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Statement of
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Quality Management in the Veterans Health Administration
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Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today on Quality Management in the Department of Veterans Affairs. I will focus on the results of two reports that we recently published in this area (1) Healthcare Inspection – Evaluation of Quality Management in Veterans Health Administration Facilities Fiscal Year 2008 and (2) Healthcare Inspection – Evaluation of the Veterans Health Administration's National Patient Safety Program. I will also discuss our recent report, Healthcare Inspection – Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities. I am accompanied by Dr. John D. Daigh, Assistant Inspector General for Healthcare Inspections, Office of Inspector General (OIG) and Victoria H. Coates, Regional Director of the Atlanta Office of Healthcare Inspections, OIG.

Background
The Joint Commission (JC), an accrediting body, describes quality management (QM) as a continuous process that involves measuring the functioning of important patient care processes and services and, when indicated, identifying changes that enhance performance. JC conducts triennial surveys at all Veterans Health Administration (VHA) medical facilities. However, external surveyors typically do not focus on VHA requirements. Also, the JC changed the focus of their survey process in 2004, resulting in a reduction in the JC's onsite attention to those standards that define many requirements for an effective QM program.

Since the early 1970s, VA has required its health care facilities to operate comprehensive QM programs to monitor the quality of care provided to patients and to ensure compliance with VA directives and accreditation standards. Several VHA offices have created programs to evaluate and seek improvement in patient care and safety. 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.

In 1999, VHA issued the National Patient Safety Improvement Handbook, which established a policy for identifying, reporting, and mitigating vulnerabilities that may result in adverse patient events (such as patient falls and medication errors). VHA facility staff are expected to identify

and report actual adverse patient events. Facility patient safety managers (PSMs) prioritize them for severity and probability. A root cause analysis (RCA) may be 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 more serious events. PSMs enter adverse event information into the National Center for Patient Safety's (NCPS) database. The NCPS has access to all reported patient adverse events, close calls, and RCAs across the VA system.

The OIG is required by Public Law 100-322, Veterans' Benefits and Services Act of 1988, to oversee VHA's QM programs at every level. Oversight is provided through four different approaches:
• Combined Assessment Program (CAP) Reviews – These site visits are scheduled at each VHA facility approximately every 3 years and cover a variety of patient care administration and QM topics. The QM program review has been a consistent focus during CAP reviews since 1999.
• National Reviews – These system-wide reviews vary by topic and scope but have repercussions for VHA policies and practices. The review of VHA's National Patient Safety (NPS) Program is an example of a national program review.
• Hotline Complaint Inspections – These inspections address complaints made to the OIG Hotline. They may address issues at one facility, several facilities, or may be wider in scope.
• Community Based Outpatient Clinic Reviews (CBOC) – This new program of site visits began in April 2009. The goal is to visit all CBOCs over time. A variety of quality and safety topics will be covered in these reviews.

The Evaluation of Quality Management in VHA Facilities
The OIG conducted CAP reviews in 44 VA medical facilities during fiscal year (FY) 2008. To evaluate QM activities, we interviewed facility directors, chiefs of staff, and QM personnel, and we reviewed plans, policies, and other relevant documents. Some of the areas reviewed did not apply to all VHA facilities because of differences in functions or frequencies of occurrences.

The components of a typical QM program are not standardized. For a complete list of the program areas we defined to comprise a comprehensive QM program, please see our report , but some of the areas we chose to include are:
• QM and Performance Improvement (PI) committees, activities, and teams.
• Peer reviews.
• Patient complaints management.
• Disclosure of adverse events.
• Patient safety functions.
• Reviews of patient outcomes of resuscitation efforts.
• Medical record documentation quality reviews.

As a result of our review we made five recommendations, which VHA concurred with:
• Patient complaints needed to be critically analyzed and actions taken when trends are identified.
• Medication reconciliation needed to be actively monitored.
• Medical records needed to be reviewed for inappropriate use of the copy and paste functions

and a system-wide fix needed to be made a high priority.
• Compliance with moderate sedation monitoring requirements needed to be reinforced.
• The length of privileges granted to physicians needed to match the length of the employment association.

In addition to these five issues, we expressed concern about the following seven areas and will continue to monitor them:

• Adverse event reporting.
• Utilization management.
• Patient flow.
• Peer review.
• RCA timeliness.
• Implementing and evaluating corrective actions.
• Continuous performance monitoring for physicians.

Although all 44 facilities we reviewed during FY 2008 had established comprehensive QM programs and performed ongoing reviews and analyses of mandatory areas, the St. Louis VA Medical Center and John D. Dingell VA Medical Center, Detroit, Michigan, had significant weaknesses. While facility senior managers supported their QM programs and were actively involved, they needed to implement and/or reinforce efforts to improve action item implementation and evaluation.

Evaluation of VHA's National Patient Safety Program
On June 18, 2009, we published the results of our evaluation of VHA's NSP Program . We reviewed the VHA National Patient Safety Improvement Handbook (VHA Handbook 1050.01, May 23, 2008), reports, training materials, and other relevant documents. We interviewed NCPS staff in July 2008, as well as staff at VA Central Office, at the Veteran Integrated Service Network (VISN) level, and at the facility level. Also, we assessed patient safety review results and feedback gathered from VHA facilities during CAP reviews.

It is important to identify as many safety concerns as possible from all available sources in order to understand the magnitude of the concerns and prioritize actions to address them. 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 by directives. 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 VA Central Office 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.

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 found that although the NCPS monitors selected data elements within required processes, it does not provide comprehensive oversight of the NPS Program. 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 and VISN staff, resulting in confusion. The NCPS does not document the 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. We identified the following four areas that would benefit from systematic assessment and possible revision.

- Cumbersome processes and content.
- Follow-up of action items.
- Inter-rater reliability.
- Adverse event disclosure.

As a result of our review, we made three recommendations:

- All relevant patient data sources needed to 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 needed to be systematically provided by either the NCPS or another VHA entity.
- VHA needed to develop a plan to systematically review all aspects of the NPS Program for efficiency and effectiveness and make revisions as appropriate.

VHA concurred with our recommendations and provided an implementation plan that is responsive to our recommendations.

Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities
Based on requests from the VA Secretary, the Chairmen and Ranking Members of our oversight committees, and other interested Members of Congress, we conducted a review of the reprocessing of endoscopic equipment at several specific VA medical centers (VAMCs), and assessed the extent of related problems throughout VHA . We visited the facilities that had been the subject of considerable media attention: the Bruce W. Carter VAMC in Miami, FL; the Tennessee Valley Healthcare System-Alvin C. York Campus in Murfreesboro, TN; and the Charlie Norwood VA Medical Center in Augusta, GA. We reviewed applicable regulations, policies, procedures, guidelines, and conducted unannounced onsite visits at 42 randomly selected VHA facilities to examine pertinent endoscope reprocessing documentation.

We estimated that VA medical facilities:

• Have the appropriate endoscope Standard Operating Procedures (SOPs) available 78 percent of the time.
• Have documented proper training of staff 50 percent of the time.
• Are compliant with both SOPs and documentation of competency 43 percent of the time.

We concluded that facilities did not comply with directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. Endoscope reprocessing requires a standardized, monitored approach to ensure that these instruments are safe for use in patient care. The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure.

As a result of our review, we made three recommendations:

• Ensure compliance with relevant directives regarding endoscope reprocessing.
• Explore possibilities for improving the reliability of endoscope reprocessing with VA and non-VA experts.
• Review the VHA organizational structure and make the necessary changes to implement quality controls and ensure compliance with directives.

VHA has concurred with our recommendations and will provide an action plan for implementation within 30 days.

Conclusion
The OIG works diligently to provide oversight of quality and safety activities and programs in VA's large and complex health care system. While our reports indicate that VA has a program in place for quality management and patient safety activities, it is important that VHA and facility senior managers strengthen QM programs through increased compliance with existing Joint Commission standards and VHA requirements and continue to improve the NPS Program's effectiveness and oversight.

When internal controls and supervisory monitoring fail, as in the case of endoscope reprocessing, it is essential that appropriate actions are taken to standardize the processes, strengthen the monitoring, and holding staff accountable for performance failures.

Mr. Chairman, thank you again for this opportunity to appear before the Committee. We would be pleased to answer any questions that you or Members of the Committee may have.