Report No. DODIG-2015-183

HALLETTETTETTELLE



INSPECTOR GENERAL

U.S. Department of Defense

SEPTEMBER 30, 2015



Evaluation of DoD's Force Health Protection Measures During Operation United Assistance

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Results in Brief

Evaluation of DoD's Force Health Protection Measures During Operation United Assistance

September 30, 2015

Objective

Our evaluation was intended to assist the Department of Defense by ensuring the health and well-being of all personnel deployed during Operation United Assistance. The numerous endemic diseases of West Africa presented a force health protection threat to all deployed personnel. We examined the force health protection measures used to protect against malaria, yellow fever, food and water borne illnesses, Ebola virus disease, and other illnesses and injuries. Our evaluation also supported the Department of Defense's efforts to maintain the public's trust in preventing the inadvertent transmission of these diseases in the United States.

This report's findings and recommendations will impact DoD's future capability to respond to similar infectious disease epidemics.

Findings

We identified three findings:

First, the Department of Defense's policies on the transportation and treatment of known or suspected highly contagious patients were incongruent with the capabilities that DoD created for Operation United Assistance. This disconnect between policy and capability will place the training and sustainment of these capabilities at risk for future operational requirements.

Second, there are conflicting clinical laboratory requirements for the storage of blood products from patients who have been diagnosed with highly contagious

Findings (cont'd)

diseases, such as Ebola virus. These conflicting requirements could jeopardize the hospital's accreditation status with one or more of the U.S. laboratory-certifying agencies.

Third, we found an inequitable disbursement of family separation allowance for those Service members who were required to spend 21 days physically separated from their families following their deployment to Ebola virus endemic regions of West Africa. Individuals who were returned to their permanent station did not receive family separation allowance, while those who were not at their permanent station did receive the allowance.

Recommendations

We recommend the Department of Defense conduct a comprehensive requirements review to identify the enduring capabilities required to transport and treat highly contagious patients. We also recommend that the Department of Defense issue guidance that clarifies how clinical laboratories transfer or destroy patient samples that contain highly contagious diseases. Finally, we recommend that the Department of Defense take appropriate steps to address the inequitable disbursement of family separation allowance when unusual operational requirements prevent routine reintegration.

Management Comments and Our Response

We received comments from the Director, Defense Health Agency, Deputy Assistant Secretary of Defense for Military Personnel Policy, and the Acting Assistant Secretary of Defense for Homeland Defense and Global Security. The Director, Defense Health Agency and the Acting Assistant Secretary of Defense for Homeland Defense and Global Security concurred with recommendations. The Deputy Assistant Secretary of Defense for Military Personnel Policy non-concurred with the recommendation.

We request the Acting Under Secretary of Defense for Personnel and Readiness provide additional information in response to Recommendation 3. These comments are required by October 30, 2015.

Recommendations Table

Management	Recommendations Requiring Comment	No Additional Comments Required
Under Secretary of Defense for Policy	N/A	1
Under Secretary of Defense for Personnel and Readiness	3	N/A
Assistant Secretary of Defense (Health Affairs)	N/A	2

Please provide Management Comments by October 30, 2015.



INSPECTOR GENERAL DEPARTMENT OF DEFENSE 4800 MARK CENTER DRIVE ALEXANDRIA, VIRGINIA 22350-1500

September 30, 2015

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE FOR POLICY UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Evaluation of DoD's Force Health Protection Measures During Operation United Assistance (Report No. DODIG-2015-183)

We are providing this report for review and additional comment. This report relates to the overseas contingency operation, Operation United Assistance. It was completed in accordance with the OIG's oversight responsibilities, as described in Section 8L of the Inspector General Act of 1978, as amended. We conducted this assessment from November 2014 to August 2015 in accordance with the "Quality Standards for Inspections and Evaluations," published in January 2012 by the Council of Inspectors General on Integrity and Efficiency.

This report is the first of two reports that Special Plans and Operations will release on force health protection during Operation United Assistance. This report includes three findings and recommendations for DoD that are relevant to current policy, legislation, and force health protection measures. While this report examined force health protection during Operation United Assistance, these findings and recommendations have implications for the Department during similar operations in the future. The second report will focus on future planning considerations, or lessons learned, that do not require changes to legislation, policy, or doctrine.

We considered management comments to a draft of this report when preparing the final report. The comments provided from the Office of the Under Secretary of Defense for Policy and the Office of the Assistant Secretary of Defense (Health Affairs) addressed the specifics of the recommendations and no additional comments are required. We request the Acting Under Secretary of Defense for Personnel and Readiness provide additional comments to Recommendation 3 in response to the final report. Your comments should describe what action you have taken or plan to take to accomplish the recommendation and include the completion dates of your actions. Please send copies of documentation supporting the actions you may have already taken.

DoD Instruction 7650.03 requires that recommendations be resolved promptly. Please send a PDF file containing your comments to <u>SPO@dodig.mil</u>. Copies of your comments must have the actual signature of the authorizing official for your organization. We cannot accept the /Signed/ symbol in place of the actual signature. If you arrange to send classified comments electronically, you must send them over the SECRET Internet Protocol Router Network (SIPRNET). We should receive these comments by October 30, 2015.

will provide a formal briefing on the results if management requests.

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Kenneth P. Moorefield Deputy Inspector General Special Plans and Operations

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Introduction

Introduction

The most recent African Ebola Virus outbreak began in December 2013 in Guinea, but was not recognized and reported by the government of Guinea until March 2014. It has been the largest outbreak of Ebola virus disease (EVD) in history and the first in West Africa - concentrated in Liberia, Sierra Leone, and Guinea.

As of June 24, 2015, there were nearly 27,500 cases and more than 11,000 deaths related to this outbreak throughout the world. This epidemic has killed more people than all previous EVD epidemics combined.





Source: Armed Forces Health Surveillance Center [AFHSC]

On August 8, 2014, the Director-General of the World Health Organization (WHO) declared the EVD outbreak in West Africa a Public Health Emergency of International Concern (PHEIC). The WHO called exposure of healthcare workers to the Ebola virus, "an alarming feature of this outbreak." As of June 24, 2015, 514 healthcare workers had died from EVD.

The United Nations initiated the UN Mission for Ebola Emergency Response (UNMEER) on September 19, 2014. UNMEER had five priorities known by the acronym STEPP: 1) Stop the outbreak, 2) Treat the infected, 3) Ensure essential services, 4) Preserve stability, and 5) Prevent further outbreaks.

On September 16, 2014, President Obama announced a major increase in the U.S. response to the crisis in Liberia, Sierra Leone, and Guinea. The White House issued a fact sheet that detailed the extent of the proposed whole-of-government response to the epidemic. The President designated the U.S. Agency for International Development (USAID) as the lead in the Ebola response effort with the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services, U.S. Public Health Service, DoD, and other government agencies in a supporting role.

In support of the USAID-led effort, DoD directed U.S. Africa Command¹ (USAFRICOM) to initiate Operation United Assistance (OUA). Initial DoD resource commitments to OUA included a request to Congress to reprogram \$500M and commit approximately 3,000 personnel to this effort. On November 17, 2014, DoD Office of the Inspector General (OIG) announced this project to evaluate DoD Force Health Protection (FHP) measures applied during OUA.

Objective

The objective of our evaluation of FHP measures taken during OUA was to:

- 1. Identify policy, programs, and logistics requirements for FHP measures that applied to DoD military, civilian, and contractor personnel.
- 2. Identify any gaps between FHP requirements and implementation that applied towards policy, programs, logistics, and healthcare delivery.
- 3. Recommend FHP improvements.

Our evaluation was intended to assist DoD by ensuring the health and well-being of all personnel deployed during OUA. The numerous endemic diseases of West Africa presented a FHP threat to all deployed personnel. We examined the FHP measures used to protect against malaria, yellow fever, food and water borne illnesses, EVD, and other illnesses and injuries. Our evaluation also supported DoD's efforts to maintain the public's trust in preventing the inadvertent transmission of these diseases in the United States.

¹ USAFRICOM is the geographic combatant command assigned responsibility for DoD activities and operations on the African continent and its littoral regions.

Scope

This evaluation's scope examined the policies, processes, and implementation of all DoD FHP measures. These FHP measures included antimalarial prophylaxis, field and waste sanitation, and OUA specific pre-deployment training. Particular attention was given to the education and training measures intended to protect against EVD. Our scope included pre-deployment, deployment, and postdeployment measures for all military and DoD civilian personnel who were engaged in OUA.

Background

The Defense Intelligence Agency's National Center for Medical Intelligence (NCMI) issued its first medical alert on the EVD outbreak in Guinea on March 25, 2014. This initial report coincided with the CDC's initial report. Both of these reports were based on the report (issued by Guinea's Ministry of Health) of 86 confirmed cases of EVD, which included 59 fatalities, in four districts of Guinea.

DoD organizations, agencies, and the military Services began monitoring the situation in West Africa as the outbreak grew in magnitude and spread into the neighboring countries of Sierra Leone and Liberia. Some military units and individuals who deployed to the affected region during this time received Ebola virus-specific education and preventive measure training. Throughout the spring and summer of 2014, NCMI continued to monitor and issue updates and alerts regarding the EVD outbreak in West Africa.

Staff from USAFRICOM briefed the emerging threat to its leadership and supporting commands on July 29, 2014. At the time, USAFRICOM did not have an assigned mission related to the EVD outbreak. However, its staff recommended an internal review of their Pandemic Flu/Infectious Disease Containment Plan.

On July 30, 2014, NCMI issued a report citing significant resource and security challenges facing health care workers in West Africa. Additionally, this report classified the outbreak as a sub-regional epidemic and not a pandemic.²

² According to Essentials of Epidemiology in Public Health, Second Edition, (Aschengrau & Seage, 2008,) a pandemic is, "worldwide epidemics involving millions of people."

Operation United Assistance

As illustrated in Figure 2, in August and September of 2014, the EVD outbreak in West Africa markedly increased in the three most affected countries. During this time, the greatest increase in cases occurred in Liberia.

In early September 2014, Secretary of Defense Hagel approved a Department of State request to deploy and establish an expeditionary hospital for the express purpose of creating an EVD treatment facility for health care workers in Liberia.



Figure 2. Ebola Virus Disease Outbreak in Liberia, Sierra Leone, and Guinea Over Time

The Joint Staff issued a Secretary of Defense approved execute order on September 15, 2014, which directed USAFRICOM and other DoD elements to support the U.S. Government response to the EVD epidemic. This execute order named USAFRICOM as the supported command; and U.S. European Command, U.S. Northern Command, U.S. Transportation Command, the Defense Logistics Agency, and the Defense Threat Reduction Agency as supporting commands.

President Obama announced the United States' whole-of-government response to the EVD epidemic in West Africa on September 16, 2014. While, the majority of the activities announced by the President were focused on Liberia, it did include some activities and efforts in the neighboring countries of Sierra Leone and Guinea.

USAFRICOM published orders for OUA following the President's announcement. USAFRICOM identified four lines of effort in support of the U.S. Government and international efforts. These lines of effort were: USAID support, training support, engineering support, and logistics support. In addition to these lines of effort, USAFRICOM also identified six key tasks:

1. Establish a Joint Force Command - United Assistance (JFC-UA) in order to provide command and control (C2) of military activities and coordination with U.S. Government interagency and international relief efforts.

Source: DoD OIG based on data from WHO and CDC

- 2. Establish an intermediate staging base in West Africa designed to facilitate and expedite the flow of personnel, equipment, and supplies into the affected area of West Africa. (USAFRICOM selected Dakar, Senegal for this intermediate staging base)
- 3. Establish engineering capabilities in Liberia to provide site selection and construction in support of validated USAID requests.
- 4. Establish training base(s)/site(s) and mobile training teams in Liberia capable of training up to 500 health care support personnel per week.
- 5. Deploy/employ capabilities to protect personnel, equipment, facilities, and infrastructure.
- 6. Be prepared to protect U.S. personnel and facilities in the event of civil unrest.

Of note, USAFRICOM prohibited deployed DoD medical personnel and organizations from providing direct medical treatment for non-DoD EVD patients. However, it did authorize DoD personnel to provide health care for DoD personnel, including cases of suspected or confirmed EVD exposure.

USAFRICOM directed U.S. Army Africa (USARAF), stationed in Vicenza, Italy, to provide the initial DoD presence in Liberia, and to coordinate with the other U.S. Government agencies and entities. USARAF selected key locations suitable for the operations and logistics of the follow-on forces, and established the conditions for the flow and receipt of DoD equipment and supplies. The USARAF Commanding General and elements of his staff arrived in Monrovia on September 16, 2014, to initiate OUA operational activities.

Additionally, USAFRICOM directed USARAF to transition the mission and OUA activities to the Army's 101st Airborne Division following its arrival from the United States. Elements of the 101st Airborne Division Headquarters began arriving in Liberia on October 20, 2014 and assumed the JFC-UA mission on October 25, 2014.

Given the nature of the mission in West Africa, DoD employed a wide range of capabilities and organizations. Some units and capabilities included:

- the Kentucky National Guard's 123rd Contingency Response Group deployed on October 5, 2014, and established an intermediate staging base in Dakar, Senegal,
- a total of three clinical laboratories supported by the Defense Threat Reduction Agency (DTRA) were established in Liberia, Sierra Leone, and Guinea to improve each nation's capacity for testing patient blood samples for EVD, and

• the Marine Corps' Special Purpose Marine Air-Ground Task Force-Crisis Response, based in Moron, Spain, deployed on October 9, 2014, with four MV-22 tilt-rotor aircraft and provided the initial tactical mobility in Liberia.





Source: AFHSC

- the Air Force's 633rd Medical Group deployed on September 26, 2014, to Monrovia, Liberia, and constructed a deployable tactical hospital, known within the Air Force as an Expeditionary Medical Support System,
- the Navy's Construction Battalion 133, provided some of the initial engineering capability required for the site selection and construction of the Monrovia Medical Unit, the Health Care Training Center, and the Ebola Treatment Units,
- a total of six mobile laboratories, two from the Navy and four from the Army, deployed to Liberia and provided on-site testing of patient blood samples for EVD,

In addition to these tactical assets, DoD also employed strategic lift assets in the form of U.S Transportation Command's Air Mobility Command and the Military Sealift Command. These two organizations moved DoD personnel, equipment, and supplies: they also moved material for other U.S. Government departments, agencies, and international partners when authorized.

Accomplishments:

During OUA, DoD contributed to the whole-of-government response across its declared mission's four lines of effort (USAID support, logistics support, training support, and engineering support). Specifically DoD:

- completed 59 requests for direct support to USAID and the international community through the Mission Tasking Matrix (MiTaM) process,
- provided engineering support (horizontal construction, vertical construction, site preparation, and road improvement) in Liberia and Senegal, and
- accomplished other support as depicted in Figure 4.

Figure 4. OUA Accomplishments



Source: DoD Public Affairs

Operation ONWARD LIBERTY

DoD transitioned follow-on and close-out requirements from OUA into Operation Onward Liberty in April 2015. The 101st Airborne Division transferred command responsibility to the Army's 48th Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) Brigade. Commensurate with this transfer of authority and the downsizing of the mission from a Joint Force Command, the brigade assumed responsibility as Tactical Command Post-Operation United Assistance (TAC-OUA). TAC-OUA's mission was two-fold: to monitor the fight against EVD in Liberia in order to advise USARAF on the potential need for increased DoD support, and to conduct theater close-out logistics tasks. The 48th CBRNE Brigade performed this mission until June 9, 2015, when it returned to Fort Hood, Texas. DoD concluded its support to USAID's EVD response efforts in West Africa when the 48th CBRNE Brigade redeployed to the United States.

Noteworthy Achievements

Disease and Non-Battle Injuries

Liberia has one of the highest infectious disease risks in the world. There is a high risk for malaria, dengue fever, yellow fever, diarrheal diseases, Hepatitis A, and Typhoid. All of these diseases had the potential to significantly degrade military mission performance.

For example, in August 2003, the Marine Corps deployed 225 Marines to Roberts International Airport outside of Monrovia, Liberia. They spent 10 days at the airport living in an abandoned warehouse in an austere environment. Within 25 days of this deployment, 80 of the 225 Marines had developed a fever. Forty-four Marines were medically evacuated to military medical centers for treatment; this was about 20 percent of the deployed unit. The subsequent investigation revealed that less than half of the 44 evacuated Marines used insect repellent, none used bed netting, and adherence to the antimalarial medication regimen was low. This comparable military experience indicated the significant medical threat to be faced in Liberia.





Source: DoD IG

In comparison, there were over 2,500 Service members deployed in support of OUA from all four Services at its peak. The 101st Airborne Division, serving as the JFC-UA, reported that only 21 Service members required medical evacuation. They also reported five Service members displayed malaria symptoms post-deployment, which was only 0.2 percent of the deployed force.

Interviewed military leaders stated that the OUA pre-deployment medical threat briefing was comprehensive; discipline on the use of bed nets was maintained throughout the deployment; and command messaging reinforced preventive medicine vigilance. Several leaders suggested that the concern regarding EVD helped to focus Service members on all medical threats and contributed to their low rate of illness.

Medical Treatment Facilities Response

On September 30, 2014, an EVD case was diagnosed in Dallas, Texas, which was the first EVD case diagnosed in the United States. This patient had traveled to the United States from Liberia approximately ten days prior, and had not displayed any EDV symptoms prior to leaving West Africa. This patient had initially been treated and discharged from a Dallas area hospital emergency department, before returning to the hospital and being diagnosed with EVD. Subsequently, two Dallas-based health care workers involved in treating the first patient were diagnosed with EVD. As a result, the CDC director responded, "We have to rethink the way we address Ebola infection control, because even a single infection is unacceptable."

On November 7, 2014, the Chairman of the Joints Chiefs (CJCS) released a CJCS Instruction directing the establishment of seven "controlled monitoring areas" (CMA) to provide a 21-day medical monitoring period for all military personnel returning from OUA. The intent of this 21-day monitoring was to prevent the introduction of EVD into communities following the return of DoD personnel from West Africa. The CJCS Instruction also required a CMA to transfer any symptomatic person from the CMA location to the "nearest medical facility capable of detecting, protecting against transmission, isolating, and treating EVD." If the symptomatic person tested positive for EVD, the CJCS Instruction required they be transferred to a hospital with bio-containment care. DoD directed four military medical centers to develop the capability to treat EVD patients in a quarantine environment. On November 25, 2014, the Joint Staff designated William Beaumont Medical Center in Texas (Army), Portsmouth Naval Medical Center in Virginia (Navy), Wright-Patterson Medical Center in Ohio (Air Force), and Walter Reed National Military Medical Center in Maryland (Defense Health Agency) as these four military medical centers.

Furthermore, the Joint Staff order on November 25, 2014, required all military treatment facilities "to be able to identify, isolate, and protect potential Ebola patients and arrange evacuation to an ... Ebola treatment facility."

As a result, U.S. military treatment facilities developed the capability to isolate, treat, and if necessary, evacuate a patient with EVD. Some military treatment facilities proactively developed an EVD response plan prior to the November 25, 2014, Joint Staff order. The medical staffs at several of these facilities anticipated the need to treat a symptomatic patient because Service members had deployed to West Africa from those installations/bases.

The 10 DoD military treatment facilities/hospitals visited during this evaluation (listed in Appendix A) conducted mission analysis based on its facility, staff, and population at risk. The physical layout of each hospital was different (for example, the age and size of each facility varied) which prevented a standardized approach. However, each hospital performed its own mission analysis to account for these variations in developing its unique plan. Some of these hospitals had to make minor construction changes to the hospital facility, such as adding antechambers for doffing/donning of Personal Protective Equipment (PPE) or installing observation windows in patient rooms.



Likewise, the staffing at each hospital was unique. The number of available staff and specialties of the providers varied. Some military treatment facilities were community hospitals or clinics with no infectious disease physicians and limited numbers of intensive care nurses; others were large medical centers with not only infectious disease physicians and intensive care nurses, but also critical care physicians and other medical and nursing subspecialists.

Some military treatment facilities also assessed their patient population to identify Service members, family members, and other beneficiary groups that might be at higher risk for exposure to EVD. For example, at least one military base had special operations forces that could have personnel deployed to the West Africa region. Many military bases recognized that there were family members from West Africa that might have recently traveled to the region. Therefore, the hospitals' mission analysis included each of these groups and developed a comprehensive strategy to identify and respond to suspected infectious disease patients.

The hospitals also identified the PPE requirements for their hospital based on their mission analysis and conducted initial and sustainment training. Some of the hospitals used components from their on-hand PPE intended for treating patients exposed to hazardous substances/chemicals. The hospitals also had to purchase the remainder of their PPE to meet the requirements identified in their mission analysis (for example, number of days of supply and sizes).

Ultimately, all 10 of the military treatment facilities that we visited developed detailed, site-specific standard operating procedures for screening, isolating, treating, and possibly transferring suspected EVD patients. These standard operating procedures addressed all aspects of patient care, from arrival at the hospital until discharge. They had comprehensive plans that addressed logistics, biomedical maintenance, waste disposal, housekeeping/room cleaning, etc. The staff at each of the 10 facilities rehearsed and revised these procedures over time.

Finding 1

DoD Policies were Incongruent with DoD-Developed Capabilities for Transporting and Treating Contagious Patients

DoD developed a capability to transport and treat known or suspected highly contagious patients. However, U.S. Transportation Command policy restricted the movement of highly contagious patients within the patient movement system. Similarly, DoD did not have detailed guidance on Ebola virus disease treatment at military treatment facilities.

At the start of Operation United Assistance, DoD policy did not address the transportation and/or treatment of known or suspected highly contagious Service members, such as those who may have been exposed to Ebola virus disease.

The capabilities to transport and treat known or suspected highly contagious patients that DoD developed are placed at risk for use in future military operations. DoD policy does not support programming decisions and related funding for sustainment and training of these capabilities. Loss of these capabilities may place the force health protection of Service members at risk in future infectious disease outbreaks.

Applicable Criteria

- Secretary of Defense Memorandum, subject "Transportation Policy Delegation of Authority for Movement of DoD Personnel Potentially Exposed to Ebola While Supporting Operations in West Africa," dated January 8, 2015
- Chairman of the Joint Chiefs of Staff Memorandum, subject "DoD Capabilities to Transport American Citizens Exposed to the Ebola Viral Disease," dated August 4, 2014
- U.S. Transportation Command Memorandum, subject "Policy for Patient Movement of Contaminated Contagious or Potentially Exposed Casualties," dated March 14, 2008

Discussion

Patient Movement

A March 2008 U.S. Transportation Command (USTRANSCOM) memo stated: "Patients with known or suspected highly contagious diseases will not be transported within the patient movement system." It stated that approximately two patients could be moved in "extreme circumstances" only with prior approval from the geographic combatant commanders, Commander USTRANSCOM, and the Secretary of Defense. It further stated that "treatment in place" is the preferred alternative to patient movement.

On August 4, 2014, the CJCS sent a letter to the Secretary of Defense outlining DoD's capability to transport American citizens who have been exposed to EVD. The Chairman explained, "DoD policy states we do not transport contaminated or contagious patients." He pointed out that DoD is not equipped or trained to conduct this type of patient movement. He further stated, "If tasked, DoD can accomplish this mission at significant risk."

On September 16, 2014, however, USTRANSCOM submitted a Joint Urgent Operational Needs Statement to develop an airborne patient isolation system. Working in conjunction with the Defense Threat Reduction Agency, USTRANSCOM developed the system requirements. The Joint Program Manager for Protection from the Joint Program Executive Office for Chemical and Biological Defense served as the lead program office responsible for developing, fielding, and sustaining this system.



Figure 7. Transport Isolation System Source: Fayetteville Observer

By December 2014, the Transport Isolation System (TIS) had completed operational testing and received its initial airworthiness certificate. The Secretary of Defense issued a memorandum delegating authority for using DoD aircraft to transport DoD personnel who were EVD exposed or symptomatic on January 8, 2015. The system reached initial operational capability on January 22, 2015. Yet, the March 2008 TRANSCOM policy restricted transportation of known or suspected highly contagious patients.

Medical Treatment Facilities

As discussed in the Noteworthy Achievement section of this report, the military health system built EVD response capability at its military treatment facilities. However, DoD did not issue specific guidance on how to accomplish this EVD response capability. They issued general guidance to provide the capability to "identify, isolate, quarantine, evacuate and/or treat potential EVD patients." The CDC reviewed the plans for the four military medical centers designated to treat EVD patients, and the CDC only provided recommended improvements to the military medical center's plans. Yet, DoD policy did not specify the exact capabilities (that is, clinical laboratory, dialysis, etc.) that these medical centers, and other military treatment facilities, were required to establish and maintain.

Conclusion

DoD developed a capability to transport and treat known or suspected infectious patients, a capability that required significant time, labor, and money to develop. This capability, developed for EVD patients, has positively affected the medical care provided to other infectious disease patients (for example, tuberculosis).

Having developed this EVD response capability, DoD should make a deliberate decision on the sustainment of this capability. Lacking DoD guidance, the Services and the hospitals are allocating resources on something that may (or may not) be a DoD priority. For example, the July/August edition of "Healthcare Executive" reported that North Shore LIJ, a 19-hospital network in New York, spent \$12 million to train and equip their staff on EVD response. While DoD does not track expenditures in exactly the same manner, it is reasonable to assume that DoD has spent a significant amount on the EVD transportation and treatment mission. These resource-allocating decisions have significant implications on the funding, staffing, and productivity of hospitals; and on the sustainment and training for the TIS. Furthermore, DoD procured and issued diagnostic and other medical capabilities to units (both deployable and non-deployable) that will require sustainment funding and maintenance. Therefore, a comprehensive review of requirements is necessary to facilitate policy development and, subsequently, prioritize funding for those capabilities determined to be essential to DoD.

Recommendation, Management Comments, and Our Response

Recommendation 1

Under Secretary of Defense for Policy conduct a comprehensive review of DoD requirements related to the transport and treatment of known or suspected highly contagious patients (for all types of infectious diseases) and facilitate policy development across DoD. This policy review should, at a minimum, address:

- movement of known or suspected highly contagious patients,
- treatment requirements for known or suspected highly contagious patients,
- clinical laboratory requirements, and
- maintenance and training requirements to sustain the patient movement, treatment, and laboratory capabilities.

Under Secretary of Defense for Policy Comments

The Acting Assistant Secretary of Defense for Homeland Defense and Global Security, responding for the Under Secretary of Defense for Policy, concurred with the recommendation. The Acting Assistant Secretary of Defense provided an August 10, 2015 memorandum from the Deputy Secretary of Defense directing DoD to "maintain for one year certain policies for health surveillance, personal protective equipment, medical treatment, and patient transport..." He stated that his office is collaborating with Joint Requirements Office to initiate a Capabilities-based Assessment "to study DoD's requirements for operating in an infectious disease environment."

The Acting Assistant Secretary of Defense also provided a November 7, 2014 memorandum from the Department of State that authorizes DoD to use the Department of State's contracted capabilities for conducting medical evacuation of personnel who are suspected of having been exposed to Ebola virus.

Our Response

Comments from the Acting Assistant Secretary of Defense for Homeland Defense and Global Security addressed all specifics of the recommendation. We commend the Department for its rapid response to the recommendation, and the thorough Capabilities-based Assessment approach.

We also commend the Department for its work with the Department of State to utilize an existing contract to obtain a capability to medically evacuate DoD patients safely from West Africa to meet an urgent operational requirement.



Finding 2

Conflicting Requirements for Clinical Laboratories

Leaders in clinical laboratories were uncertain what rules applied to maintaining blood samples known to contain Ebola virus.

The Assistant Secretary of Defense (Health Affairs) did not publish guidance to the Services or the National Capital Region Medical Directorate.

Hospitals with the capability to perform clinical laboratory testing on specimens containing select agents or toxins (such as Ebola virus) would have had to violate policy on select agents or toxins in order to meet laboratory-accreditation organizations' guidance and requirements. Alternatively, by following current policy, the hospital would violate the requirements of the laboratory-accrediting agencies and risk loss of their accreditation.

Applicable Criteria

- Section 42 of the Code of Federal Regulations part 73, Select Agents and Toxins (42 CFR 73)(2015)
- Section 42 of the Code of Federal Regulations part 493 Laboratory Requirements (42 CFR 493)(2011)
- Department of Defense Instruction number 6440.02, Subject: Clinical Laboratory Improvement Program (CLIP), dated May 29, 2014
- United States Army Medical Command, policy memorandum subject: Handling Instruction for Select Agents and toxins Isolated by Clinical/Diagnostic Laboratories from Specimens Presented for Diagnosis or Verification, dated September 8, 2009

Discussion

There are no approved treatments or antiviral medications for EVD. However, blood transfusions from recovered EVD patients have been used during previous EVD outbreaks. In June 1995, eight patients in Kikwit, Democratic Republic of the Congo received blood transfusions from five donors. This group of eight had a lower mortality rate (12.5 percent) than the overall case fatality rate (80 percent). Most recently, several patients in the United States reportedly received blood plasma from one of the first American patients from the West Africa outbreak. This type of transfusion is typically performed in an accredited hospital with an accredited clinical laboratory. DoD policy on clinical laboratory accreditation required the Military Departments to monitor accreditation agency inspection results for their respective laboratories, and to "initiate or recommend enforcement procedures" when appropriate. The Military Departments are responsible to revoke the certification of military laboratories "whose actions significantly endanger patient safety."

Clinical laboratories in DoD can be accredited by one of several approved accreditation organizations for laboratories.³ The College of American Pathologists, one of the accreditation organizations for clinical laboratories, required that pre-transfusion blood samples from a patient be held for at least seven days. The American Association of Blood Banks, another accreditation organization, required that "any red-cell-containing component" used in a transfusion be refrigerated for seven days. This allows the hospital to compare pre- and post-transfusion blood samples to identify any hemolytic transfusion reaction, which can be life threatening.

42 CFR § 73.7 prohibits nonregistered entities or individuals from possessing, using, or transferring any select agents or toxins.⁴ One of the few exemptions for nonregistered entities in the CFR applies to clinical laboratories possessing a specimen for diagnosis or verification purposes. 42 CFR § 73.5 requires that these laboratories must transfer or destroy that specimen within seven calendar days after identification as a select agent or toxin. The clinical laboratory may transfer the specimen to a registered entity in accordance with the procedures outlined in 42 CFR § 73.16.

Conclusion

Clinical laboratories are allowed to possess a specimen that contains a select agent or toxin for up to seven calendar days (three calendar days for Army clinical laboratories) for the purpose of diagnostics of the select agent or toxin before they are required to either destroy that specimen or transfer it to registered entity. After the diagnosis has been performed, the clinical laboratory is prohibited from possessing, using, or transferring any specimen that contains a select agent or toxin unless the Health and Human Services (HHS) Secretary authorizes an exception under 42 CFR § 73.5.

Therefore, it would not be permissible for any clinical laboratory that is not a registered entity to maintain a blood specimen for purposes of treatment by transfusion that contains a select agent or toxin, like Ebola virus, without obtaining an authorized exception.

³ Approved accreditation organizations for laboratories are "a private, nonprofit accreditation organization that has formally applied for and received... approval based on the organization's compliance" with 42 CFR § 493.1.

⁴ The Health and Human Services Secretary issues certificates of registration in accordance with 42 CFR § 73.1.

While no Service members tested positive for EVD, several were admitted into hospital isolation wards because they had a fever.⁵ These patients were tested for EVD. Had any of these patients been EVD-positive, the hospital would have been faced with deciding which requirement to violate.

Recommendation, Management Comments, and Our Response

Recommendation 2

Assistant Secretary of Defense (Health Affairs) clarify policy for the destruction or transfer of patient samples that contain select agents or toxins in DoD clinical laboratories.

Assistant Secretary of Defense (Health Affairs) Comments

The Director, Defense Health Agency (DHA), responding for the Assistant Secretary of Defense (Health Affairs), concurred with comments on the recommendation. The Director stated, the DHA will, "issue guidance to the Surgeons General of the military Departments regarding the specimen retention requirements."

The Director, DHA disagreed that clinical laboratory accreditation would be placed at risk if the laboratory failed to retain a specimen for seven days. The DHA's Director, Center for Laboratory Medicine Services, and the Program Manager, Operational Laboratory Policy and Programs, queried the clinical laboratory accrediting organizations. These organizations stated that a specimen could be destroyed if the reason for destruction was adequately documented, retained, and, "available for review by an inspector during the laboratory's next accreditation inspection."

Our Response

Comments from the Director, DHA addressed the specifics of the recommendation. We request that DHA provide us a copy of the guidance provided to the Surgeons General of the Military Departments.

⁵ A fever is considered one of the early symptoms of EVD. DoD Policy required anyone returning from West Africa who had a fever be hospitalized until two separate clinical laboratory tests show no sign of EVD.



Finding 3

Inequitable Disbursement of Family Separation Allowance

Service members in the mandatory 21-day controlled monitoring did not uniformly receive Family Separation Allowance.

DoD policy required all Service members who were deployed to an Ebola virus outbreak area to remain physically separated from their families during the 21-day controlled monitoring period.

United States Code authorized Family Separation Allowance payments for Service members *only* when away from the permanent station.

Service members assigned to controlled monitoring at their permanent station did not receive Family Separation Allowance, while Service members assigned to controlled monitoring at a location other than their permanent station did receive such an allowance.

Applicable Criteria

- Section 427, title 37, United States Code, Family Separation Allowance, (37 U.S.C. § 427 [2010]), paragraphs (a)(1)(c)
- Department of Defense Financial Management Regulation, (DoD 7000.14-R), Volume 7A Chapter 27, updated August 2013
- Chairman of Joint Chiefs of Staff Instruction 4200.01A, Post-Deployment Policy for 21-Day Controlled Monitoring of DOD Service Members and Civilian Employees Returning from Ebola Virus Disease Outbreak Areas in West Africa, dated December 17, 2014

Discussion

Family Separation Allowance (FSA) provides compensation to Service members when they are required to be away from their families. This compensation is for any additional expenses incurred by the family resulting from the Service member being away from home. It is paid after 30 days of enforced separation at a rate of \$250 per month (or pro-rated to \$8.33 per day for periods less than one month). Title 37 of United States Code allows for the payment of FSA when a Service member is away from their "permanent station." DoD policy required all Service members returning from an Ebola endemic region to spend 21 days in a "controlled monitoring area (CMA)." According to the CJCS, this requirement provided a "prudent and conservative approach to address the growing concerns within our military families and local communities." The December CJCS Instruction established seven CMA locations in the United States and Europe:

- 1. Fort Bliss, El Paso, Texas,
- 2. Joint Base Langley-Eustis, Hampton, Virginia,
- 3. Fort Hood, Killeen, Texas,
- 4. Fort Bragg, Fayetteville, North Carolina,
- 5. Joint Base Lewis-McCord, Tacoma, Washington,
- 6. U.S. Army Garrison Baumholder, Germany, and
- 7. Caserma Del Din, Vicenza, Italy.

The CJCS Instruction expressly prohibited personnel in the CMA from "having physical contact with family members and the general population."



Source: Fayetteville Observer

Conclusion

Service members received FSA depending on where they conducted controlled monitoring. Some served their 21-day CMA time at a location away from their permanent station and received FSA. Others had to serve their 21-days at a CMA located at their permanent station and did not receive FSA. Therefore, there was an inequitable disbursement of FSA since all Service members were restricted from being with their family members but some Service members did not receive the allowance.

Recommendation, Management Comments, and Our Response

Recommendation 3

Under Secretary of Defense for Personnel and Readiness conduct an analysis to identify viable remedies for preventing inequitable disbursement of Family Separation Allowance when operational requirements prevent timely reintegration at the permanent station. If no viable remedy is identified, then initiate a legislative change proposal that provides Family Separation Allowance waiver authority when it would be inequitable to deny the allowance to the Service member because of unusual operational circumstances.

Under Secretary of Defense for Personnel and Readiness Comments

The Deputy Assistant Secretary (Military Personnel Policy), responding for the Under Secretary of Defense for Personnel and Readiness, non-concurred and requested the recommendation be withdrawn. The Deputy Assistant Secretary stated, "the Department correctly complied with statutory requirements for paying FSA." He further stated that the Joint Staff and operational commanders were informed of the policy and implications prior to controlled monitoring. The Deputy Assistant Secretary also expressed concern that this finding falls outside the scope of the evaluation, and that "payment of FSA is not a force health protection measure..."

Our Response

Comments from the Deputy Assistant Secretary (Military Personnel Policy) did not address the specifics of the recommendation. The Office of the Inspector General acknowledges that the Department fully complied with the statute, 37 U.S.C. § 427, the implementing instruction, DoDI 1340.24, as well as the applicable Financial Management Regulation (FMR), DoD 7000.14-R, Volume 7A, Chapter 27. However, the Deputy Assistant Secretary did not comment on the Inspector General's finding that this compliance resulted in inequitable disbursements of FSA based on an operational requirement that may not have been envisioned by the proponents of the statute, the instruction, or the regulation.

During our assessment, several interviewees stated their belief that those military members negatively impacted by this implementation were treated unfairly. We believe that an equitable FSA disbursement may have improved the effectiveness of OUA and will improve similar contingency operations in the future. Members undertaking arduous, unaccompanied, humanitarian or peacekeeping operations necessitating controlled monitoring periods at their permanent station upon their return should receive FSA for the entire period of the operation, including the controlled monitoring period. This will remove a significant disincentive associated with such assignments.

The Deputy Assistant Secretary stated in his response that operational commanders were made aware of this statutory limitation. However, the fact that a senior operational commander requested an exception to allow disbursement of FSA to Service members while in controlled monitoring at their permanent station indicates that an operational commander believed this limitation was inequitable.

As to the Deputy Assistant Secretary's concern that the finding and recommendation may be outside the scope of our evaluation, our finding and recommendation directly relate to the effectiveness of a DoD program. As such, they are within the IG's overall mandate, as stated in §2 (2) of the IG Act, as amended, as well as the DoD OIG's first performance goal to recommend policies designed to promote economy, efficiency, and effectiveness in the administration of DoD programs. Additionally, they are within the scope of this particular evaluation because controlled monitoring was implemented as a force health protection measure, "to address the growing concerns within our military families and local communities." Therefore, inequitable disbursement of FSA, which was a direct result of a mandated force health protection measure, falls within the scope of this evaluation.

To be entitled to FSA, § 427(a)(1)(C) of U.S.C. title 37 requires that a member be on temporary duty away from their permanent station for a continuous period of more than 30 days and that their dependents not reside at or near the member's temporary duty station. Sections (a)(1)(A) and (a)(1)(B) contain similar provisions for members transferring to a new permanent duty station or serving duty aboard a ship "not near" or "away from" their dependents. However, FMR Volume 7A, Chapter 27, contains many provisions by which military members, already entitled to FSA, find themselves at or near their dependents and continue to receive FSA without violating the letter or the spirit of 37 U.S.C. §427(a). These include members who are on board ships, in hospitals, in confinement, and even stationed within local commutes as little as 1.5 hours from their dependents' residences. In all these situations, the members may or may not be physically very close to their dependents. The key factor appears to be that the members are "away" because they are unable to cohabitate or otherwise reintegrate with their dependents. For example, see DoD 7000.14-R, Chapters 270203, 27301 A. 2, 27304 A. 5, 27304 C, and Table 27-4, Rules 2, 3, and 7.

While none of these chapters apply specifically to the controlled monitoring situation, all show examples of the Department defining "not near" and "away from" in manners ensuring FSA entitlement when it is needed. In addition, the Department may consider making revisions that clarify the terms of a temporary duty, extended tour, or permanent change of station to include periods of controlled monitoring to ensure FSA entitlement.

Pursuant to Paragraph 5. a. (3) of DoDI 1340.24, it is the responsibility of the Principal Deputy Under Secretary for Personnel and Readiness (PDUSD (P&R)) to, "direct that changes be made as necessary to Volume 7A of DoD 7000.14-R." Accordingly, we request that the Acting Under Secretary for Personnel and Readiness reconsider the response provided on his behalf of the Deputy Assistant Secretary and review the provisions of DoD 7000.14-R (FMR) Volume 7A, Chapter 27, as well as any other applicable instructions and regulations, and determine if revisions ensuring FSA eligibility for members undergoing post-deployment controlled monitoring at their permanent station may be practicable. If it is determined that this is not practicable due to the restrictions of 37 §U.S.C. 427 (a), we again recommend that a legislative change proposal be initiated to ensure equitable disbursement of FSA, thereby improving the effectiveness of operations similar to OUA in the future.


Appendix

Scope and Methodology

We conducted this assessment from November 2014 to August 2015 in accordance with the Council of Inspectors General on Integrity and Efficiency, "Quality Standards for Inspections and Evaluations," January 2012. We planned and performed the assessment to obtain sufficient and appropriate evidence to provide a reasonable basis for our observations and conclusions, based on our assessment objectives.

This assessment focused on policy, programs, and logistics requirements for FHP measures associated with OUA. The scope of this project included analyzing and evaluating the implementation of FHP policies, programs, and measures across the DoD enterprise, beginning with pre-deployment training and concluding with post-deployment medical monitoring and record keeping documentation. Additionally, the assessment observed training, plans, and FHP measures associated with U.S. military treatment facilities that were required to develop the capability to isolate, treat, and, if necessary, evacuate a patient with EVD.

This assessment did not address policies, programs, or FHP implementation measures, procedures, or practices of non-DoD U.S. Government departments or agencies, partner nations, international, or non-governmental organizations operating within or in cooperation with Operation United Assistance. Medically technical areas beyond the scope of this project include internationally recognized medical standards, procedures, and testing protocols; diagnosis and determination of patient infection (Ebola or other diseases); training syllabus requirements for Ebola healthcare workers (HCW); hands-on and practical application of Ebola HCW training; established medical standards, and protocols for Ebola and other infectious diseases of West Africa; and any host nation, CDC, or state-imposed controlled monitoring requirements for any non-DoD personnel, specifically contractors, or DoD civilians who chose not to participate in a DoD controlled monitoring program.

During the course of this assessment, we collected and reviewed publications from the Centers for Disease Control and Prevention (CDC), The World Health Organization (WHO), DoD directives and instructions, and relevant civilian and military literature on EVD. We also reviewed policies and procedures collected from stakeholders through data calls, site visits, interviews, and briefings to the DoD OIG. We visited or contacted individuals who participated in or informed OUA and DoD's role in the EVD response at various installations, including but not limited to the following:

- Joint Base Lewis-McCord, Washington Madigan Army Medical Center and Controlled Monitoring Area;
- Fort Bragg, North Carolina Womack Medical Center and Controlled Monitoring Area;
- Joint Base Langley-Eustis, Virginia USAF Hospital Langley and Controlled Monitoring Area;
- Naval Station Norfolk, Virginia Portsmouth Naval Medical Center;
- Fort Hood, Texas Carl R. Darnall Army Medical Center and Controlled Monitoring Area;
- Baumholder, Germany Army Health Clinic and Controlled Monitoring Area;
- Landstuhl, Germany Landstuhl Regional Medical Center;
- Bethesda, Maryland Walter Reed National Military Medical Center, and
- Dayton, Ohio Wright-Patterson Medical Center.

Combatant Commands:

- US Africa Command (Command Surgeon, PAO, J1, J3, J4, J8)
- US European Command (Command Surgeon, PAO, J3, J4, J5)
- US Northern Command (Command Surgeon, J1, J7, IG)
- US Transportation Command (Command Surgeon, IG, Judge Advocate, J5, Air Mobility Command DTRA Liaison)

US Army Component Commands:

- US Army Europe (Command Surgeon, G3, G5)
- US Army Africa (Command Surgeon, G3, G4, G8)
- US Army Medical Material Command Europe

Defense Agency meetings:

- Defense Threat Reduction Agency
- Defense Logistics Agency
- US Army Medical/Installation Commands
 - Installation Management Command (Executive Officer, G3)
 - US Army Medical Command (G3, G4)
 - Western Region Medical Command

- Southern Region Medical Command
- Northern Region Medical Command
- US Army Dental Command

101st Airborne Division:

- **J-1**
- **J-2**
- J-3/5/7
- **J-4**
- **J-8**
- Division Surgeon
- 86th Combat Support Hospital
- Public Affairs Officer (PAO)

The assessment report chronology was:

November 17, 2014	Announced evaluation project
January-February 2015	Research and fieldwork in the U.S.A.
March 2015	Fieldwork in Europe
April-June 2015	Continued fieldwork in the U.S.A.
July-August 2015	Analysis and report writing
August 6, 2015	Draft assessment report issued
September 3, 2015	Management comments received and evaluated
September 30, 2015	Report published

Limitations

The assessment team was not able to visit West Africa during Operation United Assistance due to the critical mission of troops on the ground. The team also did not see the CMA locations in Germany or Italy while they were inhabited by troops.

Use of Computer-Processed Data

No computer processed data was included in this evaluation.

Use of Technical Assistance

No technical assistance was required in this evaluation.

Prior Coverage

During the last 5 years, the Government Accountability Office (GAO) and the DoD Office of the Inspector General (DoD OIG) issued three reports discussing this subject. Unrestricted GAO reports can be accessed over the Internet at <u>http://www.gao.gov</u>. Unrestricted DoD OIG reports can be accessed at <u>http://www.dodig.mil/pubs/index.cfm</u>.

GAO

GAO-07-696, "Influenza Pandemic: DoD Combatant Commands' Preparedness Efforts Could Benefit from More Clearly Defined Roles, Resources, and Risk Mitigation," June 2007

GAO-12-722, "World Health Organization: Reform Agenda Developed, but U.S. Actions to Monitor Progress Could be Enhanced," July 2012

DoD OIG

DODIG-2015-147, "U.S. Army Contracting Command–Rock Island Needs to Improve Contracting Officer's Representative Training and Appointment for Contingency Contracts," July 10, 2015

Management Comments

Under Secretary of Defense for Policy

ASSISTANT SECRETARY OF DEFENSE 2600 DEFENSE PENTAGON WASHINGTON, D.C. 20301-2600 4 105 SEP MEMORANDUM FOR INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE SUBJECT: Evaluation of DoD's Force Health Protection Measures During Operation United Assistance Thank you for the opportunity to comment on the proposed report, "Evaluation of DoD's Force Health Protection Measures During Operation United Assistance." We concur with your proposed Finding 1, stating that DoD policies were incongruent with DoD-developed capabilities for transporting and treating contagious patients. The Deputy Secretary of Defense issued a memorandum (TAB A) on August 10, 2015 directing DoD to maintain for one year certain policies for health surveillance, personal protective equipment, medical treatment, and patient transport related to the Ebola response. In support of the Deputy Secretary's memorandum, Homeland Defense and Global Security is collaborating with the Joint Requirements Office to initiate a Capabilities-based Assessment (CBA) to study DoD's requirements for operating in an infectious disease environment. We expect that the CBA will be initiated no later than September 24, 2015, and that an interim progress report will be published in late March 2016. Tom Atkin Acting Attachments: As stated

Under Secretary of Defense for Policy (cont'd)



Under Secretary of Defense for Policy (cont'd)

Further, I direct the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) to ensure that a capability is retained, through commercial resources and in a Defense Health Agency military treatment facility, to treat EVD-infected DoD personnel.

Finally, I direct that the heads of the DoD Components address promptly whether any further DoD guidance or authorities related to EVD should be rescinded, modified, or extended beyond the termination of the OUA mission.

As these steps provide only interim measures to retain the Department's capability to operate in an EVD environment, I direct that the Chairman of the Joint Chiefs of Staff, utilizing the Joint Capabilities Integration Development System, initiate an assessment within 45 days of this memo of the Department's future requirements to mitigate the risk to DoD personnel operating in an environment where there may be risk of contracting an infectious disease of operational concern, including during defense support of civil authorities, humanitarian assistance, disaster response, and combat operations. An interim progress report will be due 180 days after initiation of the assessment.

MC

Attachments:

TAB A – Selected Tasks from the OUA Transition Execute Order (February 26, 2015) to be continued by Commander, U.S. Transportation Command, and the Defense Health Agency TAB B – USD(P&R) memo: Pre-Deployment, Deployment, and Post-Deployment Training, Screening, and Monitoring Guidance for DoD Personnel Deployed to Ebola Outbreak Areas - Change 1, October 31, 2014

TAB C – Assistant Secretary of Defense for Health Affairs (ASD(HA)) memo: EVD Patient Evaluation Guidance for DoD Medical Personnel, October 17, 2014

TAB D – USD (P&R) memo: Civilian Personnel Guidance for Medical Care for DoD Civilians Deployed to Ebola Outbreak Areas, November 7, 2014

TAB E – ASD(HA) memo: Personal Protective Equipment for DoD Military Treatment Facility Healthcare Workers Assessing or Caring for EVD Patients and Others Possibly Exposed to Ebola Virus, November 7, 2014

TAB F – Guidance Concerning International Military Visitors and International Military Students Traveling From or Through Ebola-affected Countries, March 16, 2015

2

Under Secretary of Defense for Policy (cont'd)



Under Secretary of Defense for Personnel and Readiness



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE 4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

SEP 1 2015

MEMORANDUM FOR DEPUTY INSPECTOR GENERAL FOR SPECIAL PLANS AND OPERATIONS

SUBJECT: Response to Department of Defense-Inspector General Report "Evaluation of DoD's Force Health Protection Measures During Operation UNITED ASSISTANCE (Project No. D2015-D00SPO-0080.000)."

This memorandum provides the Office of the Deputy Assistant Secretary of Defense for Military Personnel Policy's response to the recommendations from the subject draft report.

Recommendation #3: "Under Secretary of Defense for Personnel and Readiness conduct an analysis to identify viable remedies for preventing inequitable disbursement of Family Separation Allowance when operational requirements prevent timely reintegration at the permanent duty station. If no viable remedy is identified, then initiate a legislative change proposal that provides Family Separation Allowance waiver authority when it would be inequitable to deny the allowance to the Service member because of unusual operational circumstances."

Response: Non-concur. Family Separation Allowance (FSA) is authorized by 37 U.S.C. §427. A member is entitled to FSA if the member is on temporary duty away from the permanent duty station for a continuous period of more than 30 days and the member's dependents do not reside at or near the temporary duty location. Members deployed for more than 30 days for Operation UNITED ASSISTANCE and who were separated from their dependents received FSA. This was the qualifying event that prompted payment of FSA. During the controlled monitoring period of Operation UNITED ASSISTANCE, those members who met the statutory requirements to receive FSA were continued to be paid, and those who returned to their permanent duty station were not. As a result, the Department correctly complied with statutory requirements for paying FSA. Prior to the controlled monitoring, Operational Commanders and the Joint Staff were made aware of the policy and implications of this decision on members' compensation.

The Office of the Assistant Secretary of Defense for Manpower and Reserve Affairs is also concerned that FSA falls outside of the scope of the evaluation. As stated in your August 5, 2015, cover memo to the report, the objective was to examine the force health protection measures for those deployed for Operation UNITED ASSISTANCE. Also in your letter, force health protection is defined as, "measures [that] promote and sustain a healthy and fit force, prevent injury and illness, protect the force from health hazards and deliver the best possible medical and rehabilitative care to the sick and injured anywhere in the world." The payment of FSA is not a force health protection measure, and we are concerned that this recommendation was made by examiners whose expertise in military compensation policy and FSA, in



Assistant Secretary of Defense (Health Affairs)



Assistant Secretary of Defense (Health Affairs) (cont'd)

DEPARTMENT OF DEFENSE OFFICE OF THE INSPECTOR GENERAL DRAFT REPORT – DATED AUGUST 5, 2015 PROJECT NO. D2015-D00SPO-0080.000 "EVALUATION OF DOD'S FORCE HEALTH PROTECTION MEASURES DURING OPERATOIN UNITED ASSISTANCE"

DEPARTMENT OF DEFENSE COMMENTS TO THE RECOMMENDATIONS

<u>RECOMMENDATION 2</u>: Assistant Secretary of Defense for Health Affairs (ASD(HA)) clarify policy for the destruction or transfer of patient samples that contain select agents or toxins in Department of Defense (DoD) clinical laboratories.

DHA RESPONSE:

Concur, <u>but an ASD(HA)-level clarification of policy is not needed for resolution of Finding 2</u>. The Center for Laboratory Medicine Services of the Defense Health Agency (DHA) oversees and administers the clinical laboratory accreditation program for all DoD clinical diagnostic laboratories. Therefore, in lieu of an ASD(HA) policy action, we propose that the Director, DHA, per direction of the ASD(HA), issue guidance to the Surgeons General of the military Departments regarding the specimen retention requirements. This guidance would be used until a change in the Federal Select Agent Program (FSAP) regulation is issued.

We agree with the DoD Inspector General (DoDIG) report that the College of American Pathologists (CAP) and American Association of Blood Banks (AABB) clinical laboratory accreditation standards for specimen retention differ from the FSAP's "7-day transfer or destroy" requirement for an Ebola virus disease specimen.

However, we disagree with the DoDIG report that a laboratory's resolution of the difference would necessarily risk the laboratory's accreditation. According to the CAP and AABB, a laboratory could, with appropriate documentation of the action taken, transfer or destroy such a patient/recipient specimen prior to the accreditation standard specimen retention time due to the safety concerns/risks associated with retaining such a specimen (e.g., one containing Ebola virus select agent, see Parts 1 and 2). A laboratory would maintain the documentation of the action taken in its quality assurance records, which would be available for review by an inspector during the laboratory's next accreditation inspection.

Additionally, the FSAP indicated that the "7-day transfer or destroy" requirement will be addressed in a forthcoming select-agent-regulations Notice of Proposed Rulemaking expected this fall (See Part 3).

Consequently, we believe an ASD(HA) "clarification of policy" is not required for resolution of this finding. We propose the DHA issue guidance to the military Departments, for the Service Surgeons General to pass to their respective laboratory officer communities, that would detail the CAP- and AABB-compliant actions that could be taken to remain compliant with FSAP regulatory requirements and CAP/AABB accreditation standards for specimen retention.

Assistant Secretary of Defense (Health Affairs) (cont'd)





Acronyms and Abbreviations

AFHSC	Armed Forces Health Surveillance Center
CBRNE	Chemical, Biological, Radiological, Nuclear, and Explosives
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CJCS	Chairman of Joint Chiefs of Staff
CLIP	Clinical laboratory Improvement Program
СМА	Controlled Monitoring Area
C2	Command & Control
DHA	Defense Health Agency
DTRA	Defense Threat Reduction Agency
EVD	Ebola Virus Disease
FHP	Force Health Protection
FSA	Family Separation Allowance
HCW	Healthcare Worker
HHS	Health and Human Services
JFC-UA	Joint Force Command-UNITED ASSISTANCE
MiTaM	Mission Tasking Matrix
NCMI	National Center for Medical Intelligence
OUA	Operation UNTIED ASSISTANCE
ΡΑΟ	Public Affairs Officer
PHEIC	Public Health Emergency of International Concern
PPE	Personal Protective Equipment
TAC-OUA	Tactical Command Post-Operation UNITED ASSISTANCE
TIS	Transportation Isolation System
UNMEER	United Nation's Mission for Ebola Emergency Response
USAFRICOM	United States Africa Command
USAID	United States Agency for International Development
USARAF	United States Army Africa
USTRANSCOM	
WHO	World Health Organization



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