DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Coordination of Care and Employee Satisfaction Concerns at the Community Living Center, Loch Raven VA Medical Center, in Baltimore, Maryland

HEALTHCARE INSPECTION | REPORT #19-08857-171 | JUNE 11, 2020

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Maryland Health Care System (system) in response to an anonymous complainant's allegations regarding coordination of care and patient safety concerns in the Community Living Center (CLC) at the Loch Raven VA Medical Center in Baltimore, Maryland. Specifically, the complainant alleged

- CLC managers
  - Discouraged incident reporting,[1]
  - Coached staff on how to talk to "survivors,"[2] and
  - Made staff fearful of managers and the repercussions of reporting concerns.
- Inadequate staffing resulted in
  - A poor outcome for a resident because
    - Nurse staffing was inadequate to care for residents,[3]
    - Provider staffing was inadequate for direct patient care and oversight, and[4]
  - An unidentified resident developed a pressure injury that led to sepsis.[5]
- Failure to properly manage laboratory specimens resulted in falsely elevated potassium results leading to subsequent unnecessary treatment.[6]
- The medication delivery process was ineffective due to
  - Delays in medication deliveries to the CLC because of no on-site pharmacy, and

[1] Incident reporting, also known as event reporting, refers to the process of reporting unusual, unexpected, or unfavorable events that a patient experiences during medical management. In this report, the term event reporting is used.

[2] The OIG interpreted survivor to mean a CLC resident or personal representative.

[3] VHA Directive 1351, *Staffing Methodology for VHA Nursing Personnel*, December 20, 2017. Nurse staffing refers to direct care staff including, but not limited to nurses, nursing assistants, and health care technicians.

[4] Provider refers to physicians, advanced practice nurses, and physician assistants providing care in the CLC.

[5] VHA Directive 1352, *Prevention and Management of Pressure Injuries,* March 21, 2019. Pressure injury, formerly known as pressure ulcer, is localized damage to the skin and underlying soft tissue, usually over a bony prominence or related to a medical or other device. The injury can be intact skin or an open ulcer and may be painful. Mayo Clinic, *Sepsis*. Sepsis is a potentially life-threatening condition caused by the body's response to an infection. https://www.mayoclinic.org/diseases-conditions/sepsis/symptoms-causes/syc-20351214. (The website was accessed on November 25, 2019.)

[6] Merck Manual, *Overview of Potassium's Role in the Body*. Potassium is a type of mineral contained within tissue cells that is necessary for the normal functioning of cells, nerves and muscles. https://www.merckmanuals.com/home/hormonal-and-metabolic-disorders/electrolyte-balance/overview-of-potassium-s-role-in-the-body#. (The website was accessed on November 4, 2019.)

  - Inadequate number of bar code medication administration scanners.[7]
- Resident room temperatures were unable to be regulated.

During the inspection, the OIG identified additional concerns related to failures of system and CLC leaders and managers to address CLC staff workplace satisfaction and issues negatively affecting the CLC. The OIG also identified concerns regarding the failure of Pathology and Laboratory Medicine Service (P&LMS) staff to ensure that ordering providers are notified of critical laboratory results.

The OIG did not substantiate that managers discouraged incident reporting, inappropriately coached staff on how to talk to "survivors," or made staff fearful of managers and the repercussions of reporting concerns. However, through on-site interviews, the OIG identified concerns affecting CLC staff workplace satisfaction, including reports of unresolved staff complaints related to personnel, accountability, and supplies for resident care. System leaders acknowledged there were persistent staff complaints and that these issues could affect resident care. System leaders reported that the flow of information between the system and the CLC was not always reliable. In response to employee feedback, CLC nurse managers developed unit-specific action plans and the Deputy Associate Director Patient Care Services implemented a CLC-wide action plan. To improve operations, the System Director detailed a site manager to the CLC in October 2019. Despite these actions, the OIG determined that unresolved issues and ongoing complaints related to employee satisfaction persisted.

The OIG did not substantiate that the CLC had inadequate nurse or provider staffing to care for residents or that inadequate staffing resulted in a poor outcome for a resident. The OIG concluded that the system maintained adequate nurse staffing to care for residents and that the staffing process was consistent with the Veterans Health Administration (VHA) directive.[8] While CLC managers and staff acknowledged chronic staffing challenges due to vacant positions, CLC managers used mitigation strategies such as overtime and intermittent staff to meet the nursing hours per patient day, which is adjusted daily based on care needs.[9] According to CLC leaders,

[7] Ross Koppel et al., "Workarounds to Barcode Medication Administration Systems: Their Occurrences, Causes, and Threats to Patient Safety," *Journal of the American Medical Informatics Association* 15, no. 4 (July–August 2008): 408–423. Bar code medication administration scanners are handheld devices used to scan bar codes on patient wristbands and medication packages. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2442264/pdf/408.S1067502708000704.main.pdf. (The website was accessed on December 18, 2019.)

[8] VHA Directive 1351, Staffing Methodology for VHA Nursing Personnel, December 20, 2017.

[9] Intermittent staff are hired by the VA but do not work a regular schedule or set number of hours per pay period. Intermittent staff hired by the system are required to work at least three times a month.

managers, and staff, the number of providers available to care for residents was sufficient. Additionally, the productivity level of providers was within the VHA acceptable range.

CLC laboratory specimens were not properly managed, which led to falsely elevated potassium results and subsequent unnecessary treatment. The OIG found that the P&LMS Acting Chief failed to ensure a thorough investigation and relied on the Quality Management Technologist to troubleshoot the cause of inaccurate laboratory results. This failure led to recurring instances of false results, which affected the ability of providers to plan care based on accurate information. These failures had a significant impact on residents who were subjected to additional tests, and, in some cases, additional medication and Emergency Department evaluations. Additionally, during the review of laboratory processes, the OIG found that ordering providers were not consistently notified of critical laboratory results.

Delays in medication deliveries to the CLC led to delays in residents receiving scheduled medications. None of the reviewed cases in which medications were delayed resulted in long-term adverse clinical outcomes.[10] However, the OIG found the lack of a standard operating procedure including a process for maintaining the chain of custody for all transported medications introduces the possibility for missing medication, delayed medication administration, and adverse clinical outcomes to patients. The lack of an on-site pharmacy likely contributed to the delay of medications due to the distance between campuses and the complex delivery process for which there was no standard operating procedure. During the inspection, the System Director announced the plan to place a pharmacy at the CLC by April 2020; however, in the midst of the coronavirus national emergency, the plan was delayed.

The OIG did not substantiate that the CLC had an inadequate number of bar code medication administration scanners but did learn of a previous issue with the scanners that was resolved shortly before the OIG's on-site visit. At the time of the OIG team's visit, system and CLC leaders and CLC nursing staff reported, and the OIG confirmed, that the CLC had an adequate number of fully operational scanners.

The OIG did not substantiate that there was an inability to regulate resident room temperatures. In each resident's room, the OIG team observed an operational thermostat (which displayed the temperature), vents, and ceiling diffusers. Through interviews, the OIG learned that while there were periodic issues with the temperature, Facilities and Engineering Services staff were responsive and quick to address concerns.

[10] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care. The OIG recognizes that avoidable delays associated with the deficiencies discussed in this report may affect the convenience and quality of care received.

The OIG made five recommendations to the System Director related to management of CLC employee concerns and satisfaction, handling of laboratory specimens, investigating reports of laboratory concerns, provider notification of critical laboratory results, and the process used to deliver medication to the CLC.

Comments

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

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Contents

Abbreviations

AES	All Employee Survey
BCMA	bar code medication administration
CLC	Community Living Center
EHR	electronic health record
JPSR	Joint Patient Safety Reporting
NHPPD	nursing hours per patient day
OIG	Office of Inspector General
P&LMS	Pathology and Laboratory Medicine Service
VAMC	VA Medical Center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to allegations regarding concerns with Community Living Center (CLC) management, clinical staffing levels, handling of potassium specimens, the medication delivery process, and the temperature in resident rooms at the Loch Raven VA Medical Center (Loch Raven VAMC) in Baltimore, Maryland.

Background

The Loch Raven VAMC is part of the VA Maryland Health Care System (system) and provides primary, specialty, rehabilitative, and long-term care services. The Loch Raven VAMC campus consists of an outpatient clinic and a freestanding, two-story CLC. The system's acute care medical center (Baltimore VAMC), houses the pharmacy and laboratory that serve the Loch Raven VAMC. The system is part of Veterans Integrated Service Network (VISN) 5.[11]

The CLC has 94 operating beds divided among three nursing units: Loch Raven 1, Loch Raven 2, and Loch Raven hospice. The CLC provides short- and long-term rehabilitation, skilled nursing, and hospice care to residents with a variety of health conditions.

The CLC Medical Director oversees medical care provided to residents and reports directly to the System Director of Geriatrics and Extended Care Clinical Center. The CLC Chief Nurse oversees the nursing care provided to residents and is supported by nurse managers for each of the three units.[12] The CLC Chief Nurse reports directly to the System Deputy Associate Director Patient Care Services.

Allegations and Related Concerns

On June 24, 2019, the OIG received anonymous complaints outlining the following allegations regarding CLC coordination of care and patient safety concerns.

- CLC managers

[11] The system consists of three medical centers and five community-based outpatient clinics. From October 1, 2017, through September 30, 2018, the system served over 53,000 patients.

[12] The CLC hospice nurse manager and assistant nurse manager report to the Chief Nurse at the Perry Point VA Medical Center, one of the three medical centers in the system.

    - Discouraged incident reporting,[13]
    - Coached staff on how to talk to "survivors,"[14] and
    - Made staff fearful of managers and the repercussions of reporting concerns.
- Inadequate staffing resulted in
    - A poor outcome for a resident because
        - Nurse staffing was inadequate to care for residents,[15]
        - Provider staffing was inadequate for direct patient care and oversight, and[16]
    - An unidentified resident developed a pressure injury that led to sepsis.
- Failure to properly manage laboratory specimens resulted in falsely elevated potassium results leading to subsequent unnecessary treatment.
- The medication delivery process was ineffective due to
    - Delays in medication deliveries to the CLC because of no on-site pharmacy, and
    - Inadequate number of bar code medication administration (BCMA) scanners.
- Resident room temperatures were unable to be regulated.

During the inspection, the OIG identified additional concerns related to failures of system and CLC leaders and managers to address CLC staff workplace satisfaction and issues negatively affecting the CLC. The OIG also identified that Pathology and Laboratory Medicine Service (P&LMS) staff failed to ensure that ordering providers were notified of critical laboratory results.

Scope and Methodology

The OIG initiated the inspection on July 16, 2019, and conducted a site visit September 17–19, 2019.

The complainant was anonymous. Therefore, some aspects of the OIG inspection were limited due to the inability to clarify the intent or request additional information. No specific residents were identified in the allegations.

OIG team interviewees included VISN 5 employees; system leaders, managers, and staff; Loch Raven VAMC managers and staff; and CLC leaders, managers, staff, and residents. The OIG

[13] Incident reporting, also known as event reporting, refers to the process of reporting unusual, unexpected, or unfavorable events that a patient experiences during medical management. In this report, the term event reporting is used.

[14] The OIG interpreted survivor to mean a CLC resident or personal representative.

[15] VHA Directive 1351, *Staffing Methodology for VHA Nursing Personnel*, December 20, 2017. Nurse staffing refers to direct care staff including, but not limited to nurses, nursing assistants, and health care technicians.

[16] Provider refers to physicians, advanced practice nurses, and physician assistants providing care in the CLC.

team conducted group interviews with CLC managers and staff. Additionally, the OIG team interviewed a representative from the Veterans Health Administration (VHA) Office of Nursing Service regarding the VHA nurse staffing policy. Categories of interviewed employees and their titles are listed in appendix A.

The OIG team reviewed VHA and system policies and standard operating procedures; relevant system and CLC meeting minutes; All Employee Survey data and action plans; patient safety data and reports; staffing documents; and various administrative documents. During the site visit, the OIG team conducted observational walkthroughs of the CLC.

To determine the impact of suspected cases of falsely elevated potassium results, the OIG team conducted electronic health record (EHR) reviews on the 13 CLC residents who had critically elevated potassium results from July 1, 2018, through June 30, 2019.[17] The OIG also reviewed the EHRs of five CLC residents who had absent or delayed medication delivery.

In order to more completely understand the allegations, the OIG team reviewed emails of relevant staff for the period January 2018 through November 2019, using key terms, such as "elevated potassium," "critical potassium," "centrifuge," "staffing," and "BCMA scanners."

This report focuses on patient harm in terms of adverse clinical outcomes. Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care. The OIG recognizes that avoidable delays associated with the deficiencies discussed in this report may affect the convenience and quality of care received.

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

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a

[17] System Standard Operating Procedure 113/PL-007, *Reporting Critical Laboratory Test Results*, June 2016. A critical test result requires immediate clinical intervention, and urgent verbal notification. Critical potassium results are defined by the system as greater than 5.9 milliequivalents per liter (mEq/L).

healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

Inspection Results

1. Concerns with CLC Management

The OIG did not substantiate that CLC managers discouraged incident reporting, inappropriately coached staff on how to talk to "survivors," or that they made staff fear managers and the repercussions of reporting concerns. However, during on-site interviews, the OIG learned of additional concerns with the potential to affect CLC staff workplace satisfaction.

Incident Reporting

VHA requires staff to report actual or potential unsafe events, regardless of whether patients are harmed, to the Patient Safety Manager.[18] System policy requires that staff report adverse events, sentinel events, close calls, and intentional unsafe acts using the Joint Patient Safety Reporting (JPSR) system.[19] The Patient Safety Manager or designee reviews events entered into this system and coordinates appropriate review and assessment activities.

CLC staff described being comfortable reporting patient safety events. The OIG team was provided with patient safety report data that documented CLC staff use the JPSR system to report events. The Patient Safety Specialist indicated that if staff were uncomfortable making a report, an option for filing an anonymous report exists. CLC nurse managers reported conducting huddles to review patient safety events and noted that staff are encouraged to report events via the JPSR system. The OIG found training on the JPSR system readily available to CLC staff on the internal CLC website.

Coaching Staff on Talking to Survivors

Because the complainant was anonymous, the OIG was unable to gain a clear understanding of the type of coaching that CLC managers allegedly provided to staff, or who were being referred to as "survivors." The OIG interpreted this allegation to be related to the management of clinical

[18] VHA Handbook 1050.01, *National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was scheduled for recertification on or before the last working date of March 2016 but has not been recertified.

[19] System Policy 512-00/PS-006, *Electronic Incident Reporting Program,* September 2017.

disclosures and CLC managers directing nursing staff on how to inform a resident or personal representative of harmful or potentially harmful adverse events related to the resident's care.[20] VHA and system policy provide guidance for disclosures related to clinical care.[21] Clinical disclosures are done informally with residents or their personal representative to convey information about a harmful or potentially harmful adverse event related to care received. System policy requires the attending physician, or designee, to make the disclosure of adverse events.

None of the CLC staff interviewed raised the issue of clinical disclosure or being coached by CLC managers to provide specific content of disclosures made to residents and families. Rather, the OIG determined through interviews with medical and nursing staff that clinical disclosures are made by the attending physician involved in a resident's clinical care, as required by system policy.[22]

Staff Reporting of Concerns

The OIG found no evidence to indicate that staff feared CLC managers and the repercussions of reporting concerns. No examples of this behavior were provided to or identified by the OIG nor did interviewed staff members describe being fearful of managers and the repercussions should they report a concern. In interviews with the OIG team, nursing staff stated that they report concerns regarding their colleagues' performance of duties directly to CLC managers. Rather than fear of the managers or repercussions, CLC staff expressed disappointment that CLC managers did not adequately address or document reported concerns, specifically those affecting patient care. As a result, interviewed staff shared a lack of interest in reporting additional personnel concerns going forward.

Workplace Satisfaction Concerns

Key signs of organizational health are employees' attitudes about the workplace, supervisors, and leaders. Through on-site interviews with CLC staff, managers, and system leaders, the OIG learned of concerns affecting CLC staff workplace satisfaction. The OIG team was able to speak with approximately 13 percent of CLC direct care nursing staff during group interviews held at

[20] VHA Directive 1004.08, *Disclosure of Adverse Events to Patient*, October 31, 2018. VHA defines disclosure as "the discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future."

[21] VHA Directive 1004.08; System Policy 512-00/PS-003, *Disclosure of Adverse Events to Patients*, October 2016.

[22] System Policy 512-00/PS-003.

various times throughout the site visit.[23] CLC staff reported discontent with their workplace and that CLC managers and system leaders failed to address issues negatively affecting the CLC.

Nursing staff described an environment in which they felt CLC leaders were ineffective and lacked empathy for employees. They spoke of staff turnover, low morale, and frustration at what they perceived as the failure of CLC managers and system leaders to

- Address persistent personnel issues,
- Follow up or implement corrective actions,
- Communicate effectively,
- Ensure adequate supplies for resident care,
- Hold staff equitably accountable,
- Provide adequate staffing levels, and
- Address a lack of teamwork in caring for residents.

These negative perceptions coupled with a lack of trust led staff to feel symptoms of burnout. Nursing staff felt that burnout contributed to increasing turnover and callouts on the units, and affected staffing levels on the units.

The OIG team also conducted group interviews with CLC nurse managers and assistant nurse managers. Both groups communicated that staffing the units was a challenge, and that they used overtime and intermittent staff to address shortages.[24] Nurse managers and assistant nurse managers were also concerned about the impact of short staffing on nursing staff turnover and burnout. CLC managers acknowledged some staff peer groups function like cliques and shared awareness that staff fear exclusion from their peer group if they speak out. Managers reported that some staff were happy, but confirmed they had some dissatisfied staff.

[23] Staff group interviews were open to all non-supervisory, direct care registered nurses, licensed practical nurses, nursing assistants, medical support assistants, or technician staff assigned to the CLC. Separate group interviews for the assistant nurse managers were also conducted. The OIG recognizes the limitations of group interviews and that the perceptions of CLC staff interviewed during group and individual interviews are not necessarily those of all staff assigned to the CLC.

[24] Nurse managers reported that intermittent staff are hired by the VA but do not work a regular schedule and are required to work at least three times a month.

To determine if the concerns expressed in the group interviews had been conveyed elsewhere, the OIG team reviewed All Employee Survey (AES) results specific to the CLC.[25] A review of October 1, 2018–September 30, 2019, survey data identified that

- The CLC's Best Places to Work composite score of 39 was well below the system score of 66 and ranked as the lowest within the system and[26]
- CLC staff participation in the survey was poor with 17 percent responding, compared to 44 percent system wide.

CLC survey respondents identified communication, coworker relationships, growth, accountability, and workload as top priorities in need of improvement.[27]

System leaders acknowledged there were areas that needed improvement within the CLC. The System Director stated receiving complaints about nursing at the CLC over the last couple of years and was particularly troubled by the persistence of the complaints. The Director stated that complaints included concerns about nurse staffing levels, nursing supervision and management, duty hours, and cliques, and that sometimes these issues resulted in cases of poor nursing service provided to residents at the CLC.

In interviews, staff reported feeling disconnected from the Baltimore VAMC. System leaders admitted to not having a presence at or set schedule for visiting the Loch Raven VAMC. System leaders acknowledged communication challenges at the Loch Raven VAMC campus and that the flow of information between the system and the CLC was not always reliable. The System Director reported that at a recent Loch Raven VAMC town hall there were several questions that indicated a lack of communication among the various services. The System Director attributed the communication issues, in part, to the lack of a site manager.

[25] The All Employee Survey is a confidential and voluntary survey of VA workplace experiences that is conducted annually. Responses to survey questions are aggregated so that individual participants are not identifiable. All Employee Survey results serve as a feedback tool from employees to leadership.

[26] Best Places to Work is an overall indicator of organizational health. Best Places to Work is a weighted composite of three items: overall job satisfaction, satisfaction with the organization, and recommendation of the organization as a good place to work.

[27] The All Employee Survey describes communication as communicating necessary information timely and clearly; coworker relationships as cooperating, collaborating, and treating one another with respect; growth as creating opportunity for employee growth; accountability as holding one another accountable for performance and professional conduct; and workload as supporting a reasonable workload and distributing it fairly.

Management Response to Concerns

"Recent studies in healthcare indicate that managers can improve patient care experiences by improving employee satisfaction."[28] System and CLC managers have taken actions to address concerns with CLC nursing managers and CLC staff satisfaction.

Through interviews, the OIG team learned that within the past two years a new CLC Chief Nurse and several nurse managers, all without recent long-term care experience, were selected. Since the OIG team on-site visit, a new CLC Chief Nurse, the third in three years, had been assigned. The System Director explained that this change was made because the now former CLC Chief Nurse's skills were needed for a supervisory nursing position at the Baltimore VAMC. The System Director further explained that the CLC would benefit from a Chief Nurse with long-term care expertise.

To address CLC staff concerns, CLC nurse managers developed unit-specific action plans based on 2018 AES results and staff complaints brought to the attention of the Deputy Associate Director Patient Care Services. The plans included goals to address many of the topics raised by staff in interviews with the OIG including accountability, communication, workload, team building, workplace respect, and employee recognition.

In October 2019, the System Director detailed a site manager to the Loch Raven VAMC after identifying the need for a person on-site at that campus who reported directly to the System Director, had awareness of and the authority to manage site operations, and facilitate improved communication.

The number of staff who met with the OIG team and completed the AES reflects a small percentage of the staff working in the CLC. The OIG was unable to determine if those who engaged with the OIG team were representative of the larger group, if the level of engagement was low due to apathy, or if those interviewed represented a minority opinion.

System and CLC leaders acknowledged awareness of issues and had taken actions to address concerns. However, unresolved issues and ongoing complaints related to employee satisfaction persisted.

2. Staffing

The OIG did not substantiate that the CLC had inadequate nurse staffing to care for residents or that there was inadequate provider staffing for direct patient care and oversight. The OIG also

[28] Graham Lowe, "How Employee Engagement Matters for Hospital Performance," *Healthcare Quarterly* 15, No. 2 (2012): 29-39. https://www.researchgate.net/publication/225296126_How_Employee_Engagement_Matters_for_Hospital_Performance. (The website was accessed on December 18, 2019.)

did not substantiate that inadequate staffing resulted in poor outcomes for residents, such as pressure injuries or sepsis. During the inspection, the OIG learned that there was an increase in pressure injuries on one CLC unit that was unrelated to inadequate staffing.

Nurse Staffing

VHA policy requires medical facilities to plan staffing for nursing units using a standardized process known as the staffing methodology. The process includes a unit based expert panel recommending a staffing plan that proposes the nursing hours per patient day (NHPPD) for each nursing unit based on clinical judgment, knowledge of the nursing unit, and relevant comparison data. The proposed staffing plan is reviewed by a facility expert panel and the nurse executive and is approved by the medical center director. VHA requires that the staffing plan is reviewed annually, and the staffing methodology is completed at least biennially. Additionally, nurse leaders are required to review staffing levels daily.[29]

CLC leaders and managers described a staffing methodology process that was consistent with VHA requirements. Staffing methodology plans were completed annually, which exceeded the VHA biennial requirement. CLC managers showed OIG team members the staffing reports they reviewed daily that indicated the number and mix of staff working on the CLC units.

The Associate Director Patient Care Services and the staffing methodology coordinator reported the current target NHPPD for Loch Raven 1 and Loch Raven 2 was 6.0 hours, as documented on the VHA Support Service Center data.[30] From October 2018 through July 2019, the actual average monthly NHPPDs were consistently higher than 6 hours, ranging from 6.3 to 9.2 hours. CLC managers described the target NHPPD as a baseline and reported that staffing was adjusted daily based on residents' acuity.[31]

During interviews, system leaders and CLC managers reported chronically low nurse staffing. At the time of the OIG site visit, Loch Raven 1 and Loch Raven 2 had 29 vacant positions that were actively being filled. System leaders and CLC managers reported using overtime and intermittent

[29] VHA Directive 1351.

[30] VHA Support Service Center is an inventory of non-public VHA databases that track and report on various VHA metrics. VHA Support Service Center Capital Assets (VSSC). https://catalog.data.gov/dataset/vha-support-service-center-capital-assets-vssc. (The website was accessed on December 30, 2019.)

[31] For example, a unit with 20 residents has four nursing personnel (nurses and nursing assistants) on duty for each eight-hour shift during a 24-hour period. The number of nursing hours during each eight-hour period is 32. There are three, eight-hour shifts, so the total number of nursing hours is 96. Total number of NHPPD equals the total number of nursing hours divided by the number of residents (96/20=4.8 NHPPD). Increasing or decreasing staffing or resident census will alter the NHPPD. This is only an example of NHPPD calculations and does not reflect actual staffing at the CLC.

staff to mitigate staffing shortages, such as those caused by vacancies or residents' increased nursing needs.

System leaders provided overtime data, which indicated overtime was used to achieve staffing levels at and above the target NHPPD. For the period of October 2018 through August 2019, Loch Raven 1 and 2 combined used an average of 1,857 overtime hours per month (range 1,253 to 2,750 hours of overtime per month).

The OIG concluded that the system maintained adequate nurse staffing to care for residents. The staffing process was consistent with the VHA directive. Due to staff vacancies and the needs of residents, overtime was used to meet the NHPPD, which was adjusted daily based on care needs.

Provider Staffing for Direct Patient Care and Oversight

VHA requires facilities to have adequate staff available to ensure the provision of high-quality health care. VHA mandates facilities to monitor specialty provider group practice productivity and take remedial action for practice groups falling outside of the "Acceptable Group Practice Range of Productivity."[32]

The OIG reviewed VHA group practice productivity data and found that the system's geriatric group practice, which managed residents in the CLC, was within the acceptable group practice range of productivity. The CLC had one vacant geriatric provider position since a nurse practitioner left the CLC in 2018. The CLC Medical Director stated the vacancy was not filled because there was not a patient care need based on the resident census. CLC leaders and managers did not report concerns about provider staffing or oversight.

The OIG found provider staffing levels were adequate to provide direct care and oversight for residents in the CLC.

Resident Outcomes

VHA and system policy require staff in all clinical areas in VHA facilities, including CLCs, to prevent, assess, and manage pressure injuries.[33]

The anonymous complainant alleged that inadequate staffing resulted in an unidentified resident developing a pressure injury that led to sepsis. The Associate Director of Patient Care Services and CLC Medical Director identified one resident's case consistent with the scenario described

[32] VHA Directive 1065(1), *Productivity and Staffing Guidance for Specialty Provider Group Practice,* May 4, 2015, amended April 19, 2018. Acceptable Group Practice Range of Productivity is the acceptable range of productivity for group practices, which is productivity that is within the mean, plus or minus one standard deviation level.

[33] VHA Directive 1352, *Prevention and Management of Pressure Injuries,* March 21, 2019. System Policy 512-118-015 *Wound and Skin Care*, June 2017.

in the complaint. The OIG reviewed the EHR for this resident and found documentation describing an institutional disclosure that was provided to the resident's family indicating the pressure injury, that may have led to the resident's sepsis, was attributed to staff not turning the resident as frequently as needed. No explanation for the infrequent turning was documented. Infrequent turning can be the result of inadequate staff to provide the necessary care, or nursing staff failing to follow resident turning schedules. The OIG reviewed nurse staffing levels for the month in which the pressure injury occurred and found that the staffing levels were above the target NHPPD.

System and facility leaders and managers reported that during the quarter including July 2018 and September 2018, seven residents on Loch Raven 1 had newly acquired pressure injuries, which was an increase compared to previous quarters (range zero to four pressure injuries). System leaders attributed the increase to poor staff practices such as infrequent repositioning, failure to change residents, and lack of skin assessments. In November 2018, an action plan to reduce overall pressure injuries was implemented that included education of staff and residents; use of pressure injury prevention resources; and increased vigilance of nursing staff. In each of the quarters between October 2018 and June 2019, the unit reported zero to one incident of newly acquired pressure injuries. The unit did not experience an increase in the quarterly average NHPPD during the period of improvement.

The OIG concluded that the system maintained a staffing process that was consistent with the VHA directive and that the CLC used alternative staffing strategies to mitigate vacancies and to exceed targeted NHPPD. A review of CLC pressure injuries identified a unit-specific issue that resolved following the implementation of planned actions.

3. Failure to Properly Manage Laboratory Specimens

The OIG substantiated that CLC laboratory specimens were not properly managed, which led to falsely elevated potassium results and subsequent unnecessary treatment. Specifically, the system failed to ensure compliance with policies and procedures for the handling of laboratory specimens at the CLC and did not adequately respond to concerns regarding suspected falsely elevated results to ensure the results were investigated and resolved.[34] During the inspection, the OIG identified that P&LMS staff failed to consistently document notification of critical potassium results given to ordering providers.

[34] Ana K. Stankovic and Shrita Smith, "Elevated Serum Potassium Values, The Role of Preanalytic Variables," *American Journal of Clinical Pathology,* [2004; 121 (Suppl 1)]: S105-S112. For the purpose of this report, handling refers to transport conditions, packaging, centrifugation, and specimen storage temperature.

Failure to Ensure Compliance with Policies

The OIG determined that P&LMS and CLC leaders failed to ensure compliance with policies and procedures regarding the handling of laboratory specimens at the CLC. A VHA handbook requires written policies for the handling of laboratory specimens within VA facilities, regardless of the physical relationship to the main laboratory.[35]

Through interviews with facility and system leaders, the OIG learned that the CLC does not have an on-site laboratory. With the exception of point of care testing, such as blood sugar testing, all laboratory specimens obtained at the CLC were transported to the laboratory at the Baltimore VAMC for analysis.[36] Prior to September 2018, phlebotomists from the Baltimore VAMC collected routine laboratory specimens from the CLC and transported them to the laboratory at the Baltimore VAMC for processing.[37]

Laboratory staff informed the OIG team that in September 2018, due to decreased availability of phlebotomists at the Baltimore VAMC, phlebotomists were no longer assigned to collect routine specimens at the CLC. CLC nursing staff, who had previously only been charged with collecting specimens for urgent tests, were assigned the additional responsibility of collecting laboratory specimens for routine tests. Routine tests were not urgently transported for processing, but rather stored at the Loch Raven VAMC and transported later to the Baltimore VAMC by staff shuttle or contract courier.

Although the OIG team was provided with a written policy for the handling of laboratory specimens, P&LMS and CLC leaders, managers, and staff provided inconsistent descriptions of actual practice regarding specimen handling procedures. Specifically, one system leader reported that specimens at the CLC were taken to the Loch Raven outpatient clinic and spun using a centrifuge prior to the specimen being retrieved by a contract courier while other leaders, managers, and staff reported that specimens were sent to the Baltimore VAMC laboratory without being spun. The P&LMS Quality Management Technologist told the OIG team that tests collected at the CLC did not require refrigeration yet some of those interviewed reported that specimens were stored in a refrigerator in the CLC despite research showing that refrigeration may affect the test results. Lastly, in a review of 32 critically elevated potassium results, the OIG found that the length of time between specimens being collected, transported, and ultimately processed varied from less than one hour to more than 12 hours.

[35] VHA Handbook 1106.01.

[36] Loch Raven VAMC does not have laboratory services available on site, requiring the transport of laboratory specimens to the laboratory at the Baltimore VAMC (a 20-minute drive from the CLC) for processing.

[37] System Policy 512-113/PL-011, *STAT and Routine Clinical Laboratory Test Ordering*, February 2019. Laboratory specimens are considered routine when the results are not time sensitive. Routine orders for inpatients are typically collected early in the morning.

Compliance with written policies is an important and required component of a laboratory management program. Inconsistent specimen handling practices, such as those described above, can contribute to inaccurate results.

Failure to Investigate Suspected Falsely Elevated Lab Results

The OIG determined that CLC and P&LMS leaders failed to adequately respond to concerns regarding suspected falsely elevated potassium results. VHA policy requires the Chief of P&LMS to ensure that all reported laboratory complaints are investigated, and that corrective actions are implemented as needed.[38]

Many factors can result in falsely elevated potassium results:

- Collection techniques, such as the length of time that a tourniquet is on a patient's arm.
- Handling techniques, including vigorous shaking or spinning of the collected blood.
- Storage of the blood specimen in a refrigerator.
- Duration of more than two hours between collection and analysis of an unspun blood specimen.[39]

In December 2018, a CLC provider reported to the System Director of Geriatrics and Extended Care Clinical Center, CLC Medical Director, and P&LMS Quality Management Technologist that three residents had suspected cases of falsely elevated potassium results. The P&LMS Quality Management Technologist determined that the suspected false results were likely related to specimens being collected at the CLC and stored for more than two hours without being spun. At that time, the P&LMS Quality Management Technologist believed that the specimens were not spun due to the CLC's centrifuge being broken. The P&LMS Quality Management Technologist notified the Chief Nurse that unspun specimens needed to be delivered to the laboratory within two hours of collection. P&LMS staff were instructed to not verify potassium results of unspun specimens that did not arrive to the laboratory within two hours. According to system policy, these specimens would be rejected, and the ordering provider would be notified.

In January 2019, the P&LMS Quality Management Technologist learned that the CLC did not have a centrifuge available for nursing use since at least September 2018. Upon learning the CLC did not have a centrifuge, the P&LMS Quality Management Technologist advised nursing staff to use the centrifuge located in the Loch Raven outpatient clinic. The OIG found that no additional follow-up was conducted to ensure that specimens sent to the Baltimore VAMC laboratory were centrifuged or transported within two hours of collection until June 2019 when

[38] VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016; 42 CFR § 493.1242.

[39] Stankovic and Smith, "Elevated Serum Potassium Values the Role of Preanalytic Variables."

the P&LMS Quality Management Technologist received an additional report regarding concerns about falsely elevated potassium results.

The OIG team learned from the Patient Safety Specialist that in June 2019, the CLC Medical Director reported the ongoing concern about suspected cases of falsely elevated potassium results. The Patient Safety Specialist reached out to the P&LMS Quality Management Technologist to discuss this concern. The P&LMS Quality Management Technologist reported identifying the cause of the suspected false results to be the failure to spin specimens with a centrifuge. The P&LMS Quality Management Technologist requested the Biomedical Engineering Service to assist the CLC Chief Nurse with the purchase of a centrifuge in June 2019.

During the September 2019 site visit, the OIG found that the CLC did not have a centrifuge. The Associate Director Patient Care Services reported that P&LMS was responsible for acquiring a centrifuge, while the Acting Chief of P&LMS reported that the issue needed to be resolved by the CLC.

The OIG found that the P&LMS Acting Chief failed to ensure a thorough investigation and relied on the Quality Management Technologist to troubleshoot the cause of inaccurate laboratory results. However, neither the Patient Safety Specialist nor the P&LMS Quality Management Technologist conducted a formal quality review to determine the cause of the suspected falsely elevated potassium results. System leaders did not provide an action plan to investigate and resolve the cause of suspected false potassium results.

The failure to investigate and resolve the cause of inaccurate laboratory results represents a substantial risk of recurring instances of false results and affects the ability with which providers can plan care based on accurate information.

Unnecessary Treatment Related to Falsely Elevated Potassium

In December 2018, a CLC provider reported to the CLC Medical Director that, during recent months, three residents with suspected cases of falsely elevated potassium results were transported to local emergency departments for evaluation resulting in unnecessary treatment. After repeat potassium results were normal, the CLC provider determined that the initial elevated results were likely false.[40] CLC providers documented that the suspected inaccurate potassium results may have been due to errors in handling or processing, including delays in specimen transportation to the Baltimore VAMC laboratory.

[40] System Standard Operating Procedure 113/PL-007. The system defines normal potassium levels as 3.1 to 5.9 mEq/L.

To determine the impact of suspected falsely elevated potassium results on the treatment CLC residents received, the OIG team searched for critically elevated potassium results for CLC residents from July 2018 through June 2019. The search identified 32 critically elevated potassium results for 13 residents. The OIG team reviewed each of the residents' EHRs to determine whether appropriate interventions were taken, suspicions about falsely elevated potassium results were documented, and whether residents were transported to an emergency department for further evaluation.

The OIG found that each of the 13 residents received appropriate treatment based on their potassium results and clinical presentations.

Documentation in the EHR revealed CLC providers speculated that 11 of the 32 potassium results were falsely elevated.[41] Through EHR review, the OIG identified that each of the suspected falsely elevated results led to at least one additional diagnostic test and that 5 of the 11 results (45 percent) led to additional medication (see table 1).

[41] Eleven of 32 elevated potassium levels affected nine residents.

Table 1. Suspected Falsely Elevated Potassium Results that Led to Additional Test(s) or Medication

Test Result	Potassium Result in milliequivalents per liter (mEq/L)	Additional Test(s)	Additional Medication
1	6.9	Yes	Yes
2	8.7	Yes	No
3	6.5	Yes	No
4	6.4	Yes	Yes
5	6.0	Yes	No
6	6.0	Yes	No
7	7.3	Yes	Yes
8	6.3	Yes	Yes
9	6.2	Yes	No
10	6.0	Yes	Yes
11	10.2	Yes	No

Source: VA OIG analysis of Corporate Data Warehouse data for CLC critical potassium test results from July 1, 2018, through June 30, 2019, and EHR reviews

The EHR review identified four residents with critically elevated potassium levels who were transported to local emergency departments (see table 2).[42] Three of the four residents had repeat potassium tests performed with normal results. These three residents were returned to the CLC. One resident was admitted to a non-VA hospital for further treatment that was not directly related to high potassium. None of the 11 residents with suspected falsely elevated potassium results experienced an adverse clinical outcome.

The OIG confirmed that the three residents who had been transported to a local emergency department and had normal repeat potassium results were the same three residents that the CLC provider reported to the System Director of Geriatrics and Extended Care Clinical Center and CLC Medical Director in December 2018.

[42] Two out of four transfers were for clinical symptoms in addition to the elevated potassium level.

Table 2. Residents Transported to Emergency Departments Related to Elevated Potassium Results

Resident	Potassium Result in CLC (mEq/L)	Repeat Potassium Result (mEq/L)	Returned to CLC or Admitted
Resident A	7.3	4.9	Returned
Resident B	7.6	4.0	Returned
Resident C	6.1	Unknown	Admitted
Resident D	10.2	4.5	Returned

Source: VA OIG analysis of Corporate Data Warehouse data for CLC critical potassium test results from July 1, 2018, through June 30, 2019, and EHR reviews

Based on EHR documentation reflecting providers' concern with the accuracy of the elevated potassium results and reports of inconsistent handling of laboratory specimens, the OIG determined that the 11 elevated potassium results were likely false. Due to many variables that affect the accuracy of potassium results, the OIG was unable to identify the specific cause(s) of the falsely elevated potassium results in the reviewed cases. Providers depend on timely and accurate results of laboratory testing to provide effective care. Improper specimen management that led to falsely elevated potassium results and unnecessary treatment represented a significant risk to patient safety.

Additional Finding: Critical Result Notifications

During EHR reviews, the OIG identified that P&LMS staff failed to consistently document that notifications of critical potassium results were given to ordering providers.

VHA requires that facility leaders ensure a policy is developed and implemented for the communication of critical laboratory results.[43] The system policy requires P&LMS staff to verbally inform providers of critical laboratory results. To verify that the result was heard accurately, the provider receiving the notification is required to restate the critical result back to the laboratory staff. The laboratory staff must document the date, time, person notified, and confirmation that the provider stated the result. This notification procedure must be followed for each instance of a critically elevated potassium result, regardless of the resident's history of elevated potassium results.[44]

[43] VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015; System Standard Operating Procedure 113/PL-007.

[44] System Standard Operating Procedure 113/PL-007.

The OIG found P&LMS staff failed to document the required notification for 12 of the 32 (37 percent) critical potassium results reviewed. The OIG confirmed that despite the lack of documentation, each of the residents with a critically elevated potassium result received an appropriate medical evaluation and did not experience an adverse clinical outcome.

The failure of P&LMS staff to follow the mandated critical test notification procedure presented a risk of providers not receiving critically important laboratory results necessary to ensure timely intervention for potentially life-threatening conditions.

4. Delays in the Medication Delivery Process

The OIG substantiated delays in medication deliveries from the Baltimore VAMC to the CLC. The OIG was unable to determine if the delays were due to the lack of an on-site pharmacy at the CLC. However, the lack of an on-site pharmacy likely contributed to the delay of medications due to the distance between campuses and the complex delivery process for which a standard operating procedure did not exist.

The OIG did not substantiate that the CLC had an inadequate number of BCMA scanners but did learn of a previous issue with BCMA scanners that was resolved shortly before the OIG on-site visit.

Delays in Medication Delivery

VHA directives require that VA pharmacy services are available 24-hours a day, seven days a week, and that VA pharmacy services meet patient care needs.[45] The OIG team learned through interviews with pharmacy staff that medications for CLC residents were transported from the pharmacy at the Baltimore VAMC. A clinical pharmacist was located at the CLC to assist with processing medication orders.[46] A system policy established the use of automated dispensing cabinets in the CLC to ensure on-site availability of a limited supply of formulary medications that may be needed to meet patients' needs. These cabinets were restocked and checked monthly.[47]

System leaders, CLC managers, and CLC staff stated that there were delays in the delivery of medications from the Baltimore VAMC to the CLC. The complex and time-consuming process for medication delivery to the CLC increased the opportunities for errors and delays in

[45] VHA Directive 1108.07, *Pharmacy General Requirements,* March 10, 2017; VHA Directive 1108.06, *Inpatient Pharmacy Services,* February 8, 2017.

[46] A CLC pharmacist works Monday through Friday 7:30 AM to 4:00 PM.

[47] System Standard Operating Procedure 512-119-013, *Obtaining Medications During Non-Scheduled Hours of Operation,* October 2014.

medication administration. Through an interview with a CLC staff member, the OIG team learned of cases of failure in the medication delivery process:

- A resident had a seizure when full doses of an antiseizure medication were not delivered because of equipment failure at the Baltimore VAMC pharmacy.
- A resident missed two doses of an antibiotic because the medication was not delivered to the CLC prior to the medication administration time.
- A resident with a history of organ transplant missed one dose of two anti-rejection medications that were delivered after the scheduled administration time.
- A resident missed two doses of a chemotherapy drug when the medication was lost in the transport and delivery process.
- A resident was discharged from the CLC without a medication as CLC staff were not notified that the medication had been delivered to the CLC; the medication was found 14 days after discharge in an unlabeled bag at the CLC.

The OIG team reviewed the EHRs of these five residents and determined that none experienced long-term adverse clinical outcomes as a result of the missed doses. The OIG learned that there was no standard operating procedure for the transport and delivery of medications from the Baltimore VAMC to the CLC and received inconsistent answers from staff interviewed about the process. While not required, the Inpatient Pharmacy Manager stated that the system does not have a process to maintain chain of custody for the delivery of non-controlled medications.[48] Through interviews, the OIG determined the following to be the process of delivery of medications.

- Non-controlled medications
    - A VA driver transports drawers full of medications prescribed for CLC residents from the pharmacy at the Baltimore VAMC to the CLC during business hours on Mondays, Wednesdays, and Fridays.[49] A pharmacy technician from the Baltimore VAMC then locates the medication carts on each CLC unit and replaces the used drawers with full drawers.
    - The VA driver makes additional, unscheduled trips as needed, to deliver medications to the CLC and other system locations.

[48] A controlled substance is a drug whose use and possession is regulated by law (as title 21, chapter 13 of the U.S. Code). https://www.merriam-webster.com/dictionary/controlled%20substance. (The website was accessed on January 22, 2020.)

[49] Baltimore pharmacy business hours are Monday through Friday, 8:00 a.m. to 6:00 p.m.

  - After business hours, pharmacists at the Baltimore VAMC fill the medication orders and take the medication to the Baltimore Emergency Department where Emergency Department staff call a contract courier for delivery to the CLC.

- Controlled Medications
  - During business hours, Monday through Friday, a controlled substance pharmacy technician directly transports medications from the Baltimore VAMC to the CLC. The controlled substances are kept locked during transport. The technician is responsible for completing and filing controlled medication receipts documenting the chain of custody.[50]
  - After business hours, CLC staff call the Chief of Pharmacy or their designee who is responsible for completing the chain of custody form and facilitating the transportation of the controlled substance to the CLC.

System Actions

Prior to the OIG visit, system leaders recognized problems with the CLC medication delivery process. In interviews with the OIG, system leaders described efforts to improve the process:

- The System Director of Geriatrics and Extended Care Clinical Center described a process to print a daily missing medication report for provider review. The provider then communicates with pharmacy staff at the Baltimore VAMC to resolve reports of missing medication.
- The Inpatient Pharmacy Manager described a daily report that pharmacy staff review identifying missing medications alerted by the BCMA system.
- The Inpatient Pharmacy Manager described a process to audit medication cart drawers on return to the pharmacy to ensure drawers had been exchanged properly.
- The Associate Director for Patient Care Services and the Inpatient Pharmacy Manager described efforts to optimize the use of the CLC automated dispensing cabinets to expand the number of medications stored on-site at the CLC and reduce delays in medication delivery.[51]

In post-site visit interviews, system leaders shared, and emails confirmed, plans to open an on-site pharmacy at the CLC with services starting in April 2020. However, in the midst of the coronavirus national emergency, the opening was delayed. The System Director made mention of medication errors at the CLC as one of the contributing factors when making this decision.

[50] System Policy Memorandum 512-119-020, *Omnicell Cabinet System,* September 2017. The Omnicell System enables the system to track controlled substances from the pharmacy vault to patient administration.

[51] System Policy Memorandum 512-119-020.

Despite system actions described above, the OIG remains concerned that the lack of a standard operating procedure including a process for maintaining the chain of custody for all transported medications introduces the possibility for missing medications, delayed medication administration, and harm to patients.

Adequate Number of BCMA Scanners

The OIG found the CLC had an adequate number of BCMA scanners.

According to system policy, BCMA scanners will be used as part of the medication administration documentation process when available.[52] In circumstances such as a scanner malfunction, the policy allows staff to manually enter patient identifiers into the BCMA system.[53] The CLC Chief Nurse reported that a maximum of eight nursing staff administer medications at any given time on Loch Raven 1 and 2 nursing units.

At the time of the OIG team's visit, system and CLC leaders, managers, and nursing staff reported that the CLC had an adequate number of fully operational wireless BCMA scanners, allowing each nurse administering medications to have access to a scanner. While conducting the inspection, the OIG identified a previous issue with BCMA scanner availability believed to be the cause of the allegation. The Associate Director Patient Care Services reported that in March 2019, when the CLC's wireless BCMA scanners reached their end-of-life cycle, the devices were replaced with scanners that were tethered to medication carts. A CLC leader and CLC managers reported that the medication carts with the tethered scanners were difficult to maneuver into residents' rooms. As a result of not being able to have the scanner at the bedside with the resident, nursing staff began manually entering medication bar code numbers and patient identifiers into the BCMA system. The OIG team did not receive reports of medication errors related to nursing staff making manual entries to contend with the tethered medication scanners but did learn of two cases in which medication bar codes did not scan. The OIG reviewed these cases and found no evidence of adverse clinical outcomes due to nursing staff manually entering medication bar code numbers.

While on-site, OIG team members learned through interviews that the CLC obtained new wireless BCMA scanners in July 2019 and the team visually confirmed the presence and operability of the new scanners. The OIG team learned from a facility manager that as of December 2019, the CLC had a total of 10 scanners available for use.

[52] System Policy Memorandum 512-118-039, *Bar Code Medication Administration,* November 2017.
[53] System Policy Memorandum 512-118-039.

5. Temperature Regulation in Resident Rooms

The OIG did not substantiate the inability to regulate resident room temperatures.

Temperature in resident care areas is an important satisfier for residents, staff, and visitors. Healthcare organizations should provide temperature levels suitable for the care and services provided. VA guidelines state that residents' rooms are to be maintained between 70 and 75 degrees Fahrenheit.[54] However, through observation on the nursing units, the OIG confirmed that residents can adjust the thermostat in their room outside of this temperature range to meet their comfort.

In each resident's room the OIG team observed an operational thermostat (which displayed the temperature), vents, and ceiling diffusers. In speaking with residents, the OIG team received one complaint about temperature. The OIG team shared the complaint with Facilities and Engineering Services staff and the issue was resolved the next day. A digital thermostat was viewable in the CLC common areas for CLC staff and residents to see the temperature. The Loch Raven VAMC Maintenance Shop Supervisor stated that thermostats in the common areas can only be controlled by facility and engineering staff, were monitored daily, and maintained between 72- and 78-degrees Fahrenheit. Through interviews, the OIG learned that while there were periodic issues with the temperature, Facilities and Engineering Services staff were responsive and quick to address concerns.

Conclusion

The OIG did not substantiate that managers discouraged incident reporting, inappropriately coached staff on how to talk to "survivors," or that staff were fearful of managers and the repercussions of reporting concerns.

During on-site interviews, the OIG learned of additional concerns with the potential to affect CLC staff workplace satisfaction. System leaders acknowledged there were areas that needed improvement within the CLC. The System Director stated receiving complaints from nursing staff at the CLC over several years and was particularly troubled by the persistence of the complaints. System leaders told the OIG that the flow of information between the system and the CLC was not always reliable and described a lack of communication at the Loch Raven VAMC identified by CLC staff during recent town hall meetings. In interviews, staff reported feeling disconnected from the main system at Baltimore. To improve operations, the System Director detailed a site manager to the CLC in October 2019.

[54] VA Office of Construction and Facilities Management, *Heating, Ventilation and Air Conditioning Design Manual,* November 1, 2017.

The OIG did not substantiate that the CLC had inadequate nurse or provider staffing to care for residents. The OIG found that by completing staffing plans annually, the CLC exceeded VHA requirements for completing the nurse staffing methodology process. While CLC managers and staff acknowledged chronic staffing challenges due to vacant positions, CLC managers used mitigation strategies such as overtime and intermittent staff to meet the daily NHPPD. The OIG also did not substantiate that inadequate staffing resulted in a poor outcome for a resident. During the inspection, the OIG learned that one CLC unit experienced an increase in pressure injuries, which was unrelated to inadequate staffing. Incidents of pressure injuries decreased after an action plan was implemented.

The OIG substantiated that the CLC laboratory specimens were not properly managed, which led to falsely elevated potassium results and subsequent unnecessary treatment. The P&LMS and CLC staff reported inconsistent specimen handling practices, which can contribute to inaccurate results. Although the concern about falsely elevated potassium results was reported to P&LMS staff, a thorough investigation was not conducted, and a resolution was not implemented. These failures had a significant impact on residents who were subjected to additional tests, and, in some cases, additional medication and emergency department evaluations.

During EHR reviews, the OIG found that P&LMS staff did not consistently document notification of critical potassium results to ordering providers. The failure of P&LMS staff to follow the mandated critical test notification procedure presented a risk of providers not receiving critically important laboratory results necessary to ensure timely intervention for potentially life-threatening conditions.

Delays in medication deliveries to the CLC were substantiated. The OIG was unable to determine if the delays were due to the lack of an on-site pharmacy at the CLC. However, the lack of an on-site pharmacy likely contributed to the delay of medications due to the complexity and lengthy delivery process from the Baltimore VAMC inpatient pharmacy to the CLC. The OIG found that the system lacked a standard operating procedure for the delivery process of non-controlled substances.

The OIG did not substantiate that the CLC had an inadequate number of BCMA scanners. At the time of the OIG team's visit, system and CLC leaders and CLC nursing staff reported that the CLC had an adequate number of fully operational BCMA scanners. The OIG did identify a previous issue with BCMA scanner availability that was resolved with the purchase of new BCMA scanners in July 2019.

The OIG did not substantiate the inability to regulate resident room temperatures. The OIG found that residents could individualize room temperatures through a thermostat and that CLC common areas had reasonable temperatures. The CLC had a mechanism in place to control temperature and timely address temperature related problems.

Recommendations 1–5

1. The VA Maryland Health Care System Director conducts a comprehensive evaluation of the organizational health to include staff reporting of concerns and employee satisfaction at the Loch Raven Community Living Center, develops an action plan for improvement, and monitors progress.

2. The VA Maryland Health Care System Director reviews current laboratory specimen handling procedures at the Loch Raven Community Living Center and implements an action plan to address identified deficiencies.

3. The VA Maryland Health Care System Director ensures that concerns reported to Pathology & Laboratory Medicine Service are investigated and that action plans are instituted as needed.

4. The VA Maryland Health Care System Director ensures Pathology & Laboratory Medicine Service staff notifies providers of critical laboratory results, documents in accordance with policy, and monitors compliance.

5. The VA Maryland Health Care System Director reviews the current process for medication delivery, to include the effectiveness of recently initiated actions as described in the report, from the Baltimore VA Medical Center pharmacy to the Loch Raven Community Living Center and implements an action plan to address identified vulnerabilities.

Appendix A: Employees Interviewed

Area	Staff
VA Central Office	Program Manager, Office of Nursing Services
VISN	Human Resource Officer
	Supervisory Human Resource Specialist
System Leaders	Director
	Chief of Staff
	Associate Director for Finance
	Associate Director Patient Care Services
	Deputy Associate Director Patient Care Services
	Executive Assistant to the System Director
	Office of Information and Technology Area Manager
	Director of Geriatrics and Extended Care Clinical Center
	Chief of Acquisitions and Material Management Service
	Acting Chief of P&LMS
	Chief of Medical Administration Service
	Chief Nurse of Administration and Operations
System Managers	Inpatient Pharmacy Manager
	Managerial Cost Accounting Manager
System Staff	Nurse Recruiter
	BCMA Coordinator
	CLC Admissions Coordinator (Loch Raven and Perry Point)
	P&LMS Quality Management Technologist
	Supervisory Medical Technician
System Staff	pharmacy technicians
Loch Raven VAMC Managers	Maintenance Shop Supervisor
	Patient Safety Specialist
Loch Raven VAMC Staff	Material Handler
Loch Raven CLC Leaders	Chief Nurse
	Medical Director
	Hospice Medical Director
Loch Raven CLC Managers	Restorative Care Nurse Manager
	nurse managers
	assistant nurse managers

Area	Staff
Loch Raven CLC Staff	Pharmacist
	registered nurses
	licensed practical nurses
	restorative care assistants
	nurse educators
	medical support assistants

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 29, 2020

From: Director, VA Capitol Health Care Network (10N5)

Subj: Healthcare Inspection—Coordination of Care and Employee Satisfaction Concerns at the Community Living Center, Loch Raven VA Medical Center in Baltimore, Maryland

To: Director, Office of Healthcare Inspections, Seattle (54HL05)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed and concur with the findings and recommendations in the Office of Inspector General's (OIG) draft report entitled - Coordination of Care and Employee Satisfaction Concerns at the Community Living Center, Loch Raven VAMC, Baltimore, Maryland.
2. Further, I have reviewed and concur with the VA Maryland HCS, Medical Center Director's response.
3. Thank you for this opportunity to focus on continuous performance improvement. If you have any questions, please feel free to contact the VISN 5 Office at 410-691-1131.

(Original signed by:)

Robert M. Walton, FACHE

Appendix C: System Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 24, 2020

From: Director, VA Maryland Health Care System, Baltimore, Maryland (512/00)

Subj: Healthcare Inspection—Coordination of Care and Employee Satisfaction Concerns at the Community Living Center, Loch Raven VA Medical Center in Baltimore, Maryland

To: Director, VA Capitol Health Care Network (10N5)

1. I would like to express my appreciation to the Office of Inspector General Survey Team for their professional and comprehensive review of the "Coordination of Care and Employee Satisfaction Concerns at the Community Living Center, Loch Raven VAMC, Baltimore, Maryland" report.
2. I have reviewed the draft for the VA Maryland Health Care System, Baltimore, Maryland, and concur with the findings and recommendations.
3. Please express my gratitude to the survey team for their professionalism and assistance to us in our continuing efforts to provide the best care possible to our Veteran patients.

(Original signed by:)

Adam M. Robinson, Jr., M.D.

System Director Response

Recommendation 1

The VA Maryland Health Care System Director conducts a comprehensive evaluation of the organizational health to include staff reporting of concerns and employee satisfaction at the Loch Raven Community Living Center, develops an action plan for improvement, and monitors progress.

Concur.

Target date for completion: August 31, 2020

Director Comments

The Loch Raven Site Manager encourages the Community Living Center staff to complete the All Employee Survey (AES) to achieve 90% participation. Once the AES is complete, each Department Manager creates an Action Plan based on their employees 2 or 3 highest rated concerns. Monthly Town Hall meetings are held for employees from all shifts, with the Loch Raven Site Manager and Chief Nurse, to update staff and answer questions. Daily rounds are conducted by Nursing leadership. Nutrition and Food Service (NFS) has offered Focus Groups conducted by Social Workers at each site for employees based off AES results. NFS Management changes include; perfect attendance acknowledgments, Gold Pin awards and birthday recognitions.

All staff are encouraged to report concerns to the Joint Patient Safety Reporting System (JPSR). The total JPSR entries are:

- Fiscal year (FY)19 - 1706 of which 260 (15%) of the incidents reported were for Loch Raven (LR) CLC.
- FY20 (October 2019 through March 2020) 963 of which 127 (13%) of the incidents reported were LR CLC.

JPSR is monitored quarterly and reported to the Executive Quality Council and Executive Leadership Board through the Patient Safety Committee.

Employee satisfaction is an area that Patient Safety will focus on in FY2020. An Action Plan has been developed to address this issue. The Action Plan will be monitored and reported through Patient Safety Committee.

Recommendation 2

The VA Maryland Health Care System Director reviews current laboratory specimen handling procedures at the Loch Raven Community Living Center and implements an action plan to address identified deficiencies.

Concur.

Target date for completion: May 31, 2020

Director Comments

The following Action Plan has been implemented by Nursing Service:

- Purchase of a centrifuge for use at the Loch Raven Community Living Center.
- Implementation of standard operating procedure (SOP) NO.118-045 (PROCEDURE FOR THE HANDLING OF LABORATORY SPECIMENS IN THE COMMUNITY LIVING CENTER) adopted in November 2019.

In addition to the initial education performed with staff, Pathology & Laboratory Medicine Service (P&LMS) performed an in-service conducted by the Chemistry Supervisor on March 19, 2019 [*sic*], to review how to identify and correctly process specimens. Since the implementation and use of the new Roche Cobas analyzers in Clinical Chemistry in September 2019, there have been no issues with the processing of specimens from the Loch Raven CLC. This training is ongoing and will be reinforced if any uncentrifuged specimens are submitted for processing.

Recommendation 3

The VA Maryland Health Care System Director ensures that concerns reported to Pathology & Laboratory Medicine Service are investigated and that action plans are instituted as needed.

Concur.

Target date for completion: August 31, 2020

Director Comments

The P&LMS Quality Management Technologist will convene formal Quality Reviews/Root Cause Analyses (RCAs) in coordination with Quality, Safety, and Improvement (QSI) for any identified quality issues.

QSI has oversight for the implementation and monitoring of Action Plans from a Quality Review or RCA.

The new Roche Cobas analyzers in Clinical Chemistry provide a new safeguard because the analyzer does not report any results effected by hemolysis, such as Potassium, if there is

hemolysis in the sample. These samples are identified, held for additional review and investigation as necessary.

P&LMS has planned and will implement an additional quality monitor to track trends in the values of critical care analytes. This will allow for faster identification of trends in specific analyte results.

Recommendation 4

The VA Maryland Health Care System Director ensures Pathology & Laboratory Medicine Service staff notifies providers of critical laboratory results, documents in accordance with policy, and monitors compliance.

Concur.

Target date for completion: August 31, 2020

Director Comments

P&LMS SOP 113/PL-007 (REPORTING OF CRITICAL LABORATORT TEST RESULTS), establishes the process for the notification and documentation of the reporting of critical laboratory test results. P&LMS has developed the following process to monitor compliance with documentation of provider call-backs:

- Monthly reports run by the Laboratory Information Manager identifying all critical results and the comments appended to those results. This identifies whether a call to the provider is correctly documented.
- Distribution of these results to the Section Supervisor.
- Feedback to the Medical Technologist who verified the result about compliance with the SOP.
- Re-education of the Medical Technologists not meeting the standard to document the call to the provider.

To ensure successful hand-off of critical results, if the ordering provider cannot be contacted, P&LMS will contact the respective Clinical Center Chief for that provider with the patient information and critical lab result.

Recommendation 5

The VA Maryland Health Care System Director reviews the current process for medication delivery, to include the effectiveness of recently initiated actions as described in the report, from the Baltimore VA Medical Center pharmacy to the Loch Raven Community Living Center and implements an action plan to address any identified vulnerabilities.

Concur.

Target date for completion: December 31, 2020

Director Comments

The current process for the transportation of Pharmacy items from the Baltimore Campus to the LR CLC is as follows:

- Medication Cart exchanges and Omnicell restocks are done by a Pharmacy Technician.
- Monday, Wednesday and Friday mornings Medication Cart and Omnicell restock delivery is done by the Facilities and Engineering Service (F&ES).
- Monday through Friday between 8AM to 2:30PM (excluding holidays) F&ES delivers non-controlled pharmacy items from the Baltimore Campus to the LR CLC. All deliveries leaving the Baltimore Campus are logged on a delivery log sheet.
- On weekends, holidays, evenings and nights, non-controlled pharmacy item deliveries from the Baltimore Campus to LR CLC are handled by a contract delivery carrier. Access to a government vehicle is available on weekends, holidays, evenings and nights; the vehicle keys are temporarily locked in the Baltimore Pharmacy Inpatient Omnicell. All deliveries leaving the Baltimore Campus are logged on a delivery log sheet.
- Controlled substances are delivered from the Baltimore Campus to LR CLC in a locked box by Pharmacy staff using a government vehicle. The Pharmacy staff stocks the controlled items into the Omnicell with a nurse witness. Electronic Omnicell generated reports are audited by the Pharmacist. All deliveries leaving the Baltimore Campus are logged on a delivery log sheet.
- To address vulnerabilities identified, in addition to the construction of an inpatient Pharmacy at the LR CLC, the recently hired Associate Chief is meeting regularly with the Pharmacy staff at LR CLC, as well as, Nursing and administrative staff to proactively identify any problems and to be the liaison to Pharmacy Leadership. This has improved communications which previously was not occurring on a routine basis and was fragmented.

The VA Maryland Health Care System's Patient Safety Department will conduct a Health Care Failure Mode and Effects Analysis (HFMEA) on the new Pharmacy build at Loch Raven. The HFMEA will identify potential risk factors to the process that would affect CLC residents at any point from the ordering of medications to delivery of medications from the Baltimore Campus to Loch Raven. The first HFMEA meeting occurred during the week of March 16, 2020, with subsequent meetings scheduled monthly. The construction of an on-site Pharmacy will address a number of identified barriers; however, as the on-site Pharmacy will not be a 24/7 operation, support from the Baltimore Pharmacy will still be required on weekends, holidays, evenings, and nights. The HFMEA will look to map the current process and identify process steps and failure modes which will result in an Action Plan being developed for each item identified and scored. Through this process, a Standard Operating Procedure will be developed to identify the

procedures, responsibilities, and actions for Baltimore Pharmacy to support Loch Raven CLC during weekends, holidays, evenings, and nights.

Due to the COVID-19 pandemic, the construction of the on-site Pharmacy has been delayed. The HFMEA is continuing as planned.

Glossary

adverse event. Unexpected or untoward incidents directly associated with the medical care or services provided at VHA facilities. Examples include patient falls, administration of the wrong medication, or procedural errors.[55]

attending physician. Also known as supervising practitioners, attending physicians are licensed independent physicians who have been credentialed and privileged to provide care at a VA medical facility. Attending physicians may function as supervising practitioners for other healthcare practitioners.[56]

automated dispensing cabinets. Decentralized, computer-controlled medication systems used to store, dispense, and track medications at the point of use.[57]

bar code medication administration. A tethered or wireless handheld device used to scan bar codes on patient wristbands and medication packages. The devices are connected to computers on mobile carts, and link with the patient's EHR. By scanning bar codes, BCMAs can detect mismatches between the patient and the medication, helping to prevent medication errors.[58]

burnout. "[H]igh levels of emotional exhaustion, cynical attitudes, and a diminished sense of personal accomplishment at work." Symptoms of burnout include decreased job satisfaction, frequently arriving to work late or absence from work, reduced job performance, and increased turnover.[59]

[55] VHA Handbook 1050.01, *National Patient Safety Improvement Handbook,* March 4, 2011.

[56] VHA Directive 1400.01, *Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents*, November 7, 2019.

[57] Matthew Grissinger, "*Safeguards for Using and Designing Automated Dispensing Cabinets*," Pharmacy and Therapeutics 37, No. 9 (September 2012): 490-491. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3462599/. (The website was accessed on December 16, 2019.)

[58] Ross Koppel et al., "Workarounds to Barcode Medication Administration Systems: Their Occurrences, Causes, and Threats to Patient Safety," *Journal of the American Medical Informatics Association* 15, no. 4 (July-August 2008): 408–423. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2442264/pdf/408.S1067502708000704.main.pdf. (The website was accessed on December 18, 2019.)

[59] Michelle Salyers et al., "The Relationship Between Professional Burnout and Quality and Safety in Healthcare: A Meta-Analysis," *Journal of General Internal Medicine*, 32, No. 4 (October 2016): 475-48. https://link.springer.com/article/10.1007%2Fs11606-016-3886-9. (The website was accessed on December 2, 2019.)

centrifuge. A medical device used to separate cells from a solution through use of a rotor. After collection, blood specimens are "spun" or "centrifuged" to create a barrier between the blood cells and the blood serum, allowing the blood serum to be tested for potassium.[60]

close calls. Also called a "near miss," a close call is an incident "that could have resulted in an adverse event, but did not, either by chance or through timely intervention."[61]

diffuser. A device (such as slats at different angles) for deflecting air from an outlet in various directions.[62]

formal quality review. Used to improve and redesign system and processes. During the review, a multidisciplinary team investigates an actual or potential adverse event to determine "what happened, why it happened, and what can be done to prevent it from happening again." Formal reviews allow a proactive, systemic, engineering-based approach to identify system vulnerabilities and failures to correct them before they occur.[63]

huddles. A type of brief meeting at the beginning of a shift that allow team members to identify, communicate, and cooperatively resolve patient safety issues.[64]

institutional disclosure. A formal process used by VA medical facility leaders and clinical staff to inform a patient or family member 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."[65]

Joint Patient Safety Reporting. A system that allows VHA staff to submit an electronic incident report. Electronic incident reports are reviewed by the Patient Safety Manager or

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[60] Fisher Scientific, *Centrifugation Theory*. https://www.fishersci.se/se/en/scientific-products/centrifuge-guide/centrifugation-theory.html. (The website was accessed on November 6, 2019.) Legacy Health, *Centrifuging Blood*. https://www.legacyhealth.org/for-health-professionals/refer-a-patient/laboratory-services/collection-guidelines/centrifuging-blood.aspx. (The website was accessed on November 4, 2019.)

[61] VHA Handbook 1050.01.

[62] Merriam-Webster, *Definition of diffuser.* https://www.merriam-webster.com/dictionary/diffuser. (The website was accessed on February 26, 2020.)

[63] VA National Center for Patient Safety, *Root Cause Analysis.* https://www.patientsafety.va.gov/media/rca.asp. (The website was accessed on February 1, 2019.) Erik Stalhandske et al., "Healthcare FMEA in the Veterans Health Administration," *Patient Safety & Quality Healthcare,* (September/October 2009): 31-33. https://www.patientsafety.va.gov/docs/hfmea/PSQHarticle.pdf. (The website was accessed on February 1, 2019.)

[64] VA National Center for Patient Safety, "Patient Safety Huddle Board." https://www.patientsafety.va.gov/PATIENTSAFETY/features/Patient_Safety_Huddle_Board.asp. (The website was accessed on November 14, 2019.)

[65] VHA Directive 1004.08.

designee to determine potential severity and probability of injury. Results are analyzed to determine trends and prioritize investigative efforts.[66]

nursing hours per patient day. "The total number of nursing hours of care available divided by the number of patients, in a 24-hour period. NHPPD is a nurse staffing ratio proxy and can be proportioned by skill mix and shift distribution."[67]

phlebotomists. Staff trained to collect and prepare blood for laboratory testing.[68]

potassium. A type of mineral contained within tissue cells known as an electrolyte, potassium is necessary for the normal functioning of cells, nerves and muscles. Potassium levels are usually maintained in the body within a narrow range. However, some medications and conditions can affect the movement of potassium in and out of tissues, increasing or decreasing blood potassium levels.[69]

pressure injury. Formerly known as pressure ulcer, localized damage to the skin and underlying soft tissue, usually either over a bony prominence or related to a medical or other device. The injury can be intact skin or an open ulcer and may be painful.[70]

sentinel event. Defined by Joint Commission as "unexpected occurrences involving death, serious physical or psychological injury, or risk thereof." VHA requires immediate investigation of any event designated as a sentinel event.[71]

sepsis. A potentially life-threatening condition caused by the body's response to an infection. The body normally releases chemicals into the bloodstream to fight an infection. Sepsis occurs when the body's response to these chemicals is out of balance, triggering changes that can damage multiple organ systems.[72]

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[66] System Policy 512-00/PS-006, *Electronic Incident Reporting Program*, September 2017.

[67] VHA Directive 1351.

[68] Cambridge College of Healthcare & Technology, *Career Profile: Phlebotomist Career.* https://www.cambridgehealth.edu/career-profile-phlebotomist/. (The website was accessed on December 4, 2019.)

[69] Merck Manual, *Overview of Potassium's Role in the Body*. https://www.merckmanuals.com/home/hormonal-and-metabolic-disorders/electrolyte-balance/overview-of-potassium-s-role-in-the-body#. (The website was accessed on November 4, 2019.)

[70] VHA Directive 1352.

[71] VHA Handbook 1050.01.

[72] Mayo Clinic, *Sepsis*. https://www.mayoclinic.org/diseases-conditions/sepsis/symptoms-causes/syc-20351214. (The website was accessed on November 25, 2019.)

tourniquet. A device used by a phlebotomist while drawing blood to make the vein more prominent.[73]

[73] LabCE, *Tourniquets, Alcohol, and Gauze*. https://www.labce.com/spg263743_tourniquets_alcohol_and_gauze.aspx. (The website was accessed on December 23, 2019.)

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