sent notification of their selection, which does not commit PAHO to buy any or a certain quantity, but does bind the supplier to the price it offered in its bid for the entire year. PAHO then prepares a vaccine price list, based on weighted average prices across sellers for each product, which it sends to all member countries.

Figure 1. Operation of the PAHO EPI revolving fund

Each quarter, countries confirm or adjust their orders, which must be approved by PAHO to ensure that countries have no outstanding payments, that there is sufficient capital in the Fund, and that any adjustments make programmatic sense. PAHO compiles the countries’ orders and sends Purchase Orders to producers, who are responsible for delivery of the goods directly to each country. Within 30–45 days after arrival and acceptance of the goods in the respective country, PAHO pays the producers from the Fund. Countries must reimburse the Fund within 60 days of receipt of an invoice from PAHO, which includes freight and insurance costs and a 3% administrative service fee to cover foreign exchange losses and other contingencies. Countries are unable to place further orders until they have paid outstanding invoices back into the Fund.

The revolving fund’s growth

In its 1st year of operation in 1979, 19 countries bought 39 million doses of vaccines via the Fund, with a total value, including syringes, of $2.3 million. By 2003, 39 countries—nearly all of Latin America and the Caribbean—purchased $145 million worth of products, including 228 million doses of vaccines (Figure 2). Most countries in the region now buy 100% of their public sector vaccine needs through the Revolving Fund, while a few larger countries, such as Mexico, Brazil, and Colombia, are in and out of the Fund from year-to-year or use it to buy only certain vaccines, such as those that they do not produce locally. In 2003, of all the PAHO member states, only a few small Caribbean island nations and Chile did not make any purchases through the Revolving Fund.

Figure 2. Growth in purchases of vaccines through the PAHO EPI revolving fund

As the volume of purchases has risen, the Fund’s working capital has grown substantially (Figure 3)—most dramatically from 1996/7 to 2004 during which it more than tripled in value (from $8.2 million to more than $29 million by October 2004). Most of this growth in capitalization is due to the accumulation of the 3% administrative fees charged with each purchase, which, apart from a $100,000 reserve fund, are reinvested into the Fund’s working capital. This growth in fees in recent years is due largely to: (a) the purchase of newer, more expensive vaccines, such as measles-mumps-rubella (MMR), hepatitis B, and pentavalent (DPT-hepatitis B-Hib)—resulting in a higher value of the fees—and (b) the entry of Brazil in the program in 1997 (which primarily purchases newer vaccines through the Fund, such as MMR and hepatitis B), increasing the population served by the Fund by 57%. The increased working capital has, in turn, allowed PAHO to procure still larger quantities of newer, more expensive vaccines. By 2004, the accumulated fees accounted for around 85% of the Fund’s total capitalization (Figure 4).

The GCC group purchasing program

In 1978, the Health Ministers’ Council made up of six Persian Gulf States—Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates—decided to issue a joint tender for drugs because of the high prices paid by some of the smaller states and the difficulty in obtaining the small quantities they required. From this initial tender, involving 32 drugs and a total value of US $1.1 million, grew a group purchasing system encompassing a range of medical products—from drugs and vaccines to medical and dental supplies, chemicals, and laboratory supplies. By 2003 10 tenders were issued through this mechanism, involving nearly 8900 different...
products worth $508 million. The total population of these six states is around 30 million, with Saudi Arabia accounting for 21 million or 70%. In 2004 Yemen joined the GCC purchasing program, increasing the total GCC population to more than 49 million people.

The Health Ministers Council was merged into the Gulf Cooperation Council when it was formed in 1981 with the same six countries as a regional economic and policy cooperation group dealing with trade, health, agriculture and education. The group purchasing program is run by the Executive Office for Health Ministers, based in Riyadh, Saudi Arabia.

Based on a ‘group contracting’ model (Barraclough, 2003), the GCC program centralizes the tender and bid process for its six member countries, who then contract with and pay suppliers on their own. Unlike the PAHO Revolving Fund, the program handles only the tendering, bidding, selection, and adjudication part of the procurement process. Member countries agree to purchase at least 60% of the total value of their requirements in each product category (e.g., vaccine and sera) to ensure continued functioning of the program, while still allowing countries a degree of flexibility in their medical purchases.\(^2\) When producers contract individually with each country, they are obligated to offer the same prices across countries for the entire year as stated in their bids.

The objectives of the program are to achieve cost savings through bulk purchasing, ensure the continuous supply of medical products by reducing administrative and

\(^2\)Producer countries are required to buy only 20% of their needs for each product category through the GCC. This does not yet pertain to vaccines, since there are to date no local vaccine producers in the member countries.
financial procedures and accelerating the tender and bid process, standardizing products across member countries, and improving quality assurance through a pre-qualification process. Two additional objectives relevant more to pharmaceuticals than to vaccines are: to encourage the purchase of generic products in order to save costs and to support the local pharmaceutical industry in member countries.

**How the GCC program operates.** The annual centralized tender and bid process involves a series of meetings of committees corresponding to the different phases of the process—tender preparation, tender opening, and tender award (Figure 5). All committees include representatives from each country, as well as the GCC Executive Board. The same set of committees deals with drugs, vaccines, chemicals, and insecticides. During the Tender Preparation Committee meeting—usually held every March—countries submit their public sector vaccine requirements for the following year and the committee reviews and revises technical specifications for each product, reviews the list of companies to be invited to bid, and drafts the tender document. Only producers pre-qualified by the GCC are invited to submit bids. The committee is dissolved at the end of the meeting and the GCC secretariat compiles the countries’ requirements, finalizes the tender document, and sends out letters of invitation to all pre-qualified companies. All prospective bidders must nominate a local dealer or agent in Saudi Arabia, who will respond to the tender and act on behalf of the company. The GCC then sells the tender documents (@ $1300–$4000) to interested producers through their local agents.

After a bidding period of 30–45 days, a Tender Opening Committee is formed and meets to open all sealed bids publicly and record the offers. After the GCC secretariat
tabulates all bid information, a new Tender Award Committee convenes to select products meeting the technical specifications, on the basis of the lowest price offered. If all bidders offer much higher prices than the previous year, companies are asked to re-bid with lower prices. Once preliminary awards are announced, countries have 4 weeks to readjust or confirm their orders with the GCC and all bidders have 2 weeks to file complaints, which are handled by a separate committee that is created as needed. Final awards are formally approved by the Executive Board and health ministers from each member country. As with the PAHO program, the tender document does not commit the GCC or member countries to purchase a specific quantity of product; only once individual countries contract directly with suppliers are the quantities legally binding.

Following the tender and bid process, affiliated institutions in the member states—e.g., health ministries and several military and specialty hospitals—contract directly with the selected producers or their local agent. The contracts—often simply Purchase Orders—include the delivery, payment, and other terms and conditions for each country that are specified in the group tender document. Producers deliver the vaccines directly to each country one-to-three times per year. Most institutions pay after delivery, although not until they have proof that the producer has paid a 0.5% fee (based on the value of the order) to the GCC’s Medical Research Fund.

The GCC program’s growth and level of participation. Vaccine and sera purchases through the GCC began in 1985, with an initial purchase of 12 products worth $785,000. By 2003 the program was buying 48 vaccine and sera products worth $32.8 million (Figure 6). While countries are obligated to purchase at least 60% of their vaccine needs through the program, the actual level of country participation is considerably higher. Saudi Arabia buys 100% of its public sector vaccine requirements through the GCC each year and several other countries buy an estimated 80% of their total needs, in terms of volume, through the program.

ACHIEVEMENTS OF THE PAHO AND GCC PURCHASING MECHANISMS

We examine how successfully these programs have met two major objectives common to both: (a) achieving cost savings and (b) ensuring a continuous and adequate supply of vaccines to member countries. While not original objectives of either program, we also examine their role in accelerating the introduction of new vaccines.

Achieving cost savings

A major impetus for launching these mechanisms was to achieve significant cost savings for countries by obtaining advantageous vaccine prices through bulk purchasing and international competitive bidding. Table 1, which compares GCC 2003/04 prices with those offered through a local tender to a small Persian Gulf state (population: <3 million), shows cost savings of 4–46% per vaccine, often for the
identical product and brand name—with savings of 25% or more for half of these products. The country was able to obtain lower prices through the local tender only for two vaccines produced in Asia—hepatitis B and BCG—that were not offered through the GCC. For most vaccines, the GCC relies on a few European and American vaccine producers, since few vaccines produced outside of OECD (Organization of Economic Cooperation and Development) countries have been pre-qualified by the GCC or licensed in member states with functional regulatory authorities for biological products. Thus, the GCC program is able to achieve significant cost savings for its member states—especially those with small populations—for the industrial country vaccines that it offers, while countries that expand their range of suppliers to include high-quality producers in non-OECD countries can apparently achieve greater cost savings on their own.

Data from PAHO also indicate significant cost savings when countries buy through the Revolving Fund as compared to purchasing on their own. A comparison of prices of basic EPI vaccines offered through the Revolving Fund with those offered by suppliers directly to countries in the early days of the program revealed cost savings to countries of 70–82% as a result of purchasing through the Fund (WHO, 1983). PAHO has, in fact, been able to more or less match the low, marginal prices offered by UNICEF (Table 2). This is due to the large volume of its purchases and to the fact that, as with UNICEF, competition is open to all producers of vaccines pre-qualified by WHO, nearly half of whom are currently low-cost producers from non-OECD countries, including India, Korea, Indonesia, Bulgaria, and Brazil. A further strategy employed by PAHO to ensure the lowest possible prices is to require contract suppliers not to offer lower prices to any other customer during the contract year without also offering these same prices to PAHO.

Figure 6. Value of vaccines and sera purchased through the GCC group purchasing program, 1985–2003 (US dollars)
<table>
<thead>
<tr>
<th>Vaccine (vial size)</th>
<th>Quantity</th>
<th>Source</th>
<th>GCC price per dose (CIF)$^a$ (US$)</th>
<th>Local tender price per dose (CIF)$^a$ (US$)</th>
<th>Differential GCC/local tender price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria-tetanus-pertussis (whole cell) (DTwP) (10)</td>
<td>35 000</td>
<td>European producer (same in both tenders)</td>
<td>0.20</td>
<td>0.268</td>
<td>−25%</td>
</tr>
<tr>
<td>Diphtheria-tetanus (DT) (10)</td>
<td>50 000</td>
<td>European producer (same in both tenders)</td>
<td>0.167</td>
<td>0.236</td>
<td>−29%</td>
</tr>
<tr>
<td>Oral polio (OPV) (10)</td>
<td>450 000</td>
<td>European producer (same in both tenders)</td>
<td>0.12</td>
<td>0.15</td>
<td>−20%</td>
</tr>
<tr>
<td>Measles-mumps-rubella (MMR) (Jeryl Lynn strain) (1) Hib (10)</td>
<td>25 000</td>
<td>European producer (same in both tenders)</td>
<td>2.79</td>
<td>5.15</td>
<td>−46%</td>
</tr>
<tr>
<td></td>
<td>N/A</td>
<td>U.S. producer (same in both tenders)</td>
<td>2.40</td>
<td>2.66</td>
<td>−10%</td>
</tr>
<tr>
<td>DTwP-hepB-Hib (1)</td>
<td>N/A</td>
<td>European producer (same in both tenders)</td>
<td>4.30</td>
<td>4.50</td>
<td>−4%</td>
</tr>
<tr>
<td>BCG (20)</td>
<td>300 000</td>
<td>GCC: European producer</td>
<td>0.17</td>
<td>0.102</td>
<td>+67%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Local tender: Japanese producer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B (pediatric) (1)</td>
<td>260 000</td>
<td>GCC: European producer</td>
<td>1.31</td>
<td>0.928</td>
<td>+41%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Local tender: Indian producer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$^a$CIF = Cost, insurance and freight (included in price).
N/A = not available
Table 2. Prices offered through the PAHO Revolving Fund and UNICEF supply division for selected vaccines, 2003

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses/Vial</th>
<th>PAHO vaccine source</th>
<th>PAHO price/dose (FOB)(^a) (US$)</th>
<th>UNICEF weighted average price/dose (FOB)(^a) (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>10</td>
<td>Japan BCG</td>
<td>0.117</td>
<td>0.067</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis (whole cell) (DTwP)</td>
<td>10</td>
<td>Intervax-NCIPD (Bulgaria)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetanus Toxoid (TT)</td>
<td>10</td>
<td>Serum Institute of India</td>
<td>0.095</td>
<td>0.08</td>
</tr>
<tr>
<td>Oral polio (OPV)</td>
<td>10</td>
<td>Chiron</td>
<td>0.14</td>
<td>0.097</td>
</tr>
<tr>
<td>Measles (Edmonston)</td>
<td>10</td>
<td>Serum Institute of India</td>
<td>0.12</td>
<td>0.12</td>
</tr>
<tr>
<td>Measles-mumps-rubella (MMR) (Urabe)</td>
<td>1</td>
<td>Aventis Pasteur</td>
<td>1.49</td>
<td>1.55</td>
</tr>
<tr>
<td>Hepatitis B (pediatric dose)</td>
<td>1</td>
<td>Chiron</td>
<td>0.52</td>
<td>0.58</td>
</tr>
<tr>
<td>DTwP-hepatitis B-Hib</td>
<td>1</td>
<td>GlaxoSmithKline</td>
<td>3.76</td>
<td>3.20 (2-dose vial)</td>
</tr>
</tbody>
</table>

\(^a\)FOB = freight on board (prices before shipping and other charges are added). Prices do not include the 3% administrative service fee charged by PAHO or the 6% fee charged by UNICEF.
PAHO’s vaccine prices are substantially lower than those of the GCC program for several reasons, including its 10 times greater volume of annual purchases than the GCC (228 million doses vs. 22 million doses in 2003) and the GCC’s greater reliance on a relatively few higher priced suppliers from Europe and the US. In addition, the generally greater wealth of the oil-rich GCC countries than those in the PAHO region results in the GCC being offered higher prices, because of the tiered pricing strategy practiced by many large vaccine producers.

Besides savings in vaccine costs, group purchasing can achieve savings to participating countries in personnel costs, by reducing the time spent by health ministry staff in individual countries on vaccine tendering and procurement. Cost reductions due to time saved was cited as a “very important” reason for using the PAHO Revolving Fund by 10 of 17 respondents from health ministries to a survey about the Fund conducted by Abt Associates (Maceira et al., 2001).

Ensuring an adequate and continuous supply of vaccines

Although empirical data at the country level are lacking, both PAHO and the GCC report that their procurement programs have led to the reliable, continuous supply of vaccines to their member countries and have reduced supply disruptions. The consistency and adequacy of vaccine supply through these programs has, according to these organizations and others, helped make the eradication of polio and the elimination of measles achievable in the Americas (UNICEF, 1992) and is a major factor in the GCC countries achieving official immunization coverage rates for the third dose of DPT of 93–98% in 2001 (UNICEF, 2003).

According to the GCC, major factors responsible for improved vaccine supply through its group procurement mechanism have been the reduction in the length of the procurement process, the increased predictability of timing, and the simplification of procedures. While the GCC procurement process (from the issuance of tenders to the award to suppliers) takes around seven months, it takes the Saudi Ministry of Health 10–14 months to procure commodities locally, because of the country’s complicated procurement rules.

A key factor contributing to the infrequency of supplier-caused shortages of vaccines procured through the PAHO EPI Revolving Fund has been, according to PAHO, significant improvements in the forecasting of vaccine needs on the part of countries. These improvements in forecasting have resulted from PAHO requiring countries to forecast their vaccine needs for the entire year (by completing Country Action Plans) and reconfirm their estimates each quarter, as well as from the technical assistance that PAHO provides to countries in developing their vaccine estimates. Improved forecasting enables producers to better plan their production schedule and requirements, thus reducing the likelihood of production shortfalls.

The PAHO program has, nonetheless, experienced vaccine shortages when the sole producer of a certain vaccine had manufacturing problems (as was true for pentavalent vaccine in 2000/01) and when the increased global demand for oral polio vaccine, due to intensified polio eradication campaigns, outstripped supply in the early 2000s. These problems, experienced worldwide, are the inevitable result of the shrinkage in the number of vaccine producers supplying the developing world and
cannot be avoided completely by group purchasing. In addition, about half of the PAHO countries responding to the Abt survey reported delays in the arrival of vaccines from PAHO suppliers and several reported delays in receiving invoices from PAHO, which can affect their ability to place additional orders (Maceira et al., 2001).

Role in new vaccine introduction and in increasing the national priority of and funding for immunization

Evidence suggests that both the GCC and PAHO group purchasing programs have played a role in accelerating the introduction of new vaccines into the immunization programs of member countries. The PAHO EPI Revolving Fund first procured hepatitis B vaccine for individual countries in 1994. By 1999, 24 member countries, including low-income countries such as Honduras and Bolivia, were purchasing hepatitis B through the Revolving Fund for universal infant immunization or high-risk immunization. At this point in time the vaccine was not yet available through UNICEF and only a handful of developing or transitional countries in other regions (Eastern Europe, South Pacific) had introduced it. By 2002, all but four countries in the PAHO region were providing hepatitis B either to all infants nationwide (the majority of countries) or to high-risk areas or groups and 31 out of 39 countries in the region were procuring the vaccine through the Revolving Fund.

The introduction of Hib and MMR vaccines also occurred earlier in the PAHO region than in other parts of the developing world. By September 2001, all but eight PAHO countries had introduced Hib vaccines into their immunization programs, while few other developing countries had yet done so. Hib introduction in other parts of the developing world accelerated only once countries began receiving support from the Global Alliance for Vaccines and Immunization (GAVI) for this vaccine. The Revolving Fund has further expanded its scope to include the purchase of other, non-EPI vaccines, such as rabies, hepatitis A, and meningococcal vaccines.

The role attributed to PAHO in accelerating new vaccine introduction in member countries is twofold. First, the drop in vaccine prices resulting from bulk purchasing has made these vaccines more affordable to countries. The price per dose of Hib vaccine (in liquid form in 10-dose vials) dropped in half from $4.50 in 1996/1997—when PAHO was buying small quantities for individual countries—to $2.18 once PAHO established a contract with a producer in 1999. Second, PAHO—as an organization and not the Revolving Fund per se—has played an influential role in making recommendations concerning new vaccines, based on reviews with countries of their epidemiological and cost-effectiveness data and following sub-regional meetings. For instance, Hib vaccine introduction was greatly accelerated in Latin America after PAHO recommended use of the combination DPT-hepatitis B-Hib vaccine as a means of reducing the total number of injections a child would receive as well as the number of syringes required.

The GCC’s role in accelerating the introduction of new vaccines or formulations is due largely to the sharing of information among member states during program meetings and in developing standard technical specifications for vaccines. Information on the experiences of several member states in introducing DPT-Hib
combination vaccine led Saudi Arabia to introduce the vaccine. Conversely, a recommendation from Saudi Arabia helped lead other member countries to introduce a tetravalent meningitis vaccine.

LESSONS LEARNED FROM THE PAHO AND GCC GROUP PROCUREMENT PROGRAMS ON HOW TO DESIGN AND IMPLEMENT SUCCESSFUL GROUP PURCHASING PROGRAMS

The experiences of the PAHO EPI Revolving Fund and the GCC Group Purchasing Program provide powerful lessons about which elements help ensure the long-term success and viability of international group purchasing programs. Clearly, these programs must be designed to attract or ensure sufficient country participation to make their operations worthwhile, while at the same time remaining financially solvent. Both the PAHO Revolving Fund and the GCC program have several common design features that together balance these two criteria.

Features designed to attract countries to participate

Besides competitive prices, these features include:

*Flexibility in country participation.* Neither organization requires member countries to buy vaccines exclusively through their group procurement schemes. The PAHO Revolving Fund allows member total freedom to choose whether or not to participate each year and to what extent. Some of the larger and wealthier countries, such as Argentina and Venezuela, are in and out of the Fund from year to year, while smaller countries, such as Peru, Ecuador, and Guatemala, depend on the Fund almost entirely each year for their public sector vaccine supply.

The GCC program, which involves fewer countries and is therefore less able to be as flexible, permits members to procure up to 40% of their vaccine needs outside of the program. Some member countries issue local tenders for all vaccines at the same time that they submit their requirements to the GCC. This flexibility at least partially offsets the reduction in product choice that results from product standardization—a feature of many group procurement schemes. The GCC program allows countries the additional flexibility of revising quantities listed in their contract with suppliers by ±20% after the contracts have been signed.

*Vaccine quality assurance and control.* Quality assurance and control has been a major attraction among countries to both the PAHO and GCC programs, especially small countries lacking national regulatory authorities (NRAs) capable of assessing biological products. Quality assurance was ranked as a ‘very important’ benefit of the PAHO Revolving Fund by more countries in the Abt survey of PAHO countries than any other attribute, including price (Maceira et al., 2001). Both programs assure vaccine quality through a pre-qualification process. PAHO relies on the WHO pre-qualification system, although several countries also require that all vaccines they purchase through the Fund be licensed nationally. The GCC requires that all vaccines
be licensed either centrally through its relatively new Central Drug Registration Program or by the two member states—Saudi Arabia and Kuwait—considered within the region to have NRAs capable of evaluating biological products. The GCC hopes that the central Registration Program—an outgrowth of the bulk purchasing system—will eventually replace separate national licensure for all drugs and vaccines, reducing the licensing burden of participating suppliers. The GCC prequalification system accepts only companies “with an excellent international reputation” (World Health Organization, 1997), which has resulted in primarily vaccines from large, multi-national American, or European-based firms being pre-qualified.

Both programs also have systems in place to control the quality of specific lots following licensure. PAHO reserves the right to review batch release certificates and quality control tests from the producer countries’ national control authorities, and to have samples tested by a WHO reference laboratory. Saudi Arabia’s national control laboratory serves unofficially as the program’s reference laboratory for vaccines, often testing samples from lots delivered to other GCC member states (World Health Organization, 1997).

**Attractive payment terms.** While countries buying vaccines on the open market are often required to pay in advance—in opposition to the public procurement laws of many countries that forbid pre-payment—both the GCC and PAHO programs allow countries to pay only once the goods are accepted in-country (with exceptions in the case of PAHO for high-value purchases, as discussed below). The option of reimbursing the PAHO Revolving Fund in local currency was also an attractive feature to some poorer member countries in the past. But, because of strict payment terms and conditions, this option is currently used by few countries. Payments to GCC suppliers are made in local currency by two of the six member states (Saudi Arabia and Kuwait), while the others pay in US dollars.

**Credibility and transparency in the procurement process.** The use of an independent agency and a transparent, competitive tender and bid process can be a key incentive for countries to join an international group procurement program. This is especially true in countries with influential, local producers who often enjoy preferential treatment by the government and who may not be able to compete internationally, placing them in opposition to such programs. The ability of the government of Brazil to withstand opposition from local vaccine producers by stating that it was using an independent international agency was a key incentive for the country to join the PAHO Revolving Fund in 1997 (Clark and Moore, 2000).

**Country initiative and participation in decision-making.** It was the countries themselves and not an outside group that initiated the group purchasing program—in the case of the GCC—or that requested it be established through a formal resolution—in the case of the PAHO Revolving Fund. This fact has helped ensure country ownership in these programs, motivation for countries to participate, and the programs’ responsiveness to the needs of its member states. The GCC program ensures continual country involvement in all its major decisions by having
representatives from all member countries on the tender preparation, opening and award committees. High-level country participation in the PAHO program is less direct, being more in the form of feedback and information sharing during periodic regional meetings.

Accommodation of specific country needs. The PAHO Revolving Fund is not sufficiently capitalized to allow the use of the common fund for purchases from large countries, such as Brazil and Argentina, or for high-value orders of expensive, non-EPI vaccines, such as pneumococcal vaccine. Instead of excluding such purchases, however, PAHO accepts them as long as the countries pay PAHO in advance. Additionally, one objective of the Revolving Fund is to enable countries to place emergency orders in response to disease outbreaks or other crises. A recent example is the more than four million doses of yellow fever vaccine procured through the Fund for Colombia, in response to an outbreak in January 2004. Emergency orders account for around 10% of the total value of PAHO’s procurement each year.

The specific needs of GCC countries are stipulated in the tender document, such as delivery schedules and terms for each country and participating institution, including delivery to the district level in Saudi Arabia.

Mechanisms to ensure financial solvency

Agreements and procedures that minimize financial risk to the programs. The actual quantities that countries purchase may differ significantly from the quantities they initially request, as they may decide to purchase outside of the group procurement program or they are not able to make payments due to cash flow problems or budgetary shortfalls. Both the PAHO and the GCC programs minimize the risk of purchasing unwanted commodities and share it more evenly with producers by not guaranteeing the purchase of fixed quantities in the tender documents. Neither PAHO nor the purchasing institutions of the GCC states enter into binding agreements with producers until they actually issue Purchase Orders (or sign contracts in some cases with GCC states). The lack of official contracts in both programs, before purchases are actually made, not only reduces the risk to the purchasers, but also provides the flexibility desired by participating countries.

Sustainable financing of program operations. Some group procurement schemes are financed by administrative fees added to each order, most notably the Eastern Caribbean Drug Service (ECDS) (Huff-Rousselle and Burnett, 1996). However, it may be difficult to initially fund the operation through sales fees alone and it may require that countries buy exclusively through the program, as does the ECDS, eliminating their flexibility. The financing of both the PAHO and GCC group purchasing operations does not depend on their sales performance. The PAHO EPI Revolving Fund operation is funded out of PAHO’s general budget, and its 3% administrative service fee is used not to finance operations, but instead, has contributed substantially to the Fund’s working capital. The GCC program is financed by a combination of GCC membership dues from countries (accounting for
55% of financing in 1999) and the sale of tenders to suppliers and supplier registration fees (the remaining 45%).

Both operations are also relatively lean. Several technical, financial, procurement and administrative staff work full or part-time on the PAHO EPI Revolving Fund managing its day-to-day operation—equal to around nine full-time equivalents. The GCC, which handles tenders and bids for thousands of products per year, is run by seven to eight full-time pharmacists, technical experts and administrative staff.

Strict payment rules and criteria for country participation (PAHO EPI Revolving Fund). To ensure that the PAHO EPI Revolving Fund remained solvent and that program advice is taken seriously, countries have not been allowed to join the Fund until they had: (a) a realistic and comprehensive annual national action plan for immunization; (b) sufficient infrastructure for vaccine storage and distribution; and (c) a national immunization program manager.

PAHO nonetheless runs the risk that countries will default on or delay reimbursements to the Revolving Fund. To minimize this risk, the organization enforces the rule requiring country reimbursement within 60 days after receiving PAHO’s invoice. Countries late in their payments cannot place further orders until they have reimbursed the Fund. Countries in financial crisis can negotiate with PAHO to receive partial orders in return for partial reimbursements. While some countries have been late in payments and some have been suspended from the Fund temporarily, none has yet failed to eventually reimburse the Fund in full.

In addition, while PAHO allows its members the option of reimbursing the Fund using local currency, they must have a large enough local PAHO assistance program to absorb these payments, and they must also adhere to a schedule of regular, frequent payments to minimize losses from inflation. Consequently, most countries find it easier to reimburse the Fund in US dollars and few make use of this option any longer.

CONCLUDING REMARKS

This paper has described two models of international group purchasing for vaccines. One—the PAHO EPI Revolving Fund—based on a ‘central contracting’ model, may be more appropriate for less developed countries or those with limited contracting and procurement capabilities. The other—the GCC Group Purchasing Program—using a ‘group contracting’ approach, may be more appropriate for countries with the interest and capabilities to handle the contracting and payment aspects of procurement themselves.

Both programs have demonstrated that international group procurement, if well-designed and well-executed, can alleviate many of the challenges developing countries face in procuring vaccines on their own, by offering competitive and more predictable prices, vaccine quality assurance, transparent procurement procedures and attractive payment terms. Group purchasing appears to be especially beneficial to small countries, which are likely to achieve the greatest savings in vaccine costs and which may have less capacity in vaccine procurement than larger countries. Larger countries, such as Brazil, may be able to obtain vaccine prices nearly or as low

as those obtained through group purchasing, and in fact, several larger Latin American countries often chose to buy vaccines outside of the PAHO Revolving Fund. Their interest in participating may stem more from other benefits of group procurement, such as increased transparency and a quicker, less complex procurement process.

Arguments can also be made that these group purchasing programs have played an important role in the achievements of immunization programs in their respective regions, including polio eradication and improvements in immunization coverage. Both programs have also led to achievements or benefits beyond their original goals. One of these is the greater cooperation between immunization programs of member countries, examples being the several instances that PAHO countries have loaned vaccines to other member countries in emergency situations, and the improved coordination between GCC members in the polio eradication program. Other beneficial by-products of these programs have included the acceleration of new vaccine introduction in both regions, the passage of vaccination laws in 19 PAHO countries, and the establishment of a central drug registration system for the GCC states.

There are, however, several potential limitations of international group procurement programs. Some countries may feel they have less control over decisions regarding their vaccine supply. Group procurement also often leads to standardization of products across countries, in order to have a manageable list of products to tender and to obtain the most beneficial prices from large bulk orders of individual items. While this is certainly less of an issue for vaccines than it is for pharmaceuticals, because of the relatively small number of vaccine products, it can, nonetheless, result in reduced choice of individual countries in vaccine formulation, presentation, vial size or packaging. To avoid this limitation, the PAHO EPI Revolving Fund allows countries to order any product not on contract, though this reduces the price benefits of bulk purchasing. A third potential drawback of group purchasing is the lack of coordination between the procurement and delivery schedules of the group program and those of individual member countries.

A few published and unpublished documents have identified several elements required for successful implementation of group procurement for pharmaceuticals (UNICEF, 1992; Hessou, 1999; World Health Organization, Southeast Asia Regional Office, 1999; Clark and Moore, 2000; Asian Development Bank, 2001). These conditions—all of which are present in the GCC and PAHO programs—include:

- Strong political will and commitment from member countries
- Well-defined regulations and procedures
- Strong, consistent leadership and continuity of program staff
- A permanent, independent secretariat
- A credible, transparent procurement process
- Step-by-step implementation, allowing the mechanisms to start small and learn from experience, before expanding.

Based on the experiences of the PAHO Revolving Fund and the GCC Group Purchasing Program, we would also like to stress the following as critical elements for successful international group procurement:
Initiation from the countries themselves. Instead of being conceived and established by outside organizations, both programs were launched at the request of countries or by the countries themselves, helping to ensure country ownership in the program and their motivation to participate.

Customer-orientation, such as flexibility in country participation, attractive payment terms and accommodation to specific country needs;

The key role of quality assurance, including the use of pre-qualification, which is especially attractive to countries without fully-functioning national regulatory authorities for biologicals; and

Procedures and agreements that reduce the financial risk to the programs, including not guaranteeing purchase quantities in the bidding or award documents;

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