



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Care and Oversight
Deficiencies Related to
Multiple Homicides at the
Louis A. Johnson VA Medical
Center in Clarksburg, West
Virginia



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Executive Summary

On July 14, 2020, Reta Mays, a former nursing assistant, pled guilty to seven counts of second-degree murder and one count of assault with the intent to commit murder of patients at the Louis A. Johnson VA Medical Center (facility) in Clarksburg, West Virginia. Ms. Mays pled guilty to deliberately administering insulin to these patients in 2017 and 2018, resulting in profound hypoglycemia and death.¹ Ms. Mays, who worked primarily on the facility's general medical ward (3A), said in an interview subsequent to her guilty plea that she administered insulin to patients she believed were suffering so that they could pass "gently," and because she had a lot of stress and chaos in her personal and professional life and these actions gave her a sense of control. In that nursing assistants act in a supportive role, determining the severity of a diagnosis or the degree of suffering of a patient is not within their professional scope, experience, or training. Moreover, for all the patients described in her plea and in this report, the clinical expectation was that each would survive the condition for which they were hospitalized.

In June 2018, facility leaders identified nine patients with profound and concerning hypoglycemic events dating from November 2017 to June 2018. On June 27, 2018, the Facility Director contacted the VA Office of Inspector General's (OIG) Office of Investigations requesting an investigation with the belief that at least one criminal act, possibly more, had been committed. On June 28, the Veterans Health Administration's (VHA) then Executive in Charge informed Inspector General Michael Missal about the events. A criminal investigation was initiated that same day.

Staff from the OIG Office of Healthcare Inspections (OHI) immediately commenced a parallel healthcare inspection to assess the facility's environment, practices, and controls, and whether deficits could have contributed to these patients' deaths. Specifically, OHI assessed the following areas:

- Ms. Mays's hiring and performance
- Medication management and security
- Clinical evaluations of unexplained hypoglycemic events
- Reporting of and responding to the events

¹ Hypoglycemia refers to low blood glucose (also called "blood sugar"). It is a relatively common occurrence and complication in diabetic patients who receive medications to lower their blood glucose levels. Some of the reasons why a nondiabetic patient would experience hypoglycemia are drugs, critical illnesses, deficiencies in hormones that help keep blood glucose normal, tumors, and the use of insulin in someone who does not have diabetes. However, the primary cause of hypoglycemia, even in nondiabetic patients, remains the administration of diabetes medication or synthetic insulin.

- Quality programs and oversight activities
- Facility, Veterans Integrated Service Network (VISN), and VHA leaders' responses and corrective actions

During the course of this review, the OIG also noted areas of concern regarding hospice and palliative care practices and nursing policies and practices.

OHI staff conducted reviews of the nine patients' electronic health records (EHRs) referenced above as well as an additional 112 patients who died on ward 3A dating back to mid-2015 when Ms. Mays began employment at the facility. During this review, OHI staff identified a possible tenth patient with concerning hypoglycemia.² Also, OHI staff identified deficiencies with how medications were secured and with nursing policies and practices on ward 3A. After the OIG identified Ms. Mays as a person of interest, facility leaders removed her from patient care duties on July 5, 2018. The OIG healthcare inspection was paused shortly thereafter to ensure it did not interfere with the integrity of the ongoing criminal investigation.

After Ms. Mays pled guilty in July 2020, OHI staff resumed its healthcare inspection. Among other matters, OHI staff conducted 75 interviews and reviewed thousands of documents, including relevant VHA, VISN, and facility policies and procedures. OHI physicians also reviewed the EHRs of more than 200 patients who received medical care at the facility in support of the OIG's criminal investigation. The reviews were not designed to evaluate other possible means by which Ms. Mays could have interfered with patient care and no other criminal conduct was identified. Nevertheless, the OIG concluded that an expert clinical evaluation of patients who had verified contact with Ms. Mays and subsequently experienced an adverse outcome or other negative event, including but not limited to death, was warranted.

In every hospital, patients are exposed to known risks that are often inherent to that environment. Ultimately, quality health care is dependent on leaders who promote a culture of safety that reduces or eliminates those risks whenever possible. Providing high-quality health care to a diverse and complex patient population demands the support of, and adherence to, an organization-wide culture of safety. When this occurs, a patient-centric environment becomes the "norm." Conversely, systemic weaknesses in a facility's culture of safety can have devastating consequences. The OIG found that the facility had serious, pervasive, and deep-rooted clinical and administrative failures that contributed to Ms. Mays's criminal actions not being identified and stopped earlier. The failures occurred in virtually all the critical functions and areas required to promote patient safety and prevent avoidable adverse events at the facility. The following are

² To protect the privacy of patients and their families, the OIG used numerical identifiers 1–10 when referencing patients in the report. The OIG determined that the hypoglycemic episodes experienced by Patients 3 and 9 could have been explained by medical comorbidities (co-occurring diseases or medical conditions).

the more significant deficiencies and missed opportunities as well as facility, VISN, and VHA actions, and other associated concerns.

Hiring and Performance Reviews of Reta Mays

Policy deficiencies and practice failures resulted in VA employees missing multiple opportunities to identify concerning conduct before hiring Ms. Mays. She was formerly employed by the West Virginia Department of Corrections as a corrections officer at North Central Regional Jail from 2005–2012, where she was the subject of excessive force allegations. The VA failed to review her personnel records from that employment. Despite the Office of Personnel Management (OPM) guidance that “[r]eference checking is a vital part of a successful hiring strategy,” the OIG did not find evidence that facility staff involved in hiring Ms. Mays contacted personnel from the jail or her immediate prior employer, a non-VA residential facility, to inquire about her employment status, skills, and performance. Had they done so, it is possible that based on her conduct at the jail, she would not have been hired for, or retained in, a position at the facility that involved patient care.

A former facility employee (the adjudicator) was responsible for reviewing the contents of Ms. Mays’s background investigation file and determining her suitability for employment but did not do so. Of significance, the OPM’s background investigator checked the “Q” code box when closing the case, that stated “There are potentially actionable issue(s)...which may be disqualifying under suitability/security considerations.” The OIG found no documented evidence that the case was adjudicated, favorably or otherwise, as required by VHA. Ms. Mays worked at the facility for almost four years without this basic employment safeguard.

The facility had an additional opportunity to follow up on the “potentially actionable issue(s)” when Ms. Mays received the Secretary’s Award for Excellence/Nursing Assistant of the Year, which included a \$500 bonus, on September 12, 2017. This award, which was given at a facility level, required a completed security check documented on VA Form 0235, *Security Check for Candidate Requiring Approval of the Secretary*.³ On December 16, 2016, the former facility adjudicator, who failed to adjudicate Ms. Mays’s background investigation in 2015, improperly annotated VA Form 0235, stating that the background investigation had been favorably adjudicated. This entry was made in the absence of supporting information. Therefore, the OIG viewed this failure as another missed opportunity to evaluate and make additional inquiries.

Ms. Mays received fully successful, excellent, and outstanding performance ratings in October 2015, 2016, and 2017, respectively.⁴ Ms. Mays received a fully successful performance rating for her work through June 29, 2018, after which she was transferred to another department.

³ The purpose of this requirement is to protect the integrity of the Secretary of VA during the award process.

⁴ Employees who receive excellent and outstanding performance ratings are typically given monetary awards.

Nevertheless, according to her supervisors, Ms. Mays was verbally counseled after two incidents—the first for improperly accessing a blood sample from a blood tube, and a second for leaving a patient in soiled bedding at the end of her shift. No documentation of counseling was provided to the OIG. Additionally, facility documents included incidents when Ms. Mays reportedly disconnected intravenous (IV) lines and turned off or cleared IV pump data.⁵

Medication Management and Security

The OIG also found that medication security was inadequate on the ward where Ms. Mays primarily worked, as was the pharmacy ward's stock tracking practices. Insulin and other medications were stored on ward 3A in both a medication room and medication carts. As a nursing assistant, Ms. Mays was not permitted to access the medication room without authorization. However, the OIG found that all ward 3A staff, including Ms. Mays and other nursing assistants, had full access to the medication room. Further, some medication carts were unlocked and unattended. Given the unexplained hypoglycemic events, open access to insulin stored in the medication room and medication carts was concerning.

The OIG also noted that in 2018, the Pharmacy Service at the facility was not utilizing the VHA-required Veterans Health Information Systems and Technology Architecture Automatic Replenishment System to record ward pharmacy stock, which included vials of insulin and ampules of D50 (50 percent dextrose intravenous injection solution), for inventory accountability. D50 is a medication used to reverse severe hypoglycemia. Pharmacy Service's informal tracking process was inadequate and did not identify the extraordinary amount of D50 used on ward 3A during patients' hypoglycemic events in spring 2018. The failure to identify the high D50 use was a missed opportunity for facility staff to conduct a review and potentially discover unexplained hypoglycemic events earlier.

Clinical Evaluations of Unexplained Hypoglycemic Events

The OHI inspection team found inadequate medical workup and testing to identify the causes of patients' hypoglycemia. Hypoglycemia is rare in patients who are not receiving medication for diabetes.

The first step in determining the cause of hypoglycemia is a clinical assessment to identify medical explanations, such as a contributing illness or medication.⁶ If the clinical assessment does not reveal the reason for hypoglycemia, excess insulin is a likely cause and the source of insulin may either be insulin administered to the patient (exogenous) or insulin produced within

⁵ The OIG was unable to ascertain the exact dates of some incidents and verbal counselings, primarily because interviewees did not recall the precise dates when the incidents or responses occurred.

⁶ Critical illness including liver, kidney, or heart failure and sepsis and medications such as gatifloxacin (antibiotic) and indomethacin (anti-inflammatory) can cause hypoglycemia.

the body (endogenous), most commonly from an insulin-secreting tumor. Laboratory data obtained during an episode of hypoglycemia can help elucidate the insulin source.

The attending hospitalists did not pursue diagnostic testing in seven of the eight victims included in the plea deal, some of whom were not diabetic or not on diabetes medications. Most of the hospitalists who covered ward 3A reported encountering only one or two of these patients and were unable to appreciate the collective significance of the events. Further, three of the hospitalists and the Medical Director of Inpatient Services did not consider nefarious intent. Hypoglycemia caused by nefarious activity is very unusual and thus requires a high level of suspicion on the part of the clinician. Consequently, the hospitalists generally attributed what they considered isolated hypoglycemic events in these elderly and debilitated patients to malnutrition or acute illness, without pursuing other possibilities. Also, the hospitalists did not appear to be consistently familiar with or understand the utility of a laboratory evaluation for patients with unexplained hypoglycemia. One hospitalist said, erroneously, that testing would be of no benefit because the patient had received insulin in the past and thus testing could not discern exogenous from endogenous insulin.

After two different patients (Patients 6 and 8) had unexplained hypoglycemia two days in a row in spring 2018, one of the hospitalists (Hospitalist B) did order insulin and C-peptide levels for Patient 8, a nondiabetic, both of which were in the normal range and not consistent with surreptitious insulin administration. However, the laboratory tests were drawn after Patient 8 received two ampules of D50, which affected the blood values for the investigation of hypoglycemia. Further, the tests ordered measured only human insulin and not the synthetic insulin analogs that were administered to these patients. Hospitalist B did not follow up on the results or complete a diagnostic evaluation but discussed concerns about possible surreptitious insulin administration with the ward 3A nurse manager and Medical Director for Inpatient Services.

None of the hospitalists consulted with an endocrinologist. Endocrinology services were available through the VA Pittsburgh Healthcare System. Some hospitalists did not think it was necessary to consult with an endocrinologist, while others said that this service was not available emergently or at night and that it sometimes took two to three days to receive a response. Timely endocrinology consultation would likely have led to a more tailored assessment of these patients that could have changed the course of events.

During the relevant period, ward 3A was staffed with three hospitalists during the day and one hospitalist at night who were typically scheduled to cover inpatient wards for seven days on and seven days off. While this schedule is common for this specialty, it can present challenges for communication and continuity of care.

Hospitalists reported participating daily in inpatient interdisciplinary rounds; however, the focus of those meetings was on length of stay and discharge planning and did not typically include

patient outcomes and issues. Nurses also appeared to rely on informal communications with varying effects. An example of an unproductive interdisciplinary team meeting involved one of the impacted patients, Patient 1, who had experienced a severe hypoglycemic event the previous night. Reportedly, the discourse centered around the difficulty providers had returning Patient 1's blood glucose to a normal range necessitating the administration of repeated doses of D50. Despite the unexplained hypoglycemia and high use of D50, the quality and content of the interdisciplinary team discussion was apparently not significant enough to prompt further inquiry, evaluation, or action. Hospitalists also reported not having scheduled staff meetings or conferences, but generally reported that they completed verbal or written clinical handoffs of patient care information to oncoming providers.

The OIG found that nurses appeared to rely on informal communication methods that were not consistently effective in relaying patient-specific events or concerns. The ward 3A nurse manager discussed not always receiving reports of adverse patient events, such as patient deaths or falls, and that staff meetings where patient-related information could be discussed were not routinely convened.

Had staff members used meetings and forums to discuss patient outcomes, or had staff consistently taken the initiative to communicate concerns to leaders, it is possible that the emerging pattern of events would have been discovered sooner.

In reviewing patients' EHRs, the OHI inspection team found that physician and nursing documentation was inadequate for several patients who experienced hypoglycemic events. For example, the team reviewed the 18 hospitalist encounters for patients 1–10 and found that while hypoglycemia was acknowledged in the EHR by hospitalists, no further diagnostic testing needs or reflection of differential diagnostic rationales for the unexpected hypoglycemia were documented in 15 of the 18 notes. The absence of this critical information supports the OIG finding that the clinical care provided to these patients was inadequate. In another example, the OIG inspection team was unable to locate physician documentation relative to a patient's low glucose, interventions, and symptomatology during any time that the hypoglycemia was confirmed, nor could the OIG inspection team find documentation from the nurse who discovered the patient during the hypoglycemic event.⁷

Inadequate or nonexistent documentation prohibited other providers and staff from receiving information about the patients' clinical care and treatment and may have contributed to their inability to realize the context and degree of the hypoglycemic events.

⁷ The nurse was required to document significant changes in the patient's condition.

Reporting and Responding to the Events

Staff did not complete patient safety event reports related to the hypoglycemic events or the unusually high use of D50 in several patients in 2018. VHA policy requires staff to report patient safety events, including events that present the opportunity to explore system vulnerabilities, to the patient safety manager even if the condition has not resulted in an adverse clinical outcome or close call. Although patient safety managers are generally responsible for ensuring that staff understand the requirement to report incidents, the hospitalists and nurses the OIG inspection team interviewed were not consistently aware of what incidents to report and how to report them.

A cluster of hypoglycemic events involving four patients occurred over about a three-week period in spring 2018 with an additional two cases 8 and 10 weeks later offering several opportunities for reporting and follow-up:

- **Week 1.** Patient 6 experienced several episodes of profound hypoglycemia during two consecutive days that, at the time, providers could have viewed as isolated events attributable to Patient 6's extreme debility and malnutrition. Accordingly, the OIG did not characterize it as a missed reporting opportunity. Nonetheless, Patient 6 became the first in what would become a cluster of unexplained hypoglycemic events across several patients that did represent missed reporting opportunities.

One day after Patient 6's last hypoglycemic episode, Hospitalist A, a second hospitalist (Hospitalist B), and the ward 3A nurse manager discussed Patient 8, the second unexplained hypoglycemia case in the cluster. They notified the Medical Director of Inpatient Services, and two nurses completed a preliminary review of nursing schedules and patient assignments to explore whether a nurse had inadvertently administered insulin to the wrong patient. The nurses did not identify any common denominators to the incidents and an expanded review incorporating additional potential variables was not completed. Further, no one reported the concerns to the Chief of Staff, Associate Director for Patient Care Services (ADPCS), or Quality, Safety and Value (QSV) staff. Not reporting patient safety issues and concerns to facility leaders or QSV staff hampers the evaluation and trending of patient safety events and the robust review of patient deaths.

- **Week 2.** Patient 1 was discussed in an interdisciplinary team meeting that was held during Week 2. The Utilization Manager, who was present at the meeting, told the OIG inspection team of speaking with the Medical Director of Inpatient Services about something not "adding up" relative to Patient 1, but the OIG did not find evidence that this concern was reported to the Chief of Quality and Risk Management, who was the Utilization Manager's supervisor.⁸ No one notified Pharmacy Service staff about the

⁸ The OIG inspection team was told that the minutes for the interdisciplinary meeting during which Patient 1 was reportedly discussed were missing.

unusually high D50 use (16 ampules of D50 in a 29-hour period), which resulted in depletion of the facility's D50 supply, and several staff members told the OIG inspection team that they assumed someone else had followed up. While the Medical Director of Inpatient Services was aware of the case and D50 use, no additional reviews or actions were initiated, nor were these concerns reported to the Chief of Staff, ADPCS, or Pharmacy Service staff.⁹

- **Week 3.** Patient 4, who had no history of diabetes or insulin therapy, experienced profound hypoglycemia. No additional reviews, notifications, or actions were initiated.

In addition to these events, Patient 5 and Patient 2 experienced unexplained hypoglycemia approximately 8 and 10 weeks after the three-week cluster, respectively. Hospitalist B met with the Associate Chief of Staff after Patient 2's event and reportedly insisted that "something was going on." The Associate Chief of Staff's initial response to Hospitalist B's concerns exemplified the response of most employees—that the events were likely medically based and that there was no need to report. Nevertheless, the Associate Chief of Staff notified the Chief of Quality and Risk Management the same day, and QSV staff initiated a review of the cases.

Nursing and physician clinical leaders could not explain why their respective staff members did not promptly report concerns through their chains of command, although one leader suggested concerns were not brought forward because staff were afraid to do so. The OIG found no evidence to support this assertion.

Overall, it did not appear to the OIG that leaders and managers consistently acknowledged the opportunities that existed to prevent clinically significant adverse events from recurring at critical junctures when staff actions could have made a difference.

Quality Programs and Oversight Activities

The facility QSV Program's integrated monitoring and oversight functions were deficient, resulting in lack of communication of critical quality information and missed opportunities to identify emerging trends through the organizational reporting and committee structure. Key quality control functions including risk management and attention to patient safety concerns were inadequate to ensure reporting, evaluation, and trending of potential and actual patient safety events and a comprehensive review of patient deaths.

The former Risk Manager was responsible for, but did not perform, in-depth mortality (patient death) reviews using suggested VHA tools. The tools included automated occurrence screening

⁹ The Medical Director of Inpatient Services told the OIG of believing that someone else, specifically nursing staff, reported the D50 use to the appropriate stakeholders.

clinical review worksheets or other screening tools to evaluate the circumstances surrounding patient deaths to determine the need for additional review.

Further, the facility did not maintain a process to conduct rigorous review of mortality data to identify outliers or track and trend results. From January 2013 to June 2015, before Ms. Mays started working at the facility, there were two spikes in the unadjusted mortality rate with the highest spike at 4.5 percent. From July 2015 to July 2018, while Ms. Mays was providing direct patient care, there were nine spikes in the unadjusted mortality rate with the highest over 6 percent. While mortality spikes do not automatically imply quality of care deficits or prohibited or unlawful activities, they do reflect a change from the facility's normal mortality pattern and may merit further examination of conditions common to each of the deaths. However, responsible facility staff did not conduct additional reviews related to the mortality rate spikes. The facility was not able to provide the OIG with the reason why these additional reviews were not conducted.

Typically, mortality tracking and trending is a committee or workgroup function. The Chief of Quality and Risk Management created a mortality workgroup prior to the 2018 events but reported the group did not consistently meet due to busy schedules and competing priorities. After the QSV EHR reviews in June 2018 found the tragic events were likely connected, the Chief of Quality and Risk Management requested that the Chief of Staff and ADPCS assign facility staff to serve on a mortality workgroup to address process deficits and suggest changes to improve care; however, this request was not promptly addressed. The Chief of Quality and Risk Management told the OIG of appointing facility staff to the mortality workgroup, through the Facility Director, in July 2020. The first meeting was held in August 2020.

Facility staff lacked knowledge about the types of patient safety events to be reported and how to report them, which compromised the quality and comprehensiveness of the facility's patient safety program. The former patient safety manager did not adequately educate facility staff on the reporting processes. The OIG would expect that, had staff been successfully trained at the time of the events in 2018, patient safety events would have been submitted for, at a minimum, the high use of D50, and possibly for the unexplained hypoglycemic events.

The OIG determined that VHA and facility oversight and reporting requirements were not being followed, leading to deficient information flow and issue identification, as well as tracking actions to closure. Facility policy requires that committee recommendations involving a resource commitment, interdepartmental policy change, directive interpretation, or major initiative be documented in executive council meeting minutes and presented to the Executive Leadership Board (ELB) for final review and approval prior to implementation.¹⁰ Further, VHA policy requires meeting minutes to "track issues to resolution," and facility policy requires use of an

¹⁰ Facility Memorandum 00-05, *Medical Center Governance and Reporting Structure*, April 2017.

action log to do so.¹¹ The facility's standing committees and workgroups did not consistently submit required reports to designated executive councils. For example, one committee that would have been expected to discuss the events on ward 3A and other patient safety-related issues did not report as required to its designated executive council. Further, when committees did submit minutes, detailed documentation of critical information and recommended action tracking through closure was missing.

Executive councils also had actionable items in their meeting minutes that were not documented on the action log. With the exception of one executive council, the OIG did not find documentation in a review of meeting minutes related to the events on ward 3A to include changes or actions taken to improve processes.

Facility, VISN, and VHA Leaders' Responses and Corrective Actions

After the conduct was reported to the OIG, the facility took several actions to improve medication security, nursing policies and processes, and general oversight. Cameras were installed, providing views of ward 3A four hallways and entrance, and a motion-activated security camera was installed in the 3A medication room. A facility workgroup that included staff from QSV, nursing, and Pharmacy Service was created to develop a tracking process for rescue medications such as D50. Further, facility leaders detailed several clinical managers to other roles, reportedly to allow new leaders to gain a fresh perspective of operations relative to ward 3A.

After Ms. Mays pled guilty in July 2020, VISN personnel conducted a site visit and developed a plan largely focusing on opportunities to improve ADPCS and Chief of Staff functions, engaging the VA National Center for Organization Development, and initiating external reviews of care for the eight victims central to this report. While medication room security assessments were added to the Pharmacy Service and Patient Safety Annual Reviews for 2020, they had not been completed due to COVID-19 restrictions.

On August 28, 2019, more than a year after the nature of the hypoglycemic events became clear, VHA's Acting Deputy Chief of Staff requested and received from VHA's Deputy Chief Improvement and Analytics Officer a summary of the facility's deaths during the relevant time frame. The summary acknowledged a "blip" in the acute care standardized mortality ratio from April 1 to June 30, 2018, but said the statistical confidence limits were such that one quarter's elevation would not be considered a "worrisome signal." VHA further reviewed hypoglycemia rates and saw no unusual systemic patterns, noting that the facility's rate of glucoses under 60 milligram/deciliter for April 1 to June 30, 2018, was below the VHA average. The OIG found,

¹¹ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. This directive was in effect at the time of the events discussed in this report; it was rescinded by VHA Notice 2019-21, *Rescission of VHA Directive 1026*. Facility Memorandum 00-05.

however, that VHA did not appear to review and analyze important data from multiple angles; rather, VHA's review and findings generally centered around pre-established reports on mortality and hypoglycemia (in patients taking hypoglycemic agents) used for clinical oversight. The OIG concluded that VHA's minimalist review approach, coupled with a lack of critical analysis of the facility's hypoglycemic event data, likely resulted in missed identification of process weaknesses for the facility.

VHA completed an administrative investigation board on December 18, 2020; nine recommendations were made relating to personnel-specific administrative actions, staff education and training, quality peer reviews, and leadership accountability. The Facility Director was reassigned on December 23, 2020, and the ADPCS was reassigned on December 28, 2020, both to VISN duties.

Hospice and Palliative Care and Ward 3A Nursing Policies and Practices

The OIG found other issues not directly related to Ms. Mays's criminal conduct. For example, the facility did not have an "active hospice and palliative care team" and failed to meet portions of VHA policy. In addition, during the OIG's 2018 initial site visits, the team found nurses using workarounds that placed patients at risk; nurses lacking awareness of hypo- and hyperglycemia procedures; and nurses not being consistently up to date with annual competency requirements for blood glucose monitoring. Although these deficits were not directly related to Ms. Mays's actions, these deficiencies further reflected the casual environment on ward 3A.

Conclusion

Veterans and their families entrust their lives to VHA medical providers and staff every day at the more than 1,200 VHA facilities. They expect and deserve the highest quality of care delivered in a safe and accountable healthcare setting. However, the OIG found that the facility did not consistently promote a culture that prioritized patient safety as expected of a high-reliability organization. Consequently, a combination of clinical and administrative failures at the facility created the conditions that allowed Ms. Mays to commit these criminal acts and for them to go undetected for so long. Ultimately, the failure of leaders at multiple levels to ensure patient safety resulted in the tragic events described in this report.

Recommendations

The OIG made three recommendations to the Under Secretary for Health related to adjudicator follow-up of unreturned background investigation documentation, rescue medication security and management, and mortality data analyses. The OIG made two recommendations to the VISN Director to conduct management reviews of the care of patients discussed in this report, as well as a broader external clinical evaluation of patients who may have been harmed in other ways by

Ms. Mays's actions during her tenure at the facility. The OIG made 10 recommendations to the Facility Director related to the Pharmacy Service's inventory accountability, endocrinology consults, clinical communication expectations and forums, clinical documentation reviews, clinical care-related reporting expectations, patient safety event training, interdisciplinary mortality workgroup activities, oversight and reporting, and a culture of safety.

Comments

The Acting Under Secretary for Health concurred with recommendations 1, 13, concurred in principle with recommendation 15, and provided an acceptable action plan (see appendix B). The Veterans Integrated Service Network 5 Director concurred with recommendations 3 and 5 and provided acceptable action plan (see appendix C). The Facility Director concurred with recommendations 2, 4, 6-12, 14 and provided an acceptable action plan (see appendix D). The OIG will follow up on the planned actions until they are completed.



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Abbreviations

ACN	Associate Chief Nurse of Acute Care
ADPCS	Associate Director for Patient Care Services
COVID-19	coronavirus disease 2019
D50	50 percent dextrose intravenous injection solution
EHR	electronic health record
ELB	Executive Leadership Board
FTE	full-time equivalent
OHI	Office of Healthcare Inspections
OIG	Office of Inspector General
OPM	Office of Personnel Management
POC	point-of-care
PCCT	Palliative Care Consult Team
RAPID	Office of Reporting, Analytics, Performance, Improvement, Deployment
QSV	Quality, Safety and Value
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

On July 14, 2020, Reta Mays pled guilty to seven counts of second-degree murder and one count of assault with the intent to commit murder while employed by the VA as a [nursing assistant](#).¹ The victims were patients at the Louis A. Johnson VA Medical Center (facility) in Clarksburg, West Virginia.² In October 2020, as part of a post-plea interview required by her written plea agreement, Ms. Mays told investigators that she had deliberately inserted [insulin](#) into patients' saline mixtures that were used to flush their intravenous ports, resulting in profound [hypoglycemia](#) and death.³ Ms. Mays performed these acts between summer 2017 and late spring 2018.

Ms. Mays provided additional information in her post-plea interview. Specifically, Ms. Mays claimed that in one instance, she provided a nurse with an insulin-tainted saline flush syringe that the nurse, unaware of the tampering, administered to the patient via the intravenous port. Ms. Mays further claimed that she secured the insulin from ward 3A pharmacy stock (supplies for patient care located in the ward 3A medication room or medication carts). She also asserted that she performed these acts, on the one hand, because the patients were suffering and she wanted them to die gently and, on the other hand, because she had a lot of stress and chaos in her personal and professional life and these actions gave her a sense of control. For all the patients described in her plea and in this report, the clinical expectation was that each would survive the condition for which they were hospitalized. The purpose of this inspection was to evaluate the factors related to these crimes, including several elements and key personnel's decision-making points beginning with the hiring of Ms. Mays, medication management and security, clinical evaluation and follow-up of the events, the Quality, Safety and Value (QSV) Program and oversight activities, and leaders' actions in response to the events.

The Office of Inspector General Criminal Investigation and Initial Outcome

This OIG healthcare inspection was started in parallel with the criminal investigation that was conducted by the VA Office of Inspector General (OIG), the Federal Bureau of Investigation,

¹ The underlined terms in the text are hyperlinks to other sections in the report or the glossary.

² The facility serves approximately 70,000 veterans in north central West Virginia and adjacent counties in Maryland, Ohio, and Pennsylvania. It is part of VA's region designated as Veterans Integrated Service Network 5.

³ Hypoglycemia refers to low blood glucose (also called "blood sugar"). It is a relatively common occurrence and complication in diabetic patients who receive medications to lower their blood glucose levels. Some of the reasons why a nondiabetic patient would experience hypoglycemia are drugs, critical illnesses, deficiencies in hormones that help keep blood glucose normal, tumors, and the use of insulin in someone who does not have diabetes. However, the primary cause of hypoglycemia, even in nondiabetic patients, remains the administration of diabetes medication or synthetic insulin.

and the United States Attorney's Office, with assistance from the West Virginia State Police, and the Greater Harrison Drug & Violent Crimes Task Force. Any actions in the healthcare inspection that could potentially impede or compromise the criminal investigation were held until the appropriate time. On June 27, 2018, the Facility Director contacted the OIG's Office of Investigations after-hours duty agent requesting an investigation with the belief that there was at least one criminal act, possibly more, had been committed. On June 28, Veterans Health Administration's (VHA) Executive in Charge, Dr. Carolyn Clancy, informed VA's Inspector General Michael Missal that "there may be an 'Angel of Death' in Clarksburg. A number of patients in their 80's and 90's [*sic*] have suspiciously died of low blood sugar [glucose]." The OIG's Office of Investigations initiated an investigation that same day.

Staff from the OIG's Office of Healthcare Inspections (OHI) provided on-site assistance to the OIG's Office of Investigations July 2–3 and July 9–13, 2018. OHI also conducted additional site visits in July and August, and undertook in-depth electronic health record (EHR) reviews of nine patients identified by the facility as having experienced profoundly abnormal blood glucose levels (less than 45 milligram/deciliter (mg/dL)).⁴ OHI also reviewed all the EHRs related to 112 patient deaths that occurred on ward 3A dating back to mid-2015 when Ms. Mays began employment at the facility. During this review, OHI identified a possible tenth patient who had concerning hypoglycemia. (See this report's [Scope and Methodology](#) section for more information on the total number of patient deaths reviewed for the period Ms. Mays was employed to identify potential victims of her actions.)

On July 5, 2018, after identifying Reta Mays as a person of interest, the OIG recommended to facility leaders that she be removed from patient care. The Facility Director informed the OIG that on that same day, she was assigned to a non-clinical position where she would not be caring for patients. In October 2018, based on information provided by the OIG, the facility began a review of Ms. Mays's dishonest answers during an OIG interview. On March 6, 2019, Ms. Mays's federal employment terminated. During this time, the OIG continued the criminal investigation. Several of the concerns the OIG deemed to be urgent during the course of the inspection to ensure patient safety, such as medication security, were discussed with the Facility Director on July 11 and 13, 2018, and promptly addressed.

After pleading guilty to murder and attempted murder on July 14, 2020, Ms. Mays was remanded to the West Virginia Regional Jail and Correctional Facility pending sentencing.

Why the OIG Did This Review

The OIG considers patient safety to be of the highest concern. The families of the veterans who died deserve answers about how this could have happened. The VA, lawmakers, and the veteran community need to understand how something like this can be prevented from happening

⁴ Hypoglycemia can be mild (54–70 mg/dL), moderate (less than 54 mg/dL), or severe (often below 40 mg/dL).

anywhere else. A criminal investigation focuses on establishing a case for prosecution, whereas this healthcare inspection examines the underlying factors in the facility that contributed to Ms. Mays's actions going undetected or unreported for so long.

The OIG's interviews with facility personnel and extensive EHR reviews identified substantial quality of care concerns, primarily related to hospitalists' failures to fully evaluate the causes of the patients' unexplained hypoglycemic events. In addition, the OIG identified multiple deficits on ward 3A where Ms. Mays was primarily assigned that included lax medication management and security; nurses using workarounds that placed patients at risk; nurses lacking awareness of hypo- and hyperglycemia procedures; and nurses not being consistently up to date with annual competency requirements for blood glucose monitoring. Further, ward 3A nurse managers were unaware of these deficiencies.

To determine whether these concerns contributed to a weak clinical practice environment, and to better understand the factors that permitted Ms. Mays's actions to go undetected, the OIG evaluated the strength of key processes and conditions in the sequence of events from 2015 to 2018.

Relevant Facility Personnel and Ms. Mays's Area of Assignment

Senior leaders discussed in this report in 2017–2018 when these crimes were committed included the Facility Director, Associate Director, Chief of Staff, and Associate Director for Patient Care Services (ADPCS). Additional service level managers included the Associate Chief of Staff for Primary and Specialty Care, the Medical Director for Inpatient Services, and the Chief of Quality and Risk Management.⁵

The external review coordinator indicated the facility has 49 inpatient beds, including 24 on ward 3A where Ms. Mays was primarily assigned. The layout of ward 3A includes a centrally located nursing station and four hallways that branch off in right angles forming a "plus" shape. Ward 3A's medication room is located near the nurse manager's office and about three doors from the nurses' station.

⁵ The Facility Director is responsible for overall delivery of quality medical care to veterans served by the facility. The Associate Director told the OIG of overseeing Fiscal, Facilities Management, Police, and Pharmacy Service, among other areas. The Chief of Staff oversees clinical staff including physicians and mid-level providers in all inpatient and outpatient areas and specialty care. The ADPCS told the OIG of overseeing inpatient and outpatient nursing, Sterile Processing Services, Chaplain Service, and staff development. The Associate Chief of Staff for Primary and Specialty Care told the OIG of overseeing clinical providers in primary care, community-based outpatient clinics, the emergency department, and specialties such as cardiology and nephrology. The Medical Director for Inpatient Services told the OIG of being the lead hospitalist, managing schedules and covering shifts as needed. The Chief of Quality and Risk Management told the OIG of overseeing quality-related areas including risk management, patient safety, and organizational performance, among others.

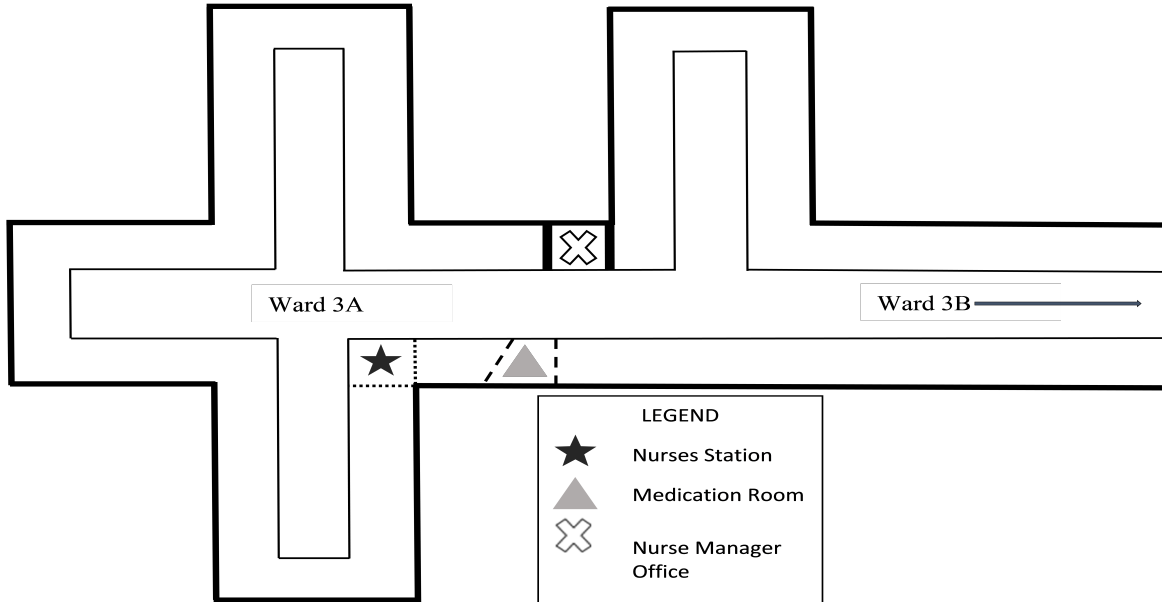


Figure 1. Diagram of Ward 3A
Source: Diagram provided by the facility.

The former Associate Chief of Staff told the OIG that during the relevant period, ward 3A was staffed with three hospitalists during the day and one nocturnist (a physician who works overnight). A spreadsheet provided by the facility to the OIG reflected that ward 3A was staffed with 25 licensed direct-care nurses, 11 nursing assistants, an assistant nurse manager, and a nurse manager.⁶ The Associate Chief Nurse (ACN) of Acute Care had overall responsibility for nursing activities on ward 3A.

Ms. Mays’s Nursing Assistant Role and Requirements

Nursing assistants are healthcare workers who work under a licensed nurse’s supervision and assist with basic patient tasks such as bathing and feeding, taking vital signs, completing glucometer testing, and providing 1:1 observation (acting as a sitter).⁷ Nursing assistants are to observe, document, and report all changes in patients’ conditions to the licensed nurse.

⁶ According to the facility, as of May 6, 2021, 31 registered nurses and 11 nursing assistants were assigned to ward 3A (including an assistant nurse manager and a nurse manager). There were 5.5 vacancies: 4.5 registered nurses (including the assistant nurse manager) and 1 nursing assistant.

⁷ Sitters may be used for agitated patients who may be combative or confused, at risk for falls, or otherwise require supervision. Victoria J. Wood., “One to one Specialling [*sic*] and Sitters in Acute Care Hospitals” *International Journal of Nursing Studies* 84. (2018) 61-77.

Ms. Mays was hired at the General Schedule pay grade 5 (GS-5) level. To be eligible for hire at this grade level, she was required under VHA's nursing assistant qualifications standards to have one year of experience in progressively responsible assignments and experience equivalent to the GS-4 level, which demonstrated knowledge, skills, and abilities directly related to the specific assignment. She was also required to have the following abilities:

- Assist in the full range of nursing care to patients with physical and behavioral problems in a hospital, long-term care, or outpatient setting under the direction of a registered nurse
- Communicate orally with patients, families, interdisciplinary team members, and other personnel (including helping to coordinate new nursing assistants' orientation and overseeing and assessing their practical experiences in a clinical setting)
- Recognize and react to emergent patient care situations and intervene while waiting for assistance (for example, recognizing the need for basic life support, controlling bleeding, or assisting with a behavioral health crisis)⁸

Nursing assistants do not have the training, expertise, or authority to independently assess the severity of a patient's medical condition or emotional distress.

⁸ VA Handbook 5005/81, Part II Appendix G46, *Nursing Assistant Qualification Standard*, March 12, 2015.

Scope and Methodology

To go back to point of origin hyperlink, press “alt” and “left arrow” keys.

The OIG initiated the inspection in July 2018 but suspended some review activities pending completion of the criminal investigation to ensure the integrity of those efforts. On July 14, 2020, the OIG resumed that work and conducted an unannounced site visit to the facility on July 27. The remainder of the inspection was conducted remotely due to coronavirus disease 2019 (COVID-19) concerns.

The OIG inspection team interviewed the Facility Director, ADPCS, Chief of Staff, and the Associate Director; leaders and staff from Education and Training, Engineering, Human Resource Management, Pharmacy, Quality and Risk Management, and VA Police Services; and relevant facility physicians, nurses, and clinical support staff with knowledge of the issues. The OIG inspection team also interviewed leaders and staff from VHA’s Offices of Analytics and Performance Integration, Veterans Integrated Service Network (VISN) 5, and VA’s Personnel Security Adjudication Center and Security and Investigation Center. Leaders and staff from the Office of Personnel Management (OPM), Defense Counterintelligence and Security Agency, and the Office of General Counsel were also interviewed. In addition, the OIG inspection team communicated with personnel at the West Virginia Regional Jail where Ms. Mays had been a corrections officer.

The OIG reviewed relevant VHA, VISN, and facility policies; training records; personnel files; All Employee Survey data; and facility mortality data. The team reviewed selected facility meeting minutes from October 2017 through August 2020 and examined relevant documents from July 2015 to July 2020.

In an effort to identify potential victims beyond the 10 patients noted earlier in this report, the OIG focused on four cohorts and reviewed the EHRs of more than 200 patients:

- 112 patients who died on ward 3A during Ms. Mays’s employment⁹
- 66 patients with laboratory evidence of at least one hypoglycemic event during Ms. Mays’s employment

⁹ Patient 10 was identified through this review.

- 21 patients who died at the facility during Ms. Mays’s employment and whose EHRs reflected one or more of the following criteria—lack of documentation, abnormal clinical decline, hypoglycemic events, or death pending transfer to lower levels of care or within 24 hours of planned discharge
- 24 patients whose families submitted inquiries to the facility, the OIG, the Federal Bureau of Investigation, the United States Attorney’s Office, and/or congressional offices after the events were widely reported by the media¹⁰

See [appendix A](#) for more information on the OIG’s EHR review methodology.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

¹⁰ Some patients fell into more than one category.

Inspection Results

The OIG reviewed the events surrounding the homicides and attempted murder admitted to by Ms. Mays to understand how such actions could have occurred, whether they could have been detected earlier, and what actions should be taken to prevent future tragedies. This inspection sought to answer six key questions:

1. Were parties responsible for Ms. Mays's hiring and supervision diligent in their activities to provide facility leaders with confidence in Ms. Mays's character and her ability to meet performance expectations?
2. Were medication security and pharmacy stock tracking practices on ward 3A sufficient to safeguard patients and prevent misuse?
3. Did clinical staff adequately evaluate the profound and unexplained hypoglycemic events in a way that supported quality of care and patient safety?
4. Did clinical staff and leaders appropriately report and respond to the unusual and concerning events?
5. Were the facility's QSV Program and oversight activities sufficient to identify, report, and act on care and safety concerns?
6. How did facility, VISN, and VHA leaders respond to the events and what actions were taken to prevent future occurrences?

In the course of addressing these six questions, the OIG noted areas of concern regarding hospice and palliative care practices and nursing policies that warranted mention and are briefly discussed in the [Final Observations](#) section of this report.

Finding 1. Facility Employee Actions Related to the Initial Hiring and Ongoing Supervision of Ms. Mays Were Perfunctory

Inadequate policies and failures in personnel practices beginning with the hiring process resulted in VA employees missing multiple opportunities to identify concerning conduct in one of Ms. Mays's previous non-VA positions. The conduct, if known, may have been disqualifying for Ms. Mays to retain a VA position in which she would be providing direct patient care. Ms. Mays had been previously employed at a residential facility from October 2012 to July 2015 and at a regional jail in West Virginia from August 2005 to September 2012.¹¹ The OIG learned that while a corrections officer at the jail, Ms. Mays was the subject of excessive force allegations.

The OIG inspection team was told by the former ward 3A nurse manager that Ms. Mays participated in a hiring fair and was interviewed by nursing leaders at that time. As a potential

¹¹ The residential facility provided services to elderly and disabled individuals needing assistance and supervision.

candidate for federal employment at the facility, Ms. Mays completed the OPM Electronic Questionnaires for Investigations Processing (e-QIP) questionnaire, Standard Form 85, *Questionnaire for Non Sensitive Positions*, on May 14, 2015, and human resource staff initiated pre-employment requirements for non-licensed clinical employees including the Special Agreement Check (SAC)/fingerprints and background investigation.¹² All VA positions are assigned a risk level classification ranging from low/non sensitive (Tier 1) to high-risk positions of public trust (Tier 4). Nursing assistant positions are classified as low risk/non sensitive. For this risk level, VHA requires a Tier 1 investigation (referred to as a "National Agency Check with Inquiries [NACI]" in 2015), which is a basic investigation that includes queries of several federal databases; fingerprints; a credit check; and law enforcement, education, and employment checks, among other scrutiny.¹³

Ms. Mays's SAC/fingerprint results, returned by OPM to the facility on May 18, 2015, reflected "no record."¹⁴ Ms. Mays received a conditional offer for employment dependent on the favorable adjudication of her background investigation. It is considered acceptable practice for sponsoring federal agencies, in this case VA, to have new employees working in certain positions while this process is completed. Ms. Mays's *Notification of Personnel Action* reflected a start date at the facility of June 28, 2015, and a starting salary of about \$32,000.

The OIG found that OPM completed its background investigation work in a timely manner, and on September 15, 2015, closed the investigation and provided the results to the requesting facility. The facility's adjudicator was responsible for determination of Ms. Mays's suitability and fitness for employment.¹⁵

¹² The "e-QIP is a web-based automated system that was designed to facilitate the processing of standard investigative forms used when conducting background investigations for federal security, suitability, fitness and credentialing purposes. The e-QIP system allows the user to electronically enter, update and transmit personal investigative data over a secure internet connection to a requesting agency," accessed September 16, 2020, <https://nbib.opm.gov/e-qip-background-investigations/>.

¹³ OPM, through the Position Designation System, provides guidance to government agencies on the proper level of investigation and screening required based on a position's risk or national security sensitivity. All VA positions are assigned a risk level classification ranging from low/non sensitive (Tier 1) to top secret/critical sensitive (Tier 4).

¹⁴ Because the SAC/fingerprint review had been returned with "no issues" on May 18, 2015, and the background investigation was in process, the facility was acting within its authority to offer interim employment to Reta Mays pending completion of the background investigation.

¹⁵ VA Directive 0710, *Personnel Security and Suitability Program*, June 4, 2010. Federal employees who perform work as suitability adjudicators, or are responsible for suitability screening or review, must receive appropriate training and provide verification of completion. VA Security and Investigations Center Standard Operating Procedures, 2013.

Failure to Complete Supervisor-Initiated Employer Reference Checks

Separate from the OPM background investigation, responsible hiring supervisors or managers at the facility often conduct reference checks with prior employers to determine whether an applicant's skills and demeanor would be a good "fit" for the position. According to OPM, supervisory reference checks are intended to verify the information an applicant provided and can offer additional context that permits a manager to better predict how the candidate would perform on the job. OPM guidance states that "Reference checking is a vital part of a successful hiring strategy."¹⁶

The OIG inspection team received confusing and conflicting statements about who was responsible for reference checks at the facility and whether they were conducted in this case. Two facility human resource officers stated that the facility did not require the completion of reference checks as part of the hiring process in 2015.¹⁷ Although not required, the former Human Resource Officer told the OIG inspection team that the selecting official (in this case, the ward 3A nurse manager) would have been responsible for the reference checks. The former ward 3A nurse manager reported not conducting reference checks in this case because that responsibility fell to the Human Resource Management Service; however, the former ward 3A nurse manager did recall being told by other facility employees who had worked with Ms. Mays at the residential facility that she was a good employee. The former ACN reported having completed the reference checks, and although the ACN did not document or comment on the results of those checks, the ACN said that the practice would not have been to hire someone with poor references.¹⁸

Because of conflicting statements and lack of documentation, the OIG could not definitively determine whether any hiring manager contacted Ms. Mays's two most recent employers to verify employment data and make additional inquiries about skills and performance. Ms. Mays's conduct while employed by the jail should, at minimum, have prompted additional evaluation and could have provided a basis for dismissal during her probationary period that ended September 2016.

¹⁶ Reference Checking, OPM, undated, accessed September 14, 2020, <https://www.opm.gov/policy-data-oversight/assessment-and-selection/other-assessment-methods/referencechecking.pdf>. For additional information, see U.S. Merit Systems Protection Board, *Reference Checking in Federal Hiring: Making the Call*, September 2005.

¹⁷ In early 2018, reference checks became an expected part of recruitment packets at the facility.

¹⁸ The ACN also reported not maintaining copies of the reference checks as that was the Human Resource Service's responsibility, but then noted the Human Resource Service "loses things quite often." The General Records Schedule authorizes destruction of interview documents contained within the official personnel file at the end of two years, so reference check documents, if obtained, likely would not have been available for OIG review in 2018 or after.

OPM Background Investigation and Adjudication of Suitability for Employment

The facility's adjudicator at the time of the events under discussion (former adjudicator) did not complete required actions to evaluate Ms. Mays's suitability for employment and adjudicate the case in a timely manner. Ms. Mays worked at the facility for almost four years without this basic employment safeguard in place.

Initial Adjudication Failure

After OPM completed its background investigation work, the case was considered "closed" and was returned to the facility on September 15, 2015. In accordance with VA guidelines, the facility's former adjudicator, who was fully trained and considered by the supervisor to be a subject matter expert within the facility, had 90 days to complete the adjudication and document the result in the Personnel Security and Processing System/Central Verification System. Of significance, at case closing, the OPM investigator checked the "Q" code box, which stated "There are potentially actionable issue(s) ... which may be disqualifying under suitability/security considerations." The OIG was unable to discern what factor(s) prompted the background investigator to use the Q code.¹⁹ In response to the Q code, the OPM instruction form guided the facility's former adjudicator to complete another form indicating personnel and adjudicative actions taken, and to return that form to OPM within 90 days.²⁰

The facility's former adjudicator was responsible for reviewing the contents of the background investigation file and, "based on careful, objective analysis of all available, relevant information, both favorable and unfavorable," determining the applicant's suitability for employment.²¹ "If a person's character or conduct, past or present, could adversely affect the integrity or efficiency of the service, the person may not be considered suitable."²² A favorable adjudication means the applicant has been determined to be suitable for federal employment. The OIG found no documented evidence of adjudication, favorable or otherwise, by December 15, 2015, and the background investigation was on VHA's "delinquent" adjudication list. The facility's current

¹⁹ The background investigation reflected credit issues, as well as home address and military date discrepancies. The OIG had no way of knowing what concerns prompted the Q code.

²⁰ OPM, INV Form 79A, *Report of Agency Adjudication Action on OPM Personnel Investigations*. Examples of possible actions included favorable determination; resigned, terminated, or withdrew application prior to determination; and not appointed, removed, or counseled based on determination, among other options.

²¹ VA Security and Investigations Center Standard Operating Procedures, December 23, 2016.

²² 5 CFR § 731.202. The adjudicator can only consider certain factors as a basis for finding a person unsuitable, including misconduct or negligence in employment; criminal or dishonest conduct; material, intentional false statement, or deception or fraud in examination or appointment; and alcohol and drug abuse without evidence of substantial rehabilitation. The adjudicator must also consider mitigating factors such as the nature of the position for which the person is applying; the seriousness and recency of the conduct; and the circumstances surrounding the conduct.

adjudicator informed OIG that the facility's former adjudicator, who was responsible for Ms. Mays's background investigation in 2015, left VA employment in late September 2018, and the position was permanently filled in December 2018. The facility's current adjudicator told the OIG inspection team of finding "stacks" of unadjudicated cases left in filing cabinets by the facility's former adjudicator.²³ However, the facility's current adjudicator told the OIG inspection team that Ms. Mays's hard-copy adjudication file was never found.²⁴ The first documentation in the Personnel Security and Processing System/Central Verification System was on February 3, 2020. Ms. Mays's federal employment terminated nearly a year prior, in March 2019.

On December 2, 2019, VHA's Deputy Under Secretary for Health for Operations and Management issued guidance outlining required actions to address delinquent adjudications.²⁵

Associated Adjudication Concern

As part of the investigative process for Tier 1-specific reviews, investigators send an OPM INV Form 41, *Investigative Request for Employment Data and Supervisor Information*, to previous employers as listed by the candidate. The INV Form 41 asks about the individual's employment status, including the circumstances of the individual's separation from previous employment; eligibility for rehire; reasons to question the individual's honesty or trustworthiness; adverse information about the individual's employment, residence, or other activities (such as legal, financial, mental stability, alcohol/drugs, general behavior, or conduct); and whether the previous employer recommends the individual for government security clearance or employment. In this case, the INV Form 41 from Ms. Mays's previous employers had not been returned by the time OPM closed the investigation.

The OIG found that VHA and OPM guidance was inconsistent and confusing on adjudicator-initiated follow-up for any unreturned INV Form 41. Specifically, managers from the VA Security and Investigations Center, as well as OPM and the current investigative service provider, told the OIG inspection team there was no requirement to follow up with previous employers after the initial attempt by the investigative service provider.²⁶ Also, two adjudicators not involved in this case told the team that follow-up is not required. However, VHA's Personnel Security Director, Workforce Management and Consulting, provided a September 2016 advisory

²³ The facility's current adjudicator told the OIG inspection team of completing more than 150 backlogged cases after finishing the adjudication training.

²⁴ In April 2020, OPM provided an electronic copy of Ms. Mays's background investigation in response to the facility's request. This was the document reviewed by the OIG.

²⁵ VHA 10N Memorandum, *Notification of Delinquent Background Investigation Adjudications* (VIEWS #1580291), December 2, 2019.

²⁶ OPM officials told the OIG inspection team that OPM did not recommend that adjudicators directly follow up with previous employers. Rather, OPM said that while not required, adjudicators could contact the subject for more information or could request the investigative service provider make additional inquiries.

entitled *VHA Adjudicator Consistency*, which stated, “With employer vouchers [INV Form 41], if OPM inquiries to prior employers are undeliverable, returned, discrepant, or present issues, follow-up with the employer should occur to obtain any relevant employment records.” The OIG found no evidence that this occurred.

Supervision

The former ward 3A nurse manager acknowledged being aware of a few concerning incidents involving Ms. Mays’s performance at the facility from 2015 to June 2018. Documentation reflected that Ms. Mays reportedly took the cap off a blood tube to access a blood sample, ostensibly to avoid subjecting the patient to another fingerstick, and on another occasion, she left a patient in soiled bedding at the end of her shift. The former ward 3A nurse manager told the OIG inspection team that Ms. Mays was verbally counseled after the blood tube incident and a verbal counseling and report of contact occurred for the patient soiling incident. Although Ms. Mays also reportedly disconnected intravenous lines and turned off or cleared intravenous pump data several times during her employment at the facility without authorization, it did not appear to the OIG that ward 3A supervisors were notified at the time of the events and no counseling occurred. The former ward 3A nurse manager did not provide the OIG with documentation that Ms. Mays had been counseled.

During interviews, some nursing colleagues told the OIG inspection team that Ms. Mays exhibited odd or aggressive behavior toward patients at times, which they typically attributed to stress in Ms. Mays’s personal life. None of the individuals the OIG inspection team interviewed reported being suspicious that Ms. Mays was responsible for or involved in the hypoglycemic events.

Performance Assessments

Although the OIG did not examine all training that Ms. Mays completed, the OIG found that documentation maintained by the former ward 3A nurse manager reflected that Ms. Mays completed training and competencies relative to matters discussed in this report, including blood glucose determination and blood glucose monitoring device procedures.

Ms. Mays received fully successful, excellent, and outstanding performance ratings in October 2015, 2016, and 2017, respectively.²⁷ She received a fully successful performance rating for her work on ward 3A through June 29, 2018, after which she was transferred to another department that did not involve patient care during the criminal investigation. Ms. Mays served on nursing

²⁷ VA Directive 5017, *Employee Recognition and Awards*, April 15, 2002; VA Handbook 5017/9, VHA Delegation of Approval Authority for Special Contribution, Performance, Suggestion, and Time Off Award; and, Quality Step Increases, Part I, Appendix B, July 7, 2010. “A one-time cash award that may be granted to a title 5, title 38 or title 38 hybrid employee based on his/her performance appraisal rating of record provided that the rating of record is at the fully successful level (or equivalent) or a above.”

morale and scheduling workgroups, completed scheduling for the nursing assistant staff, and helped with new staff orientation for ward 3A and “float pool” nursing assistants.

In December 2016, the then ward 3A nurse manager nominated Ms. Mays for the VA Secretary’s Award for Excellence in Nursing (nursing assistant category), describing Ms. Mays as a hard worker who had an excellent rapport with ward 3A’s healthcare team, and who demonstrated “a true compassion” for veterans. All awards signed by the VA Secretary require a completed security check, which is documented on VA Form 0235, *Security Check for Candidate Requiring Approval of the Secretary*.²⁸ On December 16, 2016, the former facility adjudicator improperly annotated VA Form 0235 with “Favorable NACI [National Agency Check with Inquiries] closed by OPM 9/15/15.”²⁹ This erroneous entry constituted another missed opportunity for the adjudicator to evaluate the Q code associated with Ms. Mays’s background investigation and make additional inquiries. On September 12, 2017, Ms. Mays received the Secretary’s Award for Excellence/Nursing Assistant of the Year, which is a facility-level award, along with \$500. Ms. Mays also received cash awards in February of 2017 and 2018.

Recommendation 1

Recommendation 1. The Under Secretary for Health ensures actions are taken to clarify and broadly disseminate adjudicator expectations for follow-up of an unreturned INV Form 41.

Finding 2. Ward 3A Medication Security and Pharmacy Ward Stock Tracking Practices Were Inadequate

The OIG identified several persistent medication mismanagement and security concerns on ward 3A that gave Ms. Mays the opportunity to obtain, without detection, the insulin that she used to commit the homicides. Ms. Mays claimed in a post-plea interview that she secured the insulin she administered to her victims from ward 3A pharmacy stock. Given Ms. Mays’s confession, the elapsed time since the events, and the lack of relevant documentation, the OIG did not attempt to identify specific dates, doses, or locations of missing insulin.³⁰ Notably, Ms. Mays claimed that it was a spontaneous decision with each victim, that securing the insulin was

²⁸ VA Form 0235, *Security Check for Candidate Requiring Approval of the Secretary*, Jan 1995. The purpose of this requirement is to protect the integrity of the Secretary of VA during the award process. The OIG was later told that VA Form 0235 should have been completed by VA’s Personnel Security Adjudication Center, not by the facility.

²⁹ The facility’s former adjudicator knew, or should have known, that the case had not been adjudicated, favorably or otherwise, between September 2015 and December 2016. The OIG referred concerns about this erroneous documentation to another OIG division for further evaluation and action, if indicated.

³⁰ Upon notification of the events in June 2018, OIG criminal investigators collected, when available, appropriate evidence related to insulin storage and use on ward 3A, as well as insulin administration relative to the patients discussed in this report.

not difficult, and that none of her supervisors or colleagues asked questions or otherwise appeared to be suspicious about her activities.

During the OIG's 2018 initial site visits, the OIG identified multiple deficiencies in medication management and security on ward 3A.³¹ Of note, the ward 3A assistant nurse manager and nurse manager both told the OIG inspection team that they knew of instances when the medication room or carts were accessed by nursing assistants without authorization. Neither, however, appeared to further evaluate how the nursing assistants accessed the medication room or carts, nor had they removed their ability to do so. The ACN reported in an interview not being aware of medication security deficits on ward 3A. The OIG conducted an unannounced follow-up visit on July 27, 2020, to determine whether the conditions observed in 2018 still existed or had been corrected.

Security of Medication Room, Refrigerator, and Carts

Nursing staff, including nursing assistants, had access to a key to the medication room until approximately two weeks prior to the OIG's initial July 2018 site visit. The medication refrigerator, which was located in the medication room and contained insulin, was unsecured. In addition to insulin, the medication room included anti-anxiety medications, antibiotics, steroids, heart medications, and narcotics. VHA requires "all necessary actions to reduce the likelihood of intentional or unintentional untoward use of selected...medications," including insulin. VHA also requires facilities to create a local policy that ensures medication controls, including "Medications are stored in a secure manner. Access to medication is limited to authorized personnel who dispense or administer medication"³²

The facility's security specialist told the OIG inspection team that the medication room had used a personal identity verification card and code access system since March 2016. The charge nurse reported that to gain access to the medication room, authorized staff members inserted their personal identity verification card into a card reader and then entered a six-digit code that was assigned only to them. While the team was told in 2018 that only licensed nurses and Pharmacy Service personnel were to access the medication rooms, the OIG inspection team learned through interviews with ward 3A staff that all ward 3A staff, including nursing assistants, had access to ward 3A master keys that could bypass the combined personal identity verification and code system. In the context of the unexplained hypoglycemic events, open access to insulin stored in an unsecured refrigerator was concerning.

The OIG inspection team was told during its July 2020 site visit that nursing assistants no longer had access to the medication room. According to the charge nurse on duty at the time of the

³¹ Due to the potential for patient harm, the OIG inspection team discussed the identified deficits with the Facility Director on July 11 and 13, 2018.

³² VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017.

unannounced follow-up visit, nursing assistants had “no reason to go in the medication room.” The facility security specialist was unable to provide an exact date as to when the key lock for the medication room was changed to prevent personnel from bypassing the combined personal identity verification and code system.

In 2018, medication carts on ward 3A were not consistently secured as some were unlocked and unattended, and in addition, staff were able to use the same code to unlock medication carts throughout the facility.³³ The OIG inspection team determined that the facility did not have a policy or standard operating procedure regarding the security of medication carts in 2018 because the 2019 standard operating procedure did not have a rescission date for a prior version. The initial 2018 on-site OIG team found insulin in the cart drawers. At that time, medications maintained in the carts also included antibiotics, steroids, and heart medications. In response to the OIG’s concern, the ACN sent an email on August 8, 2018, reminding relevant facility staff members that medication carts must be locked at all times, and carts that did not lock should be stored in the medication room. The email referenced that funds were secured to purchase 12 new medication carts with locking systems requiring a user-specific code. Ward 3A’s corrective action plan reflected that the medication carts arrived at the facility in January 2019 and were placed in use February 1, 2019.

The facility subsequently issued a policy in April 2019 establishing guidelines for accessing and operating medication carts, which stated that nursing staff and pharmacy technicians were responsible for keeping the carts locked.³⁴ Facility tracer rounds and email communication reflected, however, that on at least two occasions (September and December 2019), medication carts were found unlocked during these routine checks.

During the July 2020 unannounced site visit, the OIG noted six medication carts in use on ward 3A. The carts were no longer used to store medications; rather, they contained routine supplies like gauze and alcohol swabs. Patient-specific medications and insulin were being stored in an [automated dispensing cabinet](#).³⁵ The carts were used to securely transport medications from the Pyxis to the patient for medication administration. All six carts were locked.

The OIG received confirming information that nurses had been assigned user-specific codes to open medication carts to help track who accessed certain medication carts and when.

Pharmacy Ward Stock Tracking and Trending Practices

Concerns about access to insulin and lax security practices on ward 3A prompted the OIG inspection team to complete a further review of Pharmacy Service’s tracking and trending

³³ The medication cart locks may have been broken or the buttons worn out from usage.

³⁴ Facility Standard Operating Procedure 118-167, *Operation of Medication Carts*, April 2019.

³⁵ The automated dispensing cabinet in use at the facility was a Pyxis™ unit.

practices. The OIG found that the Pharmacy Service was not utilizing the VHA-required system, called the Veterans Health Information Systems and Technology Architecture Automatic Replenishment System, to record ward pharmacy stock for inventory accountability.³⁶ That stock included vials of insulin and ampules of [D50](#) (50 percent dextrose intravenous injection solution—a rescue medication to treat profound hypoglycemia).

Tracking

VHA requires Pharmacy Service staff to record stock medication sent to wards using the Pharmacy Service medication management system, and maintain the records for inventory accountability.³⁷ The Chief of Pharmacy Service told the OIG inspection team in 2018 that the facility did not use the replenishment system; therefore, the type or quantity of insulin vials distributed throughout the facility could not be tracked. The Chief of Pharmacy Service explained that due to barriers associated with the computer system, the replenishment system was not implemented. The OIG noted that the facility's inpatient ward stock list, used by Pharmacy Service staff to document and record stock sent to the ward, also instructed Pharmacy Service staff to record ward stock in the replenishment system even though the system had not been implemented. Pharmacy staff reported that, in practice, insulin was taken from pharmacy stock and delivered to the ward when pharmacy ward stock insulin levels were found to be low or when requested by nursing staff. Pharmacy Service staff did not document this restocking process on paper or in the computer.

In July 2020, the OIG found that although concerns regarding insulin storage and tracking had been largely addressed, and patient-specific medications and insulin were stored in the Pyxis, according to a Pharmacy Service leader, the required replenishment system still had not been implemented.³⁸ A Pharmacy Service leader explained that the process to implement the replenishment system was resource-intensive for the Pharmacy Service Automated Data Processing and Applications Coordinator, and a previous Pharmacy Service leader determined that implementation was a low priority. A Pharmacy Service leader also told the OIG inspection team that, in place of the replenishment system, Pharmacy Service staff tracked most

³⁶ The Veterans Health Information Systems and Technology Architecture Automatic Replenishment system is a Pharmacy Service medication management system used to track drug distribution within the facility.

³⁷ VHA Directive 1108.06.

³⁸ A pharmacy technician told the OIG that insulin was kept in the pharmacy refrigerator. On ward 3A, par levels for insulin were set at 200 units, and when the Pyxis detected that the vial was below 200 units, the level would print on the Pharmacy Service refill report. A pharmacy technician would remove insulin from the pharmacy refrigerator, label it with a 28-day expiration date, and then place it in the ward 3A Pyxis. U.S. FDA, *Information Regarding Insulin Storage and Switching Between Products in an Emergency*, accessed March 17, 2021, <https://www.fda.gov/drugs/emergency-preparedness-drugs/information-regarding-insulin-storage-and-switching-between-products-emergency>. Insulin can be unrefrigerated for 28 days.

medications on the wards using Pyxis inventory reports; however, the refrigerated medications were not linked to the Pyxis inventory.

A Pharmacy Service staff member told the OIG inspection team that pharmacy technicians currently replenished refrigerated items based on set par levels, tracking on paper the quantity that was replaced, and that tracking papers were maintained for a month. The OIG determined that although current refrigerated medications are not high-risk or high-alert, tracking is an important internal control to mitigate against loss and ensure that medications are available where and when they are needed.³⁹ A Pharmacy Service leader told the OIG inspection team that discussions related to obtaining a medication refrigerator that interfaces with the current Pyxis system were ongoing.

Trending

Although VHA requires the use of the replenishment system, VHA does not outline the requirements related to identifying trends in ward pharmacy stock usage such as insulin and D50.⁴⁰ Pharmacy Service leaders told the OIG inspection team that identification of inventory trends was an informal process and that they relied on Pharmacy Service staff to recognize and report unusual use. A common treatment of hypoglycemia for an unresponsive patient with intravenous access or a patient who cannot take anything by mouth is one ampule of D50, which typically raises the blood glucose level within minutes. However, the correction of the hypoglycemia may be temporary, requiring supplemental treatment such as continuous glucose monitoring or intravenous medication to maintain desirable blood glucose levels. Recurrent episodes of hypoglycemia necessitating repeated doses of D50 over a short period are atypical and should prompt evaluation as to the causes of the hypoglycemia.

An example of how trending identification may have prompted Pharmacy Service staff to conduct a further review of D50 occurred in spring 2018. In this case, facility staff responding to hypoglycemic events treated Patient 1 with 16 ampules of D50 in a 29-hour period. Staff reported depleting D50 ampules from multiple Pyxis units and code carts.⁴¹ Identification of the high D50 use was a missed opportunity for facility staff to conduct a review of the unusual amount used that could have led to the discovery of other hypoglycemic events.

The OIG determined that the Pharmacy Service non-standardized and informal tracking process was inadequate and contributed to a lack of situational awareness that such a large amount of D50 was administered to a single patient and that this key rescue medication was depleted from

³⁹ High-risk medications are more likely than others to result in patient harm or injury, whereas high-alert medications carry an increased risk of causing significant harm when they are used in error.

⁴⁰ VHA Directive 1108.06.

⁴¹ A code cart, or crash cart, is “a cart stocked with emergency medical equipment, supplies, and drugs for use by medical personnel especially during efforts to resuscitate a patient experiencing cardiac arrest.” <https://www.merriam-webster.com/dictionary/crash%20cart>. (This website was accessed on February 12, 2021.)

the same area within a short period of time. A Pharmacy Service leader told the OIG inspection team that the Pharmacy Service tracking process relied on multiple Pharmacy Service staff who restocked Pyxis machines and code carts throughout the facility on varying shifts to identify medication-related usage issues and trends. This leader also said that, similar to insulin, D50 is tracked in the Pyxis and not in the replenishment system. Additionally, a Pharmacy Service staff member reported that if nursing staff did not accurately enter the number of D50 ampules removed from the Pyxis, then the Pyxis inventory report did not accurately reflect remaining doses. The OIG was unable to determine whether the use of the replenishment system would have assisted in identifying irregularities with D50 ward stock. Nevertheless, VHA requires the use of this system.⁴²

The OIG would have expected that after learning about the episode of high use of D50 going “unnoticed” by current tracking systems and processes, Pharmacy Service and QSV staff would have immediately explored opportunities for system improvements. The Facility Director informed the OIG inspection team that the facility created an informal workgroup to develop a tracking process for rescue medications, including D50.⁴³ However, documentation reflected that the workgroup was not formed until late November 2019.

Recommendation 2

Recommendation 2. The Louis A. Johnson Medical Center Director ensures Pharmacy Service utilizes the required Veterans Health Information Systems and Technology Architecture Automatic Replenishment System to record medication usage data and maintain the records for inventory accountability.

Finding 3. Clinical Evaluations and Associated Professional Activities Did Not Consistently Support Quality of Care and Patient Safety

The OIG found that a confluence of factors likely permitted the unexplained hypoglycemic events to go undetected and unevaluated over several months in 2018. This section of the report discusses hospitalists’ significant failures to conduct adequate evaluations to determine the cause(s) of the profound hypoglycemic episodes, as well as communication and documentation deficits that potentially “set the stage” for the events to go undetected and unabated over a series of months.

Hypoglycemia Symptoms and Treatment

When a person’s blood glucose is too low, they may exhibit signs and symptoms that include fatigue, pale skin, shakiness, anxiety, sweating, hunger, irritability, a tingling sensation in or

⁴² VHA Directive 1108.06.

⁴³ Rescue medications are medications that counter an effect or counter a situation that could be life-threatening.

around the mouth, and an irregular heart rhythm. With severely low blood glucose, the situation is life-threatening. Complications from untreated severely low blood glucose include confusion, abnormal behavior, seizures, loss of consciousness, and death.

Glucose levels are determined through blood draw and laboratory confirmation or point-of-care (POC) testing via [glucometer](#). A glucometer is a medical device that measures the amount of glucose in a small sample of blood. According to the ADPCS office, prior to August 2018, the facility did not have an overall policy regarding hypo- and hyperglycemia parameters and notification processes.⁴⁴ Facility policy issued in August 2018 defines hypoglycemia as any blood glucose level less than 80 mg/dL and requires nursing staff to notify a provider and document accordingly.⁴⁵

In June 2018, facility leaders identified nine patients with profound and concerning hypoglycemic events dating from November 2017 to June 2018. The OIG identified a tenth patient whose profound hypoglycemic events occurred in July 2017. To promote clarity, the OIG used a numbering system of 1 through 10 to differentiate these patients in the remainder of the report. The numbering system largely reflects the order in which the facility, retrospectively, reviewed the unusual cases of hypoglycemia rather than the chronological order of when the events occurred. Table 1 below shows the timing of death in relation to the patients' hypoglycemic events.

⁴⁴ In the absence of a policy on managing hypo- and hyperglycemia, nurses reported following the established policy on critical results and values, which required that initial critical test results and values be communicated directly to a responsible care provider. The policy defined critical blood glucose levels as less than 45 mg/dL and greater than 500 mg/dL. The OIG noted that the facility did have a standard operating procedure for diabetic dialysis-patient glucose monitoring in 2014 and 2016.

⁴⁵ SOP 118-157, *Hypoglycemia and Hyperglycemia Parameters and Process to Notify Providers*, August 2018. The ADPCS office indicated that although the laboratory parameter for normal blood glucose was 70–110 mg/dL, out of an “abundance of caution,” leadership elected to use 80 mg/dL as the trigger to alert the providers. The standard treatment for a conscious patient with a blood glucose of 50–69 mg/dL who is not at risk for aspiration is 15–20 grams of a fast-acting carbohydrate such as four ounces of orange juice or four glucose tablets. The standard treatment for a conscious patient with a blood glucose level of less than 50 mg/dL is 30–40 grams of a fast-acting carbohydrate. The treatment is repeated every 15 minutes until the blood glucose level is about 70 mg/dL. Treatment for unconscious patients or those unable to take oral treatments is described earlier.

Table 1. Timing of Patients’ Hypoglycemic Events and Death⁴⁶

Patient	Timing of Event	Days from Last Hypoglycemic Event to Death
Patient 1	Spring 2018	4 days
Patient 2	Spring 2018	15 days
Patient 3	Spring 2018	Same day
Patient 4	Spring 2018	Same day
Patient 5	Spring 2018	4 days
Patient 6	Spring 2018	1 day
Patient 7	Winter 2018	1 day
Patient 8	Spring 2018	15 days
Patient 9	Fall 2017	Same day
Patent 10	Summer 2017	Same day

Source: OIG inspection team review of patient EHRs

The court accepted Ms. Mays’s plea of guilty on seven counts of second-degree murder and one count of assault with the intent to commit murder related to patients 1, 2, 4–8, and 10. While care documented within the EHR related to patients 3 and 9 was inadequate for communication and continuity of care purposes, there were other clinically reasonable explanations for their hypoglycemia and deaths. Other than a reference in the documentation section and in appendix A, patients 3 and 9 are not discussed further in this report.

In an effort to identify potential victims beyond the 10 patients noted above, the OIG examined four populations (as detailed in the Scope and Methodology section of this report) and reviewed the EHRs of more than 200 patients.⁴⁷ The OIG inspection team reviewed the cases in the context of several factors, with an emphasis on hypoglycemic events that overlapped with Ms. Mays’s shifts or occurred shortly after her shift. If during the review, the OIG inspection team either had no clinical concerns about the hypoglycemic event and how it was managed, or the event(s) did not occur during Ms. Mays’s shift, those cases were excluded from further review.

For the remaining eight patients, the OIG inspection team acknowledges that each victim’s medical history and the circumstances leading up to their deaths are unique. However, to provide an example of how these tragedies occurred, Patient 4’s hospital course is detailed below. This case, like most of the other victims’ profiles, reflects clinical events involving a patient with

⁴⁶ The patients have been deidentified to preserve their privacy and that of their families in accordance with legal mandates. Similarly, precise dates of the hypoglycemic events and deaths are not provided due to privacy concerns.

⁴⁷ Some patients fell into more than one category.

advanced age and multiple comorbidities (co-occurring diseases or medical conditions) who was expected to survive the diagnosis that prompted their hospital admission.

Brief Case Summary for Patient 4

Patient 4 was in their 80s, with a history of dementia and an irregular heartbeat who was admitted to the facility for a lung infection and lethargy.⁴⁸ Patient 4 improved with treatment and the family reported the patient was back to a normal baseline by evening of hospital day 3. In the very early morning of hospital day 4, a nurse assessed the patient as “restless” and “more verbal than normal.” Shortly thereafter, Patient 4 became “unresponsive,” “cold,” and “clammy.” A fingerstick blood glucose was performed approximately one hour after Patient 4’s mental status changes were noted. The result was critically low at 12 mg/dL and unusual since Patient 4 did not have a history of diabetes or treatment with insulin. The physician noted low blood oxygen and an abnormal chest x-ray and attributed the patient’s deterioration to either [heart failure](#) or [sepsis](#). The OIG was informed by a nurse that Ms. Mays worked the night shift on ward 3A during Patient 4’s hypoglycemic event.

Over the next several hours, Patient 4 received treatment for both heart failure and sepsis without improvement. Staff were also unable to normalize the patient’s blood sugar despite intensive interventions, which included a continuous infusion of intravenous fluid with dextrose, five ampules of D50, and one dose of [glucagon](#). After a discussion of Patient 4’s multiple comorbidities and poor prognosis, the family requested a transition to hospice care. Patient 4 died later that morning. Figure 2 below shows Patient 4’s blood glucose levels, D50 interventions, and the expected effects of the D50 over a four-hour period preceding death.

⁴⁸ The OIG uses the singular form of they (their) in this instance for the purpose of patient privacy.

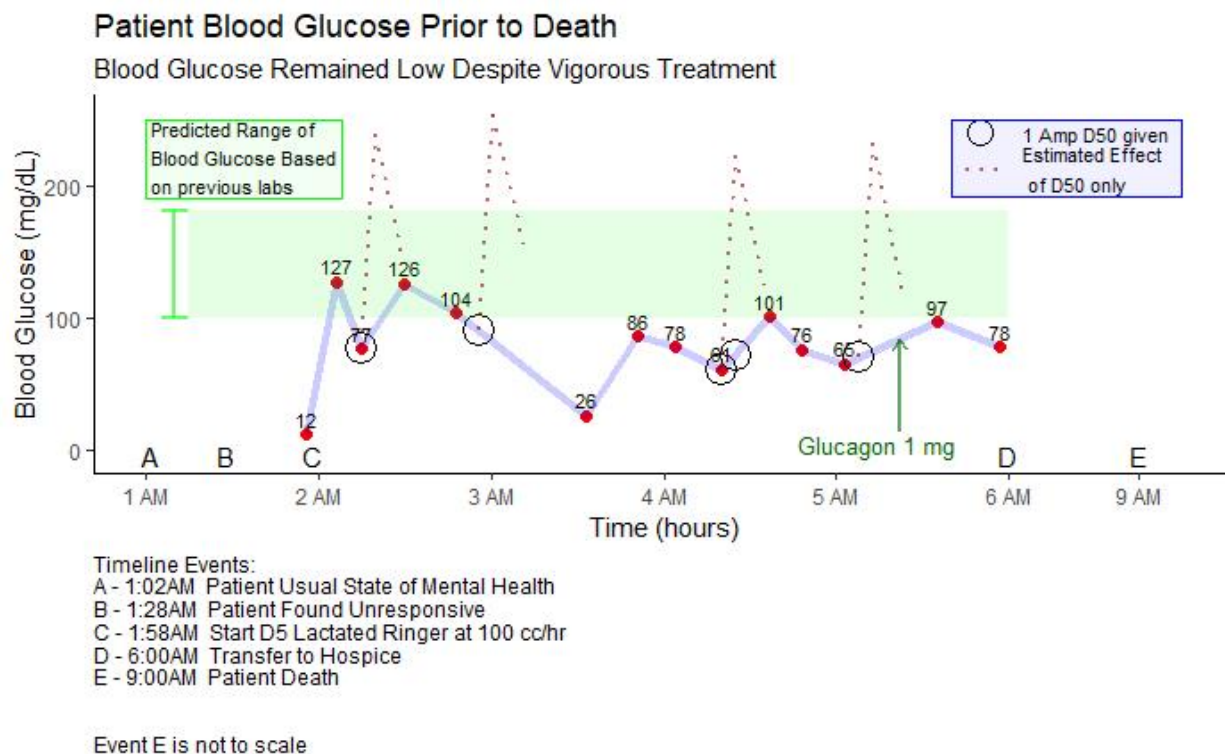


Figure 2. Patient blood glucose levels prior to death
 Source: VA OIG timeline analysis and graphic summary of Patient 4’s blood sugar levels and treatment as analyzed from Patient 4’s EHR, and anticipated response to treatment with D50 based on peer-reviewed literature⁴⁹

Failure to Conduct Robust Clinical Evaluation of the Eight Victims’ Unusual Hypoglycemic Events

The OIG inspection team found inadequate medical workup and testing to identify the causes of the eight patients’ uncommon episodes of hypoglycemia.

Hypoglycemia is rare in patients who are not receiving medication for diabetes and may be caused by many factors, including the surreptitious administration of insulin. Ms. Mays acknowledged deliberately administering insulin to eight patients without a legitimate medical indication, causing profound hypoglycemia in those patients. Four of those patients were nondiabetic. Two of those patients were diabetic, although not receiving treatment with diabetes medication. One patient with diabetes became hypoglycemic 12 hours after receiving a dose of a short-acting insulin, which generally has an effect for six to eight hours. The other patient with diabetes who was receiving insulin prior to the hypoglycemic episode required intensive and

⁴⁹ Jerry Balentine et al., “Effect of 50 Milliliters of 50% Dextrose in Water Administration on the Blood Sugar of Euglycemic Volunteers,” *Academic Emergency Medicine* 5, no. 7 (July 1998): 691-694.

protracted treatment to normalize low blood sugar levels.⁵⁰ Despite the unusual nature of these events, seven of the patients did not undergo diagnostic testing to determine the cause of their hypoglycemia.

The first step in determining the cause of hypoglycemia is a clinical assessment to identify medical explanations, such as a contributing illness or medication.⁵¹ If the clinical assessment does not reveal the reason for hypoglycemia, excess insulin is a likely cause and the source of insulin may either be insulin administered to the patient (exogenous) or insulin produced within the body (endogenous), most commonly from an insulin-secreting tumor. The incidence of such a tumor is rare, as it is reported to occur in four cases per million per year.

Laboratory data obtained during an episode of hypoglycemia can help elucidate the source of insulin. Normally, insulin levels decrease in response to hypoglycemia. In contrast, insulin levels will be high in patients with hypoglycemia caused by insulin administration.⁵²

Providers who are unable to ascertain the cause of hypoglycemia may consult with an endocrinologist who is a specialist with expertise in hormone imbalances.

As indicated earlier, the hospitalists on ward 3A did not pursue diagnostic testing in seven patients. From interviews, the OIG inspection team found there were multiple reasons provided for lack of testing. First, most hospitalists encountered only one or two of these patients, with hypoglycemic episodes separated by weeks or months, and were unable to appreciate the collective significance of events. Consequently, they were more likely to attribute isolated hypoglycemic events in these elderly and debilitated patients to malnutrition or acute illness, without pursuing other possibilities.

Furthermore, the hospitalists did not appear to be consistently familiar with or understand the utility of a laboratory evaluation for patients with unexplained hypoglycemia. One hospitalist informed the OIG inspection team that testing “whatever markers” would be of no benefit because the patient being treated had received insulin in the past and thus testing would not be able to discern exogenous from endogenous insulin. A nocturnist who encountered

⁵⁰ The patient required intravenous fluids with dextrose in addition to 16 ampules of D50 over a 24-hour period to normalize low blood sugar levels.

⁵¹ Critical illness, including liver, kidney or heart failure and sepsis and drugs such as ciprofloxacin (antibiotic) and indomethacin (anti-inflammatory), can cause hypoglycemia.

⁵² The source of insulin can be determined by measuring proinsulin (a precursor to insulin produced in the body) and C-peptide (a substance released when proinsulin is converted to insulin). Pharmaceutical insulin does not contain proinsulin or C-peptide and thus levels of these substances will be low in patients with hypoglycemia caused by insulin administration. Providers may obtain additional tests to assess hypoglycemia including the measurement of insulin secretagogues (oral medications that cause the pancreas to secrete insulin), insulin antibodies (suggest exposure to insulin or a diagnosis of an autoimmune hypoglycemia), and beta-hydroxybutyrate (a ketone suppressed by insulin).

hypoglycemic patients deferred the evaluation of hypoglycemia to the day shift and was unaware of the necessity of collecting specimens during the hypoglycemic event.

Additionally, three of the hospitalists and the Medical Director of Inpatient Services did not consider nefarious intent. Hypoglycemia caused intentionally is very unusual and thus requires a high level of suspicion on the part of the clinician. In one instance, a nocturnist who evaluated only Patient 1, suspected surreptitious insulin administration but did not pursue a hypoglycemia workup, notify leaders, or alert Hospitalist A (who assumed care the following day) of the concerns. The nocturnist chose instead to place a recommendation in the EHR for an endocrinology consultation to help determine the cause of hypoglycemia. This recommendation was not acknowledged or pursued by Hospitalist A who was caring for the patient. During an interview that occurred two years after the hypoglycemic event, Hospitalist A did not recall Patient 1 experiencing an episode of hypoglycemia.

Patient 8, a nondiabetic, underwent laboratory testing to determine the origin of the hypoglycemia. Hospitalist B noted concerning similarities after assessing two different patients (Patients 6 and 8) with unexplained hypoglycemia two days in a row in spring 2018 and told the OIG inspection team of suspecting that something “nefarious” could be occurring. According to the EHR, Hospitalist B ordered insulin and C-peptide levels for Patient 8, but when questioned by the OIG inspection team regarding the workup and diagnostic approach to hypoglycemia, Hospitalist B did not recall ordering the test and did not appear to understand the utility of testing to help determine if there was surreptitious insulin administration. In fact, Hospitalist B acknowledged never having ordered an insulin level prior to this and was uncertain if insulin testing would distinguish endogenous from exogenous insulin. Hospitalist B further described C-peptide as a “useless test,” generally obtained to determine if there is endogenous insulin production from an [insulinoma](#) and thus was unlikely to be fruitful. There is no documentation that Hospitalist B followed up on the results.

The OIG inspection team reviewed the insulin and C-peptide results for Patient 8 and determined that the testing was ill-timed and insufficient. Both insulin and C-peptide levels were in the normal range, which would not be consistent with surreptitious insulin administration. However, the OIG inspection team noted that laboratory tests were drawn after the patient received two ampules of D50. In addition, the insulin assay ordered by Hospitalist B measured only human insulin and not synthetic insulin analogs.⁵³

Hospitalist B reported to the OIG that the diagnostic evaluation was not completed, but the concerns were discussed about surreptitious insulin administration with the nurse manager and the Medical Director for Inpatient Services the day the hypoglycemic event occurred. Thinking that a nurse may have erroneously administered insulin to Patient 8 meant for another patient, the

⁵³ Some insulin assays test only for human insulin, whereas others test for both human and synthetic insulin. The ordering provider must know which assay is used when interpreting results.

assistant nurse manager told the OIG inspection team of having reviewed the assignment sheet to determine whether Patient 8's nurse was caring for a diabetic patient at the same time (which could explain a medication "mix-up"). While no medication error was identified, the event was reported to the ACN by the assistant nurse manager. According to the Medical Director of Inpatient Services, the facility did not conduct additional follow-up. (Additional information is provided in Finding 4, [Missed Opportunity, Mid-Week 1](#).)

During an interview with the Chief of Staff, the OIG learned that none of the hospitalists consulted with an endocrinologist. The Chief of Staff and hospitalists informed the OIG the facility did not have an inpatient endocrinologist on staff; however, hospitalists had the option of consulting with an endocrinologist at the VA Pittsburgh Healthcare System, either through electronic consultation in the EHR or via a call coordinated by the facility transfer coordinator. During interviews, facility healthcare providers informed the OIG inspection team that this service was not available immediately or at night and that it sometimes took two to three days to receive a response. Endocrinology consultations may have resulted in a more tailored assessment of these patients.

When the OIG investigators interviewed family members of the patients discussed in this report, one family member expressed dismay at receiving what they now believe was incomplete or inaccurate information about their loved one's condition. One family reported being unaware that their loved one's hypoglycemic event was central to [the patient's] poor condition; rather, the patient's condition was couched in terms of medical comorbidities and being part of an end-of-life process. This family said that had they received more accurate information about condition and prognosis, they would have opted to continue treatment [rather than agreeing to comfort measures only approach to care].

These clinical reviews were conducted in support of OIG's criminal investigation and applied specific and limited review criteria based on the information available from the criminal investigation. Based on these parameters, the OIG clinical reviews did not identify with a degree of certainty any other cases that were consistent with the conduct related to the criminal case or any other criminal conduct. However, the OIG's clinical reviews were not designed to evaluate all possible scenarios in which Ms. Mays could have caused harm to patients. Therefore, additional expert clinical review of specified and other cases, as arranged by the VISN, may be needed. This evaluation should be conducted by providers who are independent of the facility. Further, patient or family member concerns and inquiries about care provided by Ms. Mays should be prioritized and when appropriate, included in the expert evaluation.

Failure to Promote and Engage in Important Clinical Communication

In a healthcare setting, it is commonly understood that “Inadequate information exchange can have tragic consequences on patient safety.”⁵⁴ In addition, The Joint Commission states that patient care and treatment must be provided “in an interdisciplinary collaborative manner.”⁵⁵ Healthcare facilities often use interdisciplinary team meetings or rounds, huddles, or treatment planning meetings to exchange information and collaborate.⁵⁶ Given that the best patient outcomes “are achieved when professionals...engage in clinical audit of outcomes together,” the content and vigor of meeting discussions are important.⁵⁷

The OIG found that the facility’s interdisciplinary team and other meetings were not consistently effective in promoting communication and collaboration in support of patient care and safety. Although hospitalists participated daily in inpatient interdisciplinary rounds, where physicians, nurses, social workers, and other members of the healthcare team met to review hospitalized patients, the OIG inspection team was told by several staff members that the focus was on length of stay and discharge planning, and did not typically include patient outcomes and follow-up. Even discussion about patient events did not always translate into action. For example, the Utilization Manager told the OIG inspection team that Patient 1’s hypoglycemia was discussed during interdisciplinary rounds the day after the event. Reportedly, the discourse centered around the difficulty providers had returning Patient 1’s blood glucose to a normal range—requiring the administration of repeated doses of D50. Despite the unexplained hypoglycemia and high use of D50, the quality and content of the discussion did not prompt further inquiry, evaluation, or action.

The OIG confirmed that facility hospitalists were typically scheduled to cover inpatient wards for seven days on and seven days off. While this schedule is common for this specialty, it can present challenges for communication, continuity of care, and coordination.⁵⁸ In this context, additional opportunities that allowed for more effective group discussion and consultation of patient care issues among the physicians would be appropriate. Hospitalists generally reported that they completed verbal or written clinical handoffs of patient care information to oncoming

⁵⁴ Oren Guttman et al., “Dissecting Communication Barriers in Healthcare: A Path to Enhancing Communication Resiliency, Reliability, and Patient Safety,” *Journal of Patient Safety*, (November 9, 2018).

⁵⁵ The Joint Commission Edition, Provision of Care, Treatment and Service Standard PC.02.01.05, accessed January 4, 2021, <https://e-dition.jcrinc.com/MainContent.aspx>. (This website requires a subscription and may not be accessible to a non-subscriber.)

⁵⁶ A huddle is a short, stand-up meeting that is typically used at the start of each workday in a clinical setting. Institute for Healthcare Improvement, November 25, 2020, <http://www.ihl.org/resources/Pages/Tools/Huddles.aspx>.

⁵⁷ Carol Borrill et al., “Team Working and Effectiveness in Health Care,” *British Journal of Health Care Management* 6, no. 8 (2000): 364–371.

⁵⁸ Marlene Piturro, “Scheduling Strategies,” *The Hospitalist* 4, (April 2007).

hospitalist providers. Still, hospitalists told the OIG inspection team that they lacked scheduled staff meetings or conferences, which would provide additional opportunities for discussion and consultation on patient issues.

The OIG found that nurses appeared to rely on informal communication methods that were not consistently effective in relaying patient-specific events or concerns. According to nursing staff, there was an open-door policy for nurses to discuss issues with the nurse manager. However, adverse patient events, such as patient deaths or falls, were not always reported to the ward 3A nurse manager. Although not a requirement, reporting these types of events to the nurse manager is good practice and reflective of a transparent and patient safety-oriented environment. According to the ward 3A nurse manager, staff meetings where patient-related information could be discussed were not routinely convened.

Had clinical team members used interdisciplinary treatment rounds and other meeting opportunities more effectively to discuss patient outcomes, or had staff consistently taken the initiative to report the patients' hypoglycemic events, the emerging pattern of events may have been identified sooner.

Failure to Document Important Clinical Information

In the review of patients' EHRs, the OIG found that physician and nursing documentation was inadequate for several patients who experienced hypoglycemic events. Medical staff are responsible for managing every patient's care and must consistently document changes in the patient's condition in the EHR.⁵⁹

The OIG inspection team reviewed the 18 hospitalist encounters for all 10 patients and found the most notable documentation deficiency was that, while hypoglycemia was acknowledged in the EHR by hospitalists, no rationale or plausible explanation for the hypoglycemia was documented in 15 of the 18 notes.

For example, with Patient 9, the OIG inspection team found that hospitalists did not document the acknowledgment of and response to the patient's hypoglycemia, although laboratory results for a low glucose were imported into the EHR progress note and the patient was documented as "appearing in distress." Additionally, although a nurse took Patient 9's vital signs during the event, the EHR did not contain documented evidence that the nurse contacted the hospitalist when vital sign data met criteria for notification.

In another example, Patient 3's EHR did not contain physician documentation about Patient 3's low glucose, interventions, and symptomatology during any time in which the hypoglycemia was confirmed. Further, Patient 3's EHR should have, but did not, contain documentation from the nurse who discovered the patient during the hypoglycemic event.

⁵⁹ Facility By-laws and Rules of the Medical Staff, 2018.

The OIG inspection team also found that Continuous Close Observation Flow Sheets were not readily available in patients' EHRs as required by VHA policy.⁶⁰ Nursing assistants are routinely assigned as patient sitters, providing one to one observation of patients who may be confused, agitated, or otherwise at risk for a negative event such as a fall. Information documented on the hard-copy Continuous Close Observation Flow Sheets includes entries by sitters at least every hour about the patient's mental status and other clinical and non-clinical observations; hard copies then require timely, indexed scanning into the respective patient EHRs.⁶¹ The OIG found that the Continuous Close Observation Flow Sheets for patients 1, 5, 7, and 8 were improperly bulk-scanned into the respective patient EHRs without required indexing, resulting in the documents not being sortable or searchable.⁶² In Patient 5's case, the relevant Continuous Close Observation Flow Sheet was not searchable as it was included in a 110-page scanned document and included multiple other entries such as hand-written vital signs, fingerstick blood glucose levels, and physical therapy progress notes.

According to the former 3A nurse manager, sitters were assigned tablets to facilitate electronic documentation and data transfer to the EHR. However, one nursing assistant told the OIG inspection team that the assigned tablet had not been configured by information technology staff and had remained in [the nursing assistant's] locker for the previous six months. The OIG determined that it is important for close observation information to be readily available in the EHR as clinical data documented on flow sheets could influence medical management decisions. This concern was referred to OIG's hotline division for further evaluation.

As noted previously, the OIG healthcare inspection was paused in 2018 to ensure it did not interfere with the ongoing criminal investigation. Due to the passage of time, it was unlikely that clinical staff could accurately recall why they did not document appropriately in a specific patient's EHR. Inadequate or missing documentation prohibited other providers and staff from receiving information about patients' clinical care and treatment and may have contributed to their inability to realize the serial nature of the hypoglycemic events.

Leaders' Response to Documentation Deficiencies

During a 2018 interview, the OIG found that the facility's Chief of Staff was aware of provider-specific documentation deficiencies in the EHRs of several patients, including missing notes and omission of information after the facility's June 2018 QSV review of patient EHRs. According to VHA, the Chief of Staff "has ultimate oversight responsibility for health record timeliness, accuracy, and completion."⁶³ The Chief of Staff discussed documentation concerns

⁶⁰ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

⁶¹ VHA Handbook 1907.01; VHA Handbook 1907.07, *Management of Health Records File Room and Scanning*, May 12, 2016.

⁶² VHA Handbook 1907.01; VHA Handbook 1907.07.

⁶³ VHA Handbook 1907.01.

with the Associate Chief of Staff and Medical Director for Inpatient Services in July 2018, instructing them to inform providers that documentation reviews would be conducted regularly. Two physicians also reported that nurses' patient care documentation was an ongoing problem. The issue of poor documentation was added to a ward 3A action plan in November 2018, and updates reflected that nurse education and physician and nurse random EHR reviews were initiated in January 2019.

The Chief of Staff told the OIG inspection team that the physician random chart reviews were done a "couple of times" to ensure documentation was adequate, and two reports were submitted to the Chief of Staff before the meetings were canceled due to COVID-19. The Chief of Staff reported being informed by supervisors that physician documentation related to patient events and timeliness had improved.

Recommendations 3–8

Recommendation 3. The Veterans Integrated Service Network 5 Director conducts management reviews of the care of patients 1–10 as discussed in this report, and takes action as indicated.

Recommendation 4. The Louis A. Johnson VA Medical Center Director reviews the availability and timeliness of endocrinology consults, and takes any corrective action needed.

Recommendation 5. The Veterans Integrated Service Network 5 Director ensures evaluation of quality of care concerns or other irregularities (beyond hypoglycemia) of: cases provided by the OIG; cases that may otherwise be pertinent or concerning; and cases brought forward by patients and/or family members who express concerns or make other inquiries about care they received from Ms. Mays. As determined by the Veterans Integrated Service Network, clinical experts external to the facility should be utilized when appropriate.

Recommendation 6. The Louis A. Johnson Medical Center Director develops and disseminates guidance on clinical communication(s) to ensure that patient care and outcomes are routinely discussed in appropriate forums, such as interdisciplinary team meetings, and the discussions are documented.

Recommendation 7. The Louis A. Johnson Medical Center Director ensures that close observation documentation is readily available in the electronic health record, and monitors for compliance.

Recommendation 8. The Louis A. Johnson Medical Center Director ensures clinical documentation reviews are completed timely for patient safety and continuity of care.

Finding 4. Clinical Leaders, Managers, and Staff Missed Opportunities to Report and Respond to Concerning Events

The OIG determined that some clinical leaders, managers, and staff failed to report and follow up on the surprising number of profound hypoglycemic events that occurred in 2018. The OIG

identified inattention and missed opportunities at several junctures in spring 2018. This section focuses on the reporting of adverse events and missed opportunities to have identified the causes of an unusual cluster of hypoglycemic episodes, both at the time they occurred and in the following months.

A cluster of hypoglycemic events involving four patients occurred over about a three-week period. Table 2 reflects the timing of patient events and D50 interventions in this cluster. The hypoglycemic events during the three-week cluster, as well as additional concerning events occurring 8 and 10 weeks later, generally transpired during or immediately after one of Ms. Mays’s shifts.

Table 2. Patient Events and D50 Interventions During a Three-Week Period in 2018⁶⁴

Patient	Week of Hypoglycemia	Number of D50 Ampules
Patient 6	Week 1	7
Patient 8	Week 1	3
Patient 1	Week 2	16
Patient 4	Week 3	5

Source: OIG inspection team analysis of patient EHRs

Patient Safety Event Reporting

Facility staff did not complete patient safety event reports related to any of the hypoglycemic events discussed in this report or the unusually high use of D50 in several patients in 2018.

VHA policy requires staff to report patient safety events, including events that present the opportunity to explore system vulnerabilities, to the patient safety manager even if the condition has not resulted in an adverse clinical outcome or close call.⁶⁵ VHA policy identifies an adverse drug event as a more common type of patient safety event and further states that “untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided” may require further review and may result from a “failure to make a timely diagnosis.”⁶⁶ Reporting events is the primary mechanism through which the root cause and contributing factors of a system’s vulnerabilities can be mitigated to

⁶⁴ Precise dates of the hypoglycemic events are not provided to preserve patients’ privacy.

⁶⁵ VHA Handbook 1050.01. Facility Memorandum, 00B-04, *Electronic Patient Event Reporting (ePER) Program*, August 2015, required facility staff to use the Electronic Patient Event Reporting System to report patient safety events at the time of the events. This memorandum was replaced by Facility Policy 00B-04, *Joint Patient Safety Reporting (JPSR) Program*, June 1, 2020, which required facility staff to use the Joint Patient Safety Reporting System.

⁶⁶ VHA Handbook 1050.01.

prevent future events.⁶⁷ Physicians and nurses the OIG inspection team interviewed were not consistently aware of what incidents to report and how to report them. Patient safety managers are generally responsible for ensuring that staff understand the requirement to report incidents, what types of incidents should be reported, and the systems available that can be used to report.⁶⁸ For more information on training for patient safety event reporting, see the following section on the Quality, Safety and Value Program.

The Cluster of Cases and Several Missed Opportunities for Detection

Patient 6 was in their mid-80s and had numerous medical problems, including diabetes.⁶⁹ Patient 6 experienced multiple episodes of profoundly low blood glucose levels while hospitalized at the facility during Week 1. During this time, Patient 6 was not on insulin or other blood glucose-lowering medicines. Given that Patient 6's hypoglycemic episodes could have been attributable to extreme debility and malnutrition, Hospitalist A had not considered intentional administration of insulin to induce a hypoglycemia event as a possible cause. Patient 6 was, however, the first in what would later become a cluster of unexplained hypoglycemic events across several patients. Accordingly, the OIG does not characterize it as a missed reporting opportunity.

Missed Opportunity—Mid-Week 1

To go back to point of origin hyperlink, press "alt" and "left arrow" keys.

After the events involving Patient 8 (who was not diabetic but had a significant hypoglycemic event and tests were inadequate and ill-timed as D50 had already been administered) during Week 1, Hospitalists A and B and the ward 3A nurse manager discussed the case and notified the Medical Director of Inpatient Services. Two nurses completed a preliminary review of nursing schedules and patient assignments to determine whether it was possible that a nurse inadvertently administered insulin to the wrong patient. The nurses did not identify any common denominators to the incidents and an expanded review focusing on additional potential causal factors was not completed. Clinical leaders, managers, and staff missed opportunities to report information that may have aided in detection of intentional insulin administration. The OIG was informed through interviews that

⁶⁷ VHA Handbook 1050.01.

⁶⁸ VHA Handbook 1050.01; Facility Memorandum 00B-04; Facility Policy 00B-04.

⁶⁹ The OIG uses the singular form of they (their) in this instance for the purpose of patient privacy.

- The Medical Director of Inpatient Services did not report the concerns to the Chief of Staff,
- The ward 3A nurse manager and ACN involved in the initial discussion did not report the concerns to the ADPCS,
- No one reported the cases to QSV leaders, and
- Hospitalists A and B did not follow up with the Medical Director of Inpatient Services to determine the results of the review and what actions were indicated, if any.

When interviewed, the employees noted above either did not or could not explain why they did not report or follow up on the hypoglycemic events. Some interviewees referred to the discussions with their colleagues as informal and focused on the curiosity of the events rather than concern of wrongdoing. Some employees assumed or implied that other staff members would have or should have reported specific events.

Missed Opportunity—Week 2

Nine days later, during Week 2, Patient 1 experienced multiple episodes of unexplained hypoglycemia treated with repeated doses of D50.⁷⁰ Patient 1 was diabetic but was not receiving hypoglycemic agents at the time of the event. As discussed earlier, a nocturnist expressed concern about surreptitious insulin administration, but did not suspect it was a staff person. However, this nocturnist did not pursue a hypoglycemia workup or notify leaders of concerns about surreptitious insulin administration. The nocturnist placed a recommendation in the EHR for an endocrinology consultation to help determine the cause, which was not pursued. Patient 1's case was discussed in an interdisciplinary team meeting the following day. The Utilization Manager, who was present at the meeting, told the OIG inspection team of speaking with the Medical Director of Inpatient Services about something not “adding up” in relation to the high use of D50, but this concern was not reported to the Chief of Quality and Risk Management, who was the Utilization Manager's supervisor.⁷¹ Also noted earlier, no one notified the Pharmacy Service about the unusually high D50 use resulting in depletion of the facility's D50 supply and unavailability of D50 should it be needed. While the Medical Director of Inpatient Services was aware of two incidents of unexplained hypoglycemia in about 10 days and unusually high use of D50, no additional reviews were initiated nor were these concerns reported to the Chief of Staff or the ADPCS.

⁷⁰ Hospitalist A was the provider taking over care of the patient. As noted previously, Hospitalist A did not recall Patient 1 having an episode of severe hypoglycemia.

⁷¹ The OIG inspection team was told that the minutes for the interdisciplinary meeting during which Patient 1 was reportedly discussed were missing.

Missed Opportunity—Week 3

Five days later, during Week 3, Patient 4 experienced profound hypoglycemia although there was no history of diabetes or insulin therapy (see [case summary](#) regarding this patient who was in their 80s and admitted with a history of dementia and an irregular heartbeat). Neither of the hospitalists involved in Patient 4's care was a treating provider for patients 6, 8, or 1. Despite Patient 4 being the fourth case of unexplained hypoglycemia treated with repeated doses of D50 in less than three weeks, no additional reviews, notifications, or actions were initiated.

Late Spring Events

About 8 weeks later, after the three-week cluster, Patient 5 experienced unexplained hypoglycemia. About 10 weeks after the three-week cluster, another patient (Patient 2) experienced unexplained hypoglycemia. Hospitalist B and a nocturnist were the treating providers for both patients 5 and 2. Hospitalist B also knew about Patient 6, treated Patient 8, and met with the Associate Chief of Staff after Patient 2's event. The Associate Chief of Staff told the OIG inspection team that additional testing was recommended after hearing from Hospitalist B about the unexplained hypoglycemic events but Hospitalist B insisted that "something was going on," and that it was possibly criminal.⁷² The Associate Chief of Staff notified the Chief of Quality and Risk Management the same day, and QSV staff promptly initiated a review of the cases. The following day, the Facility Director was notified while on scheduled leave about the cases of potentially unexplainable hypoglycemia. The Facility Director advised that QSV staff should continue their review of pertinent cases and asked to be briefed further upon return from leave.

Nursing and physician clinical leaders could not explain why their respective staff members did not promptly report concerns through their chains of command, although one leader suggested concerns were not brought forward because staff were afraid to do so.⁷³ Given the totality of events known to the Associate Chief of Staff at the time, the OIG found that the Associate Chief of Staff's initial reaction that additional clinical testing was the appropriate response to this incident was concerning and not adequate.

Had facility leaders and managers escalated and pursued these adverse events sooner, additional lives might have been saved.

Recommendation 9

Recommendation 9. The Louis A. Johnson VA Medical Center Director evaluates the factors and processes surrounding employees' failures to report and follow up on the unexplained

⁷² Between Patient 5 and 2's events, Patient 3, who was not included in the plea deal, experienced profound hypoglycemia and died the same day.

⁷³ None of the employees the OIG inspection team interviewed said they feared reprisal for reporting events.

hypoglycemic events, and takes action to ensure appropriate reporting of actual or potential patient safety events, system vulnerabilities, or other unexpected events that offer opportunities for lessons learned.

Finding 5. QSV and Oversight Weaknesses Impeded Identification, Reporting, and Actions

A robust QSV program and vigorous oversight are central to achieving a culture of patient safety. Oversight weaknesses can affect the efficacy of reporting and the ability to identify underlying causes that must be addressed to prevent future quality of care and patient safety lapses. The following section describes findings related to the facility's QSV Program and oversight.

Facility's QSV Program Weaknesses

The OIG found that the QSV Program's integrated monitoring and oversight functions were deficient, resulting in lack of communication of critical information and missed opportunities to identify emerging trends through the organizational reporting and committee structure. Key quality control functions including risk management and attention to patient safety concerns were inadequate to ensure reporting, evaluation, and trending of potential and actual patient safety events and to ensure a robust review of patient deaths.

VHA policy in effect at the time of the 2018 hypoglycemic events required integration across an organizational structure to promote the exchange and flow of quality-related data and avoid organizational silos.⁷⁴ The policy further outlined a facility director's responsibility to designate an official with the appropriate background and skill set to lead facility-wide quality function integration. The facility's Chief of Quality and Risk Management started in the position in June 2017 and was the designated official responsible for oversight of the integrated organizational structure for key quality functions including risk management and patient safety.

Risk Management and Mortality Review

The OIG determined that the former Risk Manager was responsible for, but did not perform, in-depth mortality (patient death) reviews using suggested VHA tools. These included automated occurrence screening clinical review worksheets or other screening tools to evaluate the circumstances surrounding patient deaths to determine the need for additional review. During Ms. Mays's tenure, the number of actual in-hospital deaths exceeded the expected deaths

⁷⁴ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. This directive was in effect at the time of the events discussed in this report; it was rescinded by VHA Notice 2019-21, *Rescission of VHA Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value*, October 24, 2019.

multiple times. The OIG notes, however, that this data alone did not offer a sufficient basis to conclude there was a problem.

Risk management functions, as outlined in VHA policy, include conducting facility peer reviews for quality management and integrating risk management activities with patient safety and QSV functions.⁷⁵ Risk managers are generally responsible for mandatory screening of computer-generated occurrence screens that meet defined criteria, including inpatient deaths, to assess whether further action is required.⁷⁶

Risk managers should evaluate concerns such as adequacy of documentation explaining a death or whether the death appeared to be related to a hospital-incurred incident, which may trigger the need for additional review including peer or management review, or root cause analysis.⁷⁷ Automated daily occurrence screen printouts include a listing of patients meeting the occurrence screen criteria and a clinical review worksheet for each patient that contains screening questions to consider during a clinical evaluation of a patient's EHR.

The Chief of Quality and Risk Management provided a spreadsheet capturing the information gathered by the former Risk Manager for inpatient deaths occurring from October 1, 2013, through January 26, 2019. The OIG noted that the former Risk Manager did not include information such as a brief synopsis or other evidence of a broader, in-depth review of circumstances surrounding the deaths of the inpatient victims as discussed in this report. Current facility QSV staff confirmed, but did not know why, the former Risk Manager did not include additional information on the spreadsheet. When interviewed, the Chief of Quality and Risk Management stated that an examination of the mortality review process after the hypoglycemic events revealed that the former Risk Manager did not use the automated occurrence screen clinical review worksheet, which would have prompted the former Risk Manager for answers to questions related to the event and the results of an EHR review.⁷⁸

Because mortality is best understood by examining factors such as patient age, disease burden, and hospice status, among other issues, VHA offers a variety of tools for facilities to monitor mortality data and trends. Standardized trending of deaths is one method to understand spikes that occur. While mortality spikes do not automatically imply quality of care deficits or necessarily suggest prohibited or unlawful activities, spikes do reflect a change from the

⁷⁵ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

⁷⁶ VHA Directive 1190; Facility Memorandum 00B-02, *Protected Peer Review for Quality Management*, December 2015.

⁷⁷ *Occurrence Screen V. 3.0 User Manual*, September 1993. VHA Directive 1190. Facility Memorandum 00B-02, *Protected Peer Review for Quality Management*, December 2015. Additional occurrence screens include readmissions within ten days of discharge following inpatient hospitalization, admission within three days following an unscheduled ambulatory care visit, unscheduled return to the operating room within 30 days of surgery or procedure, or return to the operating room during the same admission.

⁷⁸ The former Risk Manager no longer worked at the facility and was unavailable for interview; the OIG does not have testimonial subpoena authority for individuals who are not VA employees.

facility's normal pattern and may merit further examination of conditions common to each of the deaths. However, responsible facility staff did not conduct additional reviews related to mortality rate spikes. The OIG could not determine why these additional reviews were not conducted. According to the Chief of Quality and Risk Management in late 2017, the facility conducted a "deep dive" into the mortality data, but due to poor documentation, reviewers were unable to determine whether quality of care concerns existed. The OIG found that the facility did not maintain a process to conduct rigorous review of mortality data to identify outliers or track and trend results.

After starting in June 2017, the Chief of Quality and Risk Management reported conducting a review of risk management processes and identified concerns related to the adequacy of occurrence screen mortality reviews. Specifically, the Chief of Quality and Risk Management told the OIG inspection team that the former Risk Manager was not "breaking the information down." For example, there was no trending by patient location, day of the week, or provider. The Chief of Quality and Risk Management created a mortality workgroup, but reported it was difficult to get the team members together due to busy schedules and competing priorities. After it became clear in late spring 2018 that the tragic events were connected, the Chief of Quality and Risk Management asked the Chief of Staff and ADPCS to assign physicians and a nurse to an interdisciplinary mortality review workgroup to address deficits in the process and suggest changes to improve care. However, the Chief of Quality and Risk Management reported to the OIG inspection team that the Chief of Staff and ADPCS did not promptly name appropriate workgroup candidates, so the Chief of Quality and Risk Management recruited staff during the summer of 2020 for the group. The first meeting was held on August 20, 2020.

The Chief of Quality and Risk Management told the OIG inspection team that the former Risk Manager, who was confirmed by a human resource specialist to be in the position during the 2017 and 2018 events, had not attended the Risk Manager's Boot Camp designed to provide guidance on occurrence screening and peer review until March 27–29, 2018. Despite attending the Boot Camp, which included the use of occurrence screening processes among other oversight responsibilities, the former Risk Manager did not initiate use of the suggested occurrence screen clinical worksheets, which could have assisted in the identification of the patient deaths related to unexplained hypoglycemia after attending the Boot Camp in 2018.⁷⁹

During an interview, the current Risk Manager discussed being hired in January 2020 and had planned to attend the Risk Manager Boot Camp, but it was placed on hold due to the COVID-19

⁷⁹ The Chief of Quality and Risk Management told the OIG that the facility's former Risk Manager was on leave beginning in November 2019 and retired in June 2020. A Risk Manager Boot Camp is held twice a year and provides "extensive, hands-on education covering the key components, high-level responsibilities, and areas of priority for risk managers." "Physician Leader Boot Camp & Risk Manager Boot Camp," accessed October 19, 2020, <http://vawww.qps.med.va.gov/divisions/qm/crm/crmBootCamp.aspx>. (This website is an internal one not accessible by the general public.)

pandemic. In the interim, the current Risk Manager confirmed working with another facility's risk manager to gain greater understanding of the responsibilities. The Chief of Quality and Risk Management told the OIG inspection team that the current Risk Manager is using the automated occurrence screen clinical review worksheet to conduct a more in-depth review to identify potential concerns surrounding patient deaths in real time. Further, the Facility Director reported improvements in mortality reviews and that the current Risk Manager communicates information in real time to the ADPCS and the Chief of Staff.

Patient Safety Program

Facility staff lacked knowledge and training related to reporting of patient safety events, which compromised the quality and comprehensiveness of the facility's patient safety program. Facility staff were not knowledgeable about the process and types of patient safety events to be reported, and the former patient safety manager did not adequately educate facility staff on the processes to use to report patient safety events.

VHA policy requires all staff to report patient safety events to the patient safety manager, typically through the electronic patient safety reporting system, even if the condition has not resulted in an adverse clinical outcome or close call.⁸⁰ After receipt of reported patient safety events, the patient safety manager reviews the event and assigns a severity assessment score to determine the need for further review. The patient safety manager should track and trend patient safety-related event data.⁸¹ Facility policy states that the patient safety manager is further responsible for coordinating facility staff education on the electronic patient safety reporting system and the types of patient safety events to be reported.⁸² An OIG Comprehensive Healthcare Inspection Program report on the facility, issued on October 24, 2018, stated "Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms."⁸³

As noted previously, some clinical and ward 3A staff members told the OIG inspection team that they were unaware of patient safety event reporting processes and were unclear about the types of events to be reported. For example, two clinical staff members reported completing patient safety event reports for patient falls, with one of these staff members saying a medication error could result in a patient safety event report. Two clinical staff members were unaware of a facility policy addressing the types of incidents to report in the patient safety event reporting

⁸⁰ VHA Handbook 1050.01; Facility Memorandum 00B-04; Facility Policy 00B-04.

⁸¹ VHA Handbook 1050.01 states that severity assessment scores are determined based on the severity category (events can be catastrophic, major, moderate, or minor) and the probability category (events can be frequent, occasional, uncommon, or remote) and define when a further patient safety review is required.

⁸² Facility Memorandum 00B-04; Facility Policy 00B-04.

⁸³ OIG Report, *Comprehensive Healthcare Inspection Program Review of the Louis A. Johnson VA Medical Center, Clarksburg, West Virginia*, Report No. 18-01136-313, October 24, 2018.

system. Another staff member reported that incident reports should be entered for patient falls, medication errors, patient injury, or anything that happens with the patient that should not happen. This staff member did not include critical glucose events as a type of incident that would be reported in the patient safety event reporting system.

The OIG determined that not all hospitalists were knowledgeable about patient safety event reporting. For example, Hospitalist A reported being familiar with the existence of a reporting system but nothing more specific. In addition, two physicians were not aware of the patient safety reporting system.

The former and current patient safety managers reported that facility staff primarily received patient safety-related training in new employee orientation, as well as through impromptu discussions and, more recently, through an annual training fair. With the exception of new employee orientation and a document reflecting information on the newer Joint Patient Safety Reporting system process, the current patient safety manager was unable to provide any additional documentation confirming staff education on patient safety event reporting.

The OIG would expect that, had staff been successfully trained at the time of the events in 2018, patient safety event reporting would have been submitted for, at a minimum, the high use of D50. Specifically, Patient 1 received 16 ampules of D50 to treat the profound hypoglycemia, which depleted the stock of D50 in several medication carts. As a result, this rescue medication was not readily available for other patients in the event of an emergency and therefore qualified as a reportable medication-related patient safety event. Also, while the indication was less definitive, patient safety event reports for the ongoing unexplained hypoglycemic events could have been submitted. With this information available for tracking and trending, the Patient Safety Manager may have identified the emerging pattern of troubling hypoglycemic events and could have had an informed discussion with the former Risk Manager or other clinical leaders regarding subsequent deaths of several patients.

Oversight Weaknesses and Reporting Deficits

VHA policy states “the achievement of high-quality outcomes requires strategic alignment and both horizontal and vertical integration within the organization.”⁸⁴ Facility policy assigned the Executive Leadership Board (ELB) responsibility for facility performance, patient safety, and

⁸⁴ VHA Directive 1026.

operational activity oversight as the integrated “highest level leadership group.”⁸⁵ The Facility Director served as the chairperson of the ELB with oversight responsibility for the Medical Executive, Administrative Executive, Quality Executive, and Patient Care Executive Councils.⁸⁶ Executive councils provide oversight of key areas under their organizational purview to identify changes in policy or initiatives and forward recommendations to the ELB. The ELB provides oversight of executive council activities, including final review and approval of recommendations. The ELB was required to meet at least quarterly and the executive councils were required to hold at least 10 meetings each year.⁸⁷

Figure 3 displays the facility-defined oversight and executive council reporting structure to allow for integration of quality and other critical information sources.

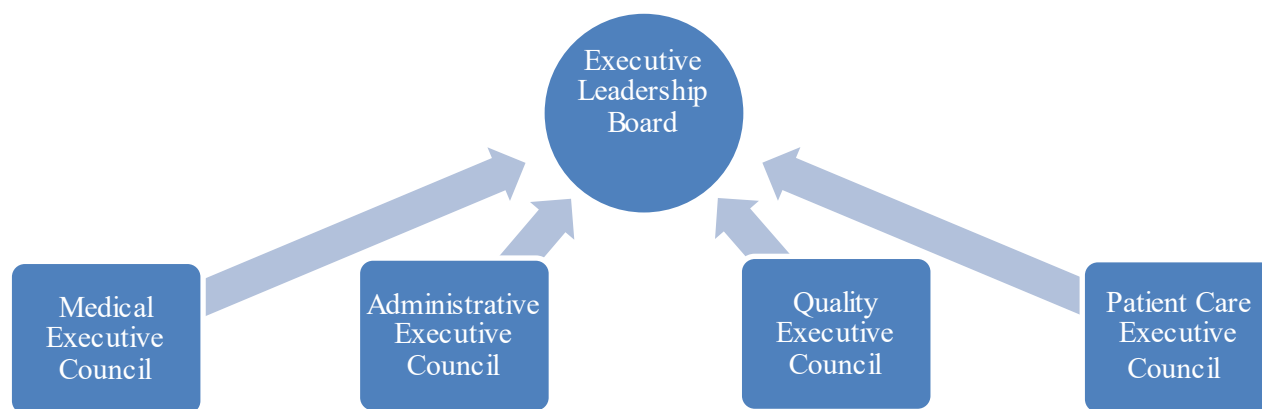


Figure 3. Illustration of facility oversight and reporting structure

Source: Facility Policy 00-05, Medical Center Governance and Reporting Structure, June 2020⁸⁸

Meeting minutes are the communication tools to ensure critical information is provided to the ELB and executive councils. Facility policy requires that recommendations involving “a resource commitment, interdepartmental policy change, directive interpretation, or major initiative” are to be documented in executive council meeting minutes and presented to the ELB for final review

⁸⁵ Facility Memorandum 00-05, *Medical Center Governance and Reporting Structure*, April 2017. The ELB was responsible for providing subordinate committee oversight. Only those committees under the jurisdiction of the ELB that pertain to the concerns under review are addressed in this report. The leadership councils reporting to the ELB include the Medical Executive Council, Administrative Executive Council, and Patient Care Executive Council. According to the *Quality Executive Council Charter 001*, May 14, 2020, the Quality Executive Council was officially named as another Council in May 2020. Facility Memorandum 00-05, *Medical Center Governance and Reporting Structure*, June 1, 2020.

⁸⁶ Facility Memorandum 00-05. *Quality Executive Council Charter 001*, May 14, 2020. The Quality Executive Council became official in May 2020. In addition to the Facility Director, the voting membership includes the Associate Director; ADPCS; Chief of Staff; Chiefs of Quality and Risk Management, Fiscal, and Human Resource Management Services; and rotational members including a representative clinical service chief; a representative administrative service chief, and an Associate Chief Nurse, Patient Care Services.

⁸⁷ Facility Memorandum 00-24, *Executive Leadership Board*, February 2018.

⁸⁸ Facility Memorandum 00-05.

and approval prior to implementation.⁸⁹ Further, VHA policy requires meeting minutes to “track issues to resolution” and facility policy requires use of an action log to ensure items are tracked to final closure.⁹⁰

The OIG found that the ELB met quarterly from October 2017 through August 2018. The OIG evaluated the meeting minutes of the ELB, the four executive councils, standing committees, and workgroups to ensure clear documentation of issues and recommended action tracking through closure.

The OIG found that the standing committees and workgroups did not consistently submit required reports to the designated executive councils. For example, one of the committees that would have been expected to discuss the events on ward 3A and other patient safety-related issues did not report as required to its designated executive council. Additionally, there was no evidence of follow-up by the executive councils to obtain the required reports.

The OIG further found that when committees did submit minutes, they did not contain detailed documentation of critical information. For example, one of the executive councils reported working on policies and procedures; however, the minutes did not identify what policy was being addressed, or any committee action items or follow-up. Meeting minutes frequently referenced attached committee minutes with no other discussion documented.

While three of the four executive councils maintained the required action log, actionable items addressed in meeting minutes were not consistently documented on the action log.⁹¹ For example, the OIG identified two instances of standing committees forwarding concerns to their designated executive councils; however, the designated executive councils’ meeting minutes did not document actions taken. The OIG found frequent workgroup formation to address performance measures; however, no reports from workgroups were submitted to the Medical Executive Council.

The OIG determined that VHA and facility oversight and reporting requirements were not being followed, leading to deficient information flow and issue identification, as well as action tracking to closure. The OIG did not find documentation related to the events on ward 3A to include changes or actions taken to improve processes.

Recommendation 10–12

Recommendation 10. The Louis A. Johnson Medical Center Director requires that all staff are trained on reporting patient safety events using the correct reporting system and monitors for compliance.

⁸⁹ Facility Memorandum 00-05.

⁹⁰ VHA Directive 1026; Facility Memorandum 00-05, April 2017; Facility Policy 00-05, June 2020.

⁹¹ Facility Memorandum 00-05, April 2017; Facility Policy 00-05, June 2020.

Recommendation 11. The Louis A. Johnson Medical Center Director ensures that the interdisciplinary mortality review workgroup meet as required with appropriate reporting through oversight council(s), and monitors for compliance.

Recommendation 12. The Louis A. Johnson Medical Center Director ensures that local oversight and reporting practices align with local policy requirements.

Finding 6. Facility, VISN, and VHA Leaders and Staff Have Taken Steps to Improve Patient Safety but Additional Responses Are Needed

Leaders and managers at all levels of VHA understood that while certain changes in practice and policy could be made during the pendency of the criminal investigation, some evaluative and corrective actions in response to the events were restricted to avoid compromising the criminal case. The OIG acknowledges this limitation.

Facility Actions

The OIG found that QSV staff took prompt action to evaluate the cases and search for potential additional cases after the former Associate Chief of Staff notified them of the concerns in late spring 2018. Further, when the QSV evaluators could not clarify the nature and connectedness of the events, the facility made appropriate notifications and status updates to VISN and VHA leaders. Because of the limitations posed by the criminal investigation, the facility could not conduct parallel in-depth (assisted by an endocrinologist), retrospective clinical reviews of patients potentially adversely affected by Ms. Mays's actions.

The facility took several actions to improve medication security, nursing policies and processes, and general oversight. Of note, facility leaders secured access to the ward 3A medication room and promptly issued a standard operating procedure related to blood sugar levels and notification of providers (*Hypoglycemia and Hyperglycemia Parameters and Process to Notify Providers*). In addition, leaders provided updated and refresher instructions on medication safety and administration practices to nursing staff, among other actions.⁹² Twelve new medication carts with user-specific locking systems were placed in use February 1, 2019. In October 2019, facility leaders began detailing several clinical managers connected to ward 3A to other roles, reportedly to allow new leaders to gain a fresh perspective of operations relative to ward 3A.

Some additional actions, either implemented or planned, are outlined below.

⁹² Facility Standard Operating Procedure 118-157, *Hypoglycemia and Hyperglycemia Parameters and Process to Notify Providers*, August 2018.

Installation of Video Surveillance Cameras on Ward 3A

At the time of the events discussed in this report, ward 3A was not monitored by patient safety or security video cameras. While VHA does not have a requirement for camera surveillance in treatment areas like ward 3A, facility directors are responsible for evaluating risk within the facility and can install cameras for patient safety or security purposes.⁹³ The facility received a cost estimate from a private local company to install security cameras on ward 3A in March 2019, and cameras were installed and operational by the end of October 2019, providing views of ward 3A's four hallways and entrance. On August 28, 2020, a motion-activated security camera was installed in the ward 3A medication room, with plans to install cameras in all medication rooms in the facility and community-based outpatient clinics by late December 2020.

When video monitoring occurs in treatment areas, signage alerting patients and other parties must be posted.⁹⁴ Cameras and signage may serve to discourage potential criminal activity; however, there are limitations to their efficacy. Specifically, the ward 3A medication room security camera did not transmit images to the VA police office for monitoring. Further, while the footage was recorded on a space-limited secure digital memory card, recordings could be overwritten depending on the amount of traffic in and out of the medication room. Therefore, the presence of the ward 3A medication room camera was more likely intended as a deterrent rather than a method to identify concerning actions in real time or perpetrators retrospectively.

Rescue Medication Tracking

Facility and VISN leaders told the OIG inspection team that a facility workgroup that included staff from QSV, nursing, and Pharmacy Service was created to develop a tracking process for rescue medications such as D50 and naloxone.⁹⁵ The Facility Director told the OIG inspection team, "Had that program been in place when these hypoglycemic events occurred, it [is] highly likely we would have found the very first one, and it would have bubbled up because we would have... found that there was [*sic*] multiple amps [ampules] of D50 administered to the patient." The Chief of Pharmacy told the OIG that processes related to rescue medication tracking were in the early stages of development at the time of this inspection. However, the OIG inspection team was told that facility leaders would receive periodic reports that would be reviewed for "outliers."

⁹³ VHA Directive 1078(1), *Privacy of Persons Regarding Photographs, Digital Images, and Video or Audio Recordings*, November 4, 2014, amended November 19, 2014.

⁹⁴ VHA Directive 1078(1).

⁹⁵ Naloxone is a synthetic potent antagonist of narcotic drugs (such as morphine and fentanyl) that is administered by injection or as a nasal spray to reverse the effects of opioids, especially in the emergency treatment of opioid overdose.

The OIG determined that the facility's efforts to identify potentially concerning events via a review of rescue medications could be a valuable tool for VHA facilities nationwide.

Activities Supporting a Patient Safety Culture

Despite facility leaders' acknowledgment of communication deficits surrounding these events, the OIG found that the facility's actions to promote a culture of patient safety were slow to take shape. For example, a safety stand down was not initiated until December 2020, more than two years after the 2018 hypoglycemia events.⁹⁶ The Chief of Quality and Risk Management reported to the OIG that, as part of the stand down, the facility conducted staff education and training regarding patient safety reporting, nursing competencies, EHR documentation, and the patient admission assessment process. The stand down also addressed procedural operations including a patient care communication board, consistent nursing and physician patient care rounds, and facility and nursing leader staffing changes. While the OIG determined the facility's recent actions were important first steps, continued vigilance through periodic facility-wide patient safety refresher training and additional safety stand downs when indicated are necessary to ensure the effectiveness of actions and further promote the facility's culture of safety.

VISN Actions

The OIG found that VISN 5 officials were notified promptly of the events after facility senior leaders were informed. Officials remained involved in ongoing communication and received ongoing updates, conducted a reasonable evaluation, and maintained awareness of facility actions. While the VISN did not have a policy describing roles and responsibilities, VISN staff generally described their responsibility to provide oversight, ensure facilities were in compliance with accrediting bodies, and confirm corrective actions were implemented to address concerns or deficiencies.

The VISN Chief Medical Officer (who was the Acting VISN Director) was notified about the hypoglycemic events on June 27, 2018. The Facility Director and VISN Chief Medical Officer agreed to make immediate notification to VHA and the OIG. Further, the VISN Chief Medical Officer reported, and the OIG inspection team confirmed, that the Facility Director provided regular updates via emails that included the status of the investigation and personnel actions. The VISN Chief Medical Officer reported that VHA leaders recommended against completing an issue brief and additional evaluation due to the ongoing criminal investigation. The OIG learned that during this time, VISN leaders did not follow up with other VISN 5 facilities to determine whether deficient medication security-related conditions existed.

⁹⁶ A safety stand-down, during which Clarksburg VA Medical Center did not accept new patients except for COVID-19 and intensive care patients, closed ward 3A and centered on reviewing patient safety and care at the facility. <https://www.military.com/daily-news/2020/12/27/west-va-va-hospital-announces-changes-after-patient-deaths.html>.

The VISN Chief Medical Officer reported reviewing the facility's mortality data and All Employee Survey results to identify potential areas of concern. The mortality data indicated a spike in the third quarter of fiscal year 2018 with a return to the normal range the following quarter. The All Employee Survey did not reveal concerns about employee psychological safety, which is measured by the item: "I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal." The VISN continued routine annual reviews of Pharmacy Service, QSV, and patient safety.

After Ms. Mays pled guilty in July 2020, the VISN conducted a site visit that included interviews with the VHA Chief Nurse Officer, VISN Chief Nursing Officer/Quality Management Officer, and others. Following this visit, a plan was developed that included several measures:

- Evaluation of facility ADPCS leadership and communication
- Provision of mentors for Chief of Staff and ADPCS
- Provision of funding support for shadowing of Chief of Staff and ADPCS
- Engagement of the National Center for Organization Development
- Initiation of external reviews of care for the eight victims central to this report

The VISN Director stated that medication room security assessments were added to the Pharmacy Service and Patient Safety Annual Reviews for 2020. However, the VISN was unable to complete on-site 2020 reviews due to ongoing COVID-19 restrictions.

VHA Actions

The Deputy Under Secretary for Health for Operations and Management was notified on June 27, 2018, of the unexplained hypoglycemic events, and the VA Executive in Charge promptly notified the VA Inspector General on June 28, 2018, of the possibility of an "Angel of Death." Further, the OIG confirmed that the facility and VISN included VHA on status update emails and that VHA's Chief Nurse Officer participated in the VISN 5 annual QSV review in April 2019 that yielded some general facility leadership training and mentoring activities.

The OIG determined, however, that VHA officials did not request the Office of Reporting, Analytics, Performance, Improvement, Deployment (RAPID) to review and report on the facility's overall mortality trends and related concerns until after the news media and West Virginia Senators Joe Manchin and Shelley Moore Capito began making inquiries into the deaths in August 2019.⁹⁷ RAPID, which is VHA's nationwide analytics and improvement office,

⁹⁷ RAPID was the relevant VHA Program Office at the time of the events. VHA has since reorganized, with the relevant functions consolidated under the Office of Analytics and Performance Integration (API). VHA's Inpatient Evaluation Center, one of the programs within RAPID, and now API, uses processes and metrics that help facilities identify opportunities for improving patient outcomes in a care, including mortality. A high-level review of data would not have constituted a fact-finding activity.

integrates data management, measurement, and improvement to identify and remedy variations in quality.⁹⁸ Additionally, the OIG found that RAPID's review, when completed, did not include in-depth analysis or discussion of some key data points that would have provided a more comprehensive view of mortality and related concerns at the facility.

On August 28, 2019, more than a year after the events, VHA's Acting Deputy Chief of Staff sent an email to VHA's Chief Improvement and Analytics Officer for RAPID, writing "I need you to run everything you can run on Clarksburg, WV- Louis A Johnson VAMC [VA medical center]. I want no surprises. I need IBs [Issue Briefs] back through 2017, data and anything else you can find. I need it as soon as you can."

The Chief Improvement and Analytics Officer responded the same day to the VHA acting deputy Chief of Staff's August 28 request with a summary of RAPID's mortality review of the facility during the relevant time frame. The summary reflected

- A "blip" in the acute care standardized mortality ratio from April 1 to June 30, 2018, but noted that the statistical confidence limits was such that one quarter's elevation would not be considered a "worrisome signal;"⁹⁹
- Consideration as to whether low patient volume meant facility providers might not see enough severely ill patients to get "really good" at managing the rare patient that does become acutely unstable, which could conceivably lead to potentially preventable mortality. Consideration was also given to whether a medication error may have occurred in the one patient who was named in a media report. The summary indicated this scenario was unlikely given the patient's comorbidities;¹⁰⁰
- No unusual systemic patterns in a review of hypoglycemia, and in relation to other VISN 5 medical centers, the facility's "rate of glucoses under 60 mg/dL for Q3 FY18 was 1.3%—below the VHA mean. The time periods straddling Q3 were even lower—0 percent;" and
- A "much higher" use of hospice at the facility when compared to other [similar size and complexity] facilities, but also noted that data provided by the Geriatrics and Extended Care Program Office showed "an active hospice and palliative care consultation team and

⁹⁸ "Analytics and Performance Integration - Quality and Patient Safety (QPS)," accessed March 15, 2021, <https://www.va.gov/QUALITYANDPATIENTSAFETY/api/index.asp>.

⁹⁹ The standardized mortality ratio is a risk-adjusted mortality metric for in-hospital deaths, measured as the number of observed (or actual) deaths divided by the number of predicted deaths from the statistical model. A standardized mortality ratio less than 1.0 means there were fewer deaths than predicted and more than 1.0 means there were more deaths than predicted.

¹⁰⁰ For privacy purposes, the names of the victims were not shared outside of approved personnel. At the time, one patient had been identified publicly in the news media, which allowed RAPID to find and examine this patient's EHR for clinical details that might explain the patient's hypoglycemic episode(s) and death.

better-than-average scores from families for end-of-life care” from the Bereaved Family Survey.¹⁰¹

In relation to RAPID’s review and role, the former Chief Improvement and Analytics Officer, who is now the Executive Director of the Office of Analytics and Performance Integration, told the OIG inspection team during a September 2020 interview, “We’re really looking at system performance and conformance to clinical practice guidelines, and these really abhorrent events, [these] horrifying veterans event[s]... we don’t have a system that’s configured to do that.”

The OIG found that RAPID did not appear to review and analyze important data from multiple angles; rather, RAPID’s review and findings generally centered around pre-established reports on mortality and hypoglycemia (in patients taking hypoglycemic agents) used for clinical oversight. As a result, VHA missed opportunities to better understand the issues at the facility, whether similar conditions existed at other VHA facilities, and whether strategies to oversee mortality and medication-related high-risk areas needed modifications.

Available performance and other clinical data, if viewed differently, would have revealed concerning clinical care and mortality patterns that overlapped with Ms. Mays’s ward 3A shifts. For example, OIG analysis of overall facility mortality data revealed that the unadjusted in-hospital mortality rate averaged about 2 percent from January 2013 to September 2019.¹⁰² From January 2013 to June 2015, before Ms. Mays started working at the facility, there were two spikes in the mortality rate with the highest spike at 4.5 percent. From July 2015 to July 2018, while Ms. Mays was providing direct patient care, there were nine spikes in the mortality rate with the highest over 6 percent. After Ms. Mays was removed from direct patient care in July 2018, there were no spikes in the mortality rate through September 2019, and the overall unadjusted mortality rate had decreased to around 1 percent.

The OIG was unable to discern RAPID’s data source showing “no unusual systemic patterns” and blood glucose rates under 60 mg/dL for the three quarters from January through September 2018 (0, 1.3, and 0 percent, respectively). As this OIG report references three patients who experienced hypoglycemic events occurring between January 1 and March 31, 2018, the suggestion that the facility had a rate of zero blood glucoses less than 60 mg/dL during that time frame was not accurate. It is possible that RAPID used an existing VHA report, *Glucose Measurements in Patients on Hypoglycemic Agents [with] Glucose Measurements Less Than 45 mg/dL*, to identify potentially concerning patterns of hypoglycemia. The referenced report, however, is generally used for clinical care compliance purposes and does not include very low

¹⁰¹ The OIG found that of the six acute care medical centers within VISN 5, the facility’s rate of hospice designation was more than quadruple that of the next highest VISN 5 medical center for the rolling 12 months from April 1, 2017, through March 31, 2018.

¹⁰² The unadjusted inpatient mortality rate is measured as the total number of in-hospital deaths divided by the number of discharges, presented as a percentage.

blood glucose levels for patients *not* taking hypoglycemic agents (as was the case for most of the initial 10 patients reviewed by the OIG).¹⁰³

In reviewing hypoglycemia data another way, OIG analysis found that from January 1, 2014, through December 31, 2017, there was, on average, one patient on ward 3A who experienced severe hypoglycemia (defined as less than 45 mg/dL) and died within 30 days of discharge each year. However, seven patients had severe hypoglycemia and died within 30 days of discharge from January 1, 2018, through June 30, 2018, while Ms. Mays was providing direct patient care. From July 2018 to September 2019, after Ms. Mays was removed from clinical care, one patient had severe hypoglycemia and died within 30 days of discharge.

The OIG also found that RAPID's willingness to accept the Geriatrics and Extended Care Program Office's statements as evidence of the facility's apparently highly functional Hospice and Palliative Care program was problematic. Specifically, the OIG found the information provided by the Geriatrics and Extended Care Program Office, as well as some VISN-level Hospice and Palliative Care program data, did not adequately explain the facility's very high use of hospice. Because patients who received hospice care within one year prior to, or on the same day of, admission are excluded from mortality models, hospice designation could be used to influence mortality rates. The OIG would have expected a more in-depth evaluation of the facility's Palliative Care Consult Team (PCCT) and hospice-related practices to ensure the facility was in compliance with VHA guidelines.

The OIG concluded that VHA's minimalist review approach, coupled with a lack of critical analysis of the facility's hypoglycemic event data, likely resulted in missed identification of process weaknesses for the facility. As a result, patient safety may be compromised resulting in potential negative outcomes. Further, per RAPID's stated intention of providing system performance and conformance to clinical practice guidelines, a comprehensive review and critical analysis of data would enhance VHA's knowledge of issues identified at a facility level.

After Ms. Mays's July 2020 guilty pleas, VHA was no longer constrained in its ability to conduct fact-finding reviews or take personnel actions and subsequently convened and completed an administrative investigation board on December 18, 2020. The administrative investigation board made nine recommendations related to personnel-specific administrative actions, staff education and training, quality peer reviews, and leadership accountability. The Facility Director was reassigned on December 23, 2020, and the ADPCS was reassigned on December 28, 2020, to VISN duties.

¹⁰³ VHA's Inpatient Evaluation Center Acute Care Medications Cube also has hypoglycemic measures at less than (<) 45 and <60 mg/dL. However, this a gain is limited to patients prescribed insulin.

Recommendations 13–15

Recommendation 13. The Under Secretary for Health determines the potential advantage of a rescue medication flagging system as an additional tool to evaluate unexplained adverse patient events, including but not limited to mortalities, and takes action as indicated.

Recommendation 14. The Louis A. Johnson VA Medical Center Director takes action to prioritize and continue efforts to promote a strong culture of safety, such as periodic facility-wide refresher patient safety training or additional patient safety stand downs when indicated, and monitors for effectiveness.

Recommendation 15. The Under Secretary for Health reevaluates how the Veterans Health Administration collects, reviews, and analyzes mortality data from VA facilities, and takes action to address identified gaps and weaknesses, as indicated.

Final Observations: Hospice and Palliative Care Policy Compliance and Ward 3A Nursing Practices

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Hospice and Palliative Care

Hospice is for patients diagnosed with a known terminal condition with a survival prognosis of less than six months and focuses on enhancing the quality of life remaining for patients. Palliative care includes hospice care but does not require the presence of an imminently terminal condition. Because patients who received hospice care within one year prior to, or on the same day of, admission are excluded from mortality models, hospice designation should be considered when analyzing mortality rates.

The OIG conducted a more in-depth evaluation of hospice and palliative care at the facility after noting the higher rate of hospice designations. In reviewing the facility’s Hospice and Palliative Care program, the OIG found that the facility did not have “an active hospice and palliative care team” and failed to meet portions of VHA policy.¹⁰⁴

VHA requires “each VA medical facility to have a fully functioning PCCT with sufficient dedicated full-time equivalent (FTE) staff to meet the needs of veterans with serious illness and their families.”¹⁰⁵ According to facility policy, the Chief of Staff has overall responsibility for implementing the policy.¹⁰⁶ The OIG found that the facility did not comply with multiple requirements of VHA and local policies including monitoring and oversight functions. Further,

¹⁰⁴ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) and VISN Leads*, June 14, 2017.

¹⁰⁵ VHA Directive 1139.

¹⁰⁶ Facility Memorandum 118-83, *Hospice and Palliative Care Program*, April 2017.

the Associate Chief Nurse informed the OIG that the facility had not had a fully functioning interdisciplinary PCCT with dedicated staff for years; rather, PCCT staffing was “on paper” only.

Leaders and staff involved in the Hospice and Palliative Care program confirmed to the OIG inspection team that the program lacked a dedicated physician or other mid-level provider as required. The Chief of Staff said that provider recruitment was a chronic problem at the facility. During a review of PCCT staffing and in an interview with the Hospice and Palliative Care Coordinator, the OIG confirmed that the nurse was 1.0 FTE and a social worker was 0.3 FTE.¹⁰⁷ The psychologist, who was a 0.3 FTE, told the OIG inspection team of having no PCCT responsibilities beyond attending a one-hour PCCT committee meeting four times per year. There were no chaplains, physicians, or providers included (or allocated) in PCCT staffing. The Chief of Staff told the OIG inspection team that providers “rotated” to the PCCT; however, the OIG inspection team found no evidence that these rotating hospitalists participated in the consult process as required.

This finding was confirmed by the Associate Chief Nurse in an interview with OIG.¹⁰⁸ Further, the Chief of Staff asserted that admitting hospitalists provided the clinical care to hospice patients (despite the seven days on, seven days off schedule), and reported that hospitalists and primary care providers caring for end-of-life patients were not required to possess a minimum number of relevant training hours or certification. The Hospice and Palliative Care Coordinator informed the OIG that the hospitalists did not complete hospice consults or provide consultative advice. The OIG found the Chief of Staff to be uninformed about the requirements of VHA policy and the expectations for provider involvement in the PCCT program and hospice care delivery.¹⁰⁹

It was unclear to the OIG how the facility’s hospice utilization could be significantly higher than like-sized facilities given the lack of a fully staffed and functional PCCT. This concern was referred to OIG’s hotline division for further evaluation.

In addition to the VA Inpatient Evaluation Center generated mortality review and VHA Chief Nursing Officer site visit, as of October 2, 2020, the OIG learned of VHA’s intention to conduct

¹⁰⁷ Used in a process to assign labor resources to the work areas where they belong, the term *full-time equivalent employment (FTE)* is used to quantify employment as a function of hours worked rather than by the number of individual employees, accessed March 19, 2021, [Federal Workforce Statistics Sources: OPM and OMB \(fas.org\)](https://www.fas.org).

¹⁰⁸ Evidence showed that the hospice nurse coordinator completed 100 percent of the hospice consults entered in the fourth quarter of fiscal year 2020; however, VHA Directive 1139 requires a physician or non-physician practitioner with physician collaborator to complete consults.

¹⁰⁹ The OIG inspection team also noted that the Chief of Staff made contradictory statements (2018 versus 2020 interviews) about conducting reviews of the cases provided by QSV. The discordance, however, was beyond the scope of this review.

further review. The OIG inspection team was not told of changes made at the national level in policies, procedures, or oversight.

Nursing Policy and Practice

During the OIG's 2018 initial site visits, the team identified multiple deficient nursing policies and practices on ward 3A.¹¹⁰ Although not directly related to Ms. Mays's actions, the deficiencies described below further reflect the casual environment on ward 3A.

Patient Identification Wristbands

Some nurses were cutting off patient wristbands and taping them to the patient's bedside or making copies as a workaround to scanning the wristband bar codes for medication administration. This was reportedly done to avoid "bothering" the patient.

Facility policy states that Bar Code Medication Administration software "is a POC solution for validating the administration of medications. Automation of the medication administration process will reduce errors and increase the efficiency of documentation." Bar code technology is used as one of the patient identifiers during medication administration. Upon admission to the hospital, a bar coded wristband is fastened to all inpatients using appropriate identity verification. A bar coded patient wristband can be printed and reapplied to the patient if the band is removed or unreadable. The policy requires inpatient nursing staff to open the EHR by scanning the bar code on the patient's wristband. The use of duplicate patient identification wristbands is not authorized.¹¹¹ When a patient's identification bar code is on an object (such as a bedside rail), a nurse could inadvertently scan the wrong patient's wristband, thereby increasing the risk of one patient receiving another patient's medication. This type of medication error could be lethal.

In response to the OIG's concerns, on August 8, 2018, the ACN sent an email to ward 3A licensed nursing staff stating that wristbands were to remain on patients at all times. Wristbands were not to be attached to bed rails, nor were wristbands to be duplicated. Further, the nursing assessment note was to include documentation that the patient's wristband was in place.

During the 2020 unannounced follow-up visit, an OIG inspection team member observed a nurse correctly scanning two different patients' wristbands before administering the respective medications. The OIG did not see duplicate wristbands being used.

¹¹⁰ Due to the potential for patient harm, the OIG inspection team discussed the identified deficits with the Facility Director on July 11 and 13, 2018.

¹¹¹ Facility Memorandum 119-15, *Bar Code Medication Administration*, October 2016. The policy makes an exception for psychiatric patients with a diagnosis of paranoia.

Insulin Administration Noncompliance

Some nurses were drawing up insulin from multidose insulin vials in patient rooms in violation of VHA policy.

VHA policy states, "If the [insulin] vial must be used for more than one person, it should be stored and prepared in a dedicated medication preparation area outside of the patient care environment and away from potentially contaminated equipment."¹¹²

In response to the OIG's concerns, on August 8, 2018, the ACN sent an email reminding ward 3A licensed nursing staff that insulin is to be drawn up before entering the patient's room. The email further stated that nursing staff were to review a series of relevant standard operating procedures and facility memorandums, and verify completion via signature by August 15, 2018. Some of the identified standard operating procedures and facility memorandums included *Use of Multiple Dose Vials of Insulin and Vaccines for Multiple Patient Administration*, *Management of High Risk Medications*, *Critical Results and Values*, and *Medication Administration Documentation in Bar Code Administration Package*.¹¹³

In September 2019, the facility issued Standard Operating Procedure 118-159, *Insulin Removal from Pyxis and Verification*, which requires a licensed nurse caring for a patient to draw up the insulin in the syringe using an aseptic technique, apply the appropriate bar code label, and return the insulin to the Pyxis.¹¹⁴ This process is to be witnessed by a nurse-verifier. The responsible nurse and nurse-verifier then go to the patient's bedside and verify the patient and the dose again in the Bar Code Medication Administration system prior to insulin administration.

Unsecured Needles and Syringes

New (unused) needles and syringes were found by the OIG in unlocked cabinets in patient rooms.¹¹⁵ Although the OIG could not identify a VHA policy requiring that medical supplies such as needles and syringes be secured, The Joint Commission suggests that syringes be kept secured to prevent theft, tampering, and unauthorized access.

¹¹² VHA Directive 1014, *Safe Medication Injection Practices*. July 1, 2015.

¹¹³ Facility Standard Operating Procedure 118-134, *Use of Multiple Dose Vials of Insulin and Vaccines for Multiple Patient Administration*, October 2016; Facility Standard Operating Procedure 118-25, *Management of High Risk Medications*, November 2017 (rescinded and replaced by Facility Standard Operating Procedure 118-25, *Management of High Risk Medications*, February 2020); Facility Memorandum 114-10, *Critical Results and Values*, March 2016; Facility Standard Operating Procedure 118-52, *Medication Administration Documentation in Bar Code Medication Administration Package*, October 2016.

¹¹⁴ Facility Standard Operating Procedure 118-159, *Insulin Removal from Pyxis and Verification*, September 2019.

¹¹⁵ The OIG inspection team was subsequently told about intravenous flush lines left in patient rooms. The OIG was unable to verify the specific nature of the concern; however, during the 2020 unannounced follow-up visit, the OIG did not find intravenous flush lines in patient rooms.

In response to the OIG's concern, the ACN sent an email on August 8, 2018, reminding relevant staff members that cabinets in patient rooms were not to store supplies other than gloves.

During the 2020 unannounced follow-up visit, the OIG did not find needles or syringes in patient rooms.

Lack of Awareness Regarding Hypo- and Hyperglycemia Policy and Procedure

Nurses were unable to explain or locate the appropriate procedure(s) for managing patients with hypo- or hyperglycemia. According to the ADPCS's office, the facility did not have a written policy on management of hypo- or hyperglycemia prior to August 2018. Rather, nurses followed the established policy on critical results and values, which required that critical blood glucose levels of less than 45 mg/dL and greater than 500 mg/dL be communicated directly to a responsible care provider. Despite the availability of this policy, some nurses could not articulate for the OIG inspection team the process for managing these patients.

The facility issued Standard Operating Procedure 118-157, *Hypoglycemia and Hyperglycemia Parameters and Process to Notify Providers*, in August 2018.¹¹⁶ The ACN sent an email to nursing staff on August 8, 2018, highlighting key points of the new procedure. During the 2020 unannounced follow-up visit, the OIG inspection team interviewed two nurses, both of whom were able to state the current procedure.

Glucometer Competency and Policy Compliance

A glucometer is a medical device that measures the amount of glucose in a small sample of blood. Glucometers are used for POC testing at the bedside or in a clinic. A droplet of blood is usually collected using a fingerstick and then absorbed onto a testing strip. The glucometer displays the results immediately, allowing the nurse to take prompt action if needed.¹¹⁷

Nurses were not consistently aware of the POC testing policy, documentation requirements, or annual competency expectations related to glucometers. In addition, nurses were not consistently up to date with annual training and competency requirements for blood glucose monitoring. To be authorized for glucometer use, nursing staff must receive training and demonstrate competence.

¹¹⁶ Facility Standard Operating Procedure 118-157.

¹¹⁷ When the glucometer is returned to its docking station, the glucose test results are automatically uploaded into the patient's EHR unless the user enters "Do Not Upload." (This entry must be free text as it is not one of the 21 "canned" comments available. It is most frequently seen when there is a high blood glucose reading and a repeat test.) Delays in redocking the glucometers meant that some blood glucose test results were not immediately available to care providers, possibly delaying needed intervention. In 2020, ward 3A's four glucometers had been moved from the medication room to the nursing station allowing for immediate access to the docking stations.

In 2018, the facility had eight ancillary testing standard operating procedures that provided staff education and guidance on the Ancillary Testing Quality Control Program, use of the glucometer, documentation, and competency training.

In 2020, 35 of 36 applicable nursing staff had completed annual POC glucometer competencies in a timely manner. One nursing staff member was out on extended leave.

Conclusion

On July 14, 2020, Reta Mays, a former nursing assistant, pled guilty to seven counts of second-degree murder and one count of assault with the intent to commit murder of patients at the facility by deliberately administering insulin to these patients in 2017 and 2018, resulting in profound hypoglycemia and death. While responsibility for these criminal acts clearly lies with Ms. Mays, the OIG found inattention and missed opportunities at several junctures, which, if handled differently, might have allowed earlier detection of Ms. Mays's actions or possibly averted them altogether.

Policy deficiencies and practice failures resulted in VA employees not identifying that while Ms. Mays was employed as a corrections officer at a West Virginia jail from 2005–2012, she was the subject of excessive force allegations. The OIG did not find evidence that any hiring manager contacted Ms. Mays's two most recent employers, including the jail, to verify employment data and make additional inquiries about skills and performance. Further, the facility adjudicator did not complete required actions to evaluate the results of Ms. Mays's background investigation, determine her suitability for employment, and adjudicate the case in a timely manner. This conduct, if known, may have been disqualifying for Ms. Mays to be hired for, or retained in, a VA position providing direct patient care.

Deficient medication management and security practices on ward 3A gave Ms. Mays situational opportunities to commit multiple murders and for those acts to go undetected over a period of months. In 2018, nursing assistants could improperly access the medication room and refrigerator, which contained insulin and other non-high-risk drugs. Further, medication carts on ward 3A, which contained insulin, were unlocked and unattended. The OIG also found that Pharmacy Service used an informal system, rather than the required replenishment system, to record ward stock. The informal tracking process was inadequate and contributed to the non-recognition of the extraordinary amount of D50 (16 ampules) administered to a single patient in spring 2018.

Even though hypoglycemia is rare in patients who are not receiving medication for diabetes, hospitalists did not conduct robust evaluation of the eight victims' clinical scenarios and did not pursue diagnostic testing in seven of the eight victims, some of whom were not diabetic or not on diabetes medications. Hospitalist B did order insulin and C-peptide levels for Patient 8, who was not diagnosed with diabetes, but did not follow up on the results or complete a diagnostic

evaluation. Overall, hospitalists did not appear to be consistently familiar with or understand the utility of a laboratory evaluation for patients with unexplained hypoglycemia, and none of the hospitalists consulted with an endocrinologist. Timely endocrinology consultation would likely have resulted in a more tailored assessment of these patients and may have changed the course of events.

Several factors contributed to the slow identification of similarities across the eight patients and over time. Most hospitalists reported encountering only one or two of these patients and were unable to appreciate the collective significance of events. Further, three of the hospitalists and the Medical Director of Inpatient Services did not consider nefarious intent. Hypoglycemia caused by nefarious activity is very unusual and thus requires a high level of suspicion on the part of the clinician. Consequently, hospitalists were more likely to attribute isolated hypoglycemic events in these elderly and debilitated patients to malnutrition or acute illness, without pursuing other possibilities.

Hospitalist schedules (seven days on and seven days off) and inadequate communication forums and processes presented challenges for clinical information sharing and continuity of care. Meeting forums for nurses to share patient information were likewise inadequate. Also, documentation deficiencies prohibited other providers and staff from receiving information about the patients' clinical care and treatment and may have contributed to staff's inability to realize the context and degree of the hypoglycemic events.

The OIG identified several missed opportunities to report and follow up relative to a cluster of hypoglycemic events involving four patients and occurring over about a three-week period, as well as two additional events 8 and 10 weeks later. Physicians and nurses interviewed by the OIG inspection team were not consistently aware of patient safety event reporting requirements. None of the interviewees submitted patient safety event reports or reported the hypoglycemic events or the unusually high use of D50 to the Chief of Staff, ADPCS, QSV, or Pharmacy Service. The reporting of events is the primary mechanism through which the root cause and contributing factors of a system's vulnerabilities can be mitigated to prevent future events. Nursing and physician clinical leaders could not explain why their respective staff members did not report concerns timely through their chains of command.

The facility's QSV Program and committee reporting structure were deficient, resulting in lack of communication of critical quality information and missed opportunities to identify emerging trends. Further, the facility did not maintain a process to conduct rigorous review of mortality data to identify outliers or track and trend results.

VHA's Deputy Chief Improvement and Analytics Officer provided a summary of the facility's deaths during the relevant time frame but did not identify any particular concerns based on the data reviewed. The OIG found, however, that VHA did not appear to review and analyze important data from multiple angles; rather, the review and findings generally centered around pre-established reports on mortality and hypoglycemia (in patients taking hypoglycemic agents)

used for clinical oversight. As a result, VHA missed opportunities to better understand the issues at the facility and whether similar conditions existed at other VHA facilities, and whether strategies to oversee mortality and medication-related high-risk areas needed modifications. VHA did complete an administrative investigation board in December 2020 and instituted reassignments of several of the facility's top leaders.

The OIG found the facility did not have an active PCCT and did not comply with multiple requirements of VHA and local policies including staffing, training, monitoring, and oversight functions. It was unclear to the OIG how the facility's hospice utilization could be significantly higher than all other facilities in VISN 5 given the lack of a fully staffed and functional PCCT.

While the OIG identified deficient nursing policies and practices in 2018 related to bar coded wristband use, insulin administration, medical supply storage, hypoglycemia policy, and training and competencies that were further reflective of the casual environment on ward 3A, the OIG found it unlikely that they were contributory to the events.

Recommendations 1–15

1. The Under Secretary for Health ensures actions are taken to clarify and broadly disseminate adjudicator expectations for follow-up of an unreturned INV Form 41.
2. The Louis A. Johnson Medical Center Director ensures Pharmacy Service utilizes the required Veterans Health Information Systems and Technology Architecture Automatic Replenishment System to record medication usage data and maintain the records for inventory accountability.
3. The Veterans Integrated Service Network 5 Director conducts management reviews of the care of patients 1–10 as discussed in this report and takes action as indicated.
4. The Louis A. Johnson VA Medical Center Director reviews the availability and timeliness of endocrinology consults, and takes any corrective action needed.
5. The Veterans Integrated Service Network 5 Director ensures evaluation of quality of care concerns or other irregularities (beyond hypoglycemia) of: cases provided by the OIG; cases that may otherwise be pertinent or concerning; and cases brought forward by patients and/or family members who express concerns or make other inquiries about care they received from Ms. Mays. As determined by the VISN, clinical experts external to the facility should be utilized when appropriate.
6. The Louis A. Johnson Medical Center Director develops and disseminates guidance on clinical communication(s) to ensure that patient care and outcomes are routinely discussed in appropriate forums, such as interdisciplinary team meetings, and the discussions are documented.
7. The Louis A. Johnson Medical Center Director ensures that close observation documentation is readily available in the electronic health record, and monitors for compliance.
8. The Louis A. Johnson Medical Center Director ensures clinical documentation reviews are completed timely for patient safety and continuity of care.
9. The Louis A. Johnson VA Medical Center Director evaluates the factors and processes surrounding employees' failures to report and follow up on the unexplained hypoglycemic events, and takes action to ensure appropriate reporting of actual or potential patient safety events, system vulnerabilities, or other unexpected events that offer opportunities for lessons learned.
10. The Louis A. Johnson Medical Center Director requires that all staff are trained on reporting patient safety events using the correct reporting system and monitors for compliance.

11. The Louis A. Johnson Medical Center Director ensures that the interdisciplinary mortality review workgroup meet as required with appropriate reporting through oversight council(s), and monitors for compliance.
12. The Louis A. Johnson Medical Center Director ensures that oversight and reporting practices align with Louis A. Johnson Medical Center policy requirements.
13. The Under Secretary for Health determines the potential advantage of a rescue medication flagging system as an additional tool to evaluate unexplained adverse patient events, including but not limited to mortalities, and takes action as indicated.
14. The Louis A. Johnson VA Medical Center Director takes action to prioritize and continue efforts to promote a strong culture of safety, such as periodic facility-wide refresher patient safety training or additional patient safety stand downs when indicated, and monitors for effectiveness.
15. The Under Secretary for Health reevaluates how the Veterans Health Administration collects, reviews, and analyzes mortality data from VA facilities, and takes action to address identified gaps and weaknesses, as indicated.

Appendix A: EHR Review Methodology

To go back to point of origin hyperlink, press “alt” and “left arrow” keys.

The OIG inspection team conducted in-depth case reviews of the nine patients identified by the facility with severe, unexplained hypoglycemic events (blood glucose level < 45 mg/dL), as well as a tenth patient identified by the OIG. The OIG inspection team reviewed these cases to determine whether there was a plausible explanation for the patients’ hypoglycemia. In an effort to identify potential victims beyond the 10 patients noted above, the OIG focused on four review populations. Some patients fell into more than one category.¹¹⁸

Table A.1. OIG Review Populations, Criteria of Review, and Findings

OIG Review Populations	Total	OIG Reviewer Criteria	Findings
Initial patients, who experienced severe, unexplained hypoglycemic events (blood glucose level < 45 mg/dL), identified by the facility	9 patients	Plausible medical explanation for hypoglycemia	<p>To varying degrees, all but one patient had plausible medical explanations for hypoglycemia. However, the frequency of critical hypoglycemic events requiring intervention was concerning.</p> <p>Patient 1 was diabetic on insulin with poor oral intake and sepsis, case notable for refractoriness of hypoglycemia</p> <p>Patient 2 was diagnosed with sepsis, though clinically improving at the time hypoglycemic event occurred</p> <p>Patient 3 was diagnosed with malnutrition, cirrhosis, pneumonia, and renal insufficiency</p> <p>Patient 4 was noted to be generally debilitated with sepsis</p> <p>Patient 5 was profoundly debilitated with poor oral intake, weight loss, and sepsis</p> <p>Patient 6 was a diabetic with malnutrition, extreme debilitation, and a history of labile blood sugar with pre-hospital episodes of hypoglycemia requiring medical care</p> <p>Patient 7 had no physiologic explanation for hypoglycemia</p> <p>Patient 8 was diagnosed with liver, kidney and cardiac failure, though physiologic explanation for hypoglycemia unclear</p>

¹¹⁸ Information contained in the Findings column of this appendix was determined by OIG medical consultants to be relevant to the specific review population.

Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

			Patient 9 was noted to be generally debilitated with sepsis and received treatment with a fluoroquinolone
Patients, who died during Reta Mays's employment, identified by the OIG from facility glucometer data ¹¹⁹	112 patients	<ul style="list-style-type: none"> • Date and time of death • Admission glucose • Date of last glucose • Last glucose check result • Blood sugar <45 within last admission • Date of episode • Reta Mays cared for patient 	<p>34 patients were cared for by Reta Mays</p> <p>1 patient cared for by Reta Mays experienced severe hypoglycemia and died the day of the hypoglycemic event</p>
Patients identified by the OIG from laboratory evidence of hypoglycemia that occurred at some point during Reta Mays's employment	66 patients	<ul style="list-style-type: none"> • Hospitalization overlapped with Reta Mays's shift • Not receiving medication for diabetes 	<p>11 patients experienced severe hypoglycemia during Reta Mays's shift, and were not treated with insulin or an oral agent</p> <p>7 patients identified in prior reviews</p> <p>4 patients with plausible explanations for their hypoglycemia¹²⁰</p>
This group of patients was identified by the facility as patients who died while receiving care in the facility during Reta Mays's employment <i>and</i> meeting one or more of the following criteria (as defined by the facility reviewers): <ul style="list-style-type: none"> • Lack of documentation 	21 patients	<ul style="list-style-type: none"> • Age • Hospice status • DNR status • Diabetes • Treatment with insulin • Hypoglycemic events • Plausible medical explanation for hypoglycemia 	<p>1 patient identified in prior review</p> <p>21 additional patients were elderly and debilitated (information below refers to these 21 patients)</p> <p>Median age 78</p> <p>11 patients were under hospice care</p> <p>20 patients had DNR orders</p> <p>12 patients were diagnosed with diabetes</p> <p>6 patients were treated with insulin</p> <p>3 patients had hypoglycemia, all with plausible medical explanations for hypoglycemia</p>

¹¹⁹ Patients identified in the facility review were not included in this review.

¹²⁰ Upon EHR review, the OIG inspection team determined that 2 of the 11 patients were receiving medications for diabetes.

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<ul style="list-style-type: none"> • Abnormal decline • Hypoglycemic event • Death which occurred pending transfer to lower levels of care or within 24 hours of planned discharge 		<ul style="list-style-type: none"> • Death time, day, and location • Death certificate for cause of death 	<p>Patients were located in 2 units, 17 different rooms</p> <p>Patient deaths occurred every day of the week and every shift</p> <p>Documentation often lacking in hours leading up to death; examples include after death documentation of medication administration and no documentation in code status change from full code to DNR for one patient</p>
<p>This group of patients was identified by members of the public submitting inquiries regarding their care or the care of their loved one after media began covering the developing events at the facility</p>	<p>24 patients</p>	<ul style="list-style-type: none"> • Review of specific allegation presented, if any • Review of care received by patient if no specific allegation 	<p>Unable to identify one patient because insufficient information was provided</p> <p>23 patients who were extremely ill; either the decline in medical condition was precipitous, they were in hospice care with DNR orders, care was deemed appropriate, or there were no concerns regarding expected sequelae of clinical care or with end-of-life care</p>

Source: OIG inspection team analysis of relevant patient EHRs

Appendix B: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: April 29, 2021

From: Acting Under Secretary for Health (10)

Subj: OIG Draft Report, Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia (VIEWS #04959617)

To: Director, Office of Healthcare Inspections (54HL03)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia. We are appreciative of OIG's inspection and the multiple other law enforcement groups who have helped bring some justice to victims and their families.
2. VA deeply regrets that Ms. Mays' actions were not discovered sooner and stopped. Knowing she is behind bars is not enough. We are committed to preventing something like this from ever happening again. We are outraged and profoundly saddened that the isolated crimes that took place in Clarksburg undermine Veterans' trust in VA and do a disservice to the many devoted VA employees who are passionate about caring for Veterans.
3. Events as horrific as these cause us to re-examine how we can better ensure those who enter through the doors of our medical facilities are safe. VA established an interdisciplinary work group to review high alert medication safety, storage and security across VA and conducted an audit of medication storage areas at all local medical centers. In total, 8,859 medication storage areas were audited. Ninety-five percent of storage areas were found to be locked. All facilities not meeting 100% of all medication storage areas locked are developing action plans for improvement.
4. As a highly reliable organization, we strive to promote employee willingness to raise concerns and to build robust systems for investigating circumstances around unusual or unexpected deaths. We learned a great deal from OIG's findings and will use them to understand where and how we can improve. To foster a learning environment, VHA works to increase transparency and willingness for employees to report challenges to their work, near misses and errors. In this way, VHA builds a just culture where employees feel safe to bring up problems and help build solutions.
5. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Richard A. Stone, M.D.

Under Secretary for Health Response

Recommendation 1

The Under Secretary for Health ensures actions are taken to clarify and broadly disseminate adjudicator expectations for follow-up of unreturned INV Form 41.

Concur.

Target date for completion: January 2022

Under Secretary for Health Comments

VHA has made significant strides since 2018 to establish consistent standards for personnel security, addressing longstanding retention issues, and ensuring that work in the vetting arena is adequately resourced.

In October 2018, VHA began efforts to implement a shared services model for human resources (HR) to improve and accelerate every aspect of HR customer experience due to the decentralized service delivery model not meeting the needs of employees, managers, or the healthcare system at large. HR Modernization is being implemented using a phased approach. Within the personnel security HR paradigm, staff have experienced high burnout and turnover rates due to VA adjudicator grade disparity when compared to other Federal agencies and ongoing resource challenges related to insufficient workforce allocations to meet key suitability-related requirements.

In October 2018, VHA also published a revised Personnel Security program policy to establish VISN-level subject matter experts to drive consistency in medical center adjudicative practices and perform oversight of day-to-day security operations.

In October 2019, VHA formed a Personnel Security Integrated Project Team (IPT) to address the grade disparity and resource allocation challenges within the security community to reduce errors, increase reliability, and build trust as key components of VHA's transformation in our healthcare delivery system and each of its supporting business systems. The IPT produced standardized position descriptions, organizational charts, and outlined expectations related to the implementation of consistent adjudicative practices within VHA.

In May 2020, VHA's Office of Workforce Management and Consulting distributed the standardized position descriptions, organizational charts, and updated standardized processes to assist VISNs with realignment efforts under HR Modernization with the expectation that each VISN would realign their personnel security activities to conform to VHA's best practice model for the security administration job series.

To ensure that Veterans Integrated Service Network (VISN) HR Offices are properly aligned and that consistent standards are uniformly applied, the following remediation plan is proposed:

The VHA Personnel Security Program Office will establish updated staffing metrics for individuals performing security administration work. This metric should capture all personnel security-related activities to ensure that realigned VISN Personnel Security Offices are adequately resourced to review and adjudicate background investigation in accordance with regulatory and Office of Personnel Management standards.

The VHA Personnel Security Program Office will conduct a program review of the 18 VISN Personnel Security Offices to verify conformity with the established metric. VISN Chief Human Resources Officers will be responsible for implementation of the metric to ensure that VISN Personnel Security Offices are adequately resourced to complete security administration work in accordance with regulatory and Office Personnel Management standards.

VHA's Office of Workforce Management and Consulting will develop an annual training plan for security administration staff. This training plan will capture baseline knowledge and implement continuing development requirements to address the review and adjudication of background investigations within VA's healthcare system and adherence to agency and administration Personnel Security policies and supplemental program guidance.

Recommendation 13

The Under Secretary for Health determines the potential advantage of a rescue medication flagging system as an additional tool to evaluate unexplained adverse patient events, including but not limited to mortalities, and takes action as indicated.

Concur.

Target date for completion: April 2022

Under Secretary for Health Comments

In December 2019, VHA convened Control of High-Risk Medications (CHRM) Workgroup to evaluate the storage and security of high-alert medications. The workgroup will review the use of a rescue medication flagging system to evaluate unexplained adverse patient events. Once completed, the CHRM Workgroup will provide recommendations to VHA senior leaders. To close this recommendation, VHA will provide documentation of the recommendations and senior leader decisions.

Recommendation 15

The Under Secretary for Health reevaluates how the Veterans Health Administration collects, reviews, and analyzes mortality data from VA facilities, and takes action to address identified gaps and weaknesses, as indicated.

Concur in principle

Target date for completion: September 2021

Under Secretary for Health Comments

Events as horrific as these cause us to re-examine processes to ensure they are robust and consistent with industry standards. That includes the collection, review, and analysis of mortality data.

Mortality monitoring at the enterprise level has not been shown to be particularly effective for identifying a determined serial killer.¹²¹ Even statistical tests with exemplary performance have difficulty identifying rare occurrences and will generate many false alarms. VHA further worries that overzealous monitoring of unadjusted mortality (including of deaths among hospice patients) would have a chilling effect on the willingness of providers to admit the critically ill or those needing inpatient care to manage their terminal illness.

This is less a matter of statistics but more a failure to note and act on the “red flags” that are often present in a case of medical murder.¹²² VHA’s systems must promote local willingness to raise and to interrogate unusual or unexpected deaths in the spirit of high reliability and continuous improvement.

For this reason, VHA’s Office of Analytics and Performance Integration’s (API) ongoing and planned future revisions to mortality and safety triggers will be aimed at supporting more effective local review and Veterans Integrated Service Network (VISN) oversight, with the additional collaboration of the VA Hospital Medicine community. API’s plan is to automate the notification of potential mortality and safety triggers in order to allow more prompt local response, with feedback systems to escalate concerns to the VISN or National levels if warranted. API is developing revised approaches now and expects to deploy and test the approaches in coming months.

¹²¹ Guthrie B et al. Routine mortality monitoring for detecting mass murder in UK general practice: test of effectiveness using modelling. *British Journal of General Practice* 2008;58:311-17.

¹²² Sackman B et al. *Behind the Murder Curtain*. New York: Post Hill Press, 2020, pp 143-50.

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 20, 2021

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

Subj: Healthcare Inspection—Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

To: Executive in Charge, Office of the Under Secretary for Health (10)

1. I have reviewed and concur with the findings and recommendations in the Office of Inspector General's (OIG's) draft report entitled "Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center, Clarksburg, West Virginia".
2. Furthermore, I have reviewed and concur with, Louis A. Johnson VA Medical Center, Interim Medical Center Director's response and implementation of actions to resolve each of the ten findings outlined in this report. No barriers to timely resolution are anticipated.
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.

(Original signed by:)

Raymond C. Chung

Acting VISN 5 Network Director, on behalf of

Robert M. Walton, FACHE

VISN 5 Network Director

VISN Director Response

Recommendation 3

The Veterans Integrated Service Network 5 Director conducts management reviews of the care of patients 1–10 as discussed in this report and takes action as indicated.

Concur.

Target date for completion: September 30, 2021

Director Comments

The Louis A. Johnson VA Medical Center (facility) coordinated management reviews for eight of the Veterans discussed in this report in October 2020. They were sent outside of the facility to the VHA contracted peer review company and were reviewed by reviewers external to the facility. Upon completion of the reviews, the VISN 5 Chief Medical Officer and VISN 5 Quality Management Officer/Chief Nursing Officer met with the facility Chief of Staff, Acting Associate Director of Patient Care Services and Chief of Quality Management to review the results. For reviews that did not meet the standard of care, if indicated, appropriate individual actions were discussed and have been communicated to the appropriate individuals. Compliance will be demonstrated when management reviews regarding the care of the two remaining Veterans discussed in this report are also completed by the same external VHA contracted peer review company. In addition, any standard of care “not met” results will have been reviewed by the same team to determine if any actions are indicated.

Recommendation 5

The Veterans Integrated Service Network 5 Director ensures evaluation of quality of care concerns or other irregularities (beyond hypoglycemia) of: cases provided by the OIG; cases that may otherwise be pertinent or concerning; and cases brought forward by patients and/or family members who express concerns or make other inquiries about care they received from Ms. Mays. As determined by the VISN, clinical experts external to the facility should be utilized when appropriate.

Concur.

Target date for completion: October 31, 2021

Director Comments

The VISN 5 Chief Medical Officer will coordinate with the VISN 5 Quality Management Officer to conduct external reviews of the quality of care in the cases provided by the OIG. Appropriate follow up for any cases that result in standard of care not met will be completed, as indicated, by

the VISN 5 Chief Medical Officer. In order to evaluate if there have been cases brought forward in the past two years since Ms. Mays was no longer employed at the Louis A. Johnson VA Medical Center, a review of patient advocate reports starting from January 2019-present (patient advocate reports prior to this date were reviewed by OIG) will be reviewed. If discovered, it will be validated by the VISN 5 Chief Medical Officer that appropriate follow up and review was completed, and contact was made with the Veteran and/or family. Compliance will be demonstrated when the external reviews of the cases provided by the OIG and the patient advocate reports from January 2019-present have been reviewed and if indicated, appropriate action was taken.

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 14, 2021

From: Interim Medical Center Director, Louis A. Johnson VA Medical Center (540/00)

Subj: Healthcare Inspection—Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

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

1. I have reviewed the report entitled “Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia”.
2. Actions are underway to resolve each of the ten findings outlined in this report. No barriers to timely resolution are anticipated.
3. The courteous and professional manner that was displayed by the OIG staff during this review is appreciated.

(Original signed by:)

Barbara Forsha, RN, MSN, ET

Interim Medical Center Director

Facility Director Response

Recommendation 2

The Louis A. Johnson Medical Center Director ensures Pharmacy Service utilizes the required Veterans Health Information Systems and Technology Architecture Automatic Replenishment System to record medication usage data and maintain the records for inventory accountability.

Concur.

Target date for completion: December 31, 2021

Director Comments

Pharmacy Service will utilize the VistA Automatic Replenishment System (ARS) for purposes of inventory medication management. Records will be maintained such as ward/clinic medication delivery confirmation, medication inventory, and signature of the employee who accepted the medications; all will be maintained for historical purposes per the VA records management policy.

Pharmacy technicians will receive training on the ARS and a service level standard operating procedure outlining proper procedure and expectations will be completed.

This recommendation will be considered compliant when there are six consecutive months of 90% or above of data showing compliance with reconciliation of ARS inventory report with Pyxis inventory reports and ward/clinic delivery confirmation reports for all ward stock items. The sampling size for the denominator for the monthly audit will be determined by The Joint Commission (TJC) sampling tool sizes. Compliance will be reported to the Pharmacy and Therapeutics Committee monthly.

Recommendation 4

The Louis A. Johnson VA Medical Center Director reviews the availability and timeliness of endocrinology consults, and takes any corrective action needed.

Concur.

Target date for completion: February 28, 2022

Director Comments

The Louis A. Johnson VA Medical Center will continue to support access (i.e., availability and timeliness) to Endocrinology as a subspecialty. The Interfacility consults with VA Pittsburgh Health Care System will continue to provide services on Endocrinology as per past practice. The identified access concerns to the specialty ultimately focus on when to access these services specifically for stat consults as opposed to overall access to Endocrinology.

All providers have been provided the information about consulting medical specialties and will continue to have monthly reminders on how to access regular consult evaluations, e-consults, and stat evaluations for transfer, as well as the awareness to the level of care that might be necessary.

This recommendation will be considered compliant once six consecutive months of data showing the timeliness of the requested service are presented as per current consult process.

- New patient consults to Endocrinology will be completed within 28 days, greater than 90% of the time
- E-consults to Endocrinology are completed within 7 days
- Stat consults for either one of the above to be completed within 24 hours, with warm hand off required from referring provider

All of the above consults will be reported monthly by Chief of Staff (COS) designee to Medical Executive Council (MEC).

Recommendation 6

The Louis A. Johnson Medical Center Director develops and disseminates guidance on clinical communication(s) to ensure that patient care and outcomes are routinely discussed in appropriate forums, such as interdisciplinary team meetings, and the discussions are documented.

Concur.

Target date for completion: February 28, 2022

Director Comments

The Louis A. Johnson Medical Center developed a templated interdisciplinary treatment team (IDT) clinical note titled “3A/ICU IDT NOTE” which is available and in use for documentation in the Computerized Patient Record System (CPRS).

An update to this templated note is being completed, which has expanded to include specific patient outcomes and additional care information pertinent to the patient’s hospital course. A policy for IDT is in draft and under review by all services.

A hospitalist memorandum of understanding (MOU) and inter-service agreements between medical specialties which will include expectations, care practices, etc., are set to be finalized.

A chart audit checklist will be created to include required elements in the updated IDT policy. Compliance will be monitored monthly, utilizing The Joint Commission sampling tool to define the sample size of chart audits conducted on monthly Intensive Care Unit and Medical Surgical admissions. This recommendation will be considered compliant when there are six consecutive

months of 90% or above compliance with the chart audit checklist. Compliance rates will be reported by the Chief Hospitalist monthly to the Medical Executive Council.

Recommendation 7

The Louis A. Johnson Medical Center Director ensures that close observation documentation is readily available in the electronic health record, and monitors for compliance.

Concur.

Target date for completion: February 28, 2022

Director Comments

The standard operating procedure (SOP) for the management and care of patients requiring a one to one (1:1) observation status, has been revised and was published on December 8, 2020 with the inclusion of a competency assessment form.

In an effort to assist nursing staff with completing the documentation requirements via the electronic health record as outlined in local policy, the local Office of Information and Technology supplied additional laptops and mobile carts to the inpatient units.

This recommendation will be considered compliant when there are six consecutive months of 90% or above compliance with close observation documentation. The numerator will be number of patient records in the month compliant with close observation documentation via the electronic health record. The denominator will be the number of unique patient 1:1 orders in the Intensive Care unit and Medical Surgical Unit that month. Compliance will be monitored and reported by the Office of Quality and Risk Management to the Patient Care Services Executive Council, monthly.

Recommendation 8

The Louis A. Johnson Medical Center Director ensures clinical documentation reviews are completed timely for patient safety and continuity of care.

Concur.

Target date for completion: February 28, 2022

Director Comments

A template specifically designed for daily hospitalist documentation has been updated to include mandatory fields for complete documentation. The updated template was developed with input from the hospitalist providers. The note was approved out of committee by the Medical Record Review Committee (MRRC) and is currently pending implementation.

The VA Approved Enterprise Standards (VAAES) documentation template was implemented on February 17, 2021. The VAAES assessment education was provided to the medical surgical unit staff during a safety stand down training and skill review. Nursing management is completing audits of VAAES documentation and providing real-time education and counseling to staff.

A monitoring tool will be completed to assess usage compliance for both the hospitalist documentation template and nursing VAAES documentation template by the Medical Record Review Committee (MRRC) on a monthly basis. The numerator will be the number of patient records compliant with VAAES and hospitalists provider templated notes in the designated sample. The Joint Commission sampling tool will be used to define the sample size of chart audits conducted of patients admitted monthly to the medical surgical unit (denominator). This recommendation will be considered compliant when there are six consecutive months of 90% or above of data showing compliance. Outcomes will be reported quarterly to the Medical Executive Council (MEC) by the Chair of MRRC.

Recommendation 9

The Louis A. Johnson VA Medical Center Director evaluates the factors and processes surrounding employees' failures to report and follow up on the unexplained hypoglycemic events, and takes action to ensure appropriate reporting of actual or potential patient safety events, system vulnerabilities, or other unexpected events that offer opportunities for lessons learned.

Concur.

Target date for completion: January 31, 2022

Director Comments

The Louis A. Johnson Medical Center (LJVMAC) medical/surgical nursing staff was provided education on diabetes mellitus, High Reliability Organization (HRO) front line training, and appropriate reporting of actual or potential patient safety events in Joint Patient Safety Reporting (JPSR) system during the safety stand down in January 2021.

The nursing SOP 118-204 Chain of Command was written and published on January 20, 2021. This new policy was shared with all nursing staff on January 20, 2021. This policy was created to provide nursing staff with appropriate direction for prompt handling of patient care issues or decisions that might adversely affect the welfare of a patient. Facility Leadership messaging on the importance of reporting of actual or potential patient safety events in addition to monthly rounds conducted by Patient Safety will serve as continued reinforcement on the importance of reporting actual and potential patient events through the Joint Patient Safety Reporting System. This recommendation will be considered compliant when documentation of monthly rounding by Patient Safety Staff for six consecutive months is provided in addition to outcome monitoring demonstrating an increased trend in the number of JPSR events entered by LJVMAC staff compared to previous four quarters.

Recommendation 10

The Louis A. Johnson Medical Center Director requires that all staff are trained on reporting patient safety events using the correct reporting system and monitors for compliance.

Concur.

Target date for completion: November 30, 2021

Director Comments

The Louis A. Johnson Medical Center is holding a 2021 Education Fair that opened in March 2021, in a virtual format, which includes a Patient Safety Module with the theme “Take the Pledge for Patient Safety”. The Patient Safety module will include JPSR education and training for all staff. This recommendation will be considered compliant when 90% or above of the staff have completed the 2021 virtual employee Education Fair.

Recommendation 11

The Louis A. Johnson Medical Center Director ensures that the interdisciplinary mortality review workgroup meet as required with appropriate reporting through oversight council(s), and monitors for compliance.

Concur.

Target date for completion: February 28, 2022

Director Comments

The Louis A. Johnson Medical Center has implemented an interdisciplinary approach to morbidity and mortality reviews, and it was initially instituted in July 2020. However, at the current time, the mortality review process is under assessment and being updated to ensure the process is congruent with SAIL educational initiatives, medical morbidity and mortality conferences, occurrence screens, peer review and individual case reviews. The charter for the interdisciplinary mortality review workgroup is being updated and it will define group meeting and oversight council reporting requirements. This recommendation will be considered compliant when the updated charter has been approved and there are six consecutive months (or two quarters) of workgroup meetings and reporting by the Associate Chief of Staff for Primary and Specialty Care Medicine or designee to Quality Executive Council documented.

Recommendation 12

The Louis A. Johnson Medical Center Director ensures that oversight and reporting practices align with Louis A. Johnson Medical Center policy requirements.

Concur.

Target date for completion: March 31, 2022

Director Comments

The Louis A. Johnson Medical Center (LAJVAMC) Executive Leadership Board (ELB) is occurring on a quarterly basis per hospital policy, however, the LAJVAMC will move to a monthly reporting basis for ELB no later than June 30, 2021. Committee and councils are under review for appropriate membership, reporting schedules and content. Currently, all governing councils (i.e. Medical Executive Council, Quality Executive Council, Administrative Executive Council and Patient Care Services Executive Council) are occurring per local policy. This recommendation will be considered compliant when the governing council reporting structure has been reviewed, updated, and all required reporting practices and councils have reported to Executive Leadership Board for six consecutive months.

Recommendation 14

The Louis A. Johnson VA Medical Center Director takes action to prioritize and continue efforts to promote a strong culture of safety, such as periodic facility-wide refresher patient safety training or additional patient safety stand downs when indicated, and monitors for effectiveness.

Concur.

Target date for completion: February 28, 2022

Director Comments

A culture of safety with emphasis on high reliability organization (HRO) is promoted by Executive Leadership. Executive Leadership began to conduct facility “We Care” rounds at a minimum of monthly to speak with front line staff and emphasize the promotion of a culture of safety. All Employee Town Hall forums continue with patient safety roles and functions highlighted during the February 2021 forum. Executive Leadership along with Patient Safety designated March 15-19, 2021 as Patient Safety Week within the facility. A patient safety story was presented, and Executive Leadership dedicated each day to a Veteran of their choice. During Patient Safety Week, Executive Leadership encouraged attendance to virtual lunch and learn sessions which promoted high reliability and patient safety practices. Patient Safety modules will continue to be presented in the Annual Employee Education Fairs.

Compliance for this recommendation will be considered complete when 90% or more Louis A. Johnson Medical Center (LAJVAMC) staff have completed both HRO 101 and 201 TMS modules and 90% or more of Chief and Supervisors have completed HRO Baseline Supervisor training. Outcome monitoring will include demonstrating an increased trend in the number of JPSR events entered by LAJVAMC staff compared to previous four quarters.

Appendix E: VHA Technical Comments

OIG Draft Report: Care and Oversight Deficiencies Related to Multiple Homicides at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

The OIG appreciates the feedback from VHA. The technical comments do not change the OIG’s understanding of the facts or recommendations; therefore, no modifications were made. The OIG has inserted responses immediately following VHA’s technical comments.

VHA Comment 1

Draft location: Page 13 (“page xi” in the footer), paragraph 1

Current language: “The OIG concluded that VHA’s minimalist review approach, coupled with a lack of critical analysis of the facility’s hypoglycemic event data, likely resulted in missed identification of process weaknesses for the facility.”

Comment and justification: Please consider deleting this sentence. “Minimalist” implies a health system ideally must, at the enterprise level, routinely monitor for hypoglycemia among patients *not known to be receiving insulin or other hypoglycemic agents*. This elevates a false standard for quality monitoring that is inconsistent with industry practice. As the draft report itself points out on electronic page 19, footnote 3 (denoted “Page 17” in footer), the primary cause of hypoglycemia, even in nondiabetic patients, remains the administration of diabetes medication or synthetic insulin.

Furthermore, it should be noted that hypoglycemia trending (e.g., as depicted in Figure 2 on electronic page 41) for those not taking glucose-lowering drugs entails direct query and trending of glucose values over time at the individual patient level – something that is technically feasible for isolated patients when there is an index of suspicion, but cannot be realistically done prospectively for a system that admits nearly a half million Veterans annually. There are pragmatic limits to the ability to detect at the enterprise level exceedingly rare occurrences – such as presence of a medical serial killer using commonly available drugs to dispatch patients who are also seriously ill. It is one thing to confirm aberrant findings retrospectively once there is suspicion of foul play; applying such an approach *prospectively*, in the absence of prior suspicion, yields far too many instances of false alarm.¹²³

OIG Response

The OIG reviewed VHA’s Comment 1 and determined no change is necessary.

¹²³ Guthrie B et al. Routine mortality monitoring for detecting mass murder in UK general practice: test of effectiveness using modelling. *British Journal of General Practice* 2008;58:311-17.

The OIG uses the term *minimalist* to describe RAPID’s approach to the review and analysis of available data that even in a *retrospective* setting could yield the development of a meaningful proactive (trigger) tool. The OIG recognizes the risk of false positives with any trigger system, but considers the potential benefits of early investigation and intervention to outweigh that burden.

VHA Comment 2

Draft location: electronic page 64 (Denoted “Page 62” in the footer), paragraph 1

Current language: “Additionally, the OIG found that RAPID’s review, when completed, did not include in-depth analysis or discussion of some key data points that would have provided a more comprehensive view of mortality and related concerns at the facility.”

Comment and justification: Please consider deleting this sentence or significantly qualifying it. As written, it implies a lack of interest in understanding the events that had occurred. RAPID staff reviewed the data that it possessed in its national tracking systems. A list of the suspected homicides was not made available to RAPID staff, nor were we asked to review those specific cases, as an active criminal investigation was still underway.

OIG Response

The OIG reviewed VHA’s Comment 2 and determined that no change is necessary.

Despite having a general awareness of the events at the facility level, RAPID’s approach to the review and analysis of available data lacked the necessary depth to prompt further investigation.

VHA Comment 3

Draft location: electronic page 65 (Denoted “Page 63” in the footer), paragraph 2

Current language: “The OIG found that RAPID did not appear to review and analyze important data from multiple angles...As a result, VHA missed opportunities to better understand issues at the facility, whether similar conditions existed at other VHA facilities, and whether strategies to oversee mortality and medication-related high-risk areas needed modifications.”

Comment and justification: Please consider deleting this paragraph or significantly qualifying it. As written, it implies a lack of interest in understanding the events that had occurred. RAPID staff reviewed data that it possessed in its national tracking systems. A list of the suspected homicides was not made available to RAPID staff, nor were we asked to review those specific cases, as an active criminal investigation was still underway.

OIG Response

The OIG reviewed VHA's Comment 3 and determined that no change is necessary. Please see the OIG responses to VHA's Comments 1 and 2.

VHA Comment 4

Draft location: electronic page 65 (Denoted "Page 63" in the footer), paragraph 3

Current language: "Available performance and other clinical data, if viewed differently, would have revealed concerning clinical care and mortality patterns "

Comment: Routinely tracking hospital performance using *unadjusted* mortality that includes patients enrolled in hospice is not an industry practice. This highly idiosyncratic approach could have a chilling effect on a provider's willingness to admit Veterans for end-of-life care.

OIG Response

The OIG reviewed VHA's Comment 4 and determined that no change is necessary.

The OIG notes that RAPID produces mortality and hospice reports quarterly and has daily-refreshed mortality trigger systems already in place. Bedside clinical decision making, including end-of-life care, involves patient wishes and providers' clinical judgment. The suggestion that VHA providers' clinical judgment and advocacy for the patients' best interests is influenced or "chilled" by performance metrics undermines their integrity and is inconsistent with the OIG's overall experience in reviewing VHA providers' care to veterans.

VHA Comment 5

Draft location: Page 65 (Denoted "Page 63" in the footer), paragraph 4

Current language: "The OIG was unable to discern RAPID's data source showing "no unusual systemic patterns" It is possible that RAPID used an existing VHA report, Glucose Measurements in Patients"

Comment and justification: The precise specifications for all VHA inpatient "Do No Harm" measures are available at <https://vaww.ipec.va.gov/metrics/>.¹²⁴ VHA sent the specification sheets for the hypoglycemia and hyperglycemia measures that we routinely track and report. These measures are based on clinical evidence for optimal blood glucose control in hospitalized patients (avoidance of both severe hyperglycemia and hypoglycemia) and are not designed to identify rare cases of hypoglycemia such as an insulinoma, or a serial killer using insulin to dispatch critically ill patients.

¹²⁴ VHA provided the website in its response to OIG. The website is an internal one not accessible to the public.

OIG Response

The OIG reviewed VHA's comment 5 and determined that no change is necessary.

The OIG acknowledges VHA's reference to IPEC metric definitions; however, review of the website information does not modify the OIG's findings.

Glossary

To go back to point of origin hyperlink, press “alt” and “left arrow” keys.

automated dispensing cabinet. A computerized drug storage space used to dispense medications electronically and in a controlled manner to track medication use. The automated dispensing cabinet in use at the facility is a Pyxis™ unit.¹²⁵

D50. An intravenous injection solution of dextrose (also known as glucose) 50 percent used for the treatment of low blood sugar to restore blood sugar concentrations.¹²⁶

dementia. A loss of mental functions that is severe enough to affect daily life and activities like memory, language skills, and trouble with everyday tasks.¹²⁷

glucagon. A hormone that is produced by cells in the pancreas. Glucagon helps to control blood sugar level by increasing blood sugar when it is too low.¹²⁸

glucose. The main sugar found in blood. It comes from food that is eaten and is the body’s main source of energy.¹²⁹

glucometer . A handheld device used to test glucose level in blood at the time and place of patient care using a drop of a blood; also known as glucose meters.¹³⁰

heart failure. A condition that occurs when the heart does not pump blood as well as it should.¹³¹

hormone. The body’s chemical messengers. Hormones travel in the blood to tissues or organs and affect processes like growth and development, how the body gets energy from food that is eaten, and mood.¹³²

¹²⁵ VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019. The directive was amended December 2, 2019, which added the definition for Automated Dispensing Cabinet.

¹²⁶ Physicians’ Desk Reference, *Dextrose Monohydrate*, accessed October 14, 2020, <https://pdr.net/drug-summary/10--Dextrose-Injection-dextrose-monohydrate-24329>.

¹²⁷ National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online, *Dementia*, accessed October 14, 2020, <https://medlineplus.gov/dementia.html#>.

¹²⁸ National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online, *Glucagon Blood Test*, accessed October 14, 2020, <https://medlineplus.gov/ency/article/003716.htm>.

¹²⁹ National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online, *Blood Sugar*, accessed October 14, 2020, <https://medlineplus.gov/bloodsugar.html>.

¹³⁰ U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health, *Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use*, accessed October 15, 2020, <https://www.fda.gov/media/119829/download>.

¹³¹ Mayo Clinic, *Heart Failure*, accessed October 15, 2020, <https://www.mayoclinic.org/diseases-conditions/heart-failure/symptoms-causes/syc-20373142>.

¹³² National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online, *Hormones*, accessed October 14, 2020, <https://medlineplus.gov/hormones.html#>.

hospitalist. A physician who provides comprehensive medical care to hospitalized patients.¹³³

hypoglycemia. A condition in which the blood sugar (glucose) is lower than normal.¹³⁴

insulin. A hormone that helps move blood sugar from the bloodstream into the cells of the body.¹³⁵

insulinoma. A tumor on the pancreas that makes extra insulin and causes blood sugar levels to drop too low.¹³⁶

lethargy. A condition marked by severe tiredness and a decreased level of mental alertness.¹³⁷

nursing assistant. A healthcare professional who provides hands-on health care, such as bathing, dressing, and other activities of daily living, under the supervision of a registered nurse or a licensed practical nurse.¹³⁸

pancreas. A gland located deep in the belly that is a vital part of the digestive system and a critical controller of blood sugar levels.¹³⁹

sepsis. A potentially life-threatening condition caused by the body's response to an infection.¹⁴⁰

¹³³ Society of Hospital Medicine, *What is a Hospitalist?* accessed October 14, 2020, <https://www.hospitalmedicine.org/about/what-is-a-hospitalist/>.

¹³⁴ Mayo Clinic, *Hypoglycemia*, accessed October 13, 2020, <https://www.mayoclinic.org/diseases-conditions/hypoglycemia/symptoms-causes/syc-20373685>.

¹³⁵ National Institutes of Health U.S. National Library of Medicine MedlinePlus Medical Encyclopedia Online, *Insulin in Blood*, accessed October 15, 2020, <https://medlineplus.gov/lab-tests/insulin-in-blood/>.

¹³⁶ Johns Hopkins Medicine, *Insulinoma*, accessed November 2, 2020, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/insulinoma>.

¹³⁷ National Institutes of Health National Cancer Institute, *Lethargy*, accessed October 20, 2020, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/lethargy>.

¹³⁸ Registerednursing.org, *What is a CNA?* accessed October 13, 2020 <https://www.registerednursing.org/certified-nursing-assistant>.

¹³⁹ Johns Hopkins University Department of Pathology, *What is the Pancreas?* accessed October 15, 2020, <http://pathology.jhu.edu/pancreas/BasicOverview1.php?area=ba>.

¹⁴⁰ Mayo Clinic, *Sepsis*, accessed October 15, 2020, <https://www.mayoclinic.org/diseases-conditions/sepsis/symptoms-causes/syc-20351214>.

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