DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Louis Stokes Cleveland VA Medical Center

Ohio

CHIP REPORT | **REPORT #19-00015-47** | **DECEMBER 19, 2019**

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Figure 1. *Louis Stokes Cleveland VA Medical Center, Ohio (Source: https://vaww.va.gov/directory/guide/, accessed on July 8, 2019)*

Abbreviations

ADPCS	associate director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
FPPE	focused professional practice evaluation
FY	fiscal year
LIP	licensed independent practitioner
MST	military sexual trauma
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
SAIL	Strategic Analytics for Improvement and Learning
TJC	The Joint Commission
UCC	urgent care center
UM	utilization management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Louis Stokes Cleveland VA Medical Center (the facility). The inspection covers key clinical and administrative processes that are associated with promoting quality care.

CHIP inspections are one element of the OIG's overall efforts to ensure that the nation's veterans receive high-quality and timely VA healthcare services. The reviews are performed approximately every three years for each facility. The OIG selects and evaluates specific areas of focus each year.

The OIG team looks at leadership and organizational risks as well as areas affecting quality patient care. At the time of the review, the clinical areas of focus were

1. Quality, safety, and value;
2. Medical staff privileging;
3. Environment of care;
4. Medication management (specifically the controlled substances inspection program);
5. Mental health (focusing on military sexual trauma follow-up and staff training);
6. Geriatric care (spotlighting antidepressant use for elderly veterans);
7. Women's health (particularly abnormal cervical pathology result notification and follow-up); and
8. High-risk processes (specifically the emergency department and urgent care center operations and management).

This unannounced visit was conducted during the week of March 18, 2019. The OIG held interviews and reviewed clinical and administrative processes related to areas of focus that affect patient care outcomes. Although the OIG reviewed a broad spectrum of clinical and administrative processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this facility's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this facility and other Veterans Health Administration (VHA) facilities to identify areas of vulnerability or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Results and Inspection Impact

Leadership and Organizational Risks

At the time of the OIG's visit, the facility leadership team consisted of the director, chief of staff, associate director for Patient Care Services (ADPCS), deputy director, and associate director (primarily nonclinical). Organizational communications and accountability were managed through a committee reporting structure, with the Executive Leadership Board having oversight for several working groups. The director was chair of the Quality, Safety, Value Council, which was responsible for tracking, identifying trends in, and monitoring quality of care and patient outcomes.

The facility's leadership team had been working together for five months, although several had served in their position for years. The leaders were all permanently assigned, with the director being the most tenured at over eight years, and the newest—the chief of staff—was in the position for about five months.

The OIG noted that selected employee satisfaction survey results indicated that facility leaders were engaged and promoted a culture of safety where employees feel safe bringing forward issues and concerns. The selected patient experience survey scores for facility leaders were generally similar to or better than the VHA average, and facility leaders had implemented processes and plans to maintain positive patient experiences.

Additionally, the OIG reviewed accreditation agency findings, sentinel events,[1] disclosures of adverse patient events, and patient safety indicator data and identified organizational risk factors, specifically with sentinel events related to surgical procedures and patient safety indicators.

The OIG recognizes that the Strategic Analytics for Improvement and Learning (SAIL) model has limitations for identifying all areas of clinical risk but is "a way to understand the similarities and differences between the top and bottom performers" within VHA.[2] Although the leadership team members were knowledgeable within their areas of responsibility about selected SAIL metrics and SAIL community living center (CLC) measures, the leaders should continue to take

[1] The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

[2] VHA's Office of Operational Analytics and Reporting developed a model for understanding a facility's performance in relation to nine quality domains and one efficiency domain. The domains within SAIL are made up of multiple composite measures, and the resulting scores permit comparison of facilities within a Veterans Integrated Service Network or across VHA. The SAIL model uses a "star rating" system to designate a facility's performance in individual measures, domains, and overall quality. http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938. (The website was accessed on March 6, 2019, but is not accessible by the public.)

actions to sustain and improve performance of the quality of care metrics and measures likely contributing to the facility's SAIL "5-star" and SAIL CLC "3-star" quality ratings.[3]

The OIG noted deficiencies in six of the eight clinical areas reviewed and issued 10 recommendations attributable to the director, chief of staff, ADPCS, and associate director. These are briefly described below.

Quality, Safety, and Value

The OIG team found there was general compliance with requirements for patient safety. However, the OIG identified noncompliance with implementation of improvement actions recommended by the Peer Review Committee, peer review of all applicable deaths within 24 hours of admission, interdisciplinary review of utilization management data,[4] and evidence of basic or advanced cardiac life support certification for code team responders.

Environment of Care

The representative community based outpatient clinic and the facility emergency management program met the performance indicators evaluated. The OIG did not note any issues with the availability of medical equipment and supplies. However, the inspection team identified noncompliance with medication safety in two patient care areas and general safety in the locked inpatient mental health unit.

Mental Health

The OIG team also found the facility complied with many of the mental health performance indicators, including the designation of a military sexual trauma (MST) coordinator, tracking of MST-related data, and provision of clinical care. The team noted a concern, however, with providers completing MST mandatory training.

Geriatric Care

For geriatric patients, providers documented reasons for prescribing medications and completed medication reconciliation. However, the OIG inspection team identified inadequate patient

[3] Based on fiscal year 2018, quarter 3 ratings at the time of the site visit.

[4] The definition of utilization management can be found within VHA Directive 1117(1), *Utilization Management Program*, July 9, 2014 (amended January 18, 2018). Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria." The January 2018 version of the directive was in effect at the time of the March 2019 review. Subsequently, the directive was replaced by VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019), which expired on July 31, 2019. The utilization management definition remained consistent in both versions of the directive.

and/or caregiver education related to newly prescribed medications and inconsistent evaluation of the education provided.

Women's Health

The OIG also noted the facility performed adequately with indicators related to women's health, including requirements for a designated women veterans program manager and clinical champion, clinical oversight of the women's health program, tracking data related to cervical cancer screenings, communication of results to patients within the required time frame, and follow-up care when indicated. However, the Women Veterans Health Committee membership lacked representation from laboratory, pharmacy, and radiology services.

High-Risk Processes

The OIG inspection revealed that the facility generally complied with many of the performance indicators used to assess the operations and management of the emergency department. However, the OIG identified inadequate signage to direct patients to the emergency department.

Summary

In reviewing key healthcare processes, the OIG issued 10 recommendations for improvement directed to the facility director, chief of staff, ADPCS, and associate director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this facility. The intent is for facility leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if left unattended, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network director and facility director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes F and G, pages 72–73, and the responses within the body of the report for the full text of the directors' comments.) The OIG considers recommendation 10 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to provide oversight of healthcare services to veterans. This focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Louis Stokes Cleveland VA Medical Center (the facility) is accomplished by examining a broad overview of key clinical and administrative processes associated with quality care and positive patient outcomes. The OIG reports its findings to Veterans Integrated Service Network (VISN) and facility leaders so that informed decisions can be made on improving care.

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting the quality agenda; and promoting a culture to sustain positive change.[5] Investments in a culture of safety and quality improvement with robust communications and leadership significantly contribute to positive patient outcomes in healthcare organizations.[6] Figure 2 shows the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

To examine risks to patients and the organization when core processes are not performed well, the OIG focused on the following nine areas of clinical and administrative operations that support quality care at the facility: [7]

1. Leadership and organizational risks
2. Quality, safety, and value (QSV)
3. Medical staff privileging
4. Environment of care
5. Medication management (specifically the controlled substances inspection program)
6. Mental health (focusing on military sexual trauma follow-up and staff training)
7. Geriatric care (spotlighting antidepressant use for elderly veterans)
8. Women's health (particularly abnormal cervical pathology results notification and follow-up)

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[5] Anam Parand, Sue Dopson, Anna Renz, and Charles Vincent, "The role of hospital managers in quality and patient safety: a systematic review," *British Medical Journal*, 4, no. 9 (September 5, 2014): e005055. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4158193/. (The website was accessed on January 24, 2019.)

[6] Institute for Healthcare Improvement, "How risk management and patient safety intersect: Strategies to help make it happen," March 24, 2015. http://www.npsf.org/blogpost/1158873/211982/How-Risk-Management-and-Patient-Safety-Intersect-Strategies-to-Help-Make-It-Happen. (The website was accessed on January 24, 2019.)

[7] See Figure 2. CHIP inspections address these processes during FY 2019 (October 1, 2018, through September 30, 2019); they may differ from prior years' focus areas.

9. High-risk processes (specifically the emergency department and urgent care center operations and management).

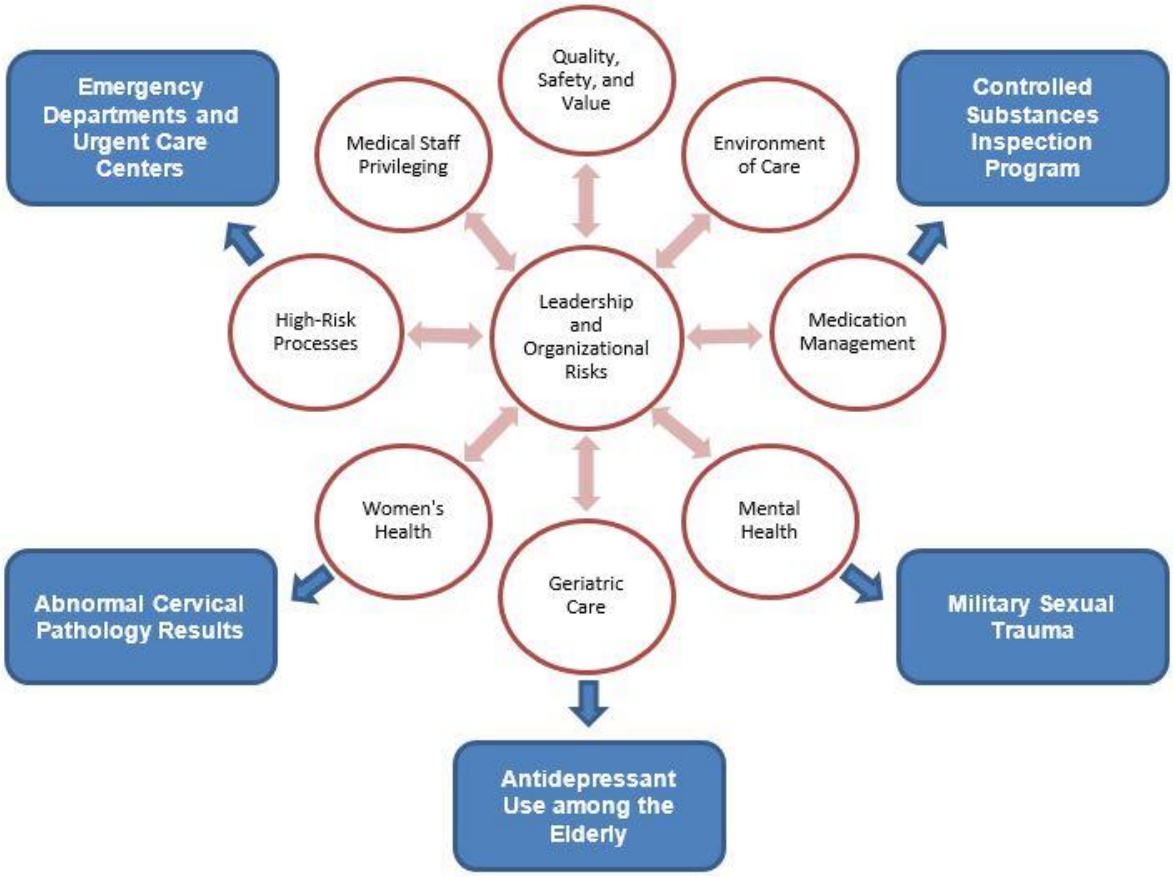

Figure 2. *Fiscal Year (FY) 2019 Comprehensive Healthcare Inspection of Operations and Services*
Source: VA OIG

Methodology

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports;[8] physically inspected OIG-selected areas; and discussed processes and validated findings with managers and employees. The OIG also interviewed members of the executive leadership team.

The inspection period examined operations from October 22, 2016, through March 22, 2019, the last day of the unannounced week-long site visit.[9] While on site, the OIG did not receive any complaints beyond the scope of the CHIP inspection.

This report's recommendations for improvement target problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the facility completes corrective actions. The facility director's comments submitted in response to the report recommendations appear within each topic area.

The OIG conducted the inspection in accordance with OIG standard operating procedures for CHIP reports and Quality Standards for Inspection and Evaluation published by the Council of the Inspectors General on Integrity and Efficiency.

[8] The OIG did not review VHA's internal survey results, instead focusing on OIG inspections and external surveys that affect facility accreditation status.

[9] The range represents the time period from the last Clinical Assessment Program review, which was performed prior to the comprehensive healthcare inspection, to the completion of the unannounced week-long CHIP site visit.

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare facility. Leadership and organizational risks can impact the facility's ability to provide care in all of the selected clinical areas of focus.[10] To assess the facility's risks, the OIG considered the following indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation and/or for-cause surveys and oversight inspections
5. Factors related to possible lapses in care
6. VHA performance data

Executive Leadership Position Stability and Engagement

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 3 illustrates this facility's reported organizational structure. The facility has a leadership team consisting of the director, chief of staff, associate director for Patient Care Services (ADPCS), deputy director, and associate director (primarily nonclinical). The chief of staff and ADPCS oversee patient care, which requires managing service directors and chiefs of programs and practices.

[10] L. Botwinick, M. Bisognano, and C. Haraden, "Leadership Guide to Patient Safety," *Institute for Healthcare Improvement*, Innovation Series White Paper. 2006. www.IHI.org. (The website was accessed on February 2, 2017.)

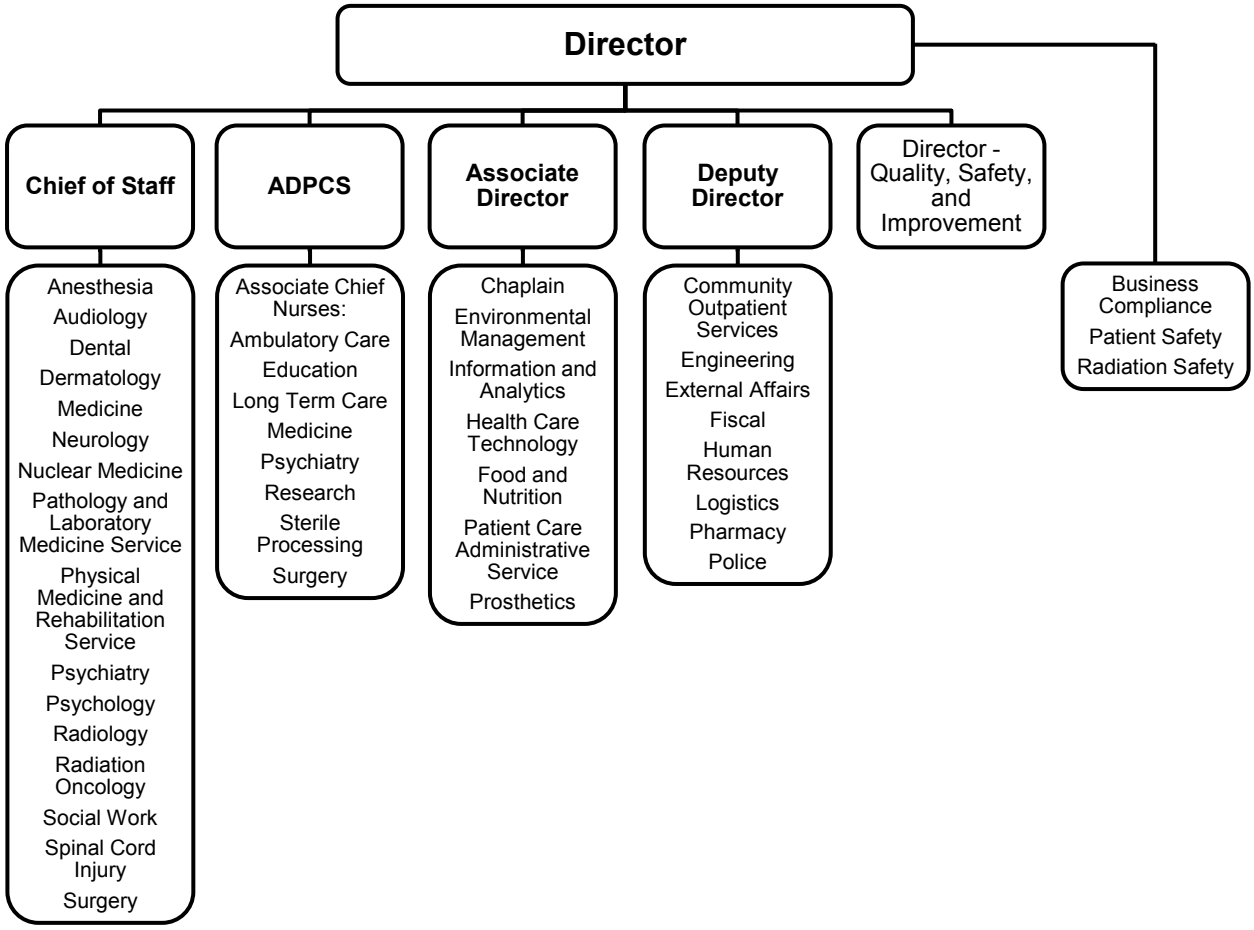

Figure 3. *Facility Organizational Chart*[11]
Source: Louis Stokes Cleveland VA Medical Center (received March 18, 2019)

At the time of the OIG site visit, the executive team had been working together for five months, although several team members have been in their position for many years (see Table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Facility director	September 26, 2010
Chief of staff	October 28, 2018
Associate director for Patient Care Services	December 30, 2012
Deputy director	November 1, 2015
Associate director	July 10, 2016

Source: Louis Stokes Cleveland VA Medical Center (received March 18, 2019)

[11] At this facility, the director is responsible for Business Compliance, Patient Safety, and Radiation Safety.

To help assess facility executive leaders' engagement, the OIG interviewed the director, chief of staff, ADPCS, deputy director, and associate director regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance.

In individual interviews, these executive leadership team members, with the exception of the chief of staff who had been in the position for only five months, generally could speak knowledgeably about actions taken during the previous 12 months in order to maintain or improve performance, as well as employee and patient survey results. In addition, the executive leaders were generally knowledgeable within their scope of responsibilities about selected Strategic Analytics for Improvement and Learning (SAIL) metrics and SAIL community living center (CLC) measures. These are discussed in greater detail below.

At this facility, the director chairs the Executive Leadership Board which has the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Executive Leadership Board oversees various working groups, such as the Quality, Safety, Value Council and Medical Executive Council.

These leaders are also engaged in monitoring patient safety and care through the Quality, Safety, Value Council, chaired by the director. The Quality, Safety, Value Council is responsible for tracking, identifying trends, and monitoring quality of care and patient outcomes and reports to the Executive Leadership Board. See Figure 4.

Figure 4. *Facility Committee Reporting Structure*[12]
Source: Louis Stokes Cleveland VA Medical Center (received March 18, 2019)

Employee Satisfaction

The All Employee Survey is an "annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential." Since 2001, the instrument has been refined several times in response to VA leaders' inquiries on VA culture and organizational health. Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point for discussions, indicate areas for further inquiry, and be considered along with other information on facility leadership.

To assess employee attitudes toward facility leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey that relate to the period of October 1, 2017,

[12] The Executive Leadership Board directly oversees Accreditation, Administrative Investigation Board and Root Cause Analysis Action Item Compliance, Community Based Outpatient Clinic Oversight, Medical Center Priorities, Safety & Quality Priorities, and Strategic Planning.

through September 30, 2018.[13] Table 2 provides relevant survey results for VHA, the facility, and selected facility executive leaders. It summarizes employee attitudes toward these selected facility leaders as expressed in VHA's All Employee Survey. With the exception of the chief of staff and associate director, the OIG found the average for several selected survey leadership questions was similar to or higher than the VHA average.[14,15] In all, employees appear generally satisfied with facility leaders.

Table 2. Survey Results on Employee Attitudes toward Facility Leadership (October 1, 2017, through September 30, 2018)

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Deputy Director Average
All Employee Survey: *Servant Leader Index Composite*[16]	0–100 where HIGHER scores are more favorable	71.7	72.8	85.7	55.0	81.3	69.4	76.4
All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.3	3.6	4.4	3.2	4.1	3.6	3.7

[13] Ratings are based on responses by employees who report to or are aligned under the director, chief of staff, ADPCS, deputy director, and associate director. It is important to note that the 2018 All Employee Survey results are not reflective of employee satisfaction with the current chief of staff.

[14] The OIG makes no comment on the adequacy of the VHA average for each selected survey element. The VHA average is used for comparison purposes only.

[15] It is important to note that the 2018 All Employee Survey results are not reflective of employee satisfaction with the current chief of staff.

[16] According to the 2018 VA All Employee Survey Questions by Organizational Health Framework, Servant Leader Index "is a summary measure of the work environment being a place where organizational goals are achieved by empowering others. This includes focusing on collective goals, encouraging contribution from others, and then positively reinforcing others' contributions. Servant Leadership occurs at all levels of the organization, where individuals (supervisors, staff) put others' needs before their own."

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Deputy Director Average
All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.5	3.7	4.5	3.5	4.2	3.6	3.8
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.8	4.5	3.6	4.4	3.8	3.9

Source: VA All Employee Survey (accessed February 11, 2019)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. Again, except for the chief of staff and associate director, the facility and executive leadership team averages for the selected survey questions were similar to or better than the VHA average.[17] Facility leaders appear to be generally maintaining an environment where employees feel safe bringing forth issues and concerns.

Table 3. Survey Results on Employee Attitudes toward the Workplace (October 1, 2017, through September 30, 2018)

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Deputy Director Average
All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.8	4.7	3.5	4.4	3.6	4.0

[17] It is important to note that the 2018 All Employee Survey results are not reflective of employee satisfaction with the current chief of staff.

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Deputy Director Average
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.7	4.3	3.5	4.2	3.4	3.8
All Employee Survey: *In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?*	0 (Never) – 6 (Every Day)	1.5	1.3	1.3	1.9	1.1	1.4	1.2

Source: VA All Employee Survey (accessed February 11, 2019)

Patient Experience

To assess patient attitudes toward facility leaders, the OIG reviewed patient experience survey results that relate to the period of October 1, 2017, through September 30, 2018. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare Experience of Patients (SHEP) program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients' experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides relevant survey results for facility leadership and compares the results to the overall VHA averages.[18]

VHA also collects SHEP survey data from Patient-Centered Medical Home, Specialty Care, and Inpatient Surveys. The OIG reviewed responses to four relevant survey questions that reflect

[18] Ratings are based on responses by patients who received care at this facility.

patients' attitudes toward facility leaders (see Table 4). For this facility, all four patient survey results reflected higher care ratings than the VHA average. Patients were generally satisfied with the leadership and care provided.

Table 4. Survey Results on Patient Attitudes toward Facility Leadership (October 1, 2017, through September 30, 2018)

Questions	Scoring	VHA Average	Facility Average
Survey of Healthcare Experiences of Patients (inpatient): *Would you recommend this hospital to your friends and family?*	The response average is the percent of "Definitely Yes" responses.	66.9	73.8
Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.2	88.1
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	76.3	82.2
Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	76.5	83.0

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed November 9, 2018)

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys, including those conducted for cause, by oversight and accrediting agencies to gauge how well leaders respond to identified problems.[19] Table 5 summarizes the relevant facility inspections most recently performed by the OIG and The Joint Commission (TJC).[20]

At the time of the site visit, the OIG also noted the facility's current accreditation status with the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.[21] Additional results included the Long Term Care Institute's inspection of the facility's CLC[22] and the Paralyzed Veterans of America's inspection of the facility's spinal cord injury/disease unit and related services.[23]

[19] The Joint Commission (TJC) conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization.

[20] According to VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017, TJC provides an "internationally accepted external validation that an organization has systems and processes in place to provide safe and quality-oriented health care." TJC "has been accrediting VA medical facilities for over 35 years." Compliance with TJC standards "facilitates risk reduction and performance improvement."

[21] According to VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs,* May 9, 2017, the Commission on Accreditation of Rehabilitation Facilities "provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies." VHA's commitment is supported through a system-wide, long-term joint collaboration with the Commission on Accreditation of Rehabilitation Facilities to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs. According to the College of American Pathologists, for 70 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." College of American Pathologists. https://www.cap.org/about-the-cap. (The website was accessed on February 20, 2019.) In accordance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

[22] The Long Term Care Institute states that it has been to over 4,000 healthcare facilities conducting quality reviews and over 1,145 external regulatory surveys since 1999. The Long Term Care Institute is "focused on long-term care quality and performance improvement; compliance program development; and review in long-term care, hospice, and other residential care settings." Long Term Care Institute. http://www.ltciorg.org/about-us/. (The website was accessed on March 6, 2019.)

[23] The Paralyzed Veterans of America inspections took place June 27-28, 2017, and June 26-27, 2018. This veteran service organization review does not result in accreditation status.

Table 5. Office of Inspector General Inspections/The Joint Commission Survey

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Clinical Assessment Program Review of the Louis Stokes Cleveland VA Medical Center, Cleveland, Ohio, Report No. 16-00553-135, March 13, 2017)	October 2016	16	0
TJC Hospital Accreditation	March 2016	16	0
TJC Behavioral Health Care Accreditation		2	0
TJC Home Care Accreditation		2	0
TJC Neurosurgery Program Accreditation	November 2016	4	0
TJC Inpatient Diabetes Certification	February 2018	4	0
TJC Methadone Program Accreditation	May 2018	2	0
TJC For Cause	July 2018	5	0

Source: OIG and TJC (inspection/survey results verified with the chief of Quality, Safety, and Improvement on March 21, 2019)

Factors Related to Possible Lapses in Care

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms. The OIG noted that three of the five sentinel events since October 22, 2016, were related to surgical procedures—one retained sponge, one removal of a sponge, and one incorrect lens implant. Table 6 lists the reported patient safety events from October 22, 2016 (the prior comprehensive OIG inspection), through March 22, 2019.[24]

[24] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the Louis Stokes Cleveland VA Medical Center is a highest complexity (1a) affiliated facility as described in Appendix B.)

Table 6. Summary of Selected Organizational Risk Factors (October 22, 2016, through March 22, 2019)

Factor	Number of Occurrences
Sentinel Events[25]	5
Institutional Disclosures[26]	8
Large-Scale Disclosures[27]	0

Source: Louis Stokes Cleveland VA Medical Center's chief of Quality, Safety, and Improvement (received March 19, 2019)

The OIG also reviewed patient safety indicators developed by the Agency for Healthcare Research and Quality within the U.S. Department of Health and Human Services. These provide information on potential in-hospital complications and adverse events following surgeries and procedures.[28] The rates presented are specifically applicable for this facility, and lower rates indicate lower risks. Table 7 summarizes patient safety indicator data from October 1, 2016, through September 30, 2018.

[25] The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

[26] According to VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an "administrative disclosure") as "a formal process by which VA medical facility leaders together with clinicians and others, as appropriate, inform the patient or [his or her] personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."

[27] According to VHA Directive 1004.08, VHA defines large-scale disclosures of adverse events (sometimes referred to as "notifications") as "a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue."

[28] Agency for Healthcare Research and Quality. https://www.qualityindicators.ahrq.gov/. (The website was accessed on December 11, 2017.)

Table 7. Patient Safety Indicator Data
(October 1, 2016, through September 30, 2018)

Indicators	Reported Rate per 1,000 Hospital Discharges		
	VHA	VISN 10	Facility
Pressure ulcer	0.74	0.45	0.90
Death among surgical inpatients with serious treatable conditions	113.42	135.14	148.15
Iatrogenic pneumothorax[29]	0.17	0.17	0.21
Central venous catheter-related bloodstream infection	0.16	0.16	0.12
In-hospital fall with hip fracture	0.09	0.12	0.23
Perioperative hemorrhage or hematoma	2.61	3.55	7.08
Postoperative acute kidney injury requiring dialysis	0.89	1.06	0.00
Postoperative respiratory failure	4.54	5.52	4.57
Perioperative pulmonary embolism or deep vein thrombosis	2.97	2.19	2.58
Postoperative sepsis	3.55	3.16	4.48
Postoperative wound dehiscence (rupture along incision)	0.82	0.91	0.90
Unrecognized abdominopelvic accidental puncture or laceration	1.00	0.82	0.84

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.

Of the 12 patient safety indicator measures, 10 facility results show a higher reported rate than VHA and/or VISN 10. The patient safety indicator measures for perioperative pulmonary embolism or deep vein thrombosis and unrecognized abdominopelvic accidental puncture/laceration show a higher reported rate than VISN 10, and measures for postoperative respiratory failure and postoperative wound dehiscence were higher than VHA. The remaining six patient safety indicator measures—pressure ulcer, death among surgical inpatients with serious treatable conditions, iatrogenic pneumothorax, in-hospital fall with hip fracture, perioperative hemorrhage or hematoma, and postoperative sepsis—show a higher reported rate than VHA and VISN 10.

The OIG also reviewed patient safety indicator data for FY 2018, quarter 4 (the most recent data) and the previous four quarters to identify any potential trends that may impact patient safety or

[29] According to Northwestern Memorial Hospital, "A Pneumothorax is a type of lung injury that allows air to leak into the area between the lungs and the chest wall, which causes mild to severe chest pain and shortness of breath. An Iatrogenic Pneumothorax is caused by medical treatment, often as an incidental event during a procedure such as a pacemaker insertion." Northwestern Medicine. http://www.nmh.org/nm/quality-lung-injury-due-to-medical-care. (The website was accessed on March 6, 2019.)

increase the risk for patient harm. It is important to note that although the data are collected and reported by quarter, each set of quarterly data represents potential complications or patient safety events over an eight-quarter or two-year period. Further, it is possible for a facility measure to exceed the VHA rate due to a single incident and for that measure to vary above or below the VHA rate over time due to differences in the number of patients treated. Figure 5 illustrates the time frames covered by the data reviewed.

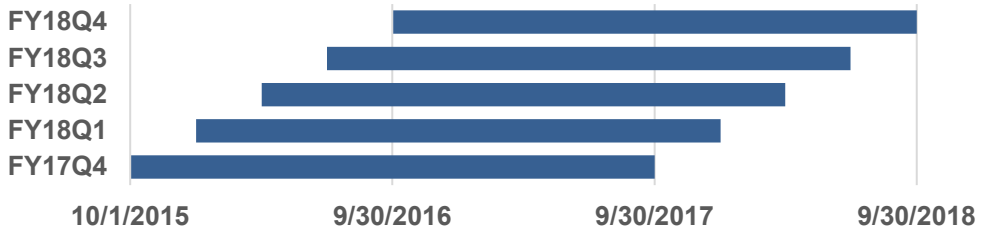

Figure 5. *Associated Time Frames for Quarterly Patient Safety Indicator Data*
Source: VA OIG
FY18Q4 = fiscal year 2018, quarter 4
FY18Q3 = fiscal year 2018, quarter 3
FY18Q2 = fiscal year 2018, quarter 2
FY18Q1 = fiscal year 2018, quarter 1
FY17Q4 = fiscal year 2017, quarter 4

Table 8 summarizes patient safety indicator data for FY 2017, quarter 4 (FY17Q4) through FY 2018, quarter 4 (FY18Q4), which includes potential complications from October 1, 2015, through September 30, 2018.

Table 8. Patient Safety Indicator Data Trending (October 1, 2015, through September 30, 2018)

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
Pressure ulcer	VHA	0.60	0.88	n/a[30]	0.76	0.74
	Facility	0.56	0.79	n/a	1.10	0.90
Death among surgical inpatients with serious treatable conditions	VHA	100.97	118.96	113.92	114.89	113.42
	Facility	85.37	108.70	117.65	141.03	148.15
Iatrogenic pneumothorax	VHA	0.19	0.19	0.17	0.15	0.17
	Facility	0.49	0.50	0.35	0.21	0.21
Central venous catheter-related bloodstream infection	VHA	0.15	0.14	0.15	0.16	0.16
	Facility	0.24	0.21	0.00	0.00	0.12

[30] According to VHA's Inpatient Evaluation Center, pressure ulcer data are not available for the time frame of April 1, 2016, through March 31, 2018.

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
In-hospital fall with hip fracture	VHA	0.08	0.09	0.08	0.09	0.09
	Facility	0.09	0.14	0.16	0.15	0.23
Perioperative hemorrhage or hematoma	VHA	1.94	2.58	2.62	2.59	2.61
	Facility	8.62	10.24	10.35	8.22	7.08
Postoperative acute kidney injury requiring dialysis	VHA	0.88	0.80	0.65	0.96	0.89
	Facility	0.67	0.61	0.70	0.71	0.00
Postoperative respiratory failure	VHA	5.55	5.34	5.11	4.88	4.54
	Facility	9.56	9.76	10.10	6.74	4.57
Perioperative pulmonary embolism or deep vein thrombosis	VHA	3.29	3.26	3.09	3.05	2.97
	Facility	3.69	3.61	2.61	2.61	2.58
Postoperative sepsis	VHA	4.00	3.96	3.72	3.70	3.55
	Facility	5.70	5.19	5.22	5.27	4.48
Postoperative wound dehiscence (rupture along incision)	VHA	0.52	1.04	1.00	0.93	0.82
	Facility	1.38	2.49	1.86	0.91	0.90
Unrecognized abdominopelvic accidental puncture or laceration	VHA	0.53	1.21	1.02	1.07	1.00
	Facility	0.00	0.39	0.45	0.85	0.84

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.

The reported rates for 9 of the 12 measures were generally above the VHA rates. Five measures (iatrogenic pneumothorax, in-hospital fall with hip fracture, perioperative hemorrhage or hematoma, postoperative respiratory failure, and postoperative sepsis) are higher than the VHA averages for all quarters reviewed. Two measures (pressure ulcer and death among surgical inpatients with serious treatable conditions) show an apparent recent upward trend.

For FY 2018, the reported rate for patients that developed pressure ulcers included nine patients; however, only one new patient was identified for FY 2018, quarter 4. The facility's wound care nurse reported reviewing each case and identified that nurses were not capturing or accurately documenting pressure ulcers present during admission. The wound care nurse stated that the facility had already begun addressing this issue.

The most recently reported rate for deaths among surgical inpatients with serious treatable conditions reflect patients admitted to the hospital between November 2016 through April 2018. Eight died during the first three quarters of FY 2018 and four died sometime in FY 2017. The facility conducted internal reviews of the patients' care individually and in aggregate; it determined that appropriate services were consulted and did not identify improvement opportunities.

Three patients developed iatrogenic pneumothorax during FY 2018, quarter 1. The facility conducted internal reviews of the patients' care individually and did not identify opportunities for improvement. There were no new incidents reported for the remainder of FY 2018.

Three patients reportedly sustained an in-hospital fall with hip fracture in FY 2018—two of which occurred in quarter 1 and one in quarter 4. The facility reported that electronic health record reviews, conducted by clinicians, determined that one patient did not sustain a fall but had fall precautions in place which was erroneously reported as a fall. Clinicians reviewed the remaining two cases individually and determined that patients received appropriate care.

Two measures (perioperative hemorrhage or hematoma and postoperative sepsis) have trended above the VHA average. The facility's perioperative hemorrhage or hematoma rates began increasing in FY 2018, quarter 1. The facility reported identifying the upward trend prior to the OIG site visit and developed an action plan which requires coders and surgeons to collaborate on proper coding procedures. Coding errors and staff turnover were cited as contributing factors to this trend.

Four patients had postoperative respiratory failure. The facility conducted internal reviews of three patients' care individually and in aggregate. One patient had a chronic condition and was reintubated while in the operating room while another patient removed the endotracheal tube, which was subsequently replaced. The facility did not identify any opportunities for improvement.

For postoperative sepsis, the facility reported four new patient cases in FY 2018; clinicians were unable to cite the reason for the upward trend. However, the facility reported their infection control nurse was conducting a deep dive to better understand the trend.

One patient developed a wound dehiscence, which was repaired. No opportunities for improvement were identified.

Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adapted the SAIL Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk. The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.[31]

[31] VHA Support Service Center (VSSC), *The Strategic Analytics for Improvement and Learning (SAIL) Value Model*, http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938. (The website was accessed on March 7, 2019, but is not accessible by the public.)

VA also uses a star-rating system where facilities with a "5-star" rating are performing within the top 10 percent of facilities and "1-star" facilities are performing within the bottom 10 percent of facilities. Figure 6 describes the distribution of facilities by star rating.[32] As of June 30, 2018, the facility was rated as "5-star" for overall quality.

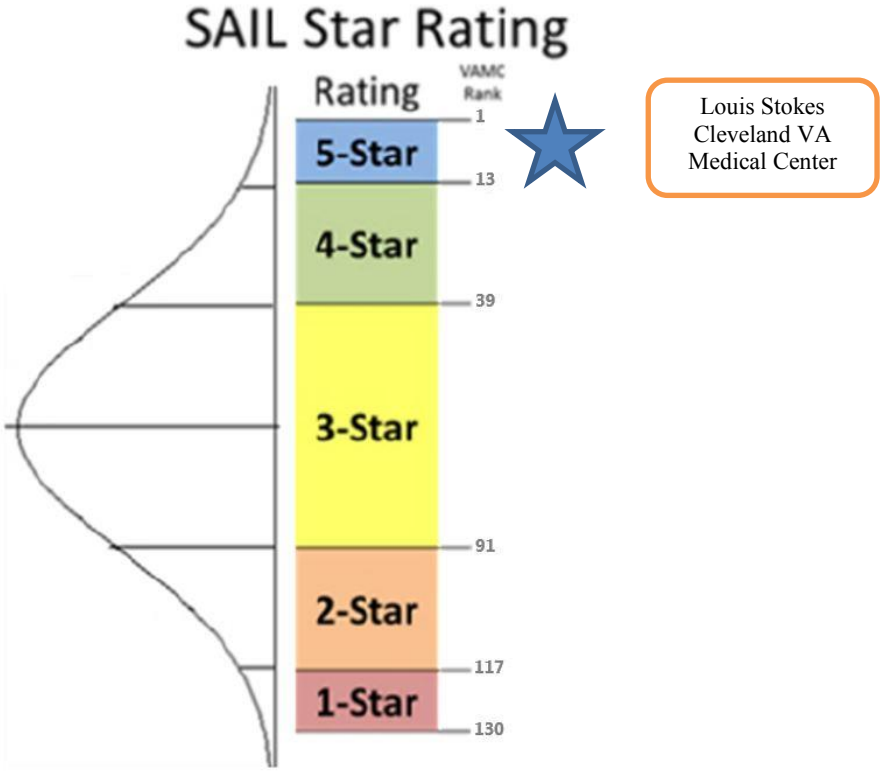

Figure 6. *Strategic Analytics for Improvement and Learning Star Rating Distribution* (*as of June 30, 2018*) *Source: VA Office of Informatics and Analytics Office of Operational Analytics and Reporting* (*accessed February 11, 2019*)

Figure 7 illustrates the facility's quality of care and efficiency metric rankings and performance compared with other VA facilities as of September 30, 2018. Of note, the figure uses blue and green data points to indicate high performance (for example, in the areas of rating (of) specialty care (SC) provider, physician capacity, and mental health (MH) continuity (of) care). Metrics that need improvement are denoted in orange and red (for example, complications, healthcare (HC) associated (assoc) infections, and admit reviews met).[33]

[32] According to the methods established by the SAIL Model, this is based on normal distribution ranking of the quality domain for 130 VA Medical Centers.

[33] For information on the acronyms in the SAIL metrics, please see Appendix D.

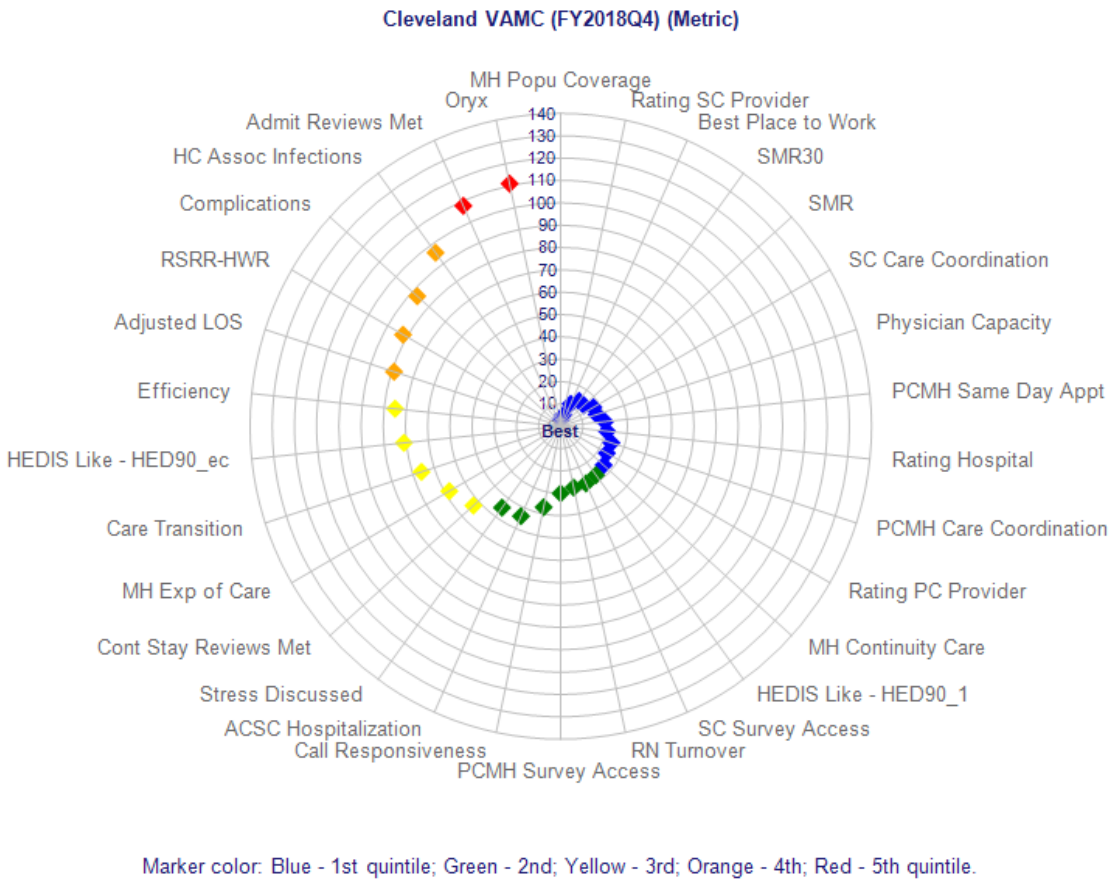

Figure 7. *Facility Quality of Care and Efficiency Metric Rankings* (*as of September 30, 2018*)
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. Also see Appendix C for sample outpatient performance measures that feed into these data points (such as wait times, discharge contacts, and where patient care is received). Data definitions are provided in Appendix D.

The SAIL Value Model also includes "SAIL CLC," which is a tool to summarize and compare the performance of CLCs in the VA. The SAIL model leverages much of the same data used in The Centers for Medicare & Medicaid Services' (CMS) *Nursing Home Compare*.[34] The SAIL CLC provides a single resource to review quality measures and health inspection results. It

[34] According to the Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers* (*CLC)*, August 22, 2019, "In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several "star" ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes."

includes star ratings for an unannounced survey, staffing, quality, and overall results.[35] Table 9 summarizes the rating results for the facility's CLC as of September 30, 2018. Although the facility has an overall "5-star" rating, its rating for quality is only a "3-star."

Table 9. Facility CLC Star Ratings (as of September 30, 2018)

Domain	Star Rating
Unannounced Survey	4
Staffing	5
Quality	3
Overall	5

Source: VHA Support Service Center

In exploring the reasons for the "3-star" quality rating, the OIG considered the radar diagram showing CLC performance relative to other CLCs for all 13 quality measures. Figure 8 illustrates the facility's CLC quality rankings and performance compared with other VA CLCs as of September 30, 2018. The figure uses blue and green data points to indicate high performance (for example, in the areas of catheter in bladder–long stay (LS), moderate-severe pain–short stay (SS), and new or worse pressure ulcers (PU) (SS)). Metrics that need improvement and were likely the reasons why the facility had a "3-star" for quality are denoted in orange and red (for example, urinary tract infection (UTI) (LS), improvement in function (SS), and high risk pressure ulcer (PU) (LS)).[36]

[35] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated August 22, 2019). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on September 3, 2019, but is not accessible by the public.)

[36] For data definitions of acronyms in the SAIL CLC measures, please see Appendix E.

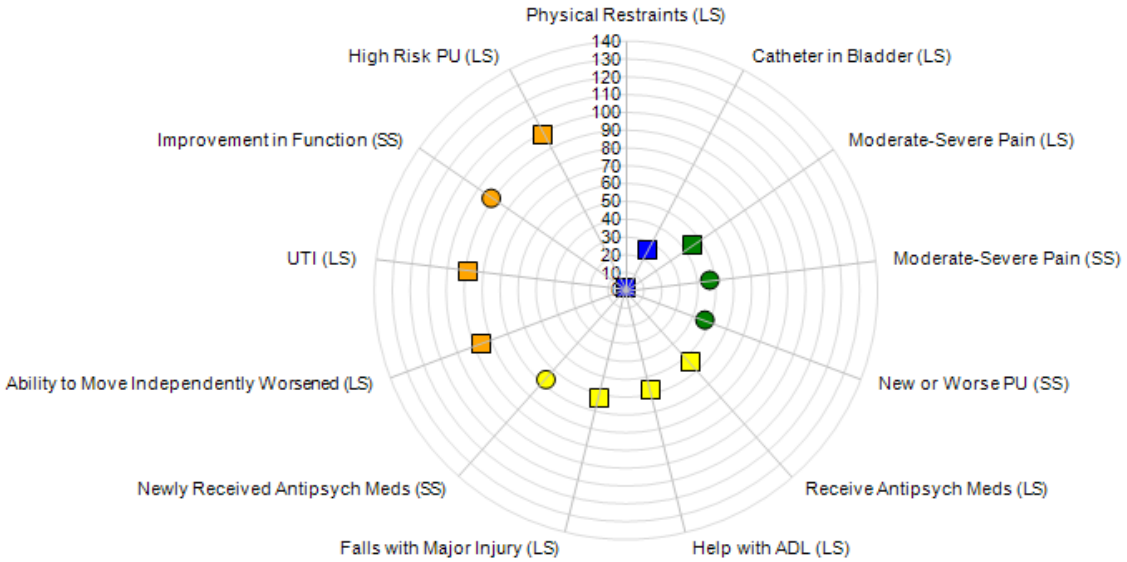

Figure 8. *Facility CLC Quality Measure Rankings (as of September 30, 2018)*
LS = Long-Stay Measure *SS = Short-Stay Measure*
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix E.

Leadership and Organizational Risks Conclusion

The facility's executive leadership team appeared relatively stable, with one of the five positions permanently filled less than six months prior to the OIG's inspection. Except for the chief of staff and associate director, selected survey scores related to employees' satisfaction with the facility executive leaders were generally similar to or better than VHA averages. Patient experience survey data revealed that scores related to satisfaction with the facility were above VHA averages. The facility leaders appeared actively engaged with employees and patients and were working to sustain and further improve employee and patient engagement and satisfaction. The leaders seemed to support efforts to improve and maintain patient safety, quality care, and other positive outcomes (such as initiating plans to maintain positive perceptions of the facility through active stakeholder engagement). The OIG reviewed accreditation agency findings, sentinel events, disclosures of adverse patient events, and patient safety indicator data and identified organizational risks and was concerned that three of five sentinel events since the last OIG Combined Assessment Program review were related to surgical procedures. Additionally, the facility did not have a consistent process to capture, track, and trend or identify opportunities for improvement in response to patient safety indicator data. The leadership team was knowledgeable, within their scope of responsibility, about selected SAIL and CLC metrics but should continue to take actions to sustain and improve performance of measures contributing to the facility SAIL "5-star" and CLC "3-star" quality ratings.

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care that involves coordinating care among members of the healthcare team. To meet this goal, VHA must foster a culture of integrity and accountability in which personnel are vigilant and mindful, proactively risk-aware, and committed to consistently providing quality care, while seeking continuous improvement.[37] VHA also strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.[38] VHA requires that its facilities operate a quality, safety, and value (QSV) program to monitor the quality of patient care and performance improvement activities.[39]

In determining whether the facility implemented and incorporated several OIG-selected key functions of VHA's Enterprise Framework for QSV into local activities, the inspection team evaluated protected peer reviews of clinical care,[40] utilization management (UM) reviews,[41] patient safety incident reporting with related root cause analyses,[42] and cardiopulmonary resuscitation (CPR) episode reviews.[43]

When conducted systematically and credibly, protected peer reviews reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and

[37] VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. (This VHA directive was scheduled for recertification on or before the last working day of August 2018 but was rescinded on October 24, 2019.)

[38] Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 2014.

[39] VHA Directive 1026.

[40] The definition of a peer review can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a critical review of care, performed by a peer, to evaluate care provided by a clinician for a specific episode of care, to identify learning opportunities for improvement, to provide confidential communication of the results back to the clinician, and to identify potential system or process improvements.

[41] The definition of utilization management can be found within VHA Directive 1117(1), *Utilization Management Program*, July 9, 2014 (amended January 18, 2018). Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria." The January 2018 version of the directive was in effect at the time of the March 2019 review. Subsequently, the directive was replaced by VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019), which expired on July 31, 2019. The utilization management definition remained consistent in both versions of the directive.

[42] The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. (This VHA handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.) A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

[43] VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018.

nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.[44]

The UM program, a key component of VHA's framework for quality, safety, and value, provides vital tools for managing the quality and the efficient use of resources. It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.[45]

Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the facility.[46]

VHA has also issued guidance to support its strategic priority of providing personalized, proactive, patient-driven care and to ensure that the provision of life-sustaining treatments, including CPR, is aligned with patients' values, goals, and preferences. VHA requires that each facility establishes a CPR Committee or equivalent that fully reviews each episode of care in which resuscitation was attempted. The ongoing review and analysis of high-risk healthcare processes is essential for ensuring patient safety and the provision of high-quality care. VHA also has established requirements for basic life support and advanced cardiac life support training and certification for clinicians responsible for administering life-sustaining treatments.[47]

The OIG interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents. Specifically, OIG inspectors evaluated the following performance indicators:[48]

- Protected peer reviews
    - Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
    - Implementation of improvement actions recommended by the Peer Review Committee
    - Completion of final reviews within 120 calendar days

[44] VHA Directive 1190.

[45] VHA Directive 1117(1).

[46] VHA Handbook 1050.01.

[47] VHA Directive 1177, VHA Handbook 1004.03, *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients' Values, Goals and Preferences*, January 11, 2017.

[48] For CHIP reviews, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

  - Quarterly review of Peer Review Committee's summary analysis by the Medical Executive Committee
  - Peer review of all applicable deaths within 24 hours of admission to the hospital
  - Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[49]
- UM
  - Completion of at least 75 percent of all required inpatient reviews
  - Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database
  - Interdisciplinary review of UM data
- Patient safety
  - Annual completion of a minimum of eight root cause analyses[50]
  - Inclusion of required content in root cause analyses (generally)
  - Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
  - Provision of feedback about root cause analysis actions to reporting employees
  - Submission of annual patient safety report to facility leaders
- Resuscitation episode review
  - Evidence of a committee responsible for reviewing resuscitation episodes
  - Confirmation of actions taken during resuscitative events being consistent with patients' wishes
  - Evidence of basic or advanced cardiac life support certification for code team responders
  - Evaluation of each resuscitation episode by the CPR Committee or equivalent

[49] VHA Directive 1190.

[50] According to VHA Handbook 1050.01, "the requirement for a total of eight [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of [root cause analyses] is driven by the events that occur and the [Safety Assessment Code] SAC score assigned to them. At least four analyses per fiscal year must be individual [root cause analyses], with the balance being Aggregated Reviews or additional individual [root cause analyses]."

Quality, Safety, Value Conclusion

The OIG found general compliance with requirements for patient safety. However, the OIG team identified concerns with the facility's implementation of improvement actions recommended by the Peer Review Committee, peer review of all applicable deaths within 24 hours of admission, interdisciplinary review of utilization management (UM) data, and evidence of basic or advanced cardiac life support certification for code team responders that warranted recommendations for improvement.

Specifically, VHA requires that when the Peer Review Committee recommends individual improvement actions, clinical managers implement those actions.[51] The OIG found that in 5 of 13 peer reviews conducted that documented a need for improvement actions, there was a lack of evidence that clinical managers implemented the individual actions. This likely prevented immediate and long-term improvements in the practice of one or multiple healthcare providers. The chief of Quality, Safety, and Improvement cited the reasons for noncompliance as a staffing issue and lack of attention to detail.

Recommendation 1

1. The chief of staff confirms that clinical managers consistently implement Peer Review Committee's recommended improvement actions and monitors managers' compliance.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: The Chief of Staff worked with the Peer Review Program Manager to develop a robust process for tracking improvement actions to completion. The Chief of Staff or designee reviews outstanding action items at the beginning of each meeting until closure of each item. The Peer Review Program Manager tracks improvement actions via a redesigned action tracker to ensure a minimum of 90 percent or greater compliance is demonstrated for six consecutive months. Service level compliance and timely closeout of actions will be monitored by the Peer Review Program Manager.

Additionally, VHA requires that peer reviews are completed for all applicable deaths within 24 hours of admission.[52] From February 11, 2018, through February 11, 2019, the OIG noted that two of six deaths within 24 hours of admission were not peer reviewed. This resulted in missed opportunities to identify and address potential improvement needs for clinical practice and organizational performance.[53] The chief of Quality, Safety, and Improvement cited the vacancy

[51] VHA Directive 1190.
[52] VHA Directive 1190.
[53] VHA Directive 1190.

in the peer review coordinator position in 2018 as the reason for noncompliance. Because coverage by a Quality, Safety, and Improvement nurse was a collateral duty assignment, the peer review program did not receive sufficient attention.

Recommendation 2

2. The chief of staff verifies that all applicable deaths within 24 hours of admission are peer reviewed and monitors Peer Review Committee's compliance.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: The Chief of Quality, Safety, and Improvement established a back-up position to support the Peer Review program in September 2019. The newly established position will review compliance with all applicable deaths being reviewed within 24 hours of admission. Compliance will be monitored by the Peer Review Program Manager until 90 percent compliance or greater is demonstrated for six consecutive months. Compliance will be reported monthly to the Medical Executive Committee (MEC) Peer Review Committee.

VHA requires interdisciplinary review of UM data. This process must include, but is not limited to, participation by representatives from UM, medicine, nursing, social work, case management, mental health, and chief Business Office revenue utilization review.[54] From January 2018 through December 2018, UM data was analyzed by two interdisciplinary committees and the Executive Leadership Board (fiscal year 2018, quarters two and three). The facility reported the development of a new committee, the Utilization Management Committee (a subcommittee of the Executive Leadership Board), which reviewed UM data for fiscal year 2018, quarter four and fiscal year 2019, quarter one. The OIG reviewed minutes from both committees and found inconsistent representation from UM, social work, case management, mental health, and revenue utilization review. This resulted in lack of expertise in the review and analysis of UM data. The UM quality, safety and improvement nurse cited the reason for noncompliance as inattention to program requirements.

Recommendation 3

3. The chief of staff makes certain that all required representatives consistently participate in interdisciplinary reviews of utilization management data and monitors representatives' compliance.

[54] VHA Directive 1117(1).

Facility concurred.

Target date for completion: June 30, 2020

Facility response: The Utilization Management Committee was redesigned by the Deputy Chief of Staff to ensure attendance of all required members or designees at monthly meetings. The Utilization Management Program Manager will audit required multi-disciplinary attendance to ensure compliance of 90 percent or greater for six consecutive months. Compliance falling below the threshold will be reported monthly to the Executive Leadership Board.

VHA requires that clinical staff are trained in basic or advanced cardiac life support to appropriately respond to resuscitation events.[55] The OIG found that in 2 of the 10 resuscitation episodes reviewed, two medical/surgical resident physician resuscitation code leaders lacked evidence of basic or advanced cardiac life support certification. This resulted in the facility not having properly trained physician providers responding to resuscitation events. The facility co-chairs of the Cardiopulmonary Committee contacted the university affiliate for confirmation of advanced cardiac life support/basic life support certification for the noncompliant medical/surgical residents. However, confirmation was not provided because the affiliate no longer had the records. The chief of Quality, Safety, and Improvement cited the reason for noncompliance as lack of attention to detail.

Recommendation 4

4. The chief of staff verifies that clinical staff responding to resuscitation events have the required basic or advanced cardiac life support certification and monitors compliance.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: A process for obtaining written proof of basic or advanced cardiac life support certification with affiliate hospitals has been established by the Chief of Staff. The Chief Nurse, Education will conduct a monthly audit to ensure compliance of 100 percent for six consecutive months. Compliance falling below the threshold will be reported monthly to the Medical Executive Council.

[55] VHA Directive 1177.

Medical Staff Privileging

VHA has defined procedures for the clinical privileging of "all healthcare professionals who are permitted by law and the facility to practice independently"—"without supervision or direction, within the scope of the individual's license, and in accordance with individually granted clinical privileges." These healthcare professionals are also referred to as licensed independent practitioners (LIPs).[56]

Clinical privileges need to be specific, based on the individual's clinical competence. They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the director. Clinical privileges are granted for a period not to exceed two years, and LIPs must undergo re-privileging prior to their expiration.[57]

VHA defines the focused professional practice evaluation (FPPE) as "a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance. The FPPE typically occurs at the time of initial appointment to the medical staff or the granting of new, additional privileges." "The on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered."[58]

According to TJC, the "FPPE for Cause" should be used when a question arises regarding a privileged provider's ability to deliver safe, high-quality patient care. The "FPPE for Cause" is limited to a particular time frame and customized to the specific provider and related clinical concerns.[59] Federal law requires VA facilities to report to the National Practitioner Data Bank when facilities take adverse clinical privileging actions, accept the surrender of clinical privileges, or restrict clinical privileges when the action is related to professional competence or professional conduct of LIPs.[60]

To determine whether the facility complied with requirements for privileging, the OIG interviewed key managers and selected and reviewed the privileging folders of several medical staff members:

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[56] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. (This VHA handbook was scheduled for recertification on or before the last working date of October 2017 and has not been recertified.)

[57] VHA Handbook 1100.19.

[58] VHA Handbook 1100.19.

[59] Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2).

[60] VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. (This VHA handbook was scheduled for recertification on or before the last working date of December 2014 and has not been recertified.)

- Eight solo or few (less than two in a specialty) practitioners hired within 18 months before the site visit or were privileged within the prior 12 months[61]
- Ten LIPs hired within 18 months before the site visit
- Twenty LIPs re-privileged within 12 months before the visit
- Six providers who underwent a FPPE for cause within 12 months prior to the visit

The OIG evaluated the following performance indicators:

- Privileging
  - Privileges requested by the provider
    - Facility-specific
    - Service-specific
    - Provider-specific[62]
  - Approval of privileges for a period of less than, or equal to, two years
- Focused professional practice evaluations
  - Criteria defined in advance
  - Use of required criteria in FPPEs for selected specialty LIPs
  - Results and time frames clearly documented
  - Evaluation by another provider with similar training and privileges
  - Executive Committee of the Medical Staff's consideration of FPPE results in its decision to recommend continuing the initially granted privileges
- Ongoing professional practice evaluations
  - Criteria specific to the service or section
  - Use of required criteria in OPPEs for selected specialty LIPs

[61] The 18-month period was from September 18, 2017, through March 18, 2019. The 12-month review period covered March 18, 2018, through March 18, 2019. VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers "few practitioners" as being fewer than three providers in the facility that are privileged in a particular specialty.

[62] According to VHA Handbook 1100.19, facility-specific means that privileges are granted only for procedures and types of services performed at the facility; service-specific refers to privileges being granted in a specific clinical service, such as neurology; and provider-specific means that the privileges should be granted to the individual provider based on their clinical competence and capabilities.

  - Service chief's determination to recommend continuation of current privileges was based in part on the results of OPPE activities
  - Evaluation by another provider with similar training and privileges
  - Executive Committee of the Medical Staff's decision to recommend continuing privileges based on OPPE results
- Focused professional practice evaluations for cause
  - Clearly defined expectations/outcomes
  - Time-limited
  - Provider's ability to practice independently not limited for more than 30 days
  - Shared with the provider in advance
- Reporting of privileging actions to National Practitioner Data Bank

Medical Staff Privileging Conclusion

Generally, the facility achieved the performance indicators listed above. The OIG made no recommendations.

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct environment of care inspection rounds and resolve issues in a timely manner. The goal of the environment of care program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional but should also promote healing.[63]

The purpose of this facet of the OIG inspection was to determine whether the facility maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the facility met requirements in selected areas that are often associated with higher risks of harm to patients, such as in the locked inpatient mental health unit. The inspection team also looked at facility compliance with emergency management processes.[64]

VHA requires its facilities to have the "capacity for [providing] mental health services for veterans with acute and severe emotional and/or behavioral symptoms causing a safety risk to self or others, and/or resulting in severely compromised functional status. This level of care is typically provided in an inpatient setting;" however, for facilities that do not have inpatient mental health services, that "capacity" could mean facilitating care at a nearby VA or non-VA facility.[65]

VHA requires managers to establish a comprehensive emergency management program to ensure the continuity of patient care and hospital operations in the event of a natural disaster or other emergency. This includes conducting a hazard vulnerability analysis and developing an emergency operations plan. These requirements are meant to support facilities' efforts to identify and minimize harm from potential hazards, threats, incidents, and events related to healthcare and other essential services.[66] Managers must also develop utility management plans to increase reliability and reduce failures of electrical power distribution systems in accordance with TJC,[67]

[63] VHA Directive 1608, *Comprehensive Environment of Care (CEOC Program)*, February 1, 2016.

[64] Applicable requirements for high-risk areas and emergency management include those detailed in or by various VHA Directives, Joint Commission hospital accreditation standards, Occupational Safety and Health Administration, American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI), and National Fire Protection Association (NFPA).

[65] VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013. (This VHA handbook was scheduled for recertification on or before the last working date of September 2018 and has not been recertified.)

[66] VHA Directive 0320.01, *Veterans Health Administration Comprehensive Emergency Management Program (CEMP) Procedures*, April 6, 2017.

[67] VHA Directive 1028, *Electrical Power Distribution Systems*, July 25, 2014. (This VHA directive was scheduled for recertification on or before the last working date of July 2019 and has not been recertified.)

Occupational Safety and Health Administration,[68] and National Fire Protection Association standards.[69] The provision of sustained electrical power during disasters or emergencies is critical to healthcare facility operations.[70]

In all, the OIG team inspected 15 areas— medical/surgical units (4B, 5A), intensive care units (medical and surgical), community living centers (3rd floor, 4th floor, 5th floor), post-anesthesia care unit, emergency department, primary care clinic (1st floor), women's health, spinal cord injury, domiciliary, mental health, and psychosocial rehabilitation and recovery center. The team also inspected the Sandusky VA Clinic. The inspection team reviewed relevant documents and interviewed key employees and managers. The OIG evaluated the following location-specific performance indicators:

- Parent facility
  - General safety
  - Environmental cleanliness and infection prevention
  - General privacy
  - Women veterans program
  - Availability of medical equipment and supplies
- Community based outpatient clinic
  - General safety
  - Environmental cleanliness and infection prevention
  - General privacy
  - Women veterans program
  - Availability of medical equipment and supplies
- Locked inpatient mental health unit
  - Mental health environment of care rounds
  - Nursing station security

[68] The Occupational Safety and Health Administration (OSHA) is part of the US Department of Labor. OSHA's mission is to assure safe and healthy working conditions "by setting and enforcing standards and by providing training, outreach, education, and assistance." https://www.osha.gov/about.html. (This website was accessed on June 28, 2018.)

[69] The National Fire Protection Association (NFPA) is a global nonprofit organization "devoted to eliminating death, injury, property, and economic loss due to fire, electrical, and related hazards." https://www.nfpa.org/About-NFPA. (This website was accessed on June 28, 2018.)

[70] TJC. Environment of Care standard EC.02.05.07.

  - Public area and general unit safety
  - Patient room safety
  - Infection prevention
  - Availability of medical equipment and supplies
- Emergency management
  - Hazard vulnerability analysis (HVA)
  - Emergency operations plan (EOP)
  - Emergency power testing and availability

Environment of Care Conclusion

The representative community based outpatient clinic and the facility's emergency management program met the performance indicators evaluated. The OIG did not note any issues with the availability of medical equipment and supplies. However, the team identified noncompliance with medication safety in two of the patient care areas inspected and general safety in the locked mental health inpatient unit seclusion room that warranted recommendations for improvement.

VHA requires multi-dose medications to be labeled with an expiration date upon opening.[71] In the two CLC units inspected,[72] the OIG team found open and undated multi-dose tuberculin skin test vials in medication refrigerators. This resulted in the lack of assurance of safe medication administration. Facility managers stated that nursing staff were aware of the requirements but did not follow medication safety procedures.

Recommendation 5

5. The associate director for Patient Care Services makes certain that nursing staff label multi-dose medication vials with an expiration date upon opening and monitors staff compliance.

[71] VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017.

[72] Community Living Centers 3rd and 4th floors.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: Nurse Managers conduct daily rounds on each unit to ensure expired medications are removed or returned to the pharmacy. Compliance will be monitored with a goal of 90 percent or greater for six consecutive months. Monthly reports to ensure sustained compliance will be given to the Associate Director for Patient Care Services and to the Environment of Care Committee.

In addition, VHA requires inpatient mental health seclusion rooms be designed to prevent patient injury. This includes floors which must be "made of a material that provides cushioning."[73] In the locked inpatient mental health unit, the OIG noted that the seclusion room floor lacked cushioning. This could harm patients or staff in the event of a fall. The chief of Engineering explained that an environment of care rounds inspection team and an external consultant recommended against installing cushion flooring because patients picked at the flooring, which they considered a safety issue. Facility managers were aware of the requirements and reported waiting for a signed waiver for the flooring, which was subsequently denied by the VA National Center for Patient Safety.

Recommendation 6

6. The associate director directs the chief of Engineering to ensure the flooring in the locked mental health unit seclusion room provides cushioning and monitors the chief's compliance.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: The Chief, Engineering and Patient Safety Manager are working through the contracting process to determine which product is the safest option for cushioning the floor in the locked mental health unit seclusion room. A monthly status update will be presented to the Executive Leadership Board until the project is completed.

[73] VHA Directive 1167, *Mental Health Environmental of Care Checklist for Mental Health Units Treating Suicidal Patients*, May 12, 2017.

Medication Management: Controlled Substances Inspection Program

The Controlled Substances Act divides controlled drugs into five categories based on whether they have an accepted medical treatment use in the United States, their relative potential for abuse, and the likelihood of causing dependence if abused.[74] Diversion of controlled substances by healthcare workers—the transfer of legally prescribed controlled substances from the prescribed individual to others for illicit use—remains a serious problem that can increase patient safety issues and elevate the liability risk to healthcare facilities.[75]

VHA requires that facility managers implement and maintain a controlled substances inspection program to minimize the risk for loss and diversion and to enhance patient safety. Requirements include the appointment of controlled substances coordinator(s) and controlled substances inspectors, implementation of procedures for inventory control, and inspections of the pharmacy and clinical areas with controlled substances.[76]

To determine whether the facility complied with requirements related to controlled substances security and inspections, the OIG team interviewed key managers and reviewed inspection reports; monthly summaries of findings, including discrepancies, provided to the facility director; inspection quarterly trend reports for the prior two completed quarters;[77] and other relevant documents. The OIG evaluated the following performance indicators:

- Controlled substances coordinator reports
  - Monthly summary of findings to the director
  - Quarterly trend reports to the director
  - Quality Management Committee's review of monthly and quarterly trend reports
  - Actions taken to resolve identified problems
- Pharmacy operations
  - Staff restrictions for monthly review of balance adjustments[78]
- Requirements for controlled substances inspectors

[74] Drug Enforcement Agency Controlled Substance Schedules. https://www.deadiversion.usdoj.gov/schedules/. (The website was accessed on March 7, 2019.)

[75] American Society of Health-System Pharmacists, "ASHP Guidelines on Preventing Diversion of Controlled Substances," *American Journal of Health-System Pharmacists,* 74, no. 5 (March 1, 2017): 325-348.

[76] VHA Directive 1108.02(1), *Inspection of Controlled Substances*, November 28, 2016 (amended March 6, 2017).

[77] The two quarters were from July 1, 2018, through December 31, 2018.

[78] Controlled substances balance adjustment reports list transactions in which the pharmacy vault inventory balance was manually adjusted.

  - No conflicts of interest
  - Appointed in writing by the director for a term not to exceed three years
  - Hiatus of one year between any reappointment
  - Completion of required annual competency assessment
- Controlled substances area inspections
  - Completion of monthly inspections
  - Rotations of controlled substances inspectors
  - Patterns of inspections
  - Completion of inspections on day initiated
  - Reconciliation of dispensing between pharmacy and each dispensing area
  - Verification of controlled substances orders
  - Performance of routine controlled substances inspections
- Pharmacy inspections
  - Monthly physical counts of the controlled substances in the pharmacy
  - Completion of inspections on day initiated
  - Security and verification of drugs held for destruction[79]
  - Accountability for all prescription pads in pharmacy
  - Verification of hard copy controlled substances prescriptions
  - Verification of 72-hour inventories of the main vault
  - Quarterly inspections of emergency drugs
  - Monthly checks of locks and verification of lock numbers
- Facility review of override reports[80]

[79] According to VHA Directive 1108.02(1), the Destructions File Holding Report "lists all drugs awaiting local destruction or turn-over to a reverse distributor." Controlled substances inspectors "must verify there is a corresponding sealed evidence bag containing drug(s) for each destruction holding number on the report."

[80] When automated dispensing cabinets are used, nursing staff can override and remove medications prior to the pharmacists' review of medications ordered by the providers.

Medication Management Conclusion

Generally, the facility achieved the performance indicators listed above. The OIG made no recommendations.

Mental Health: Military Sexual Trauma Follow-Up and Staff Training

The Department of Veterans Affairs uses the term "military sexual trauma" (MST) to refer to a "psychological trauma, which in the judgment of a mental health professional employed by the Department [of Veterans Affairs], resulted from a physical assault of a sexual nature, battery of a sexual nature, or sexual harassment which occurred while the Veteran was serving on active duty, active duty for training, or inactive duty training."[81] "MST is an experience, not a diagnosis or a mental health condition." Although posttraumatic stress disorder is commonly associated with MST, other frequently associated diagnoses include depression and substance use disorders.[82]

VHA requires that the facility director designates an MST coordinator to support national and VISN-level policies related to MST-related care and serve as a source of information; establish and monitor MST-related staff training and informational outreach; and communicate MST-related issues, services, and initiatives with leadership.[83] Additionally, the facility director is responsible for ensuring that MST-related data are tracked and monitored.[84]

VHA requires that all veterans and potentially eligible individuals seen in VHA facilities be screened for experiences of MST with the required MST clinical reminder in the computerized patient record system.[85] Those who screen positive must have access to appropriate MST-related care.[86] VHA also requires that evidence-based mental health care be available to all veterans with mental health conditions related to MST. Patients requesting or referred for mental health services must receive an initial evaluation within 24 hours of the referral to identify urgent care needs and a more comprehensive diagnostic evaluation within 30 days.[87]

The MST coordinator may provide clinical care to individuals experiencing MST and is thus subject to the same mandatory training requirements as mental health and primary care providers.[88] All mental health and primary care providers must complete MST mandatory

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[81] VHA Directive 1115, *Military Sexual Trauma (MST) Program*, May 8, 2018.

[82] Military Sexual Trauma. https://www.mentalhealth.va.gov/docs/mst_general_factsheet.pdf. (The website was accessed on November 17, 2017.)

[83] VHA Directive 1115.

[84] VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics,* September 11, 2008 (amended November 16, 2015). (This VHA handbook was scheduled for recertification on or before the last working date of September 2013 and has not been recertified.)

[85] VHA Directive 1115 states that "MST-related care is not subject to the minimum active duty service requirement set forth in 38 U.S.C. 5303A; Veterans may therefore be able to receive MST-related care even if they are not eligible for VA health care under other treatment authorities."

[86] VHA Directive 1115.

[87] VHA Handbook 1160.01.

[88] VHA Directive 1115.

training; for those hired after July 1, 2012, this training must be completed no later than 90 days after assuming their position.[89]

To determine whether the facility complied with the requirements related to MST follow-up and training, the OIG inspection team reviewed relevant documents and staff training records and interviewed key employees. The team also reviewed the electronic health records of 50 outpatients who had a positive MST screen from July 1, 2017, through June 30, 2018. The OIG evaluated the following performance indicators:

- Designated facility MST coordinator
  - Establishes and monitors MST-related staff training
  - Establishes and monitors informational outreach
  - Communicates MST-related issues, services, and initiatives with local leaders
- Evidence of tracking MST-related data
- Provision of clinical care
  - Referral for MST-related care to patients with positive MST screens
  - Initial evaluation within 24 hours of referral for mental health services
  - Comprehensive diagnostic and treatment planning evaluation within 30 days of referral for mental health services
- Completion of MST mandatory training requirement for mental health and primary care providers

Mental Health Conclusion

Generally, the OIG inspection team found compliance with many of the performance indicators, including the designation of an MST coordinator, tracking of MST-related data, and provision of clinical care. However, the inspection team noted a deficiency with mental health and primary care providers completing MST mandatory training requirements that warranted a recommendation for improvement.

Specifically, VHA requires that all mental health and primary care providers complete MST mandatory training; for those hired after July 1, 2012, this training must be completed no later

[89] VHA Directive 1115.01, *Military Sexual Trauma (MST) Mandatory Training and Reporting Requirements for VHA Mental Health and Primary Care Providers*, April 14, 2017; Acting Deputy Under Secretary for Health for Operations and Management Memorandum, *Compliance with Military Sexual Trauma (MST) Mandatory Training for Mental Health and Primary Care Providers*, February 2, 2016.

than 90 days after entering their position."[90] The OIG team found that 2 of 11 providers hired after July 1, 2012, did not complete the training within 90 days and 2 of 20 providers did not complete the training at all. This could prevent providers from administering appropriate counseling, care, and service to veterans who experienced MST. The MST coordinator stated the current process to track noncompliance for mandatory MST training did not use detailed parameters to monitor mandatory training.

Recommendation 7

7. The chief of staff makes certain that providers complete military sexual trauma mandatory training within the required time frame and monitors providers' compliance.

Facility concurred.

Target date for completion: January 31, 2020

Facility response: The Chief of Staff continues to ensure compliance with the military sexual trauma training mandate. The Military Sexual Trauma Coordinator receives automated reports which specify staff who are approaching their due date and those who are delinquent with the training requirement on a monthly basis. The Military Sexual Trauma Coordinator contacts the appropriate Service Chief to ensure completion of military sexual trauma training by their staff. Compliance will be monitored with a goal of 90 percent or greater for six consecutive months and reported to the Mental Health Council, a sub-council of the Medical Executive Council.

[90] Acting Deputy Under Secretary for Health for Operations and Management Memorandum refers to specific MST training requirements for providers assuming their position before or after July 1, 2012.

Geriatric Care: Antidepressant Use among the Elderly

VA's National Registry for Depression reported that "11 [percent] of veterans aged 65 years and older have a diagnosis of major depressive disorder."[91] The VA/DoD Clinical Practice Guideline (CPG) describes depression as "a common mental disorder that presents with depressed mood, loss of interest or pleasure in regular activities, decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, and poor concentration." This can lead to poor quality of life, decreased productivity, and increased mortality from suicide.[92]

According to the Centers for Disease Control and Prevention, older adults are at increased risk for experiencing depression because "80 [percent] of older adults have at least one chronic health condition and 50 [percent] have two or more." Further, "most older adults see an improvement in [their] symptoms when treated with antidepression drugs, psychotherapy, or a combination of both."[93]

The American Geriatrics Society revised the Beers Criteria in 2015 to include lists of potentially inappropriate medications to be avoided. Potentially inappropriate medication use in older adults continues to be associated with confusion, falls, and mortality.[94] The criteria provide guidelines that help to improve the safety of prescribing certain medications including antidepressants for older adults.

TJC requires clinicians to educate patients and families about the "safe and effective use of medications."[95] In 2015, VHA outlined essential medical information "necessary for review, management, and communication of medication information" with patients, caregivers, and their healthcare teams.[96] Further, TJC requires clinicians to perform medication reconciliation by comparing the medication a patient is actually taking to the new medications that are ordered for the patient and resolving any discrepancies.[97] The CPG recommends that clinicians monitor patients monthly after therapy initiation or a change in treatment until the patient achieves

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[91] Hans Peterson, "Late Life Depression," *U.S. Department of Veterans Affairs*, Mental Health Featured Article, March 1, 2011. https://www.mentalhealth.va.gov/featureArticle_Mar11LateLife.asp. (The website was accessed on March 8, 2019.)

[92] *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*, April 2016. https://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf. (The website was accessed November 20, 2018.)

[93] Centers for Disease Control and Prevention, "Depression is Not a Normal Part of Growing Older," January 31, 2017. https://www.cdc.gov/aging/mentalhealth/depression.htm. (The website was accessed on March 8, 2019.)

[94] American Geriatrics Society 2015 Beers Criteria Update Expert Panel, "American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults." http://www.sigot.org/allegato_docs/1057_Beers-Criteria.pdf. (The website was accessed on March 22, 2018.)

[95] TJC. Provision of Care, Treatment, and Services standard PC.02.03.01.

[96] VHA Directive 1164, *Essential Medication Information Standards*, June 26, 2015.

[97] TJC. National Patient Safety Goal standard NPSG.03.06.01.

remission. Monitoring includes assessment of symptoms, adherence to medication and psychotherapy, and any adverse effects. The CPG also recommends that treatment planning includes patient education about treatment options, including risks and benefits.[98]

To determine whether the facility complied with requirements concerning use of antidepressants among the elderly, the OIG inspection team interviewed key employees and managers. The team also reviewed the electronic health records of 41 randomly selected patients, ages 65 and older, who were newly prescribed one of seven selected antidepressant medications from July 1, 2017, through June 30, 2018.[99] The OIG evaluated the following performance indicators:

- Justification for medication initiation
- Evidence of patient and/or caregiver education specific to the medication prescribed
- Clinician evaluation of patient and/or caregiver understanding of the education provided
- Medication reconciliation

Geriatric Care Conclusion

The OIG team found general compliance with providers documenting reasons for medication initiation and completing medication reconciliation. However, the inspection team found inadequate patient and/or caregiver education related to newly prescribed medications and inconsistent evaluation of the education provided that warranted recommendations for improvement.

TJC requires that clinicians educate patients and families about safe and effective use of medications prior to administration and evaluate patient/caregiver understanding of the education provided.[100] The OIG estimated that clinicians provided this education to 68 percent of the patients at the facility, based on electronic health records reviewed.[101] In addition, the OIG estimated that clinicians evaluated patient/caregiver understanding of education provided for 64 percent of the patients at the facility, based on the records where education was provided.[102] This resulted in patients and/or caregivers not having the essential information to safely manage their own health at home. Clinical managers were aware of the requirements and cited the reasons for

[98] *VA/DoD Clinical Practice Guidelines for the Management of Major Depressive Disorder*.

[99] The seven selected antidepressant medications are amitriptyline, clomipramine, desipramine, doxepin (>6mg/day), imipramine, nortriptyline, and paroxetine.

[100] TJC. Medication Management standard MM.06.01.01.

[101] The OIG is 95 percent confident that the true compliance rate is somewhere between 53.6 and 82.1 percent, which is statistically significantly below the 90 percent benchmark.

[102] The OIG is 95 percent confident that the true compliance rate is somewhere between 46.3 and 81.6 percent, which is statistically significantly below the 90 percent benchmark.

noncompliance as inconsistent documentation methods and limited administrative time for clinicians.

Recommendation 8

8. The chief of staff makes certain that clinicians provide and document patient and/or caregiver education and evaluate understanding of education provided specific to newly prescribed medications and monitors clinicians' compliance.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: The Chief of Staff will reinforce clinician accountability for providing and documenting patient and/or caregiver education by monitoring results of a monthly random audit of the electronic health records of 30 randomly selected patients, ages 65 and older, who were newly prescribed one of seven selected antidepressant medications during their most recent visit. The medical record audit tool was developed by the Quality, Safety, and Improvement department to monitor compliance with a goal of 90 percent or greater for six consecutive months. Audit results and barriers to compliance will be discussed with the Clinical Service Chiefs at the monthly Medical Executive Council.

Women's Health: Abnormal Cervical Pathology Results Notification and Follow-Up

Each year, about 12,000 women in the United States are diagnosed with cervical cancer.[103] Human papillomavirus (HPV) can be transmitted during sexual contact and is the main cause of cervical cancer.[104] In addition to HPV infection, other risk factors for cervical cancer include smoking, human immunodeficiency virus (HIV) infection, use of oral contraceptives for five or more years, and having given birth to three or more children.[105] Cervical cancer is highly preventable through diligent screening and vaccination efforts. With early detection, it is very treatable and associated with optimal patient outcomes.[106]

VA is authorized to provide "gender-specific services, such as Papanicolaou tests (Pap smears)," to eligible women veterans. Further, VHA requires that all eligible and enrolled women veterans have access to appropriate services and preventative care. That care would include age-appropriate screening for cervical cancer.[107]

VHA requires that each facility have a "full-time Women Veterans Program Manager (WVPM) to execute comprehensive planning for women's health care." VHA also requires a medical director or clinical champion to be responsible for the clinical oversight of the women's health program. Each facility must also have a "Women Veterans Health Committee (WVHC) comprised of appropriate facility leadership and program directors, which develops and implements a Women's Health Program strategic plan." The Women Veterans Health Committee must meet at least quarterly and report to the executive leaders. The facility must also have a process to ensure the collecting and tracking of data related to cervical cancer screenings.[108]

VHA has established time frames for notifying patients of abnormal cervical pathology results. Abnormal cervical pathology results must be communicated to patients within seven calendar days from the date the results are available to the ordering provider. Communication of the

[103] Centers for Disease Control and Prevention. "Cervical Cancer" *Inside Knowledge* fact sheet, December 2016. https://www.cdc.gov/cancer/cervical/pdf/cervical_facts.pdf. (The website was accessed on February 28, 2018.)

[104] Centers for Disease Control and Prevention. *Basic Information About Cervical Cancer*, February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/index.htm. (The website was accessed on March 8, 2019.)

[105] Centers for Disease Control and Prevention. *What Are the Risk Factors for Cervical Cancer?* February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/risk_factors.htm. (The website was accessed on March 8, 2019.)

[106] Centers for Disease Control and Prevention. *Basic Information About Cervical Cancer*, February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/index.htm. (The website was accessed on February 28, 2018.)

[107] VHA Directive 1330.01(2), *Health Care Services for Women Veterans,* February 15, 2017 (amended July 24, 2018).

[108] VHA Directive 1330.01(2).

results to patients must be documented. The facility must ensure that appropriate follow-up care is provided to patients with abnormal results.[109]

To determine whether the facility complied with selected VHA requirements for the notification and follow-up care of abnormal cervical pathology results, the OIG inspection team reviewed relevant documents and interviewed selected employees and managers. The OIG team also reviewed the electronic health records of 26 women veteran patients, between ages 21 and 65, who had an abnormal pap smear or test from July 1, 2017, through June 30, 2018. OIG inspectors evaluated the following performance indicators:

- Appointment of a women veterans program manager
- Appointment of a women's health medical director or clinical champion
- Facility Women Veterans Health Committee
  - Core membership
  - Quarterly meetings
  - Reports to clinical executive leaders
- Collection and tracking of cervical cancer screening data
  - Notification of patients due for screening
  - Completed screenings
  - Results reporting
  - Follow-up care
- Communication of abnormal results to patients within required time frame
- Provision of follow-up care for abnormal cervical pathology results, if indicated

Women's Health Conclusion

Generally, the OIG team found compliance with many of the performance indicators, including requirements for a designated women veterans program manager and clinical champion, clinical oversight of the women's health program, tracking of data related to cervical cancer screenings, communication of results to patients, and follow-up care when indicated. However, the OIG noted a concern that the Women Veterans Health Committee membership lacked required representation that warranted a recommendation for improvement.

VHA requires that the core membership of the Women Veterans Health Committee includes a women veterans program manager; a women's health medical director; and "representatives

[109] VHA Directive 1330.01(2).

from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care; and a member from executive leadership."[110] The OIG reviewed three quarters of meeting minutes, from June 2018 through October 2018, and found that the committee lacked representation from laboratory, pharmacy, and radiology services. This resulted in a lack of expertise and oversight in the review and analysis of data as the committee planned and carried out improvements for quality and equitable care for women veterans. The women veterans program manager was unaware of the requirement for a laboratory representative, cited lack of pharmacy oversight related to a staffing issue, and believed that frequent planning meetings for the new women's health clinic with radiology staff met requirements.

Recommendation 9

9. The facility director confirms that the Women Veterans Health Committee is comprised of required core members and monitors the committee's compliance.

Facility concurred.

Target date for completion: June 30, 2020

Facility response: The Women's Health Program Manager reviewed and updated Medical Center Policy 011-032 to include the requirements for committee attendance. The Women's Health Program Manager also sent a formal charge letter to all required core members with an attached reporting schedule. The Quality, Safety, and Improvement department will monitor compliance with a goal of 90 percent or greater for six consecutive months. Compliance will be reported quarterly to the Executive Leadership Board.

[110] VHA Directive 1330.01(2).

High-Risk Processes: Operations and Management of Emergency Departments and Urgent Care Centers

VHA defines an emergency department as a "unit in a VA medical facility that has acute care medical and/or surgical inpatient beds and whose primary responsibility is to provide resuscitative therapy and stabilization in life-threatening situations." An urgent care center (UCC) "provides acute medical care for patients without a scheduled appointment who are in need of immediate attention for an acute medical or mental health illness and/or minor injuries."[111] A variety of emergency services may exist, dependent on "capability, capacity, and function of the local VA medical facility;" however, emergency care must be uniformly available in all VHA emergency departments and UCCs.[112]

Because the emergency department or UCC is often the first point of contact for patients seeking treatment of unexpected medical issues, a care delivery system with appropriate resources and services must be available to deliver prompt, safe, and appropriate care. VHA requires that each emergency department provide "unrestricted access to appropriate and timely emergency medical and nursing care 24 hours a day, 7 days a week." VHA UCCs are also required to provide access and timely care during established operational hours. VHA also requires that "evaluation, management, and treatment [are] provided by qualified personnel with the knowledge and skills appropriate to treat those seeking emergency care."[113]

TJC noted that patient flow problems pose a persistent risk to quality and safety and established standards for the management of the flow of patients in the emergency department and the rest of the hospital. Managing the flow of patients prevents overcrowding, which can "undermine the timeliness of care and, ultimately, patient safety." Effective management processes that "support patient flow [in the emergency department or UCC settings] (such as admitting, assessment and treatment, patient transfer, and discharge) can minimize delays in the delivery of care."[114]

The VHA national director of Emergency Medicine developed the Emergency Medicine Improvement initiative to improve the quality of emergent and urgent care provided through VA emergency departments and UCCs. As part of this initiative, all VA emergency departments and UCCs must use the Emergency Department Integration Software (EDIS) tracking program to document and manage the flow of patients.[115]

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[111] VHA Directive 1101.05(2), *Emergency Medicine*, September 2, 2016 (amended March 7, 2017).

[112] VHA Directive 1101.05(2).

[113] VHA Directive 1101.05(2).

[114] TJC. Leadership standard LD.04.03.11.

[115] VHA Directive 1101.05(2); The Emergency Medicine Management Tool (EMMT) uses data collected from EDIS to generate productivity metrics. The use of EDIS and EMMT are key tools in accomplishing Emergency Management Improvement initiative goals.

VA emergency departments and UCCs must also be designed to promote a safe environment of care.[116] Managers must ensure medications are securely stored,[117] a psychiatric intervention room is available,[118] and equipment and supplies are readily accessible to provide gynecologic and resuscitation services. VHA also requires emergency departments to have communication systems available to accept requests by local emergency medical services for transporting unstable patients to VA emergency departments.[119]

OIG inspectors examined the clinical risks of the emergency department/UCC areas by evaluating the staffing; the provision of care, including selected aspects of mental health and women's health; and the reduction of patient safety risks to optimize quality care and outcomes in those areas. In addition to conducting manager and staff interviews, the OIG team reviewed emergency department staffing schedules, committee minutes, and other relevant documents. OIG inspectors evaluated the following performance indicators:

- General
  - Presence of an emergency department or UCC
  - Availability of acute care medical and/or surgical inpatient beds in facilities with emergency departments
  - Emergency department/UCC operating hours
  - Workload capture process
- Staffing for emergency department/UCC
  - Dedicated medical director
  - At least one licensed physician privileged to staff the department at all times
  - Minimum of two registered nurses on duty during all hours of operation
  - Backup call schedules for providers
- Support services for emergency department/UCC
  - Access during regular hours, off hours, weekends, and holidays
  - On-call list for staff required to respond

[116] VHA Directive 1101.05(2).

[117] TJC. Medication Management standard MM.03.01.01.

[118] A psychiatric intervention room is where individuals experiencing a behavioral health crisis, including serious disturbances, agitation, or intoxication, may be taken immediately on arrival.

[119] VHA Directive 1101.05(2).

  - Licensed independent mental health provider available as required for the facility's complexity level
  - Telephone message system during non-operational hours
  - Inpatient provider available for patients requiring admission
- Patient flow
  - EDIS tracking program
  - Emergency department patient flow evaluation
  - Diversion policy
  - Designated bed flow coordinator
- General safety
  - Directional signage to after-hours emergency care
  - Fast tracks[120]
- Medication security and labeling
- Management of patients with mental health disorders
- Emergency department participation in local/regional emergency medical services (EMS) system, if applicable
- Women veteran services
  - Capability and equipment for gynecologic examinations
- Life support equipment

High-Risk Processes Conclusion

The facility generally complied with many of the performance indicators above for the operations and management of emergency department. However, the OIG identified a lack of directional signage that warranted a recommendation for improvement.

VHA requires that facilities have appropriate signage directing patients to the emergency department.[121] The OIG team did not find clearly visible signage at the entrances on the first floor of the facility to direct patients to the emergency department. This may result in patients not being able to locate the emergency department and potentially delay needed emergent or

[120] The emergency department fast track is a designated care area within the emergency department domain where lower acuity patients are assessed and treated.

[121] VHA Directive 1101.05(2).

urgent care. The emergency department director was unaware that the emergency room signage was not visible near the first floor entrances of the facility.

Recommendation 10

10. The associate director makes certain that directional signage to the emergency department is placed at facility entrances.[122]

Facility concurred.

Target date for completion: November 19, 2019

Facility response: The Chief, Interior Design collaborated with Medicine Service leadership and Quality, Safety, and Improvement department to place directional signage with red lettering at all entrance areas of the Emergency Department. Signage at all points of entrance is in place, therefore we request closure of this recommendation.

[122] The OIG reviewed evidence sufficient to demonstrate that the facility had completed improvement actions and therefore closed the recommendation before the report's release.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

The intent is for facility leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if left unattended, may potentially interfere with the delivery of quality health care.

Healthcare Processes	Performance Indicators	Conclusion
Leadership and Organizational Risks	• Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation and/or for-cause surveys and oversight inspections • Factors related to possible lapses in care • VHA performance data	Ten OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the director, chief of staff, ADPCS, and associate director. See details below.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	• Protected peer reviews • UM reviews • Patient safety • Resuscitation episode review	• Code team responders complete basic or advanced cardiac life support certification.	• Assigned staff implement improvement actions recommended by the Peer Review Committee. • Clinicians complete peer reviews for all applicable death within 24 hours of admission. • All required representatives participate in the interdisciplinary review of UM data.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	• Privileging • FPPEs • OPPEs • FPPEs for cause • Reporting of privileging actions to National Practitioner Data Bank	• None	• None

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement

Environment of Care	• Parent facility
	  ○ General safety
	  ○ Environmental cleanliness and infection prevention
	  ○ General privacy
	  ○ Women veterans program
	  ○ Availability of medical equipment and supplies
	• Community based outpatient clinic
	  ○ General safety
	  ○ Environmental cleanliness and infection prevention
	  ○ General privacy
	  ○ Women veterans program
	  ○ Availability of medical equipment and supplies
	• Locked inpatient mental health inpatient unit
	  ○ Mental health environment of care rounds
	  ○ Nursing station security
	  ○ Public area and general unit safety
	  ○ Patient room safety
	  ○ Infection prevention
	  ○ Availability of medical equipment and supplies
	• Emergency management
	  ○ Hazard vulnerability analysis (HVA)
	  ○ Emergency operations plan (EOP)
	• Emergency power testing and availability
		• Staff label multi-dose medication vials with an expiration date upon opening.
		• Seclusion room flooring in the inpatient mental health unit comply with the Mental Health Environment of Care Checklist.
			• None

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Controlled Substances Inspections	• Controlled substances coordinator reports • Pharmacy operations • Controlled substances inspector requirements • Controlled substances area inspections • Pharmacy inspections • Facility review of override reports	• None	• None
Mental Health: Military Sexual Trauma (MST) Follow-Up and Staff Training	• Designated facility MST coordinator • Evidence of tracking MST-related data • Provision of clinical care • Completion of MST mandatory training requirement for mental health and primary care providers	• None	• Providers complete military sexual trauma mandatory training within the required time frame.
Geriatric Care: Antidepressant Use among the Elderly	• Justification for medication initiation • Evidence of patient and/or caregiver education specific to the medication prescribed • Clinician evaluation of patient and/or caregiver understanding of the education provided • Medication reconciliation	• Clinicians provide and document patient/caregiver education and evaluate understanding of the education provided about newly prescribed medications.	• None

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Women's Health: Abnormal Cervical Pathology Results Notification and Follow-Up	• Appointment of a women veterans program manager • Appointment of a women's health medical director or clinical champion • Facility Women Veterans Health Committee • Collection and tracking of cervical cancer screening data • Communication of abnormal results to patients within required time frame • Provision of follow-up care for abnormal cervical pathology results, if indicated	• None	• The Women Veterans Health Committee is comprised of required core members.
High-Risk Processes: Operations and Management of Emergency Departments and UCCs	• General • Staffing for emergency department/UCC • Support services for emergency department/UCC • Patient flow • General safety • Medication security and labeling • Management of patients with mental health disorders • Emergency department participation in local/regional EMS system • Women veteran services • Life support equipment	• None	• Emergency department directional signage are placed at facility entrances.

Appendix B: Facility Profile and VA Outpatient Clinic Profiles

Facility Profile

The table below provides general background information for this highest complexity (1a) affiliated[123] facility reporting to VISN 10.[124]

Table B.1. Facility Profile for Louis Stokes Cleveland VA Medical Center (541) (October 1, 2015, through September 30, 2018)

Profile Element	Facility Data FY 2016[125]	Facility Data FY 2017[126]	Facility Data FY 2018[127]
Total medical care budget in dollars	$935,905,245	$1,001,352,849	$1,019,428,507
Number of:			
• Unique patients	111,416	110,376	111,234
• Outpatient visits	1,520,266	1,514,954	1,537,769
• Unique employees[128]	4,317	4,451	4,484
Type and number of operating beds:			
• Blind rehabilitation	15	15	15
• Community living center	173	173	173
• Domiciliary	180	180	180
• Medicine	115	115	115
• Mental health	30	30	30
• Neurology	6	6	6
• Rehabilitation medicine	18	18	18
• Residential psychology	25	25	25
• Spinal cord injury	58	58	58
• Surgery	54	54	54

[123] Associated with a medical residency program.

[124] The VHA medical centers are classified according to a facility complexity model; a designation of "1a" indicates a facility with "high volume, high-risk patients, most complex clinical programs, and large research and teaching programs."

[125] October 1, 2015, through September 30, 2016.

[126] October 1, 2016, through September 30, 2017.

[127] October 1, 2017, through September 30, 2018.

[128] Unique employees involved in direct medical care (cost center 8200).

Profile Element	Facility Data FY 2016[125]	Facility Data FY 2017[126]	Facility Data FY 2018[127]
Average daily census:			
• Blind rehabilitation	13	13	12
• Community living center	122	126	126
• Domiciliary	128	128	129
• Medicine	85	86	81
• Mental health	22	23	23
• Neurology	3	3	3
• Rehabilitation medicine	6	5	5
• Residential psychology	19	18	20
• Spinal cord injury	47	42	45
• Surgery	32	32	30

Source: VHA Support Service Center, and VA Corporate Data Warehouse
Note: The OIG did not assess VA's data for accuracy or completeness.

VA Outpatient Clinic Profiles[129]

The VA outpatient clinics in communities within the catchment area of the facility provide primary care integrated with women's health, mental health, and telehealth services. Some also provide specialty care, diagnostic, and ancillary services. Table B.2. provides information relative to each of the clinics.

Table B.2. VA Outpatient Clinic Workload/Encounters and Specialty Care, Diagnostic, and Ancillary Services Provided (October 1, 2017, through September 30, 2018)[130]

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[131] Provided	Diagnostic Services[132] Provided	Ancillary Services[133] Provided
Sandusky, OH	541GC	9,215	6,023	Dermatology Endocrinology Pulmonary/ Respiratory disease Poly-Trauma Eye General surgery Podiatry	EKG	Nutrition Pharmacy Prosthetics Weight management

[129] Includes all outpatient clinics in the community that were in operation as of August 15, 2018. The OIG omitted Cleveland-Superior, OH (541GM); Summit County, OH (541QA); and Cleveland-Euclid, OH (541QB), as no data were reported.

[130] The definition of an "encounter" can be found in VHA Directive 2010-049, *Encounter and Workload Capture for Therapeutic and Supported Employment Services Vocational Programs*, October 14, 2010. (This directive expired on October 31, 2015, and has not been updated.) An encounter is a "professional contact between a patient and a practitioner vested with responsibility for diagnosing, evaluating, and treating the patient's condition."

[131] Specialty care services refer to non-primary care and non-mental health services provided by a physician.

[132] Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

[133] Ancillary services include chiropractic, dental, nutrition, pharmacy, prosthetic, social work, and weight management services.

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[131] Provided	Diagnostic Services[132] Provided	Ancillary Services[133] Provided
Canton, OH	541BY	29,292	12,998	Dermatology Endocrinology Pulmonary/ Respiratory disease Rheumatology Poly-Trauma Anesthesia Cardio thoracic Eye General surgery Podiatry Urology	EKG Radiology	Nutrition Pharmacy Prosthetics Weight management
Youngstown, OH	541BZ	25,522	12,889	Dermatology Endocrinology Gastroenterology Pulmonary/ Respiratory disease Rheumatology Poly-Trauma Anesthesia Cardio thoracic Eye General surgery Podiatry Urology	EKG Radiology	Nutrition Pharmacy Prosthetics Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[131] Provided	Diagnostic Services[132] Provided	Ancillary Services[133] Provided
Lorain, OH	541GB	17,844	8,560	Dermatology Endocrinology Pulmonary/ Respiratory disease Poly-Trauma Rehab physician Eye General surgery Podiatry Urology	EKG	Nutrition Pharmacy Weight management
Mansfield, OH (David F. Winder)	541GD	22,140	10,138	Cardiology Dermatology Nephrology Pulmonary/ Respiratory disease Poly-Trauma Rehab physician Anesthesia Cardio thoracic Eye General surgery Podiatry	EKG Radiology	Nutrition Pharmacy Prosthetics Weight management
McCafferty, OH	541GE	3,839	2,016	Podiatry	EKG	Pharmacy Weight management Nutrition

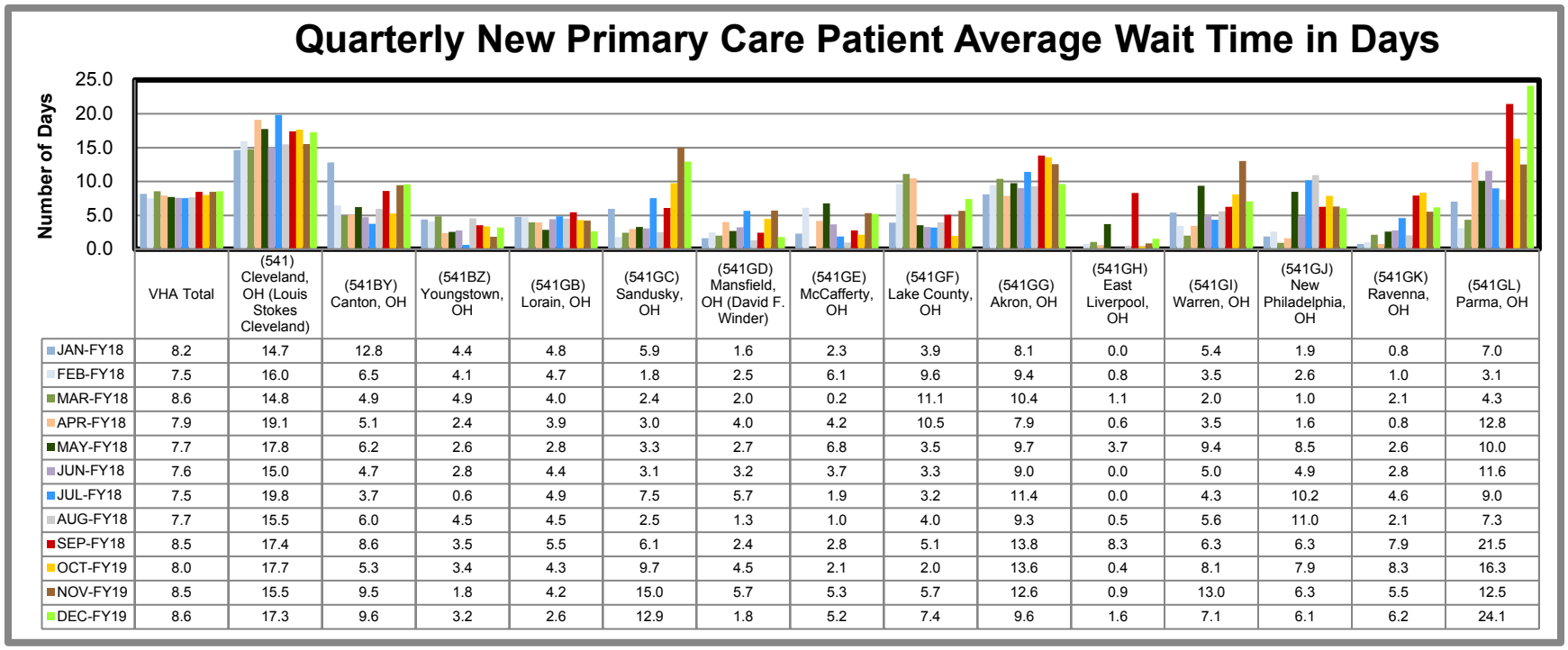
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[131] Provided	Diagnostic Services[132] Provided	Ancillary Services[133] Provided
Lake County, OH	541GF	16,742	1,482	Dermatology Endocrinology Pulmonary/ Respiratory disease Eye Podiatry	EKG	Pharmacy Weight management Nutrition
Akron, OH	541GG	31,487	18,553	Dermatology Endocrinology Pulmonary/ Respiratory disease Rheumatology Poly-Trauma Rehab physician Anesthesia Eye General surgery Podiatry	EKG Radiology Vascular lab	Nutrition Pharmacy Prosthetics Weight management
East Liverpool, OH	541GH	8,678	4,195	Cardiology Dermatology Endocrinology Pulmonary/ Respiratory disease Poly-Trauma Eye Podiatry	EKG	Nutrition Pharmacy Prosthetics Social Work Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[131] Provided	Diagnostic Services[132] Provided	Ancillary Services[133] Provided
Warren, OH	541GI	12,536	4,378	Dermatology Pulmonary/ Respiratory disease Eye Podiatry	EKG	Nutrition Pharmacy Prosthetics Weight management
New Philadelphia, OH	541GJ	10,357	4,577	Dermatology Pulmonary/ Respiratory disease Anesthesia Eye Podiatry	EKG	Pharmacy Prosthetics Weight management Nutrition
Ravenna, OH	541GK	10,039	4,818	Dermatology Pulmonary/ Respiratory disease Poly-Trauma Anesthesia Eye Podiatry	EKG	Pharmacy Weight management Nutrition

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[131] Provided	Diagnostic Services[132] Provided	Ancillary Services[133] Provided
Parma, OH	541GL	33,353	21,518	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Nephrology Neurology Pulmonary/ Respiratory disease Poly-Trauma Rehab physician Rheumatology Anesthesia Eye Podiatry Urology	EKG EMG Radiology	Nutrition Pharmacy Prosthetics Weight management
State Street, OH	541GN	n/a	5,178	Dermatology Eye General surgery Podiatry	n/a	Pharmacy

Source: VHA Support Service Center and VA Corporate Data Warehouse
Note: The OIG did not assess VA's data for accuracy or completeness.
n/a = not applicable

Appendix C: Patient Aligned Care Team Compass Metrics[134]



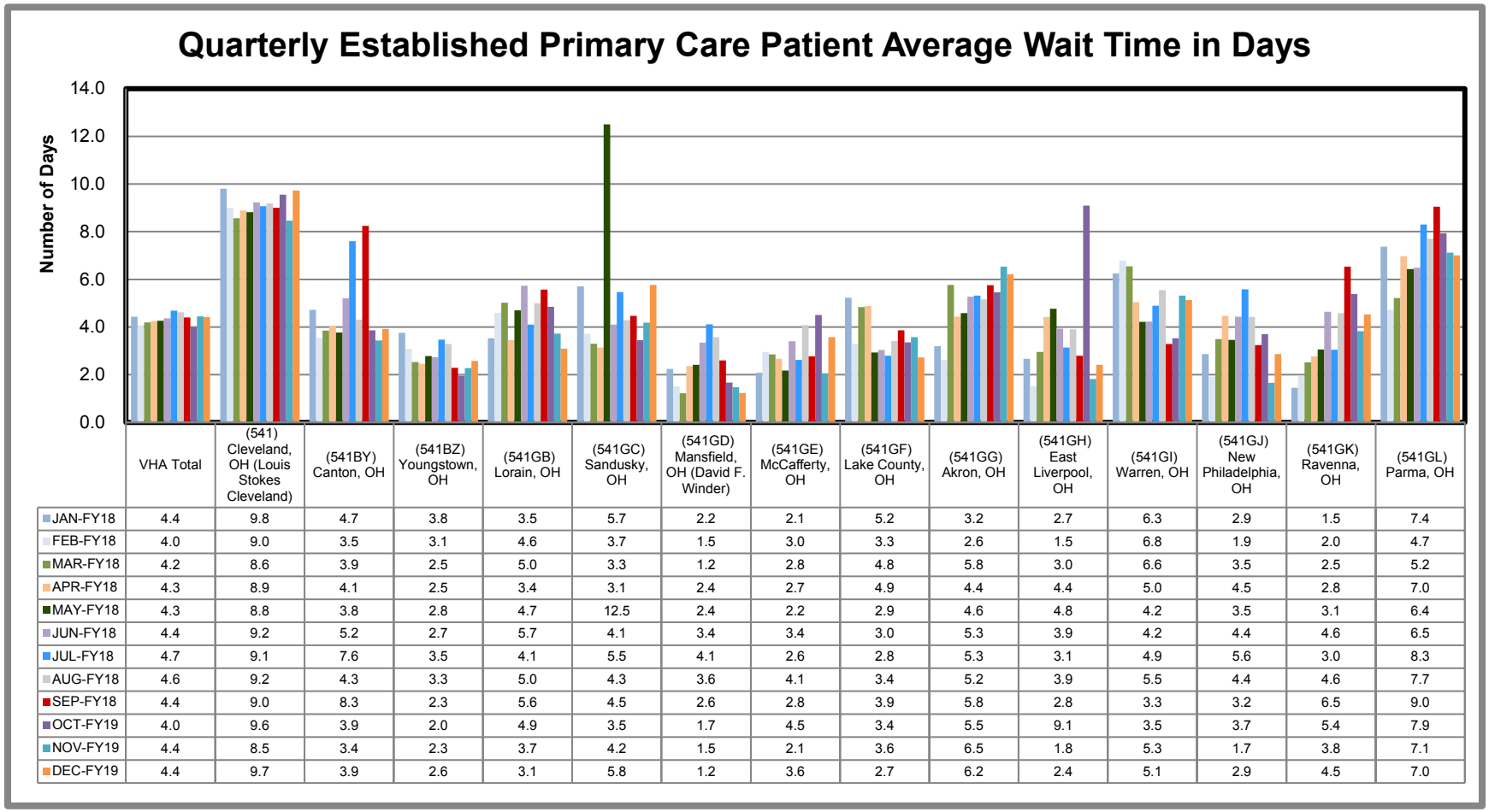
	VHA Total	(541) Cleveland, OH (Louis Stokes Cleveland)	(541BY) Canton, OH	(541BZ) Youngstown, OH	(541GB) Lorain, OH	(541GC) Sandusky, OH	(541GD) Mansfield, OH (David F. Winder)	(541GE) McCafferty, OH	(541GF) Lake County, OH	(541GG) Akron, OH	(541GH) East Liverpool, OH	(541GI) Warren, OH	(541GJ) New Philadelphia, OH	(541GK) Ravenna, OH	(541GL) Parma, OH
JAN-FY18	8.2	14.7	12.8	4.4	4.8	5.9	1.6	2.3	3.9	8.1	0.0	5.4	1.9	0.8	7.0
FEB-FY18	7.5	16.0	6.5	4.1	4.7	1.8	2.5	6.1	9.6	9.4	0.8	3.5	2.6	1.0	3.1
MAR-FY18	8.6	14.8	4.9	4.9	4.0	2.4	2.0	0.2	11.1	10.4	1.1	2.0	1.0	2.1	4.3
APR-FY18	7.9	19.1	5.1	2.4	3.9	3.0	4.0	4.2	10.5	7.9	0.6	3.5	1.6	0.8	12.8
MAY-FY18	7.7	17.8	6.2	2.6	2.8	3.3	2.7	6.8	3.5	9.7	3.7	9.4	8.5	2.6	10.0
JUN-FY18	7.6	15.0	4.7	2.8	4.4	3.1	3.2	3.7	3.3	9.0	0.0	5.0	4.9	2.8	11.6
JUL-FY18	7.5	19.8	3.7	0.6	4.9	7.5	5.7	1.9	3.2	11.4	0.0	4.3	10.2	4.6	9.0
AUG-FY18	7.7	15.5	6.0	4.5	4.5	2.5	1.3	1.0	4.0	9.3	0.5	5.6	11.0	2.1	7.3
SEP-FY18	8.5	17.4	8.6	3.5	5.5	6.1	2.4	2.8	5.1	13.8	8.3	6.3	6.3	7.9	21.5
OCT-FY19	8.0	17.7	5.3	3.4	4.3	9.7	4.5	2.1	2.0	13.6	0.4	8.1	7.9	8.3	16.3
NOV-FY19	8.5	15.5	9.5	1.8	4.2	15.0	5.7	5.3	5.7	12.6	0.9	13.0	6.3	5.5	12.5
DEC-FY19	8.6	17.3	9.6	3.2	2.6	12.9	1.8	5.2	7.4	9.6	1.6	7.1	6.1	6.2	24.1

Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted Cleveland-Superior, OH (541GM); State Street, OH (541GN); Summit County, OH (541QA); and Cleveland-Euclid, OH (541QB), as no data were reported.

Data Definition: "The average number of calendar days between a New Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date." Note that prior to FY15, this metric was calculated using the earliest possible create date.

[134] Department of Veterans Affairs, *Patient Aligned Care Teams Compass Data Definitions*, accessed September 13, 2018.



	VHA Total	(541) Cleveland, OH (Louis Stokes Cleveland)	(541BY) Canton, OH	(541BZ) Youngstown, OH	(541GB) Lorain, OH	(541GC) Sandusky, OH	(541GD) Mansfield, OH (David F. Winder)	(541GE) McCafferty, OH	(541GF) Lake County, OH	(541GG) Akron, OH	(541GH) East Liverpool, OH	(541GI) Warren, OH	(541GJ) New Philadelphia, OH	(541GK) Ravenna, OH	(541GL) Parma, OH
JAN-FY18	4.4	9.8	4.7	3.8	3.5	5.7	2.2	2.1	5.2	3.2	2.7	6.3	2.9	1.5	7.4
FEB-FY18	4.0	9.0	3.5	3.1	4.6	3.7	1.5	3.0	3.3	2.6	1.5	6.8	1.9	2.0	4.7
MAR-FY18	4.2	8.6	3.9	2.5	5.0	3.3	1.2	2.8	4.8	5.8	3.0	6.6	3.5	2.5	5.2
APR-FY18	4.3	8.9	4.1	2.5	3.4	3.1	2.4	2.7	4.9	4.4	4.4	5.0	4.5	2.8	7.0
MAY-FY18	4.3	8.8	3.8	2.8	4.7	12.5	2.4	2.2	2.9	4.6	4.8	4.2	3.5	3.1	6.4
JUN-FY18	4.4	9.2	5.2	2.7	5.7	4.1	3.4	3.4	3.0	5.3	3.9	4.2	4.4	4.6	6.5
JUL-FY18	4.7	9.1	7.6	3.5	4.1	5.5	4.1	2.6	2.8	5.3	3.1	4.9	5.6	3.0	8.3
AUG-FY18	4.6	9.2	4.3	3.3	5.0	4.3	3.6	4.1	3.4	5.2	3.9	5.5	4.4	4.6	7.7
SEP-FY18	4.4	9.0	8.3	2.3	5.6	4.5	2.6	2.8	3.9	5.8	2.8	3.3	3.2	6.5	9.0
OCT-FY19	4.0	9.6	3.9	2.0	4.9	3.5	1.7	4.5	3.4	5.5	9.1	3.5	3.7	5.4	7.9
NOV-FY19	4.4	8.5	3.4	2.3	3.7	4.2	1.5	2.1	3.6	6.5	1.8	5.3	1.7	3.8	7.1
DEC-FY19	4.4	9.7	3.9	2.6	3.1	5.8	1.2	3.6	2.7	6.2	2.4	5.1	2.9	4.5	7.0

Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted Cleveland-Superior, OH (541GM); State Street, OH (541GN); Summit County, OH (541QA; and Cleveland-Euclid, OH (541QB), as no data were reported.

Data Definition: "The average number of calendar days between an Established Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date."

Appendix D: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions[135]

Measure	Definition	Desired Direction
ACSC hospitalization	Ambulatory care sensitive conditions hospitalizations	A lower value is better than a higher value
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
Admit reviews met	Percent acute admission reviews that meet interqual criteria	A higher value is better than a lower value
APP capacity	Advanced practice provider capacity	A lower value is better than a higher value
Best place to work	All employee survey best places to work score	A higher value is better than a lower value
Call responsiveness	Call center speed in picking up calls and telephone abandonment rate	A lower value is better than a higher value
Care transition	Care transition (Inpatient)	A higher value is better than a lower value
Complications	Acute care risk adjusted complication ratio (observed to expected ratio)	A lower value is better than a higher value
Comprehensiveness	Comprehensiveness (PCMH)	A higher value is better than a lower value
Cont stay reviews met	Percent acute continued stay reviews that meet interqual criteria	A higher value is better than a lower value
Efficiency	Overall efficiency measured as 1 divided by SFA (Stochastic Frontier Analysis)	A higher value is better than a lower value
Efficiency/capacity	Efficiency and physician capacity	A higher value is better than a lower value
Employee satisfaction	Overall satisfaction with job	A higher value is better than a lower value

[135] VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL)* (last updated December 26, 2018). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938. (The website was accessed on March 7, 2019, but is not accessible by the public.)

Measure	Definition	Desired Direction
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like	Outpatient performance measure (HEDIS)	A higher value is better than a lower value
HEDIS like – HED90_1	HEDIS-EPRP based PRV TOB BHS	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS-eOM based DM IHD	A higher value is better than a lower value
MH wait time	Mental health care wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx	ORYX	A higher value is better than a lower value
PC routine care appt	Timeliness in getting a PC routine care appointment (PCMH)	A higher value is better than a lower value
PC urgent care appt	Timeliness in getting a PC urgent care appointment (PCMH)	A higher value is better than a lower value
PCMH care coordination	PCMH care coordination	A higher value is better than a lower value
PCMH same day appt	Days waited for appointment when needed care right away (PCMH)	A higher value is better than a lower value
PCMH survey access	Timely appointment, care and information (PCMH)	A higher value is better than a lower value
Physician capacity	Physician capacity	A lower value is better than a higher value
PC wait time	PC wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
PSI	Patient safety indicator (observed to expected ratio)	A lower value is better than a higher value

Measure	Definition	Desired Direction
Rating hospital	Overall rating of hospital stay (inpatient only)	A higher value is better than a lower value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RN turnover	Registered nurse turnover rate	A lower value is better than a higher value
RSMR-AMI	30-day risk standardized mortality rate for acute myocardial infarction	A lower value is better than a higher value
RSMR-CHF	30-day risk standardized mortality rate for congestive heart failure	A lower value is better than a higher value
RSMR-COPD	30-day risk standardized mortality rate for COPD	A lower value is better than a higher value
RSMR-pneumonia	30-day risk standardized mortality rate for pneumonia	A lower value is better than a higher value
RSRR-AMI	30-day risk standardized readmission rate for acute myocardial infarction	A lower value is better than a higher value
RSRR-cardio	30-day risk standardized readmission rate for cardiorespiratory patient cohort	A lower value is better than a higher value
RSRR-CHF	30-day risk standardized readmission rate for congestive heart failure	A lower value is better than a higher value
RSRR-COPD	30-day risk standardized readmission rate for COPD	A lower value is better than a higher value
RSRR-CV	30-day risk standardized readmission rate for cardiovascular patient cohort	A lower value is better than a higher value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
RSRR-med	30-day risk standardized readmission rate for medicine patient cohort	A lower value is better than a higher value
RSRR-neuro	30-day risk standardized readmission rate for neurology patient cohort	A lower value is better than a higher value
RSRR-pneumonia	30-day risk standardized readmission rate for pneumonia	A lower value is better than a higher value
RSRR-surg	30-day risk standardized readmission rate for surgery patient cohort	A lower value is better than a higher value

Measure	Definition	Desired Direction
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC routine care appt	Timeliness in getting a SC routine care appointment (specialty care)	A higher value is better than a lower value
SC survey access	Timely appointment, care and information (specialty care)	A higher value is better than a lower value
SC urgent care appt	Timeliness in getting a SC urgent care appointment (specialty care)	A higher value is better than a lower value
Seconds pick up calls	Average speed of call center responded to calls in seconds	A lower value is better than a higher value
SMR	Acute care in-hospital standardized mortality ratio	A lower value is better than a higher value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Specialty care wait time	Specialty care wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value
Telephone abandonment rate	Telephone abandonment rate	A lower value is better than a higher value

Source: VHA Support Service Center

Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Community Living Center (CLC) Measure Definitions[136]

Measure	Definition
Ability to move independently worsened (LS)	Long-stay measure: percentage of residents whose ability to move independently worsened.
Catheter in bladder (LS)	Long-stay measure: percent of residents who have/had a catheter inserted and left in their bladder.
Falls with major injury (LS)	Long-stay measure: percent of residents experiencing one or more falls with major injury.
Help with ADL (LS)	Long-stay measure: percent of residents whose need for help with activities of daily living has increased.
High risk PU (LS)	Long-stay measure: percent of high-risk residents with pressure ulcers.
Improvement in function (SS)	Short-stay measure: percentage of residents whose physical function improves from admission to discharge.
Moderate-severe pain (LS)	Long-stay measure: percent of residents who self-report moderate to severe pain.
Moderate-severe pain (SS)	Short-stay measure: percent of residents who self-report moderate to severe pain.
New or worse PU (SS)	Short-stay measure: percent of residents with pressure ulcers that are new or worsened.
Newly received antipsych meds (SS)	Short-stay measure: percent of residents who newly received an antipsychotic medication.
Physical restraints (LS)	Long-stay measure: percent of residents who were physically restrained.
Receive antipsych meds (LS)	Long-stay measure: percent of residents who received an antipsychotic medication.
UTI (LS)	Long-stay measure: percent of residents with a urinary tract infection.

[136] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated August 22, 2019). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on September 3, 2019, but is not accessible by the public.)

Appendix F: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: November 26, 2019

From: Director, VA Healthcare System (10N10)

Subj: Comprehensive Healthcare Inspection of the Louis Stokes Cleveland VA Medical Center, OH

To: Director, Los Angeles Office of Healthcare Inspections (54CH01)

Director, GAO/OIG Accountability Liaison (VHA 10EG GOAL Action)

1. I have reviewed the draft report of the Comprehensive Healthcare Inspection of the Louis Stokes Cleveland VA Medical Center, OH.
2. I concur with the responses and action plans submitted by the Louis Stokes Cleveland VA Medical Center Director.
3. Thank you for the opportunity to respond to this report.

(Original signed by:)

RimaAnn O. Nelson

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

Appendix G: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: November 20, 2019

From: Director, Louis Stokes Cleveland VA Medical Center (541/00)

Subj: Comprehensive Healthcare Inspection of the Louis Stokes Cleveland VA Medical Center, OH

To: Director, VA Healthcare System (10N10)

1. Enclosed for your review is the draft report of our Comprehensive Healthcare Inspection Program (CHIP) review of the Louis Stokes Cleveland VA Medical Center, Ohio.
2. I concur with the report.

(Original signed by:)

Jill K. Dietrich, JD, MBA, FACHE

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

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