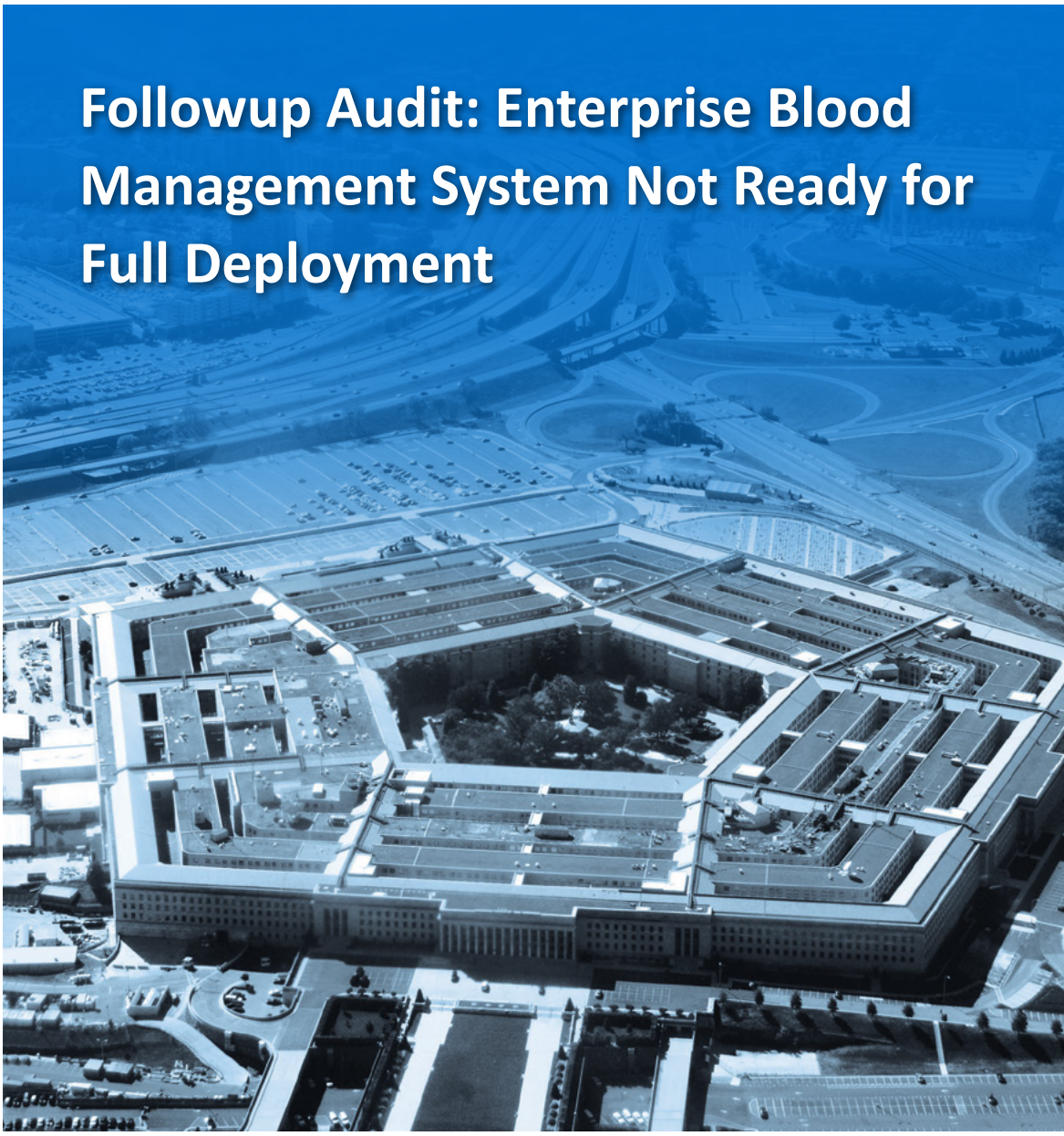
Report No. DODIG-2015-008

# INSPECTOR GENERAL

*U.S. Department of Defense*

OCTOBER 23, 2014

# Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment



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# Results in Brief

*Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment*

**October 23, 2014**

## Objective

Our objective was to determine whether the system configuration and early operational assessment for the Enterprise Blood Management System (EBMS) will meet the system requirements as agreed to in Recommendations A.4. and B.3 from DoD OIG Report No. D-2002-010, "Armed Services Blood Program Defense Blood Standard System," and whether these corrective actions intended to mitigate the identified problems.

## Findings

The Program Executive Officer for the Defense Health Clinical Systems could not demonstrate that the system design, configuration, and early operational assessment for EBMS will meet the requirements as agreed. This occurred because the Program Executive Officer was still in the early stages of the acquisition process for the donor system and did not initially require the Composite Health Care System to interface with the transfusion system. As a result, after 13 years, the Program Executive Officer's actions were not completed to show that EBMS will meet the intent of Recommendations A.4 and B.3.a. The Military Health System leaders deployed the Theater Blood capability to meet the intent of recommendation B.3.b instead of EBMS.

The Program Executive Officer planned to acquire three stand-alone DoD blood product information technology capabilities that will manage information about the donors, donations, transfusions, and blood

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### *Findings (cont'd)*

product inventories. This occurred because the Program Executive Officer and the Component Acquisition Executive for Defense Health Agency did not manage the donor, transfusion, and the Theater Blood capability as a DoD information technology portfolio. As a result, the Program Executive Officer did not achieve maximum efficiencies for the Department's blood program and is at an increased risk of not fully reaching the overall blood program's performance goals.

## Recommendations

The Program Executive Officer should continue efforts to implement corrective actions as agreed to in Recommendation A.4 and B.3.a of DoD OIG Report No. D-2002-010. The Component Acquisition Executive should evaluate how EBMS, Theater Blood capability, and any other DoD information technology blood product capabilities would benefit from being interoperable as an information technology portfolio, as required.

## Management Comments and Our Response

The Director, Defense Health Agency, responding for the Component Acquisition Executive, Program Executive Officer, and Director, Armed Services Blood Program, fully addressed all specifics of the recommendations, and no further comments are required. Please see the Recommendations Table on the back of this page.

Figure. Scanning inventory.
Source: Af.mil

## *Recommendations Table*

| Management | Recommendations Requiring Comment | No Additional Comments Required |
|---|---|---|
| Component Acquisition Executive for Defense Health Agency | | B.1, B.2, B.3 |
| Program Executive Officer for the Defense Health Clinical Systems | | A.1, A.2 |
| Director, Armed Services Blood Program | | A.1, A.2 |

**INSPECTOR GENERAL**
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4800 MARK CENTER DRIVE
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October 23, 2014

MEMORANDUM FOR DISTRIBUTION ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

SUBJECT: Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment (Report No. DODIG-2015-008)

We are providing this report for your information and use. The Program Executive Officer for the Defense Health Clinical Systems could not demonstrate after 13 years that officials implemented the necessary actions to mitigate the identified system problems as agreed. Specifically, these were interface problems with the Composite Health Care System and double counting of inventory. The Component Acquisition Executive for Defense Health Agency also did not manage the Enterprise Blood Management System or Theater Blood capability as a DoD Information Technology portfolio.

We considered management comments on the draft report when preparing the final report. Comments from the Director, Defense Health Agency addressed all specifics of the recommendations and conformed to the requirements of DoD Directive 7650.3; therefore, we do not require additional comments.

We appreciate the courtesies extended to the staff. Please direct questions to me at (703) 604-8905 (DSN 664-8905).

Amy J. Frontz
Principal Assistant Inspector General
for Auditing

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## Management Comments



## Glossary



## Acronyms and Abbreviations


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# Introduction

## Objective

Our audit objective was to determine whether the system configuration and early operational assessment for the Enterprise Blood Management System (EBMS) will meet the system requirements as agreed to in Recommendations A.4 and B.3 of DoD OIG Report No. D-2002-010, "Armed Services Blood Program Defense Blood Standard System," October 22, 2001, and whether these corrective actions intended to mitigate the identified problems.

Military Health System (MHS) leaders and the Services replaced the Theater Defense Blood Standard System (DBSS) with the Theater Blood capability instead of EBMS to meet the intent of Recommendation B.3.b. Please refer to the Appendix for additional details about our scope and methodology. Also, see the Glossary for the definition of key terms.

## Background

The Armed Services Blood Program (ASBP) is a military Services and unified Commands joint operation. The ASBP Office (ASBPO) manages the DoD blood program under the authority of the Secretary of Defense through the Assistant Secretary of Defense for Health Affairs (ASD[HA]) and the operational control of the Joint Chiefs of Staff. ASBPO's mission is to provide quality blood products and services for all customers in peace and war with specific responsibilities for:

- overseeing operations of the blood program during contingencies;
- coordinating day-to-day activities of ASBP for the Army, Navy, and Air Force Service blood programs; and
- coordinating theater blood program matters with the Combatant Commands.

The Deputy Secretary of Defense established the Defense Health Agency (DHA) on October 1, 2013. DHA is responsible for shared services, functions, and activities of the MHS. DHA's role is to accomplish greater integration of health care delivery systems by achieving medical readiness, improving health, enhancing the experience of care, and lowering healthcare costs.

Under DHA, the Program Executive Officer for the Defense Health Clinical Systems (PEO[DHCS]):

- produces and delivers products that support the MHS;
- supports health care operations through design, development, test, evaluation, and deployment of medical information systems; and
- manages the DBSS and EBMS information systems and the Theater Blood capability.

## Defense Blood Standard System

DBSS is an MHS legacy blood product information management system. According to Report No. D-2002-010, the Food and Drug Administration (FDA) cleared this system as a medical device. According to PEO(DHCS) officials, it has an estimated life-cycle cost of about $217.5 million.[1] The report stated that blood program organizations used the system to maintain and track blood donations and blood product inventories, as well as to provide transfusion service management and system administration.

According to Report No. D-2002-010, ASD(HA) officials developed Theater DBSS as an interim solution pending the release of the Theater Medical Information Program. The report stated that this program provided theater commanders with all the functional capabilities of DBSS in a theater environment. Specifically, PEO(DHCS) officials stated that Theater DBSS was a database that accounted for inventory for the blood support detachments in Iraq and Afghanistan.

## Enterprise Blood Management System

According to the Acquisition Program Baseline, EBMS is a mission essential automated information system. EBMS is comprised of two different FDA cleared medical devices, commercial off-the-shelf products–the Blood Donor Management System (donor system) and the Blood Management Blood Bank/Transfusion Service (transfusion system). The Component Acquisition Executive (CAE) for DHA considered these two systems as a single Defense acquisition category III automated information system.[2] According to the transfusion system Business Case Analysis, EBMS will enhance the DoD blood program capabilities for blood banking and transfusion services through the improved integration of blood products inventory management and shipment availability. The CAE for DHA is the milestone decision authority for EBMS.

[1] PEO(DHCS) officials stated that they did not have substantiating records for the cost from FY 1991 through FY 2010 ($174 million) because they no longer have access to verifiable cost details.

[2] Acquisition categories are established to facilitate decentralized decision-making and execution and compliance with statutory imposed requirements. Acquisition category III automated information systems are not designated as special interest nor meet the threshold of a major system (categories I or II).

The donor system's design and requirements documents state that it would support donor screening, registration, and manufacturing functions. The transfusion system's design and requirements documents state that it is used to organize the management of blood bank and transfusion services. The transfusion system will interface with outside systems such as Composite Health Care System (CHCS). The main functions of the transfusion system are to manage:

- blood products inventory levels and availability;
- blood products test results;
- pre-transfusion and compatibility test results;
- patient information;
- blood bank and services reports across the enterprise; and
- blood bank user accreditation and training in the use of the application.

The donor system would correct the double counting inventory problem and the transfusion system would mitigate the CHCS interface problem. The current life cycle cost estimate for EBMS is about $245.5 million. According to PEO(DHCS) officials, the donor system would cost about $123.2 million[3] and the transfusion system would cost about $122.3 million.[4]

Figure 1 shows bags and vials of blood waiting to be processed during an ASBP blood drive.


Figure 1. Processing of bags and vials of blood.
Source: Armylive.dodlive.mil

[3] PEO(DHCS) officials did not have any acquisition documentation to support this estimate.

[4] The estimated life cycle costs were from the approved transfusion system Acquisition Program Baseline.

## Theater Blood Capability

In 2011, MHS leaders and the Services replaced Theater DBSS with the Theater Blood capability. This capability is a module under the Theater Medical Data Store and Medical Situational Awareness in Theater. According to PEO(DHCS) officials, the Theater Blood capability addresses Combatant Command medical assets requirements for the U.S. Central Command. ASBPO official further stated they deployed the Theater Blood capability to locations in U.S. Central Command and ships afloat. The officials are considering deployment to locations in Pacific Command and U.S. Southern Command. According to officials, the capability is a web-based IT product used to track blood products in theater. Specifically, theater-based medical treatment facilities use it to track blood product inventory, collection, and disposition. Officials could not provide the estimated costs for this capability.

The FDA blood establishment computer software criteria do not apply to the Theater Blood capability. According to PEO(DHCS) officials, FDA's Blood Establishment Computer Software criteria applies to software designated for use in a blood establishment and is intended for use in the diagnosis of disease or other conditions in donors, or in the prevention of disease in humans by preventing the release of unsuitable blood and blood components. Since medical personnel located in theater use this capability only to track the blood product inventory, no FDA medical device clearance is necessary.

## 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 related to the EBMS acquisition process. Specifically, the:

- PEO(DHCS) could not demonstrate that EBMS will meet the requirements as agreed to in Recommendations A.4 and B.3.a of DoD OIG Report D-2002-010.
- PEO(DHCS) planned to acquire three stand-alone DoD blood product information technology capabilities instead of a DoD IT portfolio.

- CAE for DHA and PEO(DHCS) did not approve several critical acquisition documents for the transfusion system before entering milestone C of the DoD business capability model as required by DoD Instruction 5000.02; however, PEO(DHCS) officials provided the signed documents during this audit.

We will provide a copy of the report to the senior officials responsible for internal controls in ASD(HA).

# Finding A

## Enterprise Blood Management System Will Not Be Ready for Full Deployment

The PEO(DHCS) could not demonstrate that the system design, configuration, and early operational assessment for EBMS will meet the requirements as agreed to in Recommendations A.4 and B.3.a of DoD OIG Report D-2002-010. This occurred because PEO(DHCS) officials were still developing the donor system requirements and initially deployed the transfusion system as a stand-alone system that did not interface with CHCS. As a result, after 13 years the PEO(DHCS) officials' actions still were not complete to show that EBMS will meet the intent of Recommendations A.4 and B.3.a.

## Prior Audit Summary

According to DoD OIG Report No. D-2002-010, DBSS implementation was not adequate to meet ASBP mission needs and, as a result, the use of DBSS affected the asset accountability, increased workload and risk of inventory errors, and possibly resulted in the inappropriate release of blood product. Also, results indicated that the deployment and use of DBSS was not consistent throughout DoD. Specifically, the audit found that only 46 percent of the fixed facilities used the CHCS interface; 54 percent of the Theater DBSS laptops were ready for use; and the Theater DBSS reporting to Joint Medical Asset Repository (JMAR) was not complete. As a result, a consistent blood product management was not achieved, workload increased, and DoD may not achieve total asset accountability of blood products.

As a result, a consistent blood product management was not achieved, workload increased, and DoD may not achieve total asset accountability of blood products.

## *Finding A: Recommendation A.4*

DoD OIG Report No. D-2002-010 stated that DBSS and JMAR Project Offices did not ensure accurate reporting from DBSS to JMAR. Specifically, there was an instance when JMAR did not accurately reflect a blood product shipment that was received by a blood program organization. This potentially could have resulted in a temporary double counting of inventory.

DBSS and JMAR Project Offices did not ensure accurate reporting from DBSS to JMAR.

Recommendation A.4 stated that the JMAR and DBSS Project Offices should modify their system, as necessary, to ensure that in-transit inventory is not counted twice. ASD(HA), ASBPO, the Army, and the Navy concurred with the recommendation. ASD(HA) stated that appropriate action was initiated to ensure in-transit inventory was not counted twice in JMAR.

## *Finding B: Recommendation B.3*

DoD OIG Report No. D-2002-010 stated that the blood program offices and the DBSS Project Office did not adequately oversee the implementation of the CHCS interface with DBSS. The report further stated that users found operational problems that included having to re-enter data or create duplicate in-transit records. The blood program offices and the DBSS Project Office also did not adequately oversee the implementation of the Theater DBSS hardware and software. As a result, Military Departments identified hardware and software problems with the Theater DBSS deployment.

The blood program offices and the DBSS Project Office did not adequately oversee the implementation of the CHCS interface with DBSS.

Recommendation B.3 stated that the Service blood program offices, the ASBPO, and the DBSS Project Office jointly:

a. Develop and implement a plan to correct the software deficiencies identified with the interface between the CHCS and DBSS and establish a time frame for the Military Departments to implement the interface at military treatment facilities.

b. Develop and implement a plan to correct the hardware and software deficiencies identified with the Theater DBSS, or find another means to meet the needs of the unified commands for a blood management capability.

ASD(HA), ASBPO, and the Services concurred with the recommendation. ASD(HA) stated that the organizations were planning appropriate actions.

### *Agreed Upon Actions*

For Recommendations A.4 and B.3.a, ASD(HA) agreed to modify DBSS in 2001 to ensure the accurate reporting of JMAR to resolve double counting of inventory and the ability to interface with CHCS. However, officials were unable to modify DBSS. In 2009, MHS leaders and the Services decided to replace DBSS with EBMS to prevent the double counting of inventory and correct the system interface problems. In 2010, ASD(HA) issued a denial of authority to operate DBSS based on security vulnerabilities. The denial of authority was because DBSS did not meet the required accreditation activities to obtain a full authorization to operate the system and its overall security risk was high.

## Agreed-Upon Actions Not Demonstrated

The PEO(DHCS) could not demonstrate that EBMS will mitigate problems identified in the DoD OIG Report No. D-2002-010.

Although the PEO(DHCS) plans to replace DBSS with EBMS, the PEO(DHCS) could not demonstrate that EBMS will mitigate problems identified in the DoD OIG Report No. D-2002-010. The donor system is in the early stages of the acquisition process to verify whether it will mitigate problems with double counting of inventory (Recommendation A.4), and PEO(DHCS) officials initially deployed the transfusion system without an interface with CHCS (Recommendation B.3.a).

### *Mitigation of Double Counting Awaiting Deployment of Donor System*

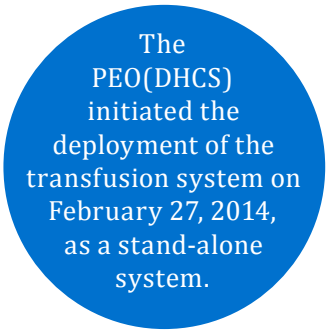
According to PEO(DHCS) officials, the donor system is in the early stages of the acquisition process and has not received a Milestone designation. PEO(DHCS) officials planned the early operational assessment for the first quarter of FY 2015, the operational test for the second quarter FY 2015, and the full deployment for the first quarter of FY 2016.[5] PEO(DHCS) officials indicated that the donor system will have the capability to obtain the necessary tracking information of blood products in real time and the donor system would eliminate the need to use JMAR for tracking blood products. We also observed a system capabilities presentation by the vendor that indicated that the system would facilitate real-time data and track blood product inventory. However, we could not substantiate the system's capabilities. There are no specifics as to how the donor system will facilitate real-time data and track blood product inventory in the Interface Control, Software Requirements Specification, and the Preliminary Design Review/Critical Design

[5] In response to the draft report, DHA indicated that they have revised deployment date for donor system from the first quarter to the fourth quarter of FY 2016.

Review documents. Therefore, the donor system is not far enough along the acquisition process to determine whether its requirements will address or mitigate the in-transit blood product inventory problems.

### *Interface with the Composite Health Care System*

The PEO(DHCS) initiated the deployment of the transfusion system on February 27, 2014, as a stand-alone system. This is because a senior MHS official approved the transfusion system, in 2009, as a stand-alone system to expedite the process. PEO(DHCS) officials obtained a waiver for the transfusion system not to interface with CHCS until FY 2015. In the meantime, technicians are required to manually input patient information into the transfusion system. PEO(DHCS) officials explained that technicians have been manually inputting information since 2010. According to PEO(DHCS) officials, EBMS's capabilities surpass the value of the system as a whole compared to the impact of manually entering the patient information into the transfusion system. Therefore, PEO(DHCS) officials were not able to demonstrate whether the transfusion system would mitigate the system interface problems with CHCS as agreed to in Recommendation B.3.a.




## Conclusion

PEO(DHCS) officials could not demonstrate whether replacing DBSS with EBMS will mitigate the problems identified in DoD OIG Report D-2002-010. PEO(DHCS) officials were still implementing the corrective actions for Recommendations A.4 and B.3.a. We will continue to monitor and consider future audits of EBMS and the Theater Blood capability.

## Management Comments on Background and Finding A and Our Response

The Director, DHA, provided the following comments related to the Background and Finding A. For the full text of the Director's technical comments, see the Management Comments section of the report.

- Capitalize the "Theater Medical Information Program" title in the second paragraph under the Defense Blood Standard System section of the Background.

- Add "Theater Medical Information Program–Joint information system" in the paragraph under the Theater Blood capability section of the Background.
- Change the title for Finding A to "PEO(DHCS) Could Not Demonstrate That EBMS Will Meet the Requirements As Agreed" because the title appears unrelated to the Finding A's conclusion.
- Revise the donor system's deployment date to the fourth quarter of FY 2016 in the paragraph under the Mitigation of Double Counting Awaiting Deployment of Donor System section of Finding A.

### *Our Response*

We capitalized the "Theater Medical Information Program" title and added a footnote in the paragraph under the section in Finding A titled, "Mitigation of Double Counting Awaiting Deployment of Donor System" to show the planned date for the donor system's deployment. However, we did not make any further changes to Finding A or the Background of the Report. We did not add "Theater Medical Information Program–Joint information system" in the Background because we did not review or verify the system as part of our audit since it was outside of our announced objective. Also, we did not change the title of Finding A, "Enterprise Blood Management System Will Not Be Ready for Full Deployment," because the title is descriptive of the finding and the conclusion that EBMS could not demonstrate it addressed what was agreed to in Recommendations A.4 and B.3 of DoD OIG Report No. D-2002-010.

## Recommendations, Management Comments, and Our Response

### *Recommendation A*

**We recommend that the Program Executive Officer for the Defense Health Clinical Systems, in coordination with the Director for Armed Services Blood Program, continue efforts to:**

1. **Ensure that in-transit inventory is not counted twice in the Enterprise Blood Management System.**
2. **Develop and implement the Blood Management Blood Bank Transfusion Services interface capability with Composite Health Care System.**

### *Director, Defense Health Agency Comments*

The Director, DHA, responding for the PEO(DHCS) and the Director, ASBP, agreed, stating that the PEO(DHCS), in coordination with the Director for ASBP, will continue to develop and implement the transfusion system interface capability with CHCS or its replacement, as required. He stated that the CHCS interface will be implemented by the fourth quarter of FY 2016.

Additionally, the Director stated that the PEO(DHCS) will continue to ensure that no issues will arise with double counting of in-transit inventory in EBMS. The Director further stated that the PEO(DHCS) planned for the deployment of the donor system for the fourth quarter of FY 2016.

### *Our Response*

The response from the Director addressed all specifics of the recommendations, and no further comments are required.

# Finding B

## DoD Management of Blood Products Information Technology Capabilities May Have Missed Opportunities to Leverage Efficiencies

The PEO(DHCS) planned to acquire three, stand-alone, DoD blood product information technology (IT) capabilities[6] that will manage information about the donors, donations, transfusions, and blood product inventories. This occurred because the PEO(DHCS) and the CAE for DHA did not manage the donor, transfusion, and the Theater Blood IT capabilities as a DoD IT portfolio as required by DoD Instruction 8115.02, "Information Technology Portfolio Management Implementation," October 30, 2006. As a result, the PEO(DHCS) and the CAE for DHA may not achieve maximum efficiencies for the Department's blood program. The program is also at an increased risk of not fully reaching the blood program's overall performance goals that ultimately could negatively impact the warfighters, veterans, and their families.

## DoD Blood Product Information Technology Capabilities Acquisition

The ASD(HA) did not comply with DoD regulatory requirements when acquiring DoD blood product IT capabilities. Specifically, when replacing DBSS, the ASD(HA) did not follow DoD Instruction 5000.02, "Operation of the Defense Acquisition System," December 8, 2008;[7] DoD Directive 8115.01, "Information Technology Portfolio Management," October 10, 2005; and DoD Instruction 8115.02, "Information Technology Portfolio Management Implementation," October 30, 2006, by acquiring three different blood product IT capabilities that would not interface with each other. According to PEO(DHCS) and ASBPO officials, there was no operational need for the IT capabilities to interface with each other. The ASD(HA) did not consider maximum efficiencies for the Department's blood program by not considering a potential IT portfolio.

The ASD(HA) did not consider maximum efficiencies for the Department's blood program by not considering a potential IT portfolio.

[6] For the purposes of this finding, we will refer to the donor system, transfusion system, and the Theater Blood capability as DoD blood product IT capabilities.

[7] DoD Instruction 5000.02 implements DoD Directive 5000.01, "The Defense Acquisition System," certified current as of November 20, 2007. DoD Instruction 5000.02 has been updated by an Interim DoD Instruction 5000.02, dated November 25, 2013, which cancelled the 2008 version, with the exception of Enclosure 9.

## *DoD Blood Products Information Technology Portfolio*

The ASD(HA) officials planned to acquire the DoD blood product IT capabilities as stand-alone IT capabilities rather than integral parts of a DoD enterprise-wide capability for managing the DoD blood program. DoD Instruction 5000.02 establishes a management framework for translating capability needs and technology opportunities, based on approved capability needs, into stable, affordable, and well-managed acquisition programs that include automated information systems. It states that the materiel development decision review is the formal entry point into the acquisition process in where multiple DoD communities assist in formulating operational goals and would consider potential materiel solutions. DoD Directive 8115.01 mandates portfolios to be used as a management tool in each of the Department's decision support systems to include the Defense Acquisition System (DoD Instruction 5000.02).

DoD Directive 8115.01 requires that the Heads of the DoD Components establish the Component portfolio so that IT investments align to Mission Area. It further requires that the head of the Component manage IT investments as portfolios to:

- ensure IT investments support the Department's vision, mission, and goals;
- ensure efficient and effective delivery of capabilities to the warfighter; and
- maximize return on investment to the Enterprise.

According to DoD Instruction 8115.02,[8] the Department has moved at an accelerating pace toward capabilities-based planning, resource allocation, and acquisition, based on the principles of joint interoperability and network-centric warfare. The instruction states that historically, IT resources have been managed and acquired as stand-alone IT capabilities rather than as integral parts of a net-centric capability having an effect of allowing duplicative investment in systems or platforms that would deliver the same or similar capabilities. According to the instruction, IT portfolio management is a key enabler of information sharing and it provides a balanced strategy based on enterprise strategic planning and integrated architectures. The instruction addresses that in order for an effective implementation, the IT portfolio management strategy requires a robust governance structure, enabled by consistent, repeatable processes at all levels to foster greater management efficiency, better communications, and effective collaboration.

[8] DoD Instruction 8115.02 implements DoD Directive 8115.01.

In addition, in a memorandum dated March 11, 2013, "Implementation of Military Health System Governance Reform," the Deputy Secretary of Defense emphasized on the responsibility for shared services, functions, and activities of the MHS and other common clinical and business processes. The Deputy Secretary of Defense further stated that:

> In doing so, we must attain greater integration of our direct and purchased healthcare delivery systems, essential to accomplishing the quadruple aim of the MHS: to assure medical readiness, improve the health of our people, enhance the experience of care, and lower our healthcare costs.

Although the donor, the transfusion, and Theater Blood IT capabilities are managed by the PEO(DHCS), duplicate work may be present when using stand-alone IT capabilities to manage the data. As indicated by a PEO(DHCS) official, a technician would have to access more than one IT capability to acquire information about a patient and input it in another IT capability to register the patient in both blood product management IT capabilities. For example, this would occur when military personnel (patient) who donated blood required a blood transfusion. As a result, officials would maximize the Department's return on investment by setting up an interface that would connect the IT capabilities and enable data sharing among these capabilities. This would also save the technicians time and streamline patient registration and blood product management processes by reusing accessible data rather than recreating it; therefore, achieving better efficiencies.

Duplicate work may be present when using stand-alone IT capabilities to manage the data.

The PEO(DHCS) officials could not provide all of the known costs for the proposed DoD blood product IT capabilities.

Additionally, the PEO(DHCS) officials could not provide all of the known costs for the proposed DoD blood product IT capabilities. According to officials, the estimated costs to phase-out DBSS and the known life-cycle costs for the IT blood products IT management capabilities totaled $289 million. Please see Table 1 for a breakdown of the known costs provided by the PEO(DHCS) officials.

*Table 1. Total Known Costs of Portfolio*

| IT Blood Product | Estimated Costs (in millions) |
|---|---|
| Transfusion | $122.3 |
| Donor | $123.2 |
| Theater Blood | Unknown[1] |
| DBSS | $43.5[2] |
| Total | $289.0 |

[1] Officials could not provide the estimated life-cycle costs.
[2] This amount represents the FY 2011 through FY 2015 estimated costs to phase-out DBSS.

By having three, stand-alone, DoD blood product IT capabilities, the PEO(DHCS) and the CAE for DHA may have missed the opportunity to leverage IT efficiencies that could have potentially increased the Department's return on investment.

## *Interface of DoD Blood Product Information Technology Capabilities*

According to PEO(DHCS) and ASBPO officials, they did not identify an operational need to have the IT blood products interface with each other. However, these IT products all provide blood management functions and capabilities. For example, the transfusion and Theater Blood[9] both track the inventory levels, availability of all blood products, test results of blood products, results of pre-transfusion, and compatibility tests. The donor and Theater Blood also have the ability to track blood products and document donors by blood types. The transfusion and donor systems have the capability of patient registrations. As a result, the Department could achieve better efficiencies if these IT capabilities shared information or interface as part of an enterprise DoD blood product solution. This could also streamline ASBP's mission to provide quality blood products and services for all worldwide customers in peace and war.

[9] Theater Blood functions and capabilities mentioned in this section were taken from PEO(DHCS) officials' statements.

The PEO(DHCS) and the CAE for DHA did not implement a joint interoperability strategy, which could result in delivering inefficient and ineffective blood product information system capabilities to the warfighter.

As a result, the PEO(DHCS) and the CAE for DHA did not implement a joint interoperability strategy, which could result in delivering inefficient and ineffective blood product IT capabilities to the warfighter. Therefore, the PEO(DHCS) and the CAE for DHA should assess EBMS (donor and transfusion systems), Theater Blood, and any other DoD blood product management IT capabilities' processes, functions, and capabilities before reaching a Milestone Decision for the donor system. The PEO(DHCS) and the CAE for DHA should then evaluate how the DoD blood product IT management capabilities would benefit from being interoperable as required by DoD Instruction 8115.02. Throughout this process, the PEO(DHCS) and the CAE for DHA should identify and document any opportunities for efficiencies and develop a plan of actions and milestones to implement the potential new strategy.

## Management Actions Taken on the Transfusion System

Although the CAE approved the transfusion system to enter into the business capability lifecycle acquisition business model at milestone C on July 9, 2013, he did not initially approve the Analysis of Alternatives, the Acquisition Strategy, the Acquisition Program Baseline, and the Life Cycle Sustainment Plan, as required by DoD Instruction 5000.02. However, based on our audit, PEO(DHCS) officials provided the approved Acquisition Program Baseline and Business Case Analysis on February 5, 2014.[10]

## Management Comments on Background and Finding B and Our Response

The Director, DHA, provided the following comments related to the Background and Finding B. For the full text of the Director's technical comments, see the Management Comments section of the report. The Director requested that we replace any reference to "systems" with the word "capabilities" when referring to the donor system, transfusion system, and Theater Blood capability throughout the Background and Finding B sections. The Director explained that it would be inaccurate for two reasons. First, the Theater Blood capability is not a system or application but a capability under the Theater Medical Data Store and Medical Situational Awareness in Theater application within the Theater Medical Information Program–Joint information system. Secondly, by calling it a system

[10] The Business Case Analysis included the Analysis of Alternatives as well as the summaries of the Acquisition Strategy and Life Cycle Sustainment Plan.

the Theater Blood capability could also be perceived as a stand-alone system. Also, the Director requested that we change the title of Finding B to "DoD Management of Blood Products Information Systems May Have Missed Opportunities to Leverage Efficiencies" because the finding's discussion did not show that specific inefficiencies were discovered, and implementation of recommendation will determine whether efficiencies can be achieved.

### *Our Response*

For accuracy and consistency in the Report, we replaced any reference to "application" with "capability" when referring to Theater Blood capability. We also replaced "systems" with "capability" when referring to the donor system, transfusion system, and the Theater Blood capability. Additionally, we changed the title of Finding B to: "DoD Management of Blood Products Information Technology Capabilities May Have Missed Opportunities to Leverage Efficiencies."

## Recommendations, Management Comments, and Our Response

### *Recommendation B*

**We recommend that prior to reaching a Milestone Decision for the Blood Donor Management System, the Component Acquisition Executive for the Defense Health Agency assess the Enterprise Blood Management System, Theater Blood capability, and any other DoD blood product information technology capabilities' processes, functions, and capabilities to determine whether efficiencies could be achieved by managing as integral parts of a net-centric interoperable information technology portfolio. This assessment should:**

1. **Evaluate how the DoD blood product information technology capabilities would benefit from being interoperable as an information technology portfolio.**
2. **Identify and document opportunities for efficiencies throughout the process among the DoD blood product information technology management capabilities.**
3. **Develop a plan of actions and milestones to implement the revised information technology portfolio interoperability strategy.**

### *Director, Defense Health Agency Comments*

The Director, DHA, responding for the CAE for DHA, agreed, stating that the CAE agreed to assess DoD blood management capabilities and determine whether DHA could leverage any potential benefits of the interoperability. The Director indicated that this evaluation was expected to be conducted in the third quarter of FY 2015.

### *Our Response*

The response from the Director addressed all specifics of the recommendations, and no further comments are required.

# Appendix

## Scope and Methodology

We conducted this performance audit from August 2013 through August 2014 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.

For Recommendations A.4 and B.3.a of DoD OIG Report No. D-2002-010, we collected, reviewed, and analyzed acquisition related documents for Defense Blood Standard System and Enterprise Blood Management System. For example, among the documents were the transfusion system Acquisition Decision Memorandum, Business Case Analysis, Acquisition Program Baseline, Life Cycle Sustainment Plan, Test and Evaluation Master Plan, and system testing documents for the early operational assessment and operations testing. Additionally, we reviewed available donor system documentation related to the system interface, requirements, and design.

For Recommendation B.3.b of DoD OIGReport No. D-2002-010, the Program Executive Officer for the Defense Health Clinical Systems officials replaced the Theater Defense Blood Standard System with the Theater Blood capability, not the Enterprise Blood Management System. This action met the intent of the recommendation to find another means to meet the needs of the unified commands for a blood management capability. However, we did not evaluate the implementation of the Theater Blood capability since it was outside the scope of the announced audit objective.

We compared the acquisition documents and testing results to applicable acquisition regulations, such as:

- DoD Instruction 4630.8, “Procedures for Interoperability and Supportability of Information Technology and National Security Systems”
- DoD Directive 5000.01, “The Defense Acquisition System”
- DoD Instruction 5000.02, “Operation of the Defense Acquisition System”
- DoD Directive 8115.01, “Information Technology Portfolio Management”
- DoD Instruction 8115.02, “Information Technology Portfolio Management Implementation”

- DoD Instruction 8510.01, "DoD Information Assurance Certification and Accreditation Process"
- Defense Acquisition Guidebook

We also interviewed representatives from:

- Component Acquisition Executive for Defense Health Agency;
- Program Executive Officer for the Defense Health Clinical Systems;
- TRICARE Management Activity Office of the Chief Information Officer, Deployment and Readiness Systems;
- Armed Services Blood Program Office;
- Army, Navy, and Air Force blood program offices; and
- Walter Reed National Military Medical Center Blood Services.

## Use of Computer-Processed Data

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

## Use of Technical Assistance

We did not use technical assistance for this audit.

## Prior Coverage

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

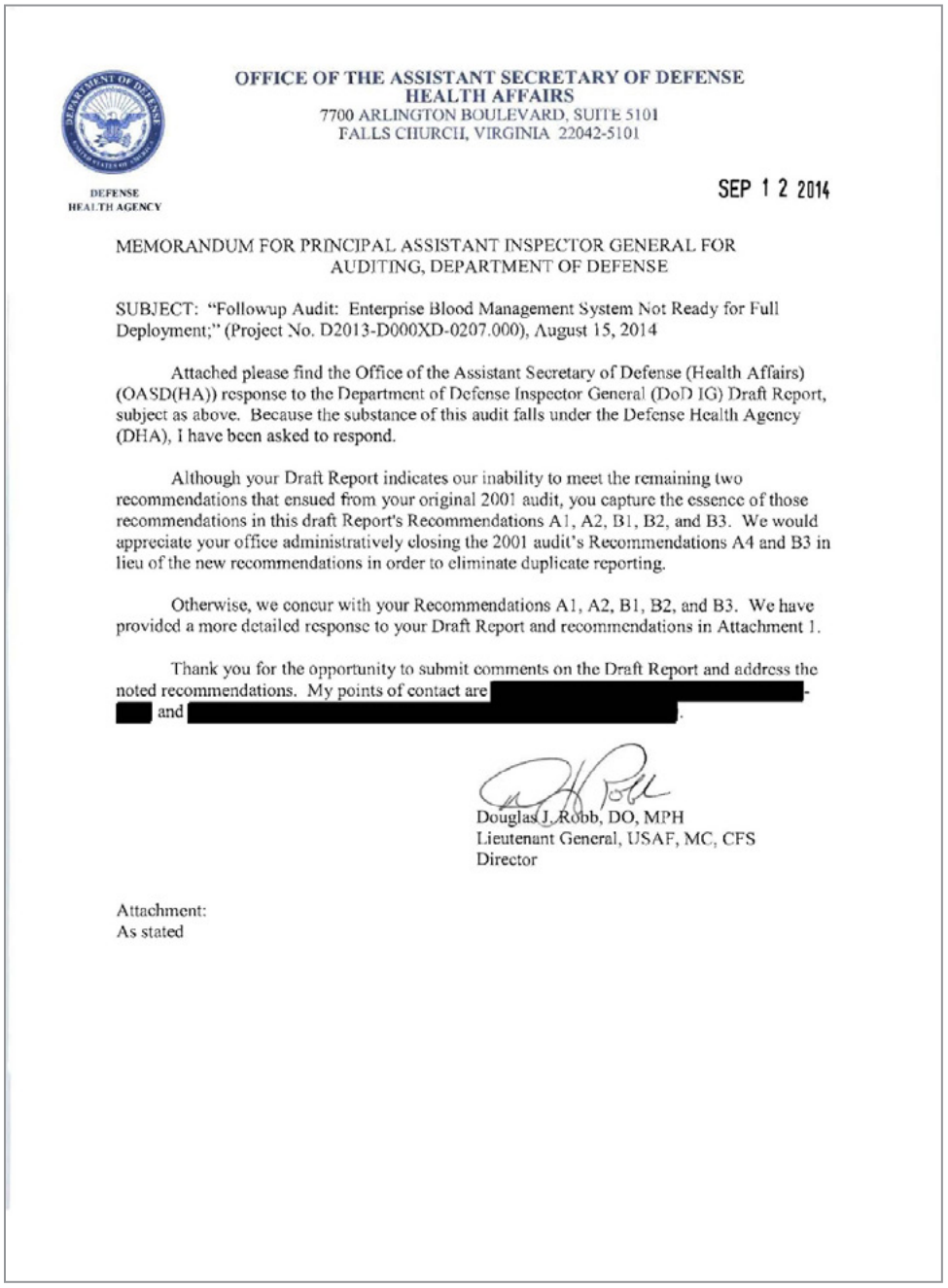
### *DoD IG*

Report No. D-2002-010, "Armed Services Blood Program Defense Blood Standard System," October 22, 2001

# Management Comments

## Defense Health Agency

**Final Report Reference**



DEFENSE HEALTH AGENCY

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

SEP 1 2 2014

MEMORANDUM FOR PRINCIPAL ASSISTANT INSPECTOR GENERAL FOR AUDITING, DEPARTMENT OF DEFENSE

SUBJECT: "Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment;" (Project No. D2013-D000XD-0207.000), August 15, 2014

Attached please find the Office of the Assistant Secretary of Defense (Health Affairs) (OASD(HA)) response to the Department of Defense Inspector General (DoD IG) Draft Report, subject as above. Because the substance of this audit falls under the Defense Health Agency (DHA), I have been asked to respond.

Although your Draft Report indicates our inability to meet the remaining two recommendations that ensued from your original 2001 audit, you capture the essence of those recommendations in this draft Report's Recommendations A1, A2, B1, B2, and B3. We would appreciate your office administratively closing the 2001 audit's Recommendations A4 and B3 in lieu of the new recommendations in order to eliminate duplicate reporting.

Otherwise, we concur with your Recommendations A1, A2, B1, B2, and B3. We have provided a more detailed response to your Draft Report and recommendations in Attachment 1.

Thank you for the opportunity to submit comments on the Draft Report and address the noted recommendations. My points of contact are [redacted] and [redacted].

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

Attachment:
As stated

# Defense Health Agency (cont'd)

**Final Report Reference**

Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment
*Project No. D2013-D000XD-0207.000*, Draft Report

**DHA Response to DoD IG Recommendations**

**RECOMMENDATION A:** We recommend that the Program Executive Officer for the Defense Health Clinical Systems, in coordination with the Director for Armed Services Blood Program, continue efforts:

1. Ensure that in-transit inventory is not counted twice in the Enterprise Blood Management System.
2. Develop and implement the Blood Management Blood Bank Transfusion Services interface capability with Composite Health Care System.

**DHA Response:** Concur. The Program Executive Officer (PEO) Defense Health Clinical Systems (DHCS) concurs with the recommendation to continue to develop and implement the Blood Management Blood Bank Transfusion Services (BMBB/TS) interface capability with Composite Health Care System (CHCS) or its replacement, as required and will coordinate those efforts with the Director, Armed Services Blood Program (ASBPO). Currently, the BMBB/TS-CHCS interface is anticipated to be implemented in Fiscal Year (FY) 2016.

As a stand-alone system since 2010, the Defense Blood Standard System (DBSS) can no longer interface with the Joint Medical Asset Repository, so it is no longer possible to double count in-transit inventory. The PEO DHCS in coordination with the Director, ASBPO, will continue to ensure that no issues with double counting in-transit inventory arise in the Enterprise Blood Management System.

**RECOMMENDATION B:** We recommend that prior to reaching a Milestone Decision for the Blood Donor Management System, the Component Acquisition Executive for the Defense Health Agency assess the Enterprise Blood Management System, Theater Blood application, and any other DoD blood management systems' processes, functions, and capabilities to determine whether efficiencies could be achieved by managing as integral parts of a net-centric interoperable information technology portfolio. This assessment should:

1. Evaluate how the DoD blood management systems would benefit from being interoperable as an information technology portfolio.
2. Identify and document opportunities for efficiencies throughout the process among the DoD blood management systems.
3. Develop a plan of actions and milestones to implement the revised information technology portfolio interoperability strategy.

**DHA Response:** Concur. The Component Acquisition Executive for the DHA concurs with the recommendation to assess DoD blood management capabilities to evaluate the potential benefits of their interoperability. This evaluation is expected to be conducted in FY2015.

1

# Defense Health Agency (cont'd)

**Final Report Reference**

Followup Audit: Enterprise Blood Management System Not Ready for Full Deployment
*Project No. D2013-D000XD-0207.000*, Draft Report

**Technical Comments**

**1. Throughout**: The Theater Blood application is referenced as a "system."

**Recommendation**: Replace references to "system" with "capability."

**Rationale**: Accuracy. As written, the statement implies that the Theater Blood application is an independent information system, which is not accurate. This recommended change clarifies that Theater blood application is a capability within the Theater Medical Information Program-Joint (TMIP-J) information system's Theater Medical Data Store (TMDS) and Medical Situational Awareness in Theater (MSAT) applications.

Replaced throughout the Report

**2. Page 2, 3rd Paragraph, 1st Sentence**: "According to Report No. D-2002-010, ASD(HA) officials developed Theater DBSS as an interim solution pending the release of the Theater medical information program."

**Recommendation**: Capitalize the entire name of the referenced program as follows: "Theater Medical Information Program (TMIP)."

**Rationale**: Accuracy. As written, it is unclear that TMIP was the name of the program.

Revised Background Section on Page 2

**3. Page 4, 1st Paragraph, 1st and 2nd Sentences**: "In 2011, MHS leaders and the Services replaced Theater DBSS with the Theater Blood application. This application is a module under the Theater Medical Data Store and Medical Situational Awareness in Theater."

**Recommendation**: Revise this sentence to read: "…This application is a module under the Theater Medical Data Store (TMDS) and Medical Situational Awareness in Theater (MSAT) applications within the Theater Medical Information Program-Joint (TMIP-J) information system."

**Rationale**: Clarity. Without clarification that the MSAT and TMDS applications fall under the TMIP-J system, this sentence could be interpreted to imply that the Military Health System (MHS) strayed from the strategy outlined in the Department of Defense Inspector General's (DoD IG) 2001 report by failing to replace the Theater Defense Blood Standard System (DBSS) with TMIP as originally planned. This recommended change clarifies that the Theater blood functionality was indeed incorporated into TMIP-J (via its TMDS/MSAT applications), consistent with the strategy outlined in the DoD Inspector General's (IG) 2001 report: "Theater DBSS was developed as an interim solution pending the release of the Theater medical information program" (p. 4, 3rd paragraph).

2

# Defense Health Agency (cont'd)

**4. Page 5, 2nd Bullet (repeated on Page i, 3rd Paragraph, 1st Sentence)**: "PEO(DHCS) planned to acquire three standalone DoD blood product information systems instead of a DoD IT portfolio."

**Recommendation**: Replace this sentence with the following statement: "PEO(DHCS) planned to acquire three standalone DoD blood capabilities instead of a DoD IT portfolio."

**Rationale**: Clarity. As written, the statement implies that the MHS acquired the Theater Blood application as an independent information system, which is not accurate. This recommended change clarifies that the Theater blood functionality was integrated into the existing TMDS/MSAT applications within the TMIP-J information system, consistent with the strategy outlined in DoD IG's 2001 report (see Comment #3 above).

Replaced throughout Finding B

**5. 6th Page, 1st Paragraph, Heading**: "Finding A: Enterprise Blood Management System Will Not Be Ready for Full Deployment"

**Recommendation**: Replace this sentence with the following statement: "PEO(DHCS) Could Not Demonstrate That EBMS Will Meet the Requirements As Agreed."

**Rationale**: Clarity. As written, Finding A appears to be unrelated to the following text in that section and Recommendations A1 and A2. This recommended change clarifies DoD IG's conclusion from this discussion, summarized from the "Conclusion" paragraph on page 9.

**6. 8th Page, 4th Paragraph, 2nd Sentence**: "PEO(DHCS) officials planned the early operational assessment for the 1st quarter of FY 2015, the operational test for the 2nd quarter FY 2015, and the full deployment for the 1st quarter of FY 2016."

Added Footnote in Finding A on Page 8

**Recommendation**: Revise this sentence to read: "PEO(DHCS) officials planned to deploy the donor system in the 4th quarter of FY 2016."

**Rationale**: Accuracy. The donor system schedule has evolved since these dates were discussed with DoD IG earlier this year. Full deployment is now anticipated in the 4th quarter of FY 2016.

**7. 11th Page, 1st Paragraph, Heading**: "Finding B: DoD Management of Blood Products Information Systems Was Inefficient"

**Recommendation**: Revise this sentence to read: "Finding B: DoD Management of Blood Products Information Systems May Be Inefficient"

**Rationale**: Accuracy. As written, Finding B implies that evidence of specific inefficiencies has already been discovered and analyzed, which is not supported by DoD IG's discussion in the remainder of the report. It is also inconsistent with Recommendation B's requirement for DHA to conduct an assessment to determine if efficiencies can be achieved. This recommended change eliminates the inconsistency by placing the statement to the future tense.

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# Glossary

**Application** – A computer program that accomplishes a specific task for the user.

**Capability** – The ability to execute a specified course of action.

**Composite Health Care System** – The automated medical information system supporting all military treatment facilities worldwide in providing comprehensive health care to military personnel, retirees, and their dependents. Specifically, it provides the Services with patient facility data management and communication capabilities such as patient administration, reporting, scheduling, laboratory orders, quality control, and medication processing.[11]

**Deployment** – Fielding a weapon system by placing it into operational use with units in the field/fleet.

**Information Technology (IT)** – Any equipment, or interconnected system or subsystem of equipment, which is used in the interchange, transmission, or reception of data or information.

**Information Technology Portfolio** – A grouping of IT investments by capability to accomplish a specific functional goal, objective, or mission outcome. An IT investment is the development and sustainment resources needed in support of IT or IT-related initiatives. Resources include research, development, test, and various types of appropriations, such as procurement appropriations.

**Interface** – Computer hardware or software connections that allow two or more IT components to share data and communicate with each other.

**Interoperability** – The ability of systems to exchange data, information, or materiel and services that enable them to operate effectively together.

**Joint Medical Asset Repository** – A data repository designed to integrate information from various medical logistics systems throughout DoD into a centrally managed data warehouse that gives users the ability to see the location and status of medical supplies and equipment whether in storage, in transit, or in theater.[12]

[11] This information is from Appendix C of DoD OIG Report No. D-2002-010, "Armed Services Blood Program Defense Blood Standard System," October 22, 2001.

[12] This information is from Appendix C of DoD OIG Report No. D-2002-010, "Armed Services Blood Program Defense Blood Standard System," October 22, 2001.

**Materiel Solution** – The correction of a deficiency, satisfaction of a capability gap, or incorporation of new technology that results in the development, acquisition, procurement, or fielding of a new item necessary to equip, operate, maintain, and support military activities without disruption as to its application for administrative or combat purposes.

**Materiel Development Decision** – The decision that a new product is needed and activities to analyze alternative solutions will occur.

**Medical Situational Awareness in Theater** – A web-based application through Secret Internet Protocol Router Network, which combines information from multiple databases to provide worldwide asset visibility and decision support for Combatant Commands and Joint Task Force Commanders' medical staff.

**Net-centricity** – Robust, globally interconnected network environment in which data is shared timely and seamlessly among users, applications, and platforms. Net-centricity enables improved military situational awareness and significantly shortened decision-making cycles.

**Real Time** – The actual time in which a process under computer control occurs.

**Stand-alone** – A computer or other device that is able to function independently of other devices.

**Theater Medical Data Store** – It provides web-based access to service member information collected at theater-based medical treatment facilities using other systems.

# Acronyms and Abbreviations

| | |
|---|---|
| **ASBP** | Armed Services Blood Program |
| **ASBPO** | Armed Services Blood Program Office |
| **ASD(HA)** | Assistant Secretary of Defense (Health Affairs) |
| **CAE** | Component Acquisition Executive |
| **CHCS** | Composite Health Care System |
| **DBSS** | Defense Blood Standard System |
| **DHA** | Defense Health Agency |
| **EBMS** | Enterprise Blood Management System |
| **FDA** | Food and Drug Administration |
| **IT** | Information Technology |
| **JMAR** | Joint Medical Asset Repository |
| **MHS** | Military Health System |
| **PEO(DHCS)** | Program Executive Officer for the Defense Health Clinical Systems |


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