July 2015

VA HEALTH CARE

Actions Needed to Assess Decrease in Root Cause Analyses of Adverse Events

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Why GAO Did This Study

Adverse events are incidents that pose a risk of injury to a patient as the result of a medical intervention or the lack of an appropriate intervention. VAMCs use the RCA process to identify and evaluate systems or processes that caused an adverse event, recommend changes to prevent the event's recurrence, and determine whether implemented changes were effective.

GAO was asked to review VA's processes and procedures for responding to adverse events. In this report, GAO examined (1) the extent to which VAMCs used the RCA process to respond to adverse events and (2) how VHA oversees the RCA process and uses information from the process to make system-wide improvements. To conduct this work, GAO reviewed VHA policy and guidance documents, analyzed VHA data on RCAs completed from fiscal years 2010 through 2014, and interviewed officials from NCPS—the VHA office responsible for monitoring RCA data. GAO also analyzed local RCA data and interviewed officials from four VAMCs selected to provide variation in factors such as complexity and location.

What GAO Recommends

GAO recommends that VA (1) analyze the declining number of completed RCAs, including identifying the contributing factors and taking appropriate actions, and (2) determine the extent to which VAMCs are using alternative processes to address adverse events, and collect information on their results. VA concurred with GAO's recommendations.

What GAO Found

To address adverse events, Department of Veterans Affairs (VA) medical centers (VAMC) completed 18 percent fewer root cause analyses (RCA) in fiscal year 2014 compared to fiscal year 2010, and the Veterans Health Administration (VHA) has not analyzed the reasons for the decrease. VHA's National Center for Patient Safety (NCPS) officials told GAO they were aware of the decrease, but were not certain why the number of completed RCAs had decreased over time, especially in light of a 7 percent increase in reports of adverse events over the same time period. NCPS officials suggested several potential factors that could contribute to the decrease, including VAMCs' use of processes other than RCAs to address adverse events. However, NCPS is unaware of how many VAMCs use these other processes or their results. VHA's lack of analysis is inconsistent with federal internal control standards which state that agencies should compare data to analyze relationships and take appropriate actions. Because NCPS has not conducted an analysis of the relationship between the decrease in RCAs and possible contributing factors, it is unclear whether the decrease indicates a negative trend in patient safety at VAMCs or a positive one. In addition, without understanding the extent to which VAMCs use alternative processes and their results, NCPS has limited awareness of what VAMCs are doing to address the root causes of adverse events.

RCAs Completed at VAMCs, Fiscal Years 2010 through 2014

Number of RCAs

Fiscal year	Number of RCAs
2010	1,862
2011	1,743
2012	1,664
2013	1,660
2014	1,523
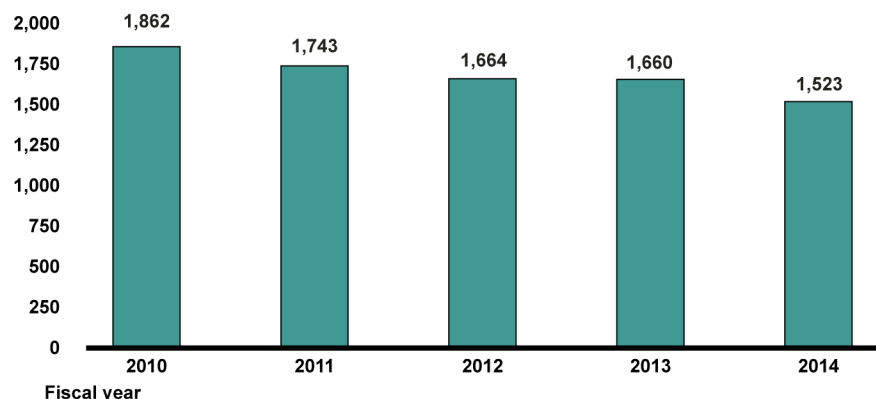
Source: Veterans Health Administration. | GAO-15-643

NCPS oversees the RCA process by monitoring VAMC compliance, and develops system-wide patient safety initiatives informed by RCA data. NCPS monitors each VAMC's compliance with requirements by reviewing RCA database information and conducting site visits. NCPS uses RCA information to inform system-wide patient safety initiatives, such as Patient Safety Alerts and Advisories—urgent notifications sent to VAMCs that describe a safety issue and include instructions and due dates for implementing actions to prevent recurrence.

_____ **United States Government Accountability Office**

Contents

July 29, 2015

Congressional Requesters

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) operates one of the largest integrated health care delivery systems in the United States. In fiscal year 2014, it provided health care services to about 5.8 million veterans, a 14 percent increase from fiscal year 2009. VHA's health care system includes 150 VA medical centers (VAMC) nationwide that offer a variety of outpatient, residential, and inpatient services.

Adverse events—incidents that pose a risk of injury to a patient as the result of a medical intervention or the lack of an appropriate intervention, such as a missed or delayed diagnosis—occur in all health care settings, including VAMCs.[1] Adverse events may not always be attributable to an error made by a provider, and can be due to systems vulnerabilities or process failures. VHA requires that its VAMCs take appropriate action to report and evaluate adverse events, which can include conducting a root cause analysis (RCA)—a process to identify and evaluate systems or processes that caused an adverse event, recommend changes to prevent the event's recurrence, and determine whether implemented changes were effective. Information gleaned through an RCA may be used to make system or process changes within a specific VAMC or VHA's health care system more broadly.

You asked us to review VA's processes and procedures for responding to adverse events that occur within its health care system. We previously reported on the processes VAMCs can use to examine a clinician's

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[1]An example of an adverse event is the improper sterilization of medical equipment that can lead to veterans being exposed to infectious diseases.

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actions as they relate to an adverse event.[2] In this report, we examine the RCA process, which may be used to assess whether a systems or process issue caused an adverse event. Specifically, this report examines (1) the extent to which VAMCs used the RCA process to respond to adverse events and (2) how VHA oversees the RCA process and uses information from the process to make system-wide improvements.

To determine the extent to which VAMCs used the RCA process to respond to adverse events, we reviewed and analyzed VHA data on the total number of RCAs completed across VHA during the past 5 fiscal years (2010 through 2014), as well as the extent to which those RCAs were required and whether individual VAMCs met VHA's RCA requirements. We reviewed VHA policy and guidance and interviewed officials from VHA's National Center for Patient Safety (NCPS)—the VHA office responsible for monitoring RCA data—to identify RCA requirements. We also interviewed NCPS officials to obtain their views on trends we identified in the data. We evaluated VHA's actions with respect to identified trends within the context of federal internal control standards, as documented in GAO's *Standards for Internal Control in the Federal Government*.[3] We also reviewed documentation on VHA's centralized RCA reporting system, and we spoke with NCPS officials about how RCA data are collected and documented, and any limitations to the data. We determined that these data were sufficiently reliable for our purposes.

We also reviewed data and documents and interviewed officials from four VAMCs: (1) Salt Lake City Health Care System (Salt Lake City, Utah); (2) Robley Rex VAMC (Louisville, Kentucky); (3) Southeast Louisiana Veterans Healthcare System (New Orleans, Louisiana); and (4) James E. Van Zandt VAMC (Altoona, Pennsylvania). These VAMCs were selected to provide variation in the number of RCAs conducted in fiscal year 2013 (the most recent year of complete RCA data available at the time we

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[2]To examine a clinician's actions, VAMCs may use (1) peer review, (2) clinical care review, and (3) administrative investigation boards. For more information about these processes, see GAO, *VA Health Care: Improvements Needed in Processes Used to Address Providers' Actions That Contribute to Adverse Events*, GAO-14-55 (Washington, D.C.: Dec. 3, 2013); *Veterans Health Care: Veterans Health Administration Processes for Responding to Reported Adverse Events*, GAO-12-827R (Washington, D.C.: Aug. 24, 2012); and *VA Administrative Investigations: Improvements Needed in Collecting and Sharing Information*, GAO-12-483 (Washington, D.C.: Apr. 30, 2012).

[3]GAO, *Internal Control: Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

selected sites), geographic location, and VAMC complexity level.[4] For the selected VAMCs, we analyzed VHA data on the RCAs conducted at each VAMC from fiscal year 2010 through fiscal year 2014 to provide illustrative examples of how the RCA process is conducted at the local level. We interviewed officials from the selected VAMCs responsible for convening, participating in, and approving RCAs to determine how they implemented the RCA process.

To determine how VHA oversees the RCA process and uses information from the process to make system-wide improvements, we reviewed VHA policy and guidance documents and interviewed NCPS officials. We also reviewed documentation of the results of NCPS analyses related to RCAs. For the four selected VAMCs, we interviewed patient safety officers from the associated Veterans Integrated Service Networks (VISN),[5] to obtain information about their role in overseeing the RCA process, and disseminating information regarding system-wide improvements.

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

Background

VHA's National Patient Safety Improvement Handbook identifies key staff involved in the RCA process, establishes minimum requirements for conducting RCAs, and outlines the RCA process.[6]

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[4]VHA categorizes VAMCs according to complexity level, which is determined on the basis of the characteristics of the patient population, clinical services offered, educational and research missions, and administrative complexity.

[5]VISNs are regional systems of care that oversee the day-to-day functions of VAMCs that are within their network. Each VAMC is assigned to one of VA's 21 VISNs.

[6]Department of Veterans Affairs, Veterans Health Administration, *VHA National Patient Safety Improvement Handbook,* Handbook 1050.01 (Washington, D.C.: Mar. 4, 2011).

Key VHA Staff Involved in the RCA Process

Within VHA, NCPS supports the RCA process VHA-wide as part of its broader efforts to reduce and prevent inadvertent harm to patients as a result of their care. NCPS staff categorize and analyze RCA data, and provide training and education for VAMCs on the RCA process. According to VHA policy, NCPS is also responsible for disseminating important information learned from RCAs to VAMCs. NCPS reports to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, but also works with other VHA offices, including the Office of the Deputy Under Secretary for Health for Operations and Management, which directs operations at the VISN and VAMC levels. At the VISN level, patient safety officers may provide additional oversight of the RCA process and disseminate information from NCPS to the VAMCs within their networks. Each VAMC has a patient safety manager who facilitates the RCA process at the local level.

RCA Requirements

An RCA may be required by VHA policy if a VAMC's initial review of an adverse event finds that there is a risk to the safety of veterans, based on the severity of the event and its likelihood of recurrence. VHA requires that each VAMC complete a minimum of eight RCAs each fiscal year, four of which must be on individual adverse events. The other four RCAs can be a combination of individual RCAs and aggregated RCAs, the latter of which review a group of similar adverse events to identify common causes and actions to prevent future occurrences. VHA requires that VAMCs conduct aggregated RCAs on three types of adverse events— falls, adverse drug events, and missing patients—to the extent that they occur in a given year.[7] All RCA-related information is required to be entered into VHA's centralized RCA reporting system—WebSPOT, a software application within VHA's Patient Safety Information System. WebSPOT is the means by which RCA information is provided to NCPS and to VISN patient safety officers.

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[7]If a VAMC experiences only one adverse event in any of the three categories required for aggregated RCAs, the VAMC must conduct an individual RCA on that event. If a VAMC does not experience any adverse events in an aggregated RCA category, the VAMC can conduct either additional individual or aggregated RCAs to meet VHA requirements.

Information obtained through the RCA process is protected and confidential, according to federal law, and cannot be used to inform an adverse action or privileging action against a provider.[8] Therefore, the RCA process is referred to as a protected process.[9]
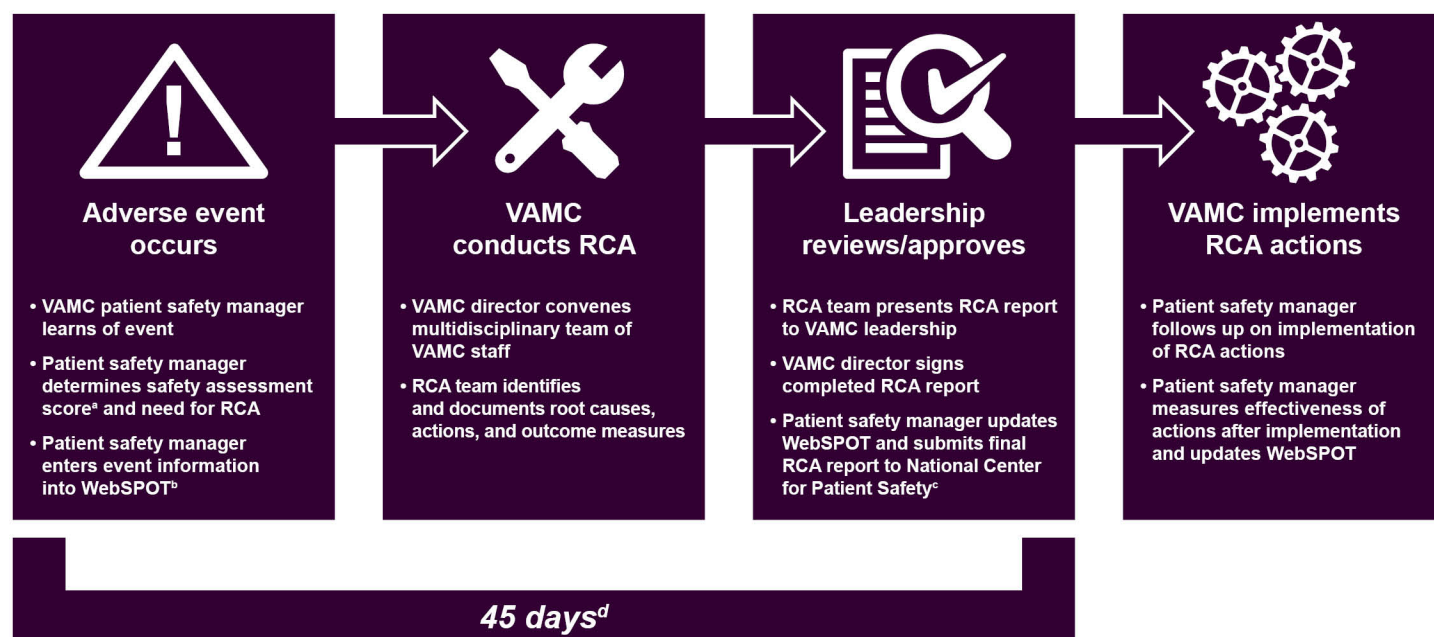
RCA Process

VAMCs use the RCA process to examine whether a systems or process issue caused an adverse event. Figure 1 provides an overview of the RCA process at VAMCs.

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[8]Under federal law, records and documents created as part of VHA's medical quality assurance program are confidential and privileged and may only be disclosed under limited circumstances. See 38 U.S.C. § 5705; 38 C.F.R. §§ 17.500-17.511. VHA's medical quality assurance program consists of systematic health care reviews carried out by or for VHA for the purposes of improving the quality of medical care or improving the utilization of health care resources in VHA medical facilities. The RCA process is part of VHA's medical quality assurance program; therefore, documents generated through this process are confidential and privileged.

[9]According to VHA policy, if in the course of conducting an RCA it appears that the adverse event under consideration is the result of an intentionally unsafe act, the RCA is halted and the VAMC can conduct a nonprotected review, such as an administrative investigation board. However, because the RCA process is protected, the information collected through the RCA may not be used in the nonprotected review. After the nonprotected review is complete, VAMCs may choose to resume the RCA.

Figure 1: Root Cause Analysis (RCA) Process at VA Medical Centers (VAMC)

Adverse event occurs
- VAMC patient safety manager learns of event
- Patient safety manager determines safety assessment score[a] and need for RCA
- Patient safety manager enters event information into WebSPOT[b]

VAMC conducts RCA
- VAMC director convenes multidisciplinary team of VAMC staff
- RCA team identifies and documents root causes, actions, and outcome measures

Leadership reviews/approves
- RCA team presents RCA report to VAMC leadership
- VAMC director signs completed RCA report
- Patient safety manager updates WebSPOT and submits final RCA report to National Center for Patient Safety[c]

VAMC implements RCA actions
- Patient safety manager follows up on implementation of RCA actions
- Patient safety manager measures effectiveness of actions after implementation and updates WebSPOT

45 days[d]

Source: Veterans Health Administration. | GAO-15-643

[a]To determine if an RCA is required, the VAMC patient safety manager evaluates the adverse event using the Veterans Health Administration's (VHA) safety assessment code matrix to score the severity of the event and its likelihood of recurrence on a scale of 1 (lowest risk) to 3 (highest risk). As directed by VHA policy, adverse events with a score of 3 always require an RCA; VAMCs have discretion in determining whether to conduct RCAs on adverse events with scores of 1 or 2.

[b]WebSPOT is VHA's centralized RCA reporting system, a software application within VHA's Patient Safety Information System.

[c]The National Center for Patient Safety is the VHA office responsible for monitoring RCA data.

[d]This time period applies to individual RCAs only, and refers to the time period from the determination of the need for an RCA to when the RCA report must be signed by the VAMC director. For aggregated RCAs—which review a group of similar adverse events—reports must be signed by the VAMC director within 60 days of the determination of the need for an RCA.

Adverse event occurs. The RCA process at a VAMC begins with the recognition of an adverse event. At the VAMC, the patient safety manager receives information from VAMC staff about an adverse event that occurs at the VAMC. To determine if an RCA is required, the patient safety manager evaluates the event using VHA's safety assessment code matrix to score the severity of the event and its likelihood of recurrence on a scale of 1 (lowest risk) to 3 (highest risk). As directed by VHA policy, adverse events with a score of 3 always require an RCA. VAMCs have discretion in determining whether to conduct RCAs on adverse events with scores of 1 or 2.

VAMC conducts RCA. After determining the need for an RCA, the VAMC director convenes a multidisciplinary team of VAMC staff to identify root causes and actions to be taken with associated outcome measures.[10] VHA policy states that those staff directly involved in the adverse event cannot participate on the RCA team; however, the RCA team may interview these staff as part of its investigation to obtain their perspectives on the event that occurred and suggestions for preventing its recurrence.

The RCA team is required to develop a report, which includes a description and flowchart of the adverse event, identifies one or more root causes, and includes actions to be taken with associated outcome measures. Actions describe VAMC-level changes to reduce or eliminate future occurrences of similar adverse events. Each action is also required to have at least one outcome measure—a specific, quantifiable, and time-bound means by which responsible staff can determine the extent to which the action has been taken to address the root cause. For example, in the case of an overdose of an anesthesia medication from a pump that held an unsafe amount of medication, the action might be to use a different type of pump that holds less medication and prevents an accidental overdose; an outcome measure might be to measure patient outcomes 1 year later to ensure that no such overdoses occurred.

Leadership reviews/approves. Upon completion of the RCA report, the RCA team presents its findings to VAMC leadership. The completed RCA report is required to be signed by the VAMC director within 45 days of the determination of the need for an RCA.[11] The date of the director's signature is the date the RCA is considered complete. The patient safety manager then submits the completed report to NCPS through WebSPOT.

VAMC implements RCA actions. After an RCA report is submitted to NCPS, patient safety managers follow up with VAMC staff on the implementation of identified actions, and, after implementation, evaluate the effectiveness of those actions in addressing the identified root causes.

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[10]A multidisciplinary team is composed of individuals from clinical and administrative roles, such as physicians, nurses, staff assistants, and VA police officers.

[11]This time period applies to individual RCAs only. For aggregated RCAs, reports must be signed by the VAMC director within 60 days from the determination of the need for an RCA.

Patient safety managers also update WebSPOT with the actual implementation date of each action. If a VAMC does not implement an action, the patient safety manager can indicate in WebSPOT that the action was not implemented and the reason why. VAMCs may not implement certain actions identified by the RCA team for several reasons, including funding constraints and other unforeseen complications, like building design limitations.[12] After implementation, patient safety managers update WebSPOT to add any comments associated with implementation, as well as information about the effectiveness of each action in addressing identified root causes on a five-point scale from "much worse" to "much better." In fiscal year 2014, VAMCs most commonly rated RCA actions as having made the related system or process "better" or "much better."

Upon receipt of a completed RCA report, NCPS staff categorize key aspects, such as the type of adverse event, location of the event, corrective actions, and outcome measures. NCPS staff also categorize RCA actions according to an action strength hierarchy of stronger, intermediate, or weaker. (See table 1 for descriptions of stronger, intermediate, and weaker actions.) NCPS recommends using stronger or intermediate actions to the extent possible to improve the likelihood that actions will remove human error from processes and be more successful in addressing the root causes of an adverse event. About two-thirds (68 percent) of all actions resulting from RCAs in fiscal year 2014 were categorized as stronger or intermediate.

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[12]For example, an RCA may identify constructing walls as an action to reduce noise distraction in a particular unit, but the VAMC may learn later that it is unable to do so because the resulting patient rooms would be too small.

Table 1: Descriptions of Stronger, Intermediate, and Weaker Actions Resulting from Root Cause Analyses at VA Medical Centers
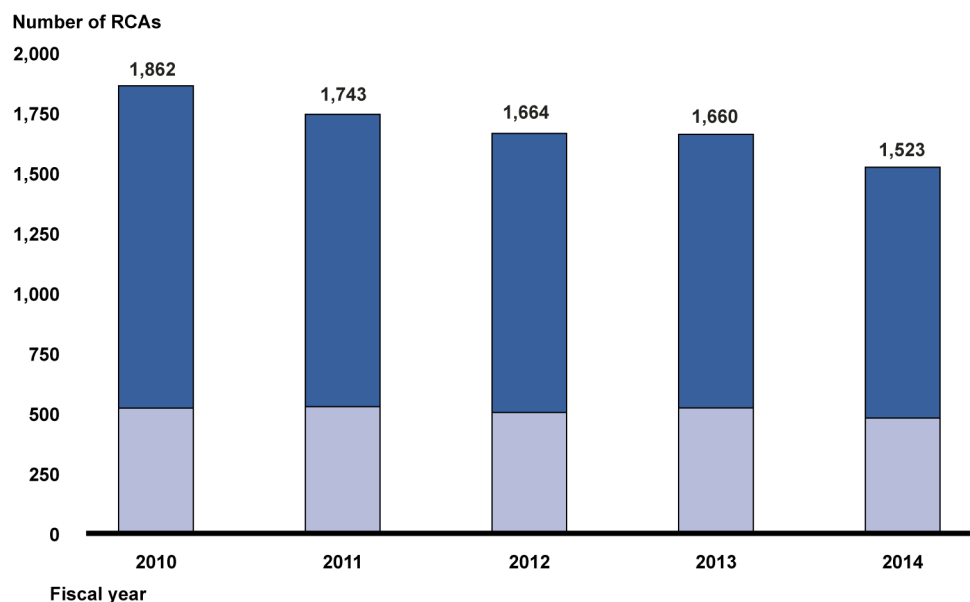
Action strength	Description
Stronger	• Architectural and physical plant changes • Simplifying processes and removing unnecessary steps
Intermediate	• Reducing or eliminating distractions; for example, interruptions of pharmacists preparing medication • Software enhancements or modifications
Weaker	• New procedures, memoranda, or policies • Training programs

Source: Veterans Health Administration. | GAO-15-643

VAMCs Completed Fewer RCAs Each Year from Fiscal Year 2010 through Fiscal Year 2014, but VHA Has Not Analyzed the Reasons for the Decrease

Total completed RCAs (both individual and aggregated) at VAMCs decreased in each of the past 5 fiscal years. Overall, from fiscal years 2010 through 2014, the total number of RCAs completed at VAMCs decreased by 18 percent—from 1,862 in fiscal year 2010 to 1,523 in fiscal year 2014. (See fig. 2.) Individual RCAs accounted for 88 percent of the decrease during this time period.

GAO-15-643 VA Root Cause Analysis

Figure 2: Root Cause Analyses (RCA) Completed at VA Medical Centers (VAMC), Fiscal Years 2010 through 2014

	2010	2011	2012	2013	2014
■ Individual RCAs[a]	1,341 (72%)	1,216 (70%)	1,161 (70%)	1,138 (69%)	1,043 (68%)
■ Aggregated RCAs[b]	521 (28%)	527 (30%)	503 (30%)	522 (31%)	480 (32%)

Source: Veterans Health Administration. | GAO-15-643

[a]Individual RCAs are based on individual adverse events.

[b]Aggregated RCAs examine a group of similar adverse events. The Veterans Health Administration requires that VAMCs conduct aggregated RCAs on three types of adverse events—falls, adverse drug events, and missing patients—to the extent that they occur in a given year. If a VAMC experiences only one adverse event in any of the three categories required for aggregated RCAs, the VAMC must conduct an individual RCA on that event. If a VAMC has zero events in an aggregated RCA category, the VAMC can conduct either additional individual or aggregated RCAs to meet VHA requirements.

VHA's NCPS officials told us they are not certain why the number of completed RCAs has decreased over time, especially in light of an increase in reports of adverse events over the past 5 fiscal years. Specifically, our analysis of adverse event reports in WebSPOT shows that they increased by 7 percent in the past 5 fiscal years (from 109,951 in fiscal year 2010 to 117,136 in fiscal year 2014). An increase in reports does not necessarily mean that there should also be an increase in the number of RCAs conducted, as it is possible that the safety assessment code score was not high enough to require an RCA, giving the VAMC the discretion to address the adverse event through other available

processes. However, NCPS officials told us they have not conducted an analysis to determine the contributing factors to the decrease. Without further analysis, it is unclear whether an increase in adverse event reports at the same time that the number of completed RCAs is decreasing is a cause for concern. NCPS's lack of analysis is not consistent with federal internal control standards, which state that control activities should include comparisons and assessments of different sets of data so that analyses of the relationships can be made and appropriate actions taken.[13]

NCPS officials told us they were aware of the decrease in completed RCAs, but have not conducted an analysis of the decrease because it is difficult to determine causal relationships between many possible contributing factors. Although they have not conducted an analysis, NCPS officials suggested possible contributing factors to the decrease in completed RCAs, including: (1) a change in the culture of safety at VAMCs; (2) VAMCs using alternative processes to address adverse events in place of RCAs; and (3) an increasing number of VAMCs conducting the minimum of four individual RCAs each fiscal year.

> **Change in the culture of safety at VAMCs**. NCPS officials stated that they have observed a change in the culture of safety in recent years in which staff feel less comfortable reporting adverse events than they did previously.[14] Officials added that this change is reflected in NCPS's periodic survey on staff perceptions of safety; specifically, 2014 scores showed decreases from 2011 on questions measuring staff's overall perception of patient safety, as well as decreases in perceptions of the extent to which staff work in an environment with a nonpunitive response to error. As previously noted, however, the number of adverse event reports has been increasing, despite NCPS officials' observation of a change in the culture of safety.

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[13]GAO/AIMD-00-21.3.1.

[14]The Agency for Healthcare Research and Quality states that a culture of safety is established when an organization maintains a commitment to safety at all levels, from frontline providers to managers and executives. Department of Health and Human Services, Agency for Healthcare Research and Quality, Patient Safety Network, "Patient Safety Primers: Safety Culture," (July 2014), accessed March 25, 2015, http://psnet.ahrq.gov/primer.aspx?primerID=5.

VAMCs' use of alternative processes. NCPS officials told us that VAMCs sometimes choose alternative processes, such as those based on Lean methods, to address adverse events when an RCA is not required.[15] However, VHA is unaware how many VAMCs use these alternative processes. From fiscal year 2009 through fiscal year 2014, VHA trained over 20,000 staff on the use of Lean methods, but an official from the VA Center for Applied Systems Engineering—the VHA office that conducted the trainings—told us VHA has not conducted any follow-up to determine how these methods are being applied at VAMCs. The official added that, after training, it is up to VAMC leadership to implement Lean methods in their VAMCs, and that the Center for Applied Systems Engineering began working with NCPS about a year ago to begin aligning the RCA process with Lean methods. The lack of follow-up on the use of alternative processes is not consistent with standards for internal control. Without information on the extent to which VAMCs are using alternative processes like Lean methods in place of RCAs, NCPS has limited awareness of the extent to which VAMCs are addressing the root causes of adverse events.

Three of the four VAMCs in our review completed fewer RCAs in fiscal year 2014 compared to fiscal year 2010. Officials at one of these VAMCs told us the reason they had completed fewer RCAs was because the VAMC director supported the use of a Lean method to understand and act on the root cause of an adverse event when an RCA was not required. Officials at this VAMC also told us that they thought their Lean method was sometimes more appropriate for reviewing low-severity events because it yielded similar results to an RCA and allowed for a broader, more complete view of the issue being examined. NCPS officials told us they support VAMCs' use of these alternative processes when appropriate, but acknowledged loss of information as the results of these processes are not required to be entered into WebSPOT, or otherwise shared with NCPS.

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[15]Lean is a systematic approach to improving the reliability of processes through the identification and elimination of operational barriers and sources of variability within a process or system. Lean originated in the automotive industry and has been adapted for use in other industries, including health care.

Increasing numbers of VAMCs conducting the minimum of 4 individual RCAs each fiscal year. NCPS officials told us they were aware that by setting a requirement in 2007 that VAMCs conduct a minimum of 4 individual RCAs each fiscal year, VAMCs that had previously completed many more than 4 might decrease the number of individual RCAs they completed over time. Our analysis of RCA data shows that from fiscal years 2010 through 2014, the number of VAMCs completing more than 4 individual RCAs declined by 8 percent (from 135 to 124 VAMCs). In addition, the number of VAMCs completing exactly 4 individual RCAs in this time period more than doubled, from 4 VAMCs in fiscal year 2010 to 10 VAMCs in fiscal year 2014. All 10 of these VAMCs completed more than 4 individual RCAs in fiscal year 2010, with totals ranging from 5 to 14 individual RCAs. Officials stated that the selection of 4 individual RCAs as a minimum (as well as the selection of 8 as a minimum total of individual and aggregated RCAs), was arbitrary but seemed reasonable. They expressed concern that raising the annual individual RCA minimum requirement may result in lower-quality RCAs.

Because NCPS has not conducted an analysis to understand the relationship between the decrease in RCAs and possible contributing factors, such as the increase in adverse event reports and use of alternative processes, it is unclear whether the decrease indicates a negative trend in patient safety at VAMCs or a positive one. For example, the decrease can indicate a negative trend of VAMCs not reporting severe adverse events that would require RCAs, or a positive trend reflecting fewer severe adverse events occurring. Moreover, without complete information on the extent to which VAMCs are using alternative processes to address the root causes of adverse events and the results of those processes, NCPS lacks important data that may be helpful in better identifying trends and system-wide patient safety improvement opportunities.

VHA Oversees the RCA Process by Monitoring VAMC Compliance, and Develops System-Wide Patient Safety Initiatives Informed by RCA Data

NCPS and VISN patient safety officers oversee the RCA process by monitoring each VAMC's compliance with RCA requirements, including by reviewing RCA information in WebSPOT and conducting site visits.

Reviewing RCA information in WebSPOT. NCPS conducts quarterly reviews of RCA information in WebSPOT to monitor VAMCs' progress toward meeting annual RCA requirements. NCPS monitors, for example, each VAMC's progress toward completing the required number of individual and aggregated RCAs for the fiscal year. Our analysis of WebSPOT data shows that, from fiscal year 2010 through fiscal year 2014, almost all VAMCs completed the minimum number of RCAs required each year: an average of 98 percent of VAMCs completed four or more individual RCAs, and an average of 96 percent of VAMCs completed eight or more total RCAs. NCPS officials told us that their review of WebSPOT information also provides insight into the effectiveness of a VAMC's RCA process. NCPS submits quarterly reports of VAMCs' progress to the Deputy Under Secretary for Health for Operations and Management.

NCPS officials told us that when they find that a VAMC has not met the annual requirement for the number of completed RCAs, they may contact the VAMC's patient safety manager to ask if barriers to the RCA process exist. Officials said that, in one such instance, the patient safety manager at a VAMC that had not completed the required number of RCAs told NCPS that the medical center director was not supportive of the RCA process. According to NCPS officials, in situations such as this they may then contact the VAMC's leadership to remind them of the importance of completing RCAs and of the benefits to the entire system of having complete information in WebSPOT, and to offer their assistance. VISN patient safety officers we spoke with told us that they also monitor VAMCs' compliance with RCA requirements through reviews of RCA information in WebSPOT, and by meeting with VAMC patient safety managers.

Conducting site visits to VAMCs. NCPS officials said they may conduct a site visit to provide consultation and feedback to a VAMC that appears to be encountering challenges in meeting RCA requirements, such as completing individual RCAs within 45 days. NCPS site visits can also include an examination of other aspects of the RCA process, including reviewing a sample of RCAs to examine the assignment of safety assessment scores,

the strength of corrective actions, and the implementation status of the actions. Officials stated that the 12 to 20 site visits they conduct each year are the most valid way for them to verify the implementation of RCA actions because they provide NCPS with the ability to observe implemented activities and the effectiveness of RCA-based improvements. NCPS officials told us that they visit VAMCs at the request of the VAMC director or as participants in a visit made by other VHA offices, including the Deputy Under Secretary for Health for Operations and Management.[16] In addition to NCPS, patient safety officers at three of the four VISNs in our review told us that they also conduct annual site visits to some or all VAMCs in their networks to assess implementation of RCA actions and to consult with VAMC patient safety managers.[17]

In addition to monitoring compliance, NCPS uses RCA information to inform system-wide initiatives to improve patient safety. Not all initiatives are based solely on RCAs, but officials told us that RCAs are a contributing factor to NCPS's larger patient safety improvement efforts. Officials told us that they focus their initiatives on problems that pose the greatest risk to patients or are the most prevalent in VA's health care system, such as suicide. Officials explained that their choice of which initiative to pursue is determined by what will have the greatest impact on a problem. Examples of NCPS's initiatives include Patient Safety Alerts and Advisories, topic summaries, and Clinical Team Training.

Patient Safety Alerts and Advisories. Patient Safety Alerts and Advisories are urgent notifications sent to VAMCs that contain a description of a safety issue, instructions for implementing actions

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[16]According to VHA policy, NCPS is also required to cooperate with reviews and site visits conducted by VHA's Office of the Inspector General and VHA's Office of the Medical Inspector, which may also monitor RCAs to assess their adequacy and to identify problems with processes of care that warrant attention. See VHA, *VHA National Patient Safety Improvement Handbook*. The Joint Commission—an independent, not-for-profit organization that accredits and certifies health care organizations and programs—may also review RCAs as part of its accreditation reviews of VAMCs.

[17]At the fourth VISN in our review, we were told that the patient safety officer had conducted patient safety site visits in the past, but at the time of our review annual visits were not possible because of budget constraints. However, the patient safety officer also indicated that if a patient safety issue is identified at one of the VAMCs in that network, then the VISN's chief quality officer, to whom the patient safety officer reports, may conduct a site visit to address the issue.

to prevent recurrence of the problem, and due dates for completion of actions.[18] NCPS officials told us that alerts and advisories can come from several sources, including reports from VAMCs, other VHA offices, and medical device manufacturers. Patient Safety Alerts and Advisories are developed by NCPS and then issued by the VHA Deputy Under Secretary for Health for Operations and Management. For example, VHA issued a Patient Safety Alert after a patient in a VAMC behavioral health unit hanged himself from an air conditioning vent. The RCA team recommended a structural change to the vents to prevent recurrence, which VHA then required to be implemented at all VAMCs. NCPS also tracks the date that VAMCs completed implementation of actions. From fiscal year 2010 through fiscal year 2014, NCPS has developed 57 alerts and 7 advisories.[19]

Topic summaries. Officials told us that NCPS may issue an RCA topic summary if they identify a trend in adverse events or RCAs in WebSPOT. An RCA topic summary provides background context for the relevant adverse event, discusses root causes that were identified through the RCAs conducted, and describes corrective actions taken by VAMCs. For example, NCPS officials told us that after their review of RCAs identified a trend in adverse events caused by the misidentification of patients, they determined that system-wide improvements were needed. NCPS prepared topic summaries on misidentification related to specimens and transporting patients, as well as a guidance document on patient wristbands, which included best practices for VAMCs. NCPS officials told us topic summaries are distributed to VAMCs as part of the agenda for monthly conference calls that NCPS conducts with patient safety staff at VAMCs and VISNs, and that they are also made available through NCPS's internal

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[18]Patient Safety Alerts require specific, mandatory, and timely action. Patient Safety Advisories provide general recommendations when equipment design, procedural issues, or training pose potential harm. Recommendations in Patient Safety Advisories must either be implemented as described, or the VAMC must show that it has taken actions that implement an equivalent or higher level of safety than that recommended by the Patient Safety Advisory.

[19]NCPS officials told us that not all Patient Safety Alerts and Advisories result solely from RCAs.

website and via e-mail. From fiscal year 2010 through fiscal year 2014, NCPS has issued 12 topic summaries.

NCPS may also determine the need for a topic summary on the basis of requests for WebSPOT searches from VAMC and VISN patient safety staff interested in knowing whether RCAs have been conducted for similar adverse events at other VAMCs.[20] NCPS officials estimated that they conduct about 200 such searches annually, and that these searches provide VAMC and VISN staff with information on similar adverse events, such as the corrective actions identified at other locations to address the adverse event. According to officials, NCPS may determine through these searches that several locations are encountering similar patient safety issues, prompting the preparation of a topic summary.

Clinical Team Training. NCPS implemented Clinical Team Training for surgical teams in 2007 following analysis of RCA information in WebSPOT that found communication failure to be a root cause or contributing factor in 75 percent of the more than 7,000 RCAs reviewed. The objective of Clinical Team Training is to enhance teamwork and overcome obstacles to effective communication across professional boundaries. The training curriculum includes 2 months of preparation by the VAMC; a day-long onsite learning session consisting of lectures, group interaction, and videos; and quarterly interviews of the clinical team to assess training implementation. One study found that surgical mortality decreased 11 percent more in VAMCs that received Clinical Team Training compared to those that had not received it.[21] NCPS officials told us they have expanded Clinical Team Training beyond surgical teams, and have provided this training, for example, to teams in emergency departments, intensive care units, and inpatient behavioral health units.

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[20]NCPS officials told us that, for confidentiality reasons, VAMC patient safety managers' access to WebSPOT is limited to information from their VAMC.

[21]Julia Neily et al., "Association between Implementation of a Medical Team Training Program and Surgical Mortality," *Journal of the American Medical Association*, vol. 304, no. 15 (2010).

Conclusions

RCAs are an important tool for VAMCs to identify the systems or processes that contributed to an adverse event, and implement actions to address them. They are also an important contributor to NCPS initiatives to improve patient safety across VA's health care system. It is unclear whether the 18 percent decrease in total RCAs completed from fiscal year 2010 to fiscal year 2014 is a negative trend reflecting less reporting of serious adverse events, or a positive trend reflecting fewer serious adverse events that would require an RCA. VHA has not, as would be consistent with federal internal control standards, conducted an analysis to determine the relationship between data showing a decrease in RCAs and factors that may be contributing to this trend, including VAMCs use of alternative processes, such as Lean methods, when RCAs are not required. Although the choice to use alternative processes may be appropriate, NCPS is not aware of the extent to which these processes are used, the types of events being reviewed, or the changes resulting from them. Without analyzing the reasons for declining RCAs, and understanding the extent that VAMCs use alternative processes and their results, NCPS has limited awareness of what VAMCs are doing to address the root causes of adverse events. Moreover, the lack of complete information may result in missed opportunities to identify needed system-wide patient safety improvements.

Recommendations for Executive Action

To ensure that appropriate steps are being taken to address the root causes of adverse events within VHA, the Secretary of Veterans Affairs should direct the Under Secretary for Health to take the following two actions:

- Conduct an analysis of the declining number of completed RCAs within the VA health care system, including identifying contributing factors, and take appropriate actions to address them.

- Determine the extent to which VAMCs are using alternative processes to address the root causes of adverse events when an RCA is not required, and collect information from VAMCs on the number and results of those alternative processes.

Agency Comments

We provided a draft of this report to VA for comment. In its written comments, reproduced in appendix I, VA generally agreed with our conclusions and concurred with our recommendations. In its comments, VA also provided information on an initial analysis it had conducted, as well as its plans for implementing each recommendation, with an estimated completion date of November 2015.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Secretary of Veterans Affairs, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

Debra A. Draper
Director, Health Care

List of Requesters

The Honorable Bernard Sanders
Ranking Member
Committee on Budget
United States Senate

The Honorable Richard Blumenthal
Ranking Member
Committee on Veterans' Affairs
United States Senate

The Honorable Corrine Brown
Ranking Member
Committee on Veterans' Affairs
House of Representatives

The Honorable Patty Murray
United States Senate

The Honorable Eddie Bernice Johnson
House of Representatives

Appendix I: Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

July 7, 2015
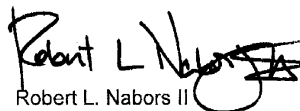
Ms. Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Draper:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, *"VA HEALTH CARE: Actions Needed to Assess Decrease in Root Cause Analyses of Adverse Events"* (GAO-15-643). VA generally agrees with GAO's conclusions and concurs with GAO's recommendations to the Department.

The enclosure specifically addresses GAO's recommendations and provides an action plan. VA appreciates the opportunity to comment on your draft report.

Sincerely,

Robert L. Nabors II
Chief of Staff

Enclosure

Department of Veterans Affairs (VA) Response to
Government Accountability Office (GAO) Draft Report
*"VA HEALTH CARE: Actions Needed to Assess Decrease in Root Cause
Analyses of Adverse Events"*
(GAO-15-643)

GAO Recommendation: To ensure that appropriate steps are being taken to
address the root causes of adverse events within VHA, the Secretary of Veterans
Affairs should direct the Under Secretary for Health to take the following two
actions:

Recommendation 1: Conduct an analysis of the declining number of completed
RCAs within the VA health care system, including identifying contributing factors,
and take appropriate actions to address them.

VA Comment: Concur. The National Center for Patient Safety (NCPS) has conducted
an initial analysis of the relationship between decreases of root cause analyses (RCAs)
and possible contributing factors. As a result of that evaluation, we modified our fiscal
year 2015 Cornerstone Program, which now uses the number of safety reports entered
into our database (WebSPOT) per 10,000 unique patients as a significant criterion to
determine the recognition category (Gold, Silver, or Bronze) a facility can achieve. This
design encourages increased reporting of events, which in turn should increase the
number of RCAs chartered and completed. NCPS also identified barriers that Patient
Safety Managers face as a result of their realignment under the facility Quality
Management Office. Finally, NCPS identified vulnerabilities related to the restriction of
the number of site visits permitted by our office. Target Completion Date: November
2015.

Recommendation 2: Determine the extent to which VAMCs are using alternative
processes to address the root causes of adverse events when an RCA is not
required, and collect information from VAMCs on the number and results of those
alternative processes.

VA Comment: Concur. NCPS will further investigate which Veterans Affairs Medical
Centers (VAMCs) are using alternative processes to address root causes of adverse
events and present its findings on the number and results of those alternative
processes. Every VAMC is required to evaluate their adverse events in accordance
with Veterans Health Administration's National Patient Safety Improvement Handbook
1051.01 and use other processes to sustain actions associated with RCAs and other
events at their facilities. Each VAMC has a system redesign office that utilizes the
LEAN, Six Sigma, or equivalent model. All facilities use processes other than RCAs to
address adverse events. However, these processes are not a replacement for RCAs,
but rather are designed to strengthen and enhance the sustainability of system wide
improvements. Target Completion Date: November 2015.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Acknowledgments

In addition to the contact named above, Janina Austin, Assistant Director; Jennie F. Apter; Frederick K. Caison; Christine Davis; Kaitlin McConnell; Vikki L. Porter; Emily Wilson; and Malissa G. Winograd made key contributions to this report.