February 2021

ELECTRONIC HEALTH RECORDS

VA Has Made Progress in Preparing for New System, but Subsequent Test Findings Will Need to Be Addressed

Accessible Version

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ELECTRONIC HEALTH RECORDS

VA Has Made Progress in Preparing for New System, but Subsequent Test Findings Will Need to Be Addressed

Why GAO Did This Study

VA relies on its health information system— the Veterans Health Information Systems and Technology Architecture (VistA)—to deliver health care to 9 million patients annually. VistA contains the department's EHR and exchanges information with many other applications and interfaces. However, VistA is a technically complex system, has been in operation for more than 30 years, is costly to maintain, and does not fully support VA's needs. In May 2018, VA contracted to acquire a commercial EHR system as part of its EHRM program over 10 years at a maximum cost of $10 billion.

GAO was asked to review VA's EHR deployment. This report discusses progress VA is making on implementing the new EHR system, among other topics.

To perform its review, GAO assessed VA's progress toward making system configuration decisions, developing system capabilities, developing system interfaces, completing end user training, and resolving system test findings. GAO also interviewed relevant officials.

What GAO Recommends

GAO is making two recommendations, including that VA should postpone deployment of its new EHR system at planned locations until any resulting critical and high severity test findings are appropriately addressed.

VA concurred with the recommendations and described actions the department plans to take to address them.

What GAO Found

In an October 22, 2020, briefing, GAO informed Congressional staff that the Department of Veterans Affairs (VA) had made progress toward implementing its new electronic health record (EHR) system by making system configuration decisions, developing system capabilities and system interfaces, conducting end user training, and completing system testing events. However, GAO noted that the department had not yet resolved all critical severity test findings (that could result in system failure) and high severity test findings (that could result in system failure, but have acceptable workarounds), as called for in its testing plan. Specifically, 17 critical severity test findings and 361 high severity test findings remained open as of late September 2020. As a result, VA was at risk of deploying a system that did not perform as intended and could negatively impact the likelihood of its successful adoption by users if these test findings were not resolved prior to initial deployment. Accordingly, GAO recommended that VA delay deployment of the new EHR until the (1) critical severity test findings were closed, and (2) high severity findings were closed or otherwise addressed with workarounds.

VA deployed its new EHR system in Spokane, Washington, on October 24, 2020, with no open critical severity test findings and with 306 of the 361 high severity test findings closed (see figure). Of the 55 remaining, 47 had workarounds that were accepted by the user community, seven were associated with future deployments, and one had a solution identified at the time of initial deployment. VA's actions reflect implementation of GAO's October recommendations.

The Department of Veterans' Affairs Electronic Health Record Modernization Open Critical and High Severity Test Findings May 2020-October 2020

Number of residual test findings
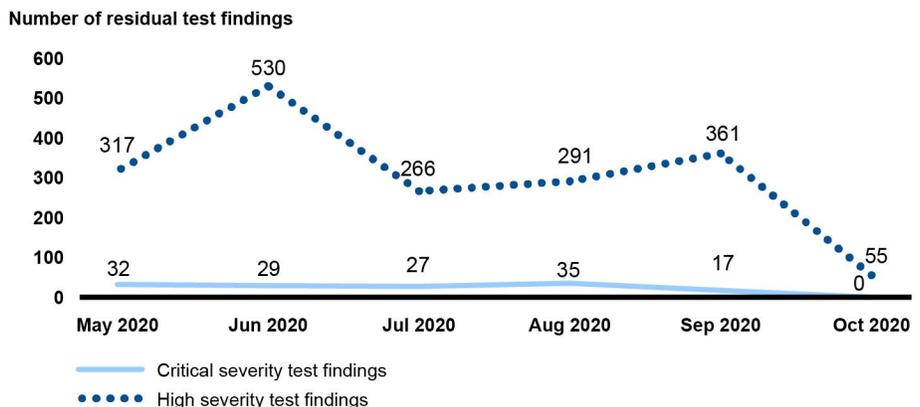
Source: Department of Veterans Affairs' test finding exports from May 2020-October 2020. | GAO-21-224

Nevertheless, as the department moves forward with deployment of additional capabilities at new locations, VA will likely identify new critical and high severity test findings. If VA does not close or appropriately address all critical and high severity test findings prior to deploying at future locations, the system may not perform as intended.

United States Government Accountability Office

Contents

Abbreviations

Cerner	Cerner Government Services, Inc.
CSS	Centralized Scheduling Solution
DOD	Department of Defense
EHR	electronic health record
EHRM	Electronic Health Record Modernization
VA	Department of Veterans Affairs
OEHRM	Office of Electronic Health Record Modernization
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture

February 11, 2021

Congressional Committees

Within the Department of Veterans Affairs (VA), the Veterans Health Administration (VHA) operates one of the nation's largest health care systems, serving about 9 million patients annually. VA's health information system—the Veterans Health Information Systems and Technology Architecture (VistA)—has long been essential to the department's ability to deliver health care to veterans. VistA contains the department's electronic health record (EHR) and exchanges information with many other applications and interfaces, such as the department's time and attendance program and its billing system.[1]

However, our prior work has found that this technically complex system, which has been in operation for more than 30 years, is costly to maintain and does not fully support VA's need to electronically exchange health records with other organizations, such as the Department of Defense (DOD) and private health care providers.[2] In 2015, we designated VA health care as a high-risk area for the federal government, in part due to its information technology challenges.[3]

In June 2017, VA announced the decision to acquire a commercial EHR system from Cerner Government Services, Inc. (Cerner). This new system was to be a configuration of the same system that DOD is in the

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[1]An electronic health record (EHR) is a collection of information about the health of an individual and the care provided to that individual, such as patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.

[2]See for example GAO, *Electronic Health Records: VA Needs to Identify and Report System Costs*, GAO-19-125 (Washington, D.C.: July 25, 2019). Over the last several decades, VistA has evolved into a technically complex system that supports health care delivery at more than 1,500 VA facilities, including VA medical centers, outpatient clinics, community living centers, and VA vet (readjustment counseling) centers.

[3]VA's information technology issues were highlighted in our 2015 high-risk report and in subsequent high-risk reports. See GAO, *High-Risk Series: An Update*, GAO-15-290 (Washington, D.C.: Feb. 11, 2015); *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, GAO-17-317 (Washington, D.C.: Feb. 15, 2017); and *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: Mar. 6, 2019).

process of implementing.[4] In May 2018, VA signed a contract with Cerner for a maximum amount of $10 billion over 10 years to acquire the system as part of its Electronic Health Record Modernization (EHRM) program. The department planned to deploy the system across its health care network of more than 1,500 medical facilities, including VA Medical Centers, outpatient clinics, community living centers, and VA vet centers. In June 2018, it established the Office of Electronic Health Record Modernization (OEHRM) to plan and implement the program.

The conference report accompanying the Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2019 included a provision for GAO to periodically review VA's EHR deployment.[5] Our specific objectives for this review were to determine (1) the progress VA is making on implementing the new EHR system and (2) the key risks and issues VA's EHRM program is facing and what steps the department is taking to address them.

On October 22, 2020, we provided a briefing on the results of our review to Congressional staff.[6] The purpose of this report is to deliver the published briefing slides to you and officially transmit our recommendations to the Secretary of Veterans Affairs. The briefing slides, which detail our audit scope and methodology, are reprinted in appendix I.

In performing our work for the briefing, among other steps, we reviewed VA's plans for deploying the new EHR system and compared the plans to activities performed by the department. We also analyzed information from EHRM test reports from August 2019 through September 2020. We relied on the analysis to gauge progress toward addressing system testing and the resolution of test findings, and to identify trends in the test findings, including the number of open and closed test findings by severity per month. We then compared the trends in test finding data to

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[4]Cerner is a health care information technology company based in Kansas City, Missouri, that provides clinical solutions, services, devices, and hardware. VA refers to its configuration of the Cerner EHR system as Cerner Millennium, whereas DOD refers to its configuration of the system as Military Health System (MHS) Genesis.

[5]H. Rpt. 115-929 at 265 (Sept. 10, 2018) accompanying Energy and Water, Legislative Branch, and Military Construction and Veterans Affairs, Appropriations Act, 2019, Pub. L. No. 115-244, 132 Stat. 2897, 2961 (Sept. 21, 2018).

[6]The Senate Committee on Veterans Affairs was not an addressee on the October 22, 2020, briefing, but subsequently requested to be included as an addressee for this report.

requirements for closing test findings prior to system deployment, as specified in the Joint OEHRM Master Test Plan. In addition, we reviewed EHRM risk and issue registers that included mitigation steps and action plans for addressing program risks and issues.[7]

Further, subsequent to providing the briefing, we obtained and reviewed additional information from VA regarding system test findings, which we incorporated in this report, as appropriate.[8] In addition, we compiled supplemental information, including a timeline detailing the chronology of changes in VA's EHRM deployment schedule and approach, which is included as appendix II.

We conducted this performance audit from October 2020 to January 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

VA Made Progress in Preparing for a New System, but Has Not Closed Key System Test Findings

As we reported in our briefing to the Congressional Committees' staffs, as of late September 2020, VA had made progress toward implementing its new EHR system by making necessary system configuration decisions. Also, the department had developed system capabilities and interfaces, in addition to conducting end user training. Further, VA had completed planned system tests.

Nevertheless, while VA had completed its planned tests of the EHR system, as of late September 2020, the department had not resolved all open critical severity and high severity test findings, as called for in the

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[7]OEHRM defines risks as uncertain events which, if they occur, can have a negative impact on the program, and issues as risks that have become a reality and are expected to negatively impact the program.

[8]Errors encountered during system testing are commonly referred to as defects. OEHRM refers to them as test findings.

Joint EHRM Master Test Plan.[9] Specifically, 17 critical severity test findings and 361 high severity test findings had yet to be closed. As a result, VA was at risk of deploying a system that did not perform as intended and could negatively impact the likelihood of its successful adoption by users if these test findings were not resolved prior to initial deployment. Accordingly, we recommended that VA delay deployment of the new EHR until the (1) critical severity test findings were closed and (2) high severity findings were closed or deferred with workarounds approved by the user community.

Subsequent to our briefing in October 2020, VA provided us with updated test finding data, which indicated that it had taken actions consistent with our recommendations. Specifically, the department had closed all of the critical severity test findings prior to the first deployment of the new EHR in Spokane, Washington, on October 24, 2020. Additionally, the department closed 306 of the 361 high severity test findings. Of the 55 that remained open at the time of initial deployment:

- forty-seven were deferred with accepted workarounds by the user community and would be closed at a later date;

- seven were associated with capabilities that were planned for later deployment and did not need to be closed prior to the initial deployment; and

- one was in a fixed status, meaning it was not closed, but a solution had been identified.

VA's actions reflect implementation of our October recommendations. Figure 1 indicates the number of open critical and high severity test findings for the EHRM program between August 2019 and October 2020.

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[9]According to the EHRM Master Test Plan, test findings confirmed to be valid are set to an open status and assigned a severity level. Test findings confirmed to be resolved with no other problems or errors introduced as a result of the resolution are set to a status of closed.

Figure 1: Department of Veterans' Affairs Electronic Health Record Modernization Open Critical and High Severity Test Findings, August 2019-October 2020

Number of residual test findings
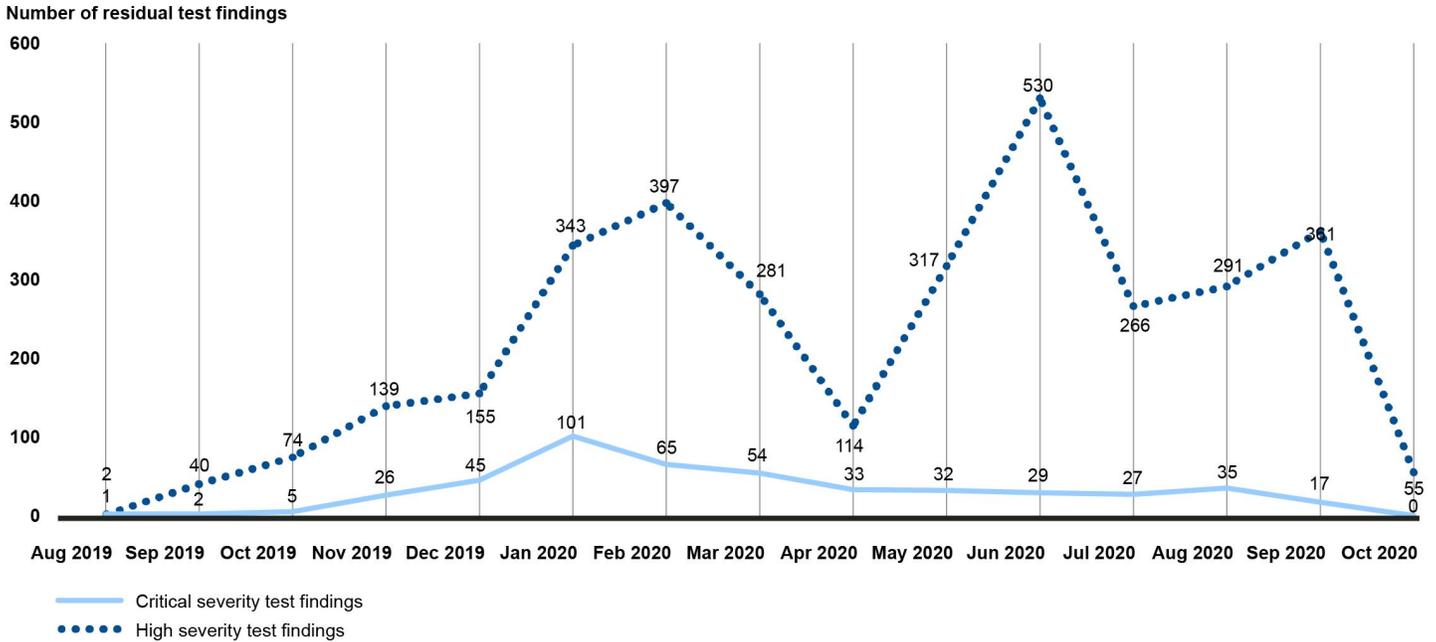
Source: Department of Veterans Affairs' test finding exports from August 2019-October 2020. | GAO-21-224

VA is planning its next system deployment at the Puget Sound Health Care System in the fourth quarter of fiscal year 2021.[10] Testing of additional capabilities prior to that and other future deployments will likely result in the identification of new critical and high severity test findings. If OEHRM does not address the 55 open high severity test findings and any additional critical severity or high severity test findings identified prior to future deployments, the system may not perform as intended and may negatively impact the likelihood of its successful adoption by users.

OEHRM Has Identified Program Risks and Issues and Steps to Address Them

OEHRM identified key risks and issues that could affect the success of the EHRM program. The office defines risks as uncertain events, which, if they occur, can have a negative impact on the program; and it defines

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[10]The Puget Sound Health Care System includes two divisions, Seattle and American Lake. VA manages the two divisions in an integrated manner.

issues as risks that have become a reality and are expected to negatively impact the program.

As of early October 2020, the department had identified 130 open risks and 45 open issues, and had prioritized them based on their potential impact to the program. In addition, OEHRM was maintaining registers to track the open risks and issues, consistent with its risk management plan. The registers also included mitigation plans to address open risks and action plans to address open issues.

Among the risks and issues that the program closed were the following:

- OEHRM identified a risk related to patient scheduling, noting that if the primary care team were unable to change the availability of staff without entering a work ticket, then there would be a very high likelihood of a delay to patient scheduling and care. The inability to change staff availability time could have had a very high impact on the providers' productivity. OEHRM mitigated this risk by confirming with the contractor that modifying availability times would be possible. Cerner provided a demonstration of the new scheduling workflow that allowed the ability to adjust staff availability time in the new system; thus, this risk was closed in September 2020.

- OEHRM identified an issue regarding VHA's and the Office of Information and Technology's lack of a completed joint implementation plan for the new medical logistics system. The lack of such a plan placed VA at risk of not meeting its obligation to have this system fielded in production 120 days prior to the new EHR deployment. Among the actions taken to close this issue, the Secretary of VA approved the recommendation for adoption of an enterprise-wide solution and the Joint Medical Logistics Functional Development Center reviewed and approved the implementation plan. According to the OEHRM Risk Lead, this issue was closed prior to having any significant impact on the program. The program closed this issue in August 2019.

Conclusions

VA made progress in preparing for the deployment of the new EHR by, for example, making system configuration decisions, developing system capabilities and system interfaces, conducting end user training, and completing system testing events. In addition, the department had taken

actions consistent with our October 2020 recommendations calling for it to resolve existing critical and high severity test findings at the time of initial EHR system deployment. Nevertheless, 55 high severity test findings remained open and additional testing of the system in advance of future deployments will likely lead to the identification of new critical and high severity test findings. If the department does not address these findings prior to deployments, it risks deploying a system that does not perform as intended.

Further, OEHRM identified key risks and issues that could negatively impact the program's cost, schedule, and performance, in accordance with its risk management plan. The office was maintaining registers to track open risks and issues and their associated mitigation plans.

Recommendations for Executive Action

We are making the following two recommendations to VA:

- The Secretary of VA should direct the Executive Director of the Office of Electronic Health Record Modernization to postpone deployment of the new EHR in new locations until all existing open critical severity test findings are resolved and closed, and until any additional critical severity findings identified before planned deployment are closed. (Recommendation 1)

- The Secretary of VA should direct the Executive Director of the Office of Electronic Health Record Modernization to postpone deployment of the new EHR in new locations until all existing open high severity test findings are either resolved and closed or deferred, and until any additional high severity test findings identified before planned deployment are either closed or deferred. (Recommendation 2)

Agency Comments and Our Evaluation

VA provided written comments on a draft of this report, which are reproduced in appendix III. In its comments, the department said it concurred in principle with our recommendations to resolve and close critical severity and high severity test findings prior to future EHR deployments; it also described actions it plans to take to address the recommendations. Specifically, VA stated that it plans to continue to test and appropriately adjudicate all critical severity and high severity test

findings prior to future deployments. The department added that it plans to resolve and close all critical severity and high severity test findings by January 2022.

The department also provided technical comments on our report, which included suggested changes to the report title and recommendations. We considered these suggested changes, but did not adopt them because we believe the tone and substance of the report title and our recommendations are appropriate, as presented.

We are sending copies of this report to interested congressional committees and the Secretary of Veterans Affairs. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staffs have any questions on the matters discussed in this report, please contact me at (202) 512-4456 or at harriscc@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

Carol C. Harris
Director, Information Technology Management Issues

List of Committees

The Honorable Jon Tester
Chairman
The Honorable Jerry Moran
Ranking Member
Committee on Veterans' Affairs
United States Senate

Ranking Member
Committee on Veterans' Affairs
United States Senate

Chair
Ranking Member
Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Debbie Wasserman Schultz
Chairwoman
The Honorable John Carter
Ranking Member
Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Committee on Appropriations
House of Representatives

Chair
Ranking Member
Subcommittee on Technology Modernization
Committee on Veterans' Affairs
House of Representatives

Appendix I: Briefing for Staff Members of Congressional Committees

GAO

Veterans Affairs: Progress Made in Preparing for a New Electronic Health Record System, but Key Activities Need to be Completed Prior to Deployment

Presented to Staff Members of the

Subcommittee on Military Construction, Veterans Affairs, and Related Agencies, Committee on Appropriations, United States Senate

Subcommittee on Military Construction, Veterans Affairs, and Related Agencies, Committee on Appropriations, House of Representatives

Subcommittee on Technology Modernization, Committee on Veterans' Affairs, House of Representatives

October 22, 2020

1

GAO

Table of Contents

2

GAO

Introduction

Within the Department of Veterans Affairs (VA), the Veterans Health Administration (VHA) operates one of the nation's largest health care systems, serving 9 million patients annually. VA's health information system—the Veterans Health Information Systems and Technology Architecture (VistA)—has been essential to the department's ability to deliver health care to veterans. VistA contains the department's electronic health record (EHR) and exchanges information with many other applications and interfaces, such as a time and attendance program and billing system.[1]

However, our prior work has found that this technically complex system, which has been in operation for more than 30 years, is costly to maintain and does not fully support VA's need to electronically exchange health records with other organizations, such as the Department of Defense (DOD) and private health care providers.[2] In 2015, we designated VA health care as a high-risk area for the federal government, in part due to its information technology challenges.[3]

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[1]An electronic health record (EHR) is a collection of information about the health of an individual and the care provided to that individual, such as patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.

[2]See for example GAO, *Electronic Health Records: VA Needs to Identify and Report System Costs*, GAO-19-125 (Washington, D.C.: July 25, 2019). Over the last several decades, VistA has evolved into a technically complex system that supports health care delivery at more than 1,500 VA facilities, including VA medical centers, outpatient clinics, community living centers, and VA vet (readjustment counseling) centers.

[3]VA's information technology issues were highlighted in our 2015 high-risk report and in subsequent high-risk reports. See GAO, *High-Risk Series: An Update*, GAO-15-290 (Washington, D.C.: Feb. 11, 2015); GAO, *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, GAO-17-317 (Washington, D.C.: Feb. 15, 2017); and GAO, *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: Mar. 6, 2019).

3

GAO

Introduction

In June 2017, VA announced the decision to acquire a commercial EHR system from Cerner Government Services, Inc. (Cerner)—a configuration of the same system that DOD is in the process of implementing.[4]

In May 2018, VA signed a contract with Cerner for a maximum amount of $10 billion over 10 years to acquire its commercial EHR system as part of its Electronic Health Record Modernization (EHRM) program. VA planned to deploy the system across its health care system of more than 1,500 medical facilities, including VA Medical Centers, outpatient clinics, community living centers, and VA vet centers.

In June 2018, VA established the Office of Electronic Health Record Modernization (OEHRM) to plan and implement the program.

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[4]Cerner is a health care information technology company based in Kansas City, Missouri, that provides clinical solutions, services, devices, and hardware. VA refers to its configuration of the Cerner EHR system as Cerner Millennium, whereas DOD refers to its configuration of the system as Military Health System Genesis.

4

GAO

Objectives

The conference report accompanying the Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2019 contains a provision for GAO to review VA's EHR deployment to keep Congress apprised of VA's progress.[5]

Our objectives were to:

1. determine the progress VA is making on implementing the new EHR system, and

2. determine the key risks and issues VA's EHRM program is facing and what steps the department is taking to address them.

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[5]H. Rpt. 115-929 at 265 (Sep. 10, 2018) accompanying Energy and Water, Legislative Branch, and Military Construction and Veterans Affairs, Appropriations Act, 2019, Pub. L. No. 115-244, 132 Stat. 2897, 2961 (Sept. 21, 2018).

5

GAO

Scope and Methodology

For the first objective, we determined VA's progress toward making system configuration decisions, developing system capabilities, developing system interfaces, completing end user training, and resolving system test findings.

- To determine progress on system configuration decision making, we observed national workshops that OEHRM held. We also reviewed presentations from these workshops, reviewed our recent report on EHRM system configuration decisions, and analyzed data on system configuration decisions obtained from the program office.[6]

- To determine progress on system capability development, we reviewed EHRM program documentation describing system capabilities and OEHRM progress briefings related to the status of the development of system capabilities and the need for workarounds for certain capabilities.

- To determine progress in developing system interfaces, we reviewed the Joint EHRM Master Test Plan and the Draft OEHRM System Interface Deployment Readiness Guide. We also analyzed test results and status briefings for system interfaces.

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[6]GAO, *Electronic Health Records: Ongoing Stakeholder Involvement Needed in the Department of Veterans Affairs' Modernization Effort*, GAO-20-473 (Washington, D.C.: June 5, 2020).

6

GAO

Scope and Methodology

- To determine progress in completing end user training, we reviewed the OEHRM training strategy and plans for training end users at initial deployment locations. We also reviewed progress reports that included the status of user training at locations in Columbus, Ohio, and Spokane, Washington.

- To gauge progress toward addressing system testing and the resolution of test findings, we obtained and analyzed summary test reports from test events that occurred from August 2019 through September 2020, and compared them to information outlined in the Joint OEHRM Master Test Plan. We also analyzed information from EHRM test reports to identify trends in the test findings, including the number of open and closed test findings by severity per month. We assessed the reliability of the test finding data by reviewing it for obvious errors and missing data and interviewed responsible officials about any discrepancies in the data. We determined the data to be sufficiently reliable for the purposes of this report.

7

GAO

Scope and Methodology

For the second objective, we analyzed relevant documentation, such as the OEHRM Risk Management Plan and OEHRM Risk and Issue Registers.[7] In addition, we obtained and analyzed the risk and issue registers and compared information in the registers to information outlined in the OEHRM Risk Management Plan. We also reviewed action plans and mitigation steps that VA developed and undertook to address program risks and issues.

We supplemented our analyses for both objectives with interviews of relevant VA officials, including the OEHRM Executive Director, Chief Medical Officer, and Chief Technology Integration Officer as well as staff at initial deployment locations in Spokane and Seattle, Washington. The results of these interviews are not generalizable to all VA staff.

We conducted this performance audit from April 2019 through October 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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[7]OEHRM defines risks as uncertain events which, if they occur, can have a negative impact on the program, and issues as risks that that have become a reality and are expected to negatively impact the program.

8

GAO

VA has made progress toward implementing its new EHR system by making system configuration decisions, developing system capabilities and system interfaces, conducting end user training, and completing system testing events. However, the department has not yet resolved all critical and high severity test findings as called for in its testing plan. As a result, VA is at risk of deploying a system that does not perform as intended and may negatively impact the likelihood of its successful adoption by users if these test findings are not resolved prior to initial deployment on October 24, 2020.

OEHRM has identified key risks and issues that could affect the success of the EHRM program. As of early October 2020, the department had identified 130 open risks and 45 open issues, and prioritized them based on their potential impact to the program. In addition, OEHRM is maintaining registers to track the open risks and issues and their mitigation plans, consistent with its risk management plan.

We are recommending that VA delay deployment of its new system until all critical and high severity test findings are resolved.

In commenting on a draft of this briefing, VA's Acting Assistant Secretary for the Office of Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, neither agreed nor disagreed with our conclusions and recommendations. The official stated, however, that the department is on track for the scheduled implementation of its new EHR system on October 24, 2020, at the Mann-Grandstaff VA Medical Center in Spokane, Washington.

Nevertheless, implementation of our recommendations will remain important as VA works toward future deployments of its new EHR.

9

GAO

Background

VistA Is VA's Longstanding EHR System

To facilitate care, clinical providers access patient medical records and document the care they provide in EHR systems. Patient information needs to be accessible and consistent to prevent risks to patients' safety, particularly when shared between providers. Information that is electronically exchanged from one provider to another must adhere to the same standards to be consistently interpreted and used in EHRs. In our prior work, we found that EHR technology has the potential to improve the quality of care that patients receive and to reduce health care costs.[8]

VistA has served as VA's EHR system for more than 30 years. Over the last several decades, it has evolved into a technically complex system comprised of about 170 modules that support health care delivery at more than 1,500 medical facilities.[9] In addition, customization of VistA, such as changes to the modules by the various medical facilities, has resulted in approximately 130 versions of the system VA-wide.

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[8]See GAO, *Electronic Health Records: Outcome-Oriented Metrics and Goals Needed to Gauge DOD's and VA's Progress in Achieving Interoperability*, GAO-15-530 (Washington, D.C.: Aug. 13, 2015).

[9]VistA products or modules can also be composed of one or more software applications that support health care functions, such as providing care coordination and mental health services.

10

GAO

Background

VA Plans to Replace VistA with Cerner's EHR

VA's contract with Cerner for its commercial EHR includes the purchase of Millennium, Cerner's core EHR system, as well as HealtheIntent, a cloud-based software platform that aggregates health data from multiple data sources to create a longitudinal patient record.[10] In addition, Millennium includes a patient scheduling module—known as the Centralized Scheduling Solution (CSS)—that is intended to increase scheduling efficiency and ensure veterans' timely access to care. VA's contract with Cerner also includes requirements to conduct reviews and assessments of medical facilities to determine facility needs prior to deployment (e.g., technology infrastructure); provide services, including project management, change management, training, and testing; and host and deploy EHRM across the VA enterprise.

Before VA transitions from VistA to the commercial EHR system, the department will have to make design configuration decisions, such as determining all the data that need to be incorporated into the EHR system. Such configuration decisions are intended to enable the system to support the work processes that VA clinicians and staff follow in delivering care. Further, the department has to assess the compatibility of the EHR system with the processes that clinicians and staff use to deliver care.

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[10]A cloud-based service can allow an agency to pay for only the information technology services used, when executed effectively.

11

GAO

Background

The original schedule for EHRM called for initial deployment[11] in March and April 2020 at sites within VHA's Veterans Integration Service Network 20 (VISN 20).[12] These initial deployment sites were the Mann-Grandstaff VA Medical Center in Spokane, Washington, and the VA Puget Sound Health Care System in Seattle, Washington.[13]

Chronology of Changes in EHRM Deployment Schedule and Approach

VA's schedule and approach to deploying EHRM has undergone multiple changes since July 2019.

- In July 2019, VA accelerated the deployment of CSS as part of the EHRM effort. The schedule for beginning its deployment was moved from fiscal year 2023 to April 2020. The initial pilot of CSS was to occur at the Chalmers P. Wylie Ambulatory Care Center in Columbus, Ohio.

- In August 2019, VA changed its plans to initially deploy the new EHR in March and April 2020, to deploy in two phases, known as capability sets 1.0 and 2.0. Capability set 1.0 was to deploy in

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[11]Initial deployment represents the system functionality that will be in place at the implementation of the new EHR at the first VA medical center where it is implemented. Additionally, the community-based outpatient clinics using that VA medical facility's version of VistA will provide care using the new EHR once it is implemented.

[12]VHA is divided into areas called Veterans Integration Service Networks (VISNs). There are currently 18 VISNs throughout VHA based on geographic location. VISNs provide oversight and guidance to the VA Medical Centers and VA Health Care Systems within their area and are sometimes called a "network." VISN 20 includes medical centers and community-based outpatient clinics in the states of Alaska, Washington, Oregon, most of Idaho, and one county each in Montana and California.

[13]The Puget Sound Health Care System includes two divisions, Seattle and American Lake. VA manages the two divisions in an integrated manner.

12

GAO

Background

March 2020 in Spokane, Washington, and capability set 2.0 was to deploy in November 2020 in Puget Sound, Washington.

- o Capability set 1.0 includes key EHR functionalities necessary to implement the system at a less complex facility.

- o Capability set 2.0 includes capability set 1.0 functionalities and remaining functionalities necessary to implement the system at a highly complex facility.

- In February 2020, VA postponed the initial deployment of the new EHR at the Spokane location until July 2020, in order to establish a more complete training environment and build interfaces between the EHR system and other VA systems.

  - o While the training environment and interfaces were being completed, VA announced that it would be able to add additional veteran-facing functionality to capability set 1.0 (e.g., consolidated mail order pharmacy and online prescription refill), known as capability set 1.1.

13

GAO

Background

- In March 2020, VA paused initial deployment of EHRM to focus the department's response on the Coronavirus Disease 2019 (COVID-19). The Secretary directed the EHRM program to limit contact with the clinicians who had been participating in the program's activities to allow the clinicians to focus on caring for veterans.

- In May 2020, VA changed the deployment approach for EHRM and announced that it would focus its efforts on deploying CSS in Columbus, Ohio, due to COVID-19 cases in Spokane, Washington. OEHRM began the deployment of CSS in Columbus, Ohio, in August 2020.

- In August 2020, VA announced a new timeline for further deploying EHRM. Specifically, the department announced plans to deploy capability set 1.1 in locations within VISNs 20 and 10[14] through fiscal year 2022; the first location is to be in Spokane, Washington, on October 24, 2020. The department plans to deploy capability set 2.0 in Seattle, Washington, in the fourth quarter of fiscal year 2021.

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[14]VISN 10 includes medical centers and community-based outpatient clinics throughout the lower peninsula of Michigan, Ohio, Northern Kentucky, and Indiana.

14

GAO

Background

EHRM Costs

In addition to the $10 billion contract signed with Cerner, the cost estimate for EHRM included $4.3 billion for technology infrastructure readiness (e.g., modifications to legacy systems and wired and wireless networks) and $1.8 billion for program management support—a total life cycle cost of $16.1 billion for the EHRM program over 10 years.

VA has reported spending about $3.3 billion on EHRM from fiscal year 2018 through fiscal year 2020 in three areas—the Electronic Health Record Contract ($2.1 billion), Infrastructure Readiness ($750 million), and Program Management ($363 million). This amount does not include money spent by VA components that have been supporting OEHRM. For example, VHA is responsible for upgrades to physical infrastructure, while the Office of Information and Technology (OIT) is responsible for modifications to legacy information technology systems that are to interface with EHRM.

VA Office of Inspector General and GAO Have Recently Reported on EHRM

In April 2020, VA's Office of Inspector General (OIG) reported on infrastructure readiness at the Spokane, Washington, deployment location.[15] The OIG reported findings related to deficient supporting infrastructure and inadequate safeguarding of critical physical infrastructure. In responding

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[15]VA Office of Inspector General, *Deficiencies in Infrastructure Readiness for Deploying VA's New Electronic Health Record System* (Washington, D.C.: Apr. 27, 2020); and *Review of Access to Care and Capabilities during VA's Transition to a New Electronic Health Records System at the Mann-Grandstaff VA Medical Center Spokane, Washington* (Washington, D.C.: Apr. 27, 2020).

15

GAO

Background

to the findings, OEHRM stated that VHA, OIT, and OEHRM agreed that the infrastructure will meet the minimum required capabilities at deployment. Additionally, OEHRM responded that it and VHA had incorporated elements of physical security into planning and assessment documents for future facilities. The Spokane Medical Center Director added that the security issues identified in the OIG's draft report were being addressed and anticipated the issues to be resolved before deployment.

In June 2020, we reported on the system configuration process for EHRM.[16] We noted that VA's decision-making procedures were generally effective, but did not always ensure key stakeholder involvement. For example, according to clinicians at the two medical facilities planned for initial deployment, VA did not always effectively communicate information to stakeholders, including medical facility clinicians and staff, to ensure relevant representation at local workshop meetings.[17] As a result, local workshops did not always include all relevant stakeholders.

We recommended that VA ensure the involvement of all relevant medical facility stakeholders in the EHR system configuration decision process. VA concurred with our recommendation and stated that it intended to further refine local workshop agendas and descriptions to facilitate subject matter expert identification and participation.

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[16]GAO-20-473.

[17]National workshops are integrated sessions during which VA and Cerner iteratively design, build, and validate the configuration of the EHR system. Local workshops generally follow the topics and structure of the national workshops, but are tailored to local VA facilities.

16

GAO

Objective 1 – Progress in Implementing New EHR

VA Has Taken Steps toward Implementing Its New Electronic Health Record System, but Has Not Resolved Key System Test Findings

VA has taken steps toward implementing its new EHR by making system configuration decisions to inform system capability needs, developing system capabilities and system interfaces, conducting user training, and completing system testing events. However, the department has not yet resolved all critical and high severity test findings.

System Configuration Decisions

OEHRM planned to create working groups comprised of subject matter experts from both clinical and functional (i.e., business) areas to work with Cerner to provide input and recommendations for developing and validating standard workflows to be used to configure the system.[18]

In fall 2018, OEHRM established the working groups in the form of 18 EHR councils, to make VA-specific EHR system configuration decisions for specific clinical and administrative areas. The councils held eight national workshops from November 2018 to October 2019, to participate in making EHR system configuration decisions (i.e., developing and validating workflows). As we previously reported, as of March 2020, the councils had made almost all of the decisions necessary

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[18]Workflows are "process maps" designed to capture the start-to-finish sequence and interactions of related steps, activities, and tasks for each work process.

17

GAO

Objective 1 – Progress in Implementing New EHR

for the deployment of capability set 1.0 of the new EHR at Spokane, Washington.[19] As of late September 2020, OEHRM reported that all workflows for capability sets 1.0 and 1.1 had been approved by the Chief Medical Officer.

OEHRM officials reported that workflow decisions for capability set 2.0—which had been planned to be completed by May 2020—were delayed due to COVID-19. Specifically, the officials stated that EHR council members were unable to meet for 4 to 6 months to make system configuration decisions necessary for capability set 2.0. According to OEHRM, as of September 2020, 170 of 337 workflows (50.4 percent) had been approved for capability set 2.0. The EHR councils with the highest numbers of workflows remaining to be approved were the Ambulatory, Rehabilitation and Acute Clinical Ancillaries, and Acute Provider councils.[20]

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[19]GAO-20-473.

[20]The Ambulatory council is responsible for developing workflows for primary care, women's health, oncology, specialty care, and health maintenance. The Rehabilitation and Acute Clinical Ancillaries council is responsible for developing workflows for rehabilitation, nutrition, chaplain services, and social work. The Acute Provider council is responsible for developing workflows for inpatient care performed by physicians, nurse practitioners, and physician assistants.

18

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Objective 1 – Progress in Implementing New EHR

System Capabilities Development

VA identified 312 total capabilities that it plans to deploy as part of its new EHR system. The department plans to deploy 216 of these capabilities as part of the initial deployment of the system on October 24, 2020, for capability set 1.1 at the Mann-Grandstaff VA Medical Center in Spokane, Washington. Capability set 2.0 is expected to include 286 of the capabilities and VA intends to begin deploying them in the fourth quarter of fiscal year 2021 at the VA Puget Sound Health Care System in Seattle, Washington.

According to the OEHRM Chief Medical Officer, a small percentage (i.e., less than 10 percent) of the 216 capabilities for capability set 1.1 will not be fully developed at the time of initial deployment of the new EHR, requiring users to take additional steps—known as workarounds—to complete activities. For example, users at the sites will employ workarounds to perform activities such as accessing the Patient Centered Management Module.[21] According to the OEHRM Chief Medical Officer, the office has prioritized providing new capabilities with workarounds and expects these workarounds to be in place until capability set 2.0 is deployed.

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[21]This module allows facilities to set up and define a patient aligned care team, assign positions to the team, and assign patients to the team. According to VA, the software is considered an important tool in measuring patient demand for primary care services and primary care providers' capacity to meet that demand.

19

GAO

Objective 1 – Progress in Implementing New EHR

<u>System Interfaces Development</u>

According to OEHRM's Data Migration and Enterprise Interface Development document, a number of applications, services, medical devices, and systems will require information exchanges to provide data to, or receive data from the new EHR system.[22] In order to achieve this exchange of information, OEHRM planned to complete interfaces for each of the capability sets. Specifically, it planned to complete the following interfaces for each set:

- Capability set 1.0 – 73 new interfaces

- Capability set 1.1 – 26 new interfaces and enhancements to existing interfaces

- Capability set 2.0 – 73 new interfaces and enhancements to existing interfaces

Interfaces associated with capability sets 1.0 and 1.1 are necessary for the initial deployment of the new EHR in Spokane, Washington, in late October 2020. In addition, interfaces associated with capability set 2.0 are necessary for the new EHR deployment in Seattle, Washington, in the fourth quarter of fiscal year 2021.

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[22]Examples of systems to be interfaced to the Cerner EHR include: Master Patient Index, the primary system for assigning and maintaining unique person identifiers; Behavioral Health Laboratory, a commercial-off-the-shelf product that is used to collect mental health assessment data captured during structured interviews with patients; and Provider Profile Management System, a customized application that enables the capability for VA staff to find and view details for provider care sites.

20

GAO

Objective 1 – Progress in Implementing New EHR

As of late September 2020, VA had made progress by completing development and testing for 64 of 73 interfaces for capability set 1.0.[23] In addition, it had completed development and testing for 25 of 26 interfaces for capability set 1.1. The OEHRM Chief Technology Integration Officer reported that the office expects to complete the remaining testing needed on interfaces before the initial deployment of the new EHR in late October 2020.

OEHRM reported that interface development and testing have been underway for capability set 2.0. According to the OEHRM Chief Technology Integration Officer, development and testing for the capability set 2.0 interfaces are planned to be completed in preparation for capability set 2.0 deployment.

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[23]Five of the interfaces cannot be fully tested until after initial deployment due to effects on live data.

21

GAO

Objective 1 – Progress in Implementing New EHR

<u>End User Training</u>

According to the EHRM Training Strategy, a combination of self-paced and instructor-led training was to occur prior to initial deployment of the new EHR in Spokane, Washington, in late October 2020, for end users and super users—a subset of end users that receive enhanced training to support the program. Specifically, 143 super users and about 2,000 end users were to receive training in support of initial deployment of the new EHR in Spokane, Washington.

As of late September 2020, OEHRM reported that all 143 super users had completed training and about half of the about 2,000 end users had completed training.

22

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Objective 1 – Progress in Implementing New EHR

System Test Finding Resolution

A key element of successful system testing is appropriately resolving test findings that are discovered during testing. Open test findings can delay the release of functionality to end users, denying them the new system's benefits. Key aspects of a sound test finding management process include the planning, identification and classification, tracking, and resolution of test findings.[24]

Test finding identification and resolution is described in the Joint EHRM Master Test Plan.[25] Further, the plan categorizes test findings according to the following categories of severity:

- Critical - The test finding results in the failure of the complete software system, of a subsystem, or of a software unit (program or module) within the system.

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[24]The Project Management Institute, Inc., *A Guide to the Project Management Body of Knowledge* (PMBOK® Guide), 6th ed., (Newtown Square, Pa.: 2017); Institute of Electrical and Electronics Engineers, *Software and systems engineering* — Software testing, ISO/TEC/IEEE Std 29119 (New York, NY.: Sept. 1, 2013); Institute of Electrical and Electronics Engineers, *IEEE Standard for Software and System Test Documentation*, IEEE Std 829-2008 (New York, NY.: July 10, 2008); Institute of Electrical and Electronics Engineers, *IEEE Standard Classification for Software Anomalies*, IEEE Std 1044-2009 (New York, NY.: Jan. 7, 2010); Software Engineering Institute, *CMMI® for Acquisition*, Version 1.3 (Pittsburgh, Pa: November 2010); Software Engineering Institute, *CMMI® for Development*, Version 1.3 (Pittsburgh, Pa: November 2010).

[25]Cerner and VA, *Joint EHRM Master Test Plan*, (Washington, D.C.: July 8, 2020).

23

GAO

Objective 1 – Progress in Implementing New EHR

- High - The test finding results in the failure of the complete software system, of a subsystem, or of a software unit (program or module) within the system. There is no way to make the failed component(s) function; however, there are acceptable workarounds, which will yield the desired result.

- Medium - The test finding does not result in a failure, but causes the system to produce incorrect, incomplete, or inconsistent results, or the test finding impairs the systems usability.

- Low - The test finding does not cause a failure, does not impair usability, and the desired processing results are easily obtained by working around the test finding.

The Joint EHRM Master Test Plan stated that there should be zero open critical or high severity test findings prior to system deployment. If a high, medium, and low severity test finding cannot be resolved prior to initial deployment, it can be deferred if it has a workaround that has been accepted by the user community.

OEHRM began testing for the new EHR in August 2019 and, as of September 2020, had conducted multiple test events in accordance with its Joint EHRM Master Test Plan. For example, OEHRM conducted user functional testing at Cerner headquarters in Kansas City, Missouri, to focus on user functionality and interfaces with VA legacy systems and VA-only capability workflows that are not used by DOD. In addition, it conducted integration validation testing events in Spokane, Washington, over 2-week periods to validate local configuration against common scenarios from the location in a pre-production environment.

24

GAO

Objective 1 – Progress in Implementing New EHR

As a result of testing, OEHRM identified test findings.[26] As of late September 2020, the office had identified 9,696 total test findings and taken action to close 7,597 (78 percent) of these findings. Of the test findings that remained open, 17 were of critical severity, 361 were of high severity, and 1,368 were of medium severity.[27]

- Examples of open critical severity test findings as of September 2020 included:

  - A May 2020 test finding related to the AudioCARE interface identified because of a clinic search error where AudioCARE was unable to store data from the response.[28]

  - Two May 2020 test findings related to Whole Health identified because there were no options to complete steps and correct errors in signing orders.[29]

  - A March 2020 test finding related to Radiologist Dictation with Voice Recognition was

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[26]Errors encountered during testing are commonly referred to as defects. OEHRM refers to defects as test findings.

[27]According to the EHRM Master Test Plan, test findings confirmed to be valid are set to an 'open' status and assigned a severity level. Test findings confirmed to be resolved with no other problems or errors introduced as a result of the resolution are set to a status of 'closed'.

[28]AudioCARE provides a health information technology solution that automatically handles both inbound and outbound communications between a VA health care facility and its patients. For medication refills, the system requires the patient make a phone call, select the pharmacy refill option and manually enter their social security number as well as the prescription number(s).

[29]In 2018, VA shifted from a health care system focused primarily on treating disease to one guided by a personalized health plan that considers the physical, mental, emotional, spiritual, and environmental needs of veterans. Whole Health acknowledges that health care involves more than the physical human body.

25

GAO

Objective 1 – Progress in Implementing New EHR

identified because testing could not continue due to poor connectivity.

- Examples of open high severity test findings as of September 2020 included:

  o A September 2020 test finding related to inconsistencies when translating messages between different systems.

  o A September 2020 test finding related to an inability to check a veteran in for an appointment for surgery.

  o A July 2020 test finding related to inconsistent dates in the system when comparing dates in the patient summary and encounter summary.

Additionally, 1,368 medium severity test findings that could cause the system to produce incorrect results or impair the usability of the system remained open as of September 2020.

- Examples of open medium severity test findings included:

  o A September 2020 test finding related to a suicide flag activation note not displaying.

  o An August 2020 test finding related to data migration where immunization records listed in the VA database were not accurately migrated to the Cerner database.

  o An August 2020 test finding related to the system displaying no medications even though medications had been entered.

26

GAO

Objective 1 – Progress in Implementing New EHR

Figure 1 indicates the number of open critical, high, and medium severity test findings for the EHRM program between August 2019 and September 2020.

Figure 1: Electronic Health Record Modernization Open Critical, High, and Medium Severity Test Findings August 2019-September 2020

Number of residual test findings

	Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020
Critical	1	1		26	45	101	65	54	33	32	29	27	35	17
High	2	2	5	139	155	343	397	281	114	317	530	266	291	361
Medium		40	74	150	298	709	724	876	872	985	1,313	1,332	1,407	1,368

Critical test findings
High test findings
Medium test findings
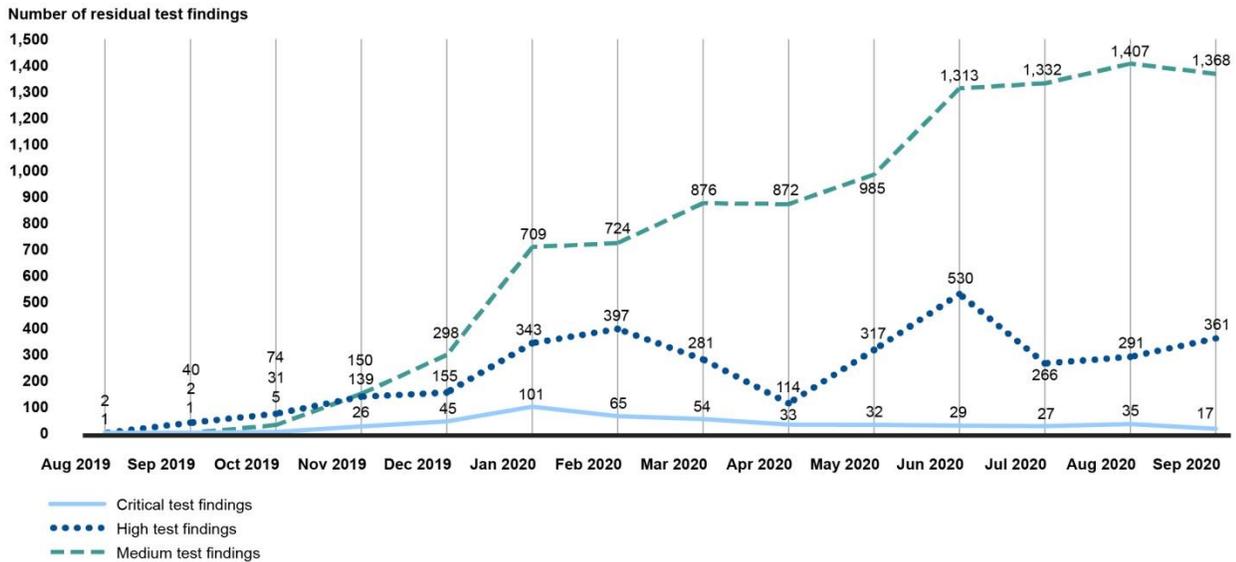
Source: OEHRM test finding exports from August 2019-September 2020.

27

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Objective 1 – Progress in Implementing New EHR

With days remaining before initial deployment, critical and high severity test findings—those that can cause a system failure—remain open. The program office is working to resolve the open test findings, including deferring 52 high severity and 538 medium severity. These deferrals mean that the findings will not be resolved until after initial deployment and that the user community has accepted the resulting workarounds. At the same time, OEHRM could identify new critical and high severity test findings in the days prior to initial deployment.

If OEHRM does not close all critical severity test findings and close or defer all high severity test findings prior to the new system's deployment, it increases the risk of system problems and potential patient safety issues. In addition, it increases the risk that users will be reluctant to adopt the new system if it does not produce expected results.

28

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Objective 2 – Risks and Issues in Implementing New EHR

OEHRM Has Identified Program Risks and Issues and Steps to Address Them

The OEHRM Risk Management Plan describes the process for identifying, assessing, and addressing risks and issues related to the EHRM program. The plan defines risks as uncertain events that, if they occur, can have a negative impact on a program's cost, schedule, or performance. In contrast, the plan defines issues as risks that have become a reality and thus, are expected to negatively impact the program's quality, schedule, budget, or scope.

OEHRM has followed its processes and maintained separate registers of the program's risks and issues, respectively, for maintaining a list of their status and tracking them to closure. These registers include information such as the title, description, and status of each risk and issue and steps taken to address them.

29

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Objective 2 – Risks and Issues in Implementing New EHR

<u>Key Risks and Mitigations</u>

Once a risk is identified, it is assessed to determine its likelihood and impact. According to the OEHRM Risk Management Plan, likelihood represents the chances of a risk occurring, and impact represents the effect of the risk, if it occurs. There are five categories of risk likelihood: very high, high, medium, low, and very low. The plan also identifies five categories of risk impact: very high, high, medium, low, and very low.

As of early October 2020, the program had identified 778 risks. Among these risks, 648 had been closed and 130 remained open.

Risks that the program had closed included the following:

- A risk identified in April 2020 related to patient scheduling stated that if the primary care team were unable to change the availability of staff without entering a work ticket, then there would be a very high likelihood of a delay to patient scheduling and care. The inability to change staff availability time could have had a very high impact on the providers' productivity. The mitigation step for this risk was to confirm with Cerner that modifying staff availability times will be possible. Cerner provided a demonstration of the new scheduling workflow that allowed the ability to adjust staff availability time in the new system and this risk was closed in September 2020.

30

GAO

Objective 2 – Risks and Issues in Implementing New EHR

- A risk identified in March 2020 stated that if COVID-19 prevented OEHRM from accessing facilities and staff, then there was a very high likelihood that progress toward deployment activities would be delayed. The mitigation steps for this risk were to create and utilize a process that allowed requests for access to facility resources. In order to mitigate this risk, OEHRM created a centralized process to communicate and work with facility resources. This risk was escalated to a moderate issue and closed in August 2020, and a new risk related to a possible second wave of COVID-19 that would prevent access to facilities was opened.

Among the 130 risks that remained open, 15 had a very high likelihood of occurring and were identified as very high impact (see table 1).

Table 1: Distribution of Open Electronic Health Record Modernization Risks

Impact	Likelihood				
	Very low	Low	Moderate	High	Very high
Very high	0	6	5	4	15
High	2	8	10	33	14
Moderate	3	1	13	7	6
Low	0	3	0	0	0
Very low	0	0	0	0	0

Source: Office of Electronic Health Record Modernization October 2020 risk export.

31

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Objective 2 – Risks and Issues in Implementing New EHR

Examples of open risks with a very high or high likelihood and very high or high impact include:

- A risk opened in September 2020 related to wildfires occurring in the areas near initial deployment sites. The wildfires could affect access to VA facilities or supporting facilities required for initial deployment, resulting in the need to adjust dates for initial deployment. The mitigation steps for this risk included reviewing the impacts at the sites on the west coast that could be affected by the wildfires and determining if any activities within the schedule can be adjusted.

- A risk opened in July 2020 related to critical open test findings related to AudioCare. This risk could lead to coding and testing being delayed for AudioCare at Spokane, Washington. The mitigation steps for this risk included testing an acceptable solution for the critical test findings.

- A risk opened in August 2020 related to outpatient pharmacy prescription labels being misaligned and formatted incorrectly. This risk could lead to unusable outpatient pharmacy labels at initial deployment sites. The mitigation steps for this risk included working with the vendor to reconfigure the automation label and the local pharmacy teams to find a solution for printer configuration.

32

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Objective 2 – Risks and Issues in Implementing New EHR

Key Issues and Steps to Address Them

After an issue has been identified, it is assessed to determine its impact on the program. The OEHRM Risk Management Plan defines the levels of impact for issues as major, moderate, or minor.

- Major impact issues result in significant increases in cost, disruption in program schedule (e.g., increment deliverable missed), degradation of performance, and/or impact on patient safety or quality of clinical care. Additional high-priority management action is required to resolve the issues.
- Moderate impact issues result in moderate increases in cost, disruption in program schedule (e.g., milestone missed, but no impact on increment deliverable), and/or degradation of performance. Special attention and management actions are required to resolve the issue.
- Minor impact issues result in little or no increase in cost, disruption in program schedule (e.g., delays easily absorbed by minor schedule adjustments), and/or loss of functionality. Actions within the planned capabilities and normal management attention should result in the resolution of the issue. No special action is required for minor impact issues, except monitoring.

33

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Objective 2 – Risks and Issues in Implementing New EHR

As of late September 2020, the program had identified 218 total issues. Of these issues, 173 had been closed and 45 remained open. Issues that the program had closed included the following:

- The program identified that VHA and OIT had not completed a joint implementation plan for the new medical logistics system, which placed VA at risk of not meeting its obligation to have this system fielded in production 120 days prior to the new EHR deployment. The program closed this major issue in August 2019. Among the actions taken to close this issue, the Secretary of VA approved the recommendation for adoption of an enterprise-wide solution and the Joint Medical Logistics Functional Development Center reviewed and approved the implementation plan. According to the OEHRM Risk Lead, this issue was closed prior to having any significant impact on the program.

- The program identified that the backlog of overdue workflow decisions was not completed as planned by the end of Workshop 8, which was held in October 2019. This backlog would have placed Cerner at risk of not completing the configuration and testing of the new EHR, impacting initial deployment. The program closed this major issue in May 2020. Among the actions taken to close this issue, Cerner provided weekly reports to OEHRM to identify overdue workflows and engaged the VA team to finish outstanding items. According to the OEHRM Risk Lead, this issue was closed prior to having any significant impact on the program.

34

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Objective 2 – Risks and Issues in Implementing New EHR

Among the open issues, 29 were designated as major impact, 15 as moderate impact, and one as minor impact as of late September 2020. Examples of the major issues that remained open included:

- The program identified as an issue in August 2019, that the solution for home-based primary care will not be developed and ready for implementation. According to the OEHRM issue register, this issue could lead to the inability to meet patient care, safety, and program accreditation standards while providing care to veterans in home-based settings. The program completed action steps to resolve this issue, which included providing the current plan for development of the solution and creating a workaround until a fully operational solution is deployed. The action step that remained to be completed as of late September 2020, was for OEHRM to provide a timeline for receiving completed coding and for placing the solution into production for VA clinicians.

- The program identified as an issue in January 2020, that Cerner was not able to provide the required functionality to manage co-payment benefit rules for high-risk veterans. According to the OEHRM Issue Register, if the required functionality was not provided, veterans that were at risk for suicide might incur a financial burden for filling prescriptions, which would result in a patient safety risk. The program completed action steps to resolve this issue, which included presenting a proposed workaround workflow and performing a feasibility analysis. The only action step remaining to close this issue as of late September 2020, was for OEHRM to conduct a solution-focused discussion with Cerner.

35

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Conclusions

VA has made progress in preparing for deployment of the new EHR by, for example, making system configuration decisions, developing system capabilities and system interfaces, conducting end user training, and completing system testing events. However, the department has not resolved all current critical and high severity test findings. Without resolving such findings and addressing any new critical and high ones identified in the remaining days before planned deployment, VA is at risk of deploying a system that does not perform as intended, could negatively impact patient safety, and could decrease the likelihood of successful system adoption by users.

OEHRM has identified key risks and issues that can negatively impact the program's cost, schedule, and performance, in accordance with its risk management plan, and it is maintaining registers to track open risks and issues and their associated mitigation plans.

36

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Recommendations for Executive Action

The Secretary of VA should direct the Executive Director of the Office of Electronic Health Record Modernization to:

- Delay deployment of the new EHR until all current open critical severity test findings are resolved and closed, and until any critical severity findings identified in the remaining days before planned deployment are resolved and closed. (Recommendation 1)

- Delay deployment of the new EHR until all current open high severity test findings are either resolved and closed or deferred, and until any high severity test findings identified in the remaining days before planned deployment are either resolved and closed or deferred with workarounds approved by the user community. (Recommendation 2)

37

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Agency Comments and Our Evaluation

In email comments on a draft of this briefing, VA's Acting Assistant Secretary for the Office of Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, neither agreed nor disagreed with our conclusions and recommendations. The official stated, however, that the department is on track for the scheduled implementation of its new electronic health record system on October 24, 2020, at Mann-Grandstaff VA Medical Center in Spokane, Washington.

Nevertheless, implementation of our recommendations will remain important as VA works toward future deployments of its new EHR.

38

Appendix II: Chronology of Changes in Electronic Health Record Modernization Deployment Schedule and Approach

The Department of Veterans' Affairs (VA) schedule and approach to deploying the new electronic health record (EHR) system has undergone multiple changes since the department announced its initial deployment plan in October 2018.

- The initial schedule for the program indicated that deployment of the new EHR was to occur first in March and April 2020 at sites in Spokane and Seattle, Washington.

- In July 2019, VA accelerated the deployment of a key EHR module—the Centralized Scheduling Solution (CSS)—as part of the Electronic Health Record Modernization (EHRM) program. The schedule for beginning its deployment was moved from fiscal year 2023 to April 2020.

- In August 2019, VA changed its plans to initially deploy the new EHR in March and April 2020, to deploy in two phases, known as capability sets 1.0 and 2.0. Capability set 1.0 was to deploy in March 2020 in Spokane, Washington, and capability set 2.0 was to deploy in November 2020 in Seattle, Washington.

  - Capability set 1.0 includes key EHR functionalities necessary to implement the system at a less complex facility.

  - Capability set 2.0 includes capability set 1.0 functionalities and remaining functionalities necessary to implement the system at a highly complex facility.

- In February 2020, VA postponed the initial deployment of the new EHR at the Spokane location until July 2020, in order to establish a more complete training environment and build interfaces between the EHR system and other VA systems.

- While the training environment and interfaces were being completed, VA announced that it would be able to add additional veteran-facing

functionality to capability set 1.0 (e.g., consolidated mail order pharmacy and online prescription refill), known as capability set 1.1.

- In March 2020, VA paused initial deployment of EHRM to focus the department's response on the Coronavirus Disease 2019. The Secretary directed the EHRM program to limit contact with the clinicians who had been participating in the program's activities to allow the clinicians to focus on caring for veterans.

- In May 2020, VA changed the deployment approach for EHRM and announced that it would focus its efforts on deploying CSS in Columbus, Ohio, due to Coronavirus cases in Spokane, Washington.

- In August 2020, VA announced a new timeline for deploying the new EHR. Specifically, the department announced plans to deploy capability set 1.1 in locations within Veterans Integrated Service Networks (VISN) 20 and 10 through fiscal year 2022; the first location was to be Spokane, Washington, on October 24, 2020.[1] The department plans to deploy capability set 2.0 in Seattle, Washington, in the fourth quarter of fiscal year 2021.
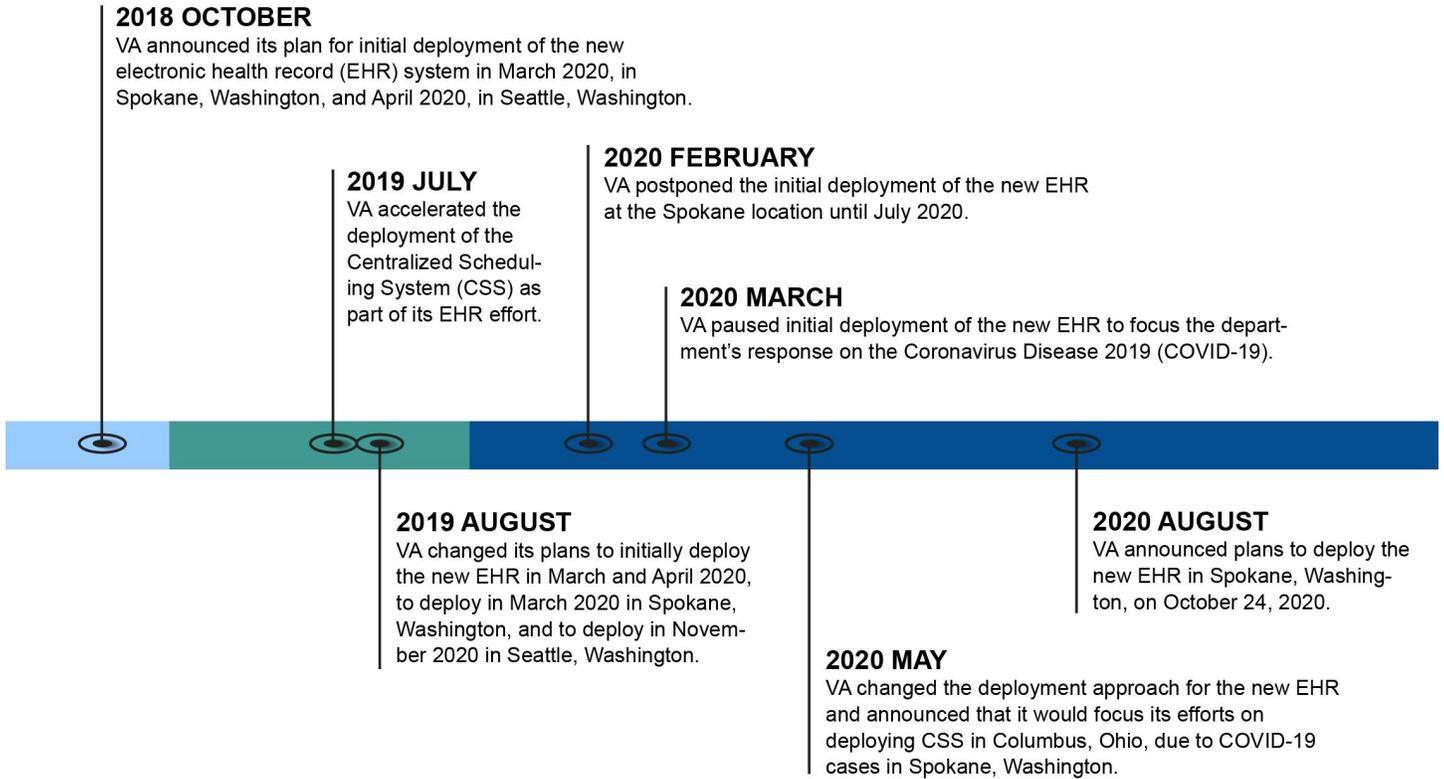
A timeline of changes to the schedule and deployment approach for the EHRM program is shown in figure 2.

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[1]VISN 10 includes medical centers and community-based outpatient clinics throughout the lower peninsula of Michigan, Ohio, Northern Kentucky, and Indiana.

Figure 2: Changes to the Schedule and Approach for Deploying the Department of Veterans Affairs' (VA) New Electronic Health Record (EHR)

2018 OCTOBER
VA announced its plan for initial deployment of the new electronic health record (EHR) system in March 2020, in Spokane, Washington, and April 2020, in Seattle, Washington.

2019 JULY
VA accelerated the deployment of the Centralized Scheduling System (CSS) as part of its EHR effort.

2020 FEBRUARY
VA postponed the initial deployment of the new EHR at the Spokane location until July 2020.

2020 MARCH
VA paused initial deployment of the new EHR to focus the department's response on the Coronavirus Disease 2019 (COVID-19).

2019 AUGUST
VA changed its plans to initially deploy the new EHR in March and April 2020, to deploy in March 2020 in Spokane, Washington, and to deploy in November 2020 in Seattle, Washington.

2020 AUGUST
VA announced plans to deploy the new EHR in Spokane, Washington, on October 24, 2020.

2020 MAY
VA changed the deployment approach for the new EHR and announced that it would focus its efforts on deploying CSS in Columbus, Ohio, due to COVID-19 cases in Spokane, Washington.

Source: Department of Veterans Affairs' Office of Electronic Health Record Modernization. | GAO-21-224

Appendix III: Comments from the Department of Veterans Affairs

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 25, 2021

Ms. Carol C. Harris
Director
Information Technology Management Issues
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Harris:

The Department of Veterans Affairs (VA) has reviewed the Government
Accountability Office (GAO) draft report: *ELECTRONIC HEALTH RECORDS: VA Has
Made Progress in Preparing for New System, but Subsequent Test Findings Will
Need to Be Addressed* (GAO 21-224).

The enclosure contains general comments and the actions to be taken to
address the draft report recommendations. VA appreciates the opportunity to comment
on your draft report.

Sincerely,

Dat P. Tran
Acting

Enclosure

Enclosure

The Department of Veterans Affairs (VA) Response to the
Government Accountability Office (GAO) Report
*ELECTRONIC HEALTH RECORDS: VA Has Made Progress in Preparing for New
System, but Subsequent Test Findings Will Need to Be Addressed
(GAO 21-224)*

GENERAL COMMENTS:

The Department of Veterans Affairs (VA) Office of Electronic Health Record
Modernization (OEHRM) appreciates the opportunity to review the Government
Accountability Office (GAO) draft report regarding the progress of the Electronic Health
Record Modernization (EHRM) program and the disposition of test findings in relation to
subsequent deployments.

On October 24, 2020, VA successfully implemented the core electronic health record
(EHR) solution at Mann-Grandstaff VA Medical Center (VAMC), four associated
Community Based Outpatient Clinics and the West Consolidated Patient Account
Center (WCPAC) with no patient safety issues. All critical and high-test findings related
to go-live were adjudicated in advance of the new EHR launch. OEHRM will continue to
track all test findings daily and adjudicate them as appropriate.

OEHRM is taking every precaution to deliver an effective system for our clinicians and
users and remain committed to getting this right for our Veterans. In addition, OEHRM is
prioritizing the safety of the OEHRM program office and VAMC staff while endeavoring
to remain agile during an unpredictable COVID-19 environment.

In addition, OEHRM recommends that GAO refocus the title and recommendations for
executive action of the report to reflect a proactive voice vice the current reactive voice.
Specifically, in the title OEHRM recommends changing the phrase "…but Subsequent
Test Findings Will Need to Be Addressed" to read "…and Test Findings are being
Addressed." In the recommendations, OEHRM recommends rather than "… postpone
deployment until…" to consider stating OEHRM should plan to adjudicate finds prior to
go-live.

OEHRM concurs-in-principle with GAO's findings and recommendations and provides
the following Action Plan to address the recommendations.

Page **1** of **3**

Enclosure

The Department of Veterans Affairs (VA) Response to the
Government Accountability Office (GAO) Report
*ELECTRONIC HEALTH RECORDS: VA Has Made Progress in Preparing for New
System, but Subsequent Test Findings Will Need to Be Addressed
(GAO 21-224)*

<u>**Recommendation 1:**</u>

**The Secretary of VA should direct the Executive Director of the Office of
Electronic Health Record Modernization to postpone deployment of the
new EHR in new locations until all existing open critical severity test
findings are resolved and closed, and until any additional critical severity
findings identified before planned deployment are closed.**

<u>**VA Comment:**</u> Concur-in-principle

VA concurs in principle with the recommendation, as OEHRM already resolves and
closes all existing open critical severity test findings prior to deployment of the EHR in
new locations. When VA went live at Mann-Grandstaff VAMC and WCPAC, OEHRM
resolved and closed all critical severity test findings. In building upon the deployment
successes at Mann-Grandstaff VAMC and WCPAC, VA will continue to test and
appropriately adjudicate all critical severity test findings prior to future deployment go-
live implementation. In the meantime, VA will continue to launch the EHR as planned.

Target Completion Date: January 2022 (to observe the resolution of all prior critical
severity test findings).

<u>**Recommendation 2:**</u>

**The Secretary of VA should direct the Executive Director of the Office of
Electronic Health Record Modernization to postpone deployment of the
new EHR in new locations until all existing open high severity test findings
are either resolved and closed or deferred, and until any additional high
severity test findings identified before planned deployment are either
closed or deferred.**

<u>**VA Comment:**</u> Concur-in-principle

VA concurs in principle with the recommendation, as OEHRM already resolves and
closes, or defers, all existing open high severity test findings prior to deployment of the
EHR in new locations. When VA went live at Mann-Grandstaff VAMC and WCPAC,
OEHRM resolved and closed, or deferred, all high severity test findings. In building
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continue to test and appropriately adjudicate all high severity test findings prior to future
deployment go-live implementation. In the meantime, VA will continue to launch the new
EHR as planned.

Page **2** of **3**

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(GAO 21-224)*

Target Completion Date: January 2022 (to observe the resolution of all prior critical
severity test findings).

Page **3** of **3**

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Carol C. Harris (202) 512-4456 or harriscc@gao.gov

Staff Acknowledgments

In addition to the individual named above, the following staff made key contributions to this report: Mark Bird (Assistant Director), Eric Trout (Analyst in Charge), Alina Budhathoki, Chris Businsky, Benjamin Cyr, Rebecca Eyler, Kenneth Mills, Katherine Noble, Scott Pettis, Christy Tyson, and Charles Youman.

Appendix V: Accessible Data

Data Tables

Accessible Data for The Department of Veterans' Affairs Electronic Health Record Modernization Open Critical and High Severity Test Findings May 2020-October 2020

Date	Critical Defects	High Defects
May 2020	32	317
Jun 2020	29	530
Jul 2020	27	266
Aug 2020	35	291
Sep 2020	17	361
Oct 2020	0	55
Oct 2020	0	55

Accessible Data for Figure 1: Department of Veterans' Affairs Electronic Health Record Modernization Open Critical and High Severity Test Findings, August 2019-October 2020

Date	Critical Defects	High Defects
Aug 2019	2	0
Sep 2019	2	39
Oct 2019	5	74
Nov 2019	26	139
Dec 2019	45	155
Jan 2020	101	343
Feb 2020	65	397
Mar 2020	54	283
Apr 2020	33	116
May 2020	33	319
Jun 2020	30	532
Jul 2020	27	270
Aug 2020	35	291
Sep 2020	21	403
Oct 2020	0	55

Agency Comment Letter

Accessible Text for Appendix III Comments from the Department of Veterans Affairs

Page 1

January 25, 2021

Ms. Carol C. Harris
Director
Information Technology Management Issues
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

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OEHRM concurs-in-principle with GAO's findings and recommendations and provides the following Action Plan to address the recommendations.

<u>Page 3</u>

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VA Comment: Concur-in-principle

VA concurs in principle with the recommendation, as OEHRM already resolves and closes all existing open critical severity test findings prior to deployment of the EHR in new locations. When VA went live at Mann-Grandstaff VAMC and WCPAC, OEHRM resolved and closed all critical severity test findings. In building upon the deployment successes at Mann-Grandstaff VAMC and WCPAC, VA will continue to test and appropriately adjudicate all critical severity test findings prior to future deployment go- live implementation. In the meantime, VA will continue to launch the EHR as planned.

Target Completion Date: January 2022 (to observe the resolution of all prior critical severity test findings).

Recommendation 2:

The Secretary of VA should direct the Executive Director of the Office of Electronic Health Record Modernization to postpone deployment of the new EHR in new locations until all existing open high severity test findings are either resolved and closed or deferred, and until any additional high severity test findings identified before planned deployment are either closed or deferred.

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VA concurs in principle with the recommendation, as OEHRM already resolves and closes, or defers, all existing open high severity test findings prior to deployment of the EHR in new locations. When VA went live at Mann-Grandstaff VAMC and WCPAC, OEHRM resolved and closed, or deferred, all high severity test findings. In building upon our deployment successes at Mann-Grandstaff VAMC and WCPAC, VA will continue to test and appropriately adjudicate all high severity test findings prior to future deployment go-live implementation. In the meantime, VA will continue to launch the new EHR as planned.

Page 4

Target Completion Date: January 2022 (to observe the resolution of all prior critical severity test findings).

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