CO-TRIMOXAZOLE MANAGEMENT AND AVAILABILITY

LOGISTICS AND SUPPLY CHAIN EXPERIENCE IN 15 U.S. PRESIDENT’S EMERGENCY PLAN FOR AIDS RELIEF COUNTRIES
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U.S. PRESIDENT’S EMERGENCY PLAN FOR AIDS
RELIEF COUNTRIES

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AIDS Support and Technical Assistance Resources Project

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<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
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<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>BUFMAR</td>
<td>Bureau des Formations Médicales Agrées du Rwanda</td>
</tr>
<tr>
<td>CAMERWA</td>
<td>Consumables and Equipment Central Procurement Agency</td>
</tr>
<tr>
<td>CAPRISA</td>
<td>Centre for the AIDS Programme of Research in South Africa</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CHAI</td>
<td>Clinton HIV/AIDS Initiative</td>
</tr>
<tr>
<td>CMAM</td>
<td>Central de Medicamentos e Artigos Medicos/Central Drugs and Medical Supplies</td>
</tr>
<tr>
<td>CMS</td>
<td>Central Medical Stores</td>
</tr>
<tr>
<td>CPDS</td>
<td>Coordinated Procurement and Distribution System</td>
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<tr>
<td>DACA</td>
<td>Drug Administration Control Authority</td>
</tr>
<tr>
<td>DOH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>DS</td>
<td>double-strength</td>
</tr>
<tr>
<td>EDT</td>
<td>electronic dispensing tool</td>
</tr>
<tr>
<td>EML</td>
<td>essential medicines list</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>FMOH</td>
<td>Federal Ministry of Health</td>
</tr>
<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>IDA</td>
<td>International Dispensary Association</td>
</tr>
<tr>
<td>iDART</td>
<td>intelligent dispensing of antiretroviral therapy</td>
</tr>
<tr>
<td>IDCC</td>
<td>infectious disease care clinic</td>
</tr>
<tr>
<td>ILS</td>
<td>integrated logistics system</td>
</tr>
<tr>
<td>IM</td>
<td>information management</td>
</tr>
<tr>
<td>JCRC</td>
<td>Joint Clinical Research Center</td>
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<tr>
<td>JMS</td>
<td>Joint Medical Stores</td>
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<tr>
<td>JSI</td>
<td>John Snow, Inc.</td>
</tr>
<tr>
<td>KEMSA</td>
<td>Kenya Medical Supplies Agency</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>---------</td>
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<tr>
<td>VPP</td>
<td>voluntary pooled procurement</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WMS</td>
<td>warehouse management system</td>
</tr>
</tbody>
</table>
INTRODUCTION

AN ESSENTIAL PUBLIC HEALTH RESOURCE

Co-trimoxazole is a simple, well-tolerated, inexpensive antibiotic. When taken regularly as prophylaxis, co-trimoxazole reduces mortality and specifically reduces the risk of pneumonia, diarrhea, malaria, and other opportunistic infections (OIs) in adults and children living with HIV. The World Health Organization (WHO) recommends co-trimoxazole is included as an integral component of the HIV chronic care package as it is key to pre-antiretroviral therapy (ART) care (WHO 2006). It is listed on WHO’s Model List of Essential Medicines in the “Other antibacterials” category (WHO 2010). Co-trimoxazole is also used in primary health care (PHC) to treat infections of the eyes, ears, skin, and genitourinary and respiratory tracts, among other infections (WHO 2008), thus rendering it a high-priority public health product.

With the scale-up of HIV care and treatment programs, substantial funding has been committed to guarantee an uninterrupted supply of co-trimoxazole for people living with HIV (PLWH), but access to this key intervention remains inconsistent. Anecdotal evidence suggests some of the product provided through donor-supported HIV programs is being used in PHC, but this is hard to verify given the fact that many health logistics systems do not track the source of the product. However, concern about leakage of donated co-trimoxazole into PHC is warranted when PLWH lack access because the product provided by donors for HIV programs is out of stock.

Following the implementation of the co-trimoxazole chemoprevention guidelines, the demand for product outpaced availability, resulting in stockouts when the supply pipelines were not adequately filled prior to implementing the guidelines. In general, in the 15 countries included in this analysis, stock imbalances were eventually corrected as donor inputs for HIV programs augmented national government procurement.

METHODOLOGY

Using a desk review approach that includes key informant interviews among multiple levels of stakeholders, this report examines the availability and management of co-trimoxazole. Information was gained from interviews with select key informants from 15 countries that were the initial focus of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR)—Botswana, Côte d’Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia. Detailed summaries are included in Appendix A. Key informant interviews included staff of the Supply Chain Management System (SCMS) project1 at both the in-country implementation level and the central project management site. As available, additional key informant interviews were held with content experts from the U.S. Agency for International Development (USAID), the Centers for Disease Control and Prevention (CDC), and SCMS to better understand global issues around co-trimoxazole availability and management. The lack of

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1SCMS is a PEPFAR project that procures and distributes essential medicines and supplies; provides technical assistance to transform existing supply chains; and collaborates with in-country and global partners to coordinate efforts, making them a key stakeholder in determining co-trimoxazole availability. The project began in 2003.
interviews at the ministry level in each country is a noted gap as these desk reviews were not field-based and relied almost exclusively on the experience of U.S. Government (USG)-funded staff.²

**PROGRAM CONSIDERATIONS**

The country desk reviews revealed that many supply chain challenges exist related to ensuring co-trimoxazole availability for all indications. Conversely, there are many innovative approaches to help ensure availability of this important antibiotic for PLWH. Examining co-trimoxazole availability from a commodity security perspective highlights areas requiring attention and support. Additionally, this approach identifies contextual factors that influence the way supply chains operate, such as access, quality, efficiency, financing, and collaboration. Table 1 provides a summary of key information collected through the 15 country desk reviews including information on stockouts; how logistics information is tracked (whether co-trimoxazole for PLWH is integrated or tracked separately); how forecasting and quantification are performed; who contributes funding for co-trimoxazole; and who procures the antibiotic.

**Table 1. Co-trimoxazole Country Summary**

<table>
<thead>
<tr>
<th>Country</th>
<th>Stockouts</th>
<th>Information Tracking of HIV and Primary Care Products</th>
<th>Forecasting and Quantification Practice</th>
<th>Funding Sources</th>
<th>Procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>None reported</td>
<td>Integrated</td>
<td>Collaborative, but uses little logistics information</td>
<td>Government, UNITAID</td>
<td>Government, the Clinton HIV/AIDS Initiative (CHAI), No SCMS procurement</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Yes, in 2009. None since then</td>
<td>Separate</td>
<td>Collaborative, for HIV programs only</td>
<td>Government, UNITAID, GFATM, PEPFAR, private providers</td>
<td>Pharmaceutical Fund and Supply Agency (PFSA), CHAI, SCMS, individual suppliers</td>
</tr>
</tbody>
</table>

²In Namibia, information was available only through the Ministry of Health and Social Services. And in South Africa, only one nongovernmental organization informant was responsive to requests for input.
<table>
<thead>
<tr>
<th>Country</th>
<th>Stockouts</th>
<th>Information Tracking of HIV and Primary Care Products</th>
<th>Forecasting and Quantification Practice</th>
<th>Funding Sources</th>
<th>Procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guyana</td>
<td>None reported</td>
<td>No logistics management information system (LMIS); one is being developed</td>
<td>Process unknown</td>
<td>Government only</td>
<td>New Guyana Pharmaceutical Corporation. No SCMS procurement</td>
</tr>
<tr>
<td>Haiti</td>
<td>Yes, prior to SCMS procurements. None since then</td>
<td>Separate</td>
<td>Each partner individually calculates co-trimoxazole need</td>
<td>Government, GFATM, PEPFAR</td>
<td>Partnership for Supply Chain Management, SCMS, government procurement agent</td>
</tr>
<tr>
<td>Kenya</td>
<td>Yes, at central level. But no stockouts at service delivery points</td>
<td>Separate</td>
<td>Monthly co-trimoxazole monitoring by partners. Annual quantification involving multiple partners</td>
<td>Government, GFATM, PEPFAR, Family Health Options for Kenya</td>
<td>Kenya Medical Supplies Agency (KEMSA), Kenya Pharma Project (USAID), Mission for Essential Drugs and Supplies (MEDS), SCMS (nonroutine)</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Yes, prior to SCMS procurements. None since then</td>
<td>Integrated</td>
<td>Comprehensive process involving multiple stakeholders quantifies need for all uses annually</td>
<td>Government, GFATM, PEPFAR, UNITAID</td>
<td>Central de Medicamentos e Artigos Medicos/Central Drugs and Medical Supplies (CMAM), SCMS, CHAI</td>
</tr>
<tr>
<td>Namibia</td>
<td>None reported</td>
<td>Integrated</td>
<td>National forecast performed by Central Medical Stores (CMS) with technical assistance from SCMS</td>
<td>Government, PEPFAR</td>
<td>CMS, SCMS (nonroutine)</td>
</tr>
<tr>
<td>Country</td>
<td>Stockouts</td>
<td>Information Tracking of HIV and Primary Care Products</td>
<td>Forecasting and Quantification Practice</td>
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<td>Procurement</td>
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</tr>
<tr>
<td>Rwanda</td>
<td>None reported in the past two years. Overstock situation in early 2010</td>
<td>Separate</td>
<td>New coordinated procurement and distribution system will begin calculating need in 2010</td>
<td>Government, UNITAID, PEPFAR, private funding</td>
<td>Consumables and Equipment Central Procurement Agency (CAMERWA), UNICEF, CHAI, SCMS, Bureau des Formations Médicales Agrées du Rwanda (BUFMAR)</td>
</tr>
<tr>
<td>Tanzania</td>
<td>None reported. Emergency shipment required in 2008</td>
<td>Separate</td>
<td>SCMS and National AIDS Control Program quantify for HIV, and Ministry of Health and Social Welfare quantifies for other uses</td>
<td>Government, GFATM, PEPFAR</td>
<td>Medical Stores Department, SCMS</td>
</tr>
<tr>
<td>Uganda</td>
<td>None at Joint Clinical Research Center (JCRC). Situation at other sites unknown</td>
<td>Separate</td>
<td>Current approach unknown. SURE Project seeking to do national quantification for co-trimoxazole</td>
<td>Government, UNITAID, PEPFAR</td>
<td>National Medical Stores, CHAI, Joint Medical Stores, SCMS (nonroutine)</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Yes, pediatric formulations in isolated geographic areas</td>
<td>Separate</td>
<td>Each hospital quantifies need for co-trimoxazole for HIV and other uses</td>
<td>Government, PEPFAR</td>
<td>Individual hospitals. No SCMS procurement</td>
</tr>
<tr>
<td>Zambia</td>
<td>Yes, at service delivery points. No national stockouts since 2007</td>
<td>Separate, but moving toward integrated system</td>
<td>Annual quantification calculates need for all purposes</td>
<td>Government, GFATM, UNITAID, PEPFAR</td>
<td>Government procurement unit, IDA, UNICEF, CHAI, SCMS</td>
</tr>
</tbody>
</table>

*South Africa was not included because information was collected only from one nongovernmental organization (NGO) implementing partner.

PARTNER RESPONSE AND COMMITMENT

As the demand for co-trimoxazole expands, governments, implementing partners, donors, and others work proactively to ensure availability of supplies and respond quickly to stockouts. In addition to the funds provided by national governments for co-trimoxazole procurement, procurements are also funded by PEPFAR (via USAID and CDC), GFATM, UNITAID, the World Bank, UNICEF, the European Union, and private donors. In many countries, government and nongovernmental partners have joined together to 1) understand the magnitude of demand for co-trimoxazole; 2) plan procurements to meet the need; and 3) develop mechanisms for managing the large inventory now available. In other countries, when partners are not well coordinated, co-
trimoxazole availability is less reliable. Strong commitment from governments and donors to ensure a sufficient supply of co-trimoxazole highlights the importance of this antibiotic. Continued commitment and coordination will be required to sustain availability of co-trimoxazole given the ever-changing landscape of donor priorities, grant awards, and funding cycles.
GLOBAL CO-TRIMOXAZOLE AVAILABILITY AND FUNDING

The country studies reveal a large number of co-trimoxazole manufacturers that require numerous sources of funding to ensure co-trimoxazole availability for HIV programs. As this report focuses on selected countries, the findings presented here only represent general information about the manufacturers who provide co-trimoxazole to those countries, and the sources of funding used for procurements.

CO-TRIMOXAZOLE MANUFACTURERS

INTERNATIONAL MANUFACTURERS: APPROVED AND NOT APPROVED BY THE U.S. GOVERNMENT

PEPFAR-funded co-trimoxazole requires that the procured product meet specific quality standards. Typically, this means that the product must be either approved by the U.S. Food and Drug Administration (FDA) or approved by an alternate stringent regulatory authority (SRA).3 Because of the high demand for co-trimoxazole in HIV programs, USAID and SCMS have prequalified seven international wholesalers,4 and three India-based companies that have been inspected by an SRA.5 With the addition of these suppliers and manufacturers, PEPFAR has been able to respond to the increased demand for co-trimoxazole required for HIV programs. In addition to these manufacturers, there are other co-trimoxazole manufacturers with registered products in the countries included in this report but have not met USG requirements. As country programs can use their own financial resources to purchase co-trimoxazole, these manufacturers may be seen as favorable sources of co-trimoxazole as prices are often lower than USG-approved manufacturers.

LOCAL MANUFACTURERS AND PRODUCT QUALITY

Local manufacturers remain important sources of product in several countries studied in this report as they can reduce costs and transport challenges. In addition, the time to fill an order can be reduced if the local manufacturer has the production capacity to respond quickly. In some countries, such as Nigeria, there are strict regulations requiring purchase of medicines that are manufactured locally when such products are available. This policy applies to co-trimoxazole and has created a challenge for PEPFAR-supported procurement as none of the local Nigerian manufacturers meet USG quality standards. To address this, SCMS was granted a two-year waiver to import co-trimoxazole for PEPFAR-supported HIV programs, and it is still in effect as of December 2010.

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3 For a list of countries with regulatory authorities that are considered as SRAs as of July 1, 2009, please see www.stoptb.org/assets/documents/gdf/drugsupply/List_of_Countries_SRA.pdf (accessed September 2010).
4 USAID prequalified co-trimoxazole international wholesalers: IDA (the Netherlands); MissionPharma (Denmark); UNICEF (Denmark); Action Medeor (Germany); IMREF (the Netherlands); Amstelpharma (the Netherlands); and Medical Export Group (the Netherlands).
5 Additional prequalified co-trimoxazole manufacturers: Medreich, Microlabs, and Cipla.
Product quality for local manufacturers depends on the stringency of the national drug regulatory authority’s registration process. Some local manufacturers fall short on quality standards, resulting in uncertain therapeutic value. Locally produced product in Nigeria and Ethiopia did not meet quality standards, as outlined in the WHO Good Manufacturing Practices (GMP), and therefore SCMS could not procure those products since USG standards must be met, and WHO GMP standards are less stringent than USG standards.

**ACTIVE PHARMACEUTICAL INGREDIENT AND PRODUCT AVAILABILITY**

While several manufacturers provide finished co-trimoxazole product, there are only a few producers of one of the key active pharmaceutical ingredients (APIs), sulfamethoxazole. Virchow Laboratories Limited is the largest producer of this API (The Indian Pharmaceutical Association 2006). In fact, Virchow’s production capacity exceeds that of all the other API producers by such a large extent that they are considered to have a worldwide monopoly on sulfamethoxazole. Currently, Virchow’s price-fixing ability has not adversely affected the cost or the availability of the finished co-trimoxazole product.

Figure 1 summarizes the country desk review findings around funding sources, procurement, distribution, and destination programs, and how these elements interrelate.

*Figure 1. Funding, Procurement, and Distribution of Co-trimoxazole*  

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6 The chains on this table can be integrated or vertical depending on country context.
FUNDING FOR CO-TRIMOXAZOLE

Funding for co-trimoxazole is provided by a range of donors and national governments. Main sources include the following.

U.S. President’s Emergency Plan for AIDS Relief
The USG, through PEPFAR, provides substantial funding for procurement of co-trimoxazole for use in HIV programs. USAID-supported PEPFAR programs fund co-trimoxazole through direct SCMS procurement. CDC has traditionally provided funds to support PEPFAR partners directly. However, at the time of this report writing, countries are generally moving toward centralized procurement (either through SCMS in parallel to Ministry of Health [MOH] procurement systems, or directly through MOH systems).

National Governments
Government procurement agencies in the countries reviewed have obtained co-trimoxazole with government funds for PHC for many years. Now, national treasury funds are often augmented with money provided by GFATM for HIV programs resulting in increased funding for co-trimoxazole. Informal reports reveal that government funding for co-trimoxazole in PHC has shifted when a perception is held that external donor funding for co-trimoxazole will be sufficient for all purposes. This is problematic because donor-funded co-trimoxazole is intended to augment supplies purchased by the national government to meet the increased demand generated by HIV programs. Therefore, if national governments reduce their contribution for co-trimoxazole, there is risk of an insufficient supply of co-trimoxazole for use in either PHC or HIV programs.

FACTORS INFLUENCING CO-TRIMOXAZOLE AVAILABILITY
Based on findings from the country studies, integration and stakeholder participation appear to influence a country’s ability to manage co-trimoxazole and ensure its availability. Table 1 illustrates how programs utilizing an integrated procurement strategy have fewer, if any, stockouts.

Integration and Country Ownership
Commitment to integration of health logistics was apparent in this analysis. Some countries, such as Ethiopia, are moving toward logistics systems that integrate the management of co-trimoxazole donated for HIV programs with co-trimoxazole purchased for PHC. Other countries, such as Botswana, Mozambique, and Namibia, already have fully—or almost fully—integrated health logistics systems. Conversely, in a number of countries, such as Côte d’Ivoire, Haiti, Rwanda, and Tanzania, co-trimoxazole provided by different donors is segregated and/or managed in different information systems. Countries reporting a product stockout (see Table 1) were more likely to manage vertical logistics systems.

Stakeholder Participation
With many stakeholders involved in the provision of health services, competing priorities abound. For example, different donor requirements can create inefficiencies with health facility staff striving to work within existing systems while also complying with a myriad of donor reporting requirements. Managing and operating separate systems and filling separate reports requires excessive health personnel time, which is taken away from patient care.
U.S. President's Emergency Plan for AIDS Relief Co-trimoxazole Procurement Experience and Role

As described earlier, there are several ways in which PEPFAR supports co-trimoxazole distribution in the 15 countries studied. The country experiences demonstrate that a variety of strategies are needed to support a continuous supply. Some countries require routine procurements, others need support for special temporary situations, and some require no PEPFAR procurement support. The following country examples present the ways PEPFAR, through SCMS and CDC, is able to work with national governments—promoting country ownership—to respond to specific country needs for co-trimoxazole in a timely manner.

- Routine USAID-supported co-trimoxazole procurement through SCMS:
  - Côte d’Ivoire
  - Ethiopia
  - Haiti
  - Mozambique
  - Rwanda
  - Tanzania
  - Zambia

- Nonroutine SCMS co-trimoxazole procurement:
  - Kenya
  - Namibia (in lieu of antiretrovirals [ARVs])
  - Nigeria
  - Uganda

- No SCMS co-trimoxazole procurement support:
  - Botswana
  - Guyana (receive management support)
  - Vietnam

By offering a variety of support mechanisms, PEPFAR has the agility to respond to specific country needs for co-trimoxazole in a timely manner.

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7 Information summarized from SCMS data marking their co-trimoxazole procurements (2007 to August 2010).
CHALLENGES: CO-TRIMOXAZOLE MANAGEMENT AND AVAILABILITY

Commodity security\(^8\) for co-trimoxazole—like commodity security for any essential health product—can be compromised by shortcomings at critical points in the supply chain and in health system management. Experience in supply chain management of essential health commodities in resource-limited settings and findings from the desk reviews show that problems may be encountered when 1) developing a forecast; 2) securing financing; 3) procuring product; and/or 4) delivering the antibiotic and storing it at service delivery points. In addition to these country level co-trimoxazole challenges, the desk reviews pointed to challenges that exist at the global and individual level. Supply chain obstacles are briefly described, followed by specific country information from the interviews.

ACCESSING AND USING INFORMATION TO ESTIMATE NEED

Poorly functioning or nonexistent LMISs do not generate enough information to understand product need. Parallel information management (IM) systems can tax health facility personnel and result in inefficient systems.

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Country Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weak functioning LMISs</td>
<td>Botswana uses a collaborative approach to forecasting and quantification of co-trimoxazole for HIV use among CMS staff and partners. Limited logistics information on need exists, resulting in the forecast being based on morbidity data and weak information from the CMS. More specific information (e.g., stock on hand and issues data) collected monthly by lower level health facilities is not used as it does not move up the supply chain, making this information unavailable for use in the central level quantification exercise. However, note that logistics data at lower levels is used to determine average monthly consumption and to order quantities at those sites.</td>
</tr>
</tbody>
</table>

\(^8\) The USAID | DELIVER PROJECT describes commodity security as a state in which every person is able to choose, obtain, and use essential health products when they are needed. To this end, local systems need to have the ability to forecast, finance, procure, and deliver essential health supplies (see http://deliver.jsi.com/).
**Ethiopia** made improvements in monitoring inventory levels of co-trimoxazole leading to a stronger understanding of co-trimoxazole need for HIV and more accurate forecasting and inventory management. The development of a national coordinated procurement plan for all HIV products has helped to improve co-trimoxazole availability. As the plan does not include co-trimoxazole PHC needs, it is unclear if the demands for PHC are being met. Future plans include implementing a new integrated logistics system (ILS) to capture this data.

**Parallel IM systems with multiple reporting requirements**

**Ethiopia** provides free co-trimoxazole for PLWH, while PHC uses requires payment. This results in separate record keeping and reporting, becoming complicated for product managers. This is particularly challenging as transport and storage of the drug is integrated for HIV and PHC use.

**Nigeria:** SCMS manages quantification and procurement of co-trimoxazole for 11 PEPFAR partners. Streamlined reporting by the partners has improved availability of logistics data for the annual quantification of ARVs and co-trimoxazole. Consumption data is now used to estimate need instead of basing need on morbidity data. Interestingly, the recent SCMS-led quantification results showed that fewer commodities were required for the PEPFAR partners.

**Uganda:** PEPFAR-funded co-trimoxazole is segregated at health facilities (both IM and storage) from co-trimoxazole used for PHC. Allowing for specific information about consumption for different programs, it also generates an increased workload for the person preparing reports as different forms are required. Completing redundant forms requires additional time and effort by health personnel, possibly detracting from overall facility management and patient care.

**Tanzania** operates two different logistics systems to manage co-trimoxazole used for HIV and PHC. Both systems require staff to complete quarterly forms at each service delivery point, thus maintaining separate dispensing registers: one for HIV-related use and one for non-HIV-related use. Co-trimoxazole is free of charge for HIV-related use and requires payment for non-HIV-related use. Their inventory systems have different maximum and minimum stock levels; as such, HIV and PHC use are calculated separately. These parallel actions take place in an environment where the antibiotics are stored in an integrated manner, making it difficult to differentiate which co-trimoxazole is designated for which use.

**SECURING AND SUSTAINING FINANCING**

Finance challenges range from restrictive policies to difficulties coordinating multiple donors.

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Country Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complicated donor coordination</td>
<td><strong>Nigeria</strong> has too many donors providing too much product. In 2009, an influx of co-trimoxazole procurements by different HIV partner organizations resulted in an overstock with some of the product expected to expire. As a result, donated co-trimoxazole was distributed to federal MOH health facilities for use in PHC. Having too much product is not a typical problem; however, it can lead to product wastage and the possibility that donors will discontinue support.</td>
</tr>
<tr>
<td>Funding restrictions</td>
<td><strong>Vietnam</strong>’s funding restrictions posed a challenge to co-trimoxazole availability. Hospital annual drug budgets allow them to procure and sell drugs to patients while under the PEPFAR-supported LIFE-GAP Project. Hospitals receive reimbursement from CDC for HIV products they distribute, significantly differing from their standard system where the Provincial AIDS Centers (PAC) receive advance funds. During the first round of funding, funds arrived late, with hospitals concerned about not getting reimbursed. Therefore, some waited to purchase stock resulting in delays in co-trimoxazole provision to PLWH; this has now been addressed.</td>
</tr>
</tbody>
</table>
OVERCOMING PROCUREMENT OBSTACLES

Procurement, under the best circumstances, can be complicated and challenging. Add administrative barriers, problems with product quality, and registration restrictions to that equation, and the challenges mount.

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Country Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative barriers</td>
<td>Vietnam: Co-trimoxazole procurement and management is completely decentralized to the hospital level where product and price lists are generated annually. When co-trimoxazole was introduced for HIV use, there was a lag in availability until the hospital lists included the necessary products. To date, some hospital price lists still do not include the pediatric syrup.</td>
</tr>
<tr>
<td>Importation waivers</td>
<td>Ethiopia: SCMS initially attempted to procure co-trimoxazole using the Drug Administration Control Authority (DACA)-approved manufacturers, but the product did not meet even the WHO GMP quality standards, which are less stringent than USG standards. So DACA provided a waiver for SCMS to allow importation of co-trimoxazole that was not registered, providing assurance of high-quality standards with SCMS staff visiting production sites. Subsequently, SCMS shared their inspection data with DACA, helping them prioritize inspections and raising their awareness of their quality standards. Nigeria has locally produced products that did not meet USG standards. Therefore, a two-year waiver was provided by the government allowing SCMS and UNICEF to import co-trimoxazole. The government’s ban on importation is meant to increase local capacity to manufacture co-trimoxazole and boost the local economy. But partners argued local manufacturers 1) did not meet USG or WHO qualifications for good manufacturing practices and 2) could not meet the demand in a timely manner. Mozambique is reforming the registration process moving from a local manufacturer/supplier format to a more open format. As the new requirements are not in place, importation remains restrictive. In order to ensure co-trimoxazole is available, they have instituted a transition period allowing manufacturers and suppliers to import products that are not yet registered. This raises the question of which quality standards are being applied during the interim period.</td>
</tr>
<tr>
<td>Procurement delays</td>
<td>Kenya: The lack of reliable procurements using GFATM funds has resulted in stock shortages, requiring programs to secure product from alternate sources. Botswana: Procurement delays from CHAI resulted in stock shortages. This resulted in the need to use government-funded product to fill the gap.</td>
</tr>
</tbody>
</table>

DISTRIBUTING PRODUCT EFFECTIVELY

Lack of resupply information, timely transportation of product to service delivery points, and proper storage at those sites pose regular challenges. Co-trimoxazole can pose additional challenges given the large volume required to meet need.

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Country Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geographic barriers</td>
<td>Vietnam: Co-trimoxazole pediatric syrup is not available in some northern hills areas as some suppliers refuse to ship small volumes, so with low demand, stockouts occur. Another situation that results in stockouts is when hospitals procure product locally and the local suppliers do not stock all the required formulations.</td>
</tr>
</tbody>
</table>
Zambia has co-trimoxazole available within the MOH system. Unfortunately, while the drug remains in stock at the central level, stockouts occurred at service delivery points. These stockouts were not due to insufficient supply as the central level held product; instead, they were attributable to reporting and inventory management challenges resulting from complicated parallel inventory management systems. A system revision is underway to develop an integrated distribution and LMIS to address this problem.

Côte d'Ivoire has suffered from low LMIS reporting rates (~50 percent) with the resulting lack of information affecting stock at the district and facility levels. Failure to report low stock levels means that orders are not being filled and distributed regularly.

Rwanda’s lower level health facilities lack information about the new guidelines on universal access to co-trimoxazole, resulting in lower than anticipated consumption rates at the facility level and an overstock at the central level. Therefore, the health facility orders are not drawing down the stock at the central level as anticipated.

Many countries reported insufficient storage space to accommodate large volumes of product. Central level storage facilities often face space limitations when large consignments arrive. Storage space and management issues remain common problems at lower levels in most resource-limited health systems. Tanzania specifically mentioned challenges with inadequate space, poor ventilation, and security risks.

ENSURING SUFFICIENT ACTIVE PHARMACEUTICAL INGREDIENT

Although the global monopoly on the active pharmaceutical ingredient sulfamethoxazole, discussed previously, is not currently a problem, it could become an issue and therefore should be carefully monitored. A possible scenario could be a short-term lack of availability of the API, which would affect production. Additionally this monopoly could drive the price up, resulting in higher cost co-trimoxazole. But if the co-trimoxazole pipeline in PEPFAR countries is filled, maintained, and monitored, an API shortfall is unlikely to affect product availability at service delivery points.
IDENTIFYING AND ADDRESSING ACCESS ISSUES

One informant reported that stigma among PLWH is now associated with co-trimoxazole treatment. They stated that patients taking co-trimoxazole to treat sexually transmitted infections (STIs) or other infections fear being seen taking the antibiotic because it is widely known that PLWH take co-trimoxazole on a daily basis. The bias imposed by individual health care providers, also known as “provider bias,” poses a potential challenge for PLWH. For example, in Guyana where health providers come from an array of countries, and therefore a range of medical education standards and varying standard treatment guidelines, there is a risk that providers will apply the treatment that they are most comfortable with, which may not be the approved standard treatment according to national guidelines. Given the development of national standard treatment guidelines (STGs), this bias is reducing, but it needs to be monitored to ensure that PLWH are receiving care in line with the national STGs. Identifying and addressing access issues such as these and others will help ensure that PLWH can use this antibiotic and be free from stigma that may accompany treatment. Ensuring co-trimoxazole availability is key to increasing its use among both providers and PLWH.

INNOVATIONS TO IMPROVE CO-TRIMOXAZOLE MANAGEMENT AND AVAILABILITY

The country desk reviews revealed a range of experience in managing co-trimoxazole. In terms of product donated by PEPFAR, some countries segregate and track the co-trimoxazole donation separately from MOH-procured product (e.g., Côte d’Ivoire, Haiti, Rwanda, and Tanzania). In other cases, segregation is prohibited. For example, in Namibia, the health logistics system is completely integrated with no specific reporting for a product from a particular source. On both ends of the spectrum, the farther down you travel in the health system, the more integrated services and product management become. And as a result, tracking co-trimoxazole use is difficult even in countries that aim to track specific uses and/or sources. PEPFAR does not require co-trimoxazole provided for HIV programs to be tracked separately from PHC. However, some country programs require reporting on co-trimoxazole by program (e.g., HIV and PHC). Côte d’Ivoire is a good example where the central medical store will not deliver donated co-trimoxazole until a service delivery site submits a specific required report. Innovative approaches developed by countries to segregate, track, and report on co-trimoxazole use are described here.

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Country Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accessing and using information to estimate need</strong></td>
<td><strong>Ethiopia</strong> has different prescription pads for HIV and PHC programs, allowing facility personnel to distinguish between and track the free co-trimoxazole provided to HIV patients in contrast to the paid for co-trimoxazole used in PHC. This approach enables accurate reporting and tracking for consumption of co-trimoxazole used for different purposes.</td>
</tr>
<tr>
<td></td>
<td><strong>Kenya</strong> has a computerized dispensing tool to track ARVs with the ability to track the amount of co-trimoxazole dispensed to patients. The availability of this consumption data helps facilities establish and maintain maximum and minimum stock levels while also helping improve national forecasts when data is provided to the central level.</td>
</tr>
<tr>
<td></td>
<td><strong>Haiti</strong>’s LMIS reporting rates from SCMS-supported sites are high with over 90 percent of sites reporting. SCMS uses supply chain monitors who travel to sites to provide supportive supervision and oversight while collecting data, providing training and coaching, and ensuring proper storage techniques are being used.</td>
</tr>
</tbody>
</table>
Mozambique’s forecasting working group estimates the need for co-trimoxazole. The group is comprised of a diverse range of stakeholders, all responsible for OI management. These efforts help improve utilization of all resources including co-trimoxazole.

<table>
<thead>
<tr>
<th>Securing and sustaining financing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Côte d’Ivoire’s National Quantification Committee involves all partners in the HIV program during their annual quantification to jointly draft one national supply plan including all donors and their donated products. They use morbidity data and compare it with available consumption data as a cross-check. The PSP—the organization that manages products for the Essential Medicines Program—quantifies the remaining national needs. Unfortunately, these quantifications are not coordinated.</td>
</tr>
</tbody>
</table>

| Rwanda’s new warehouse management system (WMS) under development at the CMS is designed to manage co-trimoxazole by tracking product by donor and by the program for which it is intended. The system will also track consumption data by program and information will be traceable to the patient level. Another system that will go into operation in late 2010—the Coordinated Procurement and Distribution System (CPDS)—will use national data to determine the co-trimoxazole need for HIV programs. |

| Kenya’s key stakeholders meet on a monthly basis to review levels and consumption patterns of key HIV commodities, including co-trimoxazole. They also participate annually in a national forecast exercise. |

| Mozambique’s integrated logistics management approach adopted by the MOH and partners includes activities to improve health product distribution, quantification, procurement, and funds allocation. A national co-trimoxazole budget is jointly developed by several partners in a coordinated and collaborative manner, and fiscal responsibility for co-trimoxazole is shared among these stakeholders. |

<table>
<thead>
<tr>
<th>Overcoming procurement obstacles</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Kenya’s stock levels run low due to delays in GFATM-funded procurement, back-up systems are activated to ensure product is available for HIV programs in the public and private sectors. For example, GFATM-funded programs obtain product financed by the Government of Kenya through KEMSA, a parastatal medical supply organization, and private not-for-profit program sites obtain product through MEDS, a faith-based medical supply organization.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Distributing product effectively</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenya’s ARV and co-trimoxazole transport is outsourced to private contractors for both government- and PEPFAR-funded programs. The contractors collect product from a central storage facility and deliver it to either regional or district distribution points.</td>
</tr>
</tbody>
</table>

**A PROACTIVE APPROACH TO ENSURING CO-TRIMOXAZOLE AVAILABILITY**

From the findings revealed through the country desk reviews, it is apparent that there are many supply chain challenges posing obstacles to ensure co-trimoxazole availability for all uses. And conversely, there are many innovative approaches being developed and implemented to help ensure availability of this important antibiotic. Validating successful supply chain innovations and sustaining their implementation require technical expertise, resources, and policymakers’ commitment. The commodity security concept helps frame issues around product availability from a supply chain point of view. And it also points to the fact that contextual factors influence the way in which a supply chain operates. Five key contextual topics to consider when working toward improving availability of health commodities include access, quality, efficiency, financing, and collaboration.
### Considerations to Strengthen Co-trimoxazole Systems

| **Access** | Additional attention is needed on access issues such as the following:  
| - Designing service delivery mechanisms to respond to customer requirements  
| - Addressing the needs of marginalized and geographically disadvantaged populations  
| - Creating pricing policies that encourage adherence to treatment  
| - Engaging partners to enhance participation, improve coordination, and increase service coverage. |

| **Quality** | PEPFAR’s efforts to prequalify co-trimoxazole suppliers and manufacturers have largely addressed quality requirements for SCMS-supported procurements. But country-level efforts to ensure medicines are of high quality may require additional technical assistance. For example, Ethiopia’s DACA was receptive to technical assistance provided by SCMS that helped them prioritize inspections and focus attention on improving DACA’s quality standards. |

| **Efficiency** | Improving supply chain efficiency is an ongoing struggle. The country reviews found that co-trimoxazole management can be fully integrated with other health products, completely segregated, or managed through a hybrid system of supply management. Which one is most efficient depends on the desired outcomes. Supply chain efficiency is a topic that will continue to receive immense attention by the private sector and hopefully increasing attention by public sector health supply chain managers and donors. There have already been improvements in public sector supply chains through the development of improved LMISs that generate data for decision making. These gains improve supply chain efficiency and ultimately the quality of health services when the result is that a product is available when a patient/client/customer needs it. |

| **Financing** | Financing health services is always a challenge, and public sector health services are particularly vulnerable to funding shortfalls. As a result, focused attention on financing for HIV is required to ensure that funds are available for commodity procurements. It is difficult to imagine that the need for donations of co-trimoxazole will decline in the short run. Coordinated financing, including contributions from national governments and donors, will continue to be needed to close product availability gaps. Household/out-of-pocket expenditures on health care, while often higher than realized, will remain a necessary contribution, even when the product is provided at no cost to PLWH. Greater exploration of financing issues around co-trimoxazole would help all contributors understand the value of their inputs, and the cost savings that result from using co-trimoxazole to prevent and treat infection in PLWH. |

| **Collaboration** | The benefits of effective collaboration among partners are evident with coordination being key at points of service delivery, logistics system design, quantification, financing, and procurement. At every junction, there are partners who are willing and able to step forward and contribute what they can for the benefit of PLWH and others requiring health services. In many countries, without collaboration, co-trimoxazole availability would be inconsistent or insufficient to cover the needs of both HIV and PHC. Coordination and collaboration among stakeholders improves the chances of ending up with quality health service provision including co-trimoxazole preventive therapy and treatment. |
REFERENCES


APPENDIX A:

COUNTRY SUMMARIES
CO-TRIMOXAZOLE COUNTRY SUMMARY: BOTSWANA

PROGRAMS USING CO-TRIMOXAZOLE

Co-trimoxazole is used in Botswana for the clinical management of susceptible infections according to their antibiotic guidelines and the 2007 version of Botswana’s treatment guide. It is also used for prevention and treatment of many HIV OIs listed in the National Guidelines for the management of HIV-Infected and HIV-Exposed Adults and Children (August 2006), and the Botswana National HIV/AIDS Treatment Guidelines (2008).

Botswana runs one national supply chain for the distribution of ARVs and essential medicines. Vertical supply chains do not exist to satisfy donor requirements in Botswana; all ARVs and essential medicines run through the same supply chain regardless of funding source. The donors are seen as contributing to the overall health system and all patients are considered government patients. Co-trimoxazole is primarily managed in the essential medicines program. ARVs and essential medicines share one CMS, and procurements are performed with one source of funding, but at times, due to inefficiencies with the national supply chain, some small functions, such as distribution of ARVs and reporting may be performed separately. ART and co-trimoxazole for chemoprophylaxis and treatment are dispensed at infectious disease care clinics (IDCCs), where they exist. At lower levels of the health system, clinics provide both ARVs and essential medicines due to the shortage of human resources. There is an expectation that the ARV and essential medicines programs will eventually be integrated at all levels and for all functions.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNITAID and possibly other sources</td>
<td>CHAI (provided 100 percent coverage for pediatric requirements and 20 percent coverage of adult requirements)</td>
<td>Different purchasing mechanisms have resulted in different products for each tender</td>
</tr>
<tr>
<td>Government of Botswana</td>
<td>CMS</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

A national procurement plan exists for all pharmaceuticals, including co-trimoxazole. Previously, government funds for co-trimoxazole used in HIV programs were earmarked in the national budget. Now, those funds are augmented with donations from CHAI. National quality assurance policies and procedures are implemented by the National Drug Quality Control Laboratory, a unit within the CMS.

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole is categorized as a vital medicine, and it is generally available across the Botswana health system. There have not been any stockouts reported at health facilities, but there have been shortages in the pipeline due to delays in supplies of products procured by CHAI. At the central level, co-trimoxazole from all sources is stored together. At the facility level, it is possible to have co-trimoxazole in two locations: the dispensary and the IDCC where HIV patients are treated. At smaller health facilities, co-trimoxazole is commonly provided for both PHC and HIV care.
**CHALLENGES**

Delays in receipt of supplies donated by CHAI have resulted in additional government funds being used to procure co-trimoxazole to fill the gap.

The CMS, with assistance from partners, performs an annual national forecast. The morbidity-based forecast includes co-trimoxazole needs (chemoprophylaxis and treatment) for children using data collected by CHAI, and the estimated need for treatment for all patients with HIV-related pneumonia. Using information from an LMIS would improve forecast accuracy, but unfortunately, one does not exist yet. The CMS currently keeps only issues data. With the assistance of the SCMS project, a national LMIS is currently being developed. The system is proposed to aggregate and analyze logistics data and disseminate information to stakeholders to improve supply management and decision making. It will also facilitate the provision of feedback to lower levels of the health system through the Drug Management Unit—the MOH department overseen by the Chief Pharmacist that includes management of information, the CMS, the drug regulatory authority, and the quality control lab, for example.

At service delivery points, a physical inventory is conducted monthly to collect data on stock on hand. Additionally, issues data from bin cards (i.e., stock moved from the storeroom to the dispensaries) is documented, but this data is not shared with the central level. Service delivery point staff also have the responsibility of determining the average monthly consumption of the medicines they hold and for determining their order quantities.

**INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE**

Technical assistance provided by SCMS, such as development of the LMIS and a logistics management certification system, supports overall health logistics system development, but these activities are not specific to co-trimoxazole management. The health commodity logistics management certification system aims to entrench and sustain logistics management initiatives in the public health sector.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE**

When the Government of Botswana realized that they could not manage all patients that required ART, they entered into a public-private partnership (PPP) agreement for ART, but not for comprehensive HIV care. Through this agreement, established patients on ART can be referred to private physicians and get their ARVs at private dispensaries. These ARVs are sourced from the CMS and are provided at no charge to the patients. However, patients using the PPP arrangement who require co-trimoxazole are referred to government facilities to collect co-trimoxazole as co-trimoxazole is not distributed from the CMS to private dispensaries, like ARVs. As a result, if patients want to obtain their co-trimoxazole from the private dispensary at the same time they pick up their free-of-charge ARVs, they would have to pay for the co-trimoxazole.
CO-TRIMOXAZOLE COUNTRY SUMMARY: CÔTE D’IVOIRE

PROGRAMS USING CO-TRIMOXAZOLE

Both the HIV program and the malaria control program use co-trimoxazole to treat and/or prevent health problems. Co-trimoxazole is included in both programs’ STGs. The essential medicines program also uses co-trimoxazole, but it is not clear if it is included in any STGs.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Fund</td>
<td>CARE</td>
<td>Internationally procured</td>
</tr>
<tr>
<td>World Bank</td>
<td>PUMLS</td>
<td>Internationally procured</td>
</tr>
<tr>
<td>USAID</td>
<td>SCMS</td>
<td>Internationally procured: Beltapharm, Cipla, Microlabs</td>
</tr>
<tr>
<td>Government (non-HIV funding)</td>
<td>PSP-CI (Pharmcacy de la Sante Publique, the CMS for CI)</td>
<td>Locally and internationally procured</td>
</tr>
<tr>
<td>European Union (for non-HIV programs)</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE

Since receiving PEPFAR funding, co-trimoxazole availability has increased; while there have not been stockouts at the central level, districts and facilities have reported stockouts. However, there have not been reports of co-trimoxazole stockouts for HIV programs in the past three (or more) years. Co-trimoxazole is available for PHC; however, the quantification/procurement process for the essential medicines program is separate from the HIV program. Co-trimoxazole is part of the cost-recovery system for non-HIV programs.

CHALLENGES

Some challenges are as follows:

- The MOH has had difficulty obtaining quality consumption data due to low LMIS reporting rates (~50 percent). Low reporting rates have also affected stock levels at the district and facility levels, as failure to report means that orders are not being regularly filled and distributed; this has resulted in stockouts at the district and facility level.

- Currently, data aggregation is a manual process, which is time-consuming and prone to errors.

INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE

Some innovation approaches to managing co-trimoxazole are as follows:

- The warehouse management system, MACS, has separate codes for different donors and programs.

- Presently, Côte d’Ivoire is upgrading the currently-used ARV Dispensing Tool (SIMPLE I) to the Essential Drug Dispensing Tool. This tool will facilitate medicine and dispensing
management, and the data will be used to support the annual HIV commodities quantification, which includes co-trimoxazole.

- Proposed is automation of the LMIS tools to improve reporting rates, data quality, and ease of data aggregation. The automated LMIS is scheduled for implementation between 2011 and 2012.

- The National Quantification Committee involves all partners involved in the HIV program during their annual quantification and drafts one national supply plan including all donors and their donated products.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE**

Some issues raised are as follows:

- **Product management, storage, and distribution:** Co-trimoxazole is tracked by donor and by program in the MACS WMS. At the central level, co-trimoxazole stock is stored together; however, at the facility level stock may be segregated (at the discretion of the pharmacist). Warehouse staff use the ARV/Laboratory LMIS standard operating procedures, which includes a section on storage, as guidance for best storage practices.

- **LMIS:** Monthly data submissions have, thus far, been irregular. Quarterly supervision visits aim to improve reporting rates and data quality. The LMIS tools are currently being redesigned with the goal of enhancing data quality and on-time reporting.

- **Inventory control:** The MACS WMS sets maximum and minimum levels at the central level. Pharmacists at each of the sites determine their stock levels. While co-trimoxazole has been consistently available at the central level since PEPFAR donations began, district and facility level stockouts have been reported. These stockouts have been attributed to a failure by facility staff to place orders.

- **Quantification:** The National Quantification Committee does an annual forecast for all HIV commodity needs while the PSP—who manages the products for the Essential Medicines Program—quantifies for the remaining national needs. The HIV program quantification uses morbidity data and compares it with available consumption data as a cross-check.

- **Funding:** A cost-recovery system is used to fund procurements of co-trimoxazole that are not part of the HIV program. The government of Côte d’Ivoire does not provide funding for co-trimoxazole for HIV programs.

- For pediatric formulations, mothers have shown a preference for liquid formulations. However, there have been reports of problems concerning mixing the liquid with unclean water and children getting sick as a result.
CO-TRIMOXAZOLE COUNTRY SUMMARY: ETHIOPIA

PROGRAMS USING CO-TRIMOXAZOLE

Co-trimoxazole is used in HIV programs, and for PHC. CHAI has been providing pediatric formulations for the past four years and will continue to provide for one additional year. Co-trimoxazole is included in the OIs STGs and the general treatment guidelines. It is also included in all three editions of the essential medicines list (EML).

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>USAID/PEPFAR</td>
<td>SCMS</td>
<td>Manufacturers meeting SCMS quality standards</td>
</tr>
<tr>
<td>UNITAID</td>
<td>CHAI</td>
<td>Pediatric formulations only</td>
</tr>
<tr>
<td>GFATM</td>
<td>MOH procurement through PFSA</td>
<td>DACA currently has registered co-trimoxazole formulations, produced both locally and internationally by a range of manufacturers*</td>
</tr>
<tr>
<td>MOH Essential Drugs Program</td>
<td>MOH procurement through PFSA</td>
<td>DACA-registered formulations*</td>
</tr>
<tr>
<td>Private sector providers</td>
<td>Individual procurement</td>
<td>Injectable co-trimoxazole is available only through the private sector; the public sector does not procure it</td>
</tr>
</tbody>
</table>

*Sulphamethoxazole + trimethoprim: 960 mg tabs; 480 mg tabs; 240mg/5 mL 60 mL suspension; 240mg/5 mL 100 mL suspension; 800 + 160 mg/3 mL injection; 120 mg tab; 800 + 80 mg tab; and 15 percent ophthalmic solution 10 mL.

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole has been available for HIV programs continuously for the past year. There were stockouts in 2009, but since then inventory levels have been monitored more closely. Co-trimoxazole for PHC is not currently monitored, but once the ILS is implemented, stock levels will be reported. The private sector in Ethiopia is robust and therefore shortfalls of co-trimoxazole in the public sector are covered by product available through private outlets.

CHALLENGES

*Working toward integration while trying to segregate products: Ethiopia is working toward an ILS for essential public health products including co-trimoxazole and other medicines used to manage OIs. At present, however, information management of co-trimoxazole used for different programs is segregated, while distribution of the product is integrated. This poses challenges to stock managers as they are required to provide donated product free-of-charge and levy a fee for co-trimoxazole used in PHC. It also creates a challenge for health workers who do not distinguish between the source of health products dispensed at the facility level, but who are required to submit reports on consumption for various programs.
INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE

**Differentiated prescription pads:** Co-trimoxazole provided by PEPFAR is stored and managed separately at the hospital level, but at the health facility level it is stored together with co-trimoxazole provided for PHC. In both cases, however, separate prescription pads are used to document for which program the product will be used. The PEPFAR-funded co-trimoxazole is only provided to ARV and prevention of mother-to-child transmission (PMTCT) sites; all of these sites also offer PHC services. Staff at these facilities are advised to provide the donated co-trimoxazole only for HIV patients, but in some regions, this direction is not followed. The different prescription pads are used to distinguish between and track the co-trimoxazole that is provided for free (to HIV patients) in contrast to the fee that must be paid for co-trimoxazole used for other purposes. This approach helps to track products and enable accurate reporting.

**Quantification:** An annual comprehensive approach to co-trimoxazole quantification for HIV programs has been adopted and undertaken three times. It is led by government bodies, including PFSA, and is guided by the HIV commodities quantification document. A clinical review is also conducted in relation to the quantification exercise, and during that time, expressed opinions and input are obtained from content experts and stakeholders. A strong complement of data are considered, including both morbidity data and logistics data (issues and stock on hand, which are collected every two months). Quantimed and PipeLine software applications are used to develop forecasts and supply plans. The standard treatment guidelines, EML, and the guidelines on co-trimoxazole were all recently reviewed; however, the quantification is not an estimate of national need for all purposes, but rather it focuses only on the need for HIV programs. Although there is a national procurement plan for HIV, which includes products obtained with GFATM and PEPFAR funds, it does not include co-trimoxazole needs for PHC.

**OTHER ISSUES**

Storage space is insufficient in about half of health facilities. While there is an effort to segregate co-trimoxazole procured through different sources at smaller facilities with less storage space, the product is likely to be stored together, regardless of source.

When SCMS initially attempted to procure using DACA-approved manufacturers, the product did not meet quality standards. As a result, DACA provided a waiver for SCMS to import co-trimoxazole that was not registered, providing assurance that the manufacturers they use have high-quality standards and that SCMS staff conduct site visits to the production sites. Subsequently, SCMS shared their manufacturing facility inspection data with DACA, which helped them prioritize inspections and served to raise DACA’s awareness of their quality standards.
CO-TRIMOXAZOLE COUNTRY SUMMARY: GUYANA

PROGRAMS USING CO-TRIMOXAZOLE

The Guyana MOH recommends co-trimoxazole for prophylaxis and treatment of certain OIs in both adults and children in the National Guidelines for the Management of HIV-Infected and HIV-Exposed Adults and Children (August 2006). Co-trimoxazole is also recommended in the newly developed Standard Treatment Guidelines for Primary Health Care for diarrhea and other infections susceptible to co-trimoxazole.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government of Guyana</td>
<td>New Guyana Pharmaceutical Corporation: Private company with contract to be sole supplier for essential medicines including co-trimoxazole</td>
<td>Imports are made from Ranbaxy and other international manufacturers</td>
</tr>
</tbody>
</table>

The Government of Guyana has no donor funding for co-trimoxazole and GFATM provides funding for first-line ARVs only.

Medicines imported into Guyana must be registered. Quality is assured through several means. The Food and Drug Department within the MOH conducts random laboratory testing. With the current assistance of the SCMS project, which jointly operates and manages the Materials Management Unit (MMU), all pharmaceutical products received into the warehouse are tested at the mini-laboratory testing site established at the main MMU location. As a result of this collaborative work, a satellite warehouse was also established in order to improve the storage conditions for products. Warehousing, storage, and distribution best practices and a WMS have been implemented.

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole is available at all 16 HIV treatment sites in Guyana, and no stockouts have been reported at these sites. Patients requiring co-trimoxazole, but not ARVs, can theoretically obtain their medicine at the over 350 health centers in Guyana. But because there is no functioning LMIS, this cannot be verified. Expiration of products is also not reported and cannot be quantified.

CHALLENGES

Some challenges are as follows:

- An LMIS does not currently exist in Guyana. National standards do not exist for consumption reports, registers, or records; therefore, there is no consistency in their use at health facilities. This makes ordering and inventory management difficult at both the facility level and the central level. With the assistance of the SCMS project, a national LMIS is currently under development. To date, SCMS and the government have developed a process flow/schematic diagram that depicts flow of information from the combined requisition and issues vouchers from facilities to the MMU, and movement of products through a distribution pathway from MMU to the facilities. The USAID | DELIVER PROJECT-developed Logistics Indicators Assessment Tool

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has been used to assess the logistics system at the facility level and inform the development of
the LMIS. Training and supervision of staff will be required once the new LMIS is operational.

- There are numerous doctors of different nationalities practicing in Guyana. Prior to the
development of the _Standard Treatment Guidelines for Primary Health Care_, these physicians
prescribed based on their training outside of Guyana and their own national STGs. This
impacted ordering at facility level and procurement at the national level.

**INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE**

Technical assistance provided by SCMS, such as the development of the LMIS, and approval of
_Standard Treatment Guidelines for Primary Health Care_ support the overall health logistics system
development and health systems strengthening, but these activities are not specific to co-trimoxazole
management.
CO-TRIMOXAZOLE COUNTRY SUMMARY: HAITI

PROGRAMS USING CO-TRIMOXAZOLE

The HIV, mother and child, and respiratory disease programs all use co-trimoxazole to treat and/or prevent health problems. Co-trimoxazole is included in the HIV STGs. It is not clear if co-trimoxazole is explicitly included in the STGs of the other programs.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPFAR</td>
<td>SCMS</td>
<td>Microlabs, Beltapharm, Medopharm, Roche, Cipla</td>
</tr>
<tr>
<td>GFATM</td>
<td>Partnership for Supply Chain Management (PFSCM) via voluntary pooled procurement (VPP)</td>
<td>Cipla, Roche, Microlabs, Medopharm</td>
</tr>
<tr>
<td>MOH</td>
<td>Unknown</td>
<td>Unknown</td>
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</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole availability is good. There have not been any stockouts since SCMS has been handling procurement. It is also available for PHC, but it is more difficult to obtain specific information about co-trimoxazole availability from other programs.

CHALLENGES

Procurement lead times are very long and orders must be placed nearly a year in advance.

INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE

The SCMS Haiti program uses MACS—a warehouse management information system—to manage co-trimoxazole funded by PEPFAR. When VPPs arrive, they will be stored in the same warehouse as the PEPFAR commodities, but the drugs will be managed separately.

OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE

Other issues are as follows:

- In Haiti, the HIV programs do not consolidate goods into one central location. SCMS procures for PEPFAR, but GFATM HIV procurement and warehousing has thus far been separate. However, in the very near future, PFSCM via the VPP program with support of the SCMS staff in Haiti will be procuring for GFATM. SCMS will support the warehousing and distribution of the commodities but will not be responsible for reporting. This means that moving forward, SCMS will have more visibility into the overall stock status of co-trimoxazole in country, but there still will not be a national supply plan.
- Quantification is done individually by partners; there is not a national quantification for the HIV program. However, SCMS invites other partners to attend their quantification discussions and provide inputs around the assumptions used to derive the amount of stock needed.

- At the central level, stock procured with PEPFAR funds is managed according to specific PEPFAR program area—adult, child, PMTCT—with MACS. At the service delivery site level, it is managed by donor (e.g., PEPFAR or GFATM). This arrangement supports the different reporting requirements of PEPFAR and GFATM.

- SCMS LMIS reporting rates are high, with over 90 percent of sites reporting. SCMS uses supply chain monitors who travel to sites to collect data, provide training and coaching, and ensure proper storage techniques are being used. For other programs, the implementing partner—or “network” partner as they are referred to in Haiti—(CARE, etc.) is responsible for collecting the data. SCMS uses the LMIS data for the quantification, to place orders, and to redistribute stock. This data, however, does not include procurement or consumption data from the implementing partners. They are involved in the quantification process to validate assumptions, but their data is not considered.

- SCMS uses a push inventory management system whereby they collect data from service delivery sites, analyze the data, and fill orders based on available stock and needs at the service delivery site level.

- Maximum-minimum systems are established based on the delivery schedule (sites receive quarterly deliveries), the amount of storage space available, and other logistical considerations. These levels were adjusted from nine months of stock to one year of stock following the dissemination of the universal access guidelines.

- All PEPFAR sites are in “acceptable” or better condition according to the results of an SCMS review of each site prior to being operational. All sites also receive supervision from SCMS supply chain monitors. To help ensure that storage is managed correctly, SCMS uses the USAID DELIVER PROJECT storage guidelines at the site level.

- SCMS holds an annual quantification exercise for co-trimoxazole, and other products, which results in a two-year forecast and a one-year supply plan. To ensure that the supply plan remains accurate, it is reviewed twice a year.

- To ensure quality, SCMS programs follow STGs defined by the project management office whereby random samples are collected after delivery to country but before being sent to the sites. GFATM has a similar procedure in place.
CO-TRIMOXAZOLE COUNTRY SUMMARY: KENYA

PROGRAMS USING CO-TRIMOXAZOLE

The Kenya Ministry of Medical Services recommends co-trimoxazole for prophylaxis and treatment of certain OIs in both adults and children in the Guidelines for Antiretroviral Drug Therapy in Kenya (December 2005). Co-trimoxazole is also recommended in the National Standard Treatment Guidelines (2010) for diarrhea, certain STIs, and respiratory and other infections that are susceptible to co-trimoxazole.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPFAR/USAID</td>
<td>Kenya Pharma Project</td>
<td>USAID prequalified suppliers</td>
</tr>
<tr>
<td>GFATM</td>
<td>National AIDS and Sexually Transmitted Infections Control Program (NASCOP) conducts forecasting, KEMSA conducts procurement</td>
<td>WHO prequalified and other suppliers (mainly international) that meet quality requirements</td>
</tr>
<tr>
<td>Government of Kenya</td>
<td>NASCOP conducts forecasting, KEMSA conducts procurement</td>
<td>Local and international suppliers</td>
</tr>
<tr>
<td>Private not-for-profit organization (Family Health Options of Kenya)</td>
<td>NASCOP and if out of stock, then MEDS</td>
<td>International suppliers</td>
</tr>
</tbody>
</table>

Products imported into Kenya must be registered by the Medicines Regulatory Authority. Key informants indicated that all co-trimoxazole procured was registered. Quality assurance is accomplished through testing samples at the time of the tender and/or through various prequalification requirements (USAID prequalification, WHO prequalification, and/or quality assurance through testing by the National Quality Control Laboratory for Drugs and Medical Devices).

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole is available at lower levels of the health system for HIV programs despite the fact that there have been stockouts at the central level. For GFATM-financed co-trimoxazole, there have been delays due to their funding cycles and longer lead times (up to six months) because of minimum procedural times when tenders are conducted by KEMSA. All programs interviewed had identified ways to obtain co-trimoxazole, with minimal reliance on the private sector due to the increase in cost, when stockouts were imminent. For example, GFATM-funded programs can obtain Government of Kenya/KEMSA-procured stock at the central or facility level. Private not-for-profit sites can obtain co-trimoxazole through MEDS, a faith-based medical supply organization.

Co-trimoxazole is available at the lowest level of the health system in Kenya for PHC. The levels authorized to use this product include teaching, referral, secondary, and primary hospitals; health centers; maternity facilities; nursing homes; and dispensaries/small clinics.

Co-trimoxazole appears to be available in Kenya at the service delivery level. A computerized ARV dispensing tool added the ability to track co-trimoxazole dispensed to patients. A monthly report that includes consumption and patient data is sent by comprehensive care clinics (i.e., the clinics that
provide HIV care) to NASCOP. Co-trimoxazole stock levels are set at a minimum of one month and a maximum of three months at these clinics. Their staff are trained in storage and inventory management, and they learn to calculate average monthly consumption in order to ensure that minimum and maximum levels are set correctly. At a monthly meeting of stakeholders that includes GFATM, USAID, MEDS, and NASCOP, for example, ARV and co-trimoxazole stock levels are reviewed, and consumption patterns are evaluated. These partners also meet annually to conduct a national forecast. Information is shared among key stakeholders on a regular basis.

**CHALLENGES**

One challenge is a lack of reliable procurements using GFATM funds. Fortunately, this has not had a negative impact on stock availability at the facility level.

Although most programs have been procuring double-strength (DS) tablets (800/160), this strength is not included on the EML. During the next review, it should be considered for inclusion.

**INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE**

Private contractors are used to transport ARVs and co-trimoxazole for both government- (including GFATM) and PEPFAR-funded programs. Co-trimoxazole is stored at KEMSA, and private contractors pick it up and deliver it to the regions and districts. From there, either health facility staff pick up the medications or they wait to have them delivered to the lower level distribution point.

As most comprehensive care clinics are in different physical locations than primary care dispensaries, stock is kept separately and, therefore, it can be accounted for. There is a requirement by both GFATM and PEPFAR that HIV-associated products be used for HIV patients. It is possible that products are used for other health reasons, but there is little concern about that. GFATM recently audited the Kenya program, paying particular attention to the supply chain. The results are not yet available, but there did not appear to be any issues regarding co-trimoxazole supply management.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE**

One provider stated that there is an issue arising with stigma associated with taking co-trimoxazole. Patients taking co-trimoxazole to treat STIs or other infections fear being seen taking this medication because it is widely known that PLWH take co-trimoxazole on a daily basis.
CO-TRIMOXAZOLE COUNTRY SUMMARY: MOZAMBIQUE

PROGRAMS USING CO-TRIMOXAZOLE

Mozambique presents an integrated public health management system. Therefore, all the health care services as well as logistics management of health commodities are integrated.

The different indications for co-trimoxazole, which are included on Mozambique’s EML, include the following:

- Prophylactic treatment for HIV patients under the direction of the National AIDS Control Programme (NACP)
- Treatment of infections requiring a sulfa antibiotic, such as urinary tract infections and respiratory tract infections.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

A national co-trimoxazole budget is jointly developed by CMAM, SCMS, and CHAI in a coordinated and collaborative manner. The budget is based on an integrated quantification process (described subsequently), and fiscal responsibility for co-trimoxazole is shared among donors and CMAM.

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>USAID/PEPFAR</td>
<td>SCMS</td>
<td>Four co-trimoxazole preparations are approved by the Mozambique Food and Drug Authority (MFDA)</td>
</tr>
<tr>
<td>UNITAID</td>
<td>CHAI</td>
<td></td>
</tr>
<tr>
<td>GFATM</td>
<td>MOH procurement through CMAM</td>
<td></td>
</tr>
<tr>
<td>MOH Essential Drugs Program</td>
<td>MOH procurement through CMAM</td>
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</tr>
</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE

Prior to PEPFAR-supported SCMS project procurements, stockouts occurred. Now, with regular monitoring of stock, the inventory of this product is in balance. Although monitoring and evaluation using performance indicators has shown improvements in co-trimoxazole availability, some uncertainty on full availability still exists as the integrated management of health products makes it difficult to know if all needs for different programs are being met.

SCMS in Mozambique reports that co-trimoxazole was included in the country operational plans in 2008. Subsequently, an integrated supply plan was developed by the forecasting working group comprised of CMAM, SCMS, CHAI, and the section within the MOH responsible for OI drugs. The supply plan addressed the co-trimoxazole needs for the various uses of the product in both tablet and suspension formulations. Although the drug distribution system is integrated, it was estimated that 90 percent of the co-trimoxazole need in-country is for HIV clients.

SCMS provides technical assistance to CMAM, the government entity responsible for the annual quantification process. To estimate the needs, a working group formed by CMAM, SCMS, relevant programs of the MOH, and CHAI consolidate and review logistics data and epidemiological data, as well as targets set by the MOH.
Distribution of co-trimoxazole is consolidated with other commodities on a multitier centralized system from central level to provincial level, districts, and finally to health facilities.

**CHALLENGES**

As part of the registration process for new suppliers and products, quality certification is performed at laboratories outside of Mozambique—either in Portugal or Kenya—resulting in a lengthy registration process. A transition period is in place for manufacturers and suppliers whose products are not yet registered by the MFDA. During this period, products not registered in the MFDA list will be permitted for use. It was requested that the transition period be extended until January 2012 to allow sufficient time for product registrations to be finalized.

**INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE**

SCMS has been working with CMAM to incorporate logistics performance indicators into their monitoring and evaluation efforts. This will help verify improvements in the management of OIs, STIs, ARVs and antimalarial drugs, rapid tests, contraceptives, and condoms.

The integrated management approach by the MOH and partners include activities to improve health product distribution, quantification, procurement, and funds allocation. These efforts have helped to improve utilization of resources, especially for products with different applications such as co-trimoxazole.

As part of the Pharmaceutical Logistics Master Plan (PLMP), SCMS has been working with CMAM on the implementation of an integrated computerized LMIS, making logistics data for different programs within the MOH readily available for decision making.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE**

Although there have been improvements in storage conditions over the last five years, there is still room for improvement at different levels. SCMS is working with CMAM on the implementation of the PLMP that includes assessing and improving storage conditions.
CO-TRIMOXAZOLE COUNTRY SUMMARY: NAMIBIA

PROGRAMS USING CO-TRIMOXAZOLE

Co-trimoxazole is recommended for prophylaxis and treatment for various health conditions in the Guidelines for Antiretroviral Treatment (April 2003) and the Guidelines for the Clinical Management of HIV and AIDS. It is also recommended for various other susceptible infections, such as certain STIs and diarrhea in the National Standard Treatment Guidelines of Namibia.

Co-trimoxazole is included on the Namibia Essential Medicines List (NEMLIST). The medications included on the list are procured with the assistance of the Ministry of Health and Social Services’ (MoHSS) CMS—regardless of funding source, stored at CMS warehouses, and distributed with ARVs and other essential medicines to health facilities through an established distribution system. The CMS serves both government institutions and faith-based organizations, such as the Lutheran Medical Services and Catholic Health Services health facilities.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPFAR</td>
<td>SCMS funds in 2009 that were set aside for ARVs were not needed as there was enough stock of ARVs in Namibia. In order to not lose this funding, co-trimoxazole was procured instead.</td>
<td>Nine approved registered products including five tablet formulations and four suspensions.</td>
</tr>
<tr>
<td>Government of Namibia</td>
<td>CMS</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

Fast track registration exists and is used for medicines of high public health importance, such as those on the NEMLIST and ARVs. Some contracts are awarded to local wholesalers, but the same regulation applies to all CMS purchases. There is a quality assurance system in place for all essential medicines in the country. A sample is tested during the tendering process and also when stocks arrive in the CMS. Any problem in quality is notified to the regulators as well as CMS and appropriate actions are taken.

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole is available at all sites providing HIV treatment and care and PHC. Co-trimoxazole from all sources is stored together both at the central level and facility level. There have not been any stockouts at the national level.

In the revised pharmacy management information system, the districts and medical stores will record the number of days this item is out of stock. The pharmacy uses data from stock records on availability and average monthly consumption to know when to order more stock. Each district hospital is responsible for setting its own maximum and minimum stock levels for all pharmaceutical items. In clinics and health centers, the maximum and minimum levels are calculated with support from the district pharmacy staff or regional pharmacist. These levels are recalculated approximately every six months. Storage facilities and health facilities endeavor to comply with good storage practices as much as possible considering the infrastructure available.
A national forecast is performed by the CMS with assistance from technical assistance providers (SCMS).

**CHALLENGES**

Insufficient staff and storage space pose challenges to supply chain management for all pharmaceuticals in Namibia. Segregated storage requirements imposed by donors would not be feasible to implement, even though they may provide for easier auditing, information management, and reporting for donors. There is already a lack of storage space at both the CMS and at facilities, so special handling requirements—not warranted by the composition of the medicine—would be impossible to comply with. The CMS is responsible for over 500 items, and it would be difficult to track co-trimoxazole for HIV compared to PHC use.

**INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE**

The MoHSS has taken the approach that parallel systems should be avoided at all costs. The system that is in place works well, and it would not be appropriate to separate stocks of any medicine according to what the medicine is used to treat. The MoHSS position is that holistic management of all medicines and related supplies in one supply system is a best practice and should be encouraged wherever it is feasible; fragmentation of supply chain should be avoided.

The electronic dispensing tool (EDT) is used at all ARV dispensing sites. It tracks patient register information and ARVs, co-trimoxazole, and other related pharmaceuticals dispensed. It is in full use for tracking ARVs dispensed, but it is not fully implemented for other pharmaceuticals. Although the EDT is used in only a limited capacity for tracking co-trimoxazole dispensed at the facility, because the product is tracked as it is issued from the main pharmacy store to the ART clinic, the issues data can be used as a proxy for dispensed to user data. The MoHSS is not overly concerned for the lack of implementation of this aspect of the EDT at the facility level.

ART clinic pharmacies are being promoted as a one-stop shop so that clients can obtain comprehensive care while picking up their ARVs and other medicines, such as co-trimoxazole at the pharmacy, in addition to other health products such as contraceptives and vitamins.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE**

Expanding availability of pediatric oral syringes and stoppers would benefit the ART program as a whole and the pediatric services specifically.
CO-TRIMOXAZOLE COUNTRY SUMMARY: NIGERIA

PROGRAMS USING CO-TRIMOXAZOLE

NASCOP, a part of the Federal Ministry of Health (FMOH) in Nigeria, operates an expansive HIV program including 44 ART sites and over 400 testing facilities. PEPFAR implementing partners provide support to over 80 percent of these FMOH sites either directly with staff and technical assistance or with commodities. GFATM also directly supports over 135 FMOH sites, primarily with commodities. PEPFAR partners provide comprehensive ART services to over 300 sites in the country. UNITAID—previously through CHAI but currently through UNICEF—donates co-trimoxazole for PMTCT in Nigeria for all HIV-related programs. Co-trimoxazole is listed on the EML, and it is prescribed for OIs. Co-trimoxazole preventive therapy is approved for use (according to 2007 HIV treatment guidelines, which are currently under review) in the prevention of several secondary bacterial and parasitic infections in individuals living with HIV, including those who are:

- PLWH with symptomatic HIV
- Asymptomatic PLWH with a CD4 count <350 cells/mm³
- PLWH with active tuberculosis at any CD4 count
- Pregnant PLWH after the first trimester
- Any child born to an mother living with HIV who is at least six weeks old
- Any child identified as living with HIV within the first year of life.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Program</th>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMOH/NASCOP/HIV Program</td>
<td>Government of Nigeria</td>
<td>Local suppliers/procurement unit within the government procures</td>
<td>Emzor Pharmaceuticals, Fidson Pharmaceuticals, SKG Pharmaceuticals, etc. Approximately 10 local suppliers in Nigeria</td>
</tr>
<tr>
<td>GFATM</td>
<td></td>
<td>Crown Agents Nigeria Limited</td>
<td>Local suppliers</td>
</tr>
<tr>
<td>UNITAID</td>
<td></td>
<td>UNICEF/IDA</td>
<td>International suppliers (via a UNICEF special waiver)</td>
</tr>
<tr>
<td>PEPFAR ART Program</td>
<td>PEPFAR (CDC, USAID, Department of Defense)</td>
<td>SCMS</td>
<td>International suppliers (via a special two-year waiver from 2009 to 2010)</td>
</tr>
</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole has been generally available with no major stockouts reported. However, last year an influx of procurements by partner organizations resulted in a stock imbalance—an overstock situation—and co-trimoxazole intended for use in HIV programs was expected to expire at current...
consumption rates. As a result, donated co-trimoxazole was distributed to FMOH health facilities for non-HIV-related use.

CHALLENGES
Currently, the SCMS project manages quantification and procurement of co-trimoxazole for 11 PEPFAR partners who utilize this product in their programs. PEPFAR was granted a two-year waiver by the government allowing them to import co-trimoxazole; UNICEF was also issued a waiver for PMTCT programs. The government ban on importation is meant to increase local capacity to manufacture co-trimoxazole and boost the local economy. However, these waivers have waylaid the original intent of the ban. Partners argued successfully that local manufacturers 1) did not meet FDA or WHO qualifications for good manufacturing processes and 2) could not meet the demand in a timely manner. Additionally, PEPFAR implementing partners currently run a parallel supply chain to that of the FMOH. SCMS receives all PEPFAR partner co-trimoxazole supply, and the partners are then responsible for distribution to their sites (these sites also have different inventory control maximum and minimum levels). FMOH does its own procurement and distribution of co-trimoxazole. Similar to other countries, even though co-trimoxazole might be purchased for HIV programs, it has been found that co-trimoxazole is used for all purposes upon reaching the health facility.

INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE
SCMS pools procurement for 11 PEPFAR implementing partners who utilize co-trimoxazole in their programs. The decision to pool procurement helped streamline forecasting and reporting requirements by partners; an annual quantification exercise for ARVs and co-trimoxazole for HIV-related use is part of the country operation plan activities. SCMS led the design process of the logistics management information records for PEPFAR partners (including the PEPFAR Nigeria LMIS: Quarterly LMIS Report—ARVs and OI/Palliative Care Medicines). PEPFAR-supported ART sites submit these reports that eventually reach the SCMS office, where the data is tabulated in a spreadsheet. SCMS also assisted the FMOH in the design of—and now analysis of data from—the Combined Report, Requisition, Issues, and Receipt Form for ARV and OI drugs. SCMS records this data centrally and provides bimonthly feedback to CMS Oshodi, Lagos, based on the data that is collected to inform resupply to the facilities. Data from both the PEPFAR partners and the FMOH is shared at two different HIV Logistics Technical Working Group Meetings that John Snow, Inc. (JSI)/SCMS hosts—the PEPFAR group meets quarterly and the FMOH/GFATM group meets bimonthly.

OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE
With logistics data collected from the reporting forms on the use of co-trimoxazole, SCMS conducted the annual quantification using dispensed-to-user (i.e., consumption) data instead of previously used morbidity data (used in lieu of logistics data, based on estimated number of cases and STGs). Interestingly, the quantification results showed that fewer commodities needed to be procured for the PEPFAR partners. The SCMS project also supports the FMOH program to utilize consumption data in conducting their annual forecast for HIV-related co-trimoxazole use, but it is not involved in the FMOH procurement process for those commodities.
CO-TRIMOXAZOLE COUNTRY SUMMARY: RWANDA

PROGRAMS USING CO-TRIMOXAZOLE
The HIV program uses co-trimoxazole to treat and/or prevent health problems, and co-trimoxazole is included in the program’s STGs. The community health program does not use co-trimoxazole for respiratory infections; instead, amoxicillin is used.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
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<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>USAID</td>
<td>SCMS</td>
<td>Microlabs, Cadila, Medicamen, Medopharm</td>
</tr>
<tr>
<td>UNITAID</td>
<td>CHAI</td>
<td>Strides, Cipla, Aurobindo, and Microlabs</td>
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<tr>
<td>GFATM (proposed, but not yet funding)</td>
<td>CAMERWA</td>
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<tr>
<td>UNITAID</td>
<td>UNICEF</td>
<td>Strides, Cipla, Aurobindo, and Microlabs</td>
</tr>
<tr>
<td>Government</td>
<td>CAMERWA (non-HIV programs)</td>
<td>Unknown</td>
</tr>
<tr>
<td>Private</td>
<td>BUFMAR (non-HIV programs)</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE
Co-trimoxazole is available for HIV programs, and the program’s STGs promote universal access to co-trimoxazole beginning September 2010. Some overstocks were reported in early 2010 at the central level as they move toward increased access and attempt to fill the pipeline. Although co-trimoxazole is available for PHC, amoxicillin is the preferred medication for treatment of infections requiring a broad-spectrum antibiotic. There have not been any stockouts of co-trimoxazole reported for the past two years.

CHALLENGES
Some challenges are as follows:

- **Issues with the flow of information.** Communication to lower level health facilities about the introduction of new guidelines on universal access to co-trimoxazole has not been effective. This has had the result of less than anticipated amounts of co-trimoxazole being consumed, resulting in overstocks at the central level.

- **Facilities report LMIS data quarterly; however, specific responsibilities and reporting dates for sites to report to the central level are not clear.** Also, a system for review of completeness of reports and data quality does not exist. This has led to limited reporting back to lower level health facilities, and a limited ability at the central level to consider consumption data during quantification exercises.

- **CAMERWA is piloting active distribution in 11 districts.** Under this approach, CAMERWA distributes directly to the district level. This approach to distribution may have an effect on co-trimoxazole availability; however, the programmatic impact is unclear at this early phase of
implementation. Currently, the system operated by CAMERWA does not aggregate fill rate data for commodities dispensed to private pharmacies from other in-country medical stores such as BUFMAR, a private Christian nonprofit medical association that also performs pharmaceutical procurements. Integrating private pharmacy data into active distribution might possibly enhance visibility around co-trimoxazole consumption.

INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE

The new WMS at CAMERWA, which is under development, is designed to manage co-trimoxazole by tracking product by donor and by the program for which it is intended. It will also track consumption data by program. Information will be traceable to the patient level. The system implementation was scheduled to go live at the end of October 2010. For HIV programs, the CPDS coordinates donors, manages the forecasting exercise, and determines the national co-trimoxazole need for HIV programs. Once CAMERWA goes live, CPDS will use the data from the new system for decision making.

OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE

Some other issues are as follows:

- **LMIS:** SCMS is working with the USAID | DELIVER PROJECT to harmonize LMIS forms, including co-trimoxazole data. Harmonized forms were to be rolled out in November 2010. A computerized LMIS is under development.

- **Procurement:** Currently, CAMERWA is using inventory levels and distribution data to project months of stock and identify reorder points and quantities.

- **Quality assurance:** There is no drug registration system in Rwanda. The country uses WHO- and FDA-approved manufacturers or has to procure from suppliers that have been prequalified. They have also set quality assurance requirements based on good manufacturing practice. Private sector pharmacies procure directly from suppliers. Their importation documents must be shared with the Pharmacy Task Force—a group that falls under the management of the MOH—for customs clearing. Private sector pharmacy procurement requirements are the same as for the public sector.

- **Inventory control:** Co-trimoxazole stock is managed separately for different programs. HIV stock is stored separately at both the central and facility levels. The Treatment, Research, and AIDS Center; Pharmacy Task Force; CAMERWA; and the Treatment Center for HIV/AIDS develop guidelines and provide supervision for inventory control. Supervision visits are intended to investigate the situation at health facilities and gather clinical data to validate consumption data. This is for other products in addition to co-trimoxazole.

- **Training:** Training on the new WHO recommendations for pediatric HIV was conducted in September 2009.
CO-TRIMOXAZOLE COUNTRY SUMMARY: SOUTH AFRICA

PROGRAMS USING CO-TRIMOXAZOLE

The Centre for the AIDS Programme of Research in South Africa (CAPRISA) was established in 2002 under the National Institutes of Health-funded Comprehensive International Program of Research on AIDS by five partner institutions: University of KwaZulu-Natal, University of Cape Town, University of Western Cape, National Institute for Communicable Diseases, and Columbia University in New York. CAPRISA is a designated Joint U.N. Programme on HIV/AIDS Collaborating Centre for HIV Prevention Research. The main goal of CAPRISA is to undertake globally relevant and locally responsive research that contributes to understanding HIV pathogenesis, prevention, and epidemiology as well as the links between tuberculosis and AIDS care.

CAPRISA receives PEPFAR funding to initiate, maintain, and care for patients on ART and has two PEPFAR-funded sites: one in the urban municipality of eThekwini and one in Vulindlela. CAPRISA treatment programs are relatively small scale, with 2,000 active ART patients per site. CAPRISA has “seamlessly” incorporated co-trimoxazole procurement, storage, and distribution into day-to-day pharmacy operations. Co-trimoxazole is made available by clinician prescription to all HIV patients who require it. All co-trimoxazole for CAPRISA’s programs is designated for use with HIV patients. Pharmacy databases are used to record co-trimoxazole allergy (Dapsone is substituted in these cases).

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

CAPRISA’s co-trimoxazole is obtained either through the South African Department of Health (DOH) or from the private sector, using PEPFAR funds. Three formulations of co-trimoxazole are available for use in South Africa: oral tablet, pediatric suspension, and intravenous infusion. CAPRISA sites utilize Cozole by Ranbaxy Be-tabs, Nucotrim by GulfDrug, Lagatrim by Thebe Pharmaceuticals, or Sandoz Co-Trimoxazole by Sandoz.

<table>
<thead>
<tr>
<th>Program</th>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPRISA eThekwini site</td>
<td>Donated by South Africa DOH</td>
<td>Provincial Pharmaceutical Services Depot (PPSD) via government clinic—Mafakatini Primary Health Centre</td>
<td>Manufacturer depends on approved tender. Most frequently used source is Ranbaxy Be-Tabs</td>
</tr>
<tr>
<td>CAPRISA Vulindlela site</td>
<td>Donated by South Africa DOH</td>
<td>PPSD via the eThekwini Municipality DOH</td>
<td>Manufacturer depends on approved tender. Most frequently used source is Ranbaxy Be-Tabs</td>
</tr>
</tbody>
</table>

*All co-trimoxazole used is manufactured locally by Aidco-Generics, Al Pharm, Ranbaxy Be-Tabs, Thebe Pharmaceuticals, GulfDrug, Aspen Pharmacare, Sandoz, or CAPS tablets. South African Medicines Control Council handles all pharmaceutical registration.

AVAILABILITY OF CO-TRIMOXAZOLE

According to CAPRISA, stock shortages of varying lengths have occurred three times between January and August 2010 in the public sector, requiring CAPRISA to obtain co-trimoxazole from

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9 This summary is limited to findings from CAPRISA (www.caprisa.org). Other stakeholders opted out of participation in this information-gathering process.
local wholesalers in order to meet patient needs. The stock shortage did not result in a stockout, but the stock available in the public sector was reserved for DOH sites. As an NGO partner, CAPRISA is only able to access DOH supplies when they are in full supply. Local manufacturer delays in production and delivery as well as “inaccurate” ordering of co-trimoxazole supplies from the PPSD by DOH PHC sites have also contributed to co-trimoxazole stock shortages.

CHALLENGES

CAPRISA’s major challenge is intermittent stockouts due to relying on DOH supplies. Currently, site pharmacists usually order a bit more than they need from the DOH as a buffer against uncertainty. Most clinics hold two months of stock (approximately 1,600 units) at a time and at least one month of stock (800 units). A typical order is 1,000 units; on average, only 400 units are received. CAPRISA would like the DOH to institute a warning system to alert pharmacists of imminent stock shortages. CAPRISA suggests increasing stock availability by having the DOH establish arrangements with multiple providers in order to prevent stock shortages when a major supplier is not able to meet demand. CAPRISA has found that for their own programs, having access to co-trimoxazole via both public and private sources is useful when stockouts occur, but private source purchases come at a higher cost for CAPRISA than DOH-supplied co-trimoxazole.

INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE

In order to streamline and automate pharmacy record keeping and reporting, CAPRISA enlisted the assistance of the Desmond Tutu HIV Foundation and Cell-Life, an NGO based in Cape Town, to develop the intelligent dispensing of ART (iDART) “open source” software. iDART is used by pharmacists to manage ARV stocks, print reports, and manage collection of drugs by patients. The software is also designed to address the reporting requirements of funders, such as PEPFAR, and provides internal clinical data, such as early identification of patients who have not collected their medication on time. In mid-September 2009, the CAPRISA Vulindlela and eThekwini pharmacies transitioned from the manual dispensing processes to the iDART computerized system. The key benefits include, but are not limited to, accurate tracking of patient treatment (including history), automatic generation of reports, accurate ARV stock control management, time saving of pharmacy dispensing through faster processing, and reduction and identification of loss of ARVs through the stock take functionality. The system operates through clearly identifiable (doses are in large font), multilingual, bar-coded labels that are created for every drug and patient package and also include the patient’s next appointment date.

OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE

Based on attempts to connect with other DOH and NGO contacts, it appears that most PEPFAR partners receive their co-trimoxazole stock from the public sector supply. How the DOH manages co-trimoxazole for HIV-related versus non-HIV-related usage is still unclear.
CO-TRIMOXAZOLE COUNTRY SUMMARY: TANZANIA

PROGRAMS USING CO-TRIMOXAZOLE
Co-trimoxazole is utilized as a prophylactic treatment in the NACP, as a curative treatment within the STI program, and as an antibiotic prescribed for other ailments such as urinary tract infections. As a pharmaceutical on the EML in Tanzania, co-trimoxazole is approved for use down to the lowest level of health facilities in the country as tablets, injections, and syrups.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Program</th>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>NACP</td>
<td>PEPFAR</td>
<td>SCMS</td>
<td>FDA- and Tanzania Food and Drug Authority (TFDA)-approved</td>
</tr>
<tr>
<td>GFATM</td>
<td>SCMS</td>
<td>SCMS</td>
<td>TFDA-approved; WHO prequalified</td>
</tr>
<tr>
<td>STI Programme</td>
<td>GFATM</td>
<td>MSD</td>
<td>TFDA-approved; WHO prequalified</td>
</tr>
<tr>
<td>Ministry of Health and Social Welfare</td>
<td>MSD</td>
<td>MSD</td>
<td>Shelys Pharmaceuticals, Zenufa, InterChem; Tanzania Pharmaceutical Industries (TFDA-approved source, can be from local distributors representing foreign manufacturers)</td>
</tr>
</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE
The SCMS project in Tanzania reports that co-trimoxazole supplies have been erratic most likely due to the use of co-trimoxazole across a number of programs. SCMS provided an emergency shipment of co-trimoxazole in December 2008 to avoid a stockout, and those quantities that have been procured by SCMS in 2009 and 2010 are intended to cover use of co-trimoxazole by health facilities for HIV program clients. This co-trimoxazole does not necessarily cover co-trimoxazole needs for home-based care kits or for non-HIV-related use.

SCMS works with NACP to conduct annual quantification exercises to estimate program needs utilizing logistics data as well as other data. The Ministry of Health and Social Welfare is responsible for the quantification and procurement of co-trimoxazole for other uses where morbidity data (number of cases of ailments where co-trimoxazole is the recommended treatment) is typically used to forecast need.

CHALLENGES
Currently, two different logistics systems in Tanzania manage co-trimoxazole. The HIV logistics system manages all products related to HIV including HIV test kits, ARVs, and some medicines to
treat OIs, including co-trimoxazole. The ILS manages co-trimoxazole for all other uses of co-
trimoxazole as well as over 150 other products.

Each logistics system has a quarterly Report and Request (R&R) form that is used to report usage of
co-trimoxazole as well as other commodities; however, at the service delivery point level, it is
difficult to determine which stock of co-trimoxazole is designated for HIV- and non-HIV-related
health problems, resulting in the possibility of inaccurate usage reports.

While both logistics systems are pull systems, each system has different maximum and minimum
levels—the ARV and OI system has a six-month maximum while the ILS has a seven-month
maximum. In addition, service delivery points have two possible reports on which they can order
co-trimoxazole: the R&R for ARVs and OIs, and the ILS R&R. In addition, they have two different
dispensing registers: one for HIV-related use and one for non-HIV-related use.

Another added challenge is that co-trimoxazole for HIV-related use is given free-of-charge to ART
facilities (1,127 service delivery points) that use the R&R for ARVs and OIs to order from MSD;
however, facilities that use the ILS to order co-trimoxazole (approximately 3,300 service delivery
points) are charged by MSD for the co-trimoxazole through a deduction from their facility account.

**INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE**

By incorporating the management of co-trimoxazole for OIs into the ARV and OI logistics systems,
the NACP, with support from SCMS, is able to collect quarterly data on quantities of co-trimoxazole
that each ART facility dispenses for HIV-related use. These reports and requests are sent to the
MSD as orders to be packed and distributed. The SCMS project receives a copy of this report and
enters the information into a database that tracks commodity information including opening and
closing balances for the quarter, quantity dispensed, quantity received, losses and adjustments, and
quantity dispensed to users.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY
IMPORTANCE/SIGNIFICANCE**

Challenges exist at some service delivery points in terms of good storage practices, including having
adequate space, ventilation, and security.
CO-TRIMOXAZOLE COUNTRY SUMMARY: UGANDA

PROGRAMS USING CO-TRIMOXAZOLE

The MOH budgets for co-trimoxazole for their essential medicines program (for PHC), and the CDC provides funds for co-trimoxazole for HIV programs to the National Medical Stores (NMS) (an autonomous government corporation responsible for distribution of pharmaceutical products) and the Joint Medical Stores (JMS) (a private not-for-profit NGO licensed by the National Drug Authority to import, export, and sell medicines and related health supplies). USAID, through SCMS, has provided co-trimoxazole to USAID-funded implementing partners, such as the JCRC, on a nonroutine basis. Co-trimoxazole is included in the OI STGs, and it is included on the EML for all levels of the health system. Two co-trimoxazole manufacturers have registered co-trimoxazole by the National Drug Authority: Medicamen Biotech Ltd. and Micro Labs Ltd.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPFAR/USAID</td>
<td>SCMS</td>
<td>Micro Labs</td>
</tr>
<tr>
<td>PEPFAR/CDC</td>
<td>NMS and JMS</td>
<td>Specific manufacturers not known. Products listed in respective product catalogs follow. NMS: Co-trimoxazole 400/80 mg tablet JMS: Co-trimoxazole 100/20 mg Ped Tab Co-trimoxazole 960 mg tablet Co-trimoxazole 400/80 mg tablet</td>
</tr>
<tr>
<td>UNITAID</td>
<td>CHAI</td>
<td>Pediatric formulations sourced from Macleods and Cipla (registration in process)</td>
</tr>
<tr>
<td>MOH essential medicines fund</td>
<td>NMS</td>
<td>Unknown*</td>
</tr>
</tbody>
</table>

*Co-trimoxazole is produced locally. Locally produced product is reported to be used typically by the private sector, and at times public facilities purchase product from the private sector. According to the National Drug Authority’s list of registered drugs, there are two registered co-trimoxazole products of different strengths.

AVAILABILITY OF CO-TRIMOXAZOLE

The USAID-supported HIV programs of the JCRC have not experienced stockouts of co-trimoxazole in the past six months. They have received procurement support from SCMS since 2009. It is not clear if other organizations’ HIV programs have avoided stockouts. The USAID-supported SURE Project is seeking to do a national quantification, which should help address shortfalls in other programs. At the time of this report, USAID has not supported quantification of co-trimoxazole; the procurements they have supported are irregular. The availability of co-trimoxazole for PHC is unknown.
CHALLENGES
PEPFAR-funded co-trimoxazole is segregated at health facilities, both by information management and physical storage. This requires the person preparing reports every two months to complete two different forms.

INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE
Co-trimoxazole procured with USAID funding for HIV programs is used only for those programs. They have separate drug management forms, such as their unique Request and Order Forms.
CO-TRIMOXAZOLE COUNTRY SUMMARY: VIETNAM

PROGRAMS USING CO-TRIMOXAZOLE

CDC, through the Government of Vietnam’s LIFE-GAP Project, funds hospitals to obtain co-trimoxazole through local suppliers who obtain the medicine from local and international manufacturers. The product is used for both HIV care and for PHC. Co-trimoxazole is included in the HIV and malaria STGs. It is also included on the EML, but there is no requirement to use the list for local procurement.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
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<th>Funding Source</th>
<th>Supplier/Procurement Agent</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC</td>
<td>Hospitals obtain co-trimoxazole from local suppliers</td>
<td>Local and international manufacturers (specific manufacturers not known)</td>
</tr>
</tbody>
</table>

AVAILABILITY OF CO-TRIMOXAZOLE

Overall, there appears to be insufficient product to cover need, although funding appears to be sufficient. HIV patients obtain their medicines from an outpatient clinic, and primary care patients get their medicines from a dispensary. Because there are no standardized reporting forms, it is difficult to know if there is a shortage and, if so, how extensive it is. Stockouts of specific formulations have been documented in hill areas where access to medicines is constrained.

CHALLENGES

Some challenges are as follows:

- **Hospitals could not obtain DS co-trimoxazole tablets or syrup until the drugs were included on their lists.** Each year, each hospital and/or province does their own procurement. They establish a price list for products they will procure during the year. When DS co-trimoxazole was recommended for HIV care, it was not included on all hospitals’ price lists. As a result, the HIV program had to wait until the next year when the hospital undertook the process of revising their list. In some cases, they had to lobby for the inclusion of DS co-trimoxazole on the list.

- **Hospitals have an annual drug budget.** They obtain what they need and then they sell it to patients. Under the LIFE-GAP Project, the hospitals get reimbursed by CDC for the HIV products they distribute; this is a different procedure from their standard system. In this system, the PAC receive advance funds for the reimbursements. But because the funds came late in the first round of financing, the hospitals were concerned about not getting reimbursed and therefore some waited to purchase stock, delaying the provision of co-trimoxazole to HIV patients. In other cases, hospitals were willing to forward fund their purchases for the HIV program.

- **Co-trimoxazole syrup is not available in some northern hill areas.** The 480 mg formulation is used for pediatric HIV care. Suppliers refuse to ship small volumes, and demand for this formulation is low, resulting in stockouts. Another case is when hospitals procure locally, and not all
formulations are available through local suppliers. Finally, the syrup is not uniformly included on the approved price list of some hospitals.

**OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE**

The highly decentralized drug management system in Vietnam makes it very difficult to monitor any specific product. Some advanced hospitals maintain a drug management system, but it is not uniform. Each hospital’s LMIS is obtained and operated independently of the other hospitals. Consumption data is neither collected nor used. Because quantification is completely decentralized, it is dependent on the skill of the pharmacist and the managers at each site, who tend to not use any standard quantification tools in their calculations.
CO-TRIMOXAZOLE COUNTRY SUMMARY: ZAMBIA

PROGRAMS USING CO-TRIMOXAZOLE

The Zambian MOH currently recommends co-trimoxazole for use in its ARV program under the NACP for the treatment of HIV/tuberculosis coinfections as well as a prophylaxis in the prevention of HIV-related pneumococcal infections. Co-trimoxazole is also prescribed within the essential medicines program for infective diarrhea and respiratory tract infections.

SOURCES OF CO-TRIMOXAZOLE PROCUREMENT

<table>
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<tbody>
<tr>
<td>MOH-ARV Program</td>
<td>Zambian Government</td>
<td>Zambian Government Procurement Unit</td>
<td>Often purchased through a wholesaler who purchases product from manufacturers in India</td>
</tr>
<tr>
<td></td>
<td>PEPFAR</td>
<td>SCMS</td>
<td>Medopharm, India</td>
</tr>
<tr>
<td></td>
<td>UNITAID</td>
<td>CHAI</td>
<td>Cipla, India</td>
</tr>
<tr>
<td></td>
<td>GFATM</td>
<td>IDA/UNICEF</td>
<td>Unknown</td>
</tr>
<tr>
<td>MOH-essential medicines program</td>
<td>Zambian Government</td>
<td>Zambian Government Procurement Unit</td>
<td>Often through a wholesaler who purchases product from manufacturers in India</td>
</tr>
</tbody>
</table>

*Registering medicines in-country through the Pharmaceutical Regulatory Agency is a lengthy nine-month process; however, there are currently 15 brands of co-trimoxazole registered in Zambia of which 14 are manufactured in India. See registered product list on the Pharmaceutical Regulatory Agency’s website for a list of the manufacturers.

AVAILABILITY OF CO-TRIMOXAZOLE

Co-trimoxazole is generally available across all levels of the Zambian MOH system. At the central level at the Medical Stores Limited (MSL), no stock problems have been reported for co-trimoxazole. At service delivery points, some sites experience stockouts that last less than one month, but these stockouts are not due to a lack of product being available in the system. Rather, they are usually due to nonreporting or non-HIV-related use of co-trimoxazole. At the facility level, co-trimoxazole is not stored or managed separately for HIV- and non-HIV-related use. Therefore, co-trimoxazole present in a storeroom can be used for any indicated health problem.

CHALLENGES

The most significant logistics challenges with co-trimoxazole are monitoring purpose of use (HIV- and non-HIV-related) and forecasting. At present, facilities have to choose to designate their co-trimoxazole stock as for either HIV- or non-HIV-related use, or not separate them and order their entire co-trimoxazole need through the ARV logistics system (which then overreports co-trimoxazole use for HIV-related issues). At the central level, all co-trimoxazole is stored together (regardless of the designated use). Storage space is also a challenge at the facility level.
INNOVATIVE APPROACHES TO MANAGING CO-TRIMOXAZOLE

In conjunction with the USAID | DELIVER PROJECT, SCMS, and JSI Logistics Services, the MOH has established an integrated distribution and LMIS for 34 ARV program commodities (including two formulations of co-trimoxazole). The MOH also piloted an Essential Drug Logistics System that included two formulations of co-trimoxazole in its list of 65 products. Currently, dispensed-to-user data is captured nationally for co-trimoxazole for HIV-related medical issues in the ARV Drug Logistics System. When the Essential Drug Logistics System is rolled out nationally, it is anticipated that all uses of co-trimoxazole will only be reported in the Essential Drug System and eliminated from the R&R forms in the ARV Drug Logistics System. In each system, facilities report monthly on quantities of co-trimoxazole received, issued/dispensed, lost/adjusted, and ending balances, and they calculate average monthly consumption figures and maximum resupply quantities. These reports are sent to MSL at the national level where they are processed, and where orders are packed per facility and delivered to the district level, where facility orders are either distributed or picked up.

The SCMS project in Zambia is also currently completing extensive storage assessments at service delivery points and hoping to procure “storerooms-in-a-box” as approval is granted by the MOH. These “storerooms” are a smaller scale version of the “warehouse-in-a-box” innovations from SCMS partner PHD International. All that is required is a small concrete slab foundation to set up this prefabricated storeroom (which comes in three sizes depending on the size of the facility). Assessment results will allow the project, with MOH approval, to target the facilities with the greatest need.

OTHER ISSUES RAISED BY INFORMANTS OF KEY IMPORTANCE/SIGNIFICANCE

With assistance from the USAID | DELIVER PROJECT and SCMS, MSL has established a logistics management unit (LMU) that electronically compiles all of the logistics data reported up to MSL on the ARV Drug Logistics System R&R and will also eventually compile that information for the Essential Drug Logistics System. This data capture, in a Supply Chain Manager-based database, allows Essential Drug and ARV Program managers make informed decisions about distribution, quantification, and supervision. The LMU data managers also produce critical feedback reports based on this data, which are then distributed to national, provincial, district, facility, and program partners.

Currently, during the annual ARV drug quantification, the quantities of co-trimoxazole (for all uses) are also determined. Dispensed-to-user data from the LMU database for HIV-related use of co-trimoxazole is used as well as data from sample health facilities on non-HIV-related use of co-trimoxazole (which is then used for extrapolation) to compile a national co-trimoxazole forecast. Data from the PipeLine software database, which helps track national stock levels of co-trimoxazole, is then used to development a procurement plan. The USAID | DELIVER PROJECT and SCMS project anticipate that current partner support for co-trimoxazole commodities is actually more than enough to meet the entire national need (HIV- and non-HIV-related); however, until actual dispensed-to-user data is available for non-HIV-related uses, estimated calculations will be used.
For more information, please visit aidstar-one.com.