Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Evaluation of the Veterans Health Administration's National Patient Safety Program

Report No. 08-02075-148 **June 18, 2009**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time, Monday through Friday, excluding Federal holidays

E-Mail: vaoighotline@va.gov

Contents

Executive Summary

Introduction

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) completed an evaluation of the Veterans Health Administration's (VHA's) National Patient Safety (NPS) Program. The purposes of the evaluation were to determine whether VHA's NPS Program (1) has been effective in accomplishing its stated goal of preventing inadvertent harm to patients receiving VHA care and (2) has provided efficient and effective coordination, oversight, and continuous improvement.

Results and Recommendations

We concluded that VHA took important, positive steps in 1998 when it expanded existing patient safety activities and created the National Center for Patient Safety (NCPS). VHA's NPS Program has been the foundation for many national and international patient safety initiatives. We noted several opportunities to strengthen the NPS Program's effectiveness, oversight, and continuous improvement.

We recommended that the Acting Under Secretary for Health ensure that:

- All relevant patient data sources be assessed for patient safety significance, coordinated across VHA's quality and safety programs, and used to drive change.
- Organized, coordinated oversight of the NPS Program is systematically provided by either the NCPS or another VHA entity.
- VHA develops a plan to systematically review all aspects of the NPS Program for efficiency and effectiveness and make revisions as appropriate.

Comments

The Acting Under Secretary for Health concurred with the findings and recommendations. The implementation plan is acceptable, and we will follow up until all actions are complete.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Introduction

Summary

The VA Office of Inspector General (OIG), Office of Healthcare Inspections (OHI) completed an evaluation of the Veterans Health Administration's (VHA's) National Patient Safety (NPS) Program. The purposes of the evaluation were to determine whether VHA's NPS Program (1) has been effective in accomplishing its stated goal of preventing inadvertent harm to patients receiving VHA care and (2) has provided efficient and effective coordination, oversight, and continuous improvement.

Background

The medical literature in the past several years has reported as many as 98,000 deaths annually due to errors in medical care, many of which are preventable. Preventable medical errors have been estimated to cost between $17 and $29 billion per year nationwide.[1] VHA responded to these numbers, as well as to intense media scrutiny following several high profile cases, by placing more emphasis on patient safety within its long-standing quality review and risk management programs. Several VHA offices have created programs to evaluate and seek to improve patient care and safety. These offices include the Deputy Under Secretary for Health for Operations and Management (DUSHOM), the Office of Quality and Performance, the Office of the Medical Inspector, and the National Center for Patient Safety (NCPS). Each of these offices has access to comprehensive patient databases and can obtain reports that assess performance against metrics, such as procedure complication rates, surgery waiting times, and patient satisfaction. Some specific programs have developed databases tailored for their patient care review needs, such as the National Surgical Quality Improvement Program (NSQIP), the Inpatient Evaluation Center, and the Cardiac Assessment Reporting and Tracking System.

Although VHA has been recognized in the health care community worldwide as a leader in patient safety and has advocated a system-wide culture change, OHI and Government Accountability Office reviews have identified concerns with or suggestions for improvement in effectiveness and efficiency.

Scope and Methodology

For the purpose of this review, we defined the NPS Program as the activities described in the NPS Improvement Handbook[2] (the handbook), which are performed by the NCPS, Veterans Integrated Service Network (VISN), and VHA facility staff. To evaluate VHA's NPS Program, we reviewed the handbook, reports, training materials, and other

[1] Institute of Medicine, "To Err is Human: Building a Safer Health System," November 1999, p. 1.
[2] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, May 23, 2008.

relevant documents. We visited the NCPS office July 9–10, 2008, and interviewed NCPS staff. We interviewed VA Central Office (VACO), VISN, and facility staff. Also, we reviewed patient safety review results and feedback gathered from VHA facilities during fiscal year (FY) 2007 Combined Assessment Program (CAP) reviews. As mentioned previously, other VHA programs and offices have data and activities relevant to patient quality and safety, and although we mention these occasionally, we did not review them in detail as part of this report.

We conducted the review in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

National Patient Safety Program Overview

VHA has historically had a mechanism for reporting and reviewing unplanned patient incidents. In 1997, VHA established a patient safety oversight committee and an expert advisory panel and issued a patient safety handbook. In 1998, the panel met and issued a report recommending that a national patient safety program office be created and a program director be hired. In order to represent a significant change in the normal way of doing business with headquarters in VACO, the committee recommended that the program office be established outside of the Washington, DC, area. The NCPS office was established in Ann Arbor, MI, as a separate entity from the VHA office that was responsible for monitoring patient care quality. A Director was appointed who reported directly to the Under Secretary for Health. The goals for the new office were to change VHA's culture to one of concern for patient safety, to prevent harm to patients under VHA care, and to involve staff in all VHA facilities. Since 2007, the NCPS Director has reported to the Associate Deputy Under Secretary for Health for Quality and Safety. The NCPS is a program office and has no line authority over staff in VISN offices or VHA facilities.

In 1999, the revised handbook was issued, which established a policy for identifying, reporting, and mitigating vulnerabilities that may result in adverse patient events (such as falls and medication errors) and close calls. VHA facility staff are expected to identify and report actual adverse patient events and close calls. Facility patient safety managers (PSMs) prioritize these events and close calls for severity and probability using the safety assessment code (SAC). A root cause analysis (RCA) is a tool used by facility staff to determine the reasons why events occurred and to try to prevent future occurrences. The handbook describes two types of RCAs—aggregated and individual. Aggregated RCAs may be used for four events (falls, adverse drug events, parasuicides [actual or attempted suicides], and missing patients) for which data are gathered over time and evaluated annually. Individual RCAs are conducted for events with higher SAC scores. PSMs enter adverse event information into the NCPS's patient safety information system database, known as SPOT (not an acronym). The NCPS has access to all reported patient adverse events, close calls, and RCAs across the VHA system. The SPOT database

contains only de-identified data—no patient or staff names and no social security numbers.

Some of the accomplishments of the NCPS include:

- Tools for uniform analysis of unsafe situations (RCAs) and Healthcare Failure Mode and Effects Analysis (HFMEA).
- Development of approaches and tools to prevent unsafe situations (including falls prevention toolkit, a program to ensure correct surgery, and a series of cognitive aids for anesthesiology).
- Development of patient safety alerts and advisories, which are forwarded to the DUSHOM for release to VHA facilities.
- National education and training programs.
- Internal and external websites and publications (newsletters and peer-reviewed journals).
- Data sharing (facility, VISN, and VHA analysis; topic summaries; and tailored reports).
- Collaboration with and dissemination of techniques to national and international health care organizations (including The Joint Commission, the National Patient Safety Foundation, and the World Health Organization).

Also, the NCPS led and participated with other VHA program offices in the development of directives for the prevention of retained surgical items and for emergency airway management outside the operating room. Additionally, the NCPS created the Medical Team Training program, which is leading improvement efforts at all VHA facilities with surgical programs.

In 2004, in response to safety vulnerabilities identified by the NCPS, VHA funded the Bar Code Expansion project to increase positive patient identification and decrease vulnerabilities in the labeling of all blood and laboratory specimens. This large multi-year project, which is managed by the Bar Code Resource Office, introduces handheld devices with integrated bar code scanners into patient care settings. In 2006, funds were provided to purchase the devices. In 2007, approval was given to purchase the software and hire personnel to support the project, and pilot testing began at 16 facilities that already had compatible wireless infrastructures. However, since the reorganization of information technology (IT) functions in VA, progress has virtually stopped. This is an important patient safety project and it should be kept on schedule until completion.

National Center for Patient Safety Budget and Staff Resources.

- Beginning in 1998, a program known as the Patient Safety Center of Inquiry (PSCI) received funding of $2 million. This program has provided funds to study topics such as home care safety, provider fatigue, and chemotherapy safety.

- In 1999, the NCPS Director received approval for 16 full-time employee equivalents (FTE) and an initial budget of $306,955. The NCPS FTE and budget have increased almost every year since the NCPS's inception.

- In 2000, the Patient Safety Reporting System (PSRS) was created and initially funded for $2 million. The PSRS is an independent incident reporting mechanism.

The table below shows NCPS staffing and budget figures for the period FY 2000–2008. Three FTE under VA's Office of IT are dedicated to NCPS's data systems but are not included in the table.

Table 1: National Center for Patient Safety Budget and Resources

FY	NCPS FTE	NCPS Office Budget	PSCI Budget	PSRS Budget	Total
2000	24	$2.4 million	$2 million	$200,000	$4.6 million
2001	31	$3.7 million	$2 million	$2 million	$7.7 million
2002	34.2	$3.6 million	$2 million	$3 million	$8.6 million
2003	34.2	$4.3 million	$1.5 million	$3 million	$8.8 million
2004	39.7	$5.8 million	$1.5 million	$1.4 million	$8.7 million
2005	39.7	$4.9 million	$1.8 million	$1.6 million	$8.3 million
2006	39.7	$6.5 million	$1.4 million	$1.4 million	$9.3 million
2007	48	$8.6 million	$1.6 million	$1.4 million	$11.6 million
2008	50	$10 million	$1.5 million	$1.4 million	$12.9 million

In addition to NCPS staff, each VHA facility is required to have at least one FTE PSM, and each VISN office has one FTE Patient Safety Officer (PSO). This totals approximately 180 FTE dedicated to patient safety. These positions report to the facility and the VISN, respectively, and are not accountable to the NCPS.

National Center for Patient Safety Goal. The NCPS goal of preventing inadvertent harm to patients as a result of their care is laudable but difficult to measure. It appears that data from the entire U.S. health care system does not support a conclusion that

typical patient safety programs prevent harm to patients.[3] Two reasons for this inability to state whether patients are safer are that attempts to address patient safety generally affect processes of care and that the data apply to small numbers of patients. A meaningful patient safety program should include defined program objectives, personnel, and a budget and should be monitored by regular progress reports to governance. The NCPS Director agreed that the goal is difficult to measure but cited the patient safety alerts as examples of how safety hazards had been identified and eliminated. We suggested that the program goals and objectives be modified to allow measurement and regular monitoring to determine if goals and objectives are being met.

Patient Safety Culture. The NCPS has advocated the adoption of a culture of patient safety where prevention is emphasized over punishment to mitigate system vulnerabilities and reduce adverse events. Several authoritative sources confirm that the likelihood of enlisting employee cooperation in identifying and addressing safety concerns is higher when employees are not blamed.[4,5] While VHA directives provide methods to deal with employees who have committed intentional errors or unsafe acts, tension exists between the non-punitive culture and the expectation of accountability in government.

[3] Peter J. Pronovost, MD, PhD, et al., "Tracking Progress in Patient Safety – An Elusive Target," *JAMA*, Vol. 296, No. 6, August 9, 2006.
[4] Institute of Medicine, p 2.
[5] The Joint Commission, *2008 Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, PI-1.

Inspection Results

Issue 1: Data Sources and Analyses

To obtain the most comprehensive view of patient safety in VHA facilities, it is important to identify as many safety concerns as possible from all available sources. Many programs under the broad umbrella of quality and safety have the potential to identify safety issues and adverse events. At the facility level, the following programs comprise a partial list:

- Patient incident reporting.
- Patient advocate.
- Peer review.
- Tort claim information system.
- Morbidity and mortality conferences.
- NSQIP.
- Infection control.

While some facility staff may share data from these programs to identify patient safety issues and events, no such sharing is required. Most of these programs require facility data to be entered into databases or sent in reports that are available to the responsible program offices at the VACO level. If these databases were available to all relevant program offices for use in data analysis, it is possible that resulting actions could improve patient care quality and safety. However, quality and safety information is not always well coordinated among VHA entities, including the NCPS, but data outside its database is outside its sphere of control.

The NCPS intranet website contains a variety of data that is available to VHA staff. Recently, the NCPS increased the types of trending summary reports available after receiving feedback that VACO, VISN, and facility staff have not consistently received information that they deem important. Specific examples of additional opportunities within the NCPS to improve adverse event identification and analyses follow.

Adverse Event Identification. While VHA employees are expected to identify and report adverse events that they are aware of, reporting is voluntary, and there are generally no repercussions for not reporting adverse events. Many experts state that all employee reporting programs (voluntary and mandatory) result in substantial underreporting. The Institute for Healthcare Improvement (IHI) stated:

> Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more

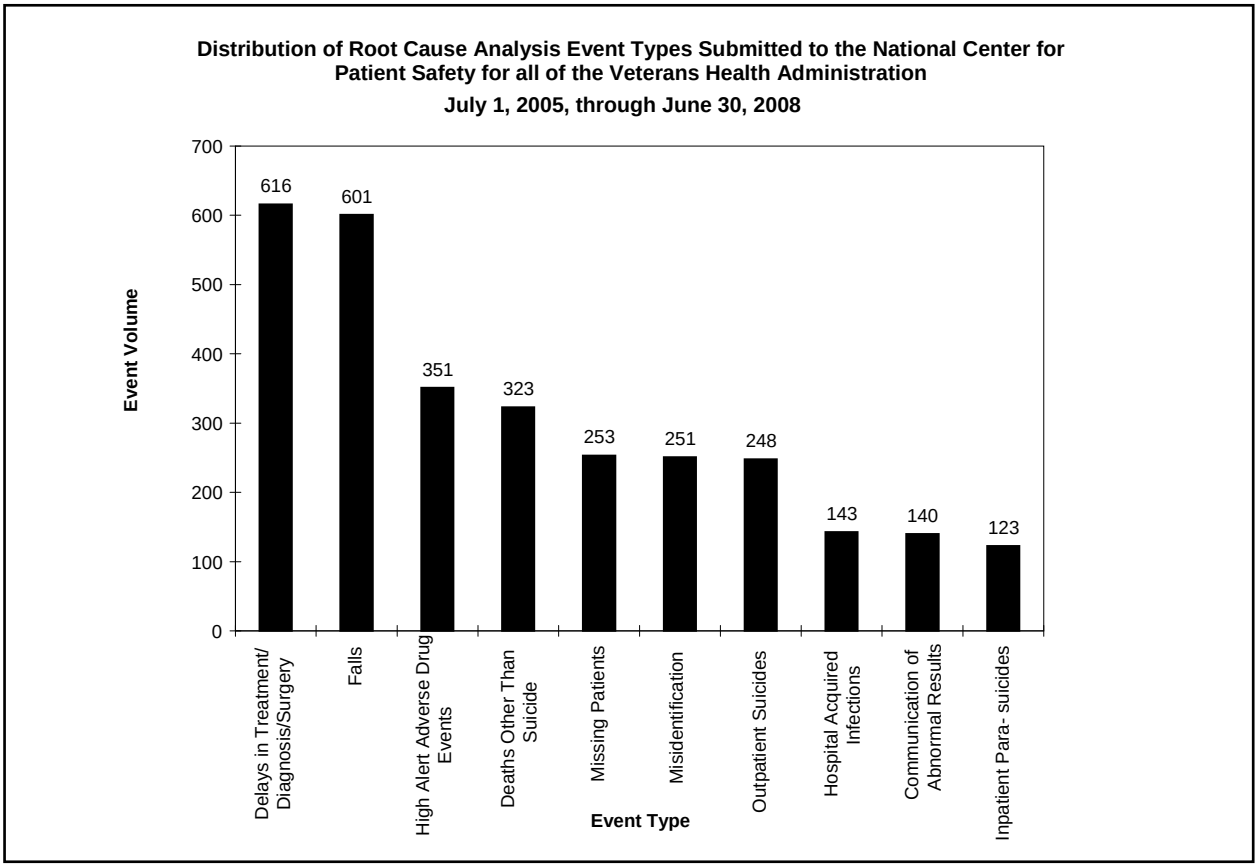
> effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.[6]

IHI explains that employee reporting alone is inadequate because it is highly subjective and often requires overburdened providers to complete time-consuming paperwork.[7] Some health care organizations have implemented adverse event identification programs that do not rely on employee reporting. Several studies have shown that computer monitoring strategies have identified many times more potential adverse events than were reported through employee reporting mechanisms.[8,9,10] While some of the events identified via these strategies were not confirmed as adverse events after review, the results provided a more complete picture of patient safety vulnerabilities that could be addressed. The NCPS has not endorsed any computer monitoring system.

It is possible that VHA policies could be affected by the limited data captured by employees voluntarily reporting patient adverse events. A more robust safety concern identification system could provide more valid information on which to focus policy changes.

Adverse Event Counts. Since 2000, PSMs have reported more than 400,000 aggregated review events and 154,000 safety reports or close calls. Facility staff have performed more than 10,000 RCAs. The graph on page 8 shows the frequency of the top 10 types of RCA events in the SPOT database.

[6] Institute for Healthcare Improvement, "Introduction to Trigger Tools for Identifying Adverse Events," http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/IntrotoTriggerToolsforIdentifyingAEs.htm, accessed on May 14, 2008.
[7] Ibid.
[8] M. K. Szekendi, et al., "Active surveillance using electronic triggers to detect adverse events in hospitalized patients," *Qual Saf Health Care*, Vol. 15, June 2006, pp. 184–190.
[9] David W. Bates, MD, MSc, et al., "Detecting Adverse Events Using Information Technology," *J Am Med Inform Assoc*, Vol. 10, No. 2, March–April 2003, pp. 115–128.
[10] C. W. Johnson, "How will we get the data and what will we do with it then? Issues in the reporting of adverse healthcare events," *Qual Saf Health Care*, Vol. 12, December 2003, p. ii64.



Aggregated RCAs address falls, adverse drug events, parasuicides, and missing patients. The highest type "delays in treatment/diagnosis/surgery" is also a frequent basis for tort claims and complaints to the OIG hotline. It would seem that this important event type could be considered for special review and analysis. NCPS staff told us that an analyst has been assigned to study this complex event type.

Adverse Event Data Availability. The SPOT database contains large amounts of de-identified data. When VACO and oversight bodies have requested VHA data regarding adverse events, such as wrong site surgeries, they have expressed frustration at receiving selected data that does not always represent the entire spectrum of events and is difficult to track to specific facilities and patients. Facility PSMs have expressed frustration that they have had to create secondary, duplicative systems in order to capture the patient information needed for effective reviews and reports. Recently, the NCPS has identified a patient incident reporting system developed at a VHA facility that could be used VHA wide and might reduce the need for a duplicate information system.

NCPS staff told us that they do not need patient-specific information because it is not relevant to understanding the adverse event or close call that occurred. They also told us that the identities of staff who report patient incidents must be kept confidential to prevent any repercussions for reporting. NCPS staff insist that other uses of SPOT data would be inappropriate. Nonetheless, we suggest that the NCPS, along with General

Counsel, re-evaluate the SPOT database and consider including patient and facility identifiers to improve utility for all users.

Patient Safety Reporting System. This voluntary, confidential safety reporting program was initiated in 2000. It was patterned after the Aviation Safety Reporting System administered by the National Aeronautic and Space Administration. The confidentiality of PSRS information only allows VHA review of de-identified information about the reported safety issues.

Approximately 750 issues were reported to the PSRS between FYs 2002 and 2007, and the frequency ranged from 84–196 reports per FY. The total cost of the PSRS program for the same 6-year period exceeded $11 million (range $1.4–$3 million per FY). The NCPS Director told us that the PSRS is a safety valve that permits individuals who are not willing to report by any other means to confidentially report events that would otherwise go unknown. However, employees who wish to report concerns anonymously have several hotline options that exist within VA (for example, the Office of Business Integrity and Compliance, the Office of Research Oversight, and the OIG), as well as options that exist outside of VA (such as The Joint Commission, the Nuclear Regulatory Commission, and the Occupational Safety and Health Administration). Patients who wish to report concerns also have options, including the VHA suicide hotline, the OIG hotline, and the Department of Defense hotline. We suggest that VHA re-evaluate the PSRS and consider eliminating it.

Summary. Patient safety could be improved by better coordinating existing data sources in various programs, expanding the identification of patient events through the addition of automated systems, making appropriately identified data available for analysis, and using the data to drive change. High frequency event types should be given appropriate attention. We recommended that VHA ensure that all relevant patient data sources be assessed for patient safety significance, coordinated across VHA's quality and safety programs, and used to drive change.

Issue 2: National Patient Safety Program Oversight

We found that although the NCPS monitors selected data elements within required processes, it does not provide comprehensive oversight of the NPS Program. The NCPS Director confirmed that his office is consultative and does not provide oversight. Although a patient safety oversight committee was in place prior to the creation of the NCPS, it ceased to exist in 2001. Specific examples of opportunities to improve oversight follow.

Site Visits. NCPS staff conduct consultative site visits to each VHA facility every 3 years. They told us that these visits serve the purpose of allowing for onsite evaluation of the facility's patient safety program using a structured patient safety assessment tool.

NCPS staff provide consultations, follow-up on patient safety alerts, and review RCAs. NCPS staff told us that facility staff have expressed appreciation for these visits. However, prior to our review, the site visits were conducted inconsistently and did not result in documented corrective action plans when deficits were identified. These issues were corrected subsequent to our review, and in February 2009 a DUSHOM memorandum was issued requiring facility managers to submit formal abatement plans following NCPS site visits. Also, prior to our review, no attempt had been made to analyze the site visits' results system wide to determine trends. Following our review, the NCPS presented trends observed during site visits to PSOs for discussion during a fall 2008 conference.

Many VISNs have created continuous readiness teams that visit facilities on a regular basis and include aspects of patient safety in their reviews. Site visits are also made through VHA's Systematic Ongoing Assessment and Review Strategy program and include patient safety aspects. Several other VHA program offices conduct site visits for internal review, including the Office of Geriatrics and Extended Care, the Office of the Medical Inspector, NSQIP, and the Office of Research Oversight. Feedback from VHA facility staff is that too many internal teams conduct visits that can be disruptive to normal business. It is not clear that results from these visits are compared or trended to identify opportunities for improvement in programs or at facilities.

Patient Safety Roles. The NCPS provides consultative services and has no line authority over PSOs or PSMs, who report to VISN and facility directors, respectively. The NCPS effects change through the DUSHOM's office. Facility compliance with patient safety processes is monitored by PSOs. However, there is some duplication and lack of role clarity between NCPS staff and PSOs regarding several patient safety responsibilities (described in Table 2 on the next page). Efficiency could be improved and frustration reduced by better defining these roles.

Table 2: Comparison of Patient Safety Responsibilities of National Center for Patient Safety Staff and Patient Safety Officers

Task	NCPS Staff	PSOs
Site visits	Every 3 years	As needed
Review all RCAs	Yes	Yes
Track RCA completion	Yes	Yes
Track RCA action item completion	Review a sample of actions, issue reports regarding strength of action items. Closed actions are tracked and the data on open and closed actions is provided on the intranet site.	Verify that actions are being implemented.
Patient safety alerts and advisories	Issue alerts and advisories, review at least two alert action plans on site visits.	Track all alert action plan implementation.
Provide training and consultation to facility staff	Yes	Yes

Summary. It is expected that organized, coordinated oversight of VHA programs be provided to determine whether policies are effective and relevant or in need of revision. Currently, there appears to be redundancy and lack of role clarity between NCPS staff and VISN PSOs, with facility PSMs receiving mixed messages. We recommended that organized, coordinated oversight of the NPS Program be systematically provided by either the NCPS or another VHA entity.

Issue 3: Evaluation and Improvement of Program Areas

We found that the NCPS does not document systematic evaluation of required patient safety processes to determine if revision is needed. It is a general philosophy of any quality review activity to continually assess and seek to improve key processes.

The NCPS Director told us that the NCPS has made the following changes in patient safety processes since 1999.

- Strength of action reviews were incorporated into RCAs.
- SPOT was revised 12 times.
- Cause and effect diagrams have been added to enhance RCAs.
- Cognitive aid books were widely distributed to assist PSMs and RCA teams.
- An advisory committee comprised of PSMs and PSOs regularly updates the patient safety assessment tool (PSAT).

However, we did not find evidence of periodic, systematic evaluation. Examples of areas that would benefit from systematic assessment and possible revision follow.

Cumbersome Processes and Content. In 1999, the NCPS developed several key processes and has since made several changes, as stated previously. However, feedback from PSOs and PSMs indicates that some items (such as RCAs, HFMEAs, and the PSAT) are overly cumbersome and would benefit from streamlining both the process and the content.

Follow-Up of Action Items. Most RCAs result in action plans to prevent future similar occurrences. Facility PSMs are expected to follow all action items to full resolution. The NCPS selects a sample of RCAs across the VHA system and rates the actions as weaker, intermediate, or stronger. Between October 1, 2004, and June 5, 2008, the NCPS found 52 percent of actions to be weaker, 25 percent to be intermediate, and 23 percent to be stronger. NCPS staff provide data about the trends in the sample of actions they review. They also provide consultation regarding action items, when requested. However, NCPS staff do not require resubmission of inadequate actions. Also, prior to our review, they did not intervene in real time to improve the strength of actions. With the Web-based SPOT, we were told that real time feedback is now possible.

Joint Commission standards require facility managers to use the information from patient safety data analysis to implement changes and to evaluate these changes to determine whether they achieved the expected results. During FY 2007 CAP reviews, we found that facility managers did not consistently assure implementation of recommended corrective actions or evaluate the effectiveness of the interventions.[11] While some facility managers had efficient corrective action tracking methods, others had none. We found inadequate implementation and evaluation of corrective actions in significant numbers of facilities in all four aggregate RCA areas. We have repeatedly recommended that facility directors effectively implement and evaluate corrective actions.

The NCPS reviews all RCAs in the SPOT database and rates selected RCAs for strength of actions. Patient safety could be improved by ensuring that RCAs result in appropriate, adequate actions that are fully implemented.

Safety Assessment Code Inter-Rater Reliability. SAC scoring determines the level and type of review required and is an important early step in adverse event evaluation. However, due to the variability of SAC scoring among facility staff, there is a chance of incorrectly scoring an adverse event, resulting in the inappropriate review process. During some FY 2007 CAP reviews, facilities corrected SAC scores, and RCAs were initiated that would not have been done based on the original SAC scores. Therefore, an

[11] *Evaluation of Quality Management in Veterans Health Administration Facilities Fiscal Year 2007* (Report No. 07-00060-126, May 14, 2008), p. 8.

inter-rater reliability process that evaluates selected SAC scores would increase confidence that adverse events are being properly scored and reviewed.

We did not find evidence of a system-wide inter-rater reliability process to evaluate the accuracy of adverse event SAC scores. While PSOs are tasked to verify the correct scoring of events, it would be useful to have guidance on how to conduct these evaluations consistently across the VHA system. Without an evaluation of the accuracy of SAC scoring, it is difficult to ensure that events receive the correct level of review to identify process or systems issues.

Adverse Event Disclosure. The handbook states that VHA facility staff have an obligation to inform—or disclose to—patients about adverse events consequent to their VHA care (for example, as a result of significant medication errors).[12] The routine disclosure of adverse events to patients has been VHA's national policy since 1995.[13,14] We requested evidence from the NCPS about adverse event disclosure but were told that the NCPS does not review serious adverse events to determine whether patients were appropriately informed. The NCPS Director stated that the NCPS has no role in the disclosure of adverse events.

During FY 2007 CAP reviews, we assessed adverse event disclosure and reported weaknesses.[15] We reported that only 21 (54 percent) of 39 facilities had completed full disclosure. We found that adverse events reported through facility patient safety programs were the most likely to be considered for disclosure. We recommended that VHA reinforce the importance of compliance with this requirement.

Barriers to disclosing adverse events include discomfort with conducting the conversations and differing interpretations of which events should be disclosed. A March 2006 consensus statement reiterated the importance of disclosure and sincere apology when patients have been injured while under medical care.[16] More than 2 years after VHA provided new guidance, compliance continues to be below expectations. It is possible that the NCPS could assist in increasing compliance with this important yet challenging requirement. An NCPS staff member agreed and stated that the RCA process could be amended to include a notation about whether or not the adverse event was disclosed.

Summary. As in all aspects of health care, standards and technologies change frequently. Periodic re-assessment of patient safety processes is necessary to keep

[12] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, May 23, 2008, p. 15.
[13] Under Secretary for Health's Information Letter, *Disclosing Adverse Events to Patients*, IL 10-2003-001, May 13, 2003.
[14] VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, October 27, 2005.
[15] *Evaluation of Quality Management in Veterans Health Administration Facilities Fiscal Year 2007,* p. 4.
[16] Massachusetts Coalition for the Prevention of Medical Errors, *When Things Go Wrong: Responding to Adverse Events,* A Consensus Statement of the Harvard Hospitals, Burlington, MA, March 2006.

current and to improve efficiency by eliminating steps that may no longer be necessary. We recommended that VHA develop a plan to systematically review all aspects of the NPS Program for efficiency and effectiveness and make revisions as appropriate.

Conclusions

We concluded that VHA took important, positive steps in 1998 when it expanded existing patient safety activities and created the NCPS. VHA's NPS Program has been the foundation for many national and international patient safety initiatives. We noted several opportunities to strengthen the NPS Program's effectiveness, oversight, and continuous improvement.

Recommendations

Recommendation 1. We recommended that the Acting Under Secretary for Health ensure that all relevant patient data sources be assessed for patient safety significance, coordinated across VHA's quality and safety programs, and used to drive change.

Recommendation 2. We recommended that the Acting Under Secretary for Health ensure that organized, coordinated oversight of the NPS Program is systematically provided by either the NCPS or another VHA entity.

Recommendation 3. We recommended that the Acting Under Secretary for Health ensure that VHA develops a plan to systematically review all aspects of the NPS Program for efficiency and effectiveness and makes revisions as appropriate.

Acting Under Secretary for Health Comments

The Acting Under Secretary for Health concurred with the recommendations and provided implementation plans with target completion dates. During a recent international conference, quality and safety experts provided useful suggestions for initiatives to enhance the focus of the NPS program. The suggestions for enhancement in the NPS Program and sharing of data systems will be reviewed and appropriately incorporated in the strategic plan for quality and safety. Also, VHA will develop and implement a system to evaluate and assess the effectiveness of the NPS Program. This assessment system will be administered by the NCPS with oversight by the Office of Quality and Safety. Periodic reports of the NPS program will be made to the Under Secretary's Coordinating Council for Quality and Safety. The full text of the comments is provided in Appendix A (beginning on page 16).

Assistant Inspector General Comments

The Acting Under Secretary for Health's comments and implementation plans are responsive to the recommendations. We will continue to follow up until all actions are completed.

Appendix A

Acting Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: May 29, 2009

From: Acting Under Secretary for Health (10)

Subject: **Healthcare Inspection – Evaluation of the Veterans Health Administration National Patient Safety Program**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the report and the recommendations. Thank you for the opportunity to review the draft report and for incorporating our technical comments in the final report. As noted in the report, VHA is recognized in the health care community worldwide as a leader in patient safety and as an advocate of system-wide culture change. The National Center for Patient Safety (NCPS) has made significant contributions to the field of patient safety and has been the foundation for many national and international initiatives; however, no program is without opportunity for improvement.

2. I agree that patient data sources should be assessed for patient significance, coordinated across VHA's quality and safety programs, and used to drive change. During a recent International Roundtable on Clinical Quality and Patient Safety, internal VA quality and safety experts and external consultants provided useful suggestions for initiatives to enhance the focus of the patient safety program. The suggestions for enhancement will be reviewed and appropriately incorporated in the strategic plan for quality and safety.

3. In addition, I also agree with your assessment of the need for comprehensive oversight of patient safety programs. The VHA Office of Quality and Safety will collaborate with the Deputy USH for Health for Operations and Management to develop and implement a system to evaluate and assess the effectiveness of the National Patient Safety (NPS) Program as defined in Handbook 1050.01, VHA National Patient Safety Improvement Handbook. This assessment system will be administered by NCPS with oversight by the Office of Quality and Safety. Periodic reports of NPS

programs will be made to the Under Secretary's Coordinating Council for Quality and Safety.

4. If you have any questions, please have a member of your staff contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 461-8470.

(original signed by:)
Gerald M. Cross, MD, FAAFP

Attachment

Acting Under Secretary for Health Comments to Office of Inspector General's Report

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

OIG Recommendations

Recommendation 1. We recommended that the Acting Under Secretary for Health ensure that all relevant patient data sources be assessed for patient safety significance, coordinated across VHA's quality and safety programs, and used to drive change.

Concur

The Acting USH agrees that data streams must be available and utilized effectively to provide data and information which drives needed change. On January 21, 2009, the USH signed a memorandum ensuring that the National Center for Patient Safety (NCPS) had unencumbered access to all data from any VHA database, data source, or report. The NCPS is empowered to work directly with other program offices, the quality programs within the Office of Quality and Safety (the Office of Quality and Performance and the Office of Quality and Safety Analytics) as well as through the Under Secretary's Coordinating Committee for Quality and Safety to coordinate patient safety initiatives and to drive organizational change. The USH recently sponsored an International Roundtable on Clinical Quality and Patient Safety during which internal VA quality and safety experts and external consultants provided useful suggestions for initiatives to enhance the focus of VHA's patient safety program. We will be studying these recommendations and incorporating them as appropriate into our quality and safety strategic plan.

Target date: In process November 2009

Recommendation 2. We recommended that the Acting Under Secretary for Health ensure that organized, coordinated oversight of the NPS Program is systematically provided by either the NCPS or another VHA entity.

Concur

The Acting USH concurs that there should be coordinated and comprehensive oversight of VHA's Patient Safety programs. The VHA Office of Quality and Safety will collaborate with the Deputy USH for

Operations and Management to develop and implement a system to evaluate and assess the effectiveness of National Patient Safety (NPS) programs as defined in Handbook 1050.01, VHA National Patient Safety Improvement Handbook**,** dated May 23, 2008. The NCPS will administer this assessment system with oversight by the Office of Quality and Safety. Periodic reports of NPS programs will be made to the USH's Coordinating Council for Quality and Safety.

Target date: In process November 2009

Recommendation 3. We recommended that the Acting Under Secretary for Health ensure that VHA develops a plan to systematically review all aspects of the NPS Program for efficiency and effectiveness and makes revisions as appropriate.

Concur

The NCPS will establish a plan for performing an annual systematic review of key national patient safety programs and as appropriate, for making revisions to address identified gaps and deficiencies. The NCPS will report its findings and coordinate programmatic initiatives through regular reports to the USH's Coordinating Council for Quality and Safety.

Target date: In process November 2009

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Julie Watrous, RN, MS Director, Combined Assessment Program (213) 253-5134
Acknowledgments	Toni Woodard

Appendix C

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
Deputy Under Secretary for Health for Operations and Management
Associate Deputy Under Secretary for Health for Quality and Safety
Office of Quality and Performance
Director, National Center for Patient Safety
Office of General Counsel
Office of the Medical Inspector
Veterans Integrated Service Network Directors (1–23)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget

This report is available at http://www.va.gov/oig/publications/reports-list.asp.