DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

The New Electronic Health Record's Unknown Queue Caused Multiple Events of Patient Harm

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Executive Summary

The VA Office of Inspector General (OIG) conducted a focused healthcare inspection to assess a Veterans Health Administration (VHA) identified high-risk patient safety concern due to an Oracle Cerner-designed element of the new electronic health record (EHR) that resulted in patient harm.[1] There has been significant interest from stakeholders, including members of Congress, on whether the use of the new EHR resulted in patient harm. In May 2021, after VHA identified several patient safety concerns with the new EHR, a VHA National Center for Patient Safety team (patient safety team) was deployed to Mann-Grandstaff VA Medical Center (facility). The patient safety team identified 60 safety concerns across nine core domains and ranked these issues based on severity. One of three concerns with the highest patient safety risk was described as the "unknown queue."[2]

The OIG reviewed the unknown queue patient safety risk and found that the new EHR sent thousands of orders for medical care to an undetectable location, or unknown queue, instead of the intended care or service location (e.g., specialty care, laboratory, diagnostic imaging). Every version of Oracle Cerner's EHR has an option to activate the unknown queue.

The intent of the unknown queue is to capture orders entered by providers that the new EHR cannot deliver to the intended location. The design of the new EHR allowed providers to select locations from a drop-down menu, that depending on the specific order, would not be recognized as a "match" by the system. This "mismatch" would ultimately send orders to an unknown queue and not to the requested service location to initiate the ordered care. Notably, the new EHR did not alert the healthcare providers that the order was not delivered to the intended location. From facility go-live in October 2020 through June 2021, the new EHR failed to deliver more than 11,000 orders for requested clinical services.

The OIG did not identify any evidence that Oracle Cerner provided actionable information of the unknown queue to VA prior to go-live. On October 28, 2020, four days after go-live, the first Oracle Cerner trouble ticket regarding lost orders was placed, this resulted in finding the unknown queue. After VHA identified the unknown queue, VHA established a process whereby facility staff were instructed to cancel and reenter each order in the unknown queue. Absent

[1] On June 8, 2022, Oracle Corporation completed the acquisition of Cerner Corporation, with Cerner then referred to as Oracle Cerner.

[2] The nine core domains identified included: behavioral health, ambulatory, referrals, roles/position/privileging, pharmacy, identity, orders, medication administration, and unspecified. The other two concerns VA staff ranked as the highest patient safety risks included resolution of identifiers that impacted matching records in the new EHR, and manual cancelation of appointments not acted on within 24 hours. The OIG found that the term "unknown queue" was used years prior to VA's adoption of Oracle Cerner's EHR. The OIG identified examples of the term dating back to 2014 used on an Oracle Cerner user online help forum.

VHA actions, the existence of the unknown queue and the unfulfilled clinical orders may not have been identified, and many patient care orders may not have been completed.

In September 2021, Oracle Cerner responded to VHA concerns by taking steps to remove the unmatched locations. In February 2022, Oracle Cerner updated the new EHR with an alert to providers when they attempted to create an order with an unmatched location. However, in May 2022 a VHA leader notified Oracle Cerner that the technology mitigations were inadequate and had not been wholly successful. On May 16, 2022, the OIG used the new EHR to generate a report of the orders in the unknown queue for VHA sites and found 206 orders.[3] The OIG contacted facility leaders who reported using the VHA-established process to monitor and remediate the unknown queue but that gaps in the mitigation process could still lead to orders remaining in the queue. Each facility that goes live with the new EHR will require an ongoing commitment from facility staff to monitor and address the new EHR's unknown queue.

The OIG found that VHA determined the new EHR's unknown queue created significant risk and caused harm to multiple patients. In late 2021, VHA informed senior VA and Office of Electronic Health Record Modernization leaders about the risk and harm to patients.[4] VHA staffing resources were required to assess, remedy, manage and mitigate the unknown queue. VHA initiated a clinical review in June 2021 to ensure that staff acted on orders sent to the unknown queue and assessed patients for harm from delays in care. The clinical review was multistep and enlisted varied healthcare providers and substantial staff hours. Assessments of patient safety events included evaluation of the severity of harm, likelihood of how frequently an event may occur, and detectability of the technology risk. The clinical reviewers conducted 1,286 facility event assessments and identified and classified 149 adverse events for patients (see table 1 for VHA-assessed patient harm examples).[5]

- Major harm: 2
- Moderate harm: 52
- Minor harm: 95

[3] During a June 23, 2022, meeting with the Electronic Health Record Modernization Integration Office (EHRM IO) Executive Director, VA and OIG leaders reviewed a draft version of this report. The EHRM IO Executive Director reported that mitigation work for the unknown queue was complete and that, on average, there were 28 orders in the unknown queue. Contrary to the EHRM IO Executive Director's assertion, the OIG checked the unknown queue on the morning of the meeting and found 522 orders.

[4] The Office of Electronic Health Record Modernization is now called the EHRM IO.

[5] VHA defined major harm as permanent decrease in the body's functioning or disfigurement, requires surgery or inpatient care; moderate as increased length of hospital stay or required increase in level of care; and minor as no injury, no increased length of stay, no increased level of care.

Table 1. Examples of VHA-Assessed Cases of Patient Harm

Level of Harm	Example
Major	A healthcare provider entered a follow-up psychiatric care order for a homeless patient identified as at risk for suicide. The new EHR sent the order to the unknown queue. The patient was not scheduled for follow-up care and later contacted the Veterans Crisis Line reporting a razor in hand and a plan to kill himself. The patient was psychiatrically hospitalized.
Moderate	A healthcare provider ordered an appointment for a patient to be measured for and receive compression hose to help with lower leg edema (swelling). However, the new EHR delivered the medical order to the unknown queue, and the patient did not receive the compression hose. The patient required urgent care treatment for worsening of the edema.
Minor	A healthcare provider entered an order for a patient with uncontrolled diabetes to be scheduled with a clinical pharmacist for diabetes education and treatment. The new EHR sent the order to the unknown queue. The patient was not scheduled for care until 14 months later after a new order was entered.

Source: OIG summary of VHA identified patient-harm incidents.
Note: Appendix A provides additional detail for each example.

Based on the multiple events of patient harm, insufficient mitigations that burden VHA staff, and continued risk to patient safety, the OIG remains concerned with the management of the new EHR's unknown queue.

The OIG made two recommendations to the Deputy Secretary related to Oracle Cerner's failure to inform VA of the unknown queue and evaluation of the unknown queue technology and mitigation process.

OIG Comments to the Deputy Secretary's Response

Following the transmittal of the draft report to VA, the OIG made limited updates to the report Those updates can be found in appendix B.[6]

The Deputy Secretary concurred with recommendations 1 and 2 and submitted action plans; however, the OIG determined the action plans do not meet the intent of the recommendations. The OIG considers the recommendations open and will follow up until they are addressed.

The OIG agrees with the Deputy Secretary's acknowledgment of the "dedication of time and effort" of VHA staff to address the unknown queue. Apart from man hours, a facility leader shared with the OIG the toll of monitoring and addressing the unknown queue.

> Only once an actual review of the orders in the patient's chart occurs, can a clinical staff member triage the priority of remediating an unknown order. The impact on patient care from unknown orders for scheduling ranges from minor

[6] The OIG addressed certain language changes sought by VA.

> scheduling inconvenience, to delays in therapies or treatment affecting quality of life, to major worsening of disease progression from lack of timely follow-up. **The impact to staff is burnout from a constant state of hypervigilance and distress from feeling a Veteran has received suboptimal care. Adding to this is doubling up on time to provide care by repeating workflows necessary [to] repair the orders.** [emphasis added by OIG]

However, the OIG is concerned with many statements and aspects of the Deputy Secretary's response to the draft report. These concerns are reviewed below.

Significantly, the Deputy Secretary's comments failed to address a central finding of the report that the unknown queue led to patient harm.[7] Acknowledgment of harm is a key element to promoting VA as a learning organization. Patient safety must anchor all the activities and operations of a hospital, including the EHR modernization effort.

In addition, the Deputy Secretary's allegation that the OIG's report "contains material errors or omissions" is not supported.

The response from the Deputy Secretary claims that the "history of the program reflects that the purpose and use of the queue were discussed and developed by the joint efforts of both Cerner and VA." The evidence reviewed and presented in this report support that Oracle Cerner did not provide VA with any actionable information regarding the unknown queue prior to go-live. As cited in the Deputy Secretary's response, VHA end-users received this information nearly a year after VA's go-live with the new EHR. VHA end-users should have received this information prior to go-live. The OIG finds it troubling that the Deputy Secretary's response appears to absolve Oracle Cerner for its failure to inform VA of the unknown queue while placing the blame for outcomes from the unknown queue on VHA end-users.

The Deputy Secretary's response contended that "EHRM IO has instituted many measures" that "have been very effective in significantly reducing patient safety events." The OIG remains concerned with the number of patient safety events related to the new EHR but commends the work of those in VHA working to address ongoing patient safety issues. VHA National Center for Patient Safety continues to identify and address patient safety concerns with the new EHR. The OIG learned that as recently as July 5, 2022, VHA National Center for Patient Safety leaders provided EHRM IO with multiple reports of new EHR patient safety problems and harm to patients. One of the patient safety concerns identified an increased number of mental-health telehealth appointment orders being sent to the unknown queue.

The Deputy Secretary responded that "the primary reason an order may go unfulfilled is human error (e.g., data entry errors)." The evidence presented in this report does not substantiate that

[7] The Deputy Secretary's response disclaims VHA-assessed patient harm with references to "**potentially** resulted in harm" and "**may have resulted** in different levels of harm" [emphasis added by OIG].

statement. The new EHR sent incorrectly mapped or unmapped and invalid orders to the unknown queue. These invalid orders, by the new EHR's design, are able to accept a provider's signing and appear to the ordering provider to have been successfully completed. These invalid orders were routed to a location that VHA end-users were not aware of and could not access directly until March 2022.

Further, the Deputy Secretary's response described the VHA-derived analogy regarding the undeliverable mail that was used to explain the idea of the unknown queue to VHA staff, as "unfairly inflammatory, misleading and a mischaracterization of the process." The OIG does not agree with this comment as the analogy reflected a VHA leader's approach to illustrate and educate clinical end-users on a complex technical issue.

The Deputy Secretary noted that the report "mentions that about 77% of these [orders sent to the unknown queue] were radiological studies." The response contested that the OIG report "does not mention that they were improperly included in the count" since "these were not 'unfilled orders.'" The OIG reported the correct number of orders that were routed to the unknown queue. Radiology was the first service to identify lost orders that were later determined to have been routed to the unknown queue. The OIG disagrees with the Deputy Secretary's contention that these were "improperly included" in the count as each order required radiology staff management to ensure appropriate patient actions for care and follow up.

The OIG does not concur with the Deputy Secretary's recommendation of determining "a baseline comparison of unfilled orders in the legacy system [EHR] how they are managed, and the manual effort required to correct them." The critical issue is the functionality and safety of the new EHR. In addition, the recommendation reflects a lack of understanding of the legacy EHR's orders function. The OIG confirmed with a subject matter expert on legacy EHR orders that invalid orders in the legacy EHR prompt an alert to the ordering provider and cannot be signed or accepted. Therefore, the legacy EHR does not send signed orders with inaccuracies to a queue that requires staff monitoring and action.

The Deputy Secretary minimized the OIG's finding that the Deputy Secretary and EHRM IO Executive Director were aware of patient harms from the unknown queue. The response focused on steps taken to resolve the backlog of orders, stating that by December 2021 "the issues concerning the unknown queue were well-known and VA had implemented processes to mitigate." However, the OIG findings of patient harm knowledge are relevant given

- the Deputy Secretary's omission of any mention of patient harm in the November 2021 congressional testimony, and
- the EHRM IO Executive Director's April 2022 congressional testimony statement that, "I don't believe that this system, that there's any evidence that it has harmed any patients, or that it will, going forward."

The Deputy Secretary's response to the report reflects VA senior leaders' lack of acknowledgment of patient harm caused by the new EHR.

The Deputy Secretary asserts that once VA became aware of the unknown queue backlog, "immediate action was taken to improve processes to ensure orders in the queues are routed to the right location or reentered." "Immediate" does not accurately describe EHRM IO and Oracle Cerner actions.

- October 28, 2020, a VHA staff member placed the first trouble ticket regarding lost orders.
- September 2021, Oracle Cerner completed VHA's request to remove unmapped locations.
- February 2022, Oracle Cerner updated the new EHR with a provider alert.
- March 2022, VHA could directly generate a report of orders in the unknown queue.

The OIG does not concur with the Deputy Secretary's response that the issue with orders in the unknown queue has been resolved. As cited in the report, the OIG's findings of a VHA leader's call for increased Oracle Cerner support in May 2022 and more than 500 orders in the unknown queue in late June 2022, support the OIG's concern that mitigations have been inadequate. Additionally, the Deputy Secretary characterized the number of orders entering the unknown queue as minimal. This characterization diminishes the challenge for VHA staff to monitor and manage the unknown queue and does not recognize the magnitude of the task as the deployment continues across VHA.

The Deputy Secretary's response cited that when asked, Pacific Northwest facility leaders "emphatically responded against eliminating the unknown queue." (Prior to May 2020, the unknown queue was not activated for the federal version of the Oracle Cerner EHR raising questions regarding the disposition of medical orders prior to VA's use of the new EHR.) The option presented by a VHA leader of eliminating or retaining the unknown queue represents a false dichotomy.[8] The OIG identifies that additional effort may ameliorate the ongoing risk of the unknown queue. The OIG recommends that the VA reconsider their determination that all actions have been completed to evaluate and address the unknown queue.

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[8] The VA OIG informed the Department of Defense OIG about this inspection's results so the Department of Defense OIG could evaluate the potential patient safety risk with the federal version of the Oracle Cerner EHR.

Contents

Abbreviations

EHR	electronic health record
EHRM	electronic health record modernization
EHRM IO	Electronic Health Record Modernization Integration Office
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a focused healthcare inspection to assess one of many identified patient safety concerns with an element of the new electronic health record (EHR). There has been significant interest from stakeholders, including members of Congress, on whether the use of the new EHR resulted in patient harm. The OIG chose to address the order entry "unknown queue" EHR safety concern after the Veterans Health Administration (VHA) assessed it as high risk and identified multiple events that resulted in patient harm.[1]

Background

"Virtually every intervention in patient care outside of surgery…is initiated by a physician's written order."[2] An EHR enables healthcare providers to generate computerized orders to enter and send treatment instructions, such as medications, laboratory, and radiology orders (see figure 1). Computerized orders

- reduce errors and improve patient safety,
- improve efficiency, and
- improve reimbursements for care provided.[3]

The benefits of computerized orders depend upon reliable delivery of the order to the requested service.

[1] On June 8, 2022, Oracle Corporation completed the acquisition of Cerner Corporation, with Cerner then referred to as Oracle Cerner. The OIG found that the term "unknown queue" was used years prior to VA's adoption of Oracle Cerner's EHR. The OIG identified examples of the term dating back to 2014 used on an Oracle Cerner user online help forum.

[2] "Computerized Physician Order Entry: Costs, Benefits and Challenges, A Case Study Approach," Agency for Healthcare Research and Quality, accessed March 17, 2022, https://digital.ahrq.gov/sites/default/files/docs/page/Leapfrog-CPOE_Costs_Benefits_Challenges.pdf.

[3] "What is computerized order entry?" Office of the National Coordinator for Health Information Technology, https://www.healthit.gov/faq/what-computerized-provider-order-entry.

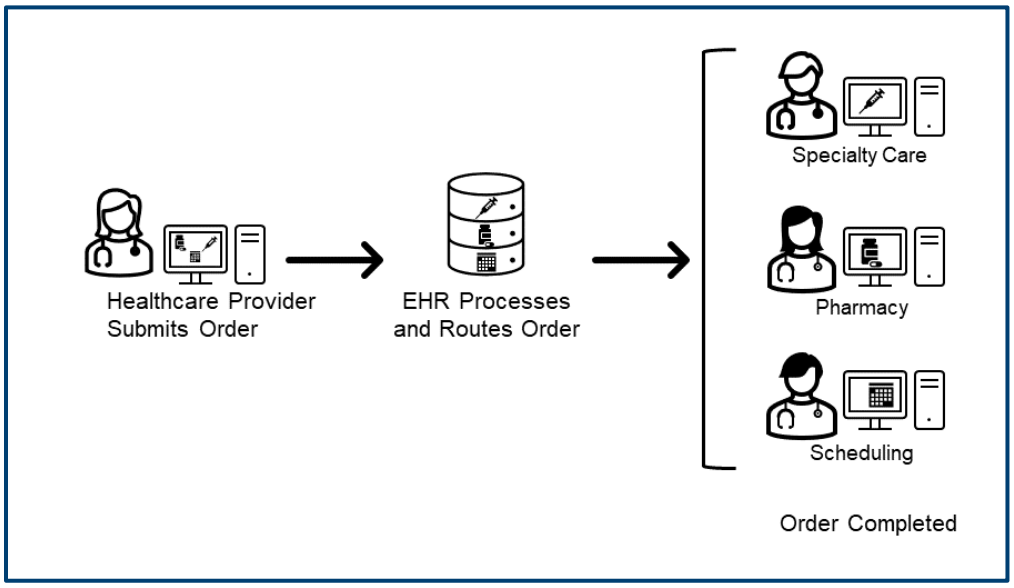

Figure 1. *Processing of an order using an EHR.*
Source: OIG analysis.

Prior OIG Reports

Prior OIG reports published on VA's implementation of the new EHR and the status of report recommendations are listed on the VA OIG site.

Concern

OIG focused on a VHA identified patient safety risk created by the new EHR that led to patient harm. Specifically, the new EHR did not deliver certain orders to the requested services but sent the orders to an undetectable location or unknown queue. The new EHR did not alert the health care providers that the order was not delivered to the requested service.

In a briefing by a VHA leader (see figure 2) this new EHR safety issue was described as analogous to the post office stuffing "undeliverable mail behind a bush instead of placing them back in your mailbox."

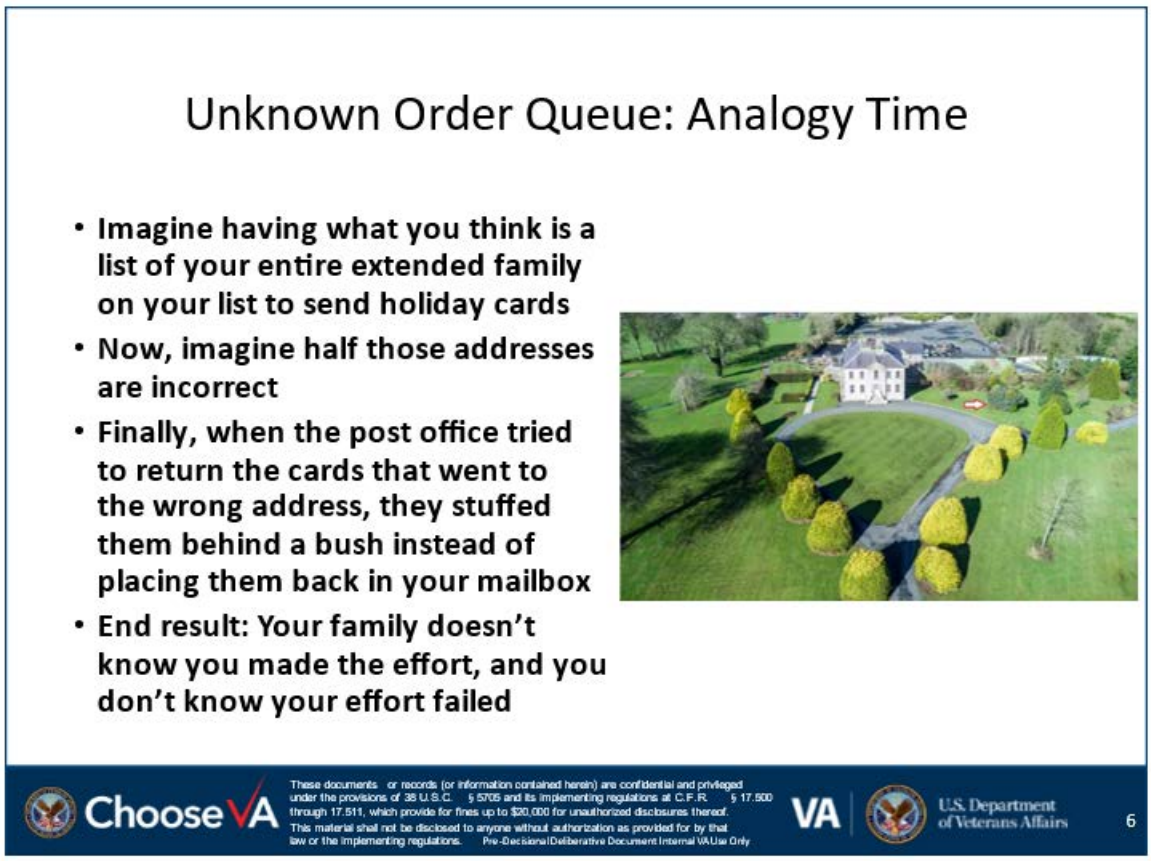

Figure 2. *VA briefing slide providing an analogy for the concern with orders not being delivered. Source: VA briefing, October 12, 2021.*

VHA's Efforts to Address EHR Safety

In May 2021, after VHA identified several patient safety concerns with the new EHR, a patient safety team was deployed to Mann-Grandstaff VA Medical Center (facility) to intervene.[4] The team was led by VHA National Center for Patient Safety and included staff from VHA program offices, leaders from the Office of Electronic Health Record Modernization (now called the Electronic Health Record Modernization Integration Office, EHRM IO), EHRM councils, VISN 20, and the facility.[5]

[4] The patient safety team was a part of a larger team tasked to address broad concerns with the new EHR.

[5] EHRM IO responsibilities include management of the preparation, deployment, and maintenance of the new EHR. The EHRM project included 18 clinical councils formed of subject matter experts from VA, VHA, and Oracle Cerner who determined what functions needed to be further developed to meet VHA's clinical and administrative requirements. Mann-Grandstaff VA Medical Center in Spokane, Washington was the first VA facility to go-live with the new EHR on October 24, 2020.

In December 2021, VA held a Safety Summit about the new EHR.[6] At the Safety Summit, the patient safety team shared the results from the comprehensive review of identified safety concerns with the new EHR. Findings included 60 safety concerns with the new EHR across nine core domains.[7] VA staff ranked the issue with the unknown queue as one of the three concerns with the highest patient safety risk.[8]

The OIG commends VHA staff that worked to identify, assess, and mitigate new EHR patient safety risks, to include the concern with the new EHR not delivering orders placed by healthcare providers. The OIG repeatedly heard of the long hours and considerable workload of VA staff dedicated to this mission and recognize their efforts to ensure safe care for veterans.

New EHR Patient Safety Risks and Facility Patient-Harm Events

VHA has worked to identify and evaluate EHR patient safety risks and harm to patients. For example, in a reference document prepared for the Deputy Secretary's attendance at the November 2, 2021, hearing of the House Committee on Veterans' Affairs Subcommittee on Technology Modernization, VHA identified that ongoing clinical reviews of facility patient safety events related to the new EHR identified 2 major harms, 21 moderate harms, and 185 "mild" harms.[9]

New EHR Patient Safety Risks and VHA Patient-Harm Events

VHA has identified safety events and patients harmed since the go-live at three facilities.[10] From October 24, 2020, through May 8, 2022, there have been 1,134 reports of patient safety events related to the new EHR. Analysis of new EHR patient safety events by VHA identified one catastrophic patient harm (death or major permanent loss of function) and two major patient

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[6] VA, *Electronic Health Record Comprehensive Lessons Learned, Progress Update*, November 2021. VA identified a planned EHR Safety Summit for December 2021 to review the "safety incident engagement process." VA published the progress update following VA's strategic review of the EHR modernization effort completed earlier in the year. The progress update did not specifically define the "safety incident engagement process."

[7] VHA, "VA, Patient Safety Domain Summary," November 10, 2021. The nine core domains of EHR safety concerns included: behavioral health, ambulatory, referrals, roles and position and privileging, pharmacy, identity, orders, medication administration, and unspecified.

[8] The other two concerns VA staff ranked as the highest patient safety risks included resolution of identifiers that impacted matching records in the new EHR and manual cancelation of appointments not acted on within 24 hours.

[9] At the time of the hearing, VHA had completed 1,225 "full clinical reviews" of reported new EHR patient safety events and acknowledged the review was ongoing with more than 2,000 reports of patient safety events still needing review. VHA definitions of major, moderate, and minor patient harms are provided in Issue 2. The reference document for the Deputy Secretary used the term "mild," however the VHA definition of harm uses the term "minor."

[10] The three VA facilities are Mann Grandstaff VA Medical Center, Spokane WA, Jonathan M. Wainwright Memorial VA Medical Center, Walla Walla, WA, and VA Central Ohio Healthcare System, Columbus.

harms (permanent lessening of bodily functioning) one of which, was related to the unknown queue.[11]

Scope and Methodology

The OIG initiated the inspection on February 10, 2022, and concluded on July 7, 2022. The inspection included interviews and written questions for VA and Oracle Cerner staff.[12] The OIG reviewed relevant VA and VHA policies. Other documents reviewed included emails, briefings, data spreadsheets, and documents related to the planning, preparation, and implementation of the new EHR.[13]

The OIG did not independently verify VHA data for accuracy or completeness.

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. 1101, 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.

Inspection Results

The OIG found that the new EHR sent thousands of orders for medical care to an undetectable location, referred to as the unknown queue. The impact of this function of the new EHR caused

[11] The analysis was from October 24, 2020, through May 8, 2022. Catastrophic harm is further defined by VA as "death or major permanent loss of function (sensory, motor, physiologic, or intellectual) **not related to the natural course of the patient's illness or underlying condition** (i.e., acts of commission or omission)." Major harm is further defined by VA as "permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) **not related to the natural course of the patient's illness or underlying condition** (i.e., acts of commission or omission)." VA caveated that one of the major patient harms may be updated to a catastrophic harm. [bolding emphasis not added by OIG]

[12] VHA program offices, EHRM IO, EHRM Councils, facility staff, and Oracle Cerner provided responses to OIG interview and written questions. Four Oracle Cerner employees (including an Oracle Cerner vice president identified by Oracle Cerner's general counsel as the company's subject matter expert on the unknown queue) responded to the OIG's request for information.

[13] The OIG utilizes electronic discovery tools to review emails.

delays in or omission of care, an "extraordinary risk" to patient safety, and multiple events of patient harm.[14]

1. The New EHR Delivered Orders to the Unknown Queue

The OIG found that the new EHR delivered thousands of patient care orders to the unknown queue without any indication of the action. Unbeknownst to facility healthcare providers who placed the orders, the new EHR did not deliver orders to a range of requested services (e.g., specialty care, laboratory, diagnostic imaging) and stored the orders in a list referred to as the unknown queue.

Relevant Policies and Standards

The OIG did not identify a relevant policy or standard related to new EHR processing of orders; however, the OIG considers that quality, safe health care is contingent on reliable and timely processing of medical orders.

Findings

The OIG made the following determinations:

The new EHR delivered certain orders to an unknown queue. The new EHR required a healthcare provider to use a service location drop-down list when entering an order for patient care (see figure 3). For the order to be delivered to the requested service, the healthcare provider was required to choose the facility location to which the specific order had been matched through the process of data "mapping" in the underlying software code.[15]

The new EHR design allowed ordering healthcare providers to select locations that were not matched to their orders. For example, when entering an order for the patient to be scheduled for a clinic follow-up appointment, the ordering provider had to select the correctly matched clinic location from a list that included all possible facility locations, both matched and unmatched. When the healthcare provider selected an unmatched location, the new EHR did not alert the provider but accepted the entry as successful and then routed the order to the unknown queue.

[14] In a VA meeting of leaders addressing EHR patient safety, a VA physician leader identified the unknown queue as an "extraordinary risk due to the chance of missed critical appointments."

[15] "What is Data Mapping," talend, accessed March 10, 2022, https://www.talend.com/resources/data-mapping/. Data mapping is the process of matching software fields from one database to another database. If not properly mapped, data may become corrupted. Oracle Cerner is responsible for mapping.

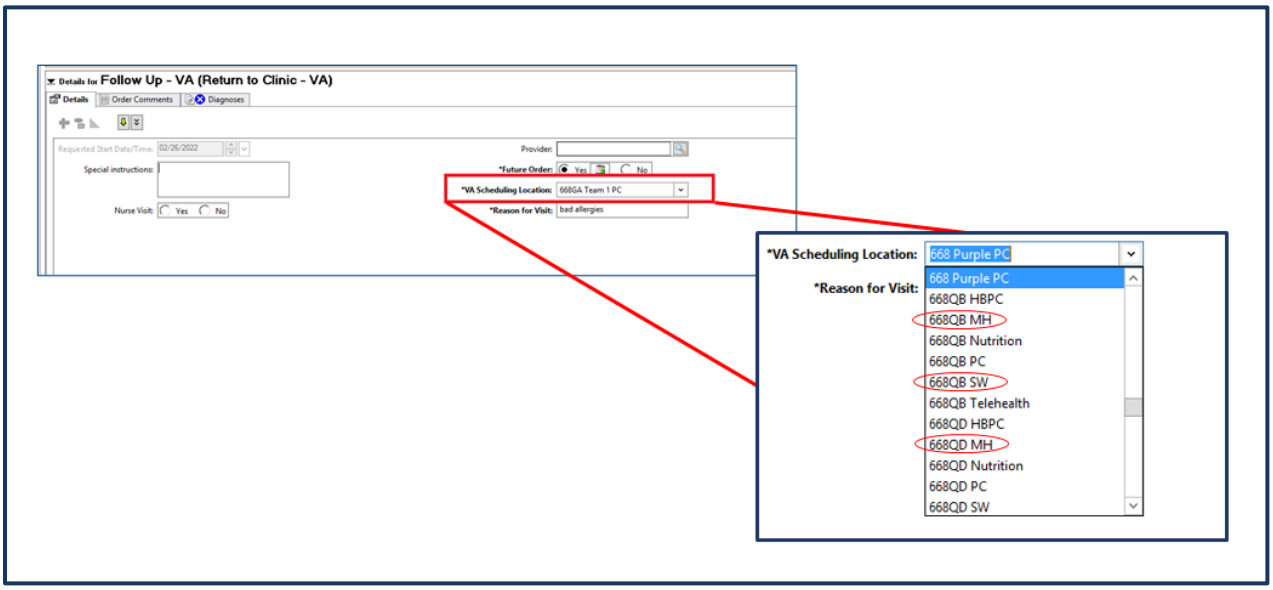

Figure 3. *View of the new EHR's order screen showing the location drop-down field.*
Source: VA EHR.
Note. The OIG added circles around the locations that were included in the drop-down list but not matched to the selected service and, if chosen, would send the order to the unknown queue.

The new EHR failed to alert providers that the orders were sent to the unknown queue. The new EHR gave healthcare providers submitting orders the false feedback that the orders had been successfully entered to be delivered to the requested service for action. However, the requested service did not receive the orders (see figure 4).

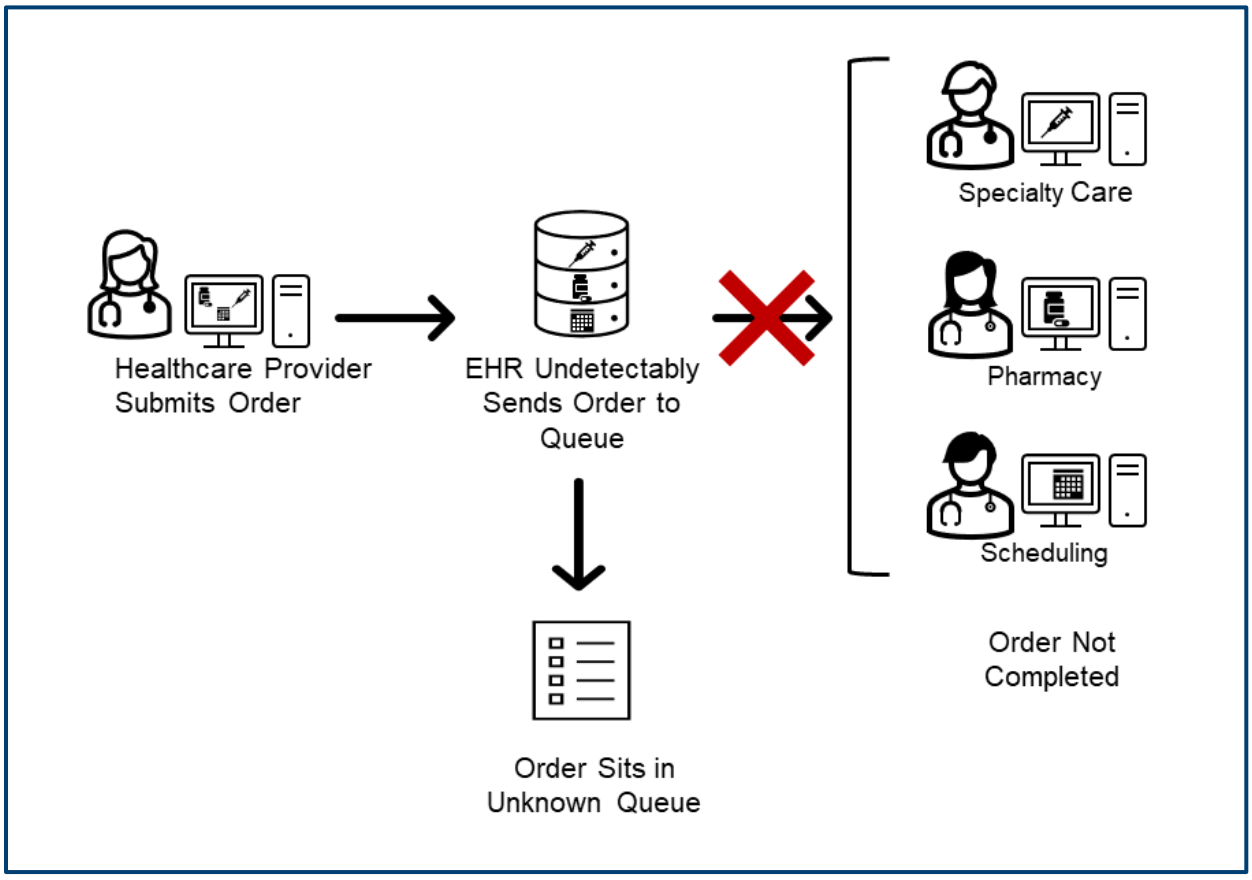

Figure 4. *Process of the new EHR routing an order to the "unknown queue."*
Source: OIG analysis.

Shortly after VA's go-live with the new EHR, facility staff identified missing orders. A VHA review of trouble tickets identified that on October 28, 2020, four days after go-live, a facility radiology technician placed the first Oracle Cerner trouble ticket regarding lost orders.[16] The next day, while responding to the trouble ticket issue, Oracle Cerner service-desk staff identified that the reported lost order was not isolated to a single event and found over 2,000 lost orders. Each of these orders had to be reentered into the new EHR by a VHA staff member for patients to be scheduled for the needed care.[17]

The new EHR failed to deliver more than 11,000 orders to the correct service locations from facility go-live from October 2020 through June 2021. The new EHR failed to deliver certain types of orders. The majority (77 percent) of orders that were not delivered were requests for

[16] The OIG learned that the facility radiology technician placed the trouble ticket after patients inquired about radiology services that had not been scheduled.

[17] The OIG learned that these unscheduled orders were created during the facility transition from VHA's legacy EHR to the new EHR. The transition required a manual reentry of legacy EHR radiology orders into the new EHR. The OIG uses the term legacy EHR to refer to VistA (Veterans Health Information Systems and Technology Architecture) the EHR used prior to the Oracle Cerner EHR.

radiology services.[18] Additionally, orders at the facility sent to the unknown queue included scheduling appointments, outpatient electrocardiogram (EKG) procedures and referrals.[19]

The unprocessed orders included

- 8,531 requests for radiology services, and[20]
- 2,512 requests for other clinical services.

Facility staff could not see orders sent to the unknown queue. To clear the unknown queue, an Oracle Cerner employee had to send a daily report of the orders to facility staff. Facility staff then had to cancel and reenter each order with a matched location.[21] Prior to March 11, 2022, VHA could not directly generate a report of unknown queue orders using the new EHR.

VA staff worked with Oracle Cerner staff to decrease the likelihood of the new EHR routing orders to the unknown queue. In June 2021, a VHA leader identified that removing unmapped locations for orders could decrease the likelihood of orders being sent to the unknown queue. In September 2021, Oracle Cerner completed the work of removing unmapped locations from the new EHR order options. In February 2022, Oracle Cerner updated the new EHR to provide an alert if a provider attempted to create an order with an unmapped location.[22]

Oracle Cerner was aware of the EHR's unknown queue prior to VA's go-live with the new EHR. A VHA leader reported finding online Oracle Cerner documentation that the unknown queue was known to be a problem by Oracle Cerner and other clients. On an Oracle Cerner user help forum, the OIG found several instances, going back to 2014, where Oracle Cerner customers identified challenges with the unknown queue. An Oracle Cerner leader reported that, while not knowing when the unknown queue was added to the Oracle Cerner EHR, every Oracle Cerner client has the unknown queue. Another Oracle Cerner leader concurred that all Oracle Cerner clients have the unknown queue in their EHR that "they monitor and work through" and has "heard it has been in existence for many years." Documentation provided by Oracle Cerner to EHRM IO describes the unknown queue as an option that can be activated for every Oracle Cerner customer.

[18] The majority of orders VHA classified as radiology were for radiographs (x-rays).

[19] Appointment types included return to clinic for follow-up, telehealth, dietary therapy, laboratory, respiratory therapy, blind rehabilitation, recreation therapy, surgery, neurology, occupational therapy, physical therapy, speech therapy, and cardiology.

[20] Unprocessed radiology orders could be found in a "virtual room" by radiology staff who had a specific EHR access level. A facility radiology technician discovered this "virtual room" of unprocessed radiology orders.

[21] A February 28, 2022, briefing for the Department of Defense and VA group overseeing EHR modernization titled, "VA Patient Safety Domains and Intellectual Property (IP) Enhancements," stated that, "currently Oracle Cerner sends an email to a group of individuals to manage the Unknown Queue, this is not sustainable for future sites."

[22] A VHA leader provided the OIG with the date for the completed work.

Oracle Cerner did not inform VA end-users of the unknown queue or provide guidance to address the unknown queue in advance of go-live with the new EHR. During the course of the OIG investigation, VA and VHA leaders reported that Oracle Cerner did not provide any information to VA regarding the unknown queue prior to VA's identification of the issue. An Oracle Cerner leader confirmed that communication by Oracle Cerner "did not occur for a few months." An Oracle Cerner vice president, identified by the company's general counsel as a subject matter expert on the unknown queue, told the OIG of having no knowledge that Oracle Cerner provided information regarding the unknown queue to OEHRM prior to VA go-live. In sum, the OIG did not identify any evidence that Oracle Cerner provided actionable information of the unknown queue to VA prior to go-live.

Following the OIG's transmittal of the draft report to VA, Oracle Cerner provided EHRM IO with Oracle Cerner documentation that asserted in January 2020 a VA leader approved the use of the unknown queue.[23] However, that VA leader and the VA leader's supervisor shared with the OIG that they had no awareness of the unknown queue prior to go-live. Oracle Cerner leaders queried by the OIG did not identify a rationale for the failure to inform VA about the unknown queue.

Absent VHA actions, the existence of the unknown queue may have not been identified, and patient care orders may have not been completed.

2. Orders Being Routed to the Unknown Queue Placed Patients at Risk and Caused Harm

VHA determined that the new EHR's unknown queue created significant patient risk and caused harm to multiple patients. VHA provided the Deputy Secretary and the EHRM IO Executive Director details of the risk and harm to patients caused by the unknown queue. VHA staffing resources were required to assess, remedy, and mitigate the unknown queue. Oracle Cerner acknowledged that the unknown queue's ongoing risk would require mitigation at future go-live sites.

A VHA physician summarized in a statement to the Deputy Secretary the safety risk and patient harm created by the new EHR's unknown queue[24]

> We have never in our careers used a system that generated unmanned queues. This is a programming deficiency which has been readily apparent in working

[23] Oracle Cerner documentation provided to EHRM IO identified that an email was used by Oracle Cerner staff to document VA's approval of the unknown queue. However, EHRM IO leaders were not able to provide that email following the OIG's request.

[24] This statement was included in materials provided to the Deputy Secretary following his November 2021 visit to the facility. The Deputy Secretary forwarded the email with this statement to the EHRM IO Executive Director in December 2021.

these queues. In discussing with Oracle Cerner personnel these queues exist even in the commercial sector, were well known but Oracle Cerner seemingly waited until we stumbled upon them. Really inexcusable and indefensible in the case of patient harm. These require a great deal of staff time to research and redirect to proper location. This is unsafe and rather than having a well-constructed conduit, these queues reflect a fraying rope, poorly constructed and conceptualized product from its foundation.

Relevant Policies and Standards

VHA National Patient Safety Improvement Handbook. This handbook provides procedures used to accomplish "VHA's goal of preventing inadvertent harm to patients" as a result of medical care. VHA defines patient safety as "ensuring freedom from accidental or inadvertent injury" while accessing health care. One factor in accomplishing this goal is identifying and reporting adverse events and close calls.[25]

Adverse event. Unexpected or untoward incidents directly associated with the medical care or services provided at VHA facilities.

Close call. An event that could have resulted in an adverse event but did not, either by chance or intervention.[26]

VHA National Center for Patient Safety, Guidebook for Assessing Reported Adverse Events. This guidebook provides direction for VHA's assessment of reported adverse events and close calls. Assessment of patient safety events includes evaluation of the severity of harm (see table 1), and the likelihood of how frequent an event may occur (see table 2) to generate an overall assessment of the event or close call.[27]

Table 1. VHA Severity of Harm

Severity of Harm	VHA Definition
Catastrophic	Death or permanent loss of functioning not related to natural course of the patient's illness or underlying condition
Major	Permanent decrease in the body's functioning or disfigurement, requires surgery or inpatient care
Moderate	Increased length of hospital stay or required increase in level of care
Minor	No injury, no increased length of stay, no increased level of care

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

[26] VHA Handbook 1050.01.

[27] VHA National Center for Patient Safety, "Guidebook for Assessing Reported Adverse Events: A resource for Safety Assessment Code (SAC) Evaluation," ver.1, May 2020.

Source: VHA National Center for Patient Safety.

Table 2. VHA Frequency of Event

Frequency of Event	VHA Definition
Frequent	Likely to occur immediately or within a short period (may happen several times a year)
Occasional	Probably will occur (may happen several times in 1 to 2 years)
Uncommon	Possible to occur (may happened sometime in 2 to 3 years)
Remote	Unlikely to occur (may happened sometime in 5 to 30 years)

Source: VHA National Center for Patient Safety.

EHRM Safety Summit Health Information Technology Risk Scoring To assess technology patient safety issues created by the new EHR, VHA added risk scoring for detectability. Detectability refers to how readily a patient safety risk created by the new EHR can be identified and ranges from very difficult to very easy to detect (see figure 5.)

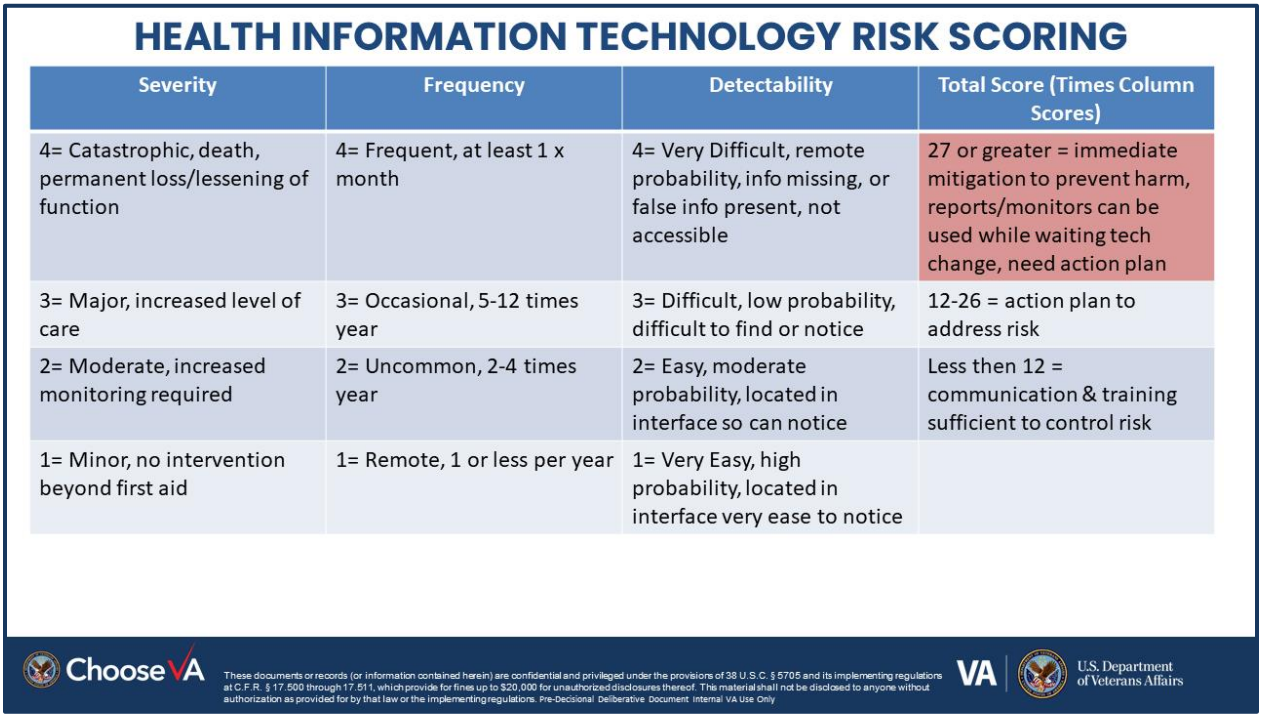

Figure 5*. VA's Scoring Matrix for Health Information Technology Patient Safety Risk.*
Source: VA EHRM Safety Summit Domain Summary, November 2021.

Findings

The OIG made the following determinations:

The new EHR's delivery of orders to the unknown queue created a patient safety risk. VHA assessed the risk as major severity, frequently occurring, and very difficult to detect. The total risk score for the unknown queue indicated the need for required actions that included

- immediate mitigation to prevent harm,
- an action plan to address the risk, and
- reporting and monitoring the risk while waiting on needed technology changes.[28]

VHA determined that the new EHR's delivery of orders to the unknown queue caused patient harm. VHA initiated a clinical review in June 2021 to ensure that staff acted on orders sent to the unknown queue and to assess patients for harm from delays in care. The clinical reviewers conducted 1,286 assessments and identified 149 adverse events for patients[29]

- Major harm: 2[30]
- Moderate harm: 52
- Minor harm: 95

The assigned level of harm measures the effect from the delay of care.[31] Table 3 provides examples of VHA identified patient harm.

Table 3. Examples of VHA-Assessed Cases of Patient Harm

Level of Harm	Example
Major	A healthcare provider entered a follow-up psychiatric care order for a homeless patient identified as at risk for suicide. The new EHR sent the order to the unknown queue. The patient was not scheduled for follow-up care and later contacted the Veterans Crisis Line reporting a razor in hand and a plan to kill himself. The patient was psychiatrically hospitalized.
Moderate	A healthcare provider ordered an appointment for a patient to be measured for and receive compression hose to help with lower leg edema (swelling). However, the new EHR delivered the medical order to the unknown queue and the patient did not receive the compression hose. The patient required urgent care treatment for worsening of the edema.
Minor	A healthcare provider entered an order for a patient with uncontrolled diabetes to be scheduled with a clinical pharmacist for diabetes education and treatment. The new EHR sent the order to the unknown queue. The patient was not scheduled for care until 14 months later after a new order was entered.

Source: OIG summary of VHA identified patient-harm incidents.
Note: Appendix A provides additional detail for each example.

[28] See Figure 5, for box shaded in red.

[29] The data provided to the OIG of the clinical reviews was dated February 24, 2022.

[30] VHA clinical review initially identified one major harm of a patient, however in July 2022 the OIG learned that VHA clinical review identified a second incident of major harm of a patient.

[31] This description was provided by a VHA physician leader.

VHA staff provided the Deputy Secretary and EHRM IO Executive Director information about the unknown queue patient safety risks and patient harm. The Deputy Secretary completed a virtual visit to the facility in November 2021 to receive staff concerns with the new EHR. A presentation included details about the safety concerns and identified patient harm due to the unknown queue. The presentation provided a description of the major patient-harm event described in this report. The Deputy Secretary received the written statement along with other virtual visit materials on November 22, 2021, and on December 27, 2021, the Deputy Secretary forwarded that information to the EHRM IO Executive Director. Furthermore, on December 23, 2021, VHA staff provided the EHRM IO Executive Director additional detailed information on new EHR related patient safety events and patient harms, that included the unknown queue.

The new EHR's delivery of orders to the unknown queue resulted in substantial VHA staff hours for clinical review to assess patient risk and harm. VHA undertook a multi-step clinical review of patients who had unknown queue orders. The initial clinical review included 1,286 orders entered by 273 different healthcare providers.[32] The first level clinical review by healthcare providers took over 400 hours to complete. A physician second level review of a subset of the orders took almost an additional 56 hours to complete. Facility staff then completed a clinical review and took necessary actions to implement the orders from the unknown queue. A facility leader estimated that staff spent 597 hours to complete the work.

Remediation of the unknown queue required significant facility staff support. The demands of remedying the unknown queue by facility staff led a facility senior leader to comment

> MG [the facility] needs outside support for monitoring this Q [unknown queue]. It is already enough loss of efficiency and time to have to reenter the orders on our side. Any additional demand on our FTEs [staff] ultimately reduces access to care on our end. Given the current poor order design that is a set up for clinician failure, I think it is reasonable and appropriate to expect Oracle Cerner to monitor the Q and help generate the comms [communication] back to providers to reenter the orders.

A facility leader estimated that facility staff monitoring and managing orders in the unknown queue from November 1, 2021, through May 3, 2022, took 165 hours.

Each facility that goes live with the new EHR will require an ongoing commitment from facility staff to monitor and address the new EHR's unknown queue. In October 2021, VHA provided a briefing to VHA, EHRM IO and Oracle Cerner staff that predicted ongoing mitigation of the unknown queue would be necessary at VHA sites for at least the year following

[32] Some patients had more than one order that the new EHR sent to the unknown queue. The most orders sent to the unknown queue for a single patient was 29.

go-live. The briefing concluded that Oracle Cerner and EHRM IO must coordinate with staff at go-live sites "from day 1" to monitor the queue. Oracle Cerner identified the unknown queue as a risk for go-live of the new EHR at future sites.[33] Oracle Cerner's mitigation plan included, "continuing to reinforce management of unknown queue in deployment activities."

The OIG has concern with the effectiveness of Oracle Cerner's plan to mitigate the safety risk of the unknown queue. On May 16, 2022, the OIG used the new EHR to generate a report of orders in the unknown queue for VHA sites and found 206 orders that had not been cleared from the unknown queue.[34] The OIG alerted VHA staff to this finding. Facility leaders reported using the established process to monitor and remediate the queue, but shared that steps in the mitigation process could lead to orders remaining in the queue.[35]

Additionally, a VHA leader identified that Oracle Cerner technology mitigations were inadequate. The VHA leader engaged Oracle Cerner in May 2022 and identified that Oracle Cerner's mitigation efforts had not been wholly successful. The VHA leader shared that "[i]n the recent past Oracle Cerner has seemed to expect the VA to prove every single hole is truly a hole" and called for a weekly check-in ("we need active vigilance") by Oracle Cerner staff to review gaps in the unknown queue's mitigations.

The EHRM IO Executive Director requested a meeting with OIG leaders to review concerns with the draft of this report. On June 23, 2022, OIG leaders met with VA leaders. The EHRM IO Executive Director reported that work to address the unknown queue was considered complete and that, on average, there were 28 orders in the unknown queue report. However, the morning of the meeting, the OIG generated a report of orders in the unknown queue and found 522 total orders across six VA medical centers.

The OIG remains concerned that the implemented technology and process mitigations do not eliminate the patient safety risk of the unknown queue.

Conclusion

The new EHR's unknown queue represented an element that ultimately led to thousands of orders for medical care not being delivered to the requested service, placed patients at risk for incomplete care, and caused multiple events of patient harm. Oracle Cerner failed to inform VA end-users of the existence of the unknown queue and put the burden on VA to identify and address the problem.

[33] Oracle Cerner shared this information in presentation slides for a planned February 3, 2022, briefing with the EHRM IO Executive Director.

[34] The OIG provided this information to VHA leaders to facilitate action to address orders in the unknown queue.

[35] The facility leaders reported that since establishing the mitigation process with VHA's National Center for Patient Safety there has been no EHRM IO or VHA contact involved in the ongoing effort to address the unknown queue.

While senior VA leaders were aware of the impact of the unknown queue, the current identification and ongoing remediation efforts continue to consume VHA staff resources. The OIG remains concerned that the mitigation process is an inadequate solution.

Recommendations

1. The Deputy Secretary reviews the process that led to Oracle Cerner's failure to inform VA of the unknown queue and takes action as indicated.

2. The Deputy Secretary evaluates the unknown queue technology and mitigation process and takes action as indicated.

Appendix A: Case Summaries of VHA-Assessed Patient Harm

Major Harm

A homeless veteran in their 60s with a history of depression, a recent positive screen for suicide risk, anxiety, and possible cognitive impairment, saw a facility psychiatrist for an assessment and medication management of symptoms of depression.

At the appointment, the facility psychiatrist documented that the patient denied suicidal ideation and the appointment concluded with a plan to re-start the patient's anti-depressant medications and for the patient to be seen again in one month for further assessment. The psychiatrist wrote an order that indicated that the patient should be scheduled for a follow-up appointment for psychiatric medication management in four weeks.

This order was routed to the "unknown queue" and no appointment was scheduled. The patient was not seen for follow-up care four weeks later as ordered by the psychiatrist.

Six weeks after the initial appointment, the patient called the veteran's crisis line (VCL) from a local park reporting suicidal ideation with a plan to use a razor for self-harm. The patient allowed the VCL respondent to call emergency services and the patient was transported to a local non-VA hospital and was subsequently admitted to the non-VA hospital's mental-health inpatient unit.

Moderate Harm

A veteran in their 60s with a history of morbid obesity, lower leg edema (swelling), and chronic knee pain called a facility nurse in late September 2020 requesting a new pair of "compression socks" for treatment of the lower leg swelling. The patient was required to come to the facility to be measured for the compression socks, an order was entered for the patient to be scheduled for an appointment.

The initial order was written in the prior legacy EHR system. The appointment had not been scheduled by the time the new EHR was started, so the order needed to be reentered into the new EHR. The new order was entered in early December 2020, for an appointment to be scheduled 11 days later.

The order could not be acted upon because it was routed by the new EHR to the "unknown queue," no scheduling action was taken, and the patient was neither measured for nor received new compression hose.

In late May, 2021, the patient presented to the facility urgent care clinic due to increased swelling in his right foot and leg. Physical examination showed swelling in both lower legs with more on the right than the left. The patient underwent an ultrasound examination of the right leg

to evaluate for the presence of a clot in the large veins of the leg. The ultrasound did not reveal a clot. The patient was diagnosed as suffering from an exacerbation of the known edema. The patient was discharged with a prescription for medications to decrease the foot and leg swelling and a plan to follow up with the primary care provider.

Minor Harm

A veteran in their 60s with hypertension and diabetes was seen by a primary care provider in March 2021 for an annual medical assessment. At the conclusion of the assessment an order was placed by the primary care provider for the patient to be scheduled for an appointment in the pharmacy's metabolic clinic for diabetes education and treatment for the patient's "uncontrolled diabetes."

The appointment was never scheduled because the order was routed to the unknown queue and scheduling staff were unaware of the order.

The primary care provider placed another order for the patient to be scheduled with the pharmacy metabolic clinic for diabetes education and treatment and the appointment took place in early May 2022.[36]

[36] During a review of the patient's EHR, OIG found that the patient was next seen by a new primary care provider in April 2022 when the diabetes was again described as "uncontrolled" and the patient was newly diagnosed with chronic kidney disease secondary to diabetes.

Appendix B: Summary of Updates to the Draft Report

Some changes were made to the report for clarification, but no changes were made to OIG findings. This summary includes substantive updates to the draft report. The updates are also reflected in the Executive Summary and Conclusion.

Table B.1. Characterization of the Unknown Queue

Page	Final Version	Draft Version
1	The VA Office of Inspector General (OIG) conducted a focused healthcare inspection to assess one of many identified patient safety concerns with *an element* of the new electronic health record (EHR).	The VA Office of Inspector General (OIG) conducted a focused healthcare inspection to assess one of many identified patient safety concerns with *a* dysfunction of the new electronic health record (EHR).
5	The OIG found that the new EHR sent thousands of orders *for medical care to an undetectable location, referred to as the unknown queue.* The impact of this *function of* the new EHR caused delays in or omission of care, an "extraordinary risk" to patient safety, and multiple events of patient harm.	The OIG found that the new EHR failed to successfully deliver thousands of orders placed by healthcare providers at the facility. The impact of this failure by the new EHR caused delays in or omission of care, an "extraordinary risk" to patient safety, and multiple events of patient harm.
6	(Heading) The New EHR *Delivered Orders to the Unknown Queue*	(Heading) The New EHR Failed to Successfully Deliver Certain Orders
6	The OIG found that the new *EHR delivered thousands of patient care orders to the unknown queue* without any indication of the *action*. Unbeknownst to facility healthcare providers who placed the orders, the new EHR *did not* deliver orders *to a range of* requested services (e.g., specialty care, laboratory, diagnostic imaging) and stored the orders in a list referred to as the unknown queue.	The OIG found that the new EHR failed to successfully process thousands of patient care orders at the facility without any indication of the dysfunction. Unbeknownst to facility healthcare providers who placed the orders, the new EHR failed to successfully deliver orders for a broad range of requested services (e.g., specialty care, laboratory, diagnostic imaging) and stored the orders in a list referred to as the unknown queue.
9	(Heading) Oracle Cerner was aware of the EHR's unknown queue prior to VA's go-live with the new EHR.	(Heading) Cerner was aware of the EHR's unknown queue *issue* prior to VA's go-live with the new EHR.

OIG Comment. EHRM IO leaders and Oracle Cerner assert that the unknown queue is a function of the new EHR and is not an error with the new EHR's software code. The OIG concluded that this element of the new EHR functions as intended, but as detailed in the report, its design and operation created a patient safety concern that led to patient harm.

Table B.2. Scope and Methodology

Page	Final Version	Draft Version
5	The OIG initiated the inspection on February 10, 2022 and concluded on *July 7, 2022*.	The OIG initiated the inspection on February 10, 2022, and concluded on May 25, 2022.
5	(Footnote 12) *Four* Oracle Cerner employees (including an Oracle Cerner vice president *identified by Oracle Cerner's general counsel as the company's subject matter expert on the unknown queue*) responded to the OIG's request for information.	(Footnote 12) Two of four Cerner employees (including a Cerner vice president) did not respond to OIG's repeated requests for information.

OIG Comment. The date of the inspection changed given additional information received and added to the report. Following multiple queries, the OIG ultimately received responses from two Oracle Cerner employees following transmittal of the draft report to VA.

Table B.3. VA's Prior Knowledge of the Unknown Queue

Page	Final Version	Draft Version
9	Documentation provided by Oracle Cerner to EHRM IO describes the unknown queue as an option that can be activated for every Oracle Cerner customer.	Not applicable.
10	(Heading) Oracle Cerner did not *inform* VA *end-users* of the unknown queue or provide guidance to address the unknown queue in advance of go-live with the new EHR.	(Heading) Cerner did not warn VA of the unknown queue or provide guidance to address the unknown queue in advance of go-live with the new EHR.
10	*In sum,* the OIG did not identify any evidence that Oracle Cerner provided *actionable* information of the unknown queue *to VA* prior to go-live. *Following the OIG's transmittal of the draft report to VA, Oracle Cerner provided EHRM IO with documentation that asserted in January 2020 a VA leader approved the use of the unknown queue. However, that VA leader and the VA leader's supervisor shared with the OIG that they had no awareness of the unknown queue prior to go-live.* Oracle Cerner leaders queried by the OIG did not identify a rationale for the failure to inform VA about the unknown queue.	The OIG did not identify any evidence that supported Cerner informed VA of the unknown queue prior to go-live. Cerner leaders did not provide a rationale for the failure to notify VA.

20	Oracle Cerner failed to inform VA *end-users* of the existence of the unknown queue and put the burden on VA to identify and address the problem.	Cerner failed to inform VA of the existence of the unknown queue and put the burden on VA to identify and address the problem.

OIG Comment. Oracle Cerner and EHRM IO leaders asserted that VA had approved and was aware of the unknown queue prior to go-live. The OIG determined that there was no substantive information provided to the OIG that VA staff had actionable knowledge of the unknown queue prior to go-live.

Table B.4. OIG Concern with Unknown Queue Mitigations

Page	Final Version	Draft Version
20	On May 16, 2022, the OIG used the new EHR to generate a report of orders in the unknown queue for VHA sites and found 206 orders that had not been cleared from the unknown queue. *The OIG alerted VHA staff to this finding.*	On May 16, 2022, the OIG used the new EHR to generate a report of orders in the unknown queue for VHA sites with the new EHR and found 206 orders that had not been cleared from the unknown queue.
20	*The EHRM IO Executive Director requested a meeting with OIG leaders to review the draft of this report. On June 23, 2022, OIG leaders met with VA leaders. The EHRM IO Executive Director reported that work to address the unknown queue was considered complete and that, on average, there were 28 orders in the unknown queue report. However, the morning of the meeting, the OIG generated a report of orders in the unknown queue and found 522 total orders across six VA medical centers.* *The OIG remains concerned that the implemented technology and process mitigations do not eliminate the patient safety risk of the unknown queue.*	Despite VHA's costly use of staffing to stem the number of patient harms, the OIG concluded that the current mitigations do not eliminate the patient safety risk of the unknown queue.

OIG Comment. The OIG remains concerned with the inadequacy of current technology and process mitigations for the unknown queue. The OIG updated the report to reflect, contrary to the EHRM IO Executive Director's assertion during a meeting with OIG leaders, that over 500 orders were in the unknown queue as of June 23, 2022.

Table B.5. Case Summaries and VHA-Assessed Patient Harms

Page	Final Version	Draft Version
6	Multiple changes to the text to remove specifics of patient care for anonymization.	Case summaries included dates of care and the gender of patients.
13	VHA clinical review *initially* identified one major harm of a patient, *however in July 2022 the OIG learned that VHA clinical review* identified a second incident of major harm *of a patient.*	While the VHA clinical review identified one major harm of a patient, an additional assessment by a facility provider identified a second incident of major harm.

OIG Comment. The OIG routinely provides details of patient care in the draft report provided to VHA in order to facilitate clinical review. These details are removed prior to publication.

Appendix C: Office of the Deputy Secretary Memorandum

Department of Veterans Affairs Memorandum

Date: July 6,2022

From: Deputy Secretary (001)

Subj: Response to Draft Report "The New Electronic Health Record's Unknown Queue Caused Multiple Events of Patient Harm" (Project Number 22-01137-HI-1241) (VIEWS 7758917)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the Department of Veterans Affairs (VA) Office of Inspector General (OIG) draft report, "The New Electronic Health Record's Unknown Queue Caused Multiple Events of Patient Harm." While I concur with both recommendations to VA in this draft report, the draft contains material errors or omissions regarding unknown queues that are important to bring to your attention. Our staffs have discussed these concerns with you, and I outline some of them in my response below. Attached, also please find the action plan jointly developed and kept current by the Veterans Health Administration (VHA) and the Electronic Health Record Modernization Integration Office (EHRM IO) that already has been completed to address the recommendations.

2. High reliability organizations encourage reporting of patient safety concerns and close calls. VA is committed to patient safety and works diligently to ensure that processes and procedures are in place to prevent patient harm. As a learning organization, VA leadership at every level takes reports of patient safety events very seriously. This is true whether or not the facility concerned is deploying a new electronic health record (EHR).

3. VA's first deployment of the new EHR was at Mann-Grandstaff VA Medical Center (VAMC). Based on the experience and lessons learned at that VAMC, EHRM IO has instituted many measures to prevent patient safety events and harm during continued implementation of the EHR at Mann-Grandstaff as well as deployment at other locations. Our preliminary data demonstrate that these measures have been very effective in significantly reducing patient safety events, not only at Mann-Grandstaff, but also for our most recent deployments in Walla Walla, Washington, Columbus, Ohio, Roseburg, Oregon, and White City, Oregon.

BACKGROUND

4. EHRs not only enable health care providers to document care provided to patients but is also the tool to enter and send orders for medications, laboratory tests and radiology exams. The primary reason an order may go unfulfilled is human error (e.g.,

data entry errors). The system may be unable to validate the clinician, the patient, or the service due to typographical errors, mismatched (topological) connections, spelling mistakes, or improperly synchronized validation services. From an enterprise software perspective, the sheer volume of transactions may inevitably lead to unfilled orders. Like other electronic health record systems, the Cerner EHR system was purposely designed to include a failsafe to capture erroneous orders; therefore, the "unknown queue," while unartfully named, is not a "dysfunction" of the EHR as repeatedly characterized in the draft. Rather, this is how the system was designed - to capture orders that cannot be delivered and filled so that they can be reviewed by staff for correction. Accordingly, the existence of the queue is not indicative of carelessness or negligence. While I do not recall the email to me referenced in the draft, I will note that based upon my understanding of the process, the author's comparing orders in the unknown queue to "stuffing undeliverable mail behind a bush instead of placing them back in your mailbox" is unfairly inflammatory, misleading and a mischaracterization of the process since the queue is meant to be checked and unfilled orders corrected.

5. The inspection result that identified "thousands of orders" (approximately 11,000 orders) that were not filled also is not accurate. The draft mentions that about 77% of these orders were radiological studies, but the draft does not mention that they were improperly included in the count (pages 1 and 13) since these were not "unfilled orders." Most VAMCs, including Mann-Grandstaff VAMC, do not allow clinicians to schedule radiological orders. Therefore, these radiological orders were from walk-ins that were mistakenly clinician-generated and put in the unknown queue and should not be considered as "unfilled orders." The remaining 2,512 indeed are the "unfilled orders" that reflect a 6-week interval where staff did not tend to the backlog of orders and Cerner did not remind VA of the need to review the queue. That incident is a shared failure of process, not technology. There was no automated mechanism to "alert providers that the orders were sent to the unknown queue." However, EHRM leadership at the time did alert VHA stakeholders of the existence of the queue; the need to manually resolve the issue; and the opportunity to automate an order's confirmation of connection.

6. Contrary to the draft's assertion "that Cerner did not warn VA of the unknown queue or provide guidance to address [it]," history of the program reflects that the purpose and use of the queue were discussed and developed by the joint efforts of both Cerner and VA. In fact, staff provided OIG with documentation (VA meeting minutes from January 2020) that demonstrates the queue was created intentionally as an ordinary failsafe mechanism consistent with typical Cerner deployments and in alignment with the Department of Defense, which shares the same EHR technology. Additionally, prior to deployment at Mann-Grandstaff VAMC, the unknown queue was discussed during a Cerner hosted workshop (Workshop #5 in 2020) in Kansas City, Missouri, with VHA staff participation. Nevertheless, shared failure between VA and Cerner to monitor and manage the Mann-Grandstaff VAMC unknown queue caused orders to accumulate in the queue after the site's go-live in October 2020. Once the backlog was identified, steps were taken to address the root cause including the attached notification entitled

"Unknown Queue Enhancement: VA Scheduling Location Order Entry Format Field Updated," which was emailed to Mann-Grandstaff VAMC on September 23, 2021, with direction to the recipients to ensure all end users receive the notification. The notification included information on the unknown queue, impacted users and mitigating actions for ordering providers as well as links to training resources.

7. Clearing the weeks-long accumulated queue "resulted in substantial VHA staff hours" to review and assess the unfilled orders. It reportedly took 400 hours. That is an understandable dedication of time and effort given that it was not found for several weeks and that the business process error created patient safety risk and potentially resulted in harm. To balance the draft's discussion of this critical issue, VA recommends determining a baseline comparison of unfilled orders in the legacy system, how they are managed, and the manual effort required to correct them.

8. The draft states that on December 27, 2021, information was forwarded to the EHRM IO Program Executive Director that included a written statement and other materials from the November 2021 virtual site visit to Mann-Grandstaff VAMC. For context, I believe that it is important to understand that by December 2021 the issues concerning the unknown queue were well-known and VA had implemented processes to mitigate and adjudicate the backlog in the unknown queue and identified subsequent actions to address associated process failures.

DISCUSSION

9. Once VA became aware of the unknown queue backlog, immediate action was taken to improve processes to ensure orders in the queues are routed to the right location or reentered, which included completion of technical configurations to prevent orders from being unnecessarily or inappropriately routed to an unknown queue. Specific actions that were taken to resolve this issue included:

a. Implemented a newly developed technical job to run daily in the background that automatically filters the VA Scheduling Location field to only show locations that will generate requests that can be routed to an available location. If there is a location build that is incorrect, new and/or not built, the system will automatically filter those out so that they are not available to providers to use while ordering.
b. Ensured that there is an alert that notifies a provider if the default location will not generate a good request.
c. Developed a Discern Report to allow sites to view the queue for their facility.
d. Created a "VA Needs Scheduling Location" option that sends orders that need to be corrected or to added to a new build to a separate queue.
e. Deployed a Functional Support Team from the VA Central Offices for multiple weeks to support VISN 20 staff on-site at Mann-Grandstaff VAMC in reviewing the unknown queue, triaging and designating risk assignments and identifying appropriate actions for each item.

f. Identified personnel at Mann-Grandstaff VAMC to monitor the unknown queues daily to ensure those orders are rerouted or reentered appropriately.
g. Developed training materials that were incorporated into sustainment training.
h. Developed analytics tools to track trends and reporting of the queue.
i. Worked with each deployment site to identify individuals that will monitor the queues, provide training and access as needed and ensure there is a process/workflow in place prior to future go-lives.

10. The issues that caused orders to be routed inappropriately to an unknown queue have been resolved and measures have been taken to facilitate resolution of orders that correctly fall to this safety net queue. This includes the establishment of a process for daily review of the unknown queue to capture orders not being routed to the intended location so that they can be corrected. In December 2020, Cerner reported an average 1,221 orders in the unknown queue at any given time at Mann-Grandstaff. Currently, Cerner reports that the average number of orders in the unknown queue at Mann-Grandstaff during May 2022 was 28. Additionally, as was stated by a VHA leader on a VA-OIG call June 23, 2022, Mann Grandstaff has had minimal number of orders in the unknown queue and in fact on the day of the meeting, there were only 5 orders in the unknown queue. The VHA leader further confirmed that the processes to review the unknown queue are well established and operating effectively at the VA sites in the Pacific Northwest. Additionally, this VHA leader stated that when they asked the Pacific Northwest VAMC leaders about eliminating the queue, they all emphatically responded against eliminating the unknown queue. Moreover, these VAMC leaders indicated that now that they knew how to use the queue, they found it very useful and determined that it actually increased safety for Veterans.

11. A document referenced in the draft reflects a categorization of patient safety events that may have resulted in different levels of harm. Each of these events was reviewed by VHA patient safety experts to determine the root cause and the impact on all Veterans affected as well. Moreover, since VA deployed the new EHR at Mann-Grandstaff almost 2 years ago, VA has taken many steps to significantly reduce risk to patients as we move forward with deployments. These steps include dispatching teams to Mann-Grandstaff to focus on issues of concern, significant changes to the system, training and processes supporting deployments and completion of a department wide strategic review in November 2021 that led to the appointment of new program leadership and a better understanding of the elements required for successful deployments.

(*Original signed by*:)/s/

Donald M. Remy

Attachments

VA Response Attachment

From: VA EHRM SYSTEM ALERTS <VAEHRMSYSTEMALERTS@va.gov>
Sent: Thursday, September 23, 2021 1:11 PM
To: VA EHRM SYSTEM ALERTS <VAEHRMSYSTEMALERTS@va.gov>
Subject: Unknown Queue Enhancement: "VA Scheduling Location" Order Entry Format (OEF) Field Updated

Distribution: You're receiving this notice as a primary contact for your VA site. Please share this information today with all impacted end users of the electronic health record (EHR).

September 23, 2021 – Unknown Queue Enhancement: "VA Scheduling Location" Order Entry Format (OEF) Field Updated

- **What:** An "Unknown Queue" technical enhancement will filter the "VA Scheduling Location" OEF field to only populate locations that have scheduling build associated effective Sept. 23.
- **Who is impacted?** All Ordering Providers and staff assigned to monitor the new Needs Scheduling Location queue.
- **What this means for you**: Ordering Providers will now be limited to scheduling locations, rather than the whole list. If a desired location is not present, that means there is no scheduling build associated with that location, and the scheduling build will need to be added via the ticketing process to route it to the appropriate scheduling request queue. A new queue has also been created to manage the "VA Needs Location" requests called "VA Needs Scheduling Location Request Queue" and will be monitored by the identified group.
- **Why**: Orders with the wrong scheduling location will route to the Unknown Queue. This change will significantly reduce the volume of incorrect location selections which contributes to unknown requests.
- **Training Resources:** Access the VA Unknown Queue – VA Scheduling Location Sheet is available on the Unknown_Queue_Mann_Grandstaff_SharePoint and the Unknown_Queue_Remote_Site_SharePoint for additional information.

If you have questions, contact the Service Desk at 855-673-4357, option 6.

Office of the Deputy Secretary Response

Recommendation 1

The Deputy Secretary reviews the process that led to Cerner's failure to inform VA of the unknown queue and takes action as indicated.

Concur.

Target date for completion: Complete

Deputy Secretary Comments

Upon learning of the patient safety concerns raised about the unknown queue, VA immediately reviewed the process to identify any failures. VA determined that there were configuration and location changes that should have been made previously and immediately implemented those changes and communicated the developed enhancements. VA also determined that additional training materials regarding maintenance of the unknown queue were required and developed such materials to incorporate into sustainment training.

As a result of the review, VA is closely monitoring Cerner's actions to build out more scheduling locations and communicate those enhancements to all stakeholders.

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 2

The Deputy Secretary evaluates the unknown queue technology and mitigation process and takes action as indicated.

Concur.

Target date for completion: Complete

Deputy Secretary Comments

VA has closely evaluated the issues that caused orders to be routed to the unknown queue and worked with VHA to develop business processes to resolve the issues caused by orders that cannot be fulfilled.

Upon identification of the unknown queue technology, VA provided a Functional Support Team (FST) on site in Mann-Grandstaff that conducted a comprehensive review of the unknown orders and established mitigation actions. As a result of lessons learned from identification of the

unknown queue in Mann-Grandstaff, Veterans Integrated Service Network 20 Electronic Health Record Modernization Deployment Leaders worked with facilities to establish an oversight process to ensure daily monitoring of the unknown queues are tracked and acted upon. This oversight process includes staff training and redundancies in staff designation of oversight three deep (1 primary and 2 backup staff) to ensure consistent review of the unknown queues. This was put into place prior to go-live at the Walla Walla, Roseburg and White City facilities and will be established for the Boise go-live scheduled in July 2022.

In the future, VA and Cerner will continue to work with each site to identify the individuals that will monitor the queues, provide training, determine appropriate access needed and ensure the site has a process in place prior to go-live.

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

OIG Contact and Staff Acknowledgments

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