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Improvement in the Patient Safety Program with Continued Opportunities to Strengthen Veterans Integrated Service Network 7 Oversight at the Tuscaloosa VA Medical Center in Alabama

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Executive Summary

The VA Office of Inspector General (OIG) conducted a follow-up healthcare inspection at the Tuscaloosa VA Medical Center (facility) in Alabama. Given the significant deficiencies identified in a 2023 OIG report, this inspection was to evaluate the status of the facility's patient safety program and Veterans Integrated Service Network (VISN) 7's oversight of the program.[1] In addition, the OIG evaluated the status of actions taken to protect residents at risk for elopement in the community living center (CLC), which were outlined in the facility's response to a 2022 OIG report.[2]

Facility leaders addressed the deficiencies identified in both the 2023 and 2022 reports. The OIG found that actions taken following the publication of the prior two reports resulted in a facility culture where patient safety has become paramount.

Improvements in Patient Safety

In contrast to the OIG's previous findings, the facility's patient safety program complied with Veterans Health Administration-mandated standards for patient safety. The OIG's analysis of the patient safety data showed the patient safety manager appropriately accepted or rejected event reports; the majority of the accepted events were finalized well within the required 14-day due date; significant safety events were considered for root cause analysis (RCA) and for fiscal year 2023 the eight annually required patient safety analyses were completed.[3]

Facility leaders implemented new processes and strategies that allow for continued oversight of the facility's patient safety program. Communication of patient safety information improved as facility leaders held daily patient safety calls and regularly scheduled meetings with the patient safety manager to review patient safety updates, events in need of further review, and opportunities identified for improvement. Additionally, the Facility Director, chief of quality management, and patient safety manager had more frequent collaborations resulting in more robust discussion, analysis, and follow-up related to the patient safety program.

Facility leaders strengthened the supervisory oversight of patient safety activities. Specifically, the chief of quality management now routinely accesses files and databases to monitor and verify

[1] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama,* Report No. 22-00031-67, February 27, 2023.

[2] Elopement refers to patients who have intent to leave a "health care facility unsupervised and undetected." "Elopement," PSNet Agency for Healthcare Research and Quality, accessed August 27, 2024, https://psnet.ahrq.gov/web-mm/elopement; VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at the Tuscaloosa VA Medical Center in Alabama*, Report No. 21-03201-185, June 29, 2022.

[3] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together; Fiscal year 2023 included October 1, 2022, through September 30, 2023.

the status of patient safety required actions such as Joint Patient Safety Reporting (JPSR) events and RCAs. To further bolster the facility's patient safety program organizational structure, the number of quality management staff with program knowledge was increased through cross training, providing support for patient safety staff.

Previously, the High Reliability Organization (HRO) and Executive Leadership Council meetings did not include patient safety specific information. The OIG found facility-level leadership committee minutes reflected documentation indicative of discussion, analysis, and tracking of patient safety activities.

The VISN patient safety officer's oversight of facility-level patient safety programs improved; however, the OIG identified the need for qualitative analysis of patient safety data. Qualitative analysis of patient safety data is necessary to ensure accuracy, identify deficiencies, and understand corrective actions needed.[4] Qualitative analysis provides an understanding of the how and why issues occur and supports the development of effective action plans.[5]

The OIG found the VISN Quality and Patient Safety committee minutes reflect quantitative patient safety data that may identify deficiencies in patient safety programs. However, without qualitative analysis of the patient safety data, action plans developed without understanding the cause of an issue may fail to resolve facility-level deficiencies. Further, the VISN 7 Quality and Patient Safety committee members are unable to assess the impact and effectiveness of the VISN patient safety programs. The OIG is not confident that the VISN patient safety officer's level of review is sufficient to identify facility-level concerns, such as those discussed in the 2023 report.

Patient Safety in the CLC

The OIG determined facility leaders addressed deficiencies identified in the 2022 report that focused on ensuring the safety and security of residents in the CLC. Additionally, CLC leaders implemented a review process to ensure electronic health record documentation for residents determined to be at risk for elopement was consistent with facility policy. The actions taken to resolve prior concerns were representative of the functionality of the patient safety program and facility oversight processes as of April 2024.

Promotion of Patient Safety Culture

In fostering a culture of safety, facility leaders and quality management staff implemented and supported facility-wide patient safety educational activities, opportunities to engage

[4] Vishnu Renjith et al., "Qualitative Methods in Health Care Research," *International Journal of Preventive Medicine* 12, no. 20 (2021), https://www.researchgate.net/publication/349749927_Qualitative_Methods_in_Health_Care_Research.

[5] Seth Stephens, "Qualitative content analysis: A framework for the substantive review of hospital incidents reports," *Journal of Healthcare Risk Management* 41, no. 4 (February 25, 2022): 17–26, https://doi.org/10.1002/jhrm.21498.

staff, and review lessons learned. Along with safety calls, facility leaders have integrated staff education and patient safety forums into daily workflow. These additions reinforce event reporting, alert staff to concerns or issues, and help staff identify reportable events including close calls.[6]

The OIG concluded that a commitment to continue to administer a high-quality patient safety program was evident in facility leaders' actions. Specifically, facility leaders demonstrated an awareness of, and responsiveness to, safety concerns in daily operations. Facility leaders established an organizational structure that emphasizes review, management of, and learning from, patient safety events while promoting a just culture. In doing so, the leaders are promoting transparency, psychological safety, and reporting of patient safety events. The actions taken by facility leaders provide VA with an example of a facility that has demonstrated a high level of resilience, another important HRO principle in health care. These actions should continue as the journey to becoming an HRO does not end.

The OIG made three recommendations to the VISN Director to ensure that the VISN patient safety officer is conducting qualitative reviews of a sample of reported JPSR events to address deficiencies, monitor follow-up actions to completion, and identify opportunities for improvement.

VA Comments

The Veterans Integrated Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes C and D). The OIG will follow up on the planned actions until they are completed.

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[6] VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024. A close call is an event or situation that could have potentially resulted in an adverse event but did not by chance or a timely intervention.

Contents

Abbreviations

CLC	community living center
EHR	electronic health record
JPSR	Joint Patient Safety Reporting
NCPS	National Center for Patient Safety
OIG	Office of Inspector General
PSM	patient safety manager
PSO	patient safety officer
RCA	root cause analysis
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a follow-up healthcare inspection at the Tuscaloosa VA Medical Center (facility) in Alabama. Given the significant deficiencies identified in a 2023 OIG report, this inspection was to evaluate the status of the facility's patient safety program and Veterans Integrated Service Network (VISN) 7's oversight of the program.[1] In addition, the OIG evaluated the status of actions taken to protect residents at risk for elopement in the community living center (CLC), which were outlined in the facility's response to a 2022 OIG report.[2]

Background

The facility, part of VISN 7, is located on a 125-acre campus and provides 335 operating beds consisting of 43 inpatient mental health, 152 CLC, and 140 residential rehabilitation treatment beds. The facility is designated as level 3, low complexity, and provides primary, mental health, long-term, and rehabilitative care.[3] From October 1, 2022, through September 30, 2023, the facility served 15,392 patients.

Prior OIG Reports

The OIG published a report on June 29, 2022, (2022 report), that included 10 recommendations with 5 of those specific to CLC environmental security for residents at risk of elopement. As of March 28, 2023, all recommendations were closed. [4]

A second OIG report published on February 27, 2023, (2023 report), included 11 recommendations specific to the Veterans Health Administration (VHA), the VISN, and the

[1] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama,* Report No. 22-00031-67, February 27, 2023.

[2] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at the Tuscaloosa VA Medical Center in Alabama*, Report No. 21-03201-185, June 29, 2022; Elopement refers to patients who have intent to leave a "health care facility unsupervised and undetected." "Elopement," PSNet Agency for Healthcare Research and Quality, accessed August 27, 2024, https://psnet.ahrq.gov/web-mm/elopement.

[3] "Data Definitions: VHA Facility Complexity Model," VHA Office of Productivity, Efficiency, and Staffing, https://dvagov.sharepoint.com/sites/VHAOPES/Pages/Facility-Complexity-Model.aspx. (This website is not publicly accessible.) The Facility Complexity Model "classifies VHA facilities at levels 1a, 1b, 1c, 2, or 3 with level 1a being the most complex and level 3 being the least complex."; VHA Office of Productivity, Efficiency, and Staffing, "VHA Facility Complexity Model: Fact Sheet." A level 3 facility has "low volume, low risk patients, few or no complex clinical programs, and small or no research and teaching programs."

[4] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at the Tuscaloosa VA Medical Center in Alabama*.

facility's patient safety programs and their oversight. As of March 28, 2024, all recommendations were closed. [5]

Areas of Review

In July 2021, the OIG conducted an inspection to assess allegations related to facility leaders' failure to address security and safety in the CLC, which led to a resident's elopement.[6] While conducting the inspection, the OIG learned of concerns related to the facility's patient safety program. The OIG then conducted a separate inspection in September 2021 to assess deficiencies in, and programmatic oversight of, the patient safety program.[7] In response to the OIG's recommendations from the two previous inspection reports, facility and VISN staff developed and implemented action plans specific to each deficiency.[8]

The OIG team recognizes that High Reliability Organization (HRO) and patient safety programs share common goals (see Appendix A). As such, an evaluation of a patient safety program incorporates a look at the facility's commitment to high reliability principles. In turn, high reliability principles provide the framework of the objectives of a patient safety program.

The OIG conducted this inspection to determine efficacy and sustainability of the facility and VISN's actions related to the HRO principles and values: patient safety, process improvement, and communication. The OIG reviewed the actions focused on

- the patient safety program's compliance with VHA requirements,
- facility and VISN leaders' structural oversight of the patient safety program, and
- patient safety in the CLC.

Scope and Methodology

The OIG initiated the inspection on March 13, 2024, and conducted a site visit April 23 – 25, 2024. The OIG interviewed National Center for Patient Safety (NCPS) directors, VISN leaders, and the facility's executive leadership team. Additionally, the team conducted

[5] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama.*

[6] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at the Tuscaloosa VA Medical Center in Alabama.*

[7] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama.*

[8] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*; VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at the Tuscaloosa VA Medical Center in Alabama.*

interviews with quality management, CLC, police, an engineering service leader, and members of root cause analysis (RCA) teams.[9]

The OIG reviewed relevant VHA, VISN, and facility policies and documents related to the patient safety program and the management of wandering and missing patients within the CLC. Documents included a list of facility staff who have access to the Joint Patient Safety Reporting (JPSR) system and SPOT, an email regarding CLC nurse training, and the electronic health records (EHRs) of CLC residents at risk for elopement. The OIG conducted an independent review of the facility's JPSR events submitted between October 1, 2022, through March 31, 2024, and facility committee meeting minutes related to patient safety for the same period. Minutes from the VISN Executive Leadership Council, VISN Patient Safety Subcommittee, VISN Healthcare Quality Safety Value Committee, and VISN Quality and Patient Safety committee were also reviewed.[10]

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the review in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

[9] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[10] VISN Executive Leadership Council minutes were dated from April 11, 2023, through October 26, 2023; the VISN Patient Safety Subcommittee minutes were dated from October 6, 2022, through October 12, 2023; the VISN Healthcare Quality Safety Value Committee minutes were dated from October 11, 2022, through December 12, 2023; and VISN Quality and Patient Safety committee minutes were dated from January 9, 2024, through July 10, 2024.

Inspection Results

1. Improvements in the Patient Safety Program

The OIG determined facility leaders addressed the deficiencies previously identified in the facility's patient safety program and ensured the program complied with VHA-mandated standards for patient safety.

Joint Patient Safety Reporting

In the 2023 report, the OIG identified deficiencies in the facility's compliance with timely review of JPSR events, resulting in two recommendations to the Facility Director:[11]

- Confirm a process to review all JPSR event reports for completion within 14 days of submission and monitor progress
- Ensure event report investigation and feedback documentation has been fully completed in the JPSR system

VHA uses JPSR to capture real-time incident data throughout the healthcare system.[12] Patient Safety Managers (PSMs) are responsible for ensuring events entered into the JPSR system are investigated, tasked for action, and completed in a timely manner.[13] The OIG reviewed events that staff entered into the JPSR system from October 1, 2022, through March 31, 2024, (see Appendix B), and determined the facility's patient safety program met JPSR requirements.[14] Specifically, the PSM appropriately accepted or rejected event reports, documented investigations, flagged events for RCAs, and provided feedback to the reporter of the event in accordance with JPSR guidance.

Timely review of JPSR entries ensures that events that may represent patient safety risks are acted upon through analysis, mitigation, and further monitoring, if indicated. During the follow-up inspection, OIG's analysis of the data showed the majority of the accepted events were

[11] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

[12] NCPS, *Joint Patient Safety Reporting (JPSR) System Business Rules*, May 1, 2018.

[13] VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024; NCPS, *Guidebook for JPSR Business Rules and Guidance*, November 2021 was updated with NCPS, *JPSR Guidebook*, December 2022, which was updated with NCPS, *JPSR Guidebook*, December 2023. These guidebooks were in place during the time of the events discussed in the 2022 and 2023 reports. Unless otherwise specified, the guidebooks contain the same or similar language regarding PSMs ensuring JPSR events are investigated and closed within 14 days of the reported date.

[14] VHA Directive 1050.01(1); NCPS, *Guidebook for JPSR Business Rules and Guidance*, November 2021; NCPS, *JPSR Guidebook*, December 2022; NCPS, *JPSR Guidebook*, December 2023.

finalized well within the required 14-day due date, an improvement from the 2023 report findings (see figure 1).[15]

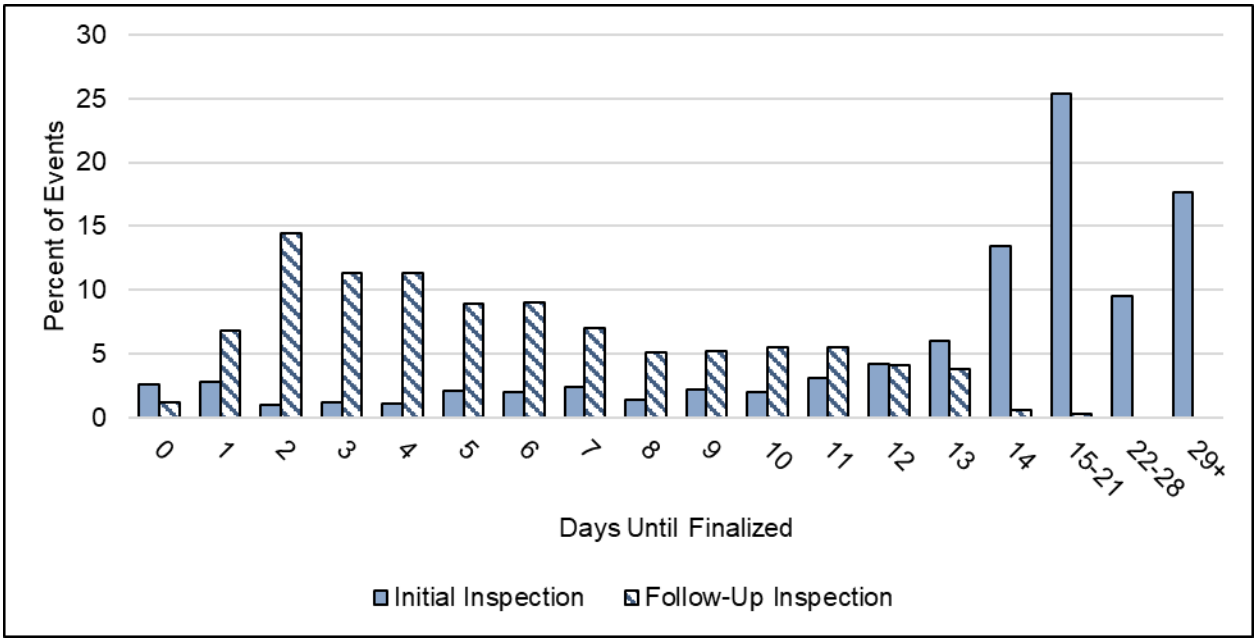

Figure 1. *Distribution of days for finalizing JPSR events: initial versus follow-up inspection.*
Source: OIG analysis of JPSR event report data from July 9, 2019, to July 19, 2021; and October 1, 2022, through March 31, 2024.

Patient Safety Analyses

Previously, the OIG identified that the facility failed to comply with VHA patient safety analysis requirements for the 12-month 2021 cycle.[16] This resulted in one recommendation requiring the Facility Director to take steps to ensure completion of the eight annually required patient safety analyses. [17]

Significant safety events are considered for RCAs. Once an RCA is initiated, the expectation is for a timely and thorough analysis that would find the root causes and recommend actions that will prevent similar events. VHA requires facility directors ensure "at least eight patient safety

[15] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

[16] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*. The facility reported the 12-month cycle timeline to be January 1 to December 31, 2021.

[17] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

analyses" made up of individual and aggregate RCAs, proactive risk assessments, and patient safety assessment tools are completed annually.[18]

The OIG reviewed documents and determined that for fiscal year 2023, the facility completed eight total individual and aggregated RCAs and four patient safety assessment tools to meet the requirement.[19] Additionally, the facility completed a proactive risk assessment within the 2023 calendar year.

2. Patient Safety Program Oversight

The OIG determined facility leaders implemented new processes and strategies that allow for continued programmatic oversight of the facility's patient safety program. The VISN patient safety officer's (PSO's) oversight of facility-level patient safety programs improved; however, the OIG identified the need for qualitative analysis of patient safety data.

Facility Organizational Structure for Oversight of the Patient Safety Program

In the 2023 report, the OIG determined the facility's organizational structure permitted multiple pathways for oversight of the patient safety program. However, the structural oversight in place was not fully operational and failed to identify or mitigate gaps in the patient safety program.[20] This led to a recommendation that the Facility Director review the organizational structure and process for oversight to ensure completion and validation of the eight annually required patient safety analyses.[21]

[18] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was in place during the time of the events discussed in the 2022 and 2023 reports until it was rescinded and replaced by VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, which was amended March 5, 2024. Unless otherwise specified, the policies contain similar language related to VHA's Patient Safety Program; VHA Assistant Under Secretary for Health for Quality and Patient Safety, "Annual Minimum Requirements for Facilities to Perform Patient Safety Analyses," memorandum to VISN Directors (10N1–23), April 25, 2022. The 2022 memoranda provided clarification on the annual requirement for patient safety analyses. VHA Directive 1050.01(1) rescinded the 2022 memorandum but maintained the annual analyses requirement. The directive also describes reporting adverse events and close calls through the JPSR as a VHA Patient Safety Program foundational principle.

[19] The facility provided one RCA chartered in fiscal year 2023 and completed during fiscal year 2024 and one additional RCA chartered and completed during fiscal year 2024. The OIG team did not review the status of action plans outlined in each RCA. Fiscal year 2023 included October 1, 2022, through September 30, 2023, and fiscal year 2024 included October 1, 2023, through September 30, 2024.

[20] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama.*

[21] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama.*

In an HRO, facility leaders promote the culture of safety to the organization and ensure that the programs that directly contribute to an HRO are functioning as intended.[22] According to VHA, the Facility Director is responsible for ensuring the oversight of a facility's patient safety program.[23]

Facility Leaders Oversight of the Patient Safety Program

During interviews, the OIG learned facility leaders employ a variety of methods to provide organizational oversight of the patient safety program. The methods include the daily patient safety call, frequent communication between the Facility Director and PSM, and reviews of patient safety activities by the chief of quality management. In OIG interviews, executive and quality management leaders and the PSM reported that the PSM-led daily patient safety call is an essential communication tool used by facility leaders to learn of, assign responsibility for, and track patient safety events. During the call, the PSM provides a general overview of JPSRs submitted within the past 24 hours and a status update of open JPSR events to help expedite closure.[24] The Facility Director told the OIG that executive and facility leaders, including service chiefs, are expected to, and all staff are encouraged to, attend the call.

Both the Facility Director and the PSM acknowledged having an open line of communication to discuss the patient safety program. In addition to the daily patient safety call, they meet biweekly to formally discuss JPSR updates, potential RCA topics, RCA analysis feedback, and opportunities for improvement. The Facility Director, chief of quality management, and the PSM told the OIG that frequent collaboration with one another has led to more robust discussion, analysis, and follow-up related to the patient safety program.

Supervisory Oversight of the PSM

In the 2023 report, the OIG found the chief of quality management's supervision of the former PSM was ineffective in part due to the use of a trust-but-not-verify approach to performance management. This approach relied on the then-PSM entering accurate, reliable, and current data. Additionally, the chief of quality management reported not having access to the VHA patient safety program databases to provide oversight of patient safety activities.[25]

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[22] The Joint Commission, *Standards Manual*, e-dition, LD.03.03.01, January 14, 2024. "Leaders use hospital wide planning to establish structures and processes that focus on safety and quality."; The Joint Commission, "The essential role of leadership in developing a safety culture," *Sentinel Event Alert* 57 (March 1, 2017, revised June 18, 2021), https://www.jointcommission.org/resources/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-57-the-essential-role-of-leadership-in-developing-a-safety-culture/.

[23] VHA Directive 1050.01(1).

[24] The patent safety call is held daily each morning (excluding weekends and holidays) at 08:30 a.m. Central Standard Time via Microsoft teams. Information shared on the call does not include protected health information.

[25] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama.*

The OIG learned of process changes since the publication of the 2023 report strengthen the supervisory oversight of patient safety activities. Specifically, the chief of quality management reported periodically accessing facility shared drive electronic files and patient safety program databases to monitor and verify information and check the status of program required actions such as RCAs.

The OIG independently confirmed that the chief of quality management and a performance improvement coordinator have access to both the JPSR and SPOT systems. The assistant chief of quality management also has access to the JPSR system to monitor and track the management of patient safety events or serve as a backup in the absence of the PSM.

Further, quality management staff reported being cross trained in other roles within the department. Cross training fosters succession planning and provides an opportunity for staff to gain specialized skills, become competent to function in another role, and provide support and coverage for one another.[26] Combined, these actions strengthen the organizational structure by expanding the number of individuals with program knowledge who can view patient safety data to ensure accuracy.

Facility Committee Reviews of Patient Safety

As reported in the 2023 report, the OIG found committees at the facility were not fully operational and missed opportunities to identify or mitigate gaps in the patient safety program. This resulted in one recommendation requiring the Facility Director to review facility HRO Committee and Executive Leadership Council meeting minutes to confirm patient safety program data, analysis, and follow-up actions were discussed.[27]

The OIG reviewed committee meeting minutes and charters from the facility Executive Leadership Council, Quality and Patient Safety Committee, and the Clinical Executive Board dated from July 2021 through May 2024.[28] In contrast to the previous finding, the OIG found documentation indicative of discussion, analysis, and tracking of patient safety activities. These minutes included information about individual RCAs that were chartered, in progress, or closed out; aggregate reviews progression; any sentinel events that may have occurred; and concerns reported through daily safety calls. Additionally, the chief of quality management reported reviewing the PSM's reports for both the Executive Leadership Council Committee and the Quality Patient Safety Committee meetings prior to submission.

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[26] Sapna Patel et al., "Expedited Cross-Training an Approach to Help Mitigate Nurse Staffing Shortages," *Journal for Nurses in Professional Development* 37, no. 6 (November/December 2021): E20-E26, https://doi.org/10.1097/nnd.0000000000000738.

[27] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

[28] The facility HRO committee was renamed the Quality Patient and Safety Committee.

VISN Oversight of Facility Patient Safety Program

In the 2023 report, the OIG found that the PSO was not aware of the extent that the facility patient safety program was out of compliance with VHA requirements and recommended the VISN 7 Director (VISN Director):

- review the JPSR Business Rules and Guidebook and determine which, if any, subset of patient safety event reports for each facility the PSO will review.[29]

VHA assigns responsibility to the PSO for "reviewing all sentinel events and a sample of patient safety events, RCAs and patient safety risk analyses (including [Patient Safety Assessment Tool] PSAT) for content, recommendations and required actions."[30] Specific to JPSRs, the PSO is to

- review and evaluate a subset of JPSR entries,
- review reports with JPSR data to identify opportunities for improvement,
- ensure "actions are taken to review, address and correct deficiencies," and
- share feedback with facility patient safety staff to facilitate consistency.[31]

In response to this OIG VISN recommendation, the VISN Director identified the following subsets for the PSO to review: JPSR timeliness, reviews, and investigations by subject matter experts, and feedback to the reporter.[32] The OIG reviewed VISN Quality and Patient Safety committee minutes and determined the PSO is reporting quantitative data about JPSR timeliness and the occurrence of feedback to the reporter.[33] However, the OIG did not find evidence indicating the PSO is reviewing the investigations by subject matter experts.

The OIG also recommended the VISN Director:

- evaluate the role of the Patient Safety/Risk Management subcommittee to determine the degree to which the subcommittee will address facility-level performance with Patient Safety Program activities and tracking of action plans when a deficiency is identified and update the subcommittee charter as warranted.[34]

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[29] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

[30] VHA Directive 1050.01(1).

[31] VHA Directive 1050.01(1). VHA NCPS, *JPSR Guidebook,* December 2022.

[32] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

[33] The OIG reviewed minutes from the VISN Executive Leadership Council, Healthcare Quality Safety and Value Committee, and the Quality and Patient Safety Committee.

[34] "The [Patient Safety/Risk Management] subcommittee is tasked with reviewing JPSR event report trends, "patient safety analyses and implementation of actions, aggregated reviews, [HFMEA], and annual patient safety reports." VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

When submitting evidence to the OIG for consideration to close this recommendation, the VISN Director reported that the Patient Safety[/Risk Management] subcommittee was integrated into the VISN Healthcare Quality Safety Value Committee and renamed the VISN Quality and Patient Safety committee.[35] The new committee charter, effective on December 20, 2023, states that the committee provides operational oversight of quality programs to mitigate risks, and promote veteran-centered, high-quality health care delivery. In alignment with VHA expectations, the charter states the committee is to review "patient safety data for the purpose of assessing impact and effectiveness of the VISN quality and patient safety programs. . .," and support the identification of "gaps in performance and recommending actions and opportunities for improvement."[36]

The OIG's review of VISN Quality and Patient Safety committee meeting minutes associated with the closure of the previous VISN recommendations confirmed the implementation and use of a dashboard to report quantitative data specific to the performance of facility-level patient safety programs. However, the OIG did not see documentation indicative of the PSO completing a qualitative analysis of patient safety data content to identify facility-level program deficiencies. For example, JPSR reports shared with the committee show the number of JPSR events pending greater than 14 days but the minutes do not include reasons for the delays or plans to close them. Similarly, the number of events related to clinical administration processes or procedures are reported in categories with one report showing "delay in treatment or care" as the category with the most event entries. Yet, the location of those delays and reasons for the delays are not included in the minutes.

The VISN quality management officer told the OIG that qualitative analysis of numerical outliers occurs directly between the PSO and facility PSMs, outside of the VISN Quality and Patient Safety committee, and provided two examples of these meetings from calendar year 2023.[37] However, the examples provided did not reflect discussion of the known or suspected cause of the outlier(s). When asked about how and where action plans are tracked to completion, the VISN quality management officer acknowledged this was not done by the VISN committee and speculated that the PSO did this to some degree.

[35] VHA Directive 1050.01(1). "The Veterans Integrated Services Networks (VISN) Quality and Patient Safety Committee (QPSC) may replace the current VISN QSV Councils or other entity that has historically provided monitoring and oversight within the VISN governance structure."

[36] VHA Directive 1050.01(1); VISN 7 Quality and Patient Safety Committee (QPSC) [Charter], December 20, 2023.

[37] The OIG learned that the PSO reports to the VISN quality management officer who is responsible for the oversight of VISN quality programs, including the patient safety program.

Qualitative analysis of patient safety data is necessary to ensure accuracy, identify deficiencies, and understand corrective actions needed.[38] Qualitative analysis provides an understanding of the how and why issues occur and supports the development of effective action plans.[39] The inclusion of the results of a qualitative analysis is necessary for the oversight committee to meet their goal of assessing the impact and effectiveness of facility patient safety programs. In addition to the lack of documentation identifying the cause of deficiencies, the OIG determined the minutes did not inform the reader of recommendations or action(s) to be taken to resolve deficiencies. Rather, the minutes simply stated that "Patient Safety Program updates will continue to be provided through this committee."[40]

The OIG found the oversight function of the VISN Quality and Patient Safety committee is hindered when members lack awareness of the reasons for outliers in patient safety program data and any action plans developed to address concern. VISN Quality and Patient Safety committee minutes reflect quantitative patient safety data that may identify deficiencies in patient safety programs. However, without qualitative analysis of the patient safety data, the committee may be unable to assess impact and effectiveness of the VISN patient safety programs. The OIG is not confident that the PSO's level of review is sufficient to identify facility-level concerns, such as those discussed in the 2023 report.

3. Patient Safety in the CLC

The OIG determined facility leaders addressed deficiencies identified in the 2022 report that focused on ensuring the safety and security of residents in the CLC. Additionally, CLC leaders implemented a review process to ensure EHR documentation for residents determined to be at risk for elopement is consistent with facility policy. The actions taken to resolve prior concerns are representative of the functionality of the patient safety program and facility oversight processes as of April 2024.

CLC Safety and Security

VHA policy states that "patients straying beyond the normal view or control of employees may be at risk for injury or death." VHA recognizes that "physically, mentally, or cognitively

[38] Vishnu Renjith et al., "Qualitative Methods in Health Care Research," *International Journal of Preventive Medicine* 12, no. 20 (2021), https://www.researchgate.net/publication/349749927_Qualitative_Methods_in_Health_Care_Research; Seth Stephens, "Qualitative content analysis: A framework for the substantive review of hospital incidents reports," *Journal of Healthcare Risk Management* 41, no. 4 (February 25, 2022): 17–26, https://doi.org/10.1002/jhrm.21498.

[39] Renjith et al., "Qualitative Methods in Health Care Research."

[40] The PSO reports to the Quality and Patient Safety Committee on a quarterly basis. Therefore, as this is a new committee, there is a limited amount of minutes for review.

impaired patients require a distinctly higher degree of monitoring and protection."[41] Staff provide this monitoring and protection through various forms, such as

- facility-specific procedures for prevention and management of wandering or missing patients;
- wandering prevention and management awareness training for staff;
- assessment and documentation of patients' cognitive impairment status; and
- a systematic process to ensure location of at-risk patients by staff, which may be enhanced by use of electronic technology.[42]

Resident Care Environment

The 2022 report discussed that a facility-initiated risk assessment team's recommendation to determine the suitability of the Azalea House for CLC residents with dementia was not completed. The OIG recommended the Facility Director confirm completion of a risk analysis.[43]

At the time of the recommendation, the Azalea House was a freestanding living area that housed residents identified as being high risk for wandering and with dementia-related diagnoses.[44] Through facility document review, the OIG verified that in April 2022, the recommended risk analysis was completed. The assessment focused on the relative risk for residents falling or wandering from the Azalea House. As part of the assessment, facility leaders analyzed data and identified that residents of the Azalea House sustained a higher number of falls in comparison to those in other areas of the CLC. The analysis further explained that the building configuration and environmental characteristics such as lighting, windows, and flooring could affect the safety risk of residents with dementia, including increasing fall risk. As a result of these findings, a recommendation was made to move the residents out of Azalea House.

The associate chief of staff for geriatrics and extended care and the CLC medical director confirmed that residents were moved from the Azalea House to Patriots Point for their safety.

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[41] VHA Directive 2010-052, *Management of Wandering and Missing Patients*, December 3, 2010, amended and replaced by VHA Directive 2010-052(1), *Management of Wandering and Missing Patients*, amended June 24, 2024. The amended directive removed the requirement for a facility policy.

[42] VHA Directive 2010-052(1). The directive defines a wandering patient as an at-risk patient who has shown a propensity to stray beyond the view or control of employees, thereby requiring a high degree of monitoring and protection to ensure the patient's safety. The directive defines missing patient as an at-risk patient who disappear from the patient care areas (on VA property), or while under control of VHA, such as during transport.

[43] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.*

[44] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.* The facility CLC has six distinct living areas: Freedom Hall, Eagles Cove, Camelia Cottage, and Magnolia Cottage, are unlocked units that house residents with long-term and skilled care needs; Patriots Point is a locked and secured unit that houses residents with dementia; and Grace Hall is a locked and secured unit that houses residents requiring psychiatric care due to treatment of serious mental illness.

The OIG toured Patriot's Point and found it was a locked unit for residents with cognitive impairments due to dementia. The OIG noted the entrance of the unit included double doors that required key access and the windows and emergency exit points were secured and locked.

The associate chief of staff for geriatrics and extended care reported seeing improvements in the safety of residents, including a decrease in resident falls and no episodes of elopement since the initiation of the 2021 OIG inspection and movement of residents from the Azalea House.[45]

The OIG also recommended the Facility Director assess the effectiveness of the outdoor fencing and gates surrounding the Azalea House as a security measure to prevent CLC residents at risk for elopement from leaving the facility campus.

Since the Azalea House is no longer in use, the OIG assessed residents' access to the outdoors from Patriots Point and found one locked, secured, and alarmed exit door leading to a patio with a fence and a locked gate. In addition, in contrast to the Azalea House, Patriots Point is configured to provide a line of site from the nurse's station to the entrance of the unit as well as two secured and alarmed emergency exits. The OIG determined all Patriots Point egresses are secured and mitigate the potential for elopement.

Electronic Alarm System

In 2018, a facility Healthcare Failure Mode and Effect Analysis identified the need to install an electronic alarm system to prevent CLC resident elopements; the OIG found that, at the time of the 2022 report, the alarms had not been purchased.[46] Therefore, the OIG recommended the Facility Director provide oversight of the purchase and installation of an electronic alarm system for each of the six distinct CLC living areas.[47]

The OIG confirmed the purchase and installation of an electronic alarm system for all CLC living areas. During the OIG onsite tour, CLC nurse managers demonstrated how the alarm system functioned. The entry doors in Grace Hall and Patriots Point were opened while an electronic alarm system armband was nearby, this triggered an audible alarm from the nurse's station. The OIG also observed the nurse managers activate an alarm when the exit doors of Grace Hall and Patriots Point were opened without using the appropriate code for the door's keypad. During an interview, a CLC nurse leader informed the OIG that residents at both units

[45] This patient elopement is discussed in the OIG's 2022 report.

[46] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama*; VHA NCPS, Guidebook of Proactive Risk Assessment Tools, Version 3, April 2023. HFMEA is a tool used for proactive risk assessment. Specifically focused on health care, HFMEA considers risks before an event occurs; Alarm systems used to prevent elopement on a locked unit may include patient tracking bracelets. VHA Directive 2010-052, *Management of Wandering and Missing Patients*, December 3, 2010, amended and replaced by VHA Directive 2010-052(1), *Management of Wandering and Missing Patients*, amended June 24, 2024.

[47] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.*

wear an electronic alarm system armband and that staff conduct weekly checks on the armband's battery life along with monthly checks to ensure the armbands alarm when taken to an exit point.

Security Cameras

The 2022 report identified that CLC security cameras were not functioning at the time of a resident's elopement in the summer of 2021.[48] The OIG recommended the Facility Director ensures that all security cameras are operable and labeled appropriately and develops and monitors a plan for ongoing testing and maintenance.[49]

In the spring of 2023, while conducting routine follow-up for this recommendation, the OIG received confirmation that all security cameras were operational and labeled. During an interview, the chief of police informed the OIG that VA police continue to monitor and ensure facility cameras are working properly. The chief of police also reported that staff are required to enter work orders for nonworking cameras. During the facility tour, the OIG confirmed facility cameras were labeled and operational. A VA police dispatcher was observed demonstrating the ability to review prior activity. The OIG also reviewed facility documents that confirmed VA police conducted testing and monitoring of cameras, documented and tracked nonworking cameras, and submitted work orders for nonworking cameras.

Elopement Risk Documentation

As part of the prior inspection, the OIG determined documentation related to the elopement risk of residents was not present in their EHRs.[50] The OIG recommended the Facility Director establish a review process to ensure CLC residents determined to be high risk for elopement have documentation consistent with facility policy in their EHRs identifying residents' risk status.[51]

Documentation in EHRs ensures that staff who may not be familiar with a resident become situationally aware when there is potential for elopement. Facility policy requires a registered nurse to assess residents for wandering or elopement risk and document their assessment on

[48] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.*

[49] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.*

[50] Wandering patients may move around a facility outside the line of supervision without the intent of leaving the area. "Elopement," PSNet Agency for Healthcare Research and Quality, accessed August 27, 2024 https://psnet.ahrq.gov/web-mm/elopement; VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.*

[51] VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at Tuscaloosa VA Medical Center in Alabama.* Facility SOP GEC-10, *Management of Community Living Center (CLC) Residents at Risk For Wandering or Elopement*, January 18, 2023.

admission and monthly.[52] A CLC nurse manager informed the OIG that nurses receive training during new employee orientation and annually on the facility requirements for documentation of residents identified as at risk for elopement.

The Geriatrics and Extended Care service performance improvement coordinator informed the OIG that CLC nurse managers perform weekly audits of EHRs to ensure nursing completion of elopement risk assessments. In addition, the OIG reviewed facility documents and found that the service also completed quarterly EHR reviews of the elopement risk assessments. The OIG conducted an EHR review of residents determined to be high risk for elopement and verified that documentation was consistent with facility policy.

4. Promotion of Patient Safety Culture

The OIG found that actions taken following the publication of the prior two reports resulted in a facility culture in which patient safety has become paramount. In fostering a culture of safety, facility leaders and quality management staff implemented and continue to support facility-wide patient safety educational activities, opportunities to engage staff, and review lessons learned.

VHA's journey to becoming an HRO requires a commitment from leaders to develop a culture of safety and continuous improvement.[53] The HRO journey is strengthened when staff are empowered in a psychologically safe environment to continuously review daily practices and incorporate lessons learned to reduce errors and potential harm to patients.[54]

The culture of safety in a facility is often difficult to assess. Nevertheless, a culture of safety is an end product of how staff addresses potentially unsafe events, their views on whether supervisors and leaders take untoward events seriously, and their ability to report errors in a just environment.

HROs exhibit four foundational practices: safety huddles, leader rounding, patient safety forums, and visual management systems.[55] A measure of the commitment to a culture of safety can be gauged by the actions that leaders incorporate into standard daily workflow.[56] Embedding safety practices into daily routine demonstrates to staff the facility leaders' objective of making

[52] Facility SOP GEC-10.

[53] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023, updated September 2024. The two documents contain the same or similar language regarding HRO principles.

[54] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023; John S Murray, et al, "Implementing Just Culture to Improve Patient Safety," *Military Medicine*, 188, no.7-8, (May 2022), 1596–1599, https://doi.org/10.1093/milmed/usac115.

[55] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023.

[56] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023; The Joint Commission, "The essential role of leadership in developing a safety culture."

investigating untoward events a priority, while at the same time underscoring their level of commitment to HRO principles.[57]

Learning Organization

As an HRO, VHA is a "learning organization," where facility leaders and staff engagement in HRO principles focuses on learning from errors and implementing practices that improve the care of patients.[58] The implementation of ongoing training using real-world examples is critical to create a culture of safety.[59] In addition to the daily safety calls, the facility has integrated staff education and patient safety forums into daily workflow. These reinforce event reporting, alert staff to concerns or issues, and help staff identify reportable events, including close calls.

During interviews with quality management and patient safety staff, the OIG learned that quality management performance improvement coordinators developed "Back to the Basics" a one-page informational handout distributed monthly to increase staff knowledge about patient safety themes identified during patient safety rounds. Themes included continuous process improvement, nurse to provider communication, and how to locate facility policies. This educational series is sent to all staff and can be printed for review at staff meetings.

The PSM told the OIG that staff also learn about patient safety events such as falls or medication issues during "JPSR Lessons Learned," which is held quarterly following the daily patient safety call. This PSM-led informational session provides an overview of aggregate JPSR incidents such as falls and medication errors, contributing factors, lessons learned, and actions implemented to prevent reoccurrence.

The chief of quality management told the OIG that the HRO coordinator leads a "Patient Safety Forum" that is open to all staff and reinforces safety goals and the benefit of reporting incidents. It also provides a review of The Joint Commission standards and the HRO theme of the month. In addition, the forum includes a safety story and the announcement of the staff nominated for the facility's HeRo Award.[60] The OIG learned that to acknowledge and share safety stories, the PSM, former risk manager, and HRO coordinator collaborated to implement the "Eagle Eye on Safety" Campaign. Each quarter, this patient safety initiative awards a unit or group that exemplifies HRO principles with an eagle statue named "Freedom" to display for the quarter.

To determine the level of familiarity staff have with HRO and patient safety principles, the OIG reviewed documents and learned that 91 percent of frontline staff and supervisors have

[57] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023.

[58] VA, "Learn, Inquire, and Improve HRO Value" (fact sheet), January 2024; VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023.

[59] John S. Murray et al., "Implementing Just Culture to Improve Patient Safety."

[60] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023. The HeRo Award is used to honor an individual or group that advance the HRO journey through demonstration of VHA's HRO principles.

completed HRO Baseline Training. This required training focuses on building behaviors that foster a just culture, error management, and continuous improvement.[61] During fiscal year 2022, 97 percent of employees attended patient safety training and 98 percent of nursing supervisors completed training on how to investigate an event in the JPSR system.[62]

Evidence of the facility's emphasis on patient safety is demonstrated by the facility receiving an award for "AES [All Employee Survey] Most Improved status for FY2022" specific to patient safety-related questions as noted in the facility's NCPS Patient Safety Annual Report.

To gain a general understanding of the degree to which the patient safety program is embedded in the organizational culture, the OIG interviewed 11 facility staff who served as team members on RCAs.

During interviews, the OIG asked RCA participants about reporting patient safety concerns in their daily work. Most reported knowing how to enter a JPSR event and more than half acknowledged having experience entering a JPSR event. A "just culture" requires staff to feel psychologically safe and empowered to speak up when observing adverse events or at-risk behavior.[63] The OIG inquired about staff speaking up to report issues and found more than half interviewed reported the belief that most staff feel comfortable speaking up and did not have concerns about how issues are addressed once reported. The interviewed staff also reported that patient safety priorities are communicated via email, during staff meetings, huddles, and on the daily safety calls. Moreover, all interviewees could describe various patient safety initiatives integrated into daily workflow. Finally, all interviewees selected to participate in an RCA reported feeling they were a significant contributor to the process and held the belief that all concerns identified during RCA team meetings were acknowledged.

Executive Leadership Initiatives

Leaders set the tone for facility culture and must create opportunities to interact with frontline staff, encourage reporting, and provide feedback when actions are taken.[64] An engaged leadership team is essential to positively affect the patient safety culture. Leaders must be visible, approachable, and communicate organizational behavioral expectations to improve patient safety.[65]

Patient safety is embedded into the facility's culture starting at new employee orientation where the Facility Director challenges staff to become involved and speak up or "stop the line" if there

[61] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023.

[62] Fiscal year 2022 included October 1, 2021, through September 30, 2022.

[63] John S. Murray et al., "Implementing Just Culture to Improve Patient Safety."

[64] Gary L. Sculli and Robin Hemphill, "Culture of Safety and Just Culture," NCPS, accessed May 31, 2024, https://uthscsa.edu/medicine/sites/medicine/files/2023-08/Culture%20of%20Safety%20and%20Just%20Culture.pdf.

[65] John S. Murray et al., "Implementing Just Culture to Improve Patient Safety."

is a patient safety concern. The Facility Director told the OIG that at the initial safety briefing, discussion included the daily patient safety call, how to report patient safety incidents, and communicating staff expectations related to reporting potential safety concerns. Additionally, during the aforementioned monthly safety forums, RCA lessons learned are shared with facility staff who join the call.

When asked about the patient safety culture, facility leaders responded:

- HRO baseline training is required for all staff to "strengthen our HRO journey . . . promoting a just culture where staff can report issues."
- "I think it's much improved and for a lot of reasons, not just because of promoting just culture and trying to be on that HRO journey. . . . I think because of the accountability that perhaps we were missing previously, or we didn't have the monitoring and the follow up. That's become so much stronger. I've been here 12 years and that's it's much stronger than it's ever been."
- "I think it's good . . . we realize it's not perfect and we're continuing to learn and that's what I really want. I want the continuous learning environment."

Rounding by leaders, a foundational HRO practice, is used to identify everyday challenges.[66] During interviews, facility leaders told the OIG the executive leadership team and service chiefs participate in "We Care" rounds. Facility leaders use these structured rounds to visit assigned areas where they talk to an employee and a veteran to identify needs, offer support, and obtain feedback. Notes are taken from "We Care" rounds to share with staff during morning report.

The OIG concluded that a commitment to continue to administer a high-quality patient safety program was evident in facility leaders' actions. Specifically, facility leaders demonstrated an awareness of, and responsiveness to, safety concerns in daily operations. Facility leaders established an organizational structure that emphasized review, management of, and learning from, patient safety events while promoting a just culture. In doing so, leaders are promoting transparency, psychological safety, and reporting of patient safety events.

Sustained improvements to the patient safety program rely on facility and VISN leaders continuing effective oversight, holding staff accountable to the specifics of the program, providing a just environment for staff to work in, and having staff trained to provide continuity of operations in the absence of colleagues. The actions taken by facility leaders provide VA with an example of a facility that has demonstrated a high level of resilience, another important HRO principle in health care. These actions should continue as the journey to becoming an HRO does not end.

[66] VHA, *High Reliability Organization (HRO) Reference Guide*, April 2023.

Conclusion

Facility leaders addressed the deficiencies previously identified in the facility's patient safety program and ensured the program complied with VHA-mandated standards for patient safety. OIG's analysis of the patient safety data showed the PSM appropriately accepted or rejected event reports; the majority of the accepted events were finalized well within the required 14-day due date; significant safety events were considered for RCAs; and for fiscal year 2023, the eight annually required patient safety analyses were completed.

The OIG found facility leaders employed a variety of methods to provide organizational oversight of the patient safety program including improved communication and collaboration between the Facility Director, chief of quality management, and PSM. Additionally, the facility HRO Committee and Executive Leadership Council meeting minutes reflected discussion about patient safety program data, analysis, and follow-up actions.

Process changes have also strengthened supervisory oversight of the PSM. The chief of quality management reported periodically accessing facility shared drive electronic files and patient safety program databases to monitor and verify information and check the status of required program actions. The chief of quality management and a performance improvement coordinator have access to both the JPSR and SPOT systems to monitor and track the management of patient safety events. Additionally, quality management staff are cross trained and can serve as back up for the PSM.

VISN oversight of the facility's patient safety program has improved with the implementation and use of a dashboard populated with quantitative information about the status of patient safety activities at each facility. The VISN Quality and Patient Safety committee minutes reflected ongoing tracking of two of the JPSR subsets identified by the VISN Director for review by the PSO (JPSR timeliness and feedback) but did not find evidence indicating review of the third (investigations by subject matter experts). Minutes from the VISN Quality and Patient Safety committee, the entity responsible for reviewing patient safety data for impact and effectiveness, included data from the dashboard. However, the minutes lacked evidence of the PSO completing qualitative analyses of the data to ascertain the cause of any deficiencies and development of targeted action plans. Therefore, the OIG lacks confidence that the PSO's level of review is sufficient to identify facility-level concerns.

Facility leaders addressed deficiencies identified in the 2022 report that focused on the safety and security of residents in the CLC. Additionally, CLC leaders implemented a review process to ensure EHR documentation for residents determined to be at risk for elopement is consistent with the facility policy.

The actions taken to resolve prior concerns are representative of the functionality of the patient safety program and facility oversight processes as of April 2024. A commitment to administer a high-quality patient safety program was evident in facility leaders' awareness of, and

responsiveness to, safety concerns in daily operations. Facility leaders are promoting transparency, psychological safety, and reporting of patient safety events through an organizational structure that emphasizes review, management of, and learning from, patient safety events within a just culture. The actions taken by facility leaders provides VA with an example of a facility that has demonstrated a high level of resilience, an important HRO principle in health care. These actions should continue as the journey to becoming an HRO does not end.

Recommendations 1–3

1. The Veterans Integrated Service Network Director confirms that the patient safety officer reviews investigations by subject matter experts for Joint Patient Safety Reporting events.
2. The Veterans Integrated Service Network Director provides evidence to demonstrate the Patient Safety Office is completing reviews of a sample of patient safety events that includes analysis of content, recommendations, and required actions, as outlined in Veterans Health Administration Directive 1050.01.
3. The Veterans Integrated Service Network Director ensures that the Veterans Integrated Service Network 7 Quality and Patient Safety Committee minutes reflect that the patient safety officer conducted analysis of patient safety data to identify opportunities for improvement and provided guidance on facilities' action plans to address the deficiencies.

Appendix A: Patient Safety Programs, High Reliability Organizations, and Culture of Safety

VHA Patient Safety Program

VHA's patient safety program was developed based on eight principles focused on the promotion of a just culture where all employees have a responsibility to reduce harm to patients, report adverse events, and study processes that may contribute to adverse events. Patient safety programs recognize the knowledge of frontline employees and their value in identifying potential risks of harm in the patient care environment. VHA provides direction for patient safety programs and the management of patient safety events through VHA Directive 1050.01(1) and multiple VHA guidance documents and memoranda.[67]

VHA established the NCPS in 1999 to provide guidance about VHA's approach to patient safety and a "culture of safety." The NCPS's primary goal is to reduce and prevent injury to VA patients throughout the course of their care.

VHA's NCPS and the Office of Quality Management are responsible for operational oversight of VHA quality and patient safety programs.[68] VISN directors are to promote quality and safety throughout VISN facilities. Facility directors are responsible for ensuring compliance with completion of VHA-mandated standards for patient safety. A facility's PSM coordinates the patient safety program and is responsible for the management, and oversight of all facility patient safety program activities. PSMs play a critical role in identifying the severity of reported patient safety events and determining the type of follow-up needed, if any.[69]

High Reliability Organization and Patient Safety

"High reliability means evidence-based, exceptional care is consistently delivered for every patient, every time, at any facility across VHA."[70] More than 20 years ago, VHA's NCPS began implementing HRO practices throughout the healthcare system as a part of VHA's "Journey to High Reliability." The goal of the journey is to transform workplace culture and empower

[67] VHA Directive 1050.01(1); NCPS, *JPSR Guidebook*, December 2023; NCPS, *Guide to Performing Root Cause Analysis*, March 2024; NCPS, *Guidebook of Proactive Risk Assessment Tools*, April 2023; NCPS, *Completing Facility Patient Safety Program Reviews: A Guide for Patient Safety Officers*, January 8, 2024; VHA Assistant Under Secretary for Health for Quality and Patient Safety, "Annual Minimum Requirements for Facilities to Perform Patient Safety Analyses," memorandum to VISN Directors (10N1–23) thru the Deputy Under Secretary for Health for Organization and Management (15); NCPS, "Patient Safety Assessment Tool (PSAT)," June 25, 2024; Executive Director, NCPS, "Clarifications: Wandering and Missing Patient, Patient Safety Assessment Tool and Aggregate Falls Root Cause Analysis," memorandum to PSOs and PSMs, October 24, 2022.

[68] VHA Directive 1050.01(1).

[69] VHA Directive 1050.01(1).

[70] VA, *VHA High Reliability Organization (HRO) Reference Guide,* April 2023.

"dedicated, compassionate VHA employees" to "continuously improve and advance toward Zero Harm across VHA."[71] In 2018, VHA established the HRO Steering Committee to "define the vision, Principles, and Values of VHA's Journey to High Reliability." The committee leads VHA-wide HRO practices, which begin with leaders who engage staff at all levels of the organization.[72] "Leadership Commitment, Culture of Safety, and Continuous Process Improvement" make up the pillars of an HRO.[73]

VHA's NCPS recognizes leaders' communications and actions as vital in creating a culture of patient safety since "poor communication has been proven to put patients in jeopardy."[74] VHA considers the commitment of leaders as one of the most critical elements to change and requires the "participation of highly visible and vocal leaders to promote and demonstrate their sustained commitment to HRO transformation through their actions."[75] VHA's HRO principles are the foundation to help guide performance improvement and VHA expects leaders to model the following HRO principles and values:

- "Sensitivity to Operations," — leaders focus on frontline staff, processes, and systems that affect care.
- "Preoccupation with Failure," — leaders anticipate and eliminate patient risk before it happens.
- "Reluctance to Simplify," — leaders find the root causes of an issue, rather than settling for basic explanations.
- "Commitment to Resilience," — leaders recover from mistakes, refocus, and "prevent those mistakes from happening again."
- "Deference to Expertise," — leaders encourage and value perspectives of experts, regardless of their role.
- "Clear Communications," — leaders use simple language to provide clear communication.[76]

[71] VA, *VHA High Reliability Organization (HRO) Reference Guide*, April 2023.

[72] VA, *VHA High Reliability Organization (HRO) Reference Guide,* April 2023.

[73] VA, *VHA High Reliability Organization (HRO) Reference Guide*, April 2023.

[74] Joe Murphy, "Developing a Culture of Safety," Federal Practitioner, E3, (January 2013):1, https://www.mdedge.com/fedprac/article/75833/developing-culture-safety; Gary L. Sculli and Robin Hemphill, "Culture of Safety and Just Culture," accessed May 31, 2024, https://uthscsa.edu/medicine/sites/medicine/files/2023-08/Culture%20of%20Safety%20and%20Just%20Culture.pdf.

[75] VA, *VHA High Reliability Organization (HRO) Reference Guide,* April 2023.

[76] VA, *VHA High Reliability Organization (HRO) Reference Guide*, April 2023. This list is not inclusive of all the HRO values and principles.

Culture of Safety

The Joint Commission describes culture within a facility as a reflection of all staff's "beliefs, attitudes, and priorities."[77] In a culture of safety, facility staff share responsibility to minimize harm to patients as a result of patient care.[78] VHA's NCPS notes that a necessary component of a culture of safety is a just culture. Just culture refers to an environment in which employees feel safe to report errors with the knowledge that their actions will be adjudicated fairly. In a just culture, leaders must create an environment where employees are "willing to report concerns, unsafe conditions, and even their own errors and deviations from protocol" and assume accountability for reporting issues they believe may be unsafe. [79]

[77] The Joint Commission, *Standards Manual,* e-dition, LD.03.01.01, January 14, 2024. "Leaders regularly evaluate the culture of quality and safety using valid, reliable tools."

[78] The Joint Commission, *Standards Manual,* e-dition, LD.03.06.01, January 14, 2024. "Those who work in the hospital are focused on improving safety and quality."

[79] NCPS. *Just Culture Implementation and Sustainment Guide for Leaders,* amended September 25, 2019.

Appendix B: Compliance with Joint Patient Safety Report Requirements

In the 2023 report, the OIG reviewed JPSR data and found that the former PSM failed to manage JPSR events within the 14-day VHA requirement.[80] Specifically, the OIG found that the majority of determinations to reject an event occurred on or after the 14-day due date, suggesting that the PSM's handling of rejected events was driven by the date the events needed to be finalized rather than managing events as they were submitted in real-time.[81] In contrast, during the follow-up inspection, the OIG reviewed data from October 1, 2022, through March 31, 2024, and found the majority of determinations to reject an event occurred within one day of submission by the original reporter (see figure B.1). The distribution of the data from the follow-up inspection suggests that the rejection of events by the PSM had limited relation to when the events were required to be finalized.

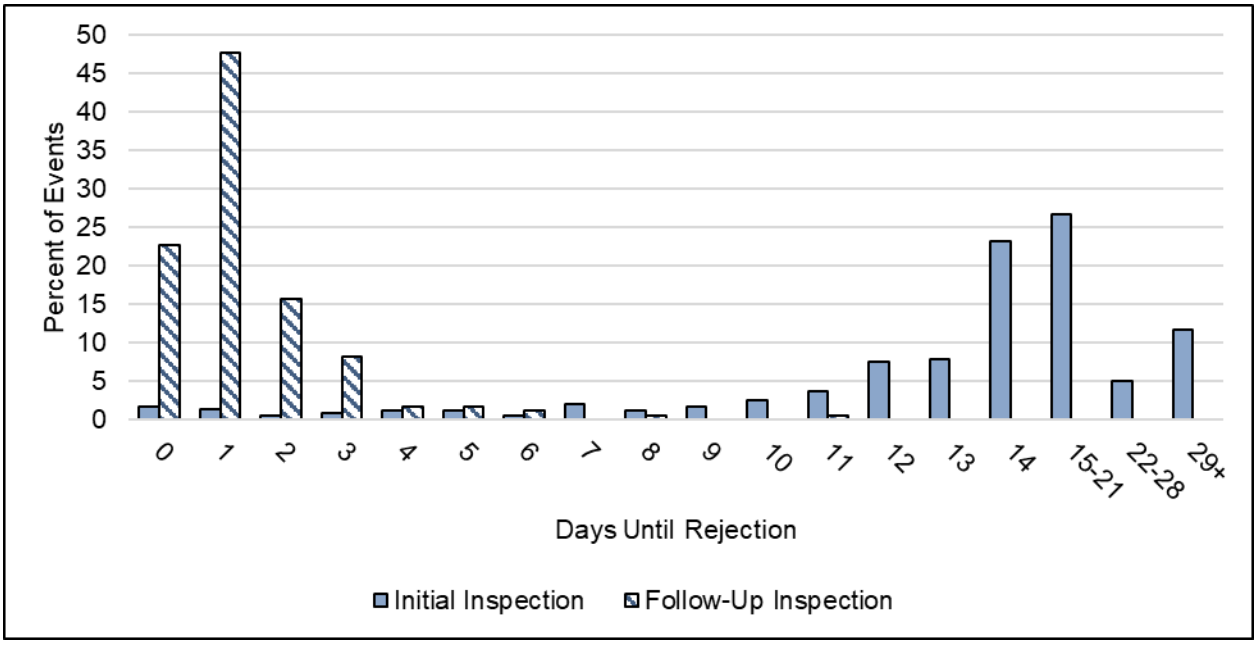

Figure B.1. *Distribution of days until rejection of JPSRs events: initial versus follow-up inspection. Source: OIG Analysis of JPSR Event Report Data from July 9, 2019, to July 19, 2021; and October 1, 2022, through March 31, 2024.*

In the 2023 report, the OIG reviewed a sample of JPSR events and found inconsistent management of reports including the failure to properly reject events and appropriately flag

[80] VHA Directive 1050.01; NCPS, *JPSR Guidebook*, December 2023. VHA requires the PSM ensure JPSR reports are investigated and closed within 14 days of the reported date.

[81] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*.

events for additional analysis.[82] The OIG estimated that the current PSM correctly rejected events 96 percent of the time (95 percent confidence interval (CI): between 92 and 99 percent), an increase from the 2023 report.[83] During the follow-up inspection, the OIG estimated with 95 percent confidence that if an event was related to a fall, medication, or missing patient, the event was being appropriately flagged for an individual or aggregate RCA between 85 and 98 percent of the time.[84] Additionally, the OIG's subsequent review found improvements in the documentation of investigation details and feedback to the original reporter of the event.[85] The OIG determined that the current PSM had improved the facility's compliance with the VHA requirement and identified that 100 percent of JPSR entries from October 1, 2022, through March 31, 2024, had information documented in the feedback to reporter field for the same time period.[86]

[82] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*. In the report, the OIG conducted a review of a statistical sample of 100 rejected JPSR events reported from January 1, 2017, through July 19, 2021.

[83] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*. In the 2023 report, the OIG found the former PSM correctly rejected events 75 percent of the time (95 percent CI: between 66 and 83 percent).

[84] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*. In the 2023 report, the OIG estimated with 95 percent confidence that if an event was related to a fall, medication, or missing patient, the event was being appropriately flagged for an individual or aggregate RCA between 33 and 56 percent of the time.

[85] VA OIG, *Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama*. In the 2023 report, the OIG identified 100 percent of finalized JPSR events lacked the documentation required to be considered a complete investigation and lacked documented reporter feedback.

[86] NCPS, *JPSR Guidebook*, December 2023. VHA requires PSMs provide feedback to the reporter of the event to reinforce that all staff have a role in patient safety and encourage future reporting.

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 20, 2024

From: Director, VA Southeast Network (10N7)

Subj: Healthcare Inspection—Improvement in the Patient Safety Program with Continued Opportunities to Strengthen Veterans Integrated Service Network 7 Oversight at the Tuscaloosa VA Medical Center in Alabama

To: Director, Office of Healthcare Inspections (54HL05)
Director, GAO/OIG Accountability Office (VHA 10OIC GOAL ACTION)

1. Thank you for the opportunity to review and comment on the draft report regarding improvement in the patient safety program with opportunities to strengthen VISN 7 oversight of Tuscaloosa VAMC. The Tuscaloosa VAMC prioritizes patient care and safety, and we appreciate the OIG's partnership in our continuous improvement efforts for our Veterans.

2. I concur with recommendations 1-3 and VISN 7's action plan.

3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.

4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

(*Original signed by:*)

David M. Walker, MD, MBA, FACHE
Network Director

[OIG comment: The OIG received the above memorandum from VHA on November 20, 2024.]

VISN Director Response

Recommendation 1

The Veterans Integrated Service Network Director confirms that the patient safety officer reviews investigations by subject matter experts for Joint Patient Safety Reporting events.

_X _Concur

____Nonconcur

Target date for completion: May 2025

Director Comments

The Veterans Integrated Service Network (VISN) Director will ensure that the VISN Patient Safety Officer (PSO) reviews investigations by [subject matter expert] (SME) for Joint Patient Safety Reporting (JPSR) events. The PSO will use an audit tool to monitor 30% of overall monthly totals of JPSRs reported. Compliance of the completed reviews will be monitored monthly in the VISN Quality Patient Safety Committee.

Recommendation 2

The Veterans Integrated Service Network Director provides evidence to demonstrate the Patient Safety Office is completing reviews of a sample of patient safety events that includes analysis of content, recommendations, and required actions, as outlined in Veterans Health Administration Directive 1050.01.

_X _Concur

____Nonconcur

Target date for completion: May 2025

Director Comments

The VISN Director will provide evidence of the Patient Safety Office completing reviews of patient safety events through required reporting monthly at VISN 7 Quality Patient Safety Committee (QPSC). The VISN QPSC minutes template will be updated to reflect reviews of JPSR completed by SMEs, Patient Safety Officer's analyses, opportunities for improvement, and any provided guidance to facilities for the development of action plans as outlined in VHA Directive 1050.1, *VHA Quality and Patient Safety Programs*.

Recommendation 3

The Veterans Integrated Service Network Director ensures that the Veterans Integrated Service Network 7 Quality and Patient Safety Committee minutes reflect that the patient safety officer conducted analysis of patient safety data to identify opportunities for improvement and provided guidance on facilities' action plans to address the deficiencies.

_X _Concur

____Nonconcur

Target date for completion: May 2025

Director Comments

The VISN Director will ensure that the VISN QPSC minutes reflect reporting on an analysis of patient safety data and monthly reports on completed, JPSR, SME, investigation reviews. The VISN QPSC minutes template will be updated to reflect reviews of JPSR SME investigations, Patient Safety Officer's analyses, opportunities for improvement, and any provided guidance to facilities for the development of action plans addressing deficiencies.

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 28, 2024

From: Director, Tuscaloosa VAMC (679/00)

Subj: Healthcare Inspection—Improvement in the Patient Safety Program with Continued Opportunities to Strengthen Veterans Integrated Service Network 7 Oversight at the Tuscaloosa VA Medical Center in Alabama

To: Director, VA Southeast Network (10N7)

1. Thank you for the opportunity to review and comment on the draft report regarding improvement in the patient safety program with opportunities to strengthen VISN 7 oversight of Tuscaloosa VA Medical Center.

2. I concur with the report as written. There were no recommendations for Tuscaloosa VA Medical Center, the VAMC commits to supporting the action plan of the VISN, as necessary.

3. Comments regarding the contents of this memorandum may be directed to the Chief of Quality Management.

(*Original signed by*:)

Tony Davis
Chief of Staff, Tuscaloosa VA Medical Center

For

John F. Merkle, FACHE, VHA-CM
Director, Tuscaloosa VA Medical Center

[OIG comment: The OIG received the above memorandum from VHA on November 20, 2024.]

Glossary

To go back, press "alt" and "left arrow" keys.

close call. An incident "that could have resulted in an adverse event, but did not, either by chance or through timely intervention." [87]

Joint Patient Safety Reporting System. A "mandated web-based system used by VHA employees to report patient safety events."[88]

patient safety assessment tool. A VHA tool that provides PSMs "with a cognitive aid to perform an environmental scan, which helps identify risk and recognize potential safety concerns" using "pre-defined assessment questions." [89]

patient safety event. An "event, incident or condition directly associated with care or services provided to a patient, that could have resulted or did result in unintentional harm. Patient safety events include but are not limited to adverse events and close calls."[90]

proactive risk assessment. "A method of evaluating a product or process to identify systems vulnerabilities and their associated corrective actions before an adverse event occurs." Healthcare Failure Mode and Effect Analysis is one type of proactive risk assessment.[91]

root cause analysis. "A process for identifying the basic causal factor(s) underlying system failures."[92]

sentinel event. A type of patient safety event that is not related to the patient's illness or underlying condition and may involve death, permanent harm, or severe temporary harm.[93]

SPOT. An information system used by VHA to capture information from root cause analysis and aggregated reviews.[94]

[87] VHA Directive 1050.01(1).
[88] VHA Directive 1050.01(1).
[89] NCPS, *Patient Safety Assessment Tool (PSAT)*, June 25, 2024.
[90] VHA Directive 1050.01(1).
[91] VHA Directive 1050.01(1).
[92] NCPS, *Guide to Performing Root Cause Analysis*.
[93] VHA Directive 1050.01(1).
[94] NCPS, *Guide to Performing Root Cause Analysis*.

OIG Contact and Staff Acknowledgments

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