



OFFICE OF INSPECTOR GENERAL

AUDIT OF USAID/KENYA'S PEPFAR-FUNDED ACTIVITIES AND COMMODITIES FOR THE PREVENTION OF MOTHER-TO- CHILD TRANSMISSION OF HIV

AUDIT REPORT NO. 4-615-09-007-P
AUGUST 17, 2009

PRETORIA, SOUTH AFRICA



August 17, 2009

MEMORANDUM

TO: USAID/Kenya Mission Director, Erna Kerst

FROM: Regional Inspector General/Pretoria, Nathan S. Lokos /s/

SUBJECT: Audit of USAID/Kenya's PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV (Report No. 4-615-09-007-P)

This memorandum transmits our final report on the subject audit. The report includes six recommendations, one of which addresses potential monetary recoveries. We have considered management's comments on the draft report and have incorporated them into the final report, as appropriate. Those comments have been included in their entirety (without attachment) in appendix II.

In light of management's comments, we consider that a management decision has been reached on recommendation no. 1. Please provide the Audit, Performance, and Compliance Division in the USAID Chief Financial Officer's Office (M/CFO/APC) with the necessary documentation to achieve final action. In addition, management decisions have been reached and final action taken on recommendations no. 2 through 4.

On the basis of management's comments, we consider that management decisions have not been reached on recommendations no. 5 and 6. We ask that you provide us with written notice within 30 days regarding any additional information related to actions planned or taken to implement these recommendations that remain without a management decision.

I want to express my sincere appreciation for the cooperation and courtesy extended to my staff during the audit.

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SUMMARY OF RESULTS

USAID's activities to combat HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency syndrome) in Kenya are structured on a provincial basis. Each province has its own cooperative agreement, which is implemented by a consortium of partners. These separate agreements are referred to as APHIA II (AIDS, Population and Health Integrated Assistance Program II), followed by the name of the province. As the name implies, each APHIA II project is a province-specific comprehensive program that covers not only the full range of HIV/AIDS prevention, care, and treatment services (including prevention of mother-to-child transmission of HIV [PMTCT]) but also activities to address tuberculosis, child survival, and malaria (see page 4).

In Kenya, PMTCT activities are prompted by four general objectives: keeping women HIV-negative during pregnancy and lactation, preventing unwanted pregnancies, providing care and treatment for HIV-infected women, and preventing the transmission of HIV by infected women to their children (see page 4). In fiscal year 2008, USAID/Kenya's share of the U.S. Government's funding for Kenya's PMTCT activities amounted to \$11.4 million (see pages 3–4).

USAID/Kenya is making positive contributions toward meeting mandated targets for several of the above objectives. The mission reported that its activities had provided counseling and testing, the crucial first steps in preventing mother-to-child transmission, to 499,415 pregnant women during the period audited, exceeding its target for that period. The mission also indicated that it had provided antiretroviral drugs to 21,600 HIV-infected women, a number far short of its target. However, that target was unrealistically high and was based upon assumptions that later were modified, so the shortfall should not be viewed as diminishing the mission's achievement in this area (see pages 5–6). Finally, the audit found that antiretroviral medications were generally available in sufficient supply to meet the demand—another crucial factor in the prevention of mother-to-child transmission (see page 10).

Notwithstanding the achievements mentioned above, certain components of USAID/Kenya's PMTCT activities could be improved, including program staffing and program monitoring. These deficiencies may be resolved largely by addressing the staffing shortages that led to weaknesses in technical oversight and insufficient documentation of site visits (see pages 8–9). In addition, controls must be strengthened over the procurement, storage, and distribution of PMTCT commodities. For example, HIV test kits, a crucial component in preventing mother-to-child transmission, were not always available to meet demand. The shortages occurred for several reasons: the distributor of HIV test kits did not exercise strong internal controls; local health care providers reported inaccurate and unreliable data on the rates of HIV test kit usage; and some 35,000 test kits, estimated to be worth \$630,000, were lost because of theft or expiration. The audit revealed specific instances of waste that resulted in substantial losses of resources and missed opportunities for treatment. Neither the mission nor its implementing partners could identify the full extent of these losses (see pages 10–16).

The report includes recommendations to address these issues. Specifically, we recommend that USAID/Kenya implement a workload distribution plan and develop suitable trip reporting aids to address staffing and documentation issues. To address the issues related to the procurement, storage, and distribution of HIV commodities, recommendations include reconsidering the policy for the selected test kit distributor, developing specific performance indicators to evaluate the procurement and storage system, determining the amount and value of HIV test kit losses, and determining whether costs associated with such losses are recoverable from the Government of Kenya.

USAID/Kenya agreed with all six recommendations and has taken final action on three. These actions have included developing a trip report template and utilizing a new, private-sector-based test kit distribution system. Also, a management decision has been reached on the recommendation regarding the development and implementation of a workload redistribution plan, but no final action has been made. Furthermore, the recommendations on developing specific performance indicators and determining the amount of HIV test kit losses do not have management decisions (see pages 17–18). We request that USAID/Kenya provide us with written notice within 30 days regarding any additional information related to actions planned or taken to implement the two recommendations that remain without a management decision.

Management comments (without attachment) have been included in their entirety in appendix II.

BACKGROUND

Since its inception in 2003, the President's Emergency Plan for AIDS Relief (PEPFAR) has made significant progress in combating HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency syndrome) throughout the world. Combining \$18.8 billion in funding and an integrated approach that includes prevention, treatment, and care, PEPFAR has supported life-saving antiretroviral treatment for 2.1 million people and care for over 10.1 million through September 2008. To build upon these achievements, President George W. Bush signed legislation in July 2008 authorizing up to \$48 billion over the next 5 years to continue the U.S. Government's global efforts against HIV/AIDS, tuberculosis, and malaria.

Kenya is one of the 15 focus countries under the PEPFAR initiative. According to the 2007 Kenya AIDS Indicator Survey, more than 1.4 million Kenyans live with HIV/AIDS—7.4 percent of adults aged 15–64. This health crisis threatens Kenya's stability and its positive contributions to regional affairs. By leading efforts to combat HIV/AIDS, PEPFAR activities in Kenya contribute not only to maintaining stability but also to promoting public diplomacy among the nation's Muslim population and furthering the overall campaign to alleviate the effects of the disease globally.

A critical component of combating HIV/AIDS is the prevention of mother-to-child transmission (PMTCT) of HIV. According to mission officials, HIV-infected women have a 30–40 percent overall risk, without intervention, of transmitting HIV to their children during pregnancy, childbirth, and breastfeeding—a transmission rate exceeded only by transfusions of HIV-infected blood. In Kenya, this equates to approximately 100 babies becoming infected each day, without intervention.

Given the human, economic, and societal costs of caring for and treating HIV-infected children, interventions to prevent mother-to-child transmission are an integral part of any comprehensive HIV/AIDS strategy. In Kenya, these interventions are prompted by four general objectives: keeping women HIV-negative during pregnancy and lactation, preventing unwanted pregnancies, providing care and treatment for HIV-infected women, and preventing the transmission of HIV by infected women to their children.

The initial step in achieving these objectives is determining the HIV status of pregnant women. Consequently, PMTCT activities include the provision of rapid-response HIV testing, in conjunction with appropriate counseling. Next, PMTCT activities provide combination short-course antiretroviral prophylaxis for both mother and infant. Counseling and support for infant feeding, links to family planning and other services, and referrals to care, treatment, and support for HIV-infected women complement these core PMTCT activities.

USAID's PEPFAR activities in Kenya are managed by the mission's Office of Population and Health.¹ These activities are structured on a provincial basis, each province having its own cooperative agreement implemented by a consortium of partners. Each agreement is referred to as APHIA II (AIDS, Population and Health Integrated Assistance Program II), followed by the name of the province. As the name implies, each APHIA II project is a comprehensive program that includes not only the full range of HIV/AIDS prevention, care, and treatment services (including PMTCT) but also activities to address tuberculosis, child survival, and malaria. While each project consists of one prime partner and several major subpartners, only the prime partner reports project data to USAID.

PEPFAR-funded initiatives in Kenya, particularly PMTCT, have grown enormously in recent years. PMTCT activities underwent a rapid expansion, increasing from 250 sites providing PMTCT services in 2004 to 1,084 by mid-2006, located in all eight provinces. Reflecting this growth, U.S. Government funding for PEPFAR activities in Kenya went from \$92.5 million in fiscal year (FY) 2004 to \$368.1 million in FY 2007. According to mission officials, \$237.1 million of this \$368.1 million was allocated to USAID. For PMTCT services in Kenya, total U.S Government funding in FY 2007 for FY 2008 activities was \$21.9 million, of which \$11.4 million was managed by USAID.

AUDIT OBJECTIVES

As part of a series of audits conducted in multiple countries under the direction of the Office of Inspector General's Performance Audits Division, the Regional Inspector General/Pretoria performed this audit to answer the following questions:

- Did USAID/Kenya's activities for the prevention of mother-to-child transmission of HIV contribute toward meeting mandated targets, and what has been the impact?
- Did USAID/Kenya procure, store, and distribute commodities for the prevention of mother-to-child transmission of HIV to help ensure that intended results were achieved, and what has been the impact?

Appendix I contains a discussion of the audit's scope and methodology.

¹ USAID's PEPFAR activities are one component of the U.S. Government's coordinated effort to fight HIV/AIDS in Kenya. Other U.S. Government agencies working in Kenya on PEPFAR include the Department of State, the Centers for Disease Control and Prevention, the Department of the Army (via its Medical Research Unit in Kenya), and the Peace Corps.

AUDIT FINDINGS

Did USAID/Kenya’s activities for the prevention of mother-to-child transmission of HIV contribute toward meeting mandated targets, and what has been the impact?

USAID/Kenya’s activities for the prevention of mother-to-child transmission of HIV (PMTCT) made significant contributions toward meeting mandated targets. Moreover, those activities were having a positive impact on the U.S. Government’s efforts in Kenya to combat HIV/AIDS. These two components of the audit objective are discussed in further detail below.

Targets and Results

USAID/Kenya reported that its counseling and testing of pregnant women—the critical first steps in the PMTCT activity pipeline—served 499,415 pregnant women in FY 2008.² As a result, these women learned their HIV status and received counseling, as appropriate. Furthermore, when pregnant women tested positive for HIV, the next stage of PMTCT activity provided treatment to reduce the chances of transmitting the virus from mother to child. According to the mission, 21,600 pregnant HIV-infected women received the antiretroviral prophylaxis required to reduce the chance of transmitting HIV to their children.

In terms of performance against targets, providing counseling and testing to 499,415 pregnant women (with a target of 497,136 women) represents the achievement of over 100 percent of the mission’s target. In terms of the antiretroviral prophylaxis, providing antiretroviral drugs to 21,600 HIV-infected women (with a target of 35,305 women) represents the achievement of 61 percent of the mission’s target. However, this lower level of achievement in relation to the target for antiretroviral prophylaxis was caused in part by the use of an unrealistic FY 2008 target, based on older data on HIV prevalence and resulting in an inflated goal.

According to mission officials, this older data came from several sources, including the 2003 Kenya Demographic and Health Survey and analyses from the Kenya National Bureau of Statistics and the Kenya Ministry of Health. The antiretroviral prophylaxis target for FY 2008 was based on an HIV prevalence rate of 9.6 percent among women of childbearing age. Actual data collected by the U.S. Government’s PMTCT program in Kenya indicated a lower rate of HIV prevalence, however—6.8 percent among the same group.³

If the lower HIV prevalence rate of 6.8 percent had been used in setting the FY 2008 target, the target would have been reduced to 25,008 HIV-infected women receiving

² The scope and methodology followed in the audit is detailed in appendix I.

³ Data from the 2003 Kenya Demographic and Health Survey were used because the survey was the only nationally accepted planning document available at the time the targets were set. Data collected by the PMTCT program have been used in setting FY 2009 targets.

antiretroviral prophylaxis, and the reported result of 21,600 would then represent 86 percent of this reduced target.

The following table presents the mission's PMTCT targets and achievements in FY 2008.

USAID/Kenya's Achievement of PMTCT Targets in FY 2008

| | Target | Actual | Achieved |
|--|---------|---------|----------|
| Pregnant women who received HIV counseling and testing for PMTCT and received their results | 497,136 | 499,415 | 100% |
| HIV-infected women who received antiretroviral prophylaxis for PMTCT in a PMTCT setting (target based on obsolete data) | 35,305 | 21,600 | 61% |
| HIV-infected women who received antiretroviral prophylaxis for PMTCT in a PMTCT setting (target based on PMTCT program data) | 25,008 | 21,600 | 86% |

The audit identified several reasons for the shortfall in the number of HIV-infected women who received antiretroviral prophylaxis.

- Approximately 800 HIV-infected women in the Rift Valley Province were recorded as not receiving prophylaxis. According to APHIA II Rift Valley officials, these women did not receive antiretroviral drugs because smaller facilities ran out of stock or the women were referred to another treatment program. In general, these smaller facilities did not have pharmacists, and stockouts were caused by poor tools for reporting commodities and by the providers' inadequate knowledge of commodity management.⁴ These officials also noted that HIV-positive women refused nevirapine in less than 5 percent of cases.⁵
- Our sample analysis identified several instances in which HIV-positive women did not receive nevirapine. According to health care workers, this occurred because, in accordance with national policy, nevirapine was distributed no earlier than the 28-week stage of pregnancy, and the women had been identified as HIV positive at the antenatal clinic prior to this point in their pregnancies. Since some women made only one visit to an antenatal clinic, this policy was changed during FY 2008 so that nevirapine was

⁴ To reduce stockouts, APHIA II Rift Valley provides training for health workers in logistics and commodity management, as well as test kits and nevirapine through the Abbot buffer stock program.

⁵ In Kenya, the prophylaxis regimen for the mother combines azidothymidine (AZT) treatment, commencing at the 28-week stage of pregnancy, with single-dose nevirapine given at the onset of labor; the infant receives nevirapine shortly after birth and AZT for 6 weeks thereafter.

distributed upon initial contact with an HIV-infected pregnant woman, rather than waiting until the 28-week stage.

Impact

Mission and implementing partner officials have not developed evaluative tools, such as performance indicators at the outcome level, to measure the overall impact of PMTCT activities in Kenya.⁶ To address this shortcoming, the mission, in association with the U.S. Centers for Disease Control and Prevention (CDC), had arranged for an evaluation to assess the impact of PMTCT activities. At the conclusion of our fieldwork, the evaluation protocol was undergoing review by CDC officials in Atlanta.

Despite the current inability to measure precisely the effectiveness of USAID/Kenya's PMTCT activities, some evidence demonstrates that those activities were having a positive impact in combating HIV/AIDS. First, the audit verified key aspects of PMTCT intervention, such as the provision of HIV testing and antiretroviral prophylaxis. Moreover, the efficacy of the antiretroviral regimen would indicate that the PMTCT program is reducing the transmission of HIV from pregnant women to their children. The Office of the Global AIDS Coordinator calculates the number of infant infections averted by multiplying the total number of HIV-positive pregnant women by 19 percent. This percentage reflects an estimate that current PMTCT interventions are reducing the rate of transmission of HIV from 35 percent to 16 percent, which equates to a 53 percent decrease in the HIV transmission rate.

Second, senior Kenyan Government officials and local health care providers testified to the importance of the mission's PMTCT activities. For example, one provincial director of medical services stated that the APHIA II project played a crucial role in providing staffing, training, reagents, and lab equipment and was instrumental in reducing the province's HIV transmission rates. Finally, USAID's implementing partners managed the distribution of PMTCT commodities donated by Abbott Laboratories. This initiative, known as the Abbott buffer stock donation program, helped alleviate commodity shortages in the national medical supply system and, in our opinion, increased the overall effectiveness of USAID's PMTCT activities. Mission officials noted that approximately 80 percent of the commodities used in those activities were provided through the Abbott program.

While USAID/Kenya's PMTCT activities were significantly contributing toward meeting mandated targets and making a positive impact, the mission could strengthen its PMTCT program in several areas. These areas are addressed in detail below.

⁶ Certain constraints in Kenya hinder the collection of such impact data. For example, according to a USAID partner, early infant diagnosis of HIV is a key tool in measuring PMTCT effectiveness; however, only three laboratories in Kenya can process early infant diagnosis samples.

Program Requires More Technical Oversight

Summary: Adequate staff is crucial to achieving results. However, because of multiple responsibilities, the mission's specialist in prevention of mother-to-child transmission of HIV was able to devote only half of her time to these activities. Consequently, the program for prevention of mother-to-child transmission did not receive the attention it warranted, and its effectiveness may have been limited.

Staffing is a vital issue for both the Federal Government and USAID. The Government Accountability Office's *Standards for Internal Control in the Federal Government* states that effective management of an organization's workforce is essential for achieving results. Specifically, the standards note that management should consider how best to retain valuable employees and ensure continuity of needed skills and abilities. Addressing USAID's "human capital crisis," the Agency's 2004–2008 *Human Capital Strategy* declared that USAID employees were particularly vulnerable to burnout and poor morale, caused in part by the high stress of multiple workload demands that have been placed upon overburdened staff.

At USAID/Kenya, the PMTCT specialist had numerous responsibilities. In addition to serving as the mission's technical expert on PMTCT, during FY 2008 this official also served as the PMTCT lead person on the interagency technical team, contracting officer's technical representative for the APHIA II Nairobi/Central program, activity manager for a smaller health initiative, and liaison officer for a sustainable health care project. This same official also assisted the monitoring and evaluation specialist in the Office of Population and Health (OPH) in addressing PEPFAR-related data quality issues.

Given this workload, the PMTCT specialist estimated that she had spent only half of her time on PMTCT issues in FY 2008. As a result, she had difficulty balancing competing priorities and completing routine yet important administrative tasks, such as drafting trip reports (see page 9). Moreover, the official observed that the PMTCT program was being underserved because, in her opinion, it warranted full-time attention. This lack of critical attention may have limited the effectiveness of the mission's PMTCT program.

According to the mission, multiple duties were laid upon the PMTCT specialist because of the acute staffing shortage that OPH faced at the beginning of FY 2008. OPH officials stated that the office had a staff of 17 when the current Director and Deputy Director arrived in August 2007. This staff level—responsible for overseeing \$237 million in PEPFAR funding allocated to USAID/Kenya in FY 2007 for FY 2008 activities—had not changed since FY 2004, when initial PEPFAR funding for Kenya was only around \$20 million. The Director noted that in the initial stages of PEPFAR, when annual funding increased substantially, the mission had focused on obligating funds and contributing to the ambitious worldwide targets established by the U.S. Government. To its credit, the mission has addressed this staffing shortage expeditiously. OPH now has 34 authorized positions, nearly all of which have been filled.

In contrast to USAID, the CDC has six personnel devoted exclusively to PMTCT activities in Kenya, even though USAID has been allocated over half of the U.S.

Government's PMTCT budget and targets. Senior OPH officials indicated that they intend to redistribute assignments to permit the mission's PMTCT specialist to devote more time to the program. Given the importance of PMTCT in a comprehensive HIV/AIDS strategy and the valuable contributions this official has made in the past, we believe that such an approach would be in the best interests of the mission, the American taxpayer, and the Kenyan people. Accordingly, we are making the following recommendation:

Recommendation No. 1: *We recommend that USAID/Kenya develop and implement a workload redistribution plan that will enable the mission to devote substantially more time to activities for the prevention of mother-to-child transmission of HIV.*

Documentation of Site Visits Should Be Strengthened

Summary: Agency guidance requires that site visits be documented adequately. However, mission officials did not always prepare trip reports documenting those visits. These reports were not prepared because competing priorities created time constraints. Such inadequate documentation can impair effective performance management.

According to USAID's Automated Directives System (ADS) 202.3.6, monitoring the quality of key outputs is a major task of USAID officials. An integral part of this monitoring activity is timely and adequate documentation of pertinent findings and lessons learned. This is recognized in both the Government Accountability Office's *Standards for Internal Control in the Federal Government* and in ADS 596.3.1c, which require appropriate documentation of transactions and internal control. Consequently, complete and timely trip reports to document site visits are necessary for both good internal control and effective performance management.

Notwithstanding this guidance, trip reports were not always completed in a timely manner. Senior OPH officials indicated that adequate trip reporting was an officewide weakness. Specifically, we found that for eight site visits made by the PMTCT specialist during FY 2008, only three trip reports were completed. Similarly, for four site visits during July and August 2008, the OPH monitoring and evaluation specialist completed one trip report and prepared three in the draft stage.

According to these officials, trip reports were not completed promptly because the competing priorities of overburdened officials created time constraints. The heavy workload resulted from the general understaffing in OPH at the beginning of FY 2008. OPH's staffing shortage and the mission's efforts to correct this problem are discussed in detail on page 6.

Inadequate documentation of site visits can hinder performance management and internal control in several ways. First, findings and lessons learned are not shared effectively with supervisory officials, and corrective action may be delayed or overlooked. Moreover, without documentation, institutional memory might be lost. At USAID/Kenya, this loss would be an acute problem if the positions of the key

PMTCT officials suddenly became vacant. Accordingly, we are making the following recommendation:

Recommendation No. 2: *We recommend that USAID/Kenya develop suitable trip reporting tools, such as an activity checklist or a reporting template, that will assist mission officials in documenting site visits with complete and timely reports.*

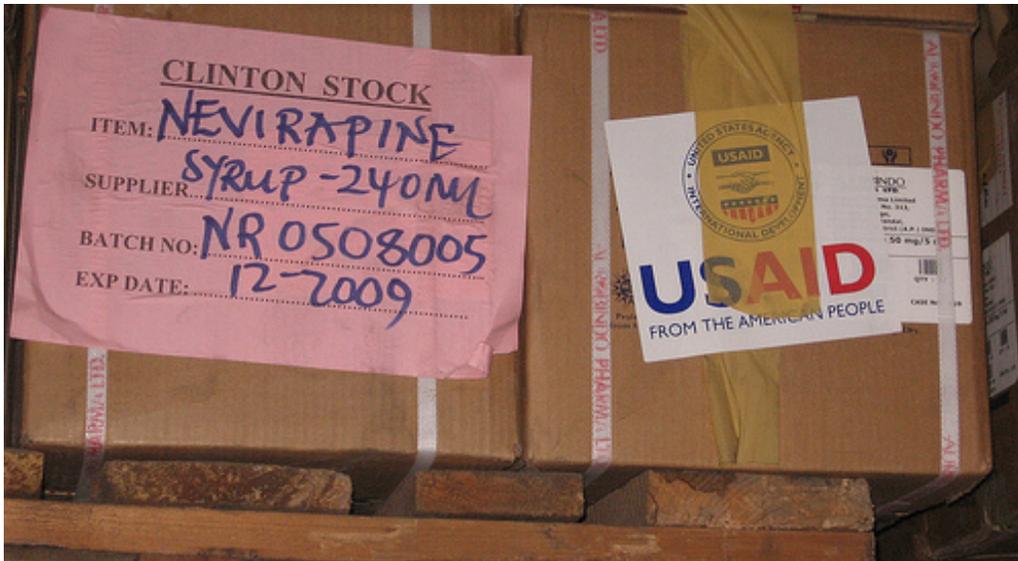
Did USAID/Kenya procure, store, and distribute commodities for the prevention of mother-to-child transmission to help ensure that intended results were achieved, and what has been the impact?

USAID/Kenya properly procured, stored, and distributed antiretroviral medication commodities for the prevention of mother-to-child transmission (PMTCT) of HIV to help ensure that intended results were achieved; however, USAID/Kenya experienced significant challenges in managing HIV test kits.⁷

With respect to antiretroviral medications, although there were no specific performance indicators, audit tests revealed that the commodities were stored effectively and distributed to intended beneficiaries as needed to meet demand. In addition, audit visits to warehouses responsible for storing antiretroviral medications found that those warehouses were clean, secure, temperature controlled, and well organized. USAID commodities were distinguished from identical commodities financed by other initiatives, such as the Clinton HIV/AIDS Initiative (see example in photo on page 11).

The audit also determined that antiretroviral usage rates provided by the implementing partner were generally reliable and served as a good basis upon which to calculate future procurement. The mission had procedures in place to reasonably ensure that expired or damaged antiretroviral medications were destroyed properly and not used for treating patients. For facilities not tested, nothing came to our attention to indicate significant losses, shortages, or stockouts of the medication. However, the audit found problems with the other major commodity, the HIV test kits, as discussed on the following pages.

⁷ Most health care facilities in Kenya do not have cold-storage capability. For this reason, 99 percent of HIV test kits procured for FY 2007 and 2008 were “rapid” test kits, which do not require cold storage. When this report discusses HIV test kits, it refers to those that do not require cold storage unless specifically indicated otherwise.



USAID antiretroviral medications were stored next to, but distinguished from, antiretroviral medications financed by the Clinton HIV/AIDS Initiative. Photograph by an OIG auditor at the Mission for Essential Medications and Services warehouse, Nairobi, Kenya, February 2009.

HIV Test Kits Were Not Always Available to Meet Demand

Summary: HIV test kits were not always available to meet demand. The audit found specific instances of HIV test kit shortages, and mission and implementing partner officials agreed that the shortages were a significant issue. Reasons for shortages included poor internal control for storing and distributing the kits and a lack of reliable information on usage to guide procurement of sufficient quantities. Further, the mission has no performance indicators that specifically address commodity procurement, distribution, and storage. Internationally accepted standards for handling health-related commodities require that managers devise and implement sound internal control procedures to ensure that commodities reach their intended recipients in a timely and effective manner. Without strong internal controls, public resources were wasted and remain at high risk for fraud, waste, and abuse. As a result, 35,000 test kits—estimated to be worth \$630,000—were lost because of theft and expiration. Under development assistance grant agreements, host-country governments are accountable for resources provided by the U.S. Government. Further, without these controls, intended beneficiaries may not be tested for HIV, may not receive needed treatment, and may be subject to inaccurate results from tainted commodities.

The testing of pregnant women to determine their HIV status is the crucial first step in preventing mother-to-child transmission of HIV. However, to successfully determine the HIV status of pregnant women, HIV test kits must be available and ready for use when needed. Despite the importance of having HIV test kits available, officials of the mission and implementing partner reported and documented frequent stockouts of HIV test kits. Such stockouts put pregnant women and their unborn children at significant risk of HIV transmission.

In addition to the assertions and documentation from mission and implementing partner officials, other evidence also indicated that there have been frequent test kit stockouts. In August 2008, one facility reported a shortage of test kits. Of 190 individuals counseled under PMTCT activities at this facility, only 50 were tested, because of the stockout. Moreover, in November 2008, CDC officials reported a widespread shortage of test kits throughout Kenya.

Similarly, an analysis of test kit usage, performed by PEPFAR implementing partner Management Sciences for Health (MSH), reported that test kit shortages were a common occurrence. For the period January 2007–May 2008, MSH reported losses of some 35,000 test kits. Calculated at 20 tests per kit,⁸ 700,000 PEPFAR-funded tests were not used for program purposes. Moreover, since at least two tests are usually required to determine an individual's HIV status, the opportunity to test approximately 350,000 individuals was lost. These 35,000 test kits represented 1.3 percent⁹ of the test kits that were available for distribution during this period. The losses were caused by pilferage, expirations, and other factors; however, the analysts were not able to identify the 35,000 losses by the type of loss. The study did note that large losses were reported for the test kit “Determine” as follows: August 2007, 4,190 kits; September 2007, 1,922 kits; October 2007, 1,001 kits; and January 2008, 4,103 kits. On further scrutiny, the analysts concluded that these losses appeared to have been caused by the expiration of test kits that were sent to sites just before their expiration dates.

A variety of factors have contributed to these stockouts of HIV test kits. These factors include poor internal control at the implementing partner level, the lack of reliable usage reporting for test kits, and the absence of performance indicators for procuring, storing, and distributing commodities. These factors are discussed in detail below.

Implementing Partner’s Poor Internal Control. A major cause of the test kit shortages concerns the test kit distributor, the Kenyan Medical Supplies Agency (KEMSA). This is a state corporation created by the Kenyan Government for the purpose of procuring, receiving, storing, and distributing all kinds of medical commodities to health facilities throughout the country. USAID/Kenya uses KEMSA for test kit warehousing and distribution. Mission officials and implementing partners cited KEMSA’s weak internal control system for distributing commodities of any kind.

Our visit to KEMSA’s central warehouse in Nairobi corroborated these observations and indicated a higher risk of fraud, waste, and abuse related to KEMSA-managed commodities when compared with the warehouses operated by the mission’s private

⁸ Depending on the manufacturer, each test kit contains 20, 25, or 30 tests.

⁹ According to a USAID Global Health Bureau official, the pharmaceutical industry’s average loss threshold for warehoused commodities that expire or become unusable is 2 percent. Although the industry might find this an acceptable rate of loss, we believe that USAID officials have the fiduciary responsibility to minimize the loss of taxpayer-funded commodities (see pages 15 and 16, which address the program’s lack of an acceptable loss limit.)

contractors who distribute antiretroviral medications. The following weaknesses were observed at the central warehouse:

- The PEPFAR test kits were not segregated from commodities received from other sources, as they were in the commercial warehouses.
- PEPFAR-financed commodities were not marked “PEPFAR” or “USAID” and could easily be confused with commodities from other sources.
- One box of test kits was mislabeled as an antiretroviral medication by the supplier (see photograph below). Although warehouse management personnel were aware of the mislabeling, the label should have been completely removed from the box and a corrected label put in its place. Those corrections would have eliminated the risk that warehouse staff might unknowingly deliver test kits to locations that had requested antiretroviral drugs.
- The warehouse was not temperature controlled. Although these particular test kits do not require cold storage, they still must be stored in temperatures under 25 degrees Celsius (77 degrees Fahrenheit)—a temperature that is frequently exceeded in Nairobi. Higher temperatures could reduce their shelf life.
- Receiving and shipping documents were not well maintained. When we asked for certain routine shipping and receiving records, the KEMSA warehousing officials took a long time to locate them, unlike the staff in the commercial warehouse.
- The warehouse was not well organized. Items were distributed haphazardly around the warehouse, and the PEPFAR items were located in two different locations in the warehouse. At the private warehouses, PEPFAR commodities were stored together.



A box of HIV test kits was mislabeled as Triomune, an antiretroviral medication. Photograph taken by an OIG auditor in the KEMSA central warehouse, Nairobi, Kenya, in February 2009.

A KEMSA Task Force report corroborated these points.¹⁰ Among its conclusions, the report criticized KEMSA's warehousing and distribution systems, commenting that:

- The KEMSA warehouses did not meet standards of distribution recommended by the World Health Organization, thereby compromising the quality of medical goods.
- KEMSA relied on untrained staff who lacked the requisite skills to manage their areas of responsibility.
- KEMSA's outsourced distributor also did not follow good distribution practices. The distributor's commodity delivery system was slow compared with its private sector counterparts.

Without a strong internal control system, the HIV test kits are exposed to a much greater risk of fraud, waste, and/or abuse. The lost PEPFAR-funded HIV test kits managed by KEMSA are not available when needed to test pregnant women at PEPFAR-supported facilities. As a result, these women may be denied knowledge of their HIV status, may not receive necessary treatment, and may face a greater risk of transmitting HIV to their unborn children. Moreover, improper storage may cause test kits to give inaccurate results.

The monetary losses also cause concern. To quantify these losses, the mission should first determine, to the extent possible, how many test kits were actually lost. The mission cannot find this figure, aside from the previously noted 35,000 kits lost in the 17-month period that ended in May 2008. A conservative estimate of the monetary value of just the 35,000 lost test kits cited in MSH's report is approximately \$630,000.¹¹

Under its Development Assistance Grant Agreement with USAID, the Government of Kenya is accountable for resources provided to it by the U.S. Government.

In light of the risk to PEPFAR resources associated with KEMSA's weak internal controls over commodities, and the unknown extent of test kit losses, we are making the following recommendations:

Recommendation No. 3: *We recommend that USAID/Kenya reevaluate its policy establishing the Kenya Medical Supplies Agency as the distributor of HIV test kits and determine whether it would be in the U.S. Government's best interest to use a different commodity distribution service.*

¹⁰ This report, commissioned by the Kenyan Minister for Medical Services, was issued in October 2008.

¹¹ The actual amount of losses to date is likely to be higher, because (1) the amount represents the 17-month period that ended in May 2008 and (2) our calculation was based on conservative assumptions. For example, we assumed that each test kit contained only 20 tests, but kits can contain 25 or 30 tests. We also used 90 cents as the value per test, which is the cost of "Determine," the least expensive of the three most frequently used HIV tests. The 90-cent value was calculated by MSH and reported in its analysis. This analysis determined that the other two HIV tests, Bioline and Unigold, cost more than a dollar each per test, although it did not specify the exact cost. Hence, we calculated the total value as \$630,000 (35,000 lost kits × 20 lost tests per kit × 90 cents).

Recommendation No. 4: *We recommend—in the event the Kenya Medical Supplies Agency is retained as the distributor of HIV test kits—that USAID/Kenya require the Kenya Medical Supplies Agency to bring its warehousing and distribution systems into compliance with industry best practices and World Health Organization guidelines.*

Recommendation No. 5: *We recommend that USAID/Kenya determine the dollar value of HIV test kits that have been lost since the program’s inception and determine whether this or any amount is recoverable under existing agreements with the Government of Kenya.*

Lack of Quality Consumption Reporting. According to USAID’s supplementary guidance TIPS Number 12, Guidelines for Indicator and Data Quality, performance data is crucial in results-oriented management. Sound decisions require current, reliable information. Mission and implementing partners need reliable usage information to predict future usage accurately and calculate procurement of test kits accordingly.

Mission officials and implementing partners reported that health care clinics administering the kits did not report consumption accurately, despite the need for such information. MSH is responsible for collecting usage rates reported by facilities, but the facilities do not always report accurate usage rates or, in other cases, do not report usage rates at all. For example, MSH concluded that for the September–October 2008 reporting period, the rate of reporting for service delivery points was only 40 percent.

To help resolve this problem, MSH developed reporting tools for use by health facilities, ordering points, and KEMSA that were supposed to improve the quality and efficiency of reporting. The mission also held regular meetings and conducted training sessions with KEMSA and health facilities to address reporting problems.

Since the mission is already addressing the reporting problem by providing training and reporting tools, we are not making a recommendation in that regard. Moreover, without more recent usage data, we were not able to determine whether these measures were improving the quality of reporting. The success or failure of the mission’s capacity-building measures will be determined ultimately by whether the problem of stockouts persists or declines.

Lack of Performance Indicators. The mission has no specific performance indicators for procuring, storing, and distributing commodities. Without indicators for procurement and storage, the mission cannot monitor and evaluate the performance of its system effectively. The mission’s lack of performance indicators, coupled with the facilities’ poor reporting record, could contribute to significant under-procurement of HIV test kits.

To better monitor and evaluate its system of procurement, storage, and distribution of commodities, the mission should utilize a system of performance indicators, including targets and milestones. For example, the mission could set an acceptable target level of test kit losses and measure actual test kit losses against it. Such a system could also evaluate the quality of its training and capacity-building activities

relating to the procurement, storage, and distribution of commodities. In its response to the draft audit report, USAID/Kenya officials, in consultation with KEMSA and other stakeholders, indicated that the Government of Kenya's Ministry of Health had such a monitoring and evaluation system. Accordingly, we are making the following recommendation:

Recommendation No. 6: We recommend that USAID/Kenya 1) identify key performance indicators to track for HIV commodity performance management purposes; 2) assess the suitability, effectiveness, and reliability of the existing HIV commodity monitoring and evaluation system; 3) resolve any deficiencies in the existing HIV commodity monitoring and evaluation system, the processes and documentation for collecting data entered into that system, and the quality of the data therein; and 4) arrange to receive periodic reporting on key performance indicators for mission review and action on areas of concern.

EVALUATION OF MANAGEMENT COMMENTS

In its response to the draft report, USAID/Kenya concurred with all six recommendations. Management decisions were reached on four recommendations, and final action was taken for three of those four recommendations. An evaluation of the management comments for each recommendation is shown below.

In response to recommendation no. 1, USAID/Kenya stated that a pediatric AIDS specialist was hired and other functions in the Office of Population and Health have been redistributed to permit greater attention to PMTCT activities. As a result of these actions, the audit team considers that a management decision has been reached on this recommendation. Documentation supporting the completed actions should be sent to the Office of the Chief Financial Officer, Audit, Performance and Compliance Division (M/CFO/APC), for final action.

Regarding recommendation no. 2, USAID/Kenya provided a sample of a standardized trip reporting template and stated that the template has been in use since March 2009. In light of management comments and the sample template provided, we consider that final action has been taken on recommendation no. 2.

In response to recommendation no. 3, USAID/Kenya stated that a private-sector distribution system has been used since May 2009, and that KEMSA systems are no longer being used for distribution of test kits. On the basis of management comments and supporting documentation provided, we consider that final action has been taken on recommendation no. 3.

In response to recommendation no. 4, USAID/Kenya stated that the mission plans to conduct a review of KEMSA to determine the estimated loss of USAID funds and provide recommendations to improve KEMSA's internal control systems. Because the mission declared that it no longer utilizes KEMSA as its HIV test kit distributor (see response to recommendation no. 3), no additional action was required on recommendation no. 4 and, consequently, we consider that final action has been taken on recommendation no. 4.

Regarding recommendation no. 5, USAID/Kenya stated that the mission will determine the extent to which the current agreement with the Government of Kenya permits the recovery of funds. Moreover, as stated in the above paragraph, the mission will use the planned system review to determine the estimated loss of USAID funds. However, since ADS 595.3.1.2 states that management decisions cannot be reached on monetary recommendations until the audit action officer indicates agreement with the proposed savings amount, a management decision will not be reached on this recommendation until the mission determines the recoverable amount for lost HIV test kits.

Recommendation no. 6 in our draft report, stated that USAID/Kenya needed to develop performance indicators to better monitor and evaluate its system for

procuring, storing, and distributing HIV commodities. In response, USAID/Kenya stated that Government of Kenya's Ministry of Health had a monitoring and evaluation system for HIV commodities, including performance indicators, already in place and that the mission's focus is on strengthening the Government of Kenya's systems rather than developing parallel ones. However, the response did not specify how that existing system, including the performance indicators, will be utilized to address the deficiencies in HIV commodity management documented in this report. Accordingly, we have revised recommendation no. 6 to focus on various elements involved in using the existing performance monitoring system to improve the management of HIV commodities. Consequently, a management decision has not been reached on recommendation no. 6.

Management comments (without attachment) are included in their entirety in appendix II.

SCOPE AND METHODOLOGY

Scope

The Office of Inspector General conducted this audit in accordance with generally accepted Government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions, based on our audit objectives. We believe that the evidence obtained provides that reasonable basis. Our audit objectives were to determine whether USAID/Kenya's activities for the prevention of mother-to-child transmission of HIV (PMTCT) contributed toward meeting mandated targets and whether the mission procured, stored, and distributed commodities for PMTCT activities to help ensure that intended results were achieved. In addition, assessment of the program's impact was an integral part of both objectives. Audit fieldwork was conducted at USAID/Kenya from February 17 to March 5, 2009. The audit covered fiscal year (FY) 2008; however, for test kit losses, we considered it appropriate to incorporate information pertaining to FY 2007, since this information referred to an ongoing issue affecting FY 2008 as well.

In planning and performing the audit, the audit team made inquiries relating to the respondents' knowledge of actual or suspected fraud in the mission's PMTCT activities. We assessed management controls over the procurement, storage, and distribution of HIV commodities at the level of the mission, implementing partner, and health care provider. We also assessed control over the handling and reporting of commodity losses. We obtained an understanding of and evaluated the test kit usage report prepared by Management Sciences for Health for the period January 2007—May 2008 and the Report of the KEMSA Task Force, issued in October 2008. We also assessed the effectiveness of management controls. Specifically, we obtained an understanding of the following:

- The FY 2007 Country Operation Plan
- The Federal Managers' Financial Integrity Act of 1982
- Implementing partner agreements
- Performance measures and results
- Data quality assessments
- Trip reports prepared by mission officials
- Financial reports

We also conducted interviews with key officials of USAID/Kenya and the implementing partners. We conducted the audit at USAID/Kenya, the offices of implementing partners, public and private Kenyan health care outlets, and Government of Kenya facilities.

Methodology

To answer the first audit objective, we interviewed mission officials to gain an understanding of the mission's PMTCT activities as well as the key indicators used to measure the contribution of those activities toward meeting mandated targets. Next, we

reviewed the results and associated targets reported to the Office of the Global AIDS Coordinator for FY 2008. We then interviewed the mission's PEPFAR monitoring and evaluation specialist to determine how these results were obtained from implementing partners. As part of this process, we gained an understanding of the antenatal clinic and maternity ward registers used to record PMTCT data, plus the monthly forms used to summarize those data for reporting to USAID/Kenya. Since those data were compiled and aggregated using an Access database program, we developed additional procedures to test the data's validity and reliability.

Sampling was significant in answering the first audit objective. To determine whether the reported results for the two key indicators were accurately computed and supported by source documentation, we selected a judgmental sample of 17 out of 2,225 health care facilities in three provinces spanning Kenya—Coast, Rift Valley, and Western. Judgmental sampling was used because audit resources were insufficient to permit random statistical sampling.

In selecting the sample, we chose provinces that had contributed the greatest portion of the mission's overall results for the two key PMTCT indicators. Within those provinces, we selected the maximum number of health care facilities that could be visited in the 2 days allotted for each province. The main criterion for selecting individual facilities was their relative volume of PMTCT patients; consideration was also given to obtaining a mix of different levels of health facility (for example, provincial hospitals, district hospitals, and dispensaries). Our sample constituted 1.8 percent of the indicator total for the number of pregnant women who had received HIV counseling and testing for PMTCT and had received their results, and 2.0 percent of the indicator total for the number of HIV-infected women who had received antiretroviral prophylaxis for PMTCT in a PMTCT setting.

Next, we interviewed implementing partner officials in each province to gain an understanding of their PMTCT activities and methods of data collection. We then obtained copies of the monthly data forms for each selected health care facility in the province. At the health care facility, we traced the results as noted on selected monthly reports to the underlying source documentation.

Our assessment of the program's impact was based in part on our interviews with mission and implementing partner staff, health care workers, and Kenyan government officials.

Finally, we reviewed documents as part of our audit procedures. These included excerpts from the mission's 2007 Country Operation Plan, agreements with selected partners, and their respective scopes of work. We also utilized the Government Accountability Office's *Standards for Internal Control in the Federal Government*, the USAID Human Capital Strategic Plan, 2004–2008, and USAID's Automated Directives System, chapters 202 and 596, in developing criteria for findings under the first audit objective.

To answer the second audit objective, we interviewed officials at the mission, implementing partners, and health care facilities to obtain an understanding of the system for procuring, storing, and distributing commodities as it pertained to PMTCT activities. We also visited private and public sector warehouses, a regional distribution center, and health care facilities to evaluate their internal control systems over

procurement, distribution, and storage of commodities. We examined shipping, storing, and distribution documentation covering PEPFAR-funded antiretroviral medications and HIV test kits at these locations, which were selected judgmentally on the basis of the amount of time and resources available for conducting these tests. We limited our conclusions resulting from these examinations to the sites selected.

MANAGEMENT COMMENTS



MEMORANDUM

To: Nathan S. Lokos, Regional Inspector General/Pretoria

From: Erna Kerst, Mission Director, USAID/Kenya /s/

Date: 22 July, 2009

Subject: Audit of USAID/Kenya's PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV (Report No. 4-615-09-0XX-P)

This memorandum transmits USAID/Kenya's management response on subject audit report (Report No. 4-615-09-0XX-P). As the audit report rightly noted, USAID/Kenya's activities for the prevention of mother-to-child transmission of HIV (PMTCT) have made significant contributions toward meeting mandated targets. Moreover, those activities have a positive impact on the U.S. Government's efforts in Kenya to combat HIV/AIDS. It is also encouraging that USAID/Kenya surpassed the target for counseling and testing for pregnant women, and reached about 86% of the target for prophylaxis for HIV-infected women in a PMTCT setting after the prevalence estimate is corrected. USAID, in association with CDC, is preparing to conduct an impact evaluation of PMTCT programs in Kenya, which should further refine targets and results.

We appreciate the audit team's attention to particular implementation issues. USAID/Kenya agrees with all the recommendations and has already taken action on most of the recommendations. Our management response is presented below.

Recommendation No. 1: *We recommend that USAID/Kenya develop and implement a workload redistribution plan that will enable the mission to devote substantially more time to activities for the prevention of mother-to-child transmission of HIV.*

Management Response: USAID/Kenya has made changes in staff workload to allow more time for PMTCT activity implementation, management, and site monitoring. OPH staffing has doubled in the past year, with recruitment now effectively completed. As the

new staff members hired in the last year settle in, more and more of the workload has been and will continue to be shared and focused programmatically.

One major action the OPH office has taken is to hire a Pediatric AIDS specialist. As a member of the PMTCT team, this specialist devotes 100% of her time to PMTCT issues. In addition, OPH office has redistributed work relating to the major APHIA II Nairobi/Central activity, and moved APHIA II Nairobi to another staff member on the HIV team. Project Management Teams have also been developed for the various Cooperative Agreements so that the projects can be better managed with the project workload distributed among staff in specific technical areas

Recommendation No.2: *We recommend that USAID/Kenya develop suitable trip reporting tools, such as an activity checklist or a reporting template, that will assist mission officials in documenting the site visits with complete and timely reports*

Management Response: USAID/Kenya's standardized field trip reporting tools became effective in March 2009. The reporting tools are in use and continue to assist the mission in effectively monitoring field trips (*sample copy attached*). This standardized reporting template has proved to be useful in helping the mission officials highlight key activities conducted while in the field, results and findings, follow-up actions and opportunities as well as observations. The OPH staff are now required to prepare and share their trip reports within fourteen working days following the trip.

Recommendation No. 3: *We recommend that USAID/Kenya reevaluate its policy establishing the Kenya Medical Supplies Agency as the distributor of HIV test kits and determine whether it would be in the U.S. Government's best interest to use a different commodity distribution service.*

Management Response: USAID/Kenya recognizes the serious consequences associated with frequent test kit stock-outs to the program. The PEPFAR implementing agencies in Kenya are currently utilizing a new private-sector driven test kit distribution system, in place since May 2009 (SCMS and local warehouses). This is also in line with the Government of Kenya Counseling and Testing roadmap (*in draft*) which advocates for an alternative distribution system to address test kit distribution in the short-to-medium term. In the long term, public supply systems will have been revamped to levels that can take on and sustain an effective and efficient test kit supply system.

In addition, USAID/Kenya has initiated a system which tracks test kits through the entire supply chain, from procurement to distribution and consumption reporting. Monthly reports of consumption of test kits from testing facilities are shared with USG agencies and the Government of Kenya on a regular basis. USAID/Kenya is no longer using KEMSA systems for distribution of test kits. No further action is planned for this recommendation.

Recommendation No. 4: *We recommend—in the event the Kenya Medical Supplies Agency is retained as the distributor of HIV test kits—that USAID/Kenya require the Kenya Medical Supplies Agency to bring its warehousing and distribution systems into compliance with industry best practices and World Health Organization guidelines.*

Management Response: USAID/Kenya recognizes the importance of supporting Government of Kenya on systems strengthening efforts as a strategy to address sustainability beyond donor support. USAID/Kenya is a key stakeholder in systems strengthening for the Kenya public supply chain system. While this has led to some improvement, there are still deficiencies in KEMSA as a reliable service provider. USAID/Kenya continues to work to strengthen Kenya’s public supply system to build systems in compliance with industry best practice. USAID/Kenya plans to conduct a systems review to determine the estimated loss of USAID funds, the causes of this loss and provide recommendations to improve the internal control systems of KEMSA and whether KEMSA can become a viable partner in the future.

Recommendation No. 5: *We recommend that USAID/Kenya determine the dollar value of HIV test kits that have been lost since the program’s inception and determine whether this or any amount is recoverable under existing agreements with the Government of Kenya.*

Management Response: USAID/Kenya will work with the relevant offices (RAAO, CONT, RLA, and PDA) to determine the extent to which the current agreement with the Government of Kenya permits recovery of funds. The planned systems review referenced in Recommendation #4 will help inform this process.

USAID/Kenya began procuring test kits in FY 2007, as part of a pooled procurement with other donors. The test kits were not individually branded by donors; it is difficult to track which donor’s test kits were lost or expired. The estimated loss and responsibility will be determined by the systems review outcome referenced above.

Recommendation No. 6: *We recommend that USAID/Kenya develop performance indicators to better monitor and evaluate its system for procuring, storing, and distributing HIV commodities.*

Management Response: USAID/Kenya has determined that the MOH has developed an adequate M&E system and also has developed satisfactory performance indicators to monitor and evaluate this system.

In discussions with the officials of KEMSA, NASCOP and MSH, USAID/Kenya has confirmed that there exists a monitoring and evaluation system for HIV commodities. Supply chain performance indicators, registers, tally sheets and summary reporting formats have all been developed. USAID/Kenya is focused on supporting and strengthening the Government of Kenya’s systems rather than developing a parallel system. USAID/Kenya will provide technical advice to senior managers and facilities’ staff to building their capacity to better manage data collection and reporting systems in

regards to commodity procurement, storage, and distribution. In addition, USAID/Kenya will work with the Government of Kenya agencies (NASCOP and KEMSA) and MSH to develop both short and long term strategies that would ensure that the existing HIV commodity monitoring and evaluation system is strengthened to meet the commodity needs of the HIV/AIDS program in the country. No further action is planned for this recommendation.

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