



OIG HIGHLIGHTS

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What OIG Audited

An important component of the Department of State Office of Medical Services (MED) health care program is the overseas health care unit. The overseas Health Unit (HU) provides medical care for embassy staff and other eligible personnel. The Office of Inspector General (OIG) conducted this audit to determine whether (1) overseas HUs were able to accurately track controlled and non-controlled drugs through the medical supply process; and (2) overseas HUs' inventories of controlled and non-controlled drugs met the current needs of the diplomatic community.

OIG performed audit work at Addis Ababa, Ethiopia; Gaborone, Botswana; Hanoi, Vietnam; Jakarta, Indonesia; Moscow, Russia; and Kingston, Jamaica.

What OIG Recommends

OIG made three recommendations to MED: (1) develop and issue standardized procedures for overseas HUs; (2) establish procedures for implementing an automated inventory system for pharmaceuticals; and (3) develop and implement training for Foreign Service medical provider (FSMP) personnel related to pharmacy administration. MED concurred with two recommendations and neither agreed nor disagreed with one recommendation, but stated steps have been taken to address the recommendation. OIG considers all three recommendations resolved, pending further action. MED's comments have been reprinted in their entirety as Appendix B.

UNCLASSIFIED

June 2015

OFFICE OF AUDITS

Contracts, Grants, and Infrastructure Division

Audit of Overseas Health Units Administration of Controlled and Non-Controlled Drugs

What OIG Found

OIG found that all five audited HUs that stocked controlled drugs had sufficient procedures in place to account for controlled drugs (Kingston, Jamaica, did not maintain any controlled drugs). However, none of the HUs at the six posts audited could fully account for non-controlled drugs, including vaccines, prescription drugs, and over-the-counter medications, throughout the entire medical supply process. This occurred, in part because:

- There are no standard operating procedures in place for guiding HUs to maintain effective controls and procedures in managing the medical supply process for non-controlled drugs.
- HUs do not have an electronic inventory system capable of tracking the receipt, dispensing, disposal, and transfer of non-controlled drugs.
- FSMPs do not receive pharmacy administration training as part of their formal medical training or MED-specific training.

Although OIG did not find any instances where HUs were not maintaining adequate drug inventory levels to meet the needs of the diplomatic community, reconciling inventories for non-controlled drugs is problematic given that HUs did not have standard operating procedures to account for all receiving, dispensing, transferring, and disposing of non-controlled drugs. As a result, HUs will continue to have difficulty reconciling their annual inventory with property records, as required by the *Foreign Affairs Manual*. Further, without systematic controls to account for the medical supply process, there is increased risk that theft, diversion, or waste of these drugs could go undetected.



OIG

Office of Inspector General

U.S. Department of State • Broadcasting Board of Governors

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Office of Audits

June 2015

Audit of Overseas Health Units Administration of Controlled and Non-Controlled Drugs

CONTRACTS, GRANTS AND INFRASTRUCTURE DIVISION

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OBJECTIVE

The Office of Inspector General (OIG) conducted this audit to determine whether (1) overseas Health Units (HU) were able to accurately track controlled and non-controlled drugs through the medical supply process; and (2) overseas HUs' inventories of controlled and non-controlled drugs met the current needs of the diplomatic community.

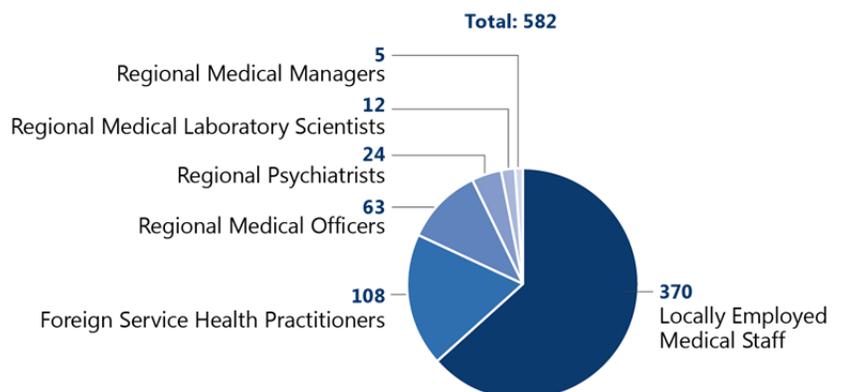
BACKGROUND

The mission of the Department of State (Department) Office of Medical Services (MED) is to promote the health and well-being of America's diplomatic community. An important component of the Department's health care program is the overseas health care unit. Overseas HUs serve patients from 75 U.S. Government agencies. This patient population includes approximately 50,000 direct-hire employees and family members who are full beneficiaries of the program and about 50,000 locally employed staff, for whom MED provides occupational health services including treatment for on-the-job injury and illness. In 2012, there were nearly 200,000 HU patient visits worldwide.

As of April 11, 2014, there were 210 HUs in embassies and consulates abroad. Overseas HUs range from HUs staffed with regional medical officers (RMO) (physicians) and/or Foreign Service health practitioners (FSHP), who are all considered a Foreign Service medical provider (FSMP),¹ to those staffed with only a locally employed registered nurse. Of the 210 HUs, 86 (41 percent) are staffed with only a locally employed registered nurse. MED's overseas staffing can be seen in Figure 1.

The HUs, depending on their size, location, and capabilities, manage medical evacuations; provide primary health care services, such as examinations and immunizations; and assist employees and family members with access to local health care facilities.

Figure 1
Office of Medical Services Overseas Staffing,
as of 4/11/2014



¹ FSMPs must have a current, valid, and unrestricted license to practice medicine in a state, the District of Columbia, or a territory of the United States. FSMPs are responsible for Department of State medical and safety policies, providing a range of medical services, and managing HU operations.

The costs associated with overseas HUs, including staffing and supplies, are fully funded through the International Cooperative Administrative Support Services program, which is a method that the U.S. Government uses to provide and to share the cost of common administrative support at posts overseas.²

Overseas Health Unit Management

Domestically, MED responsibilities include clinical services, medical clearances, occupational health, mental health services, and emergency preparedness. MED is also responsible for policies affecting health care delivery for the Foreign Service, which includes the verification and maintenance of professional credentials of their healthcare providers. In addition, MED manages the recruiting, hiring, and assignment process for FSHPs and develops the curriculum for the continuing medical education programs.

The regional medical managers are responsible for providing direct clinical oversight to RMOs and FSHPs assigned in their geographic region. The RMOs provide clinical services, oversee the clinical operation of the HU, and supervise FSHPs at the post where assigned and posts within his or her assigned region. The FSHPs provide clinical services and supervise the operation of the HU at post.

The accountability of medical supplies, including drugs, is decentralized. Individual HUs have full control over purchasing, receiving, storing, and disposing of medical supplies. MED does not mandate policies regarding the management and accountability of drugs to overseas HUs.³ Each HU is overseen by the post's Management Officer and HU staff report to the Management Officer rather than to MED. MED officials stated the Management Officers at post interpret the guidelines offered by MED and instruct the HUs to follow the guidelines. According to the *Foreign Affairs Manual* (FAM), the principal FSMP at a post is responsible for ensuring that there are internal control systems that conform to procurement, receipt, storage, and disbursement regulations for all drugs;⁴ and that supply records of controlled substances are properly maintained.⁵

Management of Controlled and Non-Controlled Drugs Supply Cycle

MED does not require specific amounts or types of drugs to be procured by its licensed providers at post, nor does it control the funding for drugs. Drugs are ordered, received, and

² U.S. agencies that establish a civilian presence at a U.S. diplomatic mission/post pay fees, on a per person basis, to the Department for administrative services.

³ MED does mandate policies for domestic HUs and these policies are also available on their intranet site for overseas HUs to utilize as a resource.

⁴ 16 FAM 741 (b), "Ordering and Maintaining Drugs, Equipment and Medical Supplies."

⁵ 16 FAM 721 (b), "Management of Controlled Substances."

maintained through a combined effort of HU staff, the General Services Officer (GSO),⁶ and the Financial Management Officer. According to International Cooperative Administrative Support Services data, the Department budgeted nearly \$32 million for medical supplies from FY 2010 to FY 2013.

Every post has different realities (local resources, geographic location, climate, transportation options, etc.) that affect medical logistics decision-making. HUs maintain and dispense drugs and vaccines to meet a variety of patient needs. HUs carry both controlled drugs (substances) as defined and identified by the Controlled Substances Act⁷ and enforced by the Drug Enforcement Administration (DEA) and non-controlled drugs,⁸ to include vaccines that are not listed in DEA schedules.

HUs must follow recordkeeping protocols for controlled drugs as prescribed in 16 FAM 720, "Controlled Substances," MED Quality Improvement Guidance, and DEA Federal requirements. To reduce the risk of abuse and diversion of controlled drugs, MED requires two signatures whenever there is a change in the inventory level. These inventory shifts are confirmed through log records, disposal records, periodic inventories, and reconciliations.

HUs are not required or requested to adhere to these same controls for non-controlled drugs and vaccines. Rather, posts follow 16 FAM 711(c), "Medical Supplies and Support," which states the FSMP responsible for each post should ensure there are internal controls systems in place so that no one individual controls all aspects of any transaction affecting the ordering, receipt, storage, or disposition of expendable medical supplies. In addition, 14 FAM 416.1(a), "Personal Property Management for Post Abroad," states that "physical inventory of... medical supplies and drugs must be taken annually and immediately reconciled with the property records."

⁶ GSOs are responsible for a range of functions that involve the management of physical resources and logistical functions at diplomatic and consular posts. They develop, plan, implement, and manage an ongoing program of support that includes contracting, inventory/property, physical facilities, space management, travel and transportation, maintenance, and repair schedules.

⁷ Controlled substances are prescription medicines, such as morphine, codeine, oxycodone, and diazepam, and are generally a drug or chemical whose manufacture, possession, or use is regulated by the Government. The Controlled Substances Act of 1970 (Public Law 91-513) is the Federal U.S. drug policy under which the manufacture, importation, possession, use, and distribution of certain substances is regulated. Controlled substance schedules categorize drugs based on whether they have a currently acceptable medical treatment in the United States and their relative abuse potential and likelihood of causing dependence when abused. With respect to pharmaceutical controlled substances, DEA statutory responsibility is twofold: to prevent diversion and abuse of these drugs while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate need.

⁸ Non-controlled drugs include prescription medicines such as antivirals, anti-malaria, pain relievers, and inhalers and over-the-counter medications such as cold medicines. Some non-controlled drugs are of high value, pilferable, or otherwise deserving of special attention.

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The HU staff is responsible for ensuring that expired items are disposed of properly unless the product's shelf life has been extended⁹ or other disposal direction has been received. According to 16 FAM 711, destruction of expired pharmaceuticals will be done in a safe and secure manner and in accordance with local law. The destruction action will be documented and forwarded to post's Property Management Officer for recordation.¹⁰ Additionally, destruction of controlled substances shall require a signed log entry and be witnessed by a designee. Department Form DS-132, Property Disposal Authorization and Survey Report, must be completed by the FSMP and forwarded to the Property Management Officer at post for approval.¹¹

⁹ The Federal Shelf Life Extension Program extends the expiration dates on qualifying drugs in Federal stockpiles and is administered by the U.S. Department of Defense in cooperation with the U.S. Food and Drug Administration. The program is an acknowledgement that the actual shelf life of drugs may be longer than their stated expiration date, depending on their storage conditions. The purpose of the Shelf Life Extension Program is to defer replacement costs of stockpiled drugs by extending their useful life.

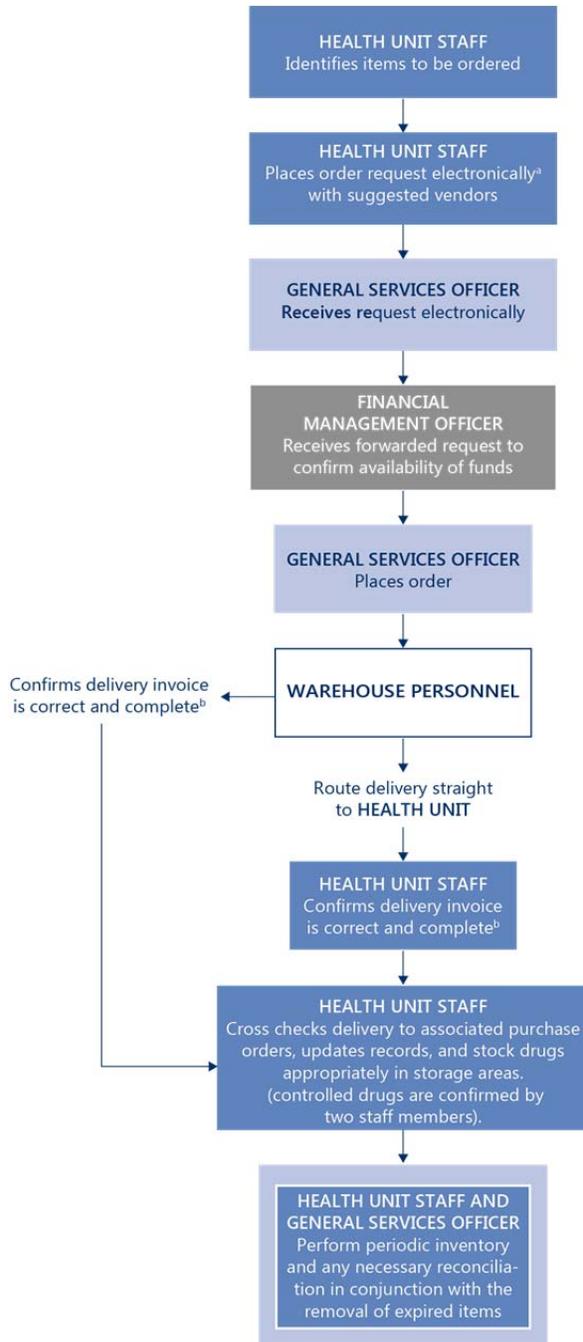
¹⁰ 16 FAM 711 (b), "Ordering and Maintaining Drugs, Equipment, and Medical Supplies."

¹¹ 16 FAM 721 (c), "Management of Controlled Substances."

Medical Supply Lifecycle of Controlled and Non-Controlled Drugs Within Overseas Health Units

According to overseas post personnel within the HUs and post GSOs, the lifecycle for most drugs can be seen in Figure 2.

Figure 2
Medical Supply Lifecycle of Controlled and Non-Controlled Drugs Within Overseas Health Units



^a Orders are placed through a commercial, off-the-shelf procurement tracking software program that deals with procurement of goods and services. The application provides functionality for customers to: submit electronic requests for supplies and services, create purchase orders, automate workflow for electronic approvals and elimination of paper routing, and improve internal controls and accountability for all procurement processes.

^b The receiving warehouse and HUs use a combination of packing lists, commercial invoices, requisitions, and receiving and inspection reports to confirm orders.

Source: OIG generated based on information provided by audited posts.

AUDIT RESULTS

Finding A: Overseas Health Units Accounted for Controlled Drugs But Improvements Are Needed to Fully Account for Non-Controlled Drugs

OIG found that all audited HUs¹² that stocked controlled drugs had sufficient procedures in place to account for these drugs. However, none of the HUs at the six audited posts could fully account for non-controlled drugs, including vaccines, prescription drugs, and over-the-counter medications, throughout the entire medical supply process. This occurred, in part because:

- There were no standard operating procedures in place for guiding HUs to maintain effective controls and procedures in managing the medical supply process for non-controlled drugs.
- HUs did not have an electronic inventory system capable of tracking the receipt, dispensing, disposal, and transfer of non-controlled drugs.
- FSMPs do not receive pharmacy administration training as part of their formal medical training or MED-specific training.

Although OIG did not find any instances where HUs were not maintaining adequate drug inventory levels to meet the needs of the diplomatic community, HUs could not reconcile their annual inventories with property records as required by the FAM.¹³ Further, without systemic controls to account for the medical supply process, there is increased risk that theft, diversion, or waste of non-controlled drugs could go undetected. See Appendix A for the scope and methodology of this audit.

Controlled Drugs Accurately Tracked

OIG found that all five audited HUs that stocked controlled drugs had adequate controls and properly accounted for the drugs from the time they were received and placed into inventory, through the time they were dispensed or underwent disposal. In addition, all HUs were conducting and reconciling their inventories of controlled drugs monthly.

OIG examined supply records for 36 controlled drugs and found all had documentation to demonstrate the medical supply process was followed.¹⁴ OIG affirmed the receipt and dispensing of controlled drugs were appropriately and accurately recorded in the controlled drug log book and witnessed by two individuals with signatures. In addition, HU staff stored and maintained the controlled drugs in a separate locked cabinet within a room that had controlled access only

¹² OIG performed audit work at Addis Ababa, Ethiopia; Gaborone, Botswana; Hanoi, Vietnam; Jakarta, Indonesia; Moscow, Russia; and Kingston, Jamaica. Kingston did not maintain any controlled drugs.

¹³ 14 FAM 416.1 (a), "Physical Inventory and Reconciliation."

¹⁴ See Table A.2 in Appendix A, Scope and Methodology, for detailed information about the posts audited, including the universe and number of drugs sampled and tested at each HU.

for authorized HU staff, as required.¹⁵ OIG also found the HUs conducted a monthly reconciliation of the controlled drugs against the inventory with two individuals witnessing the reconciliation with signatures. Further, HUs appropriately recorded the disposal of expired controlled drugs in the log book and completed the DS-132, as required.¹⁶

Insufficient Documentation for Non-Controlled Drugs

HUs at all of the six posts audited could not fully account for the receipt, dispensing, transfer, or disposal of all non-controlled drugs to include vaccines. Specifically, OIG reviewed records for 60 non-controlled drugs and 43 vaccines and found that only 13 non-controlled drugs (22 percent) and 13 vaccines (30 percent) had sufficient documentation to account for these drugs over the medical supply lifecycle. It is important that HUs fully account for these drugs because, for example, they can be of high value on the black market and therefore a target for theft. For example, approved U.S. Food and Drug Administration medicines such as antivirals, anti-malaria, pain relievers, inhalers, and adult or pediatric vaccines may not be available on the local economy where U.S. embassies are located. In addition, other medications including over-the-counter medications such as cold and allergy medicines could be utilized to make illegal drugs such as methamphetamines.

Table 1 shows the percentage of non-controlled drugs and vaccines tested that were fully accounted for over the medical supply lifecycle at each audited HU.

¹⁵ 16 FAM 721 (a), "Management of Controlled Substances."

¹⁶ 16 FAM 721 (c), "Management of Controlled Substances."

Table 1: Percentage of Non-Controlled Drugs and Vaccines Accounted For at Audited Health Units

Type of Drug	HU	Number Tested	Number With Sufficient Documentation	Accounted Percentage
Non-Controlled Drugs				
	Addis Ababa	25	0	0%
	Gaborone	5	1	20%
	Hanoi	4	1	25%
	Jakarta	10	1	10%
	Moscow	6	1	17%
	Kingston	10	9	90%
	Total	60	13	22%
Vaccines				
	Addis Ababa	10	5	50%
	Gaborone	8	3	38%
	Hanoi	6	0	0%
	Jakarta	7	1	14%
	Moscow	8	2	25%
	Kingston	4	2	50%
	Total	43	13	30%

Source: OIG analysis of data collected during audit fieldwork.

Dispensing Logs for Non-Controlled Drugs Were Not Always Maintained

OIG performed inventory testing at the audited posts between August and September 2014, and compared the results with the inventory completed by the HUs between July 14, 2014, and August 14, 2014. OIG reconciled the inventory quantities of all 65 controlled drugs in the audit sample. However, for non-controlled drugs, OIG could not reconcile the inventory quantities of 110 (15 percent) of 715 non-controlled drugs sampled. Only the HUs at Gaborone, Kingston, and Moscow maintained dispensing logs for non-controlled drugs, while HUs at Addis Ababa, Hanoi, and Jakarta did not. OIG therefore was forced to rely upon patient health records for drug dispensing information.

Further, although all of the HUs maintained vaccination log books and recorded the required information for vaccines administered, such as the date, patient name, vaccine, lot number, expiration date, manufacturer, and signature of person administering the vaccine, the logs were not always correct. OIG could not reconcile 7 of 106 vaccines sampled (7 percent) during our inventory testing. Specifically, three vaccines at Hanoi and one vaccine at Jakarta,¹⁷ according to HU staff, were administered but not recorded in the log books. Also, one vaccine at Moscow, according to HU staff, was disposed but not recorded. In addition, Kingston and Hanoi explained

¹⁷ Tetanus, Diphtheria, and Acellular Pertussis Vaccine at HU Hanoi and HU Jakarta.

that some vaccines had been transferred to other locations but had not been documented. For example, at the Kingston HU, the locally employed registered nurse said a transfer of three Hepatitis B vaccines was made to the Peace Corps. There was no record of the transfer and we could not find any documentation to explain why the transfer occurred, the amount transferred, the individual that initiated the transfer, or the individual that received the vaccine. At the Hanoi HU, the locally employed registered nurse said the HU transferred a Rho(D) Immune Globulin vaccine to the U.S. Consulate in Ho Chi Minh City. However, similar to Embassy Kingston, the transfer was not recorded in the vaccine log book. Table 2 shows the results of our inventory testing of non-controlled drugs and vaccines.

Table 2: Non-Controlled Drugs That Could Not Be Reconciled by OIG

Type of Drug	HU	Number Tested	Number Not Reconciled	Not Reconciled Percentage
Non-Controlled Drugs				
	Addis Ababa	111	35	32%
	Gaborone	24	0	0%
	Hanoi	101	24	24%
	Jakarta	201	51	25%
	Moscow	237	0	0%
	Kingston	41	0	0%
	Total	715	110	15%
Vaccines				
	Addis Ababa	25	0	0%
	Gaborone	21	0	0%
	Hanoi	16	4 ^{a,c}	25%
	Jakarta	17	1 ^a	6%
	Moscow	17	1 ^b	6%
	Kingston	10	1 ^c	10%
	Total	106	7	7%

^a Vaccine administered but not documented.

^b Vaccine disposal not documented.

^c Vaccine transfer to another government agency not documented.

Source: OIG analysis of data collected during audit fieldwork.

Deficiencies Occurred for Three Primary Reasons

The deficiencies identified in respect to the accountability of non-controlled drugs occurred for three primary reasons: (1) There are no standard operating procedures in place for guiding HUs to maintain effective controls and procedures in managing the medical supply process for non-controlled drugs; (2) HUs do not have an electronic inventory system capable of tracking the receipt, dispensing, disposal, and transfer of non-controlled drugs; and (3) FSMPs do not receive pharmacy administration training as part of their formal medical training or MED-specific training, yet are expected to manage a pharmacy as a FSMP with the Department.

In 2001, OIG reported deficiencies in the inventory process used by the Department to account for procured drugs and recommended that MED review and clarify its policies for managing the medical supply process and conduct drug inventories at overseas posts.¹⁸ In addition, the audit noted that a majority of posts did not have a computerized inventory system so the amount of drugs on hand was not readily available. It has been more than 13 years since OIG made those recommendations, but the need to implement procedures and implement an automated inventory system remains.

Although OIG found that the six audited HUs annually performed a manual inventory of drugs on hand, the inventory is often not reconciled with what has been procured or dispensed. Therefore, HUs do not know if the amount on hand agrees with what has been procured, or for example, if items have been misplaced or stolen.

Of the six posts audited, five did not have an electronic inventory system in place that complemented the drug supply lifecycle. According to MED, HUs can acquire their own pharmacy management software to manage drug inventories, if International Cooperative Administrative Support Services funds are available to procure the software. However, no guidance has been provided to ensure that HUs acquire the most appropriate software and MED does not endorse any particular software application to be used at HUs.

The HU at Embassy Addis Ababa is utilizing a commercial off-the-shelf pharmacy software program to manage their non-controlled drug inventory. However, despite the deployment of the pharmacy software program, OIG found little improvement in the inventory management due to the staff's inexperience with the program or the limited capabilities of the program. As previously discussed, we could not find a full accounting for any of the 25 non-controlled drugs or half of the vaccines tested at HU Addis Ababa. We also noted incorrect expiration dates for the drugs we sampled. Specifically, out of the 111 non-controlled drugs sampled from the HU's current inventory, the expiration date for 46 of the drugs on hand did not match the inventory provided to OIG. Therefore, OIG could only reconcile these 46 drugs by the drug lot number rather than both the lot number and expiration date because the expiration dates contained in the pharmacy program report were inaccurate. HU staff explained the pharmacy software listed the current lot number for these drugs but did not update the expiration dates when new purchases with the same National Drug Code¹⁹ already existed in the system.

MED management stated they plan to implement an electronic health records system that will be deployed at all overseas HUs that will incorporate an inventory management module. In

¹⁸ *Review of Overseas Medical Operations*, U.S. Department of State and the Broadcasting Board of Governors, Memorandum Report Number 01-HR-M-036, July 2001.

¹⁹ The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. Drug products are identified and reported using a unique three-segment number called the National Drug Code, which serves as a universal product identifier for drugs.

addition, MED stated that the Department designed a Medical Expendables software program within Ariba²⁰ that overseas HUs can utilize as a pharmacy management and inventory system. MED is completing system development on these two projects and estimate they will begin implementation of these systems in approximately 6 months.

In addition to the need for an electronic inventory system, OIG found that RMOs and FSHPs do not receive pharmacy administration training as part of their formal medical training, yet are expected to manage pharmacy operations. MED officials stated that pharmacy administration is not part of MED's annual continuing medical education conferences²¹ and the Foreign Service Institute does not offer any training on pharmacy administration. Providing such training is important because FSMP staff regularly rotate posts every 2-3 years and receiving training on the fundamentals of pharmacy administration would help ensure annual inventory reconciliation with drug procurement and dispensing records, as required by the FAM.

Conclusion

Although OIG did not find any instances that HUs were not maintaining adequate drug inventory levels to meet the needs of the diplomatic community, reconciling inventories for non-controlled drugs is problematic given that HUs did not have standard operating procedures to account for all receiving, dispensing, transferring, and disposing of non-controlled drugs. As a result, HUs will continue to have difficulty reconciling their annual inventory with property records, as required by the FAM.²² Further, without systematic controls to account for the medical supply process, there is increased risk that theft, diversion, or waste of these drugs could go undetected.

Recommendation 1: OIG recommends that the Office of Medical Services develop and issue standardized procedures for overseas Health Units to maintain effective controls and procedures for the ordering, receiving, dispensing, transferring, and disposing of non-controlled drugs, including vaccines.

Management Response: MED neither agreed nor disagreed with the recommendation, stating that it created a Pharmaceutical and Therapeutics Committee charged with developing a Basic Formulary and policies for management of pharmaceuticals overseas.

²⁰ Ariba is a commercial, off-the-shelf procurement tracking software program; one function of the Integrated Logistics Management System that deals with procurement of goods and services. The application provides functionality for customers to: submit electronic requests for supplies and services, create purchase orders, automate workflow for electronic approvals and elimination of paper routing, and improve internal controls and accountability for all procurement processes.

²¹ MED provides regular, comprehensive, and job-specific continuing medical education opportunities to the direct hire FSMPs to maintain professional competency, learn new skills, and obtain continuing medical education credits towards retention of licensure and meeting credentialing requirements.

²² 14 FAM 416.1 (a), "Physical Inventory and Reconciliation."

OIG Reply: OIG considers the recommendation resolved because steps have been taken to develop and issue standardized procedures for overseas Health Units. This recommendation can be closed when OIG reviews and accepts documentation showing that MED has established and implemented a Basic Formulary and policies for management of pharmaceuticals overseas.

Recommendation 2: OIG recommends that the Office of Medical Services establish procedures for implementing an automated inventory system for pharmaceuticals.

Management Response: MED concurred with the recommendation, stating that it is creating a Basic Formulary to be stocked and managed at each Health Unit through the new Integrated Logistics Management System "Medical Expendables" ordering and inventory system. In addition, Health Unit personnel will be trained to use the system for acquisition and maintenance of all pharmaceuticals.

OIG Reply: OIG considers the recommendation resolved because steps have been taken to establish procedures for implementing an automated inventory system for pharmaceuticals. This recommendation can be closed when OIG reviews and accepts documentation showing that MED has established a Basic Formulary to be stocked and managed at each Health Unit through the new Integrated Logistics Management System "Medical Expendables" ordering and inventory system and has trained Health Unit personnel to use the system.

Recommendation 3: OIG recommends that the Office of Medical Services develop and implement training for Foreign Service medical provider personnel related to pharmacy administration.

Management Response: MED concurred with the recommendation, stating that it will develop a mixed media training program for Foreign Service medical provider personnel on how to use the Logistics Management System "Medical Expendables" ordering and inventory system for drugs. Additionally, it will develop a standard operating procedure to provide administrative oversight following initial training and will add pharmaceutical management training topics during its annual Continuing Medical Education.

OIG Reply: OIG considers the recommendation resolved because steps have been taken to develop and implement training for Foreign Service medical provider personnel. This recommendation can be closed when OIG reviews and accepts documentation showing that MED has developed and implemented training on how to use the Logistics Management System "Medical Expendables" ordering and inventory system for drugs, developed and implemented standard operating procedure to provide administrative oversight following initial training, and added pharmaceutical management training topics during its annual Continuing Medical Education.

RECOMMENDATIONS

Recommendation 1: OIG recommends that the Office of Medical Services develop and issue standardized procedures for overseas Health Units to maintain effective controls and procedures for the ordering, receiving, dispensing, transferring, and disposing of non-controlled drugs, including vaccines.

Recommendation 2: OIG recommends that the Office of Medical Services establish procedures for implementing an automated inventory system for pharmaceuticals.

Recommendation 3: OIG recommends that the Office of Medical Services develop and implement training for Foreign Service medical provider personnel related to pharmacy administration.

APPENDIX A: SCOPE AND METHODOLOGY

The Office of Audits within the Office of Inspector General (OIG) for the Department of State (Department) and the Broadcasting Board of Governors conducted this audit to determine whether (1) overseas Health Units (HU) were able to accurately track controlled and non-controlled drugs through the medical supply process; and (2) overseas HUs' inventories of controlled and non-controlled drugs met the current needs of the diplomatic community.

The Office of Audits conducted this audit from July 2014 to February 2015 in the Washington, D.C., metropolitan area and at six overseas posts. Six HUs were selected, representing the six posts: two from the Bureau of African Affairs (Addis Ababa, Ethiopia, and Gaborone, Botswana), two from the Bureau of East Asia and Pacific Affairs (Hanoi, Vietnam, and Jakarta, Indonesia), one from the Bureau of European and Eurasian Affairs (Moscow, Russia), and one from the Bureau of Western Hemisphere Affairs (Kingston, Jamaica). The sampling methodology employed is described in the Detailed Sampling Methodology section of this appendix.

OIG conducted this performance audit in accordance with generally accepted government auditing standards. These standards require that OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions based on the audit objective. OIG believes that the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objective.

To obtain background information and criteria relating to overseas HUs' administration of drugs, OIG reviewed the *Foreign Affairs Manual*, guidance from the Office of Medical Services (MED), Drug Enforcement Administration manuals, and the Controlled Substances Act.¹ In addition, OIG reviewed prior audit work conducted by the OIG and Peace Corps OIG.

In the Washington, D.C., metropolitan area, OIG interviewed officials from the Office of Medical Services and the International Cooperative Administrative Support Services. At the posts, OIG interviewed several officials, including the regional medical officer and the Foreign Service health practitioner, who are responsible for operating and managing post's HUs. OIG also interviewed the Management Officer, General Services Officer, the Regional Security Officer, and the locally employed medical staff assigned to the HUs.

OIG reviewed supply documents such as purchase requests, purchase orders, drug and vaccine dispensing log records, and historical records of expired drug disposal. OIG also reviewed inventory lists of drugs and vaccines.

¹ The Controlled Substances Act of 1970 (Public Law 91-513).

Prior Audit Reports

OIG reviewed prior OIG audit and inspection reports to identify information previously reported relating to overseas HUs' management of controlled and non-controlled drugs. OIG conducted an audit in 2001² that identified that MED should review and clarify its policies relating to procurement of drugs by overseas posts and conducting periodic inventories.

Work Related to Internal Controls

OIG performed steps to assess the adequacy of internal controls related to the areas audited. For example, OIG gained an understanding of Department guidance and post procedures for ensuring that drugs were accurately tracked through the medical supply process and that overseas HUs' inventory of drugs met the needs of the diplomatic community. OIG reviewed ordering, receiving, dispensing, and disposal documentation to determine if deficiencies existed with the medical supply process and whether the HUs maintained proper documentation for selected drugs throughout the medical supply cycle. Work performed on internal controls during this audit is detailed in the Audit Results section of this report.

Use of Computer-Processed Data

In the course of this audit, OIG reviewed hard-copy documentation provided by overseas HUs, but the audit team did not utilize electronically processed data as evidence. Thus, information systems controls were not significant to the audit objective, and it was not necessary to assess the usage of controls for computer-processed data.

Detailed Testing Methodology

OIG's testing objective was to determine whether overseas HUs were able to accurately track controlled and non-controlled drugs through the medical supply process and whether inventories of drugs met the needs of the diplomatic community.

Identification of the Universe and the Selection of Posts

OIG identified 210 HUs as of April 11, 2014, based on data obtained from the Office of Medical Services. This universe was then sorted by regional bureaus, the amount budgeted for medical supplies from FY 2010 through FY 2013, and type of staff as of April 15, 2014.

OIG selected overseas posts in Addis Ababa, Ethiopia; Gaborone, Botswana; Hanoi, Vietnam; Jakarta, Indonesia; Moscow, Russia; and Kingston, Jamaica. OIG used a non-statistical sampling method known as judgment sampling to select the posts for site visits and testing. Because this

² *Review of Overseas Medical Operations*, U.S. Department of State and the Broadcasting Board of Governors, Memorandum Report Number 01-HR-M-036, July 2001.

method uses discretionary criteria to effect sample selection, OIG was able to use information garnered during its preliminary work to aid in making informed selections.

Within four regional bureaus, the Bureau of African Affairs, the Bureau of East Asia and Pacific Affairs, the Bureau of European and Eurasian Affairs, and the Bureau of Western Hemisphere Affairs, OIG selected HUs based on, among other factors, the amount budgeted for medical supplies by bureau, the amount budgeted for medical supplies by HU, and staff levels. The criteria for the selection of HUs also included logistical considerations.

Based on the International Cooperative Administrative Support Services data, OIG identified a Department-wide total budgeted amount of \$32,540,145 for medical supplies from FY 2010 through FY 2013. OIG took the aggregate of the FY 2010 through FY 2013 budgeted amount for medical supplies for each post within the following four regional bureaus: the Bureau of African Affairs, the Bureau of East Asia and Pacific Affairs, the Bureau of European and Eurasian Affairs, and the Bureau of Western Hemisphere Affairs, representing a total of \$24,098,468. The Bureau of Near Eastern Affairs and the Bureau of South and Central Asian Affairs were not selected because of the lesser budgeted amounts and the high cost to conduct fieldwork in those regions. Of the six HUs selected, three had the highest budgeted medical supply amounts from FY 2010 through FY 2013. Also, of the six HUs selected, four had Foreign Service medical providers (regional medical officers and/or Foreign Service health practitioners) on staff and two had only locally employed nurses on staff. A breakdown of the selection of posts is included in Table A.1.

Table A.1: Universe and Audited Posts

Bureau	Amount Budgeted for Medical Supplies by Bureau, FY 2010-13	Selected HU/ Post	Amount Budgeted for Medical Supplies, FY 2010-13, for Selected HU
African Affairs ^a	\$9,217,643	Addis Ababa, Ethiopia ^b	\$587,180
		Gaborone, Botswana ^c	\$141,748
East Asia and Pacific Affairs ^a	\$5,407,593	Jakarta, Indonesia ^b	\$1,010,082
		Hanoi, Vietnam	\$169,901
European and East Asian Affairs ^a	\$6,116,249	Moscow, Russia ^b	\$659,293
Near Eastern Affairs	\$4,359,891		
South and Central Asian Affairs	\$4,081,786		
Western Hemisphere Affairs ^a	\$3,356,983	Kingston, Jamaica ^c	\$73,500
Total	\$32,540,145		\$2,641,704

^a Selected bureau.

^b Highest budgeted amount in the bureau and staffed by a Foreign Service medical provider.

^c HU with only locally employed staff.

Source: Generated by OIG from data provided by International Cooperative Administrative Support Services and the Office of Medical Services.

Selection of Samples at Posts

To effect sample selection of controlled drugs, non-controlled drugs, and vaccines at the selected six HUs, OIG contacted the respective posts to obtain the most current inventories of these medications. Judgment sampling was utilized for the testing of inventory and reviewing supply cycle documentation at the six selected posts.

A prime consideration in the selection of drugs for both the testing of inventory and reviewing supply cycle documentation was the balance on hand. More specifically, drugs were selected from the lowest to the highest balance on hand quantities in order to ensure wide coverage of various controlled drugs, non-controlled drugs, and vaccines. If OIG had selected the largest, the second largest, etc., as is more typically done in judgment sampling, far fewer balances would have been able to be reviewed in the allotted time at each post. The expiration date of the drugs was another factor in OIG's sample selection. Any drug that had an expiration date prior to the date of OIG's site visit was added to the sample.

Inventory Testing

To determine whether overseas HUs could account for drugs, OIG judgmentally sampled controlled drugs, non-controlled drugs, and vaccines from inventory lists and performed inventory testing at the audited posts between August and September 2014, and OIG compared

the results with the inventory accounting completed by the HUs between July 11, 2014, and August 14, 2014. OIG then attempted to reconcile any differences. The details of the sample methodology are presented in Table A.2 and the results of this testing are detailed in the Audit Results section of this report.

Review of Supply Cycle Documentation

To determine whether overseas HUs could accurately track controlled drugs, non-controlled drugs, and vaccines through the medical supply process, OIG utilized judgment sampling in a similar manner as it did for inventory testing. From the initial sample of 886 drugs used for inventory testing, OIG selected a subsample of 139 to review supply cycle documentation. This subsample was much smaller than the initial sample used in inventory testing because the documentation for the entire supply cycle (i.e., from receipt of the item and initial entry into the inventory system to eventual disposal either by usage or expiration) was considerable. Using the sample previously chosen for inventory testing, OIG generally selected by category (i.e., controlled drugs, non-controlled drugs, and vaccines) and post the drug with the lowest balance on hand, then the drug with the next lowest balance on hand, and so forth until the desired sample sizes by category and post were achieved, as shown in Table A.2. The results of the testing are detailed in the Audit Results section of this report.

Table A.2: Post Universe and Sample Sizes, per Drug Category

HU	Universe of Drugs	Sample Size for Inventory Testing	Sample Size for Documentation Testing
Controlled Drugs			
Addis Ababa	11	11	9
Gaborone	10	10	3
Hanoi	24	13	4
Jakarta	30	15	10
Moscow	30	16	10
Kingston*	0	0	0
Total	105	65	36
Non-Controlled Drugs			
Addis Ababa	169	111	25
Gaborone	35	24	5
Hanoi	364	101	4
Jakarta	564	201	10
Moscow	491	237	6
Kingston	72	41	10
Total	1,695	715	60

HU	Universe of Drugs	Sample Size for Inventory Testing	Sample Size for Documentation Testing
Vaccines			
Addis Ababa	48	25	10
Gaborone	36	21	8
Hanoi	31	16	6
Jakarta	37	17	7
Moscow	39	17	8
Kingston	18	10	4
Total	209	106	43
Total Drugs	2,009	886	139

* Kingston did not maintain any controlled drugs.

Source: Generated by OIG from data provided by overseas HUs.

Required HU Log Verification

OIG reviewed HU log books for controlled drugs and verified the following required attributes, per MED, were recorded at the top of each page for each controlled drug received:

- name of drug, date received;
- total number of pills/vials;
- expiration date; and
- lot number.

OIG also verified that each time a controlled drug was dispensed HUs recorded the:

- date,
- patient name,
- drug and dose,
- number given,
- number remaining, and
- signatures of the person dispensing and witness.

In addition, OIG verified two individuals reconciled the controlled log book against the inventory at least monthly and recorded the reconciliation in the log.

Furthermore, OIG verified the following information was recorded in vaccine log books for every vaccination administered:³

- date,
- patient name,
- vaccine,
- lot number,
- expiration date,
- manufacturer, and
- signature of person administering the vaccine.

³ The key requirement is to be able to contact all patients who received a given lot number if there is a recall from the manufacturer.

APPENDIX B: DEPARTMENT OF STATE RESPONSE



United States Department of State

*Medical Director
Department of State and the Foreign Service*

Washington, D.C. 20520

May 14, 2015

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MEMORANDUM

TO: OIG/AUD – Mr. Norman P. Brown

FROM: MED – Gary D. Penner, M.D.

SUBJECT: Draft Report on Audit of Overseas Health Units
Administration of Controlled and Non-Controlled Drugs

The Office of Medical Services (MED) has reviewed your Draft Report on the Audit of Overseas Health Units; Administration of Controlled and Non-Controlled Drugs, dated May 6, 2015. MED is responding to your recommendations as indicated below.

Recommendation 1

OIG recommends that the Office of Medical Services (MED) develop and issue standardized procedures for overseas Health Units (HU) to maintain effective controls and procedures for the ordering, receiving, dispensing, transferring, and disposing of non-controlled drugs, including vaccines.

MED Response

Prior to this OIG audit, MED had independently determined that there was significant variance in HU management of non-controlled pharmaceuticals. To address this and improve the efficiency, accountability, and quality of the care provided at our Health Units, MED created a Pharmaceutical and Therapeutics (P&T) Committee charged with developing a Basic Formulary and policies for management of pharmaceuticals overseas.

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Recommendation 2:

OIG recommends that the Office of Medical Services establish procedures for implementing an automated inventory system for pharmaceuticals.

MED Response

MED agrees that implementing an automated inventory system for pharmaceuticals is beneficial and has developed a working relationship with A/ILMS to accomplish this prior to receiving the audit report draft. MED is creating a "Basic MED Formulary" (list of standardized 'core' medications) to be stocked and managed at each Heath Unit through the new A/ILMS "Medical Expendables" (ME) ordering and inventory system. HU personnel will be trained to use the ME system for acquisition and maintenance of all pharmaceutical and other expendable supplies.

Recommendation 3:

OIG recommends that the Office of Medical Services develop and implement training for Foreign Service medical provider personnel related to pharmacy administration.

MED Response

MED agrees that additional training for Foreign Service Medical Providers and Locally Employed Staff (LES) is essential. Towards this effort, MED management has committed to installing the new A/ILMS "Medical Expendables" ordering and inventory system for drugs and medical supplies worldwide. MED will work with A/ILMS staff to develop a mixed media training program for Foreign Service medical provider personnel on how to use this system and will participate in on-site training as needed. Additionally, MED will develop a standard operating procedure to provide administrative oversight following installation and initial training. MED will also add pharmaceutical management training topics during its annual Continuing Medical Education (CME) every four years.

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ABBREVIATIONS

DEA	Drug Enforcement Administration
FAM	Foreign Affairs Manual
FSHP	Foreign Service health practitioner
FSMP	Foreign Service medical provider
GSO	General Services Officer
HU	Health Unit
MED	Office of Medical Services
OIG	Office of Inspector General
RMO	Regional Medical Officer

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