



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Audits and Evaluations*

VETERANS HEALTH ADMINISTRATION

Governance of Robotic  
Surgical System Investments  
Needs Improvement

AUDIT

REPORT #19-07103-252

SEPTEMBER 25, 2020



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## Executive Summary

Robotic surgery—a computer-assisted, minimally invasive technique—enables surgeons to perform procedures with improved capabilities. Potential advantages include quicker patient recovery times, less blood loss, and reduced risk of other medical complications.

The Veterans Health Administration’s (VHA) investment in robotic surgery has increased over the years, with more VA medical facilities obtaining and using robotic surgical systems. Between 2014 and 2019, VHA expanded from 43 systems in use to an inventory of 94 total systems. Intuitive Surgical is the sole-source provider of VHA robotic surgical systems. The systems each cost between \$1.5 million and \$2.2 million, including parts and maintenance.

The acquisition of robotic surgical systems must be supported by sufficient, reliable data. Employees at VHA facilities prepare high-cost, high-tech medical equipment applications for acquisitions costing more than \$1 million, such as robotic surgical systems.<sup>1</sup> The applications must explain how investing in the systems will affect services otherwise performed through community care and provide an estimate on projected costs. These projected costs are used to calculate a return on investment for the systems.

The VA Office of Inspector General (OIG) performed this audit to determine whether VHA adequately governs use of robotic surgical systems to meet defined healthcare and investment objectives. Adequate governance helps VA leaders make informed decisions and provide strategic direction based on objectives, risks, and resources. The audit reviewed high-cost, high-tech medical equipment applications for robotic surgical systems that were recommended for approval between June 2013 and September 2018. The audit also focused on reported procedure data from calendar years 2017 and 2018. The report includes data from 2014 through 2016, and from 2019 as background information to provide additional context.

### What the Audit Found

VA medical facilities, in coordination with their respective Veterans Integrated Service Networks, determine the timing and execution of major medical equipment purchases. In June 2013, the deputy under secretary for health for operations and management issued a policy memorandum describing the application process to acquire high-cost, high-tech medical equipment. Pursuant to these requirements, the Office of Healthcare Technology Management is responsible for reviewing applications for major medical equipment purchases and

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<sup>1</sup> VA policy memo, “Process Changes for Requesting High Cost/High Tech Medical Equipment Acquisitions,” June 3, 2013. The memo explains that high-cost, high-tech medical equipment includes all medical equipment with a unit cost greater than \$1 million.

recommending approvals to the assistant deputy under secretary for health for administrative operations, who has final approval authority.

The OIG found VHA did not consistently follow requirements to properly support and justify its acquisition of robotic surgical systems. The Office of Healthcare Technology Management recommended the assistant deputy under secretary for health for administrative operations approve 45 high-cost, high-tech medical equipment applications for robotic surgical systems for 37 medical facilities between June 2013 and September 2018. However, the audit team determined 13 of those applications (29 percent) had incomplete justification information. In addition, the audit team identified 10 robotic surgical systems from nine VA medical facilities that did not have documented evidence of approval before purchase. Incomplete applications and acquisition of robotic surgical systems without approval showed inadequate VHA governance over the acquisition of the systems.

This occurred because VHA did not adequately manage the submission and review of robotic surgical system applications. The design of the applications and their associated instructions were unclear and inconsistently interpreted by medical facility employees. The Office of Healthcare Technology Management did not require facilities to provide supporting documentation with the applications to show how they determined their workload estimates and financial costs. In addition, the Office of Healthcare Technology Management did not thoroughly review the applications, and therefore did not ensure the applications were adequately completed before recommending approval. Medical facility employees also had differing interpretations of VA policy for acquiring robotic systems, which led to some facilities acquiring equipment without approval.

The VHA central office approval process helps medical facility leaders determine whether their facilities are structurally prepared and have the resources to use the equipment on-site. In addition, the process is important so VHA leaders are aware of the systems permitted for use and can centrally manage acquisition decisions for those facilities. However, VHA could not be certain its investments in robotic surgical systems were supported and appropriate. The inadequate approval process also reduced VHA's ability to reliably assess the workload and investment estimates associated with robotic surgical systems. Without the proper approvals, VHA leaders only knew which systems were officially permitted for use. They were also limited in their ability to manage system acquisition decisions for facilities.

### **VHA Internal Data on Robotic Surgical Procedures Were Not Complete**

The OIG found VHA also did not have comprehensive data on procedures conducted using robotic surgical systems. The National Surgery Office (NSO) oversees the operations of surgical programs and leads the implementation of national policies and procedures for robotic surgery. As part of its operational oversight, the NSO publishes annual reports to inform VHA leaders on

robotic surgical procedures conducted at medical facilities. The NSO reported in its fiscal year 2018 surgery report that VA medical facilities conducted more than 3,600 robotic surgical procedures. However, the audit team determined the NSO underreported the number of procedures by more than 2,300 procedures, when compared to data in the same period tracked by Intuitive, the manufacturer of the robotic surgical systems used by VA medical facilities.

The underreporting occurred due to inconsistencies in how medical facilities captured robotic surgical procedures in the Veterans Health Information Systems and Technology Architecture, VA's electronic health information records system. The NSO believed medical facility employees were applying a code to identify robotic surgery techniques. However, the audit team determined that the code was not consistently used because policy did not require facility employees to apply it to the procedure record. As a result, VHA could not comprehensively identify procedures using robotic surgical systems. Accurate data can help VHA leaders measure performance or make informed decisions at different levels and are especially important for surgical quality reviews.

The results of the audit underscore the need for adequate governance of robotic surgical systems to ensure the healthcare and investment objectives of making technology and surgical services available to veterans are achieved.

## **What the OIG Recommended**

The OIG made five recommendations to the under secretary for health:<sup>2</sup>

1. Update the high-cost, high-tech medical equipment application to provide clearer instructions on preparing requests and providing supporting documentation for robotic surgical systems. The application and instructions should be disseminated to medical facilities, Veterans Integrated Service Networks, and responsible central office organizations.
2. Establish controls to ensure information in high-cost, high-tech medical equipment applications is reviewed and validated before recommending final approval to the assistant deputy under secretary for health for administrative operations.
3. Evaluate the need and justification of the 10 robotic surgical systems at VA medical facilities that were acquired without approval by the assistant deputy under secretary for health for administrative operations.
4. Develop guidance for accurately and consistently coding robotic surgical procedures in the Veterans Health Information Systems and Technology Architecture.

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<sup>2</sup> Recommendations directed to the under secretary for health were submitted to the executive in charge who has the authority to perform the functions and duties of the under secretary for health.

5. Evaluate the need for the National Surgery Office to obtain robotic surgical procedure data from the system manufacturer to assess and validate the use of the systems at VA medical facilities.

## Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with all recommendations and provided corrective action plans. The full text of the VHA management comments is available in appendix C. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating the proposed actions have been completed.



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## Abbreviations

|        |   |
|--------|---|
| DUSHOM | deputy under secretary for health for operations and management |
| FY     | fiscal year   |
| NSO    | National Surgery Office   |
| OIG    | Office of Inspector General                                     |
| VHA    | Veterans Health Administration                                  |
| VISN   | Veterans Integrated Service Network                             |
| VistA  | Veterans Health Information Systems and Technology Architecture |



## Introduction

The Veterans Health Administration's (VHA) investment in robotic surgery has increased over previous years, with more VA medical facilities obtaining and using robotic surgical systems. The VA Office of Inspector General (OIG) performed this audit to determine whether VHA adequately governs the use of robotic surgical systems to meet defined healthcare and investment objectives. The audit team also analyzed reported procedure data from calendar years 2017 and 2018. The report includes data from 2014 through 2016, and from 2019 as background information for additional context. Adequate governance helps VA leaders make informed decisions and provide strategic direction based on objectives, risks, and resources.<sup>3</sup>

### Robotic Surgical Systems

VHA's investments in robotic surgery—a computer-assisted, minimally invasive technique—allow surgeons to perform procedures with improved capabilities such as enhanced visualization. Potential advantages include quicker patient recovery times, less blood loss, and reduced risk of other medical complications. According to VHA, the healthcare objective for implementing robotic surgery is to ensure that veterans have access to a full range of surgical services and technology.<sup>4</sup>

Intuitive Surgical is the sole-source provider of VHA robotic surgical systems. In March 2014, the VA Office of Procurement, Acquisition, and Logistics Strategic Acquisition Center awarded a national contract to Intuitive to acquire two models of surgical systems at VA medical facilities. This contract performance period was for a base year with a provision for four additional option years. VA exercised each option through 2019. These systems, including parts and maintenance, each cost between \$1.5 million and \$2.2 million depending on the model purchased. Intuitive has received more than \$225 million from VHA between March 2014 and February 2019, according to information from Office of Procurement, Acquisition, and Logistics staff.

In 2018 alone, VHA had more than 70 robotic surgical systems in use and about 6,000 surgical procedures performed at medical facilities nationwide. By 2019, there were more than 90 systems in use and about 8,000 procedures performed nationwide—more than a 30 percent increase.<sup>5</sup>

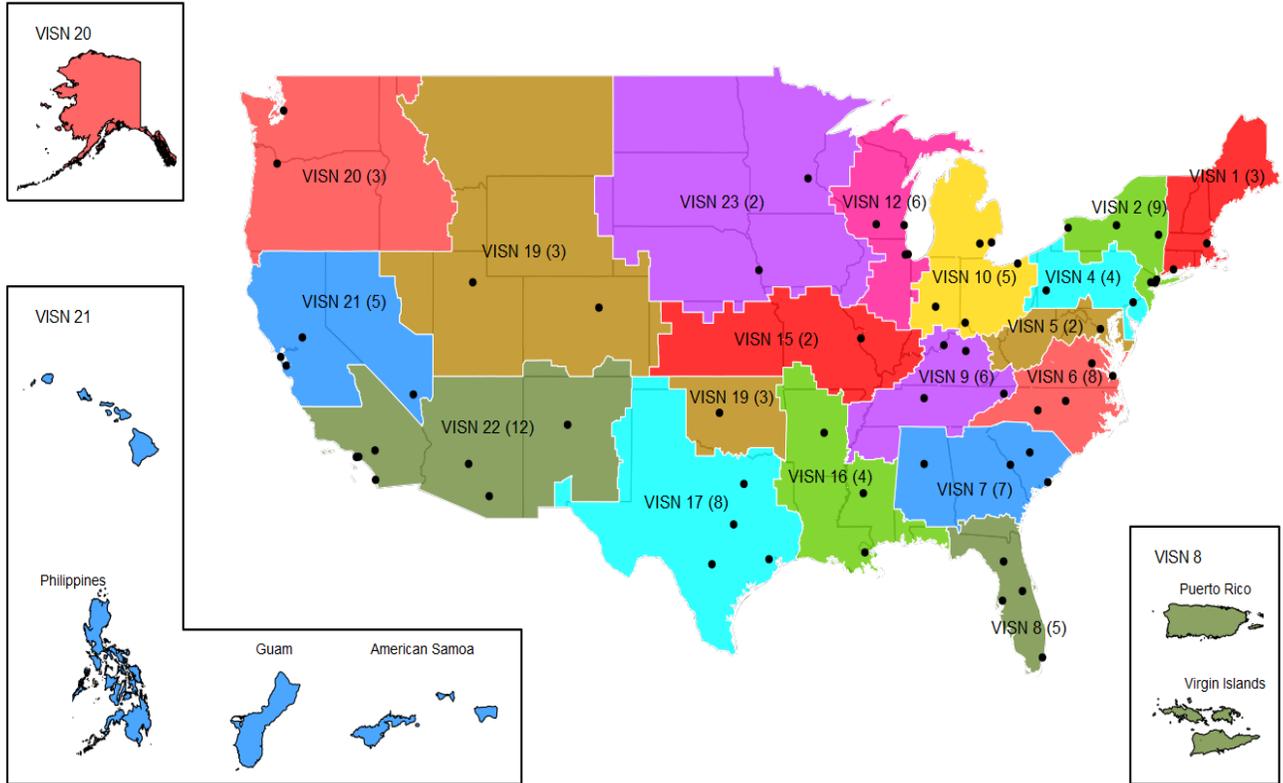
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<sup>3</sup> VA Directive 0214, *Department of Veterans Affairs Governance Structure*, August 11, 2014; rev. May 14, 2019.

<sup>4</sup> Appendix A contains more information about the use of robotic surgical systems in surgical subspecialties.

<sup>5</sup> According to Intuitive-reported procedure data.

Figure 1 shows the locations of robotic surgical systems in use in 2019 by Veterans Integrated Service Network (VISN).



**Figure 1.** Geographic dispersion of robotic surgical systems across 18 VISNs in 2019.

Source: OIG-created map based on analysis of manufacturer-reported robotic surgical system data.

Note: The number of robotic surgical systems in a VISN is shown in parentheses. Some locations have multiple robotic surgical systems.

## Requirements for the Acquisition of Robotic Surgical Systems

The acquisition of robotic surgical systems must be supported by sufficient, reliable data. The Office of Management and Budget (OMB) outlines the need for federal agencies to use current, complete, accurate, and relevant data to make informed decisions regarding the allocation of resources and to develop performance measures to monitor assets. It also requires agencies to have a process for handling capital assets that addresses project prioritization and cost-estimating to improve the accuracy of cost, scheduling, and performance measures provided to management.<sup>6</sup>

<sup>6</sup> OMB, *Capital Programming Guide Supplement to Office of Management and Budget Circular A-11: Planning, Budgeting, and Acquisition of Capital Assets*, July 1, 2016.

Employees at VHA facilities must prepare high-cost, high-tech medical equipment applications for all acquisitions that have a unit cost of more than \$1 million. Pursuant to these requirements, acquisitions of robotic surgical systems must proceed through the high-cost, high-tech medical equipment application process. Applications must be submitted for review and approval before acquisition.<sup>7</sup> The assistant deputy under secretary for health for administrative operations must approve the applications before the equipment is acquired. A key objective of this process is to manage the use of funds through planning and standardization of acquisitions.<sup>8</sup> Based on the application, medical facility employees need to explain how investing in that system will affect services otherwise performed through community care and provide an estimate on community care workload by fiscal year (FY). Facility employees also estimate annual costs, including for community care, and explain how the costs would differ with and without the system. These projected costs are then used to calculate a return on investment.

### **Oversight Roles and Responsibilities for Surgical Systems**

VA medical facilities, in coordination with their respective VISNs, determine the timing and execution of major medical equipment purchases. VISNs have equipment committees and biomedical engineers responsible for developing, reviewing, and approving requests for all high-cost, high-tech needs, including robotic surgical systems.

The Office of Healthcare Technology Management is responsible for reviewing applications for major medical equipment purchases and making recommendations to the assistant deputy under secretary for health for administrative operations, who has final approval authority. The office is also responsible for developing national policies related to medical equipment management and safety. VHA's Procurement and Logistics Office places orders for approved equipment.

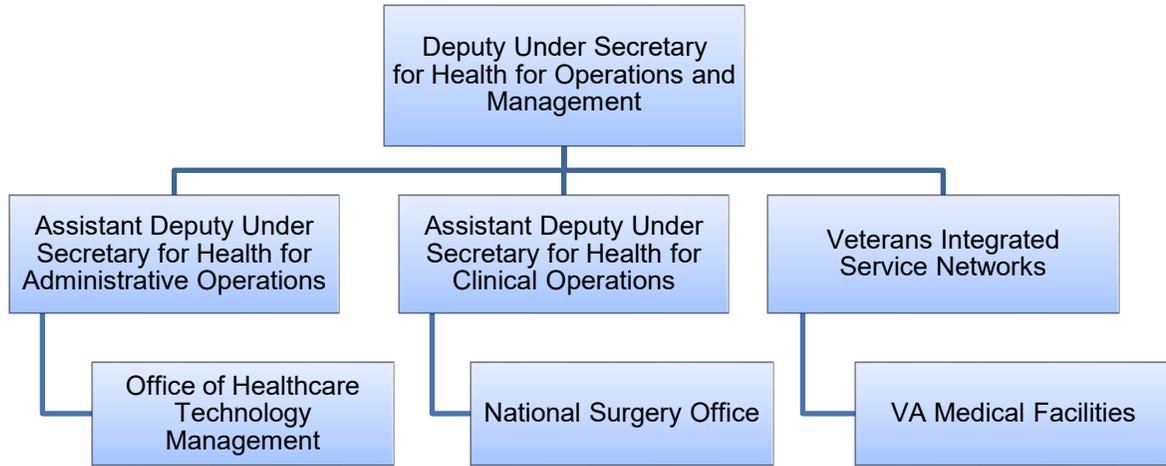
The National Surgery Office (NSO) is charged with operational oversight of surgical programs and leads the implementation of national policies and procedures for surgical services such as robotic surgery at VHA facilities. It monitors surgical quality, outcomes data, and quality improvement activities at the national, regional, and local level.

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<sup>7</sup> VA policy memo, "Process Changes for Requesting High Cost/High Tech Medical Equipment Acquisitions," June 3, 2013; Office of Healthcare Technology Management (HTM) Service Bulletin, "High Cost/High Tech Medical Equipment," May 21, 2013.

<sup>8</sup> VHA Directive 2009-017, *Acquisition of High-Cost, High-Technical Medical Equipment*, March 20, 2009.

Figure 2 illustrates the organizational structure of VHA offices with pertinent robotic surgical system oversight roles and responsibilities during the audit.



**Figure 2.** Organizational structure of VHA offices with robotic surgical system oversight roles and responsibilities.

Source: OIG analysis of organizational charts and responsibilities.

## Results and Recommendations

### **Finding 1: VHA Governance of Robotic Surgical System Acquisitions Was Inadequate**

The OIG found VHA did not consistently follow requirements to properly support and justify its acquisition of robotic surgical systems. Incomplete applications and acquisition of robotic surgical systems without approval showed inadequate VHA governance over the acquisition of these systems. Specifically, the Office of Healthcare Technology Management recommended the assistant deputy under secretary for health for administrative operations approve 45 high-cost, high-tech medical equipment applications for robotic surgical systems for 37 medical facilities between June 2013 and September 2018. However, 13 of those applications (29 percent) had incomplete information for required fields. The application process also was not consistently enforced. The OIG found 10 instances in which medical facilities acquired robotic surgical systems without documented approval by the assistant deputy under secretary for health for administrative operations.

The deficiencies in governance occurred because VHA did not adequately manage the submission and review of robotic surgical system applications. The design of the high-cost, high-tech medical equipment applications and the associated instructions were unclear and inconsistently interpreted by medical facility employees. The Office of Healthcare Technology Management did not require facility employees to provide supporting documentation with the application to show how they determined workload estimates and financial costs. In addition, Healthcare Technology Management employees did not thoroughly review the applications to ensure they were properly completed before recommending approval by the assistant deputy under secretary for health for administrative operations. Medical facility employees also had differing interpretations of VA policy for acquiring robotic systems.

As a result, VHA could not ensure its investments in robotic surgical systems were supported and appropriate. This lack of certainty also reduced VHA's ability to reliably assess the workload and investment estimates associated with robotic surgical systems. Without the proper approvals, VHA leaders only knew which systems were officially permitted for use. They were also limited in their ability to manage system acquisition decisions for facilities.

This finding discusses how

- some medical centers submitted applications for robotic surgical systems that were approved without complete justification information,
- other medical facilities invested in robotic surgical systems without completing the required approval process,

- VHA lacked adequate instructions and procedures to manage the submission and review of robotic surgical system applications, and
- VHA lacked assurance that robotic surgical system investment decisions were supported.

## **What the OIG Did**

The audit team obtained and reviewed high-cost, high-tech medical equipment applications for robotic surgical systems that were recommended for approval between June 2013 and September 2018. The team also reviewed approval memoranda associated with the applications submitted to the Office of Healthcare Technology Management. The audit work included on-site or remote site visits at four medical facilities. The audit team obtained testimonial and documentary information from program officials and staff in the Office of Healthcare Technology Management, the NSO, and various VISNs and medical facilities. Appendix B provides additional details on the audit scope and methodology.

## **Some Medical Facilities Submitted Applications for Robotic Surgical Systems That Were Approved without Complete Justification Information**

High-cost, high-tech equipment applications require information supporting the clinical and financial justification for the acquisition. As mentioned on page 5, the Office of Healthcare Technology Management recommended the assistant deputy under secretary for health for administrative operations approve 45 applications for robotic surgical systems for 37 medical facilities between June 2013 and September 2018. The audit team determined that 13 of 45 applications (29 percent) approved for 11 medical facilities were incomplete. Those applications did not have information for some fields required to ensure there is a clinical need and to evaluate the costs associated with the purchase. Example 1 shows how a medical facility provided incomplete information in an application for a robotic surgical system, yet the application was approved.

### ***Example 1***

*The James A. Haley Veterans Hospital in Tampa, Florida, submitted a high-cost, high-tech medical equipment application in 2016 for a robotic surgical system without information about estimated workload. In the clinical justification section, the application lacked future workload information for three fiscal years that would help justify the purchase. The application was approved by the assistant deputy under secretary for health for administrative operations in May 2016, even though it lacked significant information.*

The Healthcare Technology Management director also recommended the approval of applications that did not include the financial analysis to justify acquiring a robotic surgical system. Twenty approved applications justified their investment in robotic surgical systems by stating the system would reduce referrals to community care providers at a cost savings to the facility. However, the audit team determined that nine of those applications did not have the supporting financial analysis completed for the community care section or said they were already paying “zero dollars” to community providers for robotic surgical services. Example 2 shows two approved applications for robotic surgical systems, and how one medical facility provided an incomplete financial justification in its application.

### **Example 2**

*The Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin, and the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi, submitted high-cost, high-tech medical equipment applications for robotic surgical systems. Both applications indicated that having a system would reduce the costs of community care referrals. The application from the Milwaukee medical center estimated saving about \$100,000 within the first year of having its own robotic surgical system compared to \$200,000 in costs it would spend otherwise referring robotic surgical procedures to community providers. In contrast, in the financial analysis section, the application from the Jackson medical center stated that its costs for referring robotic cases to the community amounted to zero dollars. Both applications were approved by the assistant deputy under secretary for health for administrative operations without question in September 2018.*

In response to the audit team’s analysis in July 2020, the Healthcare Technology Management director said that while there may be sections in the high-cost, high-tech medical applications that were incomplete, his office includes a review of a medical facility’s clinical restructuring plan to expand its surgical service for robotic surgery. He said that plan may have additional details to support his office’s approval recommendation. The audit team did not see clinical restructuring plan reviews as part of the high-cost, high-tech application approval process in VA policy.

### **Other Medical Facilities Invested in Robotic Surgical Systems without Completing the Required Approval Process**

Employees at VHA facilities must prepare high-cost, high-tech medical equipment applications for all acquisitions with a unit cost of more than \$1 million, including additional and replacement equipment. Pursuant to these requirements, acquisitions of robotic surgical systems must proceed through the high-cost, high-tech medical equipment application process. Applications must be

submitted for review and approval before acquisition.<sup>9</sup> The assistant deputy under secretary for health for administrative operations must approve all high-cost, high-tech medical equipment applications. The Healthcare Technology Management director told the audit team he expected all equipment acquisitions costing more than \$1 million to be submitted for approval. The Office of Healthcare Technology Management updated its service bulletin in December 2019 and established the expectation that all acquisitions with a unit cost of more than \$1 million, including transfers, be submitted for approval.<sup>10</sup>

Despite that expectation and the associated requirement in VA policy, the audit team identified 10 robotic surgical systems from nine VA medical facilities that did not have documented evidence of approval before acquisition. These systems included equipment traded in or replaced by the manufacturer for a newer model or equipment transferred between facilities. Based on Intuitive data, each system cost an average of approximately \$1.8 million.

Table 1 summarizes the number of robotic surgical systems that were not approved through the required process before acquisition.

**Table 1. Summary of Robotic Surgical Systems Acquired without Documented Approvals**

| Type of system that was not approved       | Number of systems |
|--|-------------------|
| New or additional system                   | 6                 |
| Trade-in or replacement of existing system | 1                 |
| Transfer from another medical facility     | 3                 |
| <b>Total</b>                               | <b>10</b>         |

*Source: OIG analysis of robotic surgical systems acquired without documented approvals.*

The audit team’s analysis of the 10 robotic surgical systems included those that were transferred between facilities because the original unit cost from the manufacturer was more than \$1 million. According to Healthcare Technology Management employees, two transferred systems were approved after being installed at the new facility although the value of the systems was believed to have been less than \$1 million each based on their used condition at the time of the transfer. They also explained that two other robotic surgical systems identified by the audit team were approved in 2006 and 2009 under a past approval process. However, the audit team was not able to independently locate approvals for the systems installed at the facilities nearly 10 years later.

<sup>9</sup> VA policy memo, “Process Changes for Requesting High Cost/High Tech Medical Equipment Acquisitions”; Healthcare Technology Management (HTM) Service Bulletin, “High Cost/High Tech Medical Equipment.”

<sup>10</sup> HTM Service Bulletin, “High Cost/High Tech Medical Equipment,” SB2020-001, December 2019.

A similar concern regarding VHA employees purchasing a robotic surgical system without proper review and approval was identified in an earlier OIG review at the W.G. (Bill) Hefner Veterans Affairs Medical Center in Salisbury, North Carolina.<sup>11</sup>

## **VHA Lacked Adequate Instructions and Procedures to Manage the Submission and Review of Robotic Surgical System Applications**

VHA did not have clear instructions and policy for medical facilities to follow regarding the approval process to acquire robotic surgical systems. The audit team identified underlying weaknesses in the instructions and procedures to prepare and submit high-cost, high-tech medical equipment applications for robotic surgical systems. Additionally, the Office of Healthcare Technology Management's review did not ensure the applications were adequately completed before recommending approval to the assistant deputy under secretary for health for administrative operations.

### **Deficiencies in Application Instructions Led to Incomplete Justifications**

The design of the high-cost, high-tech medical equipment application instructions contributed to unreliable estimates by medical facility employees. The application asks those employees to describe how purchasing equipment like a robotic surgical system would improve the quality of care for veterans and their access to care. The application also instructs employees to estimate system workload provided in recent years at the medical facility and through community care. However, the application does not allow employees to differentiate their estimates by unique system when multiple systems are in use and there is an active community care program. This was critical for facilities such as the VA North Texas Health Care System in Dallas, whose employees requested approval to acquire more than one robotic surgical system at a time and had already been operating a system. The application also did not require facility employees to provide supporting documentation for the information in the application.

### **Different Interpretation of Approval Procedures Led to Robotic Surgical Systems Acquisitions without Central Office Approval**

Before 2019, the approval procedures did not have specific instructions for the acquisition of a system upgrade, replacement system, or the transfer of equipment between facilities. In the absence of specific guidance, employees at medical facilities interpreted the need to submit high-cost, high-tech medical equipment applications for robotic surgical systems differently.

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<sup>11</sup> VA OIG, *Alleged Unapproved Acquisition of a Robotic Surgical System for the W.G. (Bill) Hefner Veterans Affairs Medical Center*, 18-03260-102, June 19, 2019. Appendix A contains more information about this review. The total number of acquired robotic surgical systems without approval summarized in table 1 includes the system identified in that 2019 report.

The audit team determined that some medical facility employees did not submit applications for new systems if the facility had previously used a robotic surgical system. They explained that they felt new approvals were not necessary in these situations because the existing surgical program had already been approved or it was unclear whether new systems were considered upgrades or replacements.

Medical facility employees also did not submit applications for the transfer of equipment from other facilities before acquiring the systems. The employees' interpretation was that central office approval was not needed for a transferred system if the cost to obtain it from another facility was less than \$1 million—believing transfer costs under that amount did not qualify as a high-cost, high-tech medical equipment purchase. For example, the Phoenix VA Health Care System in Arizona received a system from the VA Long Beach Healthcare System in California. This may have reduced the costs to the facility to obtain the system but was inconsistent with the approval expectations from the Office of Healthcare Technology Management. The approval process ensures that the capital investment is aligned with other resources, such as staffing, site preparation, and construction at the facility.

The deputy under secretary for health for operations and management (DUSHOM) issued an updated policy memorandum and procedures during the audit and so the OIG made no recommendation for this issue.<sup>12</sup> The policy memorandum reinforced that the assistant deputy under secretary for health for administrative operations must approve all high-cost, high-tech medical equipment with a unit cost of more than \$1 million before acquisition regardless of how the equipment is obtained. The updated procedures discussed the approval requirements for additional and replacement equipment as well as equipment upgrades. The procedures also said the approval process applies to transfers of equipment valued at more than \$1 million.

### **Lack of Thorough Program Office Reviews Contributed to Incomplete Applications**

Healthcare Technology Management employees did not perform a thorough review of high-cost, high-tech medical equipment applications. Employees told the audit team that the extent of their reviews was a “spot check” of the information in the applications for reasonableness or to look for missing information. They did not validate the application information such as workload estimates or financial costs and did not have ready access to the underlying data to validate the information in the application. The expectation was that the content of the applications would be reviewed first by the requesting facility and VISN.

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<sup>12</sup> VA policy memo, “High Cost/High Tech Medical Equipment Acquisition Approval Process,” December 6, 2019; HTM Service Bulletin, “High Cost/High Tech Medical Equipment,” SB2020-001.

Executive departments are responsible for using quality information to achieve their objectives.<sup>13</sup> In line with this, the Office of Healthcare Technology Management is required to review the applications for completeness, justification, return on investment, and alignment of the capital investment with other resource elements, such as staffing, site preparation, construction, and recurring maintenance. This review must take place before the office recommends approval of the applications. The Healthcare Technology Management director explained that the intent and role of his office's review was to help medical facilities consider whether they are structurally prepared and have the resources to use requested equipment on-site. He added that his office helps ensure facilities are using the latest technology to meet their needs.

## **VHA Lacked Assurance That Robotic Surgical System Investment Decisions Were Supported**

Approvals of incomplete high-cost, high-tech medical equipment applications for robotic surgical systems meant VHA was not able to ensure that the investment decisions to acquire the systems were supported and appropriate. VHA could not reliably assess the workload and investment estimates associated with robotic surgical systems. In addition, the incomplete applications could increase the risk that medical facilities would make inefficient decisions to acquire systems and not use the systems in a timely manner. For example, the Office of Healthcare Technology Management approved an application from the VA New Jersey Health Care System in East Orange for a new robotic surgical system in 2014. The system was received in 2015, but not used until 2017 because the facility was not prepared to use it.

Based on the audit team's review of application procedures and discussions with Healthcare Technology Management employees, medical facilities were confused about when to submit requests for robotic surgical systems for central office review and approval. This confusion meant VHA was not able to ensure facilities were well-positioned to acquire robotic surgical systems. VHA central office review and approval is important so VHA leaders are aware of the systems permitted for use and can centrally manage system acquisition decisions for facilities to ensure they have the latest technology to meet their needs.

## **Finding 1 Conclusion**

VHA needs to improve governance over its processes to review and approve the acquisition of robotic surgical systems. VHA approved acquisition applications for robotic surgical systems without complete information. VA medical facilities also acquired systems without always receiving proper central office approval. VHA needs to improve controls over its high-cost,

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<sup>13</sup> OMB, Circular A-123, "Management's Responsibility for Enterprise Risk Management and Internal Control, Attachment," July 15, 2016; Government Accountability Office (GAO), *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014. Quality information is appropriate, complete, and accurate, and meets information requirements.

high-tech medical equipment application approval process for robotic surgical systems to ensure there is adequate governance and transparency over those resources and medical facilities are prepared to use them.

## Recommendations 1–3

The OIG recommended the under secretary for health take the following steps:<sup>14</sup>

1. Update the high-cost, high-tech medical equipment application to provide clearer instructions on preparing requests and providing supporting documentation for robotic surgical systems. The application and instructions should be disseminated to medical facilities, Veterans Integrated Service Networks, and responsible central office organizations.
2. Establish controls to ensure information in high-cost, high-tech medical equipment applications is reviewed and validated before recommending final approval to the assistant deputy under secretary for health for administrative operations.
3. Evaluate the need and justification of the 10 robotic surgical systems at VA medical facilities that were acquired without approval by the assistant deputy under secretary for health for administrative operations.

## Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with the OIG’s recommendations. For recommendation 1, the executive in charge stated that the assistant under secretary for health for support services will clarify the instructions for the high-cost, high-tech equipment applications and communicate the instructions to the VISNs and VA medical facilities.

For recommendation 2, the executive in charge stated the assistant under secretary will examine the existing high-cost, high-tech medical equipment application process to establish additional controls to validate the information in the applications. He said that the assistant under secretary will establish an integrated project team to evaluate the entire medical equipment application process and associated policy in connection with the minor and major construction program processes and policy. He also said the team will reengineer the process to improve governance, oversight, and visibility, and to ensure the appropriate level of integration with minor and major construction programs.

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<sup>14</sup> Recommendations directed to the under secretary for health were submitted to the executive in charge who has the authority to perform the functions and duties of the under secretary for health.

For recommendation 3, the executive in charge stated that the assistant under secretary will assess the need for the 10 robotic surgical systems that were identified as being acquired without approval by the assistant deputy under secretary for health for administrative operations.

The executive in charge anticipated implementation of these corrective actions by December 2020. The full comments from the executive in charge are included in appendix C.

## **OIG Response**

The executive in charge's comments and corrective action plans are responsive to the intent of the recommendations. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating the proposed actions have been completed.

## **Finding 2: VHA's Internal Data on Robotic Surgical Procedures Did Not Completely Capture System Workload**

VHA did not have comprehensive data on procedures conducted using robotic surgical systems. As part of its operational oversight, the NSO publishes annual reports to inform VHA leaders on surgical procedures conducted at medical facilities, including robotic surgery. The NSO reported, based on information extracted from the Veterans Health Information Systems and Technology Architecture (VistA), that VA medical facilities conducted more than 3,600 robotic surgical procedures in FY 2018. However, the OIG found the NSO underreported procedures by more than one-third, or 2,300 procedures, when compared to data tracked by Intuitive, the manufacturer of the robotic surgical systems used by VA medical facilities.

The underreporting was due in part to inconsistencies in how medical facilities captured robotic surgical procedures in VistA. The NSO's methodology for identifying robotic surgical procedures was limited and less complete due to inconsistencies in how individual medical facility employees coded those procedures in the system. The audit team determined many facility employees added a secondary code to indicate that the procedure was conducted using a robotic surgery technique, but there was no policy to require them to apply it to the procedure records. The NSO acknowledged concerns with VA's procedure data and the coding of robotic surgery but has not collected corresponding data from Intuitive. As a result, VHA could not comprehensively identify procedures using robotic surgical systems. Accurate data is needed to measure performance and make informed decisions at different levels. This is especially important when doing quality reviews to monitor and evaluate the standard of health care provided using robotic surgical systems.

### **What the OIG Did**

The audit team obtained and analyzed robotic surgical system procedure data from the manufacturer, Intuitive, and tested their reliability to corresponding records of procedures conducted in calendar years 2017 and 2018 in VistA, VA's electronic health information records system. The team compared the manufacturer's data with information reported in the NSO's FY 2018 surgery report. The team focused on the FY 2018 surgery report because it identified robotic surgical procedures within the data for calendar years 2017 and 2018 that were tested by the team. The audit team also obtained testimonial evidence from program officials and staff in the NSO and various VISNs and medical facilities. Appendix B provides additional details on the audit scope and methodology.

### **VHA Lacked Complete Data on Its Robotic Surgery Procedures**

VHA's data on robotic surgical system procedures were incomplete compared to the volume of procedures tracked by the system manufacturer, Intuitive. The NSO publishes annually for VHA leaders an overview of surgery program data from a national and regional perspective. The NSO

obtained data on robotic surgical procedures based on an extract from VistA. According to the NSO, VA medical facilities performed more than 3,600 robotic surgical procedures in FY 2018.<sup>15</sup>

Intuitive's robotic surgical systems automatically record data and generate a record for each procedure. This data is collected by Intuitive through its software system and reconciled by its service representatives, according to the manufacturer's director of government accounts.<sup>16</sup> According to Intuitive data obtained by the audit team, VHA performed approximately 5,900 robotic surgical procedures in FY 2018 using the systems at VA medical facilities nationwide—about 2,300 procedures (39 percent) more than those reported by the NSO based on VistA data for the same period.<sup>17</sup>

## **Inconsistent Procedure Coding at Medical Facilities Contributed to Incomplete Data Capture**

The audit team compared samples of robotic surgical procedure data from Intuitive to corresponding surgical records from VA medical facilities to determine their reliability. The team determined that the Intuitive data were reliable because the surgical records could be traced to the procedures identified by the robotic surgical systems. However, the NSO's methodology for extracting robotic surgical procedures from VistA was limited and thus less complete due to inconsistencies in how individual medical facility employees coded those procedures in the system. As used, the principal procedure codes for surgery do not indicate whether the procedure was conducted using robotics. Many facility employees added a secondary code to indicate that the procedure was conducted with robotics, but that coding was not done consistently nor was it required by policy.

## **VHA Had Gaps in Enterprise-Level Management of Robotic Surgical System Data**

Executive departments are responsible for obtaining quality information to achieve their reporting objectives.<sup>18</sup> NSO leaders acknowledged that there were concerns with the procedure data and coding of robotic surgery within VHA. In August 2018, the NSO director (who left this position in December 2018) said he was aware Intuitive collected robotic surgery procedure data,

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<sup>15</sup> NSO, VHA, *Annual Surgery Report*, 2018.

<sup>16</sup> The audit team compared Intuitive data to VA surgical records to confirm that they represented actual robotic surgical procedures conducted at VHA facilities.

<sup>17</sup> The scope of this audit focused on robotic surgical system procedural data during calendar years 2017 and 2018. The audit team identified robotic surgical procedures performed in FY 2018 from Intuitive to compare to the same fiscal year reporting period in the NSO's *Annual Surgery Report*.

<sup>18</sup> GAO, *Standards for Internal Control in the Federal Government*.

but had never seen a data use agreement and did not use its data.<sup>19</sup> In July 2019, the NSO director at the time of the audit said he was aware the procedure codes were insufficient to identify robotic surgery procedures.<sup>20</sup> He said the NSO does not have direct access to see and use Intuitive's robotic surgery procedure data as of March 2020. He also said the NSO has not requested that procedure data from Intuitive but has seen them occasionally whenever medical facility employees have requested them. Further, the NSO is communicating with the VHA Office of Health Information Governance concerning VistA coding for robotic surgical procedures. The NSO director anticipated that facility employees would be reeducated on how to code robotic surgery procedures.

The NSO also did not assess the number of robotic surgical procedures performed through VA's community care program to determine whether acquiring robotic systems led to a reduction in cases referred to community care providers. The NSO director said his office only assessed whether a medical facility had infrastructure in place to perform robotic surgical procedures in a safe manner when such a clinical restructuring request is received.

## **Lack of Complete Data Limited the Review and Management of Robotic Surgical Systems**

As discussed above, incomplete data on robotic surgeries limited the NSO's ability to manage the operations of robotic surgical programs in accordance with its responsibilities under VA policy.<sup>21</sup> Without comprehensive data on procedures conducted using robotic surgical systems, VHA cannot adequately measure performance or make informed decisions for its system investments at different levels. For example, VHA needs reliable information nationally on robotic surgical procedures to make decisions on service delivery under the Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018.<sup>22</sup> The VA Secretary is required to conduct market area assessments of the demand for healthcare services every four years, including the number of requests for VA healthcare services and from community care providers. However, incomplete data on robotic surgical system procedures at VA medical facilities limit VHA's ability to see the full extent of robotic surgery use and the demand for that service.

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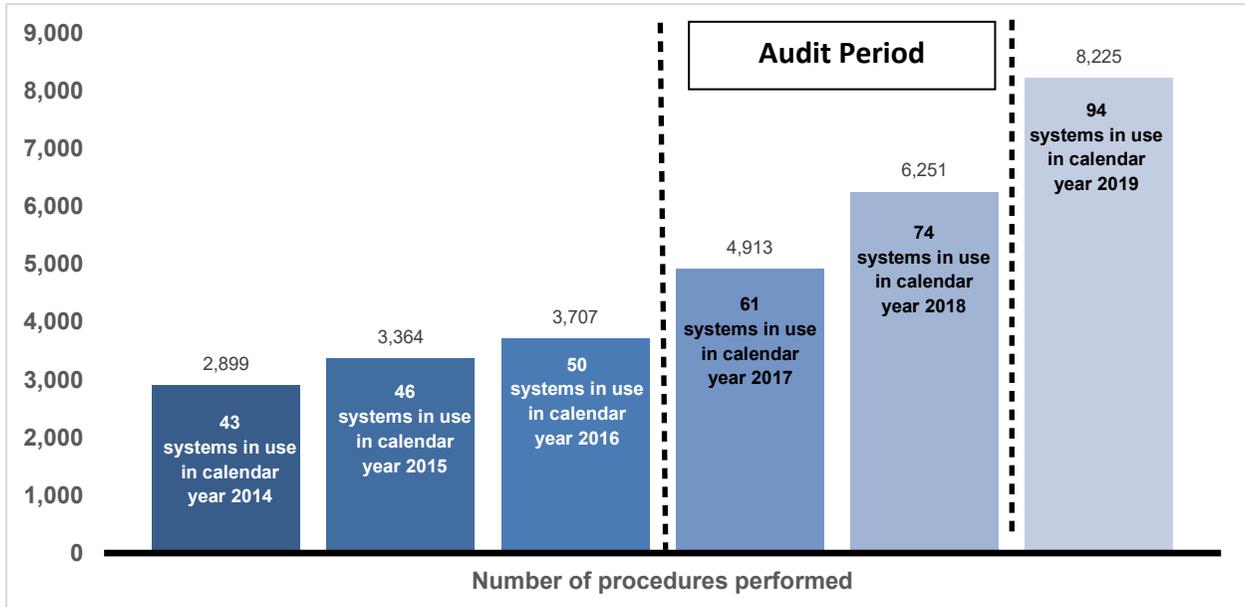
<sup>19</sup> The audit team initially brought differences between the NSO's and Intuitive's data to VHA's attention during the previous OIG review. See appendix A for more information about the OIG's June 2019 report.

<sup>20</sup> In July 2020, the NSO director clarified that he was referring to current procedural terminology codes that are also used nationally outside of VA. He said those codes do not specify robotic surgery. The American Medical Association publishes those codes, which are used by physicians to identify the procedures they have performed.

<sup>21</sup> VHA Handbook 1102.1, *National Surgery Office*, January 30, 2013.

<sup>22</sup> VA MISSION Act of 2018, Pub. L. No. 115-182, 38 U.S.C. § 7330C (2018).

Using Intuitive’s data, figure 3 shows how robotic surgical procedures and the number of systems in use have increased at VA medical facilities from calendar years 2014 to 2019.



**Figure 3.** Growth of robotic surgical systems and procedures conducted at VA medical facilities between calendar years 2014 and 2019.

Source: OIG analysis of manufacturer-reported robotic surgical system data.

Note: The scope of the audit focused on reviewing manufacturer-reported procedure data in 2017 and 2018, but the audit team reviewed data from 2014 through 2016, and from 2019 as background information for additional context.

The lack of comprehensive facility-level data on robotic surgical system procedures meant medical facilities relied on alternative methods to collect this information to support decision-making. For example, employees at the VA Loma Linda Healthcare System told the audit team they estimated robotic surgical procedures using available VistA data and a paper log. They used that information to estimate the workload for their high-cost, high-tech medical equipment applications. As discussed above, they relied on this method mainly due to inconsistent coding for robotic surgical procedures.

Finally, the lack of reliable data on robotic surgical procedures could reduce the ability of medical facilities to fully perform quality assurance reviews. According to the NSO deputy director of clinical services, medical facility employees are expected to review robotic surgical techniques applied during the first year that robotic surgery was approved at the facility to monitor the quality of procedures conducted using the systems. Robotic surgical procedure data are retrieved from VistA. However, due to procedure coding inconsistencies, first-year reviews may not include all surgical cases for which robotic surgical techniques were applied.

## Finding 2 Conclusion

VHA was not collecting reliable information on robotic surgical workload. This limited VHA's ability to comprehensively monitor the performance of its system investments or make informed decisions on an enterprise or facility level. Unless corrective action is taken, VHA's efforts to manage the potential benefits and risks of this technology going forward will be limited.

## Recommendations 4–5

The OIG recommended that the under secretary for health take the following steps:<sup>23</sup>

4. Develop guidance for accurately and consistently coding robotic surgical procedures in the Veterans Health Information Systems and Technology Architecture.
5. Evaluate the need for the National Surgery Office to obtain robotic surgical procedure data from the system manufacturer to assess and validate the use of the systems at VA medical facilities.

## Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with the OIG's recommendations. For recommendations 4 and 5, the executive in charge stated VHA's Health Information Management office will develop guidance for coding robotic surgical procedures in VistA. He also stated the NSO will include specialty-specific robotic surgical procedure data in the NSO's quarterly report to support the oversight of VA medical facilities and assessment of robotic surgical procedural data. The executive in charge anticipated implementation of the corrective actions for recommendations 4 and 5 by October 2020 and March 2021, respectively.

The full comments from the executive in charge are included in appendix C.

## OIG Response

The executive in charge's comments and corrective action plans are responsive to the intent of the recommendations. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient evidence demonstrating the proposed actions have been completed.

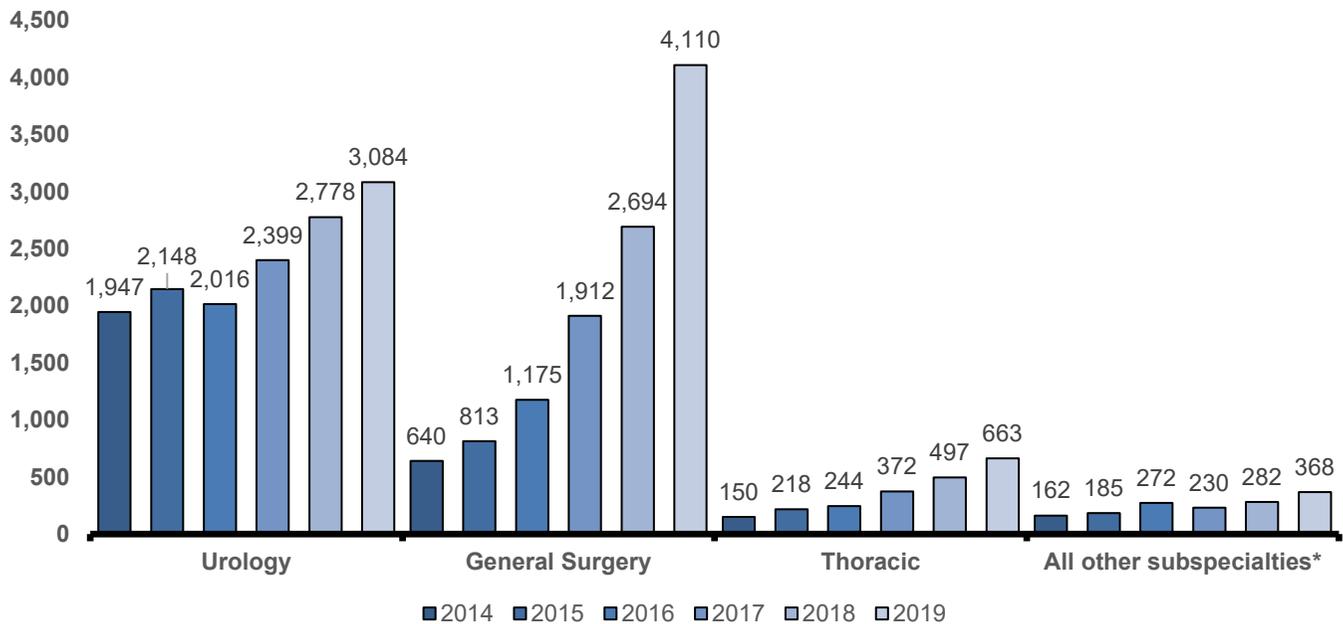
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<sup>23</sup> Recommendations directed to the under secretary for health were submitted to the executive in charge who has the authority to perform the functions and duties of the under secretary for health.

## Appendix A: Background

### Robotic Surgical Systems in Surgical Subspecialties

VA medical facilities began using robotic surgical systems primarily for urological procedures and have expanded their use over time to other surgical subspecialties. The three top subspecialties in robotic surgery were urology, general, and thoracic (figure A.1). Urology surgery includes procedures for genitourinary tract and adrenal gland conditions. General surgery refers to procedures for a broad range of conditions, including hernia repair, endoscopy, and cholecystectomy. Thoracic surgery refers to operations on organs in the chest, including the heart, lungs, and esophagus.



**Figure A.1.** Robotic system utilization for surgical subspecialty procedures by calendar year.

Source: OIG analysis of manufacturer-reported robotic surgical system data.

\* All other subspecialties include cardiac, gynecology, and head and neck.

As of December 2019, VA medical facilities have completed approximately 30,000 procedures using robotic surgical systems since 2014, according to Intuitive-reported data.

### Previous OIG Report on Robotic Surgical Systems

The OIG issued the report *Alleged Unapproved Acquisition of a Robotic Surgical System for the W.G. (Bill) Hefner Veterans Affairs Medical Center*, 18-03260-102, on June 19, 2019. The OIG substantiated an allegation that employees at the W.G. (Bill) Hefner VA Medical Center in Salisbury, North Carolina, were permitted to order new robotic surgical equipment during year-end spending without proper review and approval. This occurred due to an ineffective

capital investment review process and weak internal controls over the ordering process at VISN 6. The OIG concluded that purchasing robotic surgical systems without the required planning, review, and approval increases the risk that programs will acquire expensive equipment without alignment of VA's resources, such as site preparation and recurring maintenance on systems purchased. The OIG did not substantiate a second allegation that the robotic surgical system was unnecessary because the building that housed the equipment was unsuitable and the medical facility already had an unused system purchased in 2012. The OIG recommended that the DUSHOM and the VISN 6 network director clarify approval requirements and ensure the Capital Investment Board meets annually to review requests in a timely manner. As of June 8, 2020, all recommendations are closed.

## Appendix B: Scope and Methodology

### Scope

The audit team performed its work from March 2019 through July 2020. The audit focused on the adequacy of the governance to invest in and use robotic surgical systems at approximately 60 VA medical facilities. The audit also focused on robotic surgical system procedure data from calendar years 2017 and 2018. The audit team judgmentally selected four VA medical facilities for on-site or remote visits in Loma Linda, California; Hines, Illinois; Buffalo, New York; and Houston, Texas, to discuss topics related to the audit objective. The audit included the respective VISNs for the VA medical facilities visited.

As part of the audit, the team used applicable regulations; VA policies and procedures; high-cost, high-tech medical equipment applications; and records of robotic surgical procedures performed at medical facilities nationwide. The audit team also obtained testimonial and documentary information from responsible program officials and employees in various offices, including the Office of the DUSHOM, the Office of Healthcare Technology Management, the NSO, and various VA medical facilities.

The audit team collected manufacturer-reported data on robotic surgical system usage that occurred from January 2014 to December 2019. The data included records of the type of procedure performed, the surgical specialty, and the names of providers. The audit team also collected robotic surgical procedure data for FY 2018 from the NSO.

### Methodology

To accomplish the objective, the audit team obtained testimonial and documentary information from more than 120 VHA employees to discuss roles, responsibilities, and topics related to the audit objective on robotic surgery operations and procedures. The audit team analyzed records from VHA of high-cost, high-tech medical equipment applications and approvals that occurred between June 2013 and September 2018 to acquire robotic surgical systems. The audit team compared these records to robotic surgical systems in use as reported by the manufacturer to determine whether there was an associated approval.

The audit team reviewed robotic surgical system procedure data from Intuitive to identify the number of procedures performed at local medical facilities in calendar years 2017 and 2018. The team also reviewed procedure data from calendar years 2014 through 2016 and from calendar year 2019 for background information. The data was provided directly to the audit team from Intuitive in September 2019 and April 2020. The audit team also used the Intuitive-reported data to compare with the NSO's data on robotic surgical procedures in its FY 2018 surgery report.

## **Fraud Assessment**

The audit team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur during this audit. The team exercised due diligence and remained alert to any fraud indicators. The team did not identify any instances of fraud during this audit.

## **Data Reliability**

The audit team relied on computer-processed data from Intuitive to identify VHA's use of robotic surgical systems. To test reliability, the audit team interviewed Intuitive employees to understand their system and data collection procedures. The team also selected and compared the data with corresponding documentation from VA medical facilities through their respective VISNs. The OIG believes the data were appropriate and sufficient for the purpose in this audit based on this approach and the results of the testing.

The audit team also collected surgical procedure data from VA's VistA housed in the corporate data warehouse. The corporate data warehouse is a national repository of data from VistA. The data were extracted using the same method the NSO used to obtain its utilization data. To test reliability, the audit team reviewed VA facility processes to code these data and compared the data to Intuitive-reported data as well as supporting documentation from VHA facilities. Finding 2 of this report addresses the audit team's procedures that revealed completeness concerns with the NSO's robotic surgery workload data, for which recommendations were made to address the issue.

## **Government Standards**

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

## Appendix C: Management Comments

Department of Veterans Affairs Memorandum

Date: August 25, 2020

From: Executive In Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, VHA's Governance of Robotic Surgical System Investments Needs Improvement (Project Number 2019-07103-D2-0004)  
(VIEWS 03349100)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review the draft report on, VHA's Governance of Robotic Surgical System Investments Needs Improvement. I concur with the recommendations and provide action plans in the attachment.

2. With respect to recommendation 4, research of applicable coding guidelines and references has identified that the addition of Healthcare Common Procedure Code System (HCPCS) Code S9200 is not required, but rather may be added for additional specificity and clarity. HCPCS Code S9200 is not appropriate for Medicare patient reporting, thus would not be considered a coding error. Robotic assistance is included in the laparoscopic technique identified by the American Medical Association code description. An additional code is not required but may be added for additional specificity. (Optum360 - CODING FROM THE OPERATIVE REPORT) Since there is not a way to capture the use of robotic assistive technology, the HIM Office agreed to update guidance to append this code for internal reporting purposes and data capture only.

*The OIG removed point of contact information prior to publication.*

(Original signed by)

Richard A. Stone, M.D.

Attachments

**VETERANS HEALTH ADMINISTRATION (VHA)**

**Action Plan**

**Office of Inspector General (OIG) Draft Report: VHA's Governance of Robotic Surgical System Investments Needs Improvement**

**Date of Draft Report: July 28, 2020**

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| <b>Recommendations/<br/>Actions</b> | <b>Status</b> | <b>Target Completion Date</b> |
|-------------------------------------|---------------|-------------------------------|
|-------------------------------------|---------------|-------------------------------|

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**Recommendation 1: Update the high-cost, high-tech medical equipment application to provide clearer instructions on preparing requests and providing supporting documentation for robotic surgical systems. The application and instructions should be disseminated to medical facilities, Veterans Integrated Service Networks, and responsible central office organizations.**

**Comments:** Concur

The Assistant Under Secretary for Health for Support Services (AUSH-S) will clarify the instructions for the high-cost, high-technical equipment applications and communicate the instructions to Veterans Integrated Service Networks and VA medical facilities.

Status: In Progress

Target Completion Date: December 2020

**OIG Recommendation 2: Establish controls to ensure information in high-cost, high-tech medical equipment applications are reviewed and validated before recommending final approval to the Assistant Deputy Under Secretary for Health for Administrative Operations.**

**Comment:** Concur

The AUSH-S will examine the existing high-cost, high-tech medical equipment application review process to establish additional controls to validate information submitted with high-cost, high-tech medical equipment applications.

The AUSH-S will establish an integrated project team (IPT) to evaluate the entire high-cost, high-technical medical equipment process and associated policy in context with the minor and major construction program processes and policy. The objectives of the IPT are to reengineer the high-tech medical equipment program to improve governance, oversight, visibility, and ensure the appropriate level of integration with minor/major construction programs.

Status: In Progress

Target Completion Date: December 2020

**OIG Recommendation 3: Evaluate the need and justification of the 10 robotic surgical systems at VA medical facilities that were acquired without approval by the Assistant Deputy Under Secretary for Health for Administrative Operations.**

**VHA Comment:** Concur

The AUSH-S will assess the need for the ten robotic systems that were identified as being acquired without approval by the Assistant Deputy Under Secretary for Health for Administrative Operations (this function is now the responsibility of the AUSH-S).

Status: In Progress

Target Completion Date: December 2020

**OIG Recommendation 4: Develop guidance for accurately and consistently coding robotic surgical procedures in the Veterans Health Information Systems and Technology Architecture.**

**VHA Comment:** Concur

The Veterans Health Administration (VHA) Health Information Management (HIM) office will develop guidance for coding robotic surgical procedures in the Veterans Health Information Systems and Technology Architecture. The HIM office will provide guidance to HIM Chiefs to add the code S2900 for all surgical cases when robotic assistive equipment is indicated in the operative note, unless the current procedural terminology code assigned for the surgery specifically indicates robotic technique.

Status: In Progress

Target Completion Date: October 2020

**OIG Recommendation 5: Evaluate the need for the National Surgery Office to access robotic surgical procedure data from the system manufacturer to assess and validate the use of the systems at VA medical facilities.**

**Comment:** Concur

The VHA National Surgery Office will include specialty-specific robotic surgical procedure data reporting within the National Surgery Office Quarterly Report to support VA medical facility oversight and assessment of robotic surgical procedural data.

Status: In Progress

Target Completion Date: March 2021

*For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.*

## OIG Contact and Staff Acknowledgments

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| <b>Contact</b> | For more information about this report, please contact the Office of Inspector General at (202) 461-4720. |
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