Department of Veterans Affairs

Office of Inspector General

Audit of
Veterans Health Administration
Blood Bank Modernization Project

Contents

Executive Summary

Introduction

The Office of Inspector General (OIG) performed an audit to determine if the Veterans Health Administration (VHA) effectively planned and managed the Blood Bank Modernization Project (BBMP). The audit objectives were to determine if a system development life cycle (SDLC) methodology was effectively employed and if the project was in compliance with capital investment requirements. During the audit, as part of VA's information technology (IT) realignment, responsibility for the BBMP transferred from the VHA Office of Information (OI) to VA's Office of Information and Technology (OI&T) in February 2007. OI&T is aligned under the Assistant Secretary for Information and Technology. As a result of this realignment, our audit recommendations are addressed to the Assistant Secretary.

In October 1999, VHA OI initiated the BBMP to develop a blood bank information system to replace the Veterans Health Information Systems and Technology Architecture (VistA) Blood Bank Software, which is the current system used by the VA medical centers. A significant goal of the new system is to decrease the risk of errors and to improve the safety of blood component transfusions through the use of current technology, such as barcode scanning, to better detect inconsistencies in data input.

VHA OI officials initially planned to complete the BBMP by October 2004, but as of January 2008 the project was scheduled for completion in September 2008. The BBMP had an initial cost estimate of $12.8 million. However, from fiscal year (FY) 2000 through FY 2007, we estimate that VHA OI had spent approximately $32.9 million on the project.

Results

VHA OI officials did not properly plan and manage the BBMP. Specifically, they did not complete seven critical planning and management tasks required by the BBMP SDLC methodology, VA capital investment policies, and other project guidance. Since VHA OI officials did not treat the BBMP as a major project, as required by VA IT capital investment guidance, VHA OI officials did not ensure controls to manage IT capital investment risks were followed. As a result, VA lacked reasonable assurance that VHA OI officials selected the best project alternative, used VA resources efficiently, and implemented effective controls to safeguard sensitive project information. VA capital investment officials also had no oversight of the cost, schedule, and performance of this project, and VA did not provide a full accounting of this IT investment to the Office of Management and Budget (OMB) as required by the Clinger-Cohen Act.

The following seven critical BBMP planning and management activities were not performed:

1. **Develop adequate cost estimates of project alternatives.** OMB and VA policies required VHA OI officials to perform a cost-benefit analysis (CBA) to support the proposed BBMP. The BBMP's CBA did not include adequate cost estimates for both commercial off-the-shelf (COTS) and in-house development project alternatives. Without well-documented and comparable cost estimates for project alternatives, management did not know if the decision to develop the BBMP in-house was the most cost-effective alternative.

2. **Submit the BBMP's Capital Investment Application to VA OI&T for project approval.** For major IT projects, VA policy required project officials to complete and submit capital investment applications to VA OI&T for project approval and inclusion in VA's IT portfolio. VHA OI officials did not submit the Capital Investment Application because they concluded that the BBMP did not meet the criteria for a major project. As a result, VA capital investment officials were unaware of the BBMP and, therefore, could not ensure the BBMP supported VA's mission and strategic goals.

3. **Prepare an Exhibit 300 for capital investment reporting purposes.** OMB requires agencies to submit an Exhibit 300, also known as the Capital Asset Plan and Business Case, for major acquisitions. The Exhibit 300 must be submitted annually with the agency's budget. VHA OI officials did not prepare an Exhibit 300 for the BBMP because the former VHA Chief Information Officer (CIO) directed that the BBMP be included as a subproject of an existing major IT project's Exhibit 300. Without a BBMP specific Exhibit 300, OMB officials were unable to review project funding needs and performance.

4. **Document key decisions or maintain complete project files.** OMB and VA policies required that VHA OI officials document key decisions pertaining to project approval and development. VHA OI officials did not document key decisions, such as project approval, and project files did not contain important documents, such as the Capital Investment Application or CBA. According to a VHA OI official, project documentation was not considered a priority in the organization when the BBMP began. However, without documentation of key decisions, accountability for project management and achieving desired outcomes was not effectively established.

5. **Conduct a privacy impact assessment.** VA Handbook 6502.2, "Privacy Impact Assessment," October 2004, requires project managers to complete privacy impact assessments (PIA) promptly and accurately for the Assistant Secretary for Information and Technology's review and approval. The purpose of a PIA is to assess the risks and controls related to collecting, maintaining, and disseminating electronic information. When the BBMP project team developed the BBMP SDLC, VA did not require PIAs. However, several VHA OI officials agreed that the 2004 requirement

applied to the BBMP. The project manager did not complete a PIA because she believed that the project was included in another project's PIA.

6. **Review sufficient information before granting a waiver from independent verification and validation requirements.** VHA OI procedures require an independent testing group to perform an independent verification and validation (IV&V) review of the BBMP's system. An IV&V review confirms that a system performs its intended functions correctly and provides information about the system's quality and reliability. A VHA OI official did not adequately review the project manager's request for an IV&V waiver before approving it. Also, VHA OI did not have a procedure for granting IV&V waivers.

7. **Monitor and control project costs.** VHA OI officials did not comply with OMB and VA project development cost monitoring and control requirements. Additionally, VHA OI officials did not require the project officials to report the project's financial performance. As a result, VA management did not have reasonable assurance that VA resources were used efficiently.

The BBMP's planning and management problems occurred because of poor project oversight, weaknesses in VA's capital investment policy, and management preference for in-house development of the blood bank system.

Recommendations

1. We recommended that the Assistant Secretary for Information and Technology fully document future estimates for project alternatives presented in CBAs, including all methodologies, assumptions, and cost data sources.

2. We recommended that the Assistant Secretary for Information and Technology develop and implement procedures to ensure that capital investment officials review project categorization decisions.

3. We recommended that the Assistant Secretary for Information and Technology submit a separate Exhibit 300 for the BBMP.

4. We recommended that the Assistant Secretary for Information and Technology determine if projects included in the VistA Application Development Exhibit 300 meet VA criteria as major projects and prepare required Exhibit 300s as appropriate.

5. We recommended that the Assistant Secretary for Information and Technology require project managers to maintain comprehensive project files that contain all relevant project documentation.

6. We recommended that the Assistant Secretary for Information and Technology conduct a PIA on the new blood bank system.

7. We recommended that the Assistant Secretary for Information and Technology review the BBMP's internal testing documentation to determine if the project requires an IV&V review.

8. We recommended that the Assistant Secretary for Information and Technology develop and implement specific criteria for reviewing and approving IV&V waiver requests.

9. We recommended that the Assistant Secretary for Information and Technology require that the BBMP project manager develop performance measurement baselines, report actual costs against these baselines, and include cost impacts for project change requests in accordance with VA Directive 6061.

Assistant Secretary for Information and Technology Comments

The Assistant Secretary for Information and Technology agreed with the findings and recommendations and provided acceptable implementation plans. (See Appendix B, pages 17–20, for the full text of the Assistant Secretary's comments.) In response to the recommendations, the Assistant Secretary reported that the Deputy CIO for Enterprise Development was developing processes to ensure that Cost Benefit Analyses and Analyses of Alternatives are fully supported. He stated that a process for approving and prioritizing capital investments will be documented and that a FY 2009 OMB 300 Exhibit had been prepared for the BBMP. The Assistant Secretary's planned actions also included determining if projects in the VistA Application Development Exhibit 300 should have their own Exhibit 300s. He stated that the Deputy CIO for Enterprise Development will implement a process that ensures all IT projects have proper documentation, and the BBMP Project Manager had begun a PIA of the BBMP. The Assistant Secretary also planned to conduct a review to determine if an IV&V should be performed for the BBMP, develop an IV&V waiver process, and verify the BBMP's adherence to VA Directive 6061. We will follow up on the implementation of planned actions until they are complete.

(original signed by:)
BELINDA J. FINN
Assistant Inspector General
for Auditing

Introduction

Purpose

The purpose of the audit was to determine whether the BBMP was effectively planned and managed. The audit objectives were to determine if an SDLC methodology was effectively employed and if the project was in compliance with capital investment requirements.

Background

Blood Bank Modernization Project. VA medical facilities currently use VistA Blood Bank Software to identify and track blood and blood products from collection through use. VistA is an integrated system of clinical software applications that connects VA medical facilities' computers. In October 1999, VHA OI initiated the BBMP to develop a blood bank information system called VistA Blood Establishment Computer Software (VBECS). This new system will replace the VistA Blood Bank Software VA medical facilities currently use and operate as an independent application outside of VistA. A significant goal of the new system is to decrease the risk of errors and to improve the safety of blood component transfusions through the use of current technology, such as barcode scanning, to better detect inconsistencies in data input. VA employees, with the assistance of contractors, manage the BBMP. Initially, VHA OI officials planned to complete the BBMP by October 2004. However, as of January 2008, the project was scheduled for completion in September 2008.

Project Oversight and Management Responsibilities. When VHA initiated the BBMP in 1999, VA's IT organization was decentralized and had multiple layers. At the Department level, the VA CIO served as the principal advisor to the Secretary on all IT matters. The VA CIO was responsible for creating IT capital investment policy and reporting to oversight bodies, such as OMB, on the status of major IT projects. Administrations within VA, such as VHA and the Veterans Benefits Administration, had their own CIOs and generally functioned independently of the VA CIO. For VHA, the VHA CIO directed OI and was responsible for ensuring that VHA IT plans were compatible with Department plans. The VHA CIO was required to submit VHA budget projections for IT investments to the VA CIO for approval.

Within VHA OI, Health Systems Design and Development (HSD&D) staff were responsible for overseeing the development and maintenance of clinical software applications, including the new blood bank system. HSD&D assigned responsibility for the BBMP to a portfolio manager and a project manager.[1] The portfolio manager was responsible for monitoring the BBMP's cost, schedule, and quality. The project manager

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[1] A portfolio is a collection of IT programs and projects grouped together to facilitate effective management to meet strategic business objectives.

was responsible for overall management of the BBMP, including project planning, scheduling, monitoring, and reporting activities. In this report we use the term "project officials" when referring to activities or responsibilities shared by the portfolio manager and project manager.

In February 2007, VA realigned its IT operations and development functions, including VHA's functions, under VA OI&T. The intent of the realignment was to centralize authority over Department IT resources under the Assistant Secretary for Information and Technology, who also serves as VA's CIO. As a result, responsibility for design and development of clinical software applications, including the blood bank system, transferred to the newly created Program Executive Office for Veterans Health Information Technology in VA OI&T.

Project Management Principles and Requirements. Effective project management enables an organization to conduct projects in a disciplined, well-managed, and consistent manner so that it completes projects on time and within budget. Capital investment policies support project management principles by guiding Federal agencies in the selection and management of IT investments and ensuring that IT resources are used efficiently and align with the agency's mission.

System Development Life Cycle.[2] An SDLC is a conceptual model project managers use to enhance management's control over projects by dividing complex tasks into manageable sections. Managers organize projects into phases, allowing them to review project phases for successful completion before allocating resources to subsequent phases. The number of phases within a project's life cycle is based on the characteristics of a project and the project management methodology employed. Project managers should follow well-structured plans that clearly define the requirements of each project phase.

When VHA OI initiated the BBMP, VA did not have a uniform SDLC methodology that project managers were required to follow. Therefore, the project manager did not initially follow an SDLC methodology. However, in 2002, the BBMP project team developed an internal operating procedure that included an SDLC specific to the project. Each phase included specific steps and deliverables to ensure that the BBMP met applicable VA policies and industry best practices for developing software. The BBMP's SDLC included six project phases:

1. Initiation—This phase begins with the formal project request and includes activities such as initiating communication with the blood bank user group, developing project plans, and obtaining project approval. This phase ends when the project is formally activated.

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[2] The System Development Life Cycle is also known as the Software Development Life Cycle, and both terms are commonly accepted.

2. Development—During this phase, the team gathers and analyzes requirements, designs the software, writes computer code, and conducts independent testing to verify and validate that the software functions as designed.

3. Optimization—This phase continues validation of the system by having blood bank users field test and accept the system. During optimization, the team may rewrite some code as users uncover defects. This phase ends when the U.S. Food and Drug Administration (FDA) notifies the project manager that the system has met FDA standards and field testing has been completed.[3]

4. Implementation—During this phase, the BBMP team releases the system, training materials, and user documentation to VHA's training and support divisions.

5. Post-Implementation—During this phase, the BBMP team provides field support to users by issuing software updates as users uncover defects and request enhancements.

6. Product Sunset—This phase represents retirement and removal of the system from the field and typically coincides with the release of a replacement system.

Capital Investment Policies. Congress enacted the Clinger-Cohen Act of 1996 to improve capital planning and control of IT projects in Federal agencies. The Act required the Director of OMB to oversee the management of major Federal IT investments, evaluate the effectiveness of agency programs, and set funding priorities. The Act also required OMB to establish a process for analyzing, tracking, and evaluating the risks and results of all major IT capital investments. Furthermore, it made Federal agency heads responsible for developing agency-level capital investment policies.

In July 1997, OMB amended Circular A-11, "Preparation and Submission of Budget Estimates," to implement the Clinger-Cohen Act by requiring agencies to report IT projects meeting the criteria of major capital assets in their annual capital plans. VA Directive 6000, "VA Information Resources Management (IRM) Framework," September 1997, established policy for implementing an integrated, Department-wide IT framework. Specifically, the directive established policy and responsibilities for planning, budgeting, procurement, and management of IT under the direction of the Department CIO. Furthermore, in June 2000, VA OI&T issued the VA IT Capital Investment Guide creating procedures to ensure VA complied with the Clinger-Cohen Act, OMB, and VA Directive 6000 capital investment requirements.

Scope and Methodology

The audit covered the BBMP's planning and management activities from October 1999 through March 2007. We performed audit work, including visits to the VHA OI field office in Hines, IL from September 2006 through October 2007.

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[3] FDA considers blood bank software to be a medical device and subject to FDA review and approval.

We reviewed VA, OMB, and National Institute of Standards and Technology policies, procedures, and other guidance. We interviewed VA OI&T and VHA OI officials as well as current and former BBMP team members. We also reviewed project documentation, contract invoices, salary data, travel obligations, and equipment purchase orders. Our audit work focused on the project management aspects of the BBMP. We did not assess the adequacy of VA's SDLC policies and procedures as part of this review. Furthermore, we did not review technical aspects of the new blood bank system, such as analyzing software design or computer code.

To address our audit objectives, we did not rely on computer-processed data. However, for background purposes, we used computer-processed cost data from VA's Personnel and Accounting Integrated Data (PAID) system and Financial Management System (FMS) to estimate BBMP development costs. Consequently, we did not perform a full assessment of data reliability. However, we did perform limited testing of this cost data using source records, such as purchase orders and contractor invoices, to judge the sufficiency and accuracy of the data. We concluded that the data was sufficiently reliable.

Our assessment of internal controls focused only on those controls related to our audit objectives. We conducted the audit in accordance with generally accepted government auditing standards.

Results and Conclusions

The Blood Bank Modernization Project Was Not Properly Planned and Managed

Findings

VHA OI officials did not properly plan and manage the BBMP. Specifically, they did not complete seven critical planning and management tasks required by VA capital investment policies, the BBMP SDLC methodology, and other project guidance. Since VHA OI officials did not treat the BBMP as a major project, as required by VA IT capital investment guidance, VHA OI officials did not ensure controls to manage IT capital investment risks were followed. As a result, VA lacked reasonable assurance that VHA OI officials selected the best project alternative, used VA resources efficiently, and implemented effective controls to safeguard sensitive project information. VA capital investment officials also had no oversight of the cost, schedule, and performance of this project, and VA did not provide a full accounting of this IT investment to OMB as required by the Clinger-Cohen Act.

Critical Planning and Management Tasks Were Not Performed. As of June 2007, the BBMP project team had completed the initiation and development phases of the project and was in the optimization phase. For the two completed phases, the team had completed most tasks and deliverables as required. However, VHA OI officials did not perform the seven critical planning and management tasks described below.

VHA OI Officials Did Not Develop Adequate Cost Estimates of Project Alternatives. Before acquiring or developing a major IT capital investment, the Clinger-Cohen Act and VA Directive 6000 require the VA CIO and other agency officials to consider whether the function should be performed by a private sector source or by the Federal government. OMB Circular A-130, "Management of Federal Information Resources," and the VA IT Capital Investment Guide required VHA OI officials to perform a CBA of project alternatives to justify proposed projects to capital investment officials. The guide also required VHA OI officials to explain their decision if they concluded that an alternative was not feasible. The guide required the preparer of the CBA to include all life-cycle costs for each alternative. We concluded that the BBMP's CBA did not include adequate cost estimates for a COTS acquisition or an accurate assessment of in-house development project alternatives. A former project official who prepared the cost estimates did not document his methodology or assumptions, used poor methodologies, and included different cost elements in the estimates relied upon for decision making.

COTS Estimate—The former project official based the $60 million COTS estimate on vendor responses to a Request for Information (RFI). Three vendors submitted estimates for software, hardware, installation, training, and related annual system maintenance costs based on a single blood bank installation. The former project official took the average of the 3 estimates and multiplied the figure by 140, the number of blood bank locations, and added $7.7 million in programming costs for VistA interfaces outside of the BBMP application. We determined this methodology inflated the COTS estimate.

The methodology inflated the estimated cost because the former project official used the average of the three vendors' estimates and averaged one-time nationwide development costs, such as training, to all 140 blood bank sites. In addition, the COTS estimate may have been further inflated because the former project official did not consider the possibility of using other Federal contracts for purchasing system hardware even though three of the four vendors proposed hardware solutions that were nonproprietary, which means the Federal government was free to purchase needed hardware from other sources. Also, the former project official could not explain and had not documented a $7.7 million estimate for additional VistA interface work requirements.

A fourth vendor responded to the RFI with pricing information for a 140-site solution. While this estimate was significantly lower than the other three vendors' estimates, it was not used when the COTS estimate was developed and there was no documentation to support why the vendor's solution was not feasible.

In-House Estimate—The in-house VHA development estimate of $12.8 million was understated and incomplete. The estimate projected the cost to develop and operate the new system over a 5-year period and included four components: $3.1 million for planning and development labor costs, $3.5 million in system hardware, $1.5 million in training and installation costs, and $4.7 million for system maintenance.

The in-house estimate did not include hardware installation costs, recurring hardware maintenance, or costs related to converting data from the VistA Blood Bank Software into the BBMP. The former project official did not include these costs because sections outside of the BBMP development group were designated to perform the associated functions. However, vendors responding to the RFI were asked to include these items in their system estimates. Because the in-house estimate did not include some of the project cost elements found in the COTS projection, the two estimates were not truly comparable.

VHA OI officials we interviewed stated that when the BBMP was initiated the VHA CIO had a strong preference for in-house development of clinical applications. According to these officials, VHA management considered VistA clinical applications developed in-house to be superior to COTS software used by non-VA healthcare systems, and the perception was that in-house software projects were more likely to succeed than projects

using COTS alternatives. This culture contributed to a CBA that was developed without full consideration of project alternatives. Without the analysis of comparable cost estimates for project alternatives, IT management could not be reasonably assured that the decision to develop the BBMP in-house was justified and the goals of the Clinger-Cohen Act and VA Directive 6000 were met.

VHA OI Officials Did Not Submit the BBMP's Capital Investment Application to VA OI&T for Project Approval. OMB Circular A-11 requires agencies to report major projects to OMB to ensure that acquisitions support an agency's mission, goals, and objectives. At the time the BBMP was initiated, the VA IT Capital Investment Guide required VHA OI officials to complete capital investment applications for major projects. The guide defined a major project as meeting one of the following criteria: (1) high cost, (2) high risk, or (3) high visibility. High-cost thresholds were $10 million acquisition or $30 million life-cycle costs. A Capital Investment Application is an IT project proposal that provides detailed information, such as project goals and objectives, acquisition and recurring costs, mission, and alignment with VA IT architecture. Projects categorized as major go through a capital investment process to identify investments that best support VA mission needs.

VHA OI officials prepared a Capital Investment Application in July 2001 but did not submit the application to VA OI&T for project approval. As a result, VA capital investment officials were not aware of the BBMP and did not perform the required technical or strategic reviews. Without knowledge of the BBMP, VA and OMB capital investment officials could not ensure that the BBMP supported VA's mission and strategic goals, nor did they have a complete account of VA's IT portfolio.

VHA OI officials did not submit the Capital Investment Application because they concluded that the BBMP was not a major project since it did not meet the cost thresholds for VA IT capital investments. They had not considered whether the BBMP was a high-risk or high-visibility project which would have also qualified it as a major project. In our opinion, because the new blood bank system will contain sensitive patient information and requires FDA approval, the BBMP met the criteria as a high-risk and high-visibility project and should have been submitted to capital investment officials for approval. Although the VA IT Capital Investment Guide provided guidance on categorizing projects, it allowed VHA OI officials to categorize their projects without oversight by capital investment or other VA officials.

VHA OI Officials Did Not Prepare an OMB Exhibit 300 for Capital Investment Reporting Purposes. OMB Circular A-11 requires agencies to submit an Exhibit 300, also known as the Capital Asset Plan and Business Case, for major projects. The Exhibit 300 reports a project's progress, including a summary of cost and schedule performance goals. While an Exhibit 300 is similar to the Capital Investment Application, the purpose of an Exhibit 300 is to support the agency's IT portfolio.

Agencies use Exhibit 300s for both initial and ongoing funding approvals from OMB and are required to update Exhibit 300s annually to report project performance for major capital assets. OMB uses the information reported in the Exhibit 300 when it evaluates budgetary resources for IT investments.

VHA OI officials did not prepare an Exhibit 300 for the BBMP and submit it to capital investment officials. In part, this omission occurred because VHA OI officials did not consider the BBMP to be a major project. According to a VHA OI official, this also occurred because the former VHA CIO inappropriately directed that the BBMP, along with other clinical development projects, be classified as a subproject under VistA Legacy, a maintenance project. Neither the VA IT Capital Investment Guide nor the subsequent VA IT Portfolio Management Guide addresses subprojects.

In April 2006, in response to the VA CIO's request, the VistA Legacy Project Manager identified the BBMP and 50 other development subprojects for removal from the VistA Legacy Exhibit 300. The VistA Legacy Project Manager agreed that the BBMP should not have been included in the VistA Legacy Exhibit 300 because the BBMP is not a maintenance project. However, instead of requiring the BBMP to have its own Exhibit 300, VA staff moved the BBMP and the other development projects to the VistA Application Development Exhibit 300 as subprojects.

As a result of VHA OI officials not preparing an Exhibit 300 for the BBMP, VA capital investment and OMB officials were not aware of the BBMP and could not ensure that the project supported VA's mission needs or was consistent with OMB funding priorities. Furthermore, VA capital investment and OMB officials had no oversight of the cost, schedule, and performance of the project, and OMB did not have a full and accurate accounting of VA IT investments as required by the Clinger-Cohen Act.

<u>VHA OI Officials Did Not Document Key Decisions or Maintain Complete Project Files</u>. Complete project documentation is essential for good project management. OMB's "Model Framework for Management Control Over Automated Information Systems," March 1988, states that documentation is key to establishing effective controls. The BBMP's SDLC requires the project team to document and follow all applicable policies, processes, and procedures. VHA OI officials did not document key decisions, such as project approval or justification for including the BBMP under the VistA Legacy Exhibit 300. In fact, during our interviews, they were not sure who had made these decisions. Official project files also did not contain important documents, such as the Capital Investment Application or the CBA. We obtained these documents from a former BBMP project manager and HSD&D Budget and Contract Administration staff.

According to a VHA OI official, project documentation was not considered a priority in the organization when the BBMP began. From project initiation in October 1999 to March 2007, several key positions within VHA OI and VA OI&T changed, including

three BBMP Project Managers, four Directors of HSD&D, five VHA CIOs, and four Assistant Secretaries of Information and Technology. This management turnover highlights the need to document key project decisions to ensure continuity of project management and decision making. As a result, without documentation of key decisions, accountability for project management and achieving desired outcomes was not effectively established.

The Project Manager Did Not Conduct a PIA. The purpose of a PIA is to document the assessment of the risks and controls related to collecting, maintaining, and disseminating electronic information. VA Handbook 6502.2 requires project managers to complete PIAs in a timely and accurate manner and for the Assistant Secretary for Information and Technology to review and approve the PIAs. This requirement applied to all systems that would include personally identifiable information, such as patient names and social security numbers. When the BBMP project team developed the BBMP SDLC, VA did not require PIAs. However, several VHA OI officials agreed that the 2004 requirement applied to the BBMP. According to the project manager, she did not complete a PIA for the BBMP because she mistakenly believed that the VistA Legacy PIA covered the BBMP, but it did not.

VHA OI Did Not Review Sufficient Information Before Granting a Waiver from IV&V Requirements. An IV&V review is a key activity in the BBMP SDLC. The purpose of an IV&V review is to provide an independent appraisal of a development project and identify areas of deficiency and risk. An IV&V review confirms that a system performs its intended functions correctly and provides information about the system's quality and reliability. Identifying problems in development instead of during field testing or implementation reduces the likelihood of schedule delays and increased costs. VHA OI's testing procedures and the BBMP's SDLC required that VHA's IV&V Group perform independent testing.

Although the project manager requested an IV&V review in November 2006, the IV&V Group did not immediately conduct one because it was engaged in another project. VHA OI officials could not conduct field testing until either an IV&V review was performed or an IV&V waiver was granted. To avoid additional delays, the project manager requested an IV&V waiver from VHA OI's Enterprise VistA Support (EVS) Division. The waiver request included the project manager's assertion that an IV&V review was not needed for the project based on the BBMP internal testing processes and results.

VHA OI testing process requirements did not specify procedures for granting IV&V waivers. The EVS Division Director granted the waiver for the BBMP without reviewing testing documentation to validate the project manager's claim that an IV&V review was not needed for the project. Furthermore, the EVS Division Director did not consider alternatives, such as contracting for IV&V services. In our opinion, because of the

project's high visibility and high cost and the possible adverse impact on patient safety from a failure in the new system, a schedule restraint was not a sufficient reason to waive the IV&V review. Because IV&V reviews are an integral part of the SDLC process and help to mitigate risks associated with system development, waivers of the IV&V requirement should only be granted after a thorough, documented analysis and validation of statements made in waiver requests.

<u>VHA OI Officials Did Not Monitor and Control Project Costs</u>. BBMP internal operating procedures require the project manager to monitor project development costs. OMB Circular A-11 requires capital investments to have OMB approval for a project's initial baseline and any changes to the baseline. A project baseline consists of cost, schedule, and performance goals. Baselines for project costs should include realistic projections of the total cost to complete the project. OMB Circular A-130 and the VA IT Capital Investment Guide further required that VA control project costs by monitoring and reporting the variance between planned and actual costs. Planned costs are established when a project is approved and a baseline is prepared.

Project officials did not establish a baseline for project costs and could not tell us the total costs incurred during the initiation and development phases of the project. Furthermore, VHA OI officials did not require the project manager to report total development costs in monthly project status reports, and they approved four schedule variances that extended project completion—from October 2004 to March 2007—without requiring the project manager to calculate the financial impact of these delays. (A fifth schedule variance, extending the project to February 2008, did include an estimate of the cost impact.)

We estimated that from October 1999 through September 2007, VA spent $32.9 million on the BBMP. (See Appendix A, page 15, for a description of our cost estimate methodology.) According to a former HSD&D official, VHA OI officials were not concerned with measuring the BBMP's total development cost because they viewed the BBMP as a replacement system for the current VistA Blood Bank System. They viewed funding a blood bank system as a task that had to be performed annually regardless of whether the money was spent on maintenance of an existing system or development of a new system. The focus was on the current year program budget and not on total project development costs.

Project officials stated that they were not directly responsible for tracking project costs despite the requirements found in the BBMP's SDLC and the VA OI&T's IT Project Management Guide. However, these individuals had received training and manuals explaining how to measure and report project costs using the Primavera system. A former project official told us that using Primavera to monitor project costs was "cumbersome."

Because VHA OI officials' did not monitor and control project costs, senior management did not have reasonable assurance that VA resources were used efficiently. The BBMP's SDLC requires the project manager to ensure project resources are used efficiently and progress is reported to senior management and project stakeholders. Having this cost information would have given the VA CIO critical information needed to advise agency officials on decisions to continue funding of IT investments, to cancel the project, or to consider the feasibility of project alternatives.

In February 2006, the VA CIO issued VA Directive 6061, "VA Earned Value Management System," which incorporates best business practices to improve VA project planning and execution as well as promotes more effective management oversight. The directive requires all development projects to have performance measurement baselines with cost, schedule, and quality goals. It requires project officials to report performance monthly against these defined benchmarks. In December 2006, VHA OI also established its own change control process in which project change requests must include expected cost impact.

In March 2007, VHA OI officials reported that they were in the process of installing a performance measurement baseline and producing monthly earned value reports for senior management officials as required by the new directive. While we recognize that these policy changes should improve the internal controls over planning and management of the BBMP and other development projects, VA management must actively monitor and enforce compliance with VA Directive 6061.

The BBMP Needed Improved Oversight and Strengthened Policy Guidance. We attributed the BBMP planning and management problems to three factors: (1) poor oversight by VHA OI management, (2) weaknesses in VA's capital investment policies, and (3) VHA's preference for in-house development.

VHA OI Management Did Not Provide Sufficient Oversight of the BBMP. VHA OI officials did not provide sufficient oversight of project deliverables and costs. For example, VHA OI management did not require project officials to report total development costs, and they approved schedule variances without requiring the project manager to determine the financial impact of the delays. VHA OI officials also approved the project manager's IV&V waiver request without thoroughly reviewing the justification.

VA Capital Investment Policies Had Weaknesses. Capital investment policies should guide the selection and management of IT capital investments and include oversight mechanisms to ensure IT resources are used efficiently and align with the agency's mission. VA's capital investment policies did not address the addition of subprojects to existing Exhibit 300s, such as the VistA Legacy project. Additionally, capital investment policies allowed project officials to determine if their proposed project met the criteria for

major capital investments. In our opinion, capital investment officials should have reviewed this decision to ensure the appropriateness of the project categorization decision and compliance with oversight requirements for major IT investments. We believe policy changes to address these issues would strengthen controls and ensure capital investment officials are able to review and approve projects that align with VA's mission and goals.

VHA Preferred In-House Development. The former VHA CIO's strong preference for in-house development of clinical applications was indicative of the culture within VHA OI when the BBMP was initiated. This culture enabled a former project official to understate the cost to develop BBMP in-house and overstate the costs to acquire a COTS alternative. Many VHA OI officials believed that clinical applications developed in-house were superior to the commercial alternatives available, and VHA OI officials viewed the CBA as a paperwork exercise to comply with VA policy that they consider alternatives.

Conclusion

VHA OI officials did not properly plan and manage the BBMP. They did not perform critical planning and control activities such as develop adequate cost estimates for project alternatives, submit a Capital Investment Application for project approval, prepare an Exhibit 300, document key project decisions, conduct a PIA, obtain an IV&V review, or monitor and control project costs. These problems occurred because of poor oversight by VHA management officials, weak controls in VA's capital investment policy, and an organizational culture that preferred in-house development. As a result, VA lacked reasonable assurance that VHA OI officials efficiently used and safeguarded VA resources or complied with the Clinger-Cohen Act and OMB capital investment requirements.

Recommendations

1. We recommended that the Assistant Secretary for Information and Technology fully document future estimates for project alternatives presented in CBAs, including all methodologies, assumptions, and cost data sources.

2. We recommended that the Assistant Secretary for Information and Technology develop and implement procedures to ensure that capital investment officials review project categorization decisions.

3. We recommended that the Assistant Secretary for Information and Technology submit a separate Exhibit 300 for the BBMP.

4. We recommended that the Assistant Secretary for Information and Technology determine if projects included in the VistA Application Development Exhibit 300 meet VA criteria as major projects and prepare required Exhibit 300s as appropriate.

5. We recommended that the Assistant Secretary for Information and Technology require project managers to maintain comprehensive project files that contain all relevant project documentation.

6. We recommended that the Assistant Secretary for Information and Technology conduct a PIA on the new blood bank system.

7. We recommended that the Assistant Secretary for Information and Technology review the BBMP's internal testing documentation to determine if the project requires an IV&V review.

8. We recommended that the Assistant Secretary for Information and Technology develop and implement specific criteria for reviewing and approving IV&V waiver requests.

9. We recommended that the Assistant Secretary for Information and Technology require that the BBMP project manager develop performance measurement baselines, report actual costs against these baselines, and include cost impacts for project change requests in accordance with VA Directive 6061.

Assistant Secretary for Information and Technology Comments

The Assistant Secretary for Information and Technology agreed with our findings and recommendations and planned to complete all corrective actions by September 2008. (See Appendix B, pages 17–20, for the full text of the Assistant Secretary's comments.) The Assistant Secretary reported that the Deputy CIO for Enterprise Development was developing processes to ensure that Cost Benefit Analyses and Analyses of Alternatives are fully supported and that these processes would be documented by July 30, 2008. He also reported that a process for approving and prioritizing capital investments would be documented by September 30, 2008, and that a FY 2009 OMB 300 Exhibit had been prepared for the BBMP.

The Assistant Secretary's planned actions also included evaluating projects in the VistA Application Development Exhibit 300 to determine if these projects should have their own Exhibit 300s. Furthermore, the Deputy CIO for Enterprise Development planned to implement a process that ensures all IT projects have proper documentation. The Assistant Secretary also stated that the BBMP Project Manager had initiated a PIA and planned to have it completed and approved by June 30, 2008. The Program Executive Officer for VHIT will decide by September 30, 2008 if an IV&V should be performed for

the BBMP. Further, the Deputy CIO for Enterprise Development planned to develop an IV&V waiver process and to verify the BBMP's adherence to VA Directive 6061.

Office of Inspector General Comments

The Assistant Secretary provided an acceptable implementation plan. We will follow up on the completion of planned corrective actions.

Cost Estimate Methodology

We estimated that from FY 2000 through FY 2007, VA spent $32.9 million on the BBMP. Because project officials did not maintain a complete accounting of project costs, we had to develop our own estimate of the BBMP's costs. We discussed our methodology with the current and former portfolio managers, and they agreed that it was reasonable.

To compute our estimate of $32.9 million, we did the following:

1. **Blood Bank Development and Maintenance Costs.** We first obtained FYs 2000–2006 blood bank expenses from HSD&D's Budget and Contract Administration staff for VA salaries, contract, equipment, travel, and other costs. To validate these expenses, we compared the travel costs to FMS data, VA salaries to PAID data, equipment and other costs to VA purchase orders, and contract labor costs to paid invoices. HSD&D Blood Bank Program expenditures included both development of the BBMP and maintenance of the existing Vista Blood Bank System. These costs totaled $23.6 million. However, this total did not include FY 2000 VA salary costs. To estimate these costs, we took the 3,233 labor hours reported in the work breakdown structure (WBS)[4] in Primavera for FY 2000 and multiplied it by the $50 average BBMP VA salary rate for FY 2001. The rounded $50 average rate was calculated by dividing the FY 2001 PAID salary costs for the BBMP staff by the FY 2001 labor hours reported in the WBS. Budget and Contract Administration staff agreed this was a reasonable rate to use for FY 2000. Multiplying the labor hours by the average rate, we estimated that VA spent $161,650 for BBMP salaries in FY 2000 (3,233 labor hours x $50 average salary rate = $161,650). We added the FY 2000 VA salary estimate of $161,650 to the $23.6 million, bringing the total blood bank IT program-related costs to $23.8 million.

2. **Maintenance Costs for Current System.** Because the $23.8 million included costs to maintain the current system, we removed these maintenance costs. The BBMP staff could not determine the maintenance costs of the current blood bank system. To estimate the maintenance costs, we determined the total number of hours reported in Primavera from FY 2000 to FY 2006. We analyzed the BBMP's WBS and distinguished the hours related to development of the new system from the hours related to maintenance of the current system. Of the 268,280 total hours reported in Primavera, we determined that 34,892 hours (13 percent) were for maintenance and 233,388 (87 percent) were for development. Using the 87 percent, we estimated that $20.7 million of the $23.8 million was spent on development (87 percent x $23.8 million blood bank IT program costs = $20.7 million).

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[4] The WBS is a listing of tasks performed by the BBMP team to accomplish the project objectives and of the hours expended to complete the tasks.

3. **Hardware and Training Costs.** VHA OI's Health Systems Implementation, Training, and Enterprise Support (HSITES) was responsible for purchasing hardware, such as servers, printers, and other equipment for the 141 sites and producing manuals and training materials for the BBMP.[5] We obtained hardware costs and salary expenses related to authoring manuals and training materials for the new system from the HSITES staff. From FY 2000 to FY 2006, these costs totaled $7.1 million. We added the $7.1 million to the $20.7 million, which resulted in $27.8 million in development costs ($7.1 million hardware, implementation, and training costs + $20.7 million development costs = $27.8 million).

4. **Estimated Project Costs for FY 2007.** In July 2007, the project manager estimated that project costs for FY 2007 would total $5.1 million. This estimate included VA salaries, contract, travel, and other costs. We added the $5.1 to the $27.8 million, bringing the total estimated project costs to $32.9 million.

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[5] The VA plans to install VBECS at 141 locations. It was determined after project initiation that the VA medical facility in Canandaigua, NY needed VBECS installed to coordinate work within its VISN even though the facility does not have its own blood bank.

Assistant Secretary for Information and Technology Comments

**Department of
Veterans Affairs**   **Memorandum**

Date: January 2, 2008

From: Assistant Secretary for Information and Technology

Subj: Audit of Veterans Health Administration Blood Bank Modernization Project

To: Assistant Inspector General for Auditing, Office of Inspector General (52)

    Attached is the Office of Information & Technology's response to Audit of Veterans Health Administration Blood Bank Modernization Project report issued July 2006. If you have any questions, please contact Paul A. Tibbits, M.D., Deputy Chief Information Officer for Office of Enterprise Development at (202) 461-6931.

    (original signed by:)

    Robert T. Howard

    Attachment

Assistant Secretary for Information and Technology Comments to Office of Inspector General's Report

The following comments are submitted in response to the recommendations in the Office of Inspector General's report:

Recommendation 1: We recommend that the Assistant Secretary for Information and Technology fully document future estimates for project alternatives presented in CBAs, including all methodologies, assumptions, and cost data sources.

Concur   Target Completion: July 30, 2008

Responsible Official: Deputy CIO for Enterprise Development

Processes are being put in place to insure that Cost Benefits Analysis and Analysis of Alternatives are fully documented for new project startup. Documentation of process will be provided by completion date.

Recommendation 2: We recommend that the Assistant Secretary for Information and Technology develop and implement procedures to ensure that capital investment officials review project categorization decisions.

Concur   Target Completion: September 30, 2008

Responsible Official: Assistant Secretary for Information Technology

Documentation of project approval and prioritization process through the VA Governance Plan will be provided.

Recommendation 3: We recommend that the Assistant Secretary for Information and Technology submit a separate Exhibit 300 for the BBMP.

Concur   Target Completion: September 30, 2008

Responsible Official: Program Executive Officer VHIT

An OMB 300 Exhibit for FY 2009 has been submitted for VBECS. A copy of the Exhibit will be provided once approval and acceptance by OMB is obtained.

Recommendation 4: We recommend that the Assistant Secretary for Information and Technology determine if projects included in the VistA Application Development Exhibit 300 meet VA criteria as major projects and prepare required Exhibit 300s as appropriate.

Concur   Target Completion: September 30, 2008

Responsible Official: Deputy CIO for Enterprise Development

As OED (OI&T) moves to restructure the VHIT (the Office of Enterprise Development) OMB 300s each project will be evaluated against OMB requirements and the appropriate OMB Exhibit will be created.

Recommendation 5: We recommend that the Assistant Secretary for Information and Technology require project managers to maintain comprehensive project files that contain all relevant project documentation.

Concur   Target Completion: July 30, 2008

Responsible Official: Deputy CIO for Enterprise Development

The Enterprise Process Group for OED is reviewing project artifacts to be included in all project documentation repositories. The requirements for all project teams will be published and a process for review of these requirements will be implemented by the completion date.

Recommendation 6: We recommend that the Assistant Secretary for Information and Technology conduct a PIA on the new blood bank system.

Concur   Target Completion: June 30, 2008

Responsible Official: Program Manager Blood Bank Modernization Project currently officially named VBECS

PIA has commenced and documentation wil1 be provided by target date.

Recommendation 7: We recommend that the Assistant Secretary for Information and Technology review the BBMP's internal testing documentation to determine if the project requires an IV&V review.

Concur   Target Completion: September 30, 2008

Responsible Official: Program Executive Officer VHIT

A review will be performed and determination made as to need for IV &V for the BBMP product by target date.

Recommendation 8: We recommend that the Assistant Secretary for Information and Technology develop and implement specific criteria for reviewing and approving IV&V waiver requests.

Concur   Target Completion: September 30, 2008

Responsible Official: Deputy CIO for Enterprise Development

Development of policy for requesting and approving a waiver for IV&V is in process, documentation and implementation of the reviewed waiver process will be provided by target date.

Recommendation 9: We recommend that the Assistant Secretary for Information and Technology require that the BBMP project manager develop performance measurement baselines, report actual costs against these baselines, and include cost impacts for project change requests in accordance with VA Directive 6061.

Concur   Target Completion: September 30, 2008

Responsible Official: Deputy CIO for Enterprise Development

Documentation of adherence to VA Directive 6061 will be provided by target date.

OIG Contact and Staff Acknowledgments

OIG Contact	Claire McDonald (206)220-6651
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