OFFICE OF INSPECTOR GENERAL

WORLDWIDE AUDIT OF THE PEPFAR-FUNDED ACTIVITIES AND COMMODITIES FOR THE PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV

AUDIT REPORT NO. 9-000-10-005-P
March 10, 2010

WASHINGTON, DC

Office of Inspector General

March 10, 2010

MEMORANDUM

TO: GH/OHA Director, Robert Clay

FROM: IG/A/PA Director, Steven H. Bernstein [Michael W. Clinebell for] /s/

SUBJECT: Worldwide Audit of the PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV (Report No. 9-000-10-005-P)

This memorandum transmits our final report on the subject audit. We have considered your comments on the draft report in finalizing the audit report and have included your response in appendix II of the report.

Recommendations were made at the mission level to address the problem areas noted in the report. Therefore, this report does not make any recommendations.

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

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CONTENTS

SUMMARY OF RESULTS

The U.S. Government's efforts to combat the HIV/AIDS epidemic are executed through the President's Emergency Plan for AIDS Relief (PEPFAR), signed into law in 2003, and a subsequent reauthorization in 2008.[1] This report addresses the prevention component of PEPFAR's three goals of treatment, prevention, and care; specifically, the Prevention of Mother-to-Child Transmission (PMTCT) of HIV (see page 2).

This report summarizes the results of the Office of Inspector General audits conducted at four selected missions: Ethiopia, Kenya, Nigeria, and Tanzania. These four countries received about $39 million in fiscal year (FY) 2008 funding for PMTCT activities (see page 3).

The objectives of this audit were to determine (1) whether USAID activities for PMTCT of HIV contributed toward meeting mandated targets, and to assess what impact the activities have made; and (2) whether USAID procured, stored, and distributed commodities for the PMTCT of HIV to help ensure that intended results were achieved, and to assess the impact the activities have made (see page 3).

At the four countries audited, USAID efforts did contribute toward meeting mandated targets, and the results have had a positive impact on preventing the transmission of HIV from pregnant women to their children. While PMTCT activities have had a positive impact, in each of the four countries audited, USAID was not able to measure the impact of the PMTCT activities. Further, in the four countries visited, USAID's PMTCT activities faced numerous challenges, such as data quality deficiencies, incomplete performance management plans, lack of technical oversight, and failure to conduct thorough site visits (see pages 4–6).

For PMTCT commodities, the audit found that USAID achieved its intended results during FY 2008. It procured the desired commodities, and upon arrival in country the commodities were inventoried, segregated, stored, and distributed to intended beneficiaries. However, commodity management problems were found in each of the four countries audited. Examples included shortages of commodities at some health centers, inaccurate and incomplete inventory records, and mislabeling of test kits as antiretroviral medication. In spite of these problems, PMTCT activities had a positive impact as pregnant women had access to test kits to determine their HIV status. If results were positive, they were further able to attain antiretroviral prophylaxis treatments to prevent the transmission of HIV to their unborn children. Without USAID-provided commodities, these services could not have been provided (see pages 7–9).

Recommendations were made at the mission level to address the problem areas noted above. Therefore, this report does not make any recommendations. USAID's Bureau of Global Health, Office of HIV/AIDS, concurred with the findings in the report. Management's comments are presented in their entirety in appendix II.

[1] The PEPFAR authorization is referred to as, "United States Leadership against HIV/AIDS, Tuberculosis and Malaria Act of 2003, Public Law 108-25." The reauthorization is referred to as, "Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria reauthorization Act of 2008, Public Law 110-293."

BACKGROUND

The U.S. Government's combined efforts to combat the HIV/AIDS epidemic are executed through the President's Emergency Plan for AIDS Relief (PEPFAR) signed into law in 2003, and a subsequent reauthorization in 2008, which authorizes up to $48 billion to combat global HIV/AIDS, tuberculosis, and malaria. Of the $48 billion, $39 billion is authorized specifically for HIV/AIDS programs.

The Office of the U.S. Global AIDS Coordinator, part of the State Department, provides policy direction to U.S. Government agencies involved with PEPFAR. PEPFAR is implemented collaboratively by in-country teams made up of staff from USAID, the Department of State, the Department of Health and Human Services, and other agencies. USAID is one of the lead government agencies involved with PEPFAR. In fiscal year (FY) 2009, USAID administered 60 percent of all PEPFAR funds, amounting to about $3.4 billion. The Director of Global Health's Office of HIV/AIDS provides the technical leadership for USAID's HIV/AIDS program.

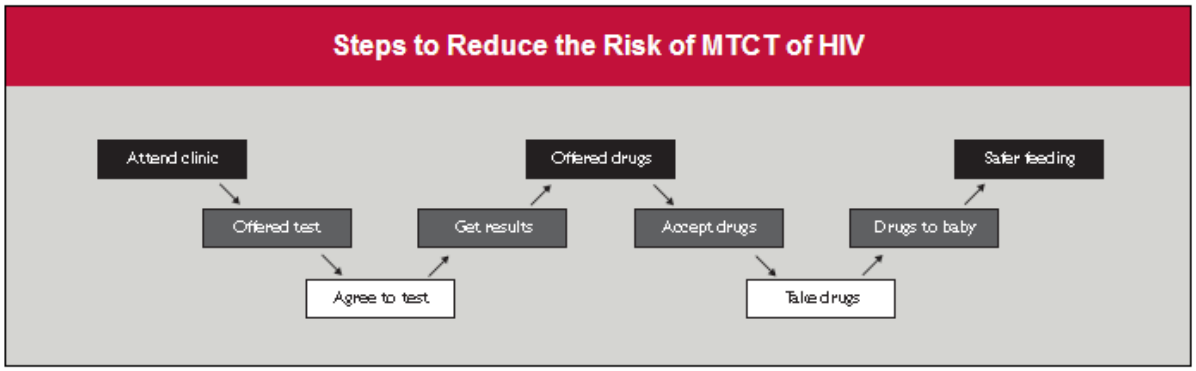
PEPFAR, in partnership with host nations, has three overall goals through FY 2013:

- Treatment for at least 3 million people
- Prevention of 12 million new infections
- Care for 12 million people, including 5 million orphans and vulnerable children

Additionally, to build sustainability, PEPFAR plans to support training of 140,000 new health care workers in HIV/AIDS prevention, treatment, and care.

This report addresses the prevention component of PEPFAR's goals, specifically Prevention of Mother-to-Child Transmission (PMTCT) of HIV. During pregnancy, HIV-infected women are at risk of transmitting HIV to their unborn children and PMTCT activities attempt to prevent this infection from occurring. USAID estimates that 90 percent of children living with HIV acquired the virus before or during birth or through breastfeeding. Figure 1 shows the various PMTCT interventions that attempt to prevent an HIV-infected, pregnant woman from transmitting the virus to her child.

Figure 1. USAID PMTCT Interventions



Source: USAID Website

This report summarizes the results of four separate audits conducted in Ethiopia, Kenya, Nigeria, and Tanzania. As depicted in table 1, the four audits reviewed PMTCT activities that received approximately $39 million in FY 2008.

Table 1. Selected Countries and PMTCT Amounts Received in FY 2008

Prevention of Mother-to-Child Transmission Amounts Received in FY 2008	
Country	Activities Audited ($ in millions)
Ethiopia	6.3
Kenya	11.4
Nigeria	7.5
Tanzania	13.8
Total	**$39.0**

AUDIT OBJECTIVES

As part of the Office of Inspector General's annual audit plan for FY 2009, the Performance Audits Division conducted this audit to answer the following questions:

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

- Did USAID 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.

AUDIT FINDINGS

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

At the four missions audited, the Prevention of Mother-to-Child Transmission (PMTCT) activities contributed toward meeting the following mandated targets:

- Service outlets provided the minimum package of PMTCT services.
- Pregnant women received HIV counseling and testing for PMTCT and received their test results.
- HIV-infected pregnant women received antiretroviral prophylaxis for PMTCT in a PMTCT setting.
- Health workers were trained in the provision of PMTCT services according to national and international standards.
- HIV-positive pregnant or lactating women received food and nutritional supplementation in a PMTCT setting.

The results have had a positive impact on preventing the transmission of HIV from pregnant women to their children. For example, it is possible to roughly estimate the number of infections of HIV averted by simply multiplying the number of patients receiving the HIV drugs by the efficacy of the treatment. In a recent annual President's Emergency Plan for AIDS Relief (PEPFAR) report, the Office of the Global AIDS Coordinator estimated that HIV prophylaxis has been effective in 19 percent of the cases in which it has been administered.[2] This indicates that, at an empirical level, the PMTCT activities had a positive effect. Other examples that indicate a positive impact include senior host nation government officials testifying to the importance of the program and interviews with women who expressed satisfaction with the services received.

While PMTCT activities have had a positive impact, in each of the four countries audited, USAID was not able to measure the impact of the PMTCT activities. Below are examples of reasons for the inability to measure impact:

- In Ethiopia, the audit team noted that not many Ethiopian women are willing or able to obtain prenatal care. Until this challenge is addressed, the mission will have difficulty showing a positive impact from program activities. Additional challenges in Ethiopia include a poor health care system and the mission's inability to retain Foreign Service Nationals working on the PEPFAR program because of salary limits.

- In Kenya, the audit team found that mission and implementing partner officials had not developed evaluative tools such as performance indicators at the

[2] The percentage reflects an estimate that current PMTCT interventions are reducing the rate of transmission of HIV from 35 percent to 16 percent, equating to a 53 percent decrease in transmission rate.

outcome level to measure the overall impact of PMTCT activities. Certain constraints hindered the collection of impact data in Kenya. For example, early infant diagnosis of HIV is a key tool in measuring PMTCT of HIV effectiveness; however, only three laboratories in Kenya can process early infant diagnosis samples.

- In Nigeria, the mission was not able to measure impact because HIV/AIDS testing of infants did not begin until 2008 and no baseline data were available for earlier years. Infants were not tested because (1) Nigeria lacked a national policy to support infant testing until 2007, and (2) the required technology was not widely available.

- In Tanzania, USAID does not have the financial or technical resources to measure the number of averted HIV infections directly. Further, the audit team noted that only four teaching hospitals in Tanzania have the ability to perform the advanced test necessary to detect the virus in infants. In addition, only a small percentage of mothers bring their babies back after delivery for HIV testing, limiting the number of babies that can be tested.

Further, at the four countries visited, USAID's PMTCT activities faced numerous challenges such as data quality deficiencies, incomplete performance management plans, lack of technical oversight, and failure to conduct thorough site visits.

Data Quality – Data quality deficiencies were present at three of four USAID missions audited: Ethiopia, Nigeria, and Tanzania. Examples of data quality deficiencies include failure to perform data quality assessments in Ethiopia, problems with both data accuracy and the data collection system in Nigeria, and implementing partners inaccurately reporting on PMTCT indicators in Tanzania. Details are discussed below:

- In Ethiopia, USAID did not perform a planned data quality assessment because other priorities prevented any assessment from being carried out. The audit team found multiple examples of data problems during field testing. For instance, audit testing identified problems with data reported for the indicator "number of pregnant women who received HIV counseling for prevention of mother-to-child transmission and received their test results." Specifically, the audit found instances where the reporting for this indicator was underreported or overreported when compared with records, such as one instance where a health center reported 5 women in July 2008 who received HIV counseling for PMTCT and received test results, whereas the records showed 195. In another instance, a health center reported a total of 384 women from June through September 2008, but the records showed 348 women.

- In Nigeria, the audit found problems with both the accuracy of the data reported and the system of data collection. Auditors verified the accuracy of reported results by implementing partners by performing spot checks of the data; reported results were significantly misstated at 5 of the 18 sites. For example, the health facility in Bankpor overreported by 11 percent the number of pregnant women who were counseled and tested from July through September 2008. The site reported that 336 pregnant women had been counseled and tested, but the supporting documentation showed that only 299 women had received these

services. On average, results were misstated by 16 percent.

- In Tanzania, two implementing partners (the Elizabeth Glaser Pediatric AIDS Foundation and EngenderHealth) reported data that did not reconcile with patient registers and monthly reports reviewed by the audit team.

Performance Management Plans – USAID/Ethiopia and USAID/Tanzania did not maintain complete and updated performance management plans.

USAID/Ethiopia's most recent performance management plan was approved in September 2004 and had not been updated to reflect the mission's current PMTCT activities. USAID/Ethiopia mission staff stated that they had not developed a performance management plan because the Department of State's Office of the Global AIDS Coordinator did not require one. The mission noted that updating its outdated performance management plan would result in a great deal of extra work and it questioned the necessity of the plan, given that the State Department does not require a performance management plan and other HIV/AIDS partners, such as the Centers for Disease Control and Prevention, are not required to develop such plans. However, USAID policy specifically requires that missions develop performance management plans.

USAID/Tanzania's performance management plan for its FY 2008 PMTCT program did not address the quality of the results data reported by implementing partners, nor did it include all indicator reference sheets, which constitute the basic format for outlining the monitoring controls to manage the individual performance indicators. The mission attributed this problem to a staff shortage and the rapid expansion of the program.

Technical Oversight – USAID/Kenya's mission specialist in PMTCT of HIV was not able to devote her entire time to the program, and as a result, the program did not receive the attention it warranted. 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 AIDS, Population and Health Integrated Assistance Program II Nairobi/Central program; activity manager for a smaller health initiative; and liaison officer for a sustainable health care project. This official also assisted the monitoring and evaluation specialist in the Office of Population and Health in addressing HIV/AIDS-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 believed that the PMTCT program was being underserved because it warranted full-time attention.

Site Visits – USAID/Kenya and USAID/Tanzania did not conduct complete and timely site visits and trip reports because of limited staff faced with competing priorities. In Kenya, the audit team found that only three trip reports were completed for eight site visits made by the PMTCT specialist during FY 2008. In Tanzania, the audit team noted that while some site visits were performed, the mission did not maintain documentation to show that data validity and reliability were verified during these site visits, especially important given that implementing partners were reporting deficient data to the mission.

Recommendations were made at the mission level to address the problem areas noted above. Therefore, this report does not make any recommendations.

Did USAID 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?

USAID procured, stored, and distributed commodities for PMTCT activities to help ensure that intended results were achieved and the impact has been positive for the four missions audited. However, problems with commodity management were reported in each of the four countries audited.

USAID's PMTCT activities achieved the intended results in the area of procurement during the FY 2008 reporting period in all four countries audited. These commodities included HIV test kits and HIV prophylaxis for the individuals who tested positive. Without these commodities, PMTCT services could not have been provided. However, shortages of some commodities were reported in three of the four countries audited.

Once the commodities arrived in country, they were inventoried, segregated, stored, and distributed to intended beneficiaries as needed. In Ethiopia, Kenya, and Tanzania, the warehouses that stored the commodities were found to be clean, secure, and well organized. However, problems were found with the inventory systems being used at the implementing partner level or the service provider level or both.[3]

In spite of these problems, PMTCT activities had a positive impact, as pregnant women had access to test kits to determine their HIV status. If results were positive, they were further able to attain antiretroviral prophylaxis treatments to prevent the transmission of HIV to their unborn children. Without USAID providing the commodities, these services could not have been provided.

Below are examples of commodity management problems and inventory records at the four selected missions: Ethiopia, Kenya, Nigeria, and Tanzania.

Commodity Management – Commodity management problems occurred in Ethiopia, Kenya, and Nigeria. Examples include shortages of commodities in stock in Ethiopia, a weak distribution system in Kenya, and a lack of compliance with storage guidelines in Nigeria. Details are discussed below:

- In Ethiopia, five out of six health centers visited experienced shortages of opportunistic-infection drugs, lab supplies, and some types of HIV test kits. Auditors found that the shortages occurred because no system was in place to ensure that adequate amounts of health commodities are kept in stock. Without accurate information on the commodities on hand and projected future consumption at each health facility, the difficulty of maintaining adequate amounts of commodities at the right places, when needed, could limit the positive impact of program activities.

[3] Implementing partners are under contract with USAID to carryout the PMTCT program. The service providers are the health clinics in the field that actually use the commodities. They may be either private, and therefore, are under contract with the implementing partner, or public, and therefore, are under the host country government.

- In Kenya, auditors observed that a main implementing partner had weak warehousing and distribution systems. The warehouses did not meet standards of distribution recommended by the World Health Organization, thereby compromising the quality of medical goods.[4] Furthermore, its outsourced distributor also did not follow good distribution practices, as evidenced by the fact that its commodity delivery system was much slower than that of its private sector counterparts.

- In Nigeria, auditors visited several storage facilities where minimum storage conditions were not being met. Antiretroviral drugs are sensitive to moisture and should be stored in dry, well-lit, ventilated storerooms. This was not always the case, as several sites were dimly lit, boxes were stored on the floor or outside,[5] and room temperatures tended to exceed the maximum recommended storage temperature.[6] Furthermore, the facilities were not secure and neither damaged nor expired commodities were being separated from inventory regularly.

Inventory Records – Poor inventory record keeping at the service provider level occurred at all four missions audited. Examples include incomplete stock cards in Ethiopia, mislabeling of commodities in Kenya, a lack of regular inventory counts in Nigeria, and poor record keeping in Tanzania. Details are discussed below:

- In Ethiopia, auditors found that stock cards were not always properly filled out to provide a complete and accurate record of status of commodities on hand. Stock cards did not include beginning inventory, quantity and value of items received, expiration dates, items disbursed or consumed, and ending inventory. Furthermore, stock cards were not updated to account for commodities on hand. The audit found that these problems contributed to a shortage or oversupply of specific commodities at the health centers visited.

- In Kenya, auditors found test kits mislabeled as antiretroviral medication. Although the service provider was 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. It was specifically noted that the service provider relied on untrained staff who lacked the requisite skills to manage their areas of responsibility.[7]

- In Nigeria, auditors found that the inventory records that were relied on to make ordering decisions and forecasts of commodities were inaccurate. No documented indication of monthly physical inventory counts could be found at the sites visited. In addition, ending balance amounts on stock cards at eight of the

[4] This statement is based on a report commissioned by the Kenyan Minister for Medical Services in October 2006.
[5] Axios, an implementing partner in Nigeria, ignored storage guidelines to the point that it stored some 150 boxes of drug commodities outside the warehouse, exposed to rain and heat and susceptible to theft.
[6] USAID's maximum recommended storage temperature is 77 degrees Fahrenheit. Temperatures were found at Magajiya and Suleja warehouses to be 90 and 82 degrees, respectively.
[7] This statement is based on a report commissioned by the Kenyan Minister for Medical Services in October 2006.

nine health facilities and at warehouses visited did not match the auditor's test counts.[8]

- In Tanzania, auditors found that 5 of 14 service providers sampled lacked inventory records for commodities, while even those that had inventory records were not always updating them when the commodities were received and dispensed.[9] Without adequate inventory records, the providers' pharmacy staffs could not determine the current level of commodities on hand, resulting in significant variances between physical counts and inventory records. Consequently, the providers could not determine whether any commodities had been lost or stolen or whether more needed to be ordered.

Recommendations were made at the mission level to address the problem areas noted above, and therefore, this report does not make any recommendations.

[8] The total of all missing and unsupported inventory at the sites visited was approximately $40,000.
[9] Some records had not been updated for 3 years.

EVALUATION OF MANAGEMENT COMMENTS

USAID's Bureau of Global Health, Office of HIV/AIDS, concurred with the findings in the draft audit report. Management comments are presented 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 a reasonable basis for our findings and conclusions based on our audit objectives. The audit was designed to determine whether (1) USAID activities for the Prevention of Mother-to-Child Transmission (PMTCT) of HIV contributed toward meeting mandated targets, and to assess what impact the activities have made; and (2) USAID procured, stored, and distributed commodities for the PMTCT of HIV to help ensure that intended results were achieved, and to assess the impact the activities have made.

The report summarized the results of audit work conducted at four overseas missions as follows:

- Ethiopia—at Washington DC, because it was a pilot audit, and at the mission and various sites from November 17 to December 4, 2008
- Kenya—at the mission and various sites from February 17 to March 5, 2009
- Tanzania—at the mission and various sites from March 9 to April 3, 2009
- Nigeria—at the mission and various sites from April 27 to May 27, 2009

These four countries received approximately $39 million in fiscal year (FY) 2008 for PMTCT activities. In planning and performing the audit, we reviewed and assessed the effectiveness of internal controls related to the President's Emergency Plan for AIDS Relief (PEPFAR) activities for PMTCT, specifically gaining an understanding of applicable management controls and testing the effectiveness of controls.

Methodology

To answer the audit objectives, we reviewed mission documentation related to managing and monitoring the PEPFAR program, country operational plans, performance management plans, implementing partner agreements, performance measures, actual performance results, certifications required under the Federal Managers' Financial Integrity Act of 1982, financial reports, data quality assessments, and trip reports prepared by mission officials. We also interviewed mission officials, implementing partners, individuals receiving treatments, and host nation government officials. We reviewed country operational plans for FY 2008 and compared plan target levels with actual results reported.

We visited clinics in all four countries to observe that the clinics existed and were providing services to women and to observe the use of HIV antiretroviral medications. Also, we verified whether reported results reconciled with to the records implementing partner used to report results.

At the warehouses, we observed storage conditions, conducted test counts of selected antiretroviral drugs and test kits, and interviewed responsible staff. We also conducted test counts, when possible, and examined commodities for expiration dates.

We reviewed applicable laws and regulations—as well as USAID policies and procedures pertaining to USAID's PMTCT program—including Federal Managers' Financial Integrity Act of 1982 certifications, Automated Directives System chapters 202 and 203, and supplemental guidance.

MANAGEMENT COMMENTS

USAID
FROM THE AMERICAN PEOPLE

March 2, 2010

TO: IG/A/PA, Steven H. Bernstein, Director

FROM: GH/OHA, Robert Clay, Director /s/

SUBJECT: Management Comments on the Worldwide Audit of PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV **(Report No. 9-000-10-00X-P)**

This memorandum transmits the Bureau for Global Health, Office of HIV/AIDS (GH/OHA) response to the draft audit report titled "Worldwide Audit of PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV" audit report no. 9-000-10-00X-P, dated March, 2010.

GH/OHA appreciates the work of the Office of the Inspector General (OIG) in this audit, and concurs with the findings as stated in the report. We expect the report to be useful in guiding future efforts in the area of Prevention of Mother-to-Child Transmission of HIV, and look forward to continuing to work with the Inspector General to ensure the efficiency and effectiveness of all of USAID's PEPFAR-related programming.

As a capstone report summarizing a series of OIG audits previously conducted in Ethiopia, Kenya, Nigeria, and Tanzania, the subject report does not contain any recommendations or action items for GH. GH/OHA has met with OIG to discuss the findings, suggest clarifications, and offer general input, and has no comments on the text of this final summary report.

We would like to thank the Office of Inspector General for the courtesies extended to our staff and the cooperative manner in which the audit was undertaken.

Cc: Michael W. Clinebell, Acting Director, IG/A/PA

Audit Reports Issued

The following reports were issued as part of this worldwide audit.
The reports are available on USAID/OIG's Web site:
http://www.usaid.gov/oig/public/aud_usaid.htm

Report No. 9-663-09-008-P, *Audit of USAID/Ethiopia's PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV*, June 25, 2009.

Report No. 4-615-09-007-P, *Audit of USAID/Kenya's PERFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV*, August 17, 2009.

Report No. 4-621-09-008-P, *Audit of USAID/Tanzania's PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV*, August 28, 2009.

Report No. 7-620-10-002-P*, Audit of USAID/Nigeria's PEPFAR-Funded Activities and Commodities for the Prevention of Mother-to-Child Transmission of HIV*, January 19, 2010.

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