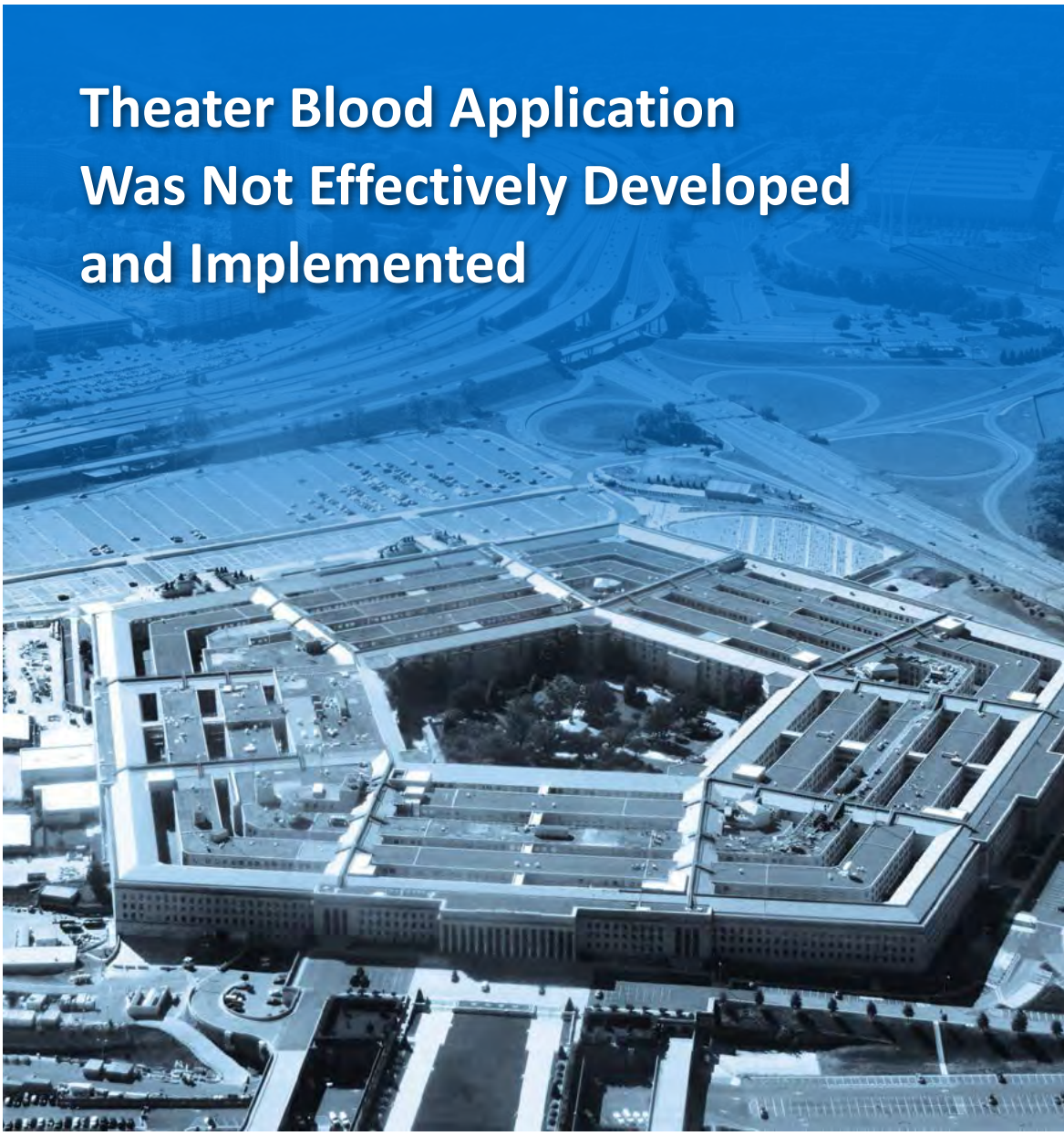
Report No. DODIG-2015-150

INSPECTOR GENERAL

U.S. Department of Defense

JULY 17, 2015

Theater Blood Application Was Not Effectively Developed and Implemented



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Results in Brief

Theater Blood Application Was Not Effectively Developed and Implemented

July 17, 2015

Objective

Our objective was to determine whether management effectively developed and implemented the Theater Blood Application to meet the needs of the warfighter.

Finding

The Program Executive Officer for the Defense Health Clinical Systems did not effectively develop and implement the Theater Blood Application. This occurred because the Program Executive Officer did not:

- establish policies and procedures to manage the requirements for its medical information systems;
- develop a long-term strategy to sustain a blood tracking capability in theater; and
- adequately train users as required in the Implementation Strategy and Deployment Plan.

The Program Executive Officer delivered an interim capability that improved the deployed warfighter's ability to track the theater blood inventory. However, the capability may not align with the initial requirements identified by users, and the warfighter is at risk of operating without a tool to adequately track the theater blood inventory.

Recommendations

Among others, we recommend that the Program Executive Officer for the Defense Healthcare Management Systems coordinate with the:

- Defense Health Agency to ensure policies and procedures to manage future requirements for medical information systems are documented, reviewed, and updated as necessary;
- Defense Health Agency and Military Departments to develop a long-term strategy and not invest additional money in the continued development of the Theater Blood Application until it can determine the application's sustainability; and
- Military Departments to develop policies and procedures for training requirements and establish and implement a program to ensure users receive initial training prior to deployment, followed by refresher training.

Management Comments and Our Response

Comments from the Program Executive Officer addressed all the specifics of the recommendations, and no further comments are required. Based on management comments, we revised Recommendation 1. Please see the Recommendations Table on the back of this page.

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Recommendations Table

Management	Recommendations Requiring Comment	No Additional Comments Required
Program Executive Officer, Defense Healthcare Management Systems		1, 2, 3.a, 3.b, 4

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

July 17, 2015

MEMORANDUM FOR PROGRAM EXECUTIVE OFFICER, DEFENSE HEALTHCARE MANAGEMENT SYSTEMS

SUBJECT: Theater Blood Application Was Not Effectively Developed and Implemented (Report No. DODIG-2015-150)

We are providing this report for information and use. The Program Executive Officer did not effectively develop and implement the Theater Blood Application. The Program Executive Officer delivered an interim capability that improved the deployed warfighter's ability to track the theater blood inventory. However, the capability may not align with initial requirements identified by users, and the warfighter is at risk of operating without a tool to adequately track the theater blood inventory. We conducted this audit in accordance with generally accepted government auditing standards.

We considered management comments on a draft of this report when preparing the final report. Based on management comments, we revised Recommendation 1. Comments from the Program Executive Officer for the Defense Healthcare Management Systems conformed to the requirements of DoD Instruction 7650.03; therefore we do not require additional comments.

We appreciate the courtesies extended to the staff. Please direct questions to me at (703) 604-9077 (DSN 664-9077).

Jacqueline L. Wicecarver

Jacqueline Wicecarver
Assistant Inspector General
Acquisition, Parts, and Inventory

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Introduction

Objective

Our objective was to determine whether management effectively developed and implemented the Theater Blood Application to meet the needs of the warfighter. See Appendix A for scope, methodology and prior coverage.

Background

According to the Armed Services Blood Program Office (ASBPO), the Armed Services Blood Program (ASBP) provides quality blood products for Service members, veterans, and their families during peace and wartime. As a joint operation among the Military Departments and combatant commands, ASBP has many components that work together to collect, process, store, distribute, and transfuse blood worldwide.

The ASBPO manages the blood program for the DoD under the authority of the Secretary of Defense through the Assistant Secretary of Defense for Health Affairs and under the operational control of the Joint Chiefs of Staff. According to a DoD Joint Publication,[1] ASBPO coordinates the day-to-day activities of ASBP in accordance with the plans, programs, standards, and procedures established by the DoD, Chairman of the Joint Chiefs of Staff, Military Departments, and the combatant commands.

The Defense Health Agency (DHA) was established October 1, 2013, and is the centerpiece of Military Health System governance reform, as outlined in a memorandum by the Deputy Secretary of Defense.[2] DHA's mission is to achieve greater integration of direct and purchased health care delivery systems to accomplish its four objectives: achieve medical readiness, improve the health of its people, enhance the experience of care, and lower its healthcare costs.

DHA assumed management responsibility for the shared services, functions, and activities of the Military Health System including health information technology, medical logistics, acquisition, and other common clinical and business processes. Within DHA, the Program Executive Officer (PEO) for Defense Health Clinical Systems (DHCS) supports health care operations through the design, development, test, evaluation, and deployment of medical information systems.

[1] Joint Publication 4-02, "Health Service Support," July 26, 2012.

[2] Deputy Secretary of Defense Memorandum, "Implementation of Military Health System Governance Reform," March 11, 2013.

In a memorandum, the Under Secretary of Defense for Acquisition, Technology, and Logistics[3] outlined the transfer of DHA's management responsibility for the activities of the Military Health System. According to the memorandum, a new joint program management office under the PEO for the Defense Healthcare Management Systems (DHMS) would provide centralized activities in support of a common operating software baseline for the Military Health System.

Theater Blood Tracking

We identified in a report[4] from 2001 that before the 1990s, DoD manually maintained the records of theater-blood-product inventory. Manual inventory tracking resulted in inconsistent availability of blood supplies, collection overages, and expired blood units. In 1999, DoD deployed the Theater Defense Blood Standard System (TDBSS), a laptop-based software developed to support blood program organizations that primarily have wartime missions. However, according to PEO DHCS, TDBSS was never fully deployed because it had maintenance and compliance problems that made it operationally unstable.

The Military Departments identified hardware and software problems when TDBSS was deployed, which were further identified in our report from 2001. According to the report, the Military Departments did not plan to provide TDBSS capability at all readiness-related facilities that handle blood products. In addition, the blood program offices did not ensure the implementation of TDBSS was standardized throughout DoD and did not adequately oversee the implementation of the TDBSS hardware and software. ASBPO and the Military Departments responded to our 2001 report stating that TDBSS was developed as an interim solution until the Theater Medical Information Program (TMIP)[5] was deployed.

As a result of the problems with TDBSS, beginning in 2002, the Army, Navy, and Air Force began to manually record theater-blood-product inventory, donation, and transfusion information in Excel spreadsheets. Individual spreadsheets were compiled and consolidated into one very large, complex spreadsheet. This system to track blood products was time-consuming and required manual manipulation that resulted in data-entry errors.

Since DoD was still in need of an automated mechanism for blood-product tracking in theater, it continued to work on a solution to automate inventory tracking for its blood products. Military Health System leaders and the Services replaced TDBSS with the Theater Blood Application in 2011.

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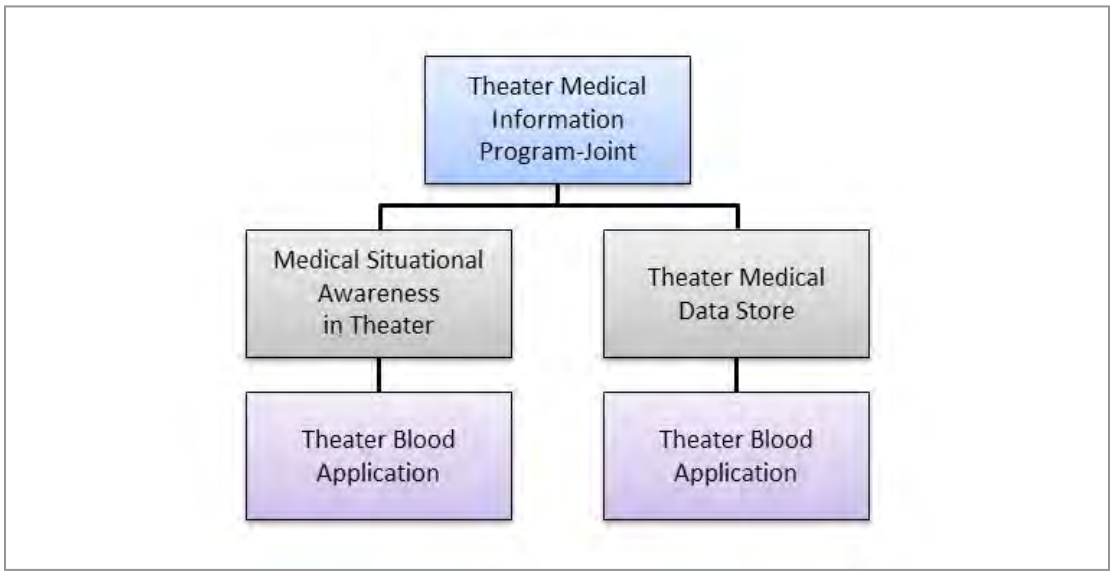
[3] Under Secretary of Defense for Acquisition, Technology, and Logistics memorandum, "Theater Medical Information Program – Joint and Defense Medical Information Exchange Acquisition Decision Memorandum," December 23, 2014.

[4] DoD OIG Report No. D-2002-010 "Armed Services Blood Program Defense Blood Standard System," October 22, 2001.

[5] TMIP is a medical information system that integrates data from existing systems and provides medical logistics information to deployed medical forces. TMIP later became a "joint" program and is now referred to as TMIP-J.

The Theater Blood Application enhances the Theater Medical Data Store (TMDS) and the Medical Situational Awareness in Theater (MSAT) applications. TMDS and MSAT are web-based applications in the Theater Medical Information Program-Joint (TMIP-J), which allows deployed medical forces to view patient health records. Figure 1 details the relationship of the Theater Blood Application within TMIP-J.

Figure 1. Theater Medical Information Program-Joint



On September 28, 2008, a contract was awarded[6] to Akimeka for a ceiling price of $23.6 million for the first year plus 2 option years. The scope of the contract was to consolidate TMDS and MSAT applications with a blood management tool. The contract was modified in September 2011 to further enhance the functionality of the blood management tool, which was named the Theater Blood Application.

Theater Blood Application

The Theater Blood Application is a blood management tool used to track the inventory of blood products in theater including, but not limited to, donations and transfusions. It is primarily used by military medical personnel in U.S. Central Command. As of October 29, 2014, the Theater Blood Application was deployed at 27 user sites in U.S. Central Command. The Theater Blood Application streamlines blood reporting by providing the capability to identify and track blood products by donation identification number. Users can process and track blood product shipments and receipts, generate inventory reports, and manage blood

[6] Contract order number W81XWH-08-F-0997.

product inventory. According to PEO DHCS officials and users, the Theater Blood Application reduces the time formerly experienced by users who manually track blood product information.

Review of Internal Controls

DoD Instruction 5010.40, "Managers' Internal Control Program Procedures," May 30, 2013, requires DoD organizations to implement a comprehensive system of internal controls that provides reasonable assurance that programs are operating as intended and to evaluate the effectiveness of the controls. We identified internal control weaknesses in the PEO DHCS's development and implementation of the Theater Blood Application. We will provide a copy of the report to the senior officials responsible for internal controls at PEO DHCS.

Finding

Theater Blood Application Was Not Effectively Developed and Implemented

PEO DHCS did not effectively develop and implement the Theater Blood Application. This occurred because PEO DHCS did not:

- establish policies and procedures to manage the requirements for medical information systems;
- develop a long-term strategy to sustain a blood tracking capability in theater; and
- adequately train users as required in the Implementation Strategy and Deployment Plan.

The PEO DHCS delivered an interim capability that improved the deployed warfighter's ability to track the theater blood inventory. However, the capability may not align with initial requirements identified by users, and the warfighter is at risk of operating without a tool to adequately track the theater blood inventory.

Policies and Procedures Were Not Established

Documented policies and procedures were not in place during the development of the Theater Blood Application.

PEO DHCS did not establish policies and procedures to manage the requirements for medical information systems. Specifically, PEO DHCS did not have documented policies and procedures in place during the development of the Theater Blood Application, which was part of the TMIP-J medical information system. PEO DHCS officials explained that in March 2007, they created a flowchart that detailed the process to develop, review, and approve the requirements for medical information systems. See Appendix B for the process flowchart.

PEO DHCS officials also stated that although the flowchart was informal and not incorporated into their policies and procedures, it was followed to develop the Theater Blood Application. However, PEO DHCS officials did not provide evidence to support that they followed the process during the Theater Blood Application development. For example, the flowchart shows that the Force Health Protection Council approves the requirements package for technical and functional requirements, submitted by the Theater Functional Working Group. However, the meeting minutes from the Theater Functional Working Group did not record that

the requirements package was approved. PEO DHCS officials stated that due to personnel turnover, they could not provide evidence that the requirements package was approved.

In August 2010, PEO DHCS officials documented their process in the Defense Health Information Management System (DHIMS)[7] Requirements Development and Management Plan. This plan established their process that was used to develop and manage the requirements to acquire, build, deploy, and maintain information technology solutions. This plan described the process to evaluate user needs, develop requirements, and manage requirement changes. The process was further outlined in a DHIMS Acquisition Verification and Validation Plan as well as supplemental standard operating procedures for project origination, execution, monitoring and control. Although PEO DHCS documented the process in 2010 before the Theater Blood Application was released in 2011, they stated that the process was not used to develop and implement the Theater Blood Application.

Inconsistent Requirements

Officials did not establish policies and procedures to develop and manage requirements for medical information systems.

Because PEO DHCS officials did not establish policies and procedures to develop and manage requirements for medical information systems, there was no clear connection from the user needs to the awarded contract. The January 1996 TMIP mission needs statement identifies the need to track blood in theater. In addition, the November 2007 TMIP-J Capabilities Production Document (production document) identifies high-level requirements to manage theater-blood-products. The production document states that TMIP-J shall provide information management capabilities to support blood management, ensure a safe blood supply, and meet the demands for blood and blood products.

According to PEO DHCS officials, U.S. Central Command identified the specific requirements to track blood in theater. These requirements were included in Appendix E of a December 2007 draft version of the Office of the Assistant Secretary of Defense for Health Affairs, Concept of Operations (CONOPS) document for theater integration. The CONOPS document included six high-level requirements for managing and reporting blood in theater:

- manage blood inventory data and reporting;
- electronically import or scan multiple blood products into a system simultaneously;

[7] In April 2013 Defense Health Information Management System Program Office was reorganized into three Program Management Offices under the PEO DHCS.

- electronically import or scan and track all blood product information simultaneously into a single, globally visible system;
- track blood product by patient and populate the Joint Theater Trauma Registry;
- track blood product by unit; and
- monitor non-Food and Drug Administration Blood Product Testing.

The CONOPS document also identified over 400 specific requirements related to blood product inventory management and reporting. However, PEO DHCS official stated the document was not approved due to their need to focus on higher priorities.

In addition to the CONOPS not being approved, PEO DHCS officials input specific user needs into their requirements management database, which was used to capture, track, and manage requirements. However, the user needs shown in the database were not consistent with those identified in the CONOPS document. For example, the officials included the user need to calculate the age of blood products at the time of a transfusion. However, this requirement was not identified in the CONOPS document.

Further, PEO DHCS officials provided a traceability matrix, which documented the contractor's clarification of the requirements used in the development of the Theater Blood Application. However, the requirements shown in the matrix were not consistent with those shown in the CONOPS document. For example, the matrix included the requirement to enter an expiration date for each unit of red blood cells. However, this requirement was not shown in the CONOPS document. The inconsistencies between the CONOPS document, requirements management database, and the traceability matrix increased the risk that the Theater Blood Application capabilities may not align with the user requirements.

The DHIMS Program Management Office is required to annually review and approve, or more frequently as required, the plan[8] and its standard operating procedures. However, there was no evidence that PEO DHCS updated the plan or the standard operating procedures. The initial lack of established policies and procedures, and the failure to review, update, and follow policies and procedures established in 2010, prevented PEO DHCS officials from developing and managing requirements for the Theater Blood Application that aligned with the original user requirements. The PEO DHMS should coordinate with DHA and ensure that policies and procedures to manage future requirements for medical information systems are documented, reviewed, and updated as necessary.

[8] DHIMS Requirements Development and Management Plan, August 2010 and standard operating procedures established by the DHIMS Program Management Office.

No Long-Term Strategy for Theater Blood Tracking

The PEO DHCS did not develop a long-term strategy to sustain a blood tracking capability in theater. PEO DHCS officials provided supporting documentation such as the 2008 contract that identified the Theater Blood Application as an interim solution. In addition, the Joint Medical Work Station (JMeWS)[9] and TMDS plan[10] stated that the Theater Blood Application would be replaced with a commercial off-the-shelf Enterprise Blood Management System.[11] According to PEO DHCS officials, when they deploy Enterprise Blood Management System, it will provide similar capabilities as the Theater Blood Application. However, PEO DHCS officials provided a conflicting response and stated that the functional community had determined that Enterprise Blood Management System was not usable in theater. PEO DHCS officials also acknowledged that the JMeWS and TMDS Plan did not reflect the long-term strategy to provide a capability to track blood in theater.

Proposed Replacement of Healthcare Systems Poses Risk

The deployed warfighter could be at risk of operating without a tool to adequately track theater blood inventory.

Because PEO DHCS officials did not develop a long-term strategy to sustain a blood tracking capability in theater, any DoD future plans for medical information systems could affect the continued existence of the Theater Blood Application. For example, DoD has ongoing plans to replace many of its legacy health care systems. Specifically, in May 2013 DoD started to acquire an integrated inpatient and outpatient electronic health care system to replace legacy health care systems, which include most components of TMIP-J, such as MSAT and TMDS. Specifically, if these applications are replaced and another solution is not identified to track blood in theater, the deployed warfighter could be at risk of operating without a tool to adequately track theater blood inventory.

PEO DHMS officials confirmed that they are working to identify a commercial off-the-shelf solution to modernize the Military Health System. They stated that the Theater Blood Application would be affected, but they will not know how it will be affected until the development document is completed in the summer of 2015.

PEO DHMS is coordinating with DHA who is leading the effort to create the development document for theater medical information requirements. PEO DHMS is also coordinating with DHA and the Departments to develop an acquisition

[9] In 2011, JMeWS was absorbed by the MSAT application.

[10] JMeWS and TMDS Implementation Strategy and Deployment Plan, dated June 2, 2010.

[11] Enterprise Blood Management System will consist of the Blood Donor Management System and the Blood Bank Transfusion Services.

strategy, which must include a detailed transition and resourcing plan for each of the legacy service programs. PEO DHMS should continue to coordinate with DHA and the Departments to develop an acquisition strategy that includes a long-term sustainment strategy to provide a blood tracking capability in theater and not invest any additional money in the continued development of the Theater Blood Application until it can determine the application's sustainability.

Application Training and Access Needs Improvement

PEO DHCS officials did not effectively coordinate with the U.S. Army to adequately train users. In addition, the PEO DHCS did not provide users timely access to the Theater Blood Application.

Inconsistent Training

The JMeWS and TMDS Plan require the Military Departments to initiate training for all deploying units. However, training was not consistent. For example, the Army users that were interviewed in theater, did not receive formal training. Instead, users received a web link to an overview of the Theater Blood Application, or received a brief instructions or a walkthrough from an experienced user. Also, users we interviewed were not aware of any local standard operating procedures to use the Theater Blood Application.

Users we interviewed were not aware of any local standard operating procedures to use the Theater Blood Application.

Inconsistent training with no standard operating procedures could cause weak internal controls and could increase the risk of user error. PEO DHCS officials acknowledged that they did not have a standardized training plan. Instead, they relied on training in theater that was focused on generating reports and other usual actions. PEO DHCS officials also stated that at the request of the Military Departments, the Army Medical Department's Center and School would develop a separate training module as part of their blood sustainment training. According to PEO DHCS, this training would be available to all Military Departments laboratory personnel prior to deployment. However, PEO DHCS did not provide a timeline or evidence of an agreement the Army Medical Department's Center and School to develop this training module. PEO DHMS should coordinate with the Departments to develop policies and procedures for the Theater Blood Application training requirements. PEO DHMS should also coordinate with the Departments to establish and implement a training program to ensure users receive initial training prior to deployment followed by refresher training.

Timely Access Needed

Users shared log-in information to the Theater Blood Application, which violated a DoD regulation.

In addition to adequate training, users needed timely access to the Theater Blood Application. Users in theater told us, once deployed, they waited up to 1 month to gain access to the Theater Blood Application. According to the users, this delay caused multiple users to share account log-in information, which is a weakness to their internal control. In addition, sharing log-in information violates a DoD regulation.[12]

The DoD regulation states that authorized users of health information shall protect all access authenticators, such as individual identification IDs and passwords on the same level as the classification or sensitivity of the information assessed. Providing timely access will enable users to perform their duties and reduce or minimize the need to share access information. PEO DHMS officials should develop policies procedures, and implement a process to ensure users are granted access to the Theater Blood Application before deployment to the theater.

Total Development Cost Unknown

Officials could not determine the total life-cycle cost for the Theater Blood Application.

PEO DHCS officials could not determine the total life-cycle cost for the Theater Blood Application. The base contract included two contract line-item numbers for development and sustainment for TMDS and MSAT applications. Although Theater Blood Application development began after contract award, the base contract did not include a specific line-item number for Theater Blood Application development.

In September 2011, PEO DHCS officials modified the contract by adding two specific line-item numbers for Theater Blood Application. Since then, the development totaled approximately $2.7 million. Although PEO DHCS officials did not track Theater Blood Application life-cycle cost from the beginning of development, they stated that the initial development cost were included within the TMDS and MSAT development cost. It would be a best practice to track the total life-cycle cost of specific application enhancement cost to improve the overall management of the TMIP-J program.

Development and Implementation Were Not Effective

PEO DCHS delivered an interim capability that improved the warfighter's ability to track the theater blood inventory. However, the capability may not align with the initial requirements identified by users, and the warfighter is at risk of operating without a tool to adequately track the theater blood inventory. Deployed medical

[12] DoD 8580.02-R "DoD Health Information Security Regulation" July 12, 2007.

forces need a blood tracking tool to ensure accurate blood inventory, patient safety, and deliver high-quality blood products to support the warfighter. PEO DHMS official's implementation of the recommendations identified in this report will improve PEO DHMS internal controls and ensure the delivery of theater medical information systems that meet the needs of the warfighter.

Management Comments on the Finding and Our Response

Management Comments on Theater Blood Application Was Not Effectively Developed and Implemented

The PEO DHMS provided comments on the finding stating that the report implied that it is the responsibility of the PEO to "establish policies and procedures to develop and manage requirements for its medical information systems." A PEO does not develop program requirements. Per Chairman of the Joint Chiefs Staff Instruction 3170.11, it is the responsibility of the Joint Staff to develop these requirements. Specifically for the Theater Blood Application, the Theater Functional Working Group in close coordination with the Joint Staff and Combatant Commands are responsible for developing these requirements.

In addition, PEO DHMS stated that the Joint Operational Medicine Information Systems program was established to sustain the legacy operation medicine system while supporting the planning, procurement, and deployment of the replacement system. The Joint Operational Medicine program is developing a tailored acquisition strategy that will drive efficiency through a joint approach.

Our Response

As a result of management comments, we removed "develop" from the report accordingly, as it related to the development of requirements. In addition, PEO DHMS commented on the Joint Operational Medicine Information Systems program and the development of the acquisition strategy in Recommendation 2. We summarized their comments and provided our response below in Recommendation 2.

Recommendations, Management Comments, and Our Response

Revised Recommendation

As a result of management comments, we revised draft Recommendation 1 to clarify the responsibilities of the PEO DHMS. In addition, we changed who the PEO DHMS should coordinate with to develop the specific functional requirements for managing blood in theater.

Recommendation 1

We recommend the Program Executive Officer for the Defense Healthcare Management Systems coordinate with Defense Health Agency and ensure that the policies and procedures to manage future requirements for medical information systems are documented, reviewed, and updated as necessary.

Program Executive Officer for the Defense Healthcare Management Systems Comments

The PEO DHMS did not agree or disagree with the recommendation. PEO DHMS suggests deleting the word "develop" from the list of tasks attributed to PEO DHMS and replace PEO DHCS with DHA. PEO DHMS stated that DHA is the Military Health System lead to develop specific functional requirements for managing blood in theater as part of the operational medicine Capabilities Development Document (development document). According to the PEO DHMS, the functional requirements are now being developed for operational medicine under a new development document that will be approved through the Joint Capabilities Integration and Development System process later this year. PEO DHMS will use a full requirement traceability process to track requirements. PEO DHMS also recommended that Recommendation 1 and 2 be combined.

Our Response

The PEO DHMS addressed all specifics of the recommendation, and no additional comments are required. We removed "develop" from the report, and Recommendation 1. In addition, we replaced PEO DHCS with DHA; however, we did not agree to combine Recommendations 1 and 2.

Recommendation 2

We recommend the Program Executive Officer for the Defense Healthcare Management Systems coordinate with Defense Health Agency and the Military Services to develop an acquisition strategy that includes a long-term sustainment strategy to provide blood-tracking capability in theater and not invest any additional money in the continued development of the Theater Blood Application until they can determine and agree on the application's sustainability.

Program Executive Officer for the Defense Healthcare Management Systems Comments

The PEO DHMS did not agree or disagree with the recommendation; however they stated that they are developing a tailored acquisition strategy in close coordination with DHA and the Joint Staff who are working to develop the operational medicine

development document. Both the Joint Staff and DHA have been advised on the program acquisition strategy. Subsequently both the Joint Staff and DHA will be included in the Defense Healthcare Management Systems Modernization product evaluation for operational medicine so that the validated requirements from the operational medicine development document are informed of the gaps between the DoD's new Electronic Health Record product and the need of the Joint Operational Medicine Information Systems follow on capabilities for operational medicine.

Our Response

The PEO DHMS addressed all specifics of the recommendation, and no additional comments are required.

Recommendation 3

We recommend the Program Executive Officer for the Defense Healthcare Management Systems coordinate with the Military Departments to:

a. Develop policies and procedures for the Theater Blood Application training requirements.

Program Executive Officer for the Defense Healthcare Management Systems Comments

The PEO DHMS did not agree or disagree with the recommendations; however, they stated that a comprehensive Joint Development and Training Plan is currently being developed and coordinated with stakeholders within the Department. The document is currently being reviewed by the Services and will address the Joint Operational Medicine Information Systems program's deployment and training strategy. The purpose of the Joint Development and Training Plan is to codify and standardize all change management, deployment, and training across operational medicine to drive efficiencies when both the new Electronic Health Record and Joint Operational Medicine Information Systems capabilities come online to replace legacy software baselines for operational medicine.

Our Response

The PEO DHMS addressed all specifics of the recommendation, and no additional comments are required.

b. Establish and implement a training program to ensure users receive initial training prior to deployment, followed by refresher training.

Program Executive Officer for the Defense Healthcare Management Systems Comments

The PEO DHMS did not agree or disagree with the recommendation; however they stated that a comprehensive Development Training and Change Management Plan is currently being developed and will include the training strategy.

Our Response

The PEO DHMS addressed all specifics of the recommendation, and no additional comments are required.

Recommendation 4

We recommend the Program Executive Officer for the Defense Healthcare Management Systems develop policies, procedures, and implement a process to ensure users are granted access to the Theater Blood Application before deployment to the theater.

Program Executive Officer for the Defense Healthcare Management Systems Comments

The PEO DHMS did not agree or disagree with the recommendation nor did they address this recommendation as it relates to granting access. PEO DHMS stated that the Services are responsible for training and equipping their personnel before deploying to theater. The Theater Blood Application and supporting training materials are available for training prior to deployment. This recommendation should be directed to the Services medical organizations that are responsible for training their service members.

Our Response

We address in the report that the Services are responsible for training their personnel before deployment. While the PEO DHMS did not address the specifics of the recommendation as it relates to gaining access, their comments to the preceding recommendations outline the initiative to replace TMIP-J, which houses the Theater Blood Application. Based on the PEO DHMS response to the preceding recommendation; no additional comments are required.

Appendix A

Scope and Methodology

We conducted this performance audit from July 2014 through May 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

To understand the Theater Blood Application, we met with personnel from:

- DHMS;
- DHA;
- Military Health System;
- Army Office of the Surgeon General;
- Army Medical Command;
- ASBPO;
- Army Blood Program;
- Navy Blood Program; and
- Air Force Blood Program.

We met with DHMS personnel to understand the transfer of management responsibility from PEO DHCS to PEO DHMS. Because PEO DHMS assumed responsibility for the management activities of the Military Health System, we addressed the recommendations to PEO DHMS.

DHA and ASBPO personnel briefed us on historical theater blood tracking, theater blood tracking requirements, enhancements to the TMDS and MSAT applications, Theater Blood Application capabilities, and locations of the theater user sites.

To assess the development of the Theater Blood Application, we requested and obtained PEO DHCS documentation that supported its design, development, and implementation. To identify the specific requirements for the Theater Blood Application, we analyzed the:

- TMIP-J Capabilities Production Document;
- December 2007 draft of Appendix E to the Document for Theater Integration written by the Office of the Assistant Secretary of Defense for Health Affairs;
- Akimeka contract order number W81XWH-08-F-0997;

- PEO DHCS process flowchart;
- Theater Functional Working Group meeting minutes;
- requirements management database; and
- traceability matrix.

To assess the implementation of the Theater Blood Application, DHA and ASBPO provided demonstrations of the Theater Blood Application's capabilities. The demonstrations included procedures to:

- enter donations;
- manage inventory;
- ship, receive, and destroy blood product units; and
- report supply levels.

We conducted site visits and interviews at the 440th Medical Detachment–Blood Support Detachment and Craig Joint Theater Hospital in Bagram, Afghanistan. We also observed theater personnel receiving and shipping blood product units.

Use of Computer-Processed Data

We did not use computer-processed data to perform this audit.

Prior Coverage

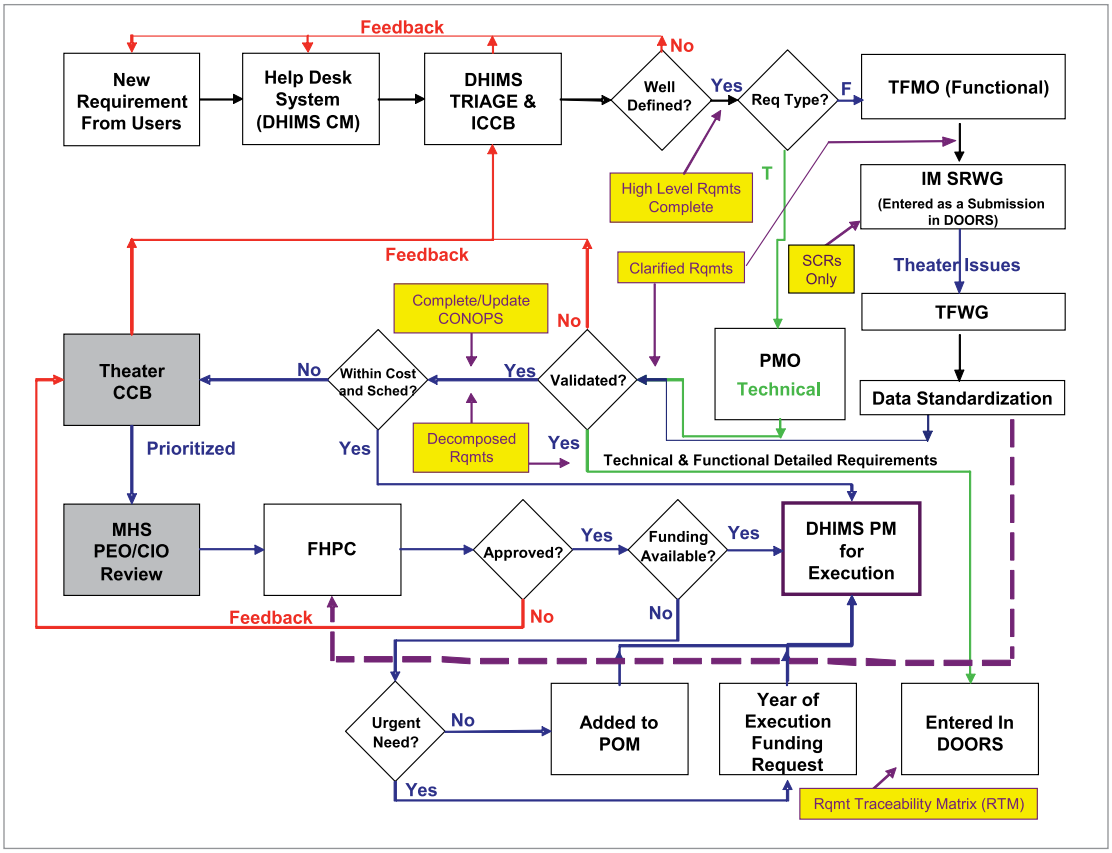
During the last 5 years, the Department of Defense Office of Inspector General (DoD OIG) issued one report related to the Theater Blood Application. Unrestricted DoD OIG reports can be accessed at http://www.dodig.mil/pubs/index.cfm.

DoD IG

Report No. DODIG-2015-008, "Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment," October 23, 2014

Appendix B

Requirements Process Flowchart



Legend

CIO	Chief Information Officer
CM	Configuration Management
DHIMS	Defense Health Information Management System Triage
DOORS	Dynamic Objective-Oriented Requirements System
FHPC	Force Health Protection Council
ICCB	Internal Configuration Control Board
IM	Information Management
MHS	Military Health System
PEO	Program Executive Office
PM	Program Manager
PMO	Program Management Office
POM	Program Objective Memorandum
RTM	Requirements Traceability Matrix
SCR	System Change Request
SRWG	Submission Review Working Group
TCCB	Theater Configuration Control Board
TFMO	Theater Functional Management Office
TFWG	Theater Functional Work Group

Management Comments

Program Executive Office Defense Healthcare Management Systems Comments

DEFENSE HEALTHCARE MANAGEMENT SYSTEMS
PROGRAM EXECUTIVE OFFICE
1700 NORTH MOORE STREET, ROSSLYN, VIRGINIA, 22209

June 19, 2015

MEMORANDUM FOR: INSPECTOR GENERAL, DEPARTMENT OF DEFENSE

SUBJECT: Management Comments, Theater Blood Application Was Not Effectively Developed and Implemented (Project No. 2014-D000AJ-0197.000)

Included with this memo are Program Executive Office Defense Healthcare Management Systems (PEO DHMS) comments regarding the recommendations presented in "Theater Blood Application Was Not Effectively Developed and Implemented (Project No. 2014-D000AJ-0197.000)."

If you have any questions, my point of contact on this audit is [redacted], who can be reached at [redacted].

Sincerely,

Christopher A. Miller
PEO DHMS

Program Executive Office Defense Healthcare Management Systems Comments (cont'd)

PEO DHMS Comments on OIG Draft Report
"Theater Blood Application Was Not Effectively Developed and Implemented" dated May 19, 2015
(Project No. 2014-D000AJ-0197.000)

There are several points within the audit that guide the recommendations, and PEO DHMS would like to offer comments on those to provide clarification and context:

- In an Acquisition Decision Memorandum (ADM) dated December 23, 2014, the Under Secretary of Defense (USD) for Acquisition, Technology, and Logistics (AT&L) transferred responsibility for the Theater Medical Information Program-Joint (TMIP-J) to the Program Executive Office (PEO) for Defense Healthcare Management Systems (DHMS). The theater blood application is one of the applications in the current TMIP-J suite. This report analyzes events which occurred from 2007-2014. All of these events predate PEO DHMS responsibility for TMIP-J. Additionally, it is implied that it is the responsibility of the PEO to "establish policies and procedures to develop and manage the requirements for its medical information systems." A PEO does not develop program requirements. Per Chairman of the Joint Chiefs Staff Instruction 3170.011, it is the responsibility of the Joint Staff to develop these requirements utilizing the JCIDS process. Outputs of the JCIDS process are used to facilitate doctrine, organization, training, material, leadership and education, personnel, facilities, and policy (DOTMLPF-P) changes. The outputs also provide validated capability requirements to drive the Defense Acquisition System (DAS) and to inform the Planning, Programming, Budgeting, and Execution (PPBE) processes. Specifically for the theater blood application, the Theater Functional Working Group in close coordination with the Joint Staff and Combatant Commands (COCOMS) are responsible for developing these requirements.

- PEO DHMS has established the Joint Operational Medicine Information Systems (JOMIS) program to sustain the legacy operation medicine system, while supporting the planning, procurement, and deployment of the modernized electronic health record and follow on theater capabilities to operational locations. Established in accordance with the ADM, dated December 23, 2014, the JOMIS program is comprised of the TMIP-J program and elements of the Medical Communications for Combat Casualty Care (MC4) Program Office, TMIP-Maritime, TMIP-Marine Corps, and TMIP-Air Force. The JOMIS program is developing a tailored acquisition strategy that will drive efficiencies through this joint approach, improve standardization across the DoD and improve care coordination between the garrison and theater operating environments.

Specific Response to Recommendations

Recommendation 1: The PEO DHMS should coordinate with PEO DHCS and ensure that policies and procedures to develop and manage future requirements for medical information systems are documented, reviewed, and updated as necessary.

Response: PEO DHMS suggests deleting the word "develop" from the list of tasks attributed to PEO DHMS and replace PEO DHCS with DHA. DHA is the Military Health System (MHS) lead to develop specific functional requirements for managing blood in theater as part of the operational medicine Capabilities Development Document (CDD). Functional requirements are now being developed for

Program Executive Office Defense Healthcare Management Systems Comments (cont'd)

operational medicine under a new CDD that will be approved through the JCIDS process later this year. PEO DHMS will track requirements via a full requirements traceability process which is currently being used for all PEO DHMS program offices. PEO DHMS recommends that this recommendation should be the first recommendation listed and should be combined with the current second recommendation to not invest additional money into the continued development of the current application.

Recommendation 2: PEO DHMS should continue to coordinate with DHA and the Departments to develop an acquisition strategy that includes a long term sustainment strategy to provide a blood tracking capability in theater and not invest any additional money in the continued development of the theater blood application until it can determine the application's sustainability.

Response: PEO DHMS is developing a tailored acquisition strategy in close coordination with DHA and the Joint Staff who are working to develop the operational medicine CDD. The JOMIS program office has advised both the Joint Staff and DHA on the program acquisition strategy. Subsequently the JOMIS program office will be including both the Joint Staff and DHA in the DHMSM product evaluation for operational medicine so that the validated requirements from the operational medicine CDD are informed of the gaps between the DoD's new Electronic Health Record (EHR) product and the need of the JOMIS follow on capabilities for operational medicine.

Recommendation 3a: PEO DHMS should coordinate with the Departments to develop policies and procedures for the theater blood application training requirements.

Response: A comprehensive Joint Deployment and Training Plan (JDTP) is currently being developed and coordinated with stakeholders within the Department. The document is currently being reviewed by the Services and will address the JOMIS program's deployment and training strategy. The purpose of the JDTP is to codify and standardize all change management, deployment, and training across operational medicine to drive efficiencies when both the new EHR and JOMIS capabilities come online to replace legacy software baselines for operational medicine.

Recommendation 3b: PEO DHMS should also coordinate with the Departments to establish and implement a training program to ensure users receive initial training prior to deployment followed by refresher training.

Response: As mentioned in 3a, comprehensive Deployment Training and Change Management Plan (DTCMP) is currently being developed and will include the training strategy.

Recommendation 4: PEO DHMS officials should develop policies procedures, and implement a process to ensure users are granted access to the theater blood application before deployment to theater.

Response: The Services are responsible for training and equipping their personnel before deploying to theater. The theater blood application and supporting training materials are available for training prior to deployment. This recommendation should be directed to the Services medical organizations that are responsible for training their service members.

Acronyms and Abbreviations

ASBP	Armed Services Blood Program
ASBPO	Armed Services Blood Program Office
CONOPS	Concept of Operations
DHA	Defense Health Agency
DHCS	Defense Health Clinical Systems
DHIMS	Defense Health Information Systems
DHMS	Defense Healthcare Management Systems
JMeWS	Joint Medical Workstation
MSAT	Medical Situational Awareness in Theater
PEO	Program Executive Officer
TDBSS	Theater Defense Blood Standard System
TMDS	Theater Medical Data Store
TMIP	Theater Medical Information Program
TMIP-J	TMIP-Joint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