

Challenges in Deploying the Oracle Cerner EHR and Potential Paths Forward

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Executive Summary:

The VA was one of the first to develop and successfully use what was then a state-of-the-art electronic health record (EHR) system named VistA (Veterans Health Information Systems and Technology Architecture). Attempts were made to upgrade VistA over time with varying degrees of success.

In 2015, the DOD decided to use a commercial-off-the-shelf (COTS) EHR from Cerner Corporation to provide a common record of medical and dental information across the DOD, NOAA, and private sector providers. To improve the exchange of data between the VA and DoD EHR systems, the VA signed a contract with Cerner in 2018 to provide, host, and deploy the same Cerner EHR.¹ The decision was also influenced by Congressional and Executive Branch pressures to outsource technology from government to private industry.

The rollout of the Cerner EHR at the VA started with a few facilities in the Pacific Northwest in 2020. It did not go smoothly and was paused in 2023. An Oracle Cerner audit after the pause found significant problems with the clinical data dictionary (called the Event Set Hierarchy, or ESH) in the Oracle Cerner EHR, including a 39% defect rate due to structural errors. Such structural errors can potentially result in display errors, lost or missing data, and ultimately clinical decision errors. An effort was started to fix these ESH defects. While some defects have been fixed, a new 2025 report finds that orphan codes (a result of the defects) continue to proliferate without a clear understanding of their causes.

During the initial rollout and later pause, many other serious problems with the Oracle Cerner EHR system beyond the ESH design problems were identified, some of which contributed to adverse events and patient harm, including deaths. These problems include:

- Potential semantic errors in the stored data;
- Undelivered messages, such as patient-related orders for lab work, that do not warn the sender that the message was never delivered;
- Limited or no configuration control with respect to changes in stored data to ensure the content is properly configured, tested, and evaluated;
- Data migrated from VistA to Millennium did not support the quality needs of clinicians;
- Usability problems such as not blocking likely sources of human error, user interfaces not optimized for clinical workflows, inadequate care coordination increasing the burden on providers, inefficiencies in staff completion of patient care functions, limited views for users that do not account for varied staff duties and coordination needs, inadvertent cancellation of patient medication orders, and so on. Surveys of the users during the rollout found that 88% found the system made them less efficient, 78% found that they were handicapped by the system in delivering high-quality care, and 70% said the new EHR did not allow them to deliver patient-centered care.
- Inadequate testing and other types of system analyses (such as usability and safety) before the rollout;
- Training that did not prepare staff for the new system;
- Inadequate installation support including response to errors found by the users; and

¹ In 2022, Oracle Corporation acquired Cerner and created a group known as Oracle Health.

- Inadequate documentation on the new system

Without fixing these problems, we believe the planned continued rollout of Millennium will result in increased patient safety risk, additional provider burden, and more cost overruns without significant value to Veterans.” In the worst case, much more money will be spent with no significantly different outcome.

The VA also contributed to the problems associated with the initial rollout, through inadequate project management and governance practices:

- Project management for the acquisition and installation was moved from the VHA to the VA level. The deep expertise in EHR and HIT that existed at the VHA was not involved in the initial procurement decisions until problems started to occur;
- Goals and requirements for the new EHR system were never clearly identified, resulting in vague and sometimes contradictory goals;
- Decisions about the configuration of Millennium were given to a poorly designed and managed Councils and Workgroups process involving a very large number of people;
- Inadequate communication with stakeholders and inadequate solicitation of inputs;
- Risk assessment and management was inadequate;
- Determination of the information to be in the EHR and oversight of the data migration process was inadequate;
- Responsibility for quality, safety, and usability was abdicated to Oracle Cerner; and
- Access to care was not well managed during the rollout;

In examining these deficiencies, one should keep in mind that attempts to install commercial off-the-shelf (COTS) EHR systems all over the world have never been successful for such a large and complex system as the VHA. This report provides more detail about other experiences.

A recent decision has been made to continue the rollout despite the fact that most of the problems identified in the initial rollout have not been fixed. Without fixing the reasons for the lack of success in the first attempts to install the Oracle Cerner EHR at the VA, the same or similar patient safety and quality of care concerns as occurred during the initial rollout are very likely to be repeated but on a larger scale. Note that this continued rollout will occur in the midst of over 500 VA cancelled contracts, a planned 15% reduction in the VA workforce, and numerous leadership and management changes. Many of the affected contractor and VA personnel have been directly supporting the Millennium implementation and VistA migration efforts.

The possibility of simply spending a lot more money and ending up with the same or worse problems is very high. The original contract for installing the Oracle Cerner EHR was \$16 billion. Estimates to complete the installation are now about \$50 billion over the next 10 years. Simply continuing without changes is very likely to cost even more than anticipated, and the result is unlikely to meet VA quality and safety standards.

Instead, a careful decision-making process is needed to decide whether efforts should be continued to try to fix the problems in Millennium and how to do this, or whether an alternative path is more promising for the future of EHR in the VA. Rushing forward without doing these things seems unwise.

Three paths forward appear to be the most feasible. Despite which one is chosen, the VA needs to institute basic system engineering processes and obtain outside expertise with their

upgrade efforts. Successfully installing COTS systems is much more difficult than it may seem to be.

Path 1: Continue deploying Millennium after fixing the problems encountered in the first rollout. Simply continuing without learning from the first failed attempts will most likely lead to continued unnecessary and unacceptable risk to patient safety, unacceptable burdens on frontline staff, losses in productivity, degraded quality of care, and escalating costs. Fixing the identified problems, however, is going to be expensive and take time. Other paths may be preferable.

Path 2: Partner with a commercial company (perhaps Oracle Health) to create a new COTS EHR (or upgrade Millennium) that could be used by the VA. Existing commercial EHR systems are all based on very old data models and rely on old software. In the future, these old data models and software are likely to impede making progress in healthcare quality and safety. While we do not believe that the VA should try to create their own new EHR system, partnering with industry to provide one could require less effort and resources than trying to upgrade and install Millennium. It could also extend the potential for upgrading EHR capabilities in the future. Such a system could be based on a more modern data model and separate the data model completely from the workflows and practices supported so that more customization, where justified, will be possible. This path could use lessons learned from the past and rapidly advancing technologies to create a new health IT future for veterans, clinicians, community care partners, and our nation.

Path 3: A third path is to contract with industry to create a modern new EHR system that satisfies the unique needs of VA healthcare without making the compromises required by COTS. The VA healthcare system is much more complex and comprehensive than most other healthcare systems using EHR technology, including the DOD. As described in this report, other countries have struggled to adopt COTS EHR systems for their national healthcare systems. The U.S. VA is not unique here. One COTS product for different users may simply not be practical or consistent with providing high quality healthcare.

As with Path 2, interoperability with the DoD could be realized through an expansion of CHDR (Clinical Data Health Repository) or through existing health information exchanges such as the Qualified Health Information Network and emerging integrated knowledge exchange environments. Also, as with Path 2, such a system could be based on a more modern data model and separate the data model completely from the workflows and practice. By separating the data storage model from the workflows and processes, justified tailoring of processes would be possible for different aspects of medical practice. Such tailoring is not allowed with the current Oracle Cerner EHR and limited in most COTS systems, adding to concerns about healthcare safety and quality in a very diverse medical system like the VA.

Caveats

Some limitations should be considered regarding the contents of this report.

- Short time line: gathering information had to be completed in two months. In that time, we interviewed VA leaders and experts in healthcare EHR but were unable to interview users of Millennium at the VA facilities where the first rollouts occurred. Instead, we used a series of VA OIG reports that extensively studied the Millennium rollout efforts. While we recognize that OIG reports can focus on problems and therefore can be misleading, the data and interviews provided by their in-depth studies can be useful. We also used Congressional hearings and testimony and various other reports as well as our own extensive prior experience with EHR systems and healthcare.
- Scheduling and overlapping ESH improvement efforts: Changes and new decisions are being made simultaneous with our study, which, in some respects, makes the system being studied a moving target.
- Limitations of access to ESH system artifacts and those involved in prior decisions: There were practical limits in access to many of those who were involved in prior and current decision making surrounding EHR systems at the VA and in obtaining some documents.
- Transparency of stakeholders/controllers: We found that most everyone was willing to speak with us about their views of the VA EHR efforts, both past and present. We assured those we talked to that they would have the opportunity to review what we wrote concerning their inputs and that their comments would remain anonymous if they desired them to be.
- Access to key informants and their willingness to participate in the study: Everyone we asked was very willing to share their knowledge with us, but the time limits of the study precluded our being able to speak with as many people as we wanted to.

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1. Introduction and Background

The VHA (Veterans Health Administration) and the DHA (Defense Health Agency) operate two of the largest healthcare systems in the world, providing services for over 9 million enrolled users each. The Veterans Health Administration is part of the Veterans Administration (VA) while the DHA is part of the Department of Defense (DOD). The VHA serves patients at 1,454 healthcare facilities, including 171 medical centers and 1,283 outpatient facilities. The DHA delivers patient care through the Military Health System (MHS) at 490 healthcare facilities, including 15 U.S. medical centers, 51 hospitals, and more than 424 clinics. In addition to the 1,944 VHA and DHA healthcare facilities, the VA and DOD also rely on more than 15,000 external providers. This number is growing rapidly to meet demand for healthcare services the federal systems cannot provide or cannot provide in a timely manner to active duty Armed Forces members and Veterans [1]. Note: A detailed Glossary of terms and their description is included in Appendix A.

For several decades, the VA developed and used what was then a state-of-the-art electronic health record (EHR) system named VistA (Veterans Health Information Systems and Technology Architecture). VistA supports a complex set of clinical and administrative capabilities and contains an EHR for each patient. The VistA electronic health record is a collection of information about the health of an individual and the care provided, such as patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data, and radiology reports.

VistA has evolved into a technically complex system that supports healthcare delivery at more than 1,500 locations, including VA medical centers, outpatient clinics, community living centers, and VA vet centers. Customization of the system by local facilities has resulted in about 130 clinical versions of VistA—commonly referred to as instances.

VA clinicians have relied on data stored in VistA to provide healthcare services. The department has also relied on health data to support reporting capabilities for patient care, operations, health surveillance, and research functions. To support these reporting capabilities, historically the VA has transferred health data from VistA into its Corporate Data Warehouse, which resides in the VA's National Data Center.

To improve the exchange of data between their VA and DOD EHR systems, the VA has worked with DOD to respond to provisions in the National Defense Authorization Act for Fiscal Year 2008. These provisions required the departments to jointly develop and implement fully interoperable EHR systems or capabilities and establish an Interagency Program Office (IPO) as a single point of accountability for their efforts. Note that this first directive does not require the same EHR but only interoperable ones.

Efforts were first initiated to improve interoperability between the two EHR systems. In 2011, the IPO initiated development of a single, integrated EHR capability for both the VA and the DOD called iEHR. iEHR was to be completed by 2017 and was estimated to have a cost of \$29 billion through fiscal year 2029. Two years later, in 2013, the VA and DOD ended the iEHR project because of unmet deadlines and cost overruns.

Other efforts were started, such as the JLV (Joint Longitudinal Viewer), which is a web application that contains a view of patient health information contained in the separate VA and DOD EHRs. The JLV was deployed in 2014. Modernization efforts for VistA also continued.

In 2015, the DOD decided to use a commercial-off-the-shelf (COTS) EHR from Cerner Corporation to provide a common record of medical and dental information across the DOD, NOAA, and private sector providers. Later the VA decided to follow suit and signed a contract with Cerner in 2018 to provide, host, and deploy a common VA/DOD EHR. In 2022, Oracle Corporation acquired Cerner and created a group known as Oracle Health.

The VA expects to replace most components of its legacy EHR system, VistA, using two Oracle Cerner products—Millennium EHR and HealthIntent. Millennium is expected to provide users, such as clinicians, with access to their patients' health data. It is also expected to support clinical capabilities, such as ordering lab tests and medications, documenting notes about the delivery of care, and scheduling appointments. The second component, HealthIntent (a cloud-based application), will be used to aggregate health data from multiple sources, including VistA (until it is replaced everywhere) and Millennium, to create a single record for each patient (known as the longitudinal record). Data in the longitudinal record are also expected to support reporting capabilities in HealthIntent and Millennium, such as patient care recommendations, clinical studies, and quality of care analyses, among other things.

The rollout of Millennium at the VA started with a few facilities in the Pacific Northwest in 2020. It did not go smoothly and was paused in 2023 [2]. An Oracle Cerner audit after the pause found significant problems with the clinical data dictionary (called the Event Set Hierarchy, or ESH) in the new Millennium EHR, including a 39% defect rate due to structural errors. Such structural errors can potentially result in display errors, lost or missing data, and ultimately clinical decision errors. Semantic errors, such as redundant entries, are also known to exist but have not been quantified. An effort was started to fix these ESH defects.

Recent analysis of the ESH indicates much progress but despite efforts to fix them, substantial defects still exist within the ESH, while internal system reporting suggests that error rates are on a downward trend [3]. Audits by the VA Office of the Inspector General (OIG) found serious problems beyond just ESH defects in the first VA facilities to install the Oracle Cerner system. The problems investigated by the OIG include data management, interoperability, medication management, patient scheduling, care coordination, pharmacy software, training, and access to care.

The VA and Congress find themselves at a point where a decision needs to be made about whether efforts should be continued to try to fix the problems in Millennium and how to do this, or whether an alternative path is more promising for the future of EHR in the VA. This critical decision is being made in the midst of over 500 VA cancelled contracts, a planned 15% reduction in the VA workforce, and numerous leadership and management changes. Many of the affected contractor and VA personnel have been directly supporting the Millennium implementation and VistA migration efforts [4]. The goal of this report is to examine why the problems in installing the new Millennium EHR system have occurred and to outline potential paths forward. Appendix B contains the timeline of major events involved, starting with the first development of EHR systems at the VA 50 years ago up to today.

More specifically, the goal of this study was to answer three general questions:

1. Why were previous attempts at upgrading or replacing VistA or creating a new shared system with the DOD unsuccessful?
2. Why was a decision made to use a COTS product rather than to continue trying to upgrade VistA or to create a new VA system?

3. Why has the VA encountered so many problems in trying to install the Cerner system in VA healthcare facilities? Did the DOD encounter the same problems when they installed Millennium (called MHS GENESIS at that time)? If not, or if the DOD healthcare context is simply different than the VA, what are the relevant differences?

2. Method

To provide information to current and future decision makers in a blame-free light, we used a state-of-the-art system engineering causal analysis tool called CAST (Causal Analysis based on Systems Theory) [5,6]. CAST starts from the assumption that the decision makers were well intentioned. Therefore, there needs to be some reason why flawed decisions, at least *in hindsight*, were made.

Looking at the events themselves is not enough: We need to understand why the events occurred, for example, why the VA decided to buy a COTS system rather than continue to upgrade VistA. Only by understanding the reasons behind the decisions made in the past can we understand how we got to where we are today and to make informed decisions about the next steps.

In CAST, each of the major players is analyzed with respect to the following:

Responsibilities:

What were the assigned responsibilities that they were trying to satisfy?

Decisions and actions contributing to the current state:

Those actions and decisions that contributed to the current or final state being analyzed.

Mental Model Flaws Involved:

All decisions are based on the decision maker's general beliefs related to the problem at hand and their understanding about the current and past states of the system at the time the decisions or actions took place. It is important not to use information about what later transpired as that introduces hindsight bias. We need to understand why their actions made sense to them at the time, not after later events provided more information about the effects of those actions.

Context:

All behavior is affected by the context in which it occurs. Understanding behavior requires identifying that context and the influence it had on the decision maker.

Once the information is generated about how the VA arrived at their current state with respect to the EHR and the reasoning behind past relevant events² and decisions, this information is used to make recommendations on how to proceed given current conditions and the future desired state.

While there is a structured process for performing a CAST analysis, only the results are described in this report.

The major groups involved in the events are Oracle Cerner, the VA, and Congress and the Executive Branch. Before looking at the role played by each of these groups, it is important to

² A detailed list of events is included in Appendix B.

understand the general contextual factors at play and the difficulties raised in developing and deployed EHR systems.

3. General Contextual Factors

3.1. A Brief History of EHR at the VA

The VA has, in the past, been successful in pioneering and successfully introducing EHR capabilities to their facilities:

- VHA was one of the first in the world to create a working EHR system, called VistA, long before the HITECH Act (2009) was passed to increase the use of EHRs by physicians and hospitals.
- VHA successfully implemented many upgrades and additions to the capabilities in VistA over time.
- My HealtheVet was launched in 2003, a personal health record portal with over 2.5 million registered users.
- For interoperability, before Millennium, VHIE, completed in 2004, enabled real-time, two-way data exchange for shared patients between VA and DOD. It also added significant capability, including the ability to view inpatient and outpatient notes. In 2007, the VA and DOD expanded the capabilities for sharing prescription and drug allergy data.
- VLER, introduced in 2009, allowed sharing select parts of a veteran patient's medical record electronically, safely, and privately with other approved healthcare facilities that are members of a secure Internet network known as the eHealth Exchange.
- In 2009, 95% of all VA prescriptions were placed electronically through computerized physical order entry (CPOE).
- JLV (Joint Longitudinal Viewer), deployed in 2014, provides a near real-time and chronological view of patient health information contained in the separate VA and DOD EHRs.
- Medical appointment scheduling system (MASS) was successfully piloted in 2017, although it was later abandoned after the Oracle Cerner Millennium system was adopted.
- In 2015, VistA patched for the state prescription monitoring system and deployed.
- In 2021, the Joint Health Information Exchange (joint HIE) was connected to 70% of the nation's community providers.
- CHDR is used in the exchange of allergy and pharmacy patient data between the DOD CDR (Clinical Data Repository) and the VA HDR (Health Data Repository) for patients who use both the DOD and the VA medical facilities. Patient data for allergy and pharma domains are maintained in the centralized repository of each agency. The CHDR application is the link between the CDR and HDR repositories providing a bidirectional exchange of standards-based, computable data as close to real-time as the systems will allow.

There have also been challenges along the way, for example, with creating a scheduling system. In the 2000s, VA sought a replacement for scheduling, but the department found “no COTS [commercial off-the-shelf] software developers appeared willing to make their scheduling application compatible with VA’s systems.” VA undertook its own Replacement Scheduling Application (RSA) development project, but after seven years of in-house development and \$127 million in funding for the total effort, the department acknowledged that it had not developed or acquired any new scheduling capabilities.

Since the failed effort to develop a scheduling solution in-house, VA has piloted commercial solutions and improved its existing scheduling system under the effort with a system called VSE (VistA Scheduling Enhancement). VSE was supposed to upgrade the old system with a modern graphical interface. VSE was not completed until 2019 (four years later than anticipated), just in time to be theoretically replaced by the Oracle Cerner scheduling system, although the Oracle Cerner scheduling system is running into problems too [7].

Shortly after the VSE contract was issued, planning began for a long-term solution called the Medical Appointment Scheduling System (MASS). In December 2018, the VA announced it would use the Oracle Cerner scheduling system due to the “return on investment in productivity and efficiency.” The Cerner scheduling system, however, is running into problems.

In 2013, a major effort, called VistA Evolution, was started to upgrade VistA. Completion was estimated by the end of 2018 at a cost of \$4 billion through 2028. VistA Evolution was to be interoperable with the DOD EHR system. While much of the planned VistA Evolution capabilities have been delivered, the GAO found that the VistA Evolution effort was not effectively managed, with delays in deployment and incomplete requirements for contractors. The OIG concluded that turnover, unresolved issues, and inadequate requirements delayed implementation [8].

It is important to note that most large IT and software projects are late and over budget. The reason may not be in the technology development and management itself but simply a product of our inability to provide good budget and schedule estimates for large software projects.

3.2. Contextual Factors for EHR in General

The 2009 HITECH Act created requirements for adoption of EHR systems in healthcare. While requirements for “meaningful use” were created, they were vague and minimal. Safety requirements were not established originally and were supposed to be determined later. EHR vendors took advantage of the vacuum.

EHR systems are now widely used in healthcare today. Most successful EHR installations, however, have been in small facilities, such as a clinical practice or a single hospital or small hospital system. Other large installations have run into problems (some examples are noted later).

The problems with information systems are not limited to healthcare. Large banks, with much simpler information systems, have found that after mergers with other banks, it was easier to run the different systems in parallel rather than trying to merge them.

EHR systems include millions of lines of software that interact in complex ways written by teams over decades. The documentation of this code base is likely to be inadequate. A basic principle of software engineering is that changing such software is very likely to introduce errors

and unintended behavior, so changes are resisted. The complexity and scale of these EHR systems is enormous compared to most commercial software. Starting over today would require an investment that a commercial company would be unlikely to be able to recoup. Some EHR systems include capabilities built on more modern software engineering principles that allow tailored modularized versions, but many commercial EHR systems are too tightly interconnected.

In healthcare, the VA is not unique in having difficulty in installing a COTS EHR system or in underestimating the cost and time required. Most EHR implementations take between 6 months to 2 years. Smaller practices may implement in 6-12 months, while larger hospitals require 18-24+ months. The key factors impacting timeline length include organization size and complexity. The VA adoption of Oracle Cerner Millennium is the largest such implementation ever attempted by far. The time required may not scale linearly, but may actually have exponential elements. Did everyone involved appreciate the difficulty and plan accordingly?

One problem is that while the current EHR systems may be usable in smaller healthcare settings, they may not scale to large governmental healthcare systems. The problems are not unique to Oracle Cerner—and some factors can be traced to the behavior of the hospitals and not just the EHR systems and their vendors. The following is a selection of examples from various countries, including some serious problems at smaller scale installations.

Cerner Problems:

- Australia: The state of Queensland introduced an Integrated Electronic Medical Record System. The installation of Cerner Millennium was costly and took more than 10 years to roll it out across the state leading to non-digital and partially digital facilities.
- Canada: the implementation at a regional hospital has been widely criticized, with staff calling it a “huge failure” due to an increase in software errors resulting in reduced efficiency. An investigation by British Columbia's Health Ministry indicated that the project was not correctly planned or implemented and that organizational dysfunction at the facility contributed to the failure.
- United States: In 2002, the installation of a computerized health system by Cerner in the UPMC Children's Hospital of Pittsburgh made it harder for the doctors and nurses to do their jobs in emergency situations and resulted in a "disaster," according to Phillip Longman, a senior fellow at the New America Foundation. Longman wrote, "According to a study conducted by the hospital and published in the journal *Pediatrics*, mortality rates for one vulnerable patient population—those brought by emergency transport from other facilities—more than doubled, from 2.8 percent before the installation to almost 6.6 percent afterward [9]."

Defenders of Cerner in the study charged that the Pittsburgh hospital did not adequately prepare for the transition to the Computerized Provider Order Entry (CPOE) system because it had simultaneously modified its pharmacy process, did not provide adequate wireless bandwidth, and did not have order sets pre-programmed on day one. They stated that other hospitals that more carefully planned the implementation did not experience the same problems [10].

- In 2014, a grand jury in California found that Cerner knew that the Ventura County healthcare agency was unprepared to complete a \$32 million installation. Also in 2014, a

\$31 million Cerner implementation at the Athens Regional Health System (ARHS) in Georgia had many problems, leading to forced resignations by the CEO and the CIO of ARHS.

- Sweden: In 2022, the regional director of the Vastra Gotaland healthcare system in Sweden sent a letter to Oracle Cerner claiming a breach of contract for deployment of the Millennium system. The letter stated that there were numerous issues with the system that Oracle Cerner had declined to address [11].

Epic Problems: The problems are not limited to Oracle Cerner. Epic has also had problems.

- Finland: Hospital District of Helsinki and Uusimaa replaced one small health record system with a district-wide system created by Epic. After the implementation, complaints from healthcare workers, especially from doctors, started accumulating. The system was accused of being too complicated and that its convoluted UI was endangering patient safety. For example, one patient was administered the wrong chemotherapeutic drug due to an unclear selection menu in the system. In July 2022, a formal complaint demanding that the issues in the system be fixed or the system be removed entirely was sent to the Finnish healthcare supervising body Valvira. The complaint was signed by 619 doctors [12].
- Norway: Central Norway started introducing Epic in November 2022. After approximately two months, the public broadcaster NRK reported that around 25% of the doctors at the region's main hospital considered quitting their job, and that 40% were experiencing stress-related health issues due to the new IT system [13]. A year after implementation, over 90% of doctors in the affected hospitals considered the Epic system a threat to patient health, and the hospital staff organized large protests at seven hospitals that had or were planning on implementing Epic systems [14].

Other EHR systems:

- United Kingdom: In 2005, the National Health Service (NHS) in the U.K. began deployment of electronic health record systems in NHS Trusts. The goal was to have all patients with a centralized electronic health record by 2010 [15]. While many hospitals acquired electronic patient record systems in this process, there was no national healthcare information exchange. Ultimately, the program was dismantled after a cost to the UK taxpayer of over \$24 billion (£12 billion), and is considered one of the most expensive healthcare IT failures [16].

By 2019, only 10% of NHS trusts claimed to be fully digitized. However, by November 2023, 90% of NHS trusts had installed independent electronic health record systems. A large number of different commercial companies provide pieces of these systems.

Interoperability has been limited. Leeds, in 2018, was the first city in the UK to make patient records available across care settings, including social care, general practice, community, mental health, and hospitals.

General Contextual Factors:

More generally, there have been many installations of EHR in a variety of healthcare organizations. As a result, the healthcare community has discovered an almost universal set of challenges:

- Lack of interoperability (within a system or between independent systems)

- Problems with availability of information (entered or stored in the wrong location or otherwise inaccessible)
- Mismatch between the design of the EHR and the clinician’s workflow (end user’s intent), disrupting the existing workflow
- Alerts and feedback are absent, incorrect, or ambiguous
- Visual display of information is confusing, cluttered, or inaccurate
- Healthcare worker burnout occurs due to design of the EHR
- Staff training and support is inadequate
- Data integrity is not maintained during migration
- Critical patient safety requirements and practices may not be satisfied by the EHR design. In general, maximizing multiple properties such as efficiency vs. safety vs. usability is difficult.
- Long-term maintenance and monitoring is difficult.
- Complex human behavioral and sociotechnical issues often occur during an EHR transition. It is not just a technical exercise, but technological design may be emphasized by those creating EHR systems over usability.
- Usability is often inadequate and not emphasized by developers.
- Changing healthcare practices can be difficult and not always result in a positive outcome.
- Determining features to include when satisfying many different customers requires tradeoffs.
- Transitions from one EHR to another brings additional challenges, such as the need for users to “unlearn” and then relearn tasks, shortcuts, and workflows.

These challenges are well known and those who successfully create and install EHR systems take steps to prevent them. Most of these challenges were experienced during the Millennium installation in the first five VA facilities.

Why are all these problems occurring? Introducing automation into complex systems is tremendously difficult, but necessary for most systems today. Healthcare is not only an extremely complex system, but it has the extra difficulty of being a human-intensive system. There are some general causes of the problems encountered in introducing an EHR that are separate from individual management or provider actions:

1. Introducing a new EHR requires changes in the way humans do their job. Making these adjustments is not always easy. While the changes may be neutral over the long term, it takes time for humans to make such adjustments. Often, they are expected to change overnight, which is not realistic.
2. Introducing an EHR or a different EHR than the one currently being used may require adjustments that can reduce quality and safety of healthcare. It requires very careful

design of the EHR to avoid quality and safety degradation. Adding a nice feature that is meant to improve quality, safety, and customer or worker experience may in fact decrease some or all of these emergent system properties. Unfortunately, human factors engineering is a new discipline and human-centered design is not widely understood. Technologists may change or even try to simplify the users' job at the expense of making the required human adjustments more difficult, leading to reduced quality and safety of care as well as increased costs and reduced efficiency.

3. Providing high-quality healthcare is extremely difficult. Even having healthcare professionals involved in the design does not guarantee that the design will be satisfactory for all types and aspects of healthcare. Other kinds of experts must also be involved, such as human factors experts, safety experts, organizational psychologists, etc.
4. Culture plays a role, not only with respect to the overall organizational culture but the culture of different aspects or types of medicine differ and often need to differ. One size or one workflow may not fit all.
5. While the 130 instances of VistA may have arisen, at least partly, due to a lack of leadership and discipline, some of the customizations may have been necessary to optimize the overall VA quality of care. Only a sophisticated systems analysis can determine what customization is necessary and what is not. Such an analysis does not seem to have been done by VA.

Specific Problems with COTS (Commercial Off-The-Shelf) Systems

Creating a COTS EHR system has challenges of its own. Building one system that satisfies the many different needs of a large healthcare system is difficult and can lead to overly complex systems or systems that do not satisfy the needs of a large customer base.

On the other hand, customized EHR systems can lead to decreased interoperability, even between their own subsystems. Customization can also make it more difficult for a customer to replace what they have with something better from a different vendor. This customization is part of the reason it has been so hard and has taken so long for the VA to transition to Millennium. Epic allows less customization than Oracle Cerner, but updating and improving Millennium is more difficult. Providing interoperability in COTS systems is disincentivized in some ways for competitive reasons.

There are lots of problems that have arisen with the VA's adoption of Millennium in the VA context, but the incentive to solve them by the vendor may be reduced by the few marketplace alternatives the VA has.

Differences between VA and Civilian Healthcare

VA healthcare has significant differences from civilian hospitals and healthcare. The differences partly stem from the different scale (size) and are partly due to the necessity to follow government policies and practices (e.g., there is no private insurance, but the system must deal with TRICARE). In addition, standardizing processes and workflows across one hospital is very different than standardizing them across hundreds of healthcare facilities. Some customization

("instances") may be necessary to provide high-quality healthcare across a very large organization with a wide range of necessary capabilities.

These differences introduce significant challenges in trying to introduce a commercial COTS EHR system into VHA. A possibility exists that the challenges make the effort more difficult and expensive than other solutions.

Interoperability between VHA and DOD Health Systems

In 2008, the National Defense Authorization Act for FY2008 required the VA and DOD to jointly develop and implement fully interoperable EHR systems or capabilities and establish an Interagency Program Office as a single point of accountability for their efforts. After attempts by the VA and DOD to work together to come up with a joint solution, the DOD independently issued a contract in 2015 to Cerner for a new EHR system (MHS GENESIS) to provide a common record of medical and dental information across all of DOD, NOAA, and community care providers.

At first, the VA continued their separate attempts to upgrade VistA and provide interoperability between the two EHR systems. In 2017, however, the VA decided to adopt the same COTS solution, Oracle Cerner's Millennium, in a stated attempt to reduce costs and increase safety. Neither goal seems to have yet been achieved for the VA through the COTS adoption.

4. Results of the Analysis

The general contextual factors in EHR, as described above, explain many of the challenges that the VA has been facing in the deployment of the Oracle Cerner Millennium EHR. These challenges are not unique and may even occur in the majority of cases. But specific decisions and factors unique to Cerner and its product Millennium and to this installation were also problematic and are necessary to understand in terms of the flawed mental models involved and the contextual influences. These decisions and factors are described in this section of the report for Oracle Cerner, VA, and Congress/Executive Branch using the CAST analysis results.

For each major player, the analysis results include their responsibilities, the actions and decisions contributing to the problems encountered, why those actions were viewed as correct at the time, and recommendations resulting from the CAST analysis.

4.1. Oracle Cerner Health Solutions

General Responsibilities

- Provide and host a comprehensive EHR system for the VA and integrate it into the VA environment.
- Provide a single, common system for the VHA and DHA.
- Host and set the agenda for national and local workshops to configure the system and validate clinical workflows.
- Assist in integrating its products into the VA environment by providing: training and go-live support; integration of workflows with the new EHR; migration of legacy data; transition support; testing and continuous monitoring; business and data analytics; innovation and enhancements; and technical support.

The Oracle Cerner contract includes requirements for Oracle Cerner to (1) conduct reviews and assessments of medical facilities to determine facility needs prior to deployment (e.g., technology infrastructure), (2) provide services, including project management, change management, training, and testing, and (3) host and deploy the EHR across the VA enterprise.

4.1.1. Oracle Cerner Actions and Decisions Contributing to the Problems

1. Created and marketed an EHR system (Millennium) based on a data model, unique to Cerner, that led to serious problems in VA operations and patient quality of care.

Description:

One of the major (discovered) problems with the use of Millennium at the VA has been the creation of orphans, where the event set hierarchy (basically the data dictionary) can have leaf nodes with no parents. Orphan event codes pose significant risks by potentially making critical patient information (such as breast cancer screening results and suicide prevention flags) inaccessible to some clinical decision makers. After the pause that followed the installation at the first five VA facilities, it was determined that 79,000 of 200,000 event codes were orphaned and not nested within a parent event set, making them unavailable through the patient's chart or through reporting systems and potentially leading to missed, delayed, or duplicative care [17].

This design flaw in the data model is clearly a concern for both patient safety and quality of care. As one example, a patient had a lab test for vitamin levels done after surgery at a non-VA facility using Millennium, and the patient was sent home. The ordering clinician could not see that the patient had a low thiamine level because that event was a parentless leaf node (orphan). Subsequent procedures, ordered without knowledge of the low thiamine level, led to patient brain damage [18].

We were told that in the attempts to reduce the number of orphans, thousands of orphan codes were simply given a foster parent [Interviews]. That would make them technically no longer an orphan and thus no longer structurally defective, but they would still be conceptually defective.

At least one cause of orphan codes has been identified. If an orphan event code is associated with a PowerForm, the collected data will only display in the textual rendition, which is analogous to the print/PDF of the completed form. The impact is that if data are recorded on the form, they cannot be pulled forward into an alert, an active view in the workflow, etc. Data is not lost, but is generally inaccessible outside the completed form, access to which is limited to the creator of the form.

While an effort to reduce the orphaned event codes has been underway for at least a year, more orphans are being created, although at a reduced rate. As the rollout continues and more parts of the VA are involved, more unique cases will arise with more PowerForms required. It is therefore very likely that more orphans will be created in new rollouts even if the existing ones are eliminated. The problem of PowerForms creating orphans clearly needs to be fixed before further rollouts, perhaps by better overall configuration control and data management processes. If there are other causes for creating orphans, they need to be identified and fixed. Simply eliminating existing orphans is clearly not a long-term solution. A new 2025 report

suggests that orphan codes continue to proliferate without a clear understanding of their causes [3].

The orphan problems may be just the tip of the iceberg with respect to fundamental data problems with the Oracle Cerner product [Interviews]. One HIT expert told us that there are semantic defects that they will probably not be able to find until an adverse event occurs related to the defect.

We were told by VA experts that the Cerner system does not have good data management in general and no discipline [Interviews]. For example, there are 500 or so roles that are all essentially equivalent; there are lots of ways to do things; and there is no standardization of naming conventions for documents.

More generally, the fundamental problem is the flawed data model used in Millennium. According to Box and Francis [17] and others with whom we spoke, this technical root cause is not being addressed.

The ESH is messy because the core architecture (data model) does not constrain it from being or becoming messy. There is a difference between customization, which the Oracle Cerner product allows, and configuration control, which needs to be built into the data model management processes. Both are important, but at different levels of the system design. Configuration control (where the data model lies) is important at the technical level while customization is important at the user level. These two levels are usually separated in modern software, but not in Millennium (which is relatively old). More about this difference is included in the final section of the report on the choices for the VA on how to proceed with its EHR modernization efforts.

If fixes involving configuration control and other data management processes cannot be devised and implemented that correct or compensate for the data model flaws, then the system may not be able to be made safe and reliable enough for acceptable use in a healthcare system as complex as the VA no matter how much effort Oracle Cerner and the VA expend.

Why did the DOD not have these same problems?

Why did the DOD version of Millennium, which was installed before the VA, not have orphans? We were told that in fact they did. But the DOD is not proliferating them, particularly with PowerForms. In comparison with the DOD and other Cerner EHR users, VA facilities require many more PowerForms due to unique patient care needs and custom workflows. Thousands of PowerForms were created at the first five VA sites, leading to a large number of orphans. Not having that number of PowerForms, the DOD may have been able to keep up manually with the process of removing orphans.

Why the Action Seemed Correct at the Time:

Mental Model Beliefs Involved in the Decision:

Oracle Cerner: *We need to differentiate our product from our competitors (the major one being Epic). One way to do that is with the underlying data model and allowing more customization.*

Oracle Cerner: *We need to create a data model and EHR system that will satisfy a large number of potential customers.*

Oracle Cerner: *The design of the ESH does not present an issue for patient safety or quality of care.*

Context:

A unique factor in healthcare is the complexity of the data and the variety of uses of that data. An example is the number of health factors. Health factors are clinical observations about a patient as well as a few process observations. When someone uses Vista, health factors are created as a string of characters. The VA has very little control over what is included and the variations that occur at each site. On the order of 200,000 unique health factors have been used in at least one VA site. Approximately 18,000 health factors have been used at every site. The complexity, amount, and breadth of important data in healthcare and in a healthcare system as comprehensive as the VA increases the difficulty of creating useful EHRs in this field compared to others. Again, scaling software developed for a simpler context is difficult and may be impossible or at least impractical.

In addition, the VA operates in almost every area of healthcare, from social work to dentistry to primary care, which exacerbates the problems of creating and using a common EHR system.

Finally, healthcare is rapidly advancing in comparison to other fields, and the data may change or new data may be needed to keep up.

Another contextual factor related to Oracle Cerner is that Oracle Cerner allows more customization than their main competitor, Epic. The discussion about customization of Millennium for the VA (and probably other customers) was at a high level and did not reach down into the ESH itself. As a result, problems in the ESH may appear many years after the initial installation.

Why are these problems with the ESH occurring? The original VA contract with Cerner had a relatively rapid timeline. To meet the deadlines, Cerner proposed taking the baseline configuration data model used by Intermountain Health, a regional healthcare system in Utah that, at the time, was viewed by both the DOD and VA as a leader in EHRs.

In 2011, Intermountain took a version of Cerner Millennium, edited it, implemented it, and tried to use it at a community hospital in Utah. It did not work adequately. They changed the data model and did a secondary rollout in 2014 that was more successful.

Intermountain later adopted the Epic EHR system citing significantly higher physician satisfaction scores as one key factor. We do not know all the reasons why Intermountain made the change to Epic (and could not find out), but some people we talked to at the VA thought it was related to the fact that Intermountain had a lot of problems with the Cerner system. There may be other more benign reasons.

In any event, the crux of the problem is that the baseline configuration used for the DOD was the failed 2011 Intermountain version, not the corrected 2014 version. Cerner then asked the VA if the configuration looked good, and the VA accepted it without understanding the potential limitations of the data model design—likely because it was the same data model already being implemented by the DOD known as MHS GENESIS.

More generally, EHR systems are enormous and very expensive and difficult to develop. Both the Epic and Cerner EHR systems are quite old and are too difficult and expensive to change significantly [Interviews].

2. Unknown queue and other problems

Description:

The flawed design of the ESH data model is not the only technical problem with the Oracle Cerner EHR system. The *unknown queue* problem is another one that has contributed to patient safety problems at the VA. Essentially, if an order or other message is placed by a clinician and the request cannot be delivered for some reason, it is placed in the “unknown queue.” The use of an unknown queue is not by itself a problem. Cerner, in fact, calls this behavior a “feature.”

However, in this case, good engineering design requires that feedback be given to the person providing the request or order telling them that it has not been delivered. Such feedback is required so the person who entered the order can respond appropriately, perhaps by finding an alternative communication channel to ensure that critical information is delivered. Feedback is one of the most basic requirements in designing for safety. The Oracle Cerner EHR does not provide such feedback when placing things into the unknown queue, demonstrating a lack of understanding of some basic engineering practices by those who designed Millennium. Software engineers are often not taught system engineering design principles.

After the Oracle Cerner EHR was installed in the initial VA sites in Washington state, it was discovered that 11,000 clinical orders for specialty care, lab work, and other services had never been delivered, and the healthcare personnel providing these orders were never alerted that the system had not delivered their orders. A VA OIG report estimated that 149 Veterans were directly harmed³ as a result, although it is difficult to provide accurate figures [19].

As an example of one case involving patient scheduling, an OIG report concluded that the unknown queue problem contributed to the accidental overdose of a patient in 2022, about seven weeks after the Veteran missed their scheduled appointment. Because of the software design flaw, the missed appointment was not routed to a queue to prompt rescheduling efforts.

When a patient does not report for their appointment, relevant healthcare staffers at VA medical facilities using the new EHR software are required to update the appointment status to “no show” in the system. This information is then routed to a “request queue” for relevant personnel to reach back out to the patient to reschedule their appointment.

OIG found, however, that while the patient’s status was updated to “no show,” it was not subsequently routed to the request queue, which resulted in schedulers not being asked to conduct their outreach efforts. “The OIG concluded that the lack of contact efforts may have contributed to the patient’s disengagement from mental health treatment and, ultimately, the patient’s substance use relapse and death,” the report said [19].

The Oracle Cerner software issues in this case were exacerbated by other problems that OIG identified, including staff not evaluating requests from the patient, staff not sending appropriate communications to the Veteran, and a psychologist not thoroughly evaluating or addressing the patient’s depression. However, all adverse events are the result of many different causal factors.

³ With respect to the unknown queue problem, the OIG determined that 2 cases caused major harm, 52 caused moderate harm, and 95 led to minor harm. The VHA defines major harm as permanent decrease in the body’s functioning or disfigurement or requiring surgery or inpatient care. Moderate harm is defined as increasing the length of hospital stay or requiring an increase in level of care. Minor involves no injury, no increased length of stay, and no increased level of care. [19] provides examples of harm caused by the unknown queue problem.

To prevent adverse events, we need to identify all related causal factors and fix the problem as a whole.

Humans are never perfect in their behavior. To require healthcare personnel to never make mistakes in order to make up for the deficiencies of technology is unrealistic and not the solution to safety problems. It is usually easier to change technology than to change humans. Humans are flexible and can make up for some technology design deficiencies, but humans are not infinitely flexible and assumptions that they can and will make up for the deficiencies lead to adverse events and less than acceptable quality of care.

Oracle Cerner’s argument that the unknown queue is a feature totally ignores the fact that this so-called feature was implemented in an unsafe way, that is, without feedback. Cerner knew about the problem after it was reported in an on-line help forum in 2014. However, users claim that Oracle Cerner did not inform the VA EHR users of the potential for the unknown queue problem nor provide guidance to address it in advance of go-live with the new EHR. Most important, they did not fix the problem when they first learned of it in 2014. It should involve a relatively straightforward fix. Such a fix should also involve more general actions such as identifying other places where feedback is not adequately provided.

Once the unknown queue was discovered by the VA facility, they created a workaround that required hiring additional staff to monitor the unknown queue to ensure that orders in the queue were routed to the right location or reentered. The VA facilities implementing the workaround reported staff stress, burnout, and low morale as a result of using the human workaround. It is important to keep in mind that what is an adequate solution to the developers may not be an acceptable solution to the users.

It took a year after the first trouble ticket was submitted to Cerner about lost orders (October 2020) for Cerner to complete the VA’s request to remove unmapped locations (September 2021) and another six months to update the EHR with a provider alert (February 2022) and to give the VA the ability to directly generate a report of orders in the unknown queue (March 2022). The OIG report claimed that they found a large number of orders in the unknown queue even after the supposed mitigations were implemented by Cerner.

Why did the DOD not have this problem?

The DOD did not run into the unknown queue problem because the queue was not activated on their version of the Oracle Cerner EHR. This raises questions, however, about the disposition of DOD undelivered medical orders prior to the VA’s use of the new EHR.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

User: <i>If I do not hear that an order was not delivered, then I can assume it has been.</i>
Developer: <i>My job is to deliver orders somewhere. If I cannot get it to the right place, then I need to stick it somewhere so the system users can deal with the problem.</i>
VA information technology personnel: <i>If the order is not delivered, the person who issued it will get feedback about what happened.</i>

Context:

The Oracle Cerner documentation provided to the EHRM IO describes the unknown queue as an option that can be activated for every Oracle Cerner customer. We did not have access to this documentation, but we were told that it does describe the implications or the additional requirements on the VA healthcare facilities to monitor this queue and deal with the contents. If the documentation does contain this information, it did not get to the users or those managing the installation at the five Millennium deployment sites.

Most software professionals are taught very little to nothing about engineering (vs. software) design and, of course, the same is true for healthcare professionals. While the basic principles of feedback are taught to engineering students in beginning classes, computer science and information systems students do not take these classes. Software classes focus on the design of software (and databases) and on how to ensure that the software operates the way the software designer assumes it should. Little attention is paid in these classes on how to ensure that the software satisfies the needs of the users and the larger system within which the software is being used. At the same time, the potential users and the larger system designers focus on what they need the software to do (the user's requirements) and not on the technical details of how the software satisfies those requirements.

The problems caused by this gap are behind most of today's poor software and information systems and failed projects [5]. Including potential users in interface design decisions is not enough. In addition, it is unrealistic to insist that users learn all the design details of the software or that software engineers become experts on the environment in which their software will be used. System engineers need to be included who can bridge the gap and ensure that the software design, working within the system context, satisfies the overall *system* goals, including properties such as efficiency, productivity, and safety. These system engineers need to understand basic engineering design principles as well as the requirements for the application being controlled or affected by the software. We have no information about the makeup of the Cerner teams that developed Millennium. The problems, of course, are exacerbated when the software is in a COTS system.

The lag in fixing the unknown queue problem once it was identified most likely resulted from problems in the ticketing process used by Oracle Cerner to learn about and fix reported problems. The flaws in this ticketing process are described later.

3. Millennium enforced limited or no configuration control with respect to changes in the stored data.

Description:

Many of the problems arising with the ESH stem from a lack of configuration control and change management. There was no system in place to ensure that content being entered into the system is properly configured, tested, and evaluated. Many people can add to or change the data being used, for example, by using PowerForms, with no centralized control over the additions.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Oracle Cerner: *Providing a flexible and usable data model that allows customer configuration of its uses in our highest priority.*

VA: *Oracle Cerner would not provide us with an EHR where there are no controls on the user making changes to the basic data and data structure if this were not good practice.*

Context:

The need for configuration control has been known for decades in the software and system engineering communities, and most information and software systems today provide it. We have no idea why Oracle Cerner implemented a system without central control over making changes.

Not understanding the complexities of the ESH model, the VA probably never thought to require the Oracle Cerner system to provide configuration control. In addition, they thought they were purchasing a COTS system that satisfied basic software and system engineering needs. COTS customers are usually not allowed to demand changes to the system being sold.

4. Created an EHR with usability problems.

Description:

The interface designs do not differ greatly between EHR providers. However, beyond the interface design, usability for health information technology (indeed for all industries) entails developing an in-depth understanding of how frontline healthcare professionals (end users) perform their work and designing systems that support the end users' needs [20].

Millennium, as delivered, had a large number of usability issues, which raises the question of what type of usability testing was done and who participated in any such testing. For example, the VA OIG's analysis of pharmacy-related patient safety issues that arose in the rollout at the VA Central Ohio Health Care System in Columbus, Ohio, found that usability was a factor in 374 of 566 patient safety reports (66 percent) [20-]. The issues noted included:

- Some parts of the Millennium user interface did not block likely sources of human error and increased patient safety risks;
- Parts of the user interface were not optimized for clinical workflows;
- Care coordination was negatively affected by patient data separated across the new EHR and increased the burden on providers;
- Navigation difficulties created inefficiencies in the staff completion of patient care functions;
- Limited and restricted views of the new EHR based on the role of the user did not account for varied staff duties and coordination needs.

As just one example, a patient safety report dated January 2023 identified an EHR usability issue that resulted in facility nurses unintentionally cancelling over 1,000 patient medication orders during the medication reconciliation process, including removing chronic maintenance medications from patients' active outpatient medication lists. At the same time, patients lost

access to medication lists and associated refills. Healthcare providers had to identify and reorder medications that were inadvertently discontinued.

The problem occurred due to confusion surrounding the purpose of a selection button within the new EHR's medication reconciliation screen that was labeled "complete." Facility nursing staff believed selecting the "complete button" indicated completion of the medication reconciliation process. However, a VHA leader told the OIG that selection of the "complete button" made a patient's medication order inactive, which led to healthcare providers not being notified of the change. Note that this example again reflects the lack of feedback to providers when critical events occurred that was noted earlier under the unknown queue problem. There are most likely other examples of this design flaw in the EHR software.

After learning of this usability problem, the Chief of Staff started an action to look back at over 1,000 canceled medication orders affecting nearly 550 patients. After that investigation was completed, facility staff developed the following remediation actions:

- Staff submitted an EHR request to disable the "complete button" for nursing staff (rather than simply changing the label on the button)⁴;
- Staff were re-trained on the function of the "complete button". A safer and more
- effective solution would have been to simply change the name of the function in the EHR along with performing a review of other potential misleading terminology; and
- Pharmacy staff monitored orders.

This solution is similar to others suggested after usability and other flaws were identified in Millennium that required humans to make up for deficiencies in the technology instead of fixing the technology itself. In this case, the technology design change (and the verification necessary to ensure that it will be effective) is relatively simple.

A VHA leader told the OIG that as of August 2023, this patient safety risk remained. The "complete button" was not disabled and testing needed to be completed to determine if removal affected other work areas.

⁴ A similar "fix" was created in response to a patient death at the East Texas Cancer Center in Tyler, Texas, in March 1986 following a massive patient radiation overdose by a medical linear accelerator called the Therac-25. Although there had been two previous overdoses by this machine, minimal investigation had ensued and users of the machine were not informed. This third (known) overdose occurred when the operator, typing quickly, made a mistake in entering treatment data for a patient who was being treated for a skin cancer on the side of his face. The operator used the up-arrow on the keyboard to move the cursor in order to correct the entry mistake, which triggered an unknown software error.

In response to the death, the company that made the Therac-25 (AECL) sent a note to all users warning that the key used for moving the cursor (inscribed "UP" with an upward-pointing arrow) not be used. To prevent accidental use of this key, AECL suggested that users pry off the key cap and fix the switch contacts in the open position using electrical tape or other insulating material. Users were told that this change would require users to re-enter the entire prescription again if incorrect data was entered. The notice did not say why this change was necessary nor mention a patient death had occurred. The company did not further investigate the overdose claiming that the fault could not have been their machine.

This type of simplistic response might be justified as a short-term "stop loss" response, but not a long-term fix. The cause was never identified and fixed until the radiation therapist at the East Texas Cancer Center, whose patient had died, investigated himself and found the software error. By the time the software was fixed, four other people had died or were permanently harmed at other healthcare facilities using the same machine [21]. The other overdoses triggered by this software error did not involve using the up-arrow key. It is surprising (and disheartening) to see the same type of simplistic response to technology flaws almost 40 years later.

The “complete button” problem is only one example and the tip of the iceberg. The OIG identified many Millennium usability problems [20]. One VHA leader told the OIG that due to the nonintuitive design of the new EHR, user errors resulting in patient safety issues can easily occur. Users are complaining about confusing alerts. Some have concluded that the new system has decreased morale and job satisfaction and increased burnout among VA staff.

Another VHA leader told the OIG that requested EHR changes intended to increase safety and usability are being submitted at a faster rate than can be delivered, and that staff vigilance is protecting patients. Additionally, VHA Essential Medication Information Standards policy defines the components of (and need for) accurate medication information and “is written with a demanding standard and the EHR does not meet that demanding standard. . . I want the EHR to fit our business practices, not our business practices to fit the EHR we happen to have” [22].

The OIG concluded usability issues that led to inaccurate medication information in patient EHRs contributed to two-thirds of facility pharmacy-related patient safety reports within the time frame reviewed. Unresolved usability issues in the new EHR will continue to contribute to pharmacy-related patient safety issues. [20,22,23]. A final complaint we heard about is that the medication lists are not patient-friendly, which was one of the overall goals for the new EHR (see Appendix C).

Years ago, a KLAS survey showed that the VA VistA CPRS (Computerized Patient Safety Record System) users were happier with VistA than the Cerner users with Millennium [25]. Therefore, it is not surprising that VA VistA users were less happy when the Cerner product was deployed. A more recent survey conducted by the FEHRM in 2022 [26] included users of Millennium (also known as GENESIS) in the DOD, the VA, and the USCG (U.S. Coast Guard).

The response rate was:

DOD: 5526 respondents with an estimated response rate of 12.9%

USCG: 109 respondents with an estimated 7.2% response rate

VA: 2102 respondents with an estimated 20.2% response rate

The results are shown in Table 1:

Table 1: Survey of Millennium Users in the DOD, USCG, and VA in 2022

<i>The electronic health record makes me as efficient as possible.</i>			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	15%	19%	66%
USCG	26%	28%	46%
VA	5%	6%	88%
<i>The electronic health record enables me to deliver high-quality care.</i>			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	23%	32%	45%
USCG	49%	31%	21%
VA	7%	15%	78%
<i>My initial training prepared me well to use the electronic health record.</i>			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	17%	13%	70%

USCG	21%	21%	58%
VA	6%	8%	86%
My on-going electronic health record training/education is helpful and effective.			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	21%	23%	50%
USCG	34%	29%	30%
VA	11%	21%	68%
Over the past two weeks, the electronic health record was available when I needed it and “down” time was not a problem.			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	24%	16%	61%
USCG	46%	18%	36%
VA	17%	12%	71%
The electronic health record has the fast response time I expect (e.g., login time, screen refresh, retrieving information).			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	15%	15%	69%
USCG	23%	18%	58%
VA	9%	12%	78%
The electronic health record allows me to deliver patient-centered care.			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	31%	26%	34%
USCG	55%	26%	15%
VA	11%	18%	70%
I am sufficiently informed about any electronic health record information or notices that will impact my day-to-day job.			
	Strongly agree/agree	Neither agree nor disagree	Strongly disagree/disagree
DOD	36%	26%	16%
USCG	51%	25%	25%
VA	22%	25%	52%

The newest OIG report results (2025) are no better three years after the VA facilities implemented Millennium.

The VHA users are clearly not yet very happy with this system. Although the DHA users are less unhappy, they are not overall extremely positive. The USCG responses, although limited, were much more positive. The differences between DOD and VA in user satisfaction might be partially explained by DHA healthcare personnel having had more time to adjust to something new, a higher expectation for DHA healthcare personnel to adjust without complaining than in the VA culture, Millennium being more attuned to DHA workflows, etc. The higher USCG satisfaction probably reflects differences in scale and scope.

Another DOD survey a year later (2023) showed improved satisfaction by DHA personnel from the previous year, but users were still dissatisfied with system response time, with their ability to work as efficiently as possible, and with their ability to deliver high quality care] [27]. Considering the question about quality care, only 29% of MHS GENESIS (the name of the Millennium system used by the DOD) users in 2023 agreed that the system enabled them to deliver high-quality care, compared to 46% of the legacy system users.

The differences in acceptance between the DOD and the VA personnel were explained to us by a provider who has worked in DHA healthcare facilities:

“Millennium requires a significant amount of end user training because it’s so incredibly complicated and non-intuitive. It is much, much more difficult to use than what DOD doctors were used to, but DOD just told the doctors to deal with it. DOD did that in 2003 with AHLTA, DOD did that again for the past five years and telling people we don't care that you have to do more work... just deal with it doctors. I'm a doctor. I use it. I know this is true. I received these messages.... VHA is never going to put up with that” [Interviews].

The VA Councils were supposed to help tailor Millennium workflows and policies to those of the VHA, but they were limited in their ability to make changes. Part of the problem was that Cerner had already made changes to match the DOD healthcare system, which was five years ahead of the VA, and a common product was desired. The 18 Councils were shown the product, were told the configuration decisions that had been made by the DOD, were told what was alterable and what was not, and they were then told to figure out how to meet the VA mission with the result. More about the VA Council process is included below.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

<p>VA: Oracle Cerner EHR systems are being used by many healthcare groups without complaints about usability and, in fact, they tout their strengths in this area. We can assume it will be usable without any special acceptance criteria.</p>
<p>Oracle Cerner and VA: Humans are flexible while computers are not. Humans can easily adjust to an EHR system and adopt standard workflows without degrading quality or safety of patient care.</p>
<p>Oracle Cerner: Our previous installations of Millennium did not raise a significant number of usability complaints.</p>
<p>Oracle Cerner: Millennium is intuitive and easy for healthcare professionals to use so we do not need any intensive training or special adjustments for the VA to use Millennium (see training issues later).</p>

Context:

While Cerner products are more tailorable than their competitors, the VA had basically signed up for a COTS product, assuming it would meet their usability and other needs. This was the first time the VA had acquired such a complex and comprehensive COTS EHR system; previous EHR development had been internal or subcontracted with internal control over the basic

design. As with many others, the advantages of COTS may be emphasized in acquisition decisions with the disadvantages either unknown or minimized. The advantages and disadvantages are discussed in more detail in Section 4.2.1.

Another important contextual factor is that usability is rarely taught or emphasized in software curriculums, except for relatively simple concepts such as screen design. Students are rarely exposed to cognitively complex topics, such as semantic distance and human-centered design. Good design for usability requires the designer to either have great familiarity with the job that must be done by the user or have access to expert users that can provide the necessary information.

One obvious question is why the same usability issues did not show up in the early DOD installations of Millennium. One answer may be, again, that the DOD culture is significantly different than that of the VA. DOD physicians were told to just deal with the system they were given. We were told by DOD physicians that they found Millennium to be more difficult to use than the previous DOD AHLTA EHR system. Even when AHLTA was installed in 2003, however, DOD physicians were expected to adjust to the system that was provided. DOD physicians are used to operating within a different culture than VA personnel.

The VA context also differs from both the comparatively small hospitals in which Oracle Cerner systems have been a success. The same kind of usability issues may not have been raised in these contexts.

A final contextual factor is that optimizing usability can be expensive and take considerable effort. EHR companies, facing little competitive pressure in this regard, may not prioritize usability over other properties that more directly affect the financial bottom line.

5. Created an EHR that does not follow national interoperability standards.

Description:

There are several different aspects of interoperability. The first is the transmission of patient information to outside healthcare providers. Most event codes (88%) in the ESH were not mapped to healthcare standards, such as SNOMED® or LOINC® at the time of the pause. Given the need to interface with providers outside the VA and DOD with community care partners, adherence to interoperability standards is a high priority for the VA and was one of the criteria for deciding to acquire a COTS product.

We have been told that the VA is working on attaching SNOMED codes to ESH event codes. We have no doubt that this relatively straightforward problem can be solved and perhaps already has by the time of this report.

A second type of operability requirement involves developing interfaces from all the medical devices to Oracle Cerner Millennium so that patient health data can be automatically uploaded from those devices, such as vitals monitors, ventilators, and infusion pumps. As new devices are obtained by VA facilities, their interfacing requirements must be established. This interfacing involves a significant amount of work. We have heard conflicting information about who is responsible for performing this task both for current devices and new devices in the future.

A third interoperability issue may not have a straightforward solution. In the initial installation of Millennium in the first five VA facilities, workflow differences with some external systems were discovered. For example, there were transmission failures of prescriptions to the

Consolidated Mail Outpatient Pharmacy due to address and direction deficiencies or package size.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Oracle Cerner: We need a competitive advantage (intellectual property) by naming and classifying terms, data, and processes unique to our products that do not follow interoperability principles.

Oracle Cerner: There are so many conflicting standards for health data interoperability, we should let our clients decide which standards they want to follow because most are recommended but not required.

Context:

We were told that EHR vendors have frequently blocked, for business reasons, the type of interoperability that would ensure more safe and reliable care [Interviews]. In addition, in the rush for meaningful use from 2005-2015, little attention, resources, or incentives were dedicated to address interoperability.

Health systems have been mostly focused on their patients within a single EHR, not what happens to patient information if the patient seeks care outside their health system. Even the most basic database programming (such as SQL) was not adopted by Cerner; instead, they created a proprietary Cerner Command Language (CCL) that likely would require ongoing maintenance contracts by the vendor.

6. Migrated data incorrectly from VistA to Millennium. The data migration process did not ensure data quality.

Description:

Migration of the data from the previous EHR (VistA) to Millennium was the responsibility of Oracle Cerner, but the VA and Oracle Cerner were to coordinate in performing manual and automated validation testing of migrated data.

The OIG reported that before the Spokane deployment, Oracle Cerner did not establish and use performance measures and goals to ensure that the quality of the migrated data supported clinicians' needs for accessible, accurate, and appropriate data in the new EHR system. In fact, in many cases it did not; data migration started without ensuring data quality was preserved by the process, and erroneous data was imported into the new EHR that did not meet the quality needs of clinicians. For example, schedulers had to manually scrub provider schedules and Veteran data for accuracy. In some instances, data expected to be migrated into the new system was not accessible. For example, one clinician noted an inability to view patients' migrated immunization data, resulting in confusion and raising patient safety concerns.

The new EHR contained incorrect names, genders, and contact information for some patients. Migrated data, such as allergies, medications, and immunizations, were frequently duplicative or contained errors. Refills available on prescriptions were not always accurate,

including those for controlled substances. Patient Record Flags used to alert staff to patients at high risk for suicide and disruptive behavior did not transfer to the new EHR system, placing patients and staff at increased risk. Deficiencies in scheduling data were rife. Future medication orders were discontinued. Registered nurses were able to order medications without the orders being reviewed or approved by a medical provider. Some outpatient medication orders were not processed. Medication lists were inaccurate and not patient friendly.

Part of the reason for medication list importation problems was that the software was not written to accept the information that was being imported. There was no way to translate Vista CPRS [Computerized Patient Record System] language to the Cerner language. In addition, the new EHR did not notify staff when future orders were discontinued or when orders did not process. Without notification, staff were unaware of the need to take other action and could not resolve the matter in a timely way. This lack of critical feedback is described under the unknown queue problem.

Patient contact information, such as names, addresses, telephone numbers, and email addresses were overridden by outdated DOD data during migration to the new EHR. Interim measures to manually correct information were unsuccessful as the DOD data remained the primary linked data source, and corrected information reverted back to the outdated data each night at midnight.

These are just some examples of the problems that occurred during the migration process. These problems all sound fixable, however, and, presumably, have already been fixed. The outstanding question is whether all general data migration processes have been fixed so that a repeat does not occur when the system is rolled out to additional sites after the current pause.

Another requirement is that the DHA and VHA need to determine what data needs to be migrated to develop a complete patient EHR. We understand that such a determination has never been done.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Oracle Cerner: *Our previous data migrations before the VA have worked fine so we will not need to make changes.*

Context:

Having problems arise in such a large data migration effort is not surprising. The question is whether stronger quality assurance methods for migrated data have now been established. Oracle Cerner must have gone through this activity in other installations. Was this effort more challenging than in other installations of Millennium? What happened with the DOD?

Another contextual factor that arose in the data migration effort is that the VA's legacy system contained patient healthcare information (including inpatient medications from past hospitalizations, and some historical mental health and women's health data) that did not align with any of the Oracle Cerner Millennium healthcare data domains and thus could not easily be migrated.

7. Oracle Cerner did not do what was needed to install Millennium safely.

Description:

While we were told by many at the VA we talked to that there have been no adverse events related to the ESH design and to Millennium in general, we were, with little effort, able to find several instances of adverse events and near misses. Dr. Neil Evans, of the EHRM IO Office, testified at a Congressional hearing that he gets reports daily that include the adverse events and near misses that have occurred [28,29].

We have no doubt that his statement is true, but the question is why other people who are responsible for the Millennium rollout do not also have this information. Either there are communication problems or there is a level of denial (called *defensive avoidance* in psychology) occurring. What appears to be clear patient safety issues have been labeled as not related to safety. Patient harm should not be required in order to raise safety alarms: near misses are the chance to catch problems before harm occurs. The OIG was able to find these events and the OIG reports were easily available to the VA staff.

In a recent briefing on March 15, 2023, VA officials informed the Senate committee staff of six "catastrophic harm" incidents, including four veteran deaths, linked to patient safety issues with Millennium—one at Spokane's Mann-Grandstaff VA Medical Center and three in Central Ohio after the launch of the Oracle Cerner system in April 2022. In the section of this report on the unknown queue problem, many patient harm events were mentioned. In addition, a lawsuit was filed against the VA in December 2023 by a veteran who claims that his prostate cancer diagnosis and treatment was delayed for over a year because a referral to a urologist was delayed in delivery by Millennium [30].

In general, potential patient safety problems linked to Millennium in the rollout at the VA included problems in prescription processing, medication management, clinical referrals, and identifying patients at risk of suicide. Surprisingly, when we asked, most of our informants did not seem to know whether the problems that occurred were related to safety or that adverse events had occurred in the operation of the new Millennium EHR. We were told that the problems did not involve patient safety as they only resulted in near misses and not actual patient harm. This kind of misunderstanding of patient safety may reflect serious problems in the VA safety management system.

Many of the adverse events that are associated with Millennium arise from other problems that are discussed separately in this report. For example, gaps in interoperability between the new EHR system and established VHA tools prevented tracking and monitoring of patients at high risk for suicide and resulted in inaccurate patient record flag data displayed in VistA, which is still in use at most VHA sites. In general, staff had limited access to suicide prevention, risk assessment, and reporting tools in the new EHR.

We have also heard that a VHA review of patient safety implications of Millennium is awaiting vendor prioritization. Responsibility for safety cannot be delegated to a contractor and particularly not to a company providing a COTS product; responsibility lies in the hands of the healthcare provider; in this case the VA.

We were surprised to find that the VHA Office of Safety and Quality had very little initial involvement in the selection and deployment of Millennium, although they seem to have been included more after the deployment problems started to occur. As an example, when rolling out

the new Pharma system to Spokane, a serious patient safety problem was identified and reported to the VA NCPS (National Center for Patient Safety). They responded immediately.

Why did the DOD not seem to have the same safety problems in rolling out Millennium that the VA had? Elsewhere in this report, the differences in culture and context between the VA and the DHA are described. In addition, they may have had patient safety problems that were never tied to the EHR. A common practice in root cause analysis is to stop after determining how the local actors contributed to the loss without examining more remote, less direct contributors, such as the design of the EHR.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

<p>Oracle Cerner and VA: <i>Humans are flexible while computers are not. Humans can easily adjust to an EHR system and can adopt standard workflows without degrading quality or safety of patient care.</i></p>

<p>Oracle/Cerner and VA: <i>Testing and training users are adequate for assuring the safety of a new EHR system.</i></p>

<p>Oracle Cerner: <i>Lack of significant safety problems in other software installations means that they will not occur in the current installation.</i></p>

Context:

A COTS vendor (or even a contractor providing systems for a government agency cannot be responsible for safety. Ultimate responsibility rests with the VA.

In addition, the safety of any software, including an EHR system, can only be evaluated in the context in which it is used. Software that is perfectly safe in one system may be unsafe in another.

Healthcare is behind other industries in employing modern hazard analysis to identify potential causes of adverse events before they arise. Informal techniques are not adequate in complex, adaptive systems like software.

8. Before rollout, Oracle Cerner did not perform adequate testing and other types of system analyses (human factors/usability and safety).

Description:

We have only very limited information about internal Cerner testing. While testing can never identify all potential flaws in a software product, the large number of problems that arose in the rollout point to inadequate testing, particularly user testing.

As just one example, the confusion over the “complete button” should have been found in comprehensive user testing. Transmission problems that arose in the transmission of pharmacy data to HDR could theoretically have been found with end-to-end testing. An EHRM IO leader noted that Oracle Health originally tested the software interfaces. However, the testing plan focused on the transmission of data from the new EHR to the HDR but did not include verification of the accuracy of the data when accessed downstream by legacy EHR (VistA) users [Interviews].

No independent operational test activity (IV&V) had been done as of January 2023 and there were no plans to do one. IV&V is standard procedure on large software projects. As an example of limited user inputs and evaluation, scheduling staff were not given the opportunity to identify limitations in the new scheduling system before installation. While it is difficult to anticipate all problems when doing a rollout of such a complex and critical COTS system, pre-rollout analysis and testing can be used to reduce the problems that do arise. Judging by the number of problems that did occur in the rollout, we assume that such activities must have been limited.

Flaws contributing to safety, however, can usually not be found in any type of testing, so the standard approach to ensuring safety, in every other industry, is to perform hazard analysis. Again, given the relatively obvious safety flaws identified after rollout, it does not appear that any type of sophisticated hazard analysis was performed. While any rollout of such a complex IT system will cause problems, most of those that occurred could and should have been avoided.

After the first deployment, the VA had to create workarounds, which caused delays in providing patient care. A large amount of resources had to be expended at the first rollout facilities to prevent safety and quality-of-care problems [31].

In response to questions we asked about what testing was done, VA personnel responsible for safety suggested that they had tested for safety by providing an unsafe input and showing that the system caught it. Unfortunately, this proves nothing about the thousands or more other potentially unsafe inputs that can occur. Only exhaustive testing can provide assurance of safety, and exhaustive testing is not possible for software. Assurance of safety must be accomplished by means other than testing.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

<p>Oracle Cerner: <i>Our standard testing process was adequate for previous smaller installs and for the DOD so it will be adequate for the VA.</i></p>
<p>Oracle Cerner: <i>Our products are used widely and therefore extensive testing for each installation is not necessary.</i></p>

Context:

It is likely that Oracle Cerner and the VA thought that the Councils and Workgroups would be able to determine if the EHR as configured for the DOD could be used for the existing VA workflows. The Councils and Workgroups were an attempt to address usability problems and related requirements, although their ability to do so was limited.

How were safety requirements going to be satisfied? Requirements that can be imposed by the customer on COTS products, even those like Millennium that allow some configuration, are obviously limited. In addition, the COTS producer cannot be expected to assume responsibility for safety of their product in every one of their customers workplaces. In fact, safety is dependent on the context in which software is used, which will differ for every customer. The VA has the ultimate responsibility for ensuring patient safety, although a COTS software provider

has a responsibility to provide the information necessary for its customers to satisfy this responsibility and must follow established safety practices in its products.

9. Oracle Cerner provided a training program that did not prepare staff for the new system.

Description:

The information we have about training is limited. We have been able to find the most information about the training for schedulers from OIG reports [108, 109, 233 [22,23,24]. Cerner started training for Columbus schedulers and providers in February 2020 and for some Spokane schedulers and providers in January 2020, but paused it shortly after due to the Covid-19 pandemic.

As Columbus prepared to implement the system in August 2020, an OEHRM internal document that summarized training-related survey feedback revealed Columbus schedulers' concerns [22]: "They felt that they had not been trained to handle real, complex scheduling scenarios; that their training was not tailored to their roles; and that they did not have enough time to practice using the system." Cerner resumed training without making changes, despite the negative feedback. The VHA and OEHRM pressed forward with further rollouts in the summer of 2020.

OIG reviews of scheduler training [23] determined that training by Cerner had insufficient content and that there was a "button-ology" approach to training and training materials. In addition, once the rollout started, there was insufficient direct support for the facility staff.

The OIG identified insufficient end-user training as a main source of the difficulties and misperceptions about certain EHR functionalities. Many users said they were not adequately trained to use the system [22,23,24]. Examples include:

- Alerts were confusing and the providers reported not receiving training or receiving incomplete training related to alerts.
- Interviewees reported a lack of training related to the proper way to enter medication reconciliation modifications in the new EHR, which led to corrected patient medication lists not staying corrected.
- Staff reported insufficient training on the management of referrals in the new EHR.
- Deficits in staff training contributed to facility staff's difficulty tracking orders. As a result, staff developed time-consuming work-arounds to confirm receipt of orders by laboratory staff.
- During interviews and observation of facility staff navigating the new EHR to perform care-related tasks, the OIG observed that the new EHR design and workflows caused display fragmentation in staff's views of patient healthcare data.
- When the new scheduling system was implemented, the fields that captured key appointment dates were different than in the old system; these new fields were labeled the "request begin date," "grace period," and "date placed on list." Scheduling supervisors told the OIG review team they were confused as to which of these new date fields they should use to measure patient wait times because schedulers had received no guidance on how these fields were defined. After examining the training materials, OIG determined the scheduling-related training did not provide guidance on these date fields.

According to an Office of Veterans Access to Care leader, VHA planned to issue an updated scheduling directive before implementation but was unable to do so because the system was not fully built, and additional steps were necessary before they could finalize a directive. As of June 2021, VHA had not finalized guidance detailing which date field in the new system schedulers should use to measure patient wait times.

- The workflows used in the training did not always line up with VA policies and procedures. The training workflows were very basic and simple, resulting in the need during real use to create workarounds to get the needed results, such as getting patients scheduled. The workarounds, in turn, led to large delays in patient care.
- A survey of Columbus schedulers included concerns that they had not been trained to handle real and complex scenarios, that their training was not tailored to their roles, and that they did not have enough time to practice using the system. Despite negative feedback, Cerner did not make changes to the training.

To evaluate the training being provided, the VA OHI (Office of Healthcare Innovation), planned evaluations (1) immediately after training, (2) 1–30 days after training, and (3) 30–90 days after training. Evaluation was done by trainee proficiency checks and participant surveys. There is some controversy about the reporting of the results [33], which we will not go into as they are not pertinent to our primary goal.

Despite voicing concerns, the respondents still rated their overall satisfaction with the course as an average of 3.9 out of 5.0. This rating was based on the effectiveness of the training, overall experience, materials, instructors, pace, and duration of the scheduling-related training courses. Note, however, that assessing training by asking the people who took it right after the training was provided is not very effective. They do not know what they were *not* taught, such as no training on alerts. They would not know they needed special training on them until they started using the new system. Indeed, after using the system, many concerns were raised such as [22]:

- “As we began working after ‘go-live’ we realized we didn’t know how to do about 25% of our normal tasks, i.e. check who went to urgent care, enter a contact attempt in patient’s chart, print a list of future appointment requests.”
- “The training was not geared toward the tasks that are required of AMSA [Advanced Medical Support Assistant] staff here at the VA. The training was geared toward inpatient and a private/community facility.”

Oracle Cerner argued that although they had done quite a bit of work in training users in the system, the users were not prepared to change their business workflows. In other words, it was the users’ fault. It is likely, however, that the Oracle Cerner training was based on much simpler workplaces in community and hospital settings, as noted by one of the trainees above. Training specialized to the VHA enterprise apparently was not created but instead standard Cerner training was used.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Oracle Cerner: *Our product is so intuitive (to us, at least) that extensive training is not necessary.*

Oracle Cerner: *Our training was adequate for the DOD and other Cerner customers.*

Context:

Oracle Cerner had never deployed Millennium in a healthcare context as complex as the VHA. In many important ways, the deployment in the DHA was simpler and more like commercial hospitals, so the standard Cerner training was closer to what was needed. Note, however, the survey results in Table 1 show high levels of both DOD and VA dissatisfaction with their training.

10. Provided inadequate installation support.

- a. Designed an inadequate ticketing process for rollout and did not staff it adequately. This process did not meet contractual requirements.*

Description:

According to the contract, Cerner is required to resolve tickets within various time frames based on priority levels: critical, high, moderate, and minor. For example, Cerner is required to resolve critical tickets within 24 hours, and 80 percent of moderate tickets within four business days. The contract also states that the contractor is responsible for coordinating the “ticket grouping, severity assignment, categorization, and ticket classification.”

The process used in the first rollouts did not meet these contractual requirements, but the May 2018 contract with Cerner provided limited enforcement mechanisms. We understand there are efforts by the VA to increase the contractual enforcement mechanisms.

From October 24, 2020, through March 31, 2021, new EHR end users placed over 38,700 tickets. The VA OEHRM and Cerner classified tickets as either incidents or change requests and each classification required different actions to process. VA OEHRM guidance described an incident as something that had functioned properly in the past or a disruption in the system that negatively affected workflow. A change request was described as an application for an enhancement or configuration of the new EHR to improve the user experience.

The OIG identified multiple deficiencies and challenges with the ticket process and problem resolution. We could learn only the details that were provided by OIG reports, and these mainly involved the scheduling system [22,23]. But the same problems seem to have also occurred in other parts of the EHR system. The following are examples described by the OIG:

- Trouble tickets with the new system were not resolved within the goals for timeliness. The VA worked with Oracle Cerner to reduce the number of tickets that were over 45 days old, but the number of tickets continued to increase. There was no oversight of ticket resolution timeliness.
- Oracle Cerner did not always inform users that tickets were closed or how they were resolved. When they did, the users often did not get a useful response. For example, users reported being told that their issues could not be resolved because the contract did not support the work or that the resolution would not be supported at the national level. Others were told that the new scheduling system lacked the necessary capabilities.
- Oracle Cerner service desk support staff were not able to view and replicate reported issues because the version of the new EHR used by the Oracle Cerner service desk support staff did not mirror the version of the new EHR used by VA end users.

- Oracle Cerner service desk support staff closed tickets prior to resolution, sometimes not informing the person who had placed the ticket.
- Often, Cerner service desk support staff did not communicate ticket status to end users: EHR users complained that tickets “entered a black hole or were deleted.” As part of VA’s agreement with Oracle Cerner, end users were to be notified and given the opportunity to agree that ticket resolution addressed the reported issue prior to Oracle Cerner service desk support staff closing a ticket. A ticket was not considered completely resolved until the VA had approved and confirmed that it had been fully addressed, thus ensuring that reported issues were fully addressed and that Cerner service desk support staff and end users were in agreement with the ticket resolution.
- Facility staff reported a lack of communication between Oracle Cerner service desk support staff and facility employees throughout the ticket process. Interactions were described as unhelpful and sometimes even rude. Often the user had no way of knowing whether their issue was being addressed or by whom. Users experienced long delays without status updates.

The ineffective change request process hindered needed EHR modifications and created potential patient safety and related concerns. Instead of continuing to place tickets, some staff just developed workarounds to address system limitations to meet patient needs, which sometimes led to other problems. Although the VA initiated a strategic review to address these concerns, only limited changes were made to the process.

As an example of the costs involved to the VA, pharmacists in Columbus logged more than 730 help desk tickets, averaging over three tickets per day for each pharmacist. Keeping track of tickets became someone’s full-time job, and they had to create a management position in the pharmacy just to deal with the EHR. As a result, the pharmacy operations at Spokane, Walla Walla, and Columbus had a \$9M deficit from increased staffing costs and lost co-pays and collections.

The pharmacists did not feel their concerns were being taken seriously, so they documented the system’s flaws. After a Spokane pharmacist wrote a 57-page patient safety domain report in August of 2021 [Interviews], Oracle Cerner released pharmacy EHR updates. The pharmacists found that these updates produced incremental improvements but they also created as many new complications as they resolved. From a list of over 100 high-priority issues, only a few had been resolved at the time of the OIG report (March 2022). The pharmacists claim that it takes three times as long to process a prescription using the Oracle Cerner software than with their previous system.

A long-term change management system is planned to integrate the VA Office of Information and Technology and Oracle Cerner help desks. It is assumed that this eventual integrated process will facilitate transparency and efficiency.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Oracle Cerner: *Our ticketing process has been acceptable in other rollouts and therefore will be adequate for the VA deployment.*

Context:

The number of problems and tickets were most likely greatly underestimated by Oracle Cerner based on their previous experience, contributing to deficiencies in designing, budgeting, and staffing the ticketing process. Oracle Cerner had never deployed Millennium in such a large and complex organization. The DHA rollout provided a misleading example because of important differences not only in size but in culture and healthcare practices between the two organizations.

- b. Designed and implemented an ineffective Non-Standard Change Request Process: involved multiple time-consuming steps that included review and approval by facility, VHA, and joint VA and DOD groups.*

Description:

There were two categories of change requests: a standard change request was used for pre-approved modifications while a non-standard change request involved new approvals. A non-standard change request required the engagement of VA Solution Experts⁵, the facility's Informatics Steering Committee, and additional committees that included members from VA, Department of Defense, and Cerner. The time frame for satisfying change requests using this process ranged from weeks to months. As a result, the VA had to create workarounds in the first deployments that caused long delays in patient care and to expend large amounts of resources to prevent safety and quality-of-care issues.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Oracle Cerner: *There will be a small enough number of major change requests that a complex process to approve change requests will not have a major impact.*

Oracle Cerner and VA: *Everyone must be involved in the change approval process.*

⁵ VA solution experts are OEHRM staff who monitor new tickets, assess validity of change requests, work with Cerner to develop solutions, and validate changes in both the version of the EHR being built by Cerner and the live version of the EHR used by VA. The Informatics Steering Committee provides local leaders, guidance, and oversight of the EHR implementation.

Context:

Experiences obtained in previous deployments of Millennium clearly did not provide a realistic estimate of the number of problems that occurred during the VA deployment. Cerner had never deployed their EHR system in such a large and complex organization. Again, the DHA did not provide an adequate example of what would be involved.

11. Provided inadequate documentation on the new system.

Description:

Poor documentation may have played an important role in the problematic rollout of the Oracle Cerner EHR and the inability to fix the problems during the pause. First, the Oracle Cerner documentation is very incomplete [Interviews]. In addition, the terminology used throughout the documentation is company specific and not standard terminology used in the field in general. The use of internal Cerner jargon makes it very difficult to understand the ESH design, even by information system and EHR experts. The groups trying to fix the ESH cannot be successful if they do not understand the fundamental design principles. Most important, it is not possible to have substantive, meaningful conversations around improving the ESH structure if it is not understood by those participating in the conversations.

Why the Action Seemed Correct at the Time:

Possible Mental Model Flaws Involved:

Oracle Cerner: <i>Everyone uses the same terminology that we use within Oracle Cerner or they can easily translate the documentation into more standard terminology used in the broader EHR community.</i>
Oracle Cerner: <i>By using nonstandard jargon, I can differentiate my product from others in the same marketplace and obscure differences and similarities, i.e., the same or very similar features can appear to be unique.</i>
Oracle Cerner: <i>Our IP and marketplace is protected somewhat by competitors not understanding our basic technology through the use of nonstandard terminology.</i>

Context:

Computer scientists are notorious for speaking in jargon and therefore having difficulty in communicating with those outside the field. It is, however, unusual for a company to create new jargon that even experts in the same field but outside their own company do not use. Inadequate technical documentation about one’s products is, unfortunately, common.

Summary of Oracle Cerner Contributions

Although this report seems to be very critical of Oracle Cerner, it needs to be remembered that creating and installing these systems in large organizations is extremely difficult. Our goal is not to stress what has been done wrong in the past but to understand why the problems occurred and provide recommendations to the VA for what alternatives should be considered

for the future. It is not possible, however, to determine why flawed decisions were made without identifying what they are, identifying the potential mental model flaws involved, and examining the context in which the decisions were made and actions taken.

4.1.2. Recommendations for the VA

Millennium is a COTS product so some recommendations may be difficult to fix without Oracle Cerner cooperation. Many changes related to these recommendations have most likely already been made. Our recommendations are addressed to the VA as we have no control over Oracle Cerner or the DOD and DHA. Additional recommendations for the VA can be found in the next section and at the end of this report.

If the VA is to continue to rollout Millennium to VA facilities, the following recommendations should be considered to prevent adverse patient safety events, VA personnel stress, reduced quality of patient care, and wasted VA resources:

1. The technical root cause of the orphaned codes must be fixed, which should stop their proliferation, and the current orphans must be eliminated. As the VA is not allowed to change any proprietary Oracle Cerner content, the VA must ensure that Oracle Cerner corrects this problem and does not introduce others in the process. Some of the other problems, such as the unknown queue, should be fixed by changing the software—simply requiring VA manual monitoring of the queue is not an acceptable fix. We do not know whether this has already been done but assume it has been.
2. There are likely semantic data problems, such as semantic duplicates, that have not yet been identified in the ESH [Interviews]. The VA should ensure that a high-quality, independent analysis is performed on the ESH model to identify (and then fix) any flaws that might exist or to show that they do not exist.
3. The VA must ensure that the new EHR satisfies current VA policies for patient care or determine that these policies are not relevant and can be eliminated or changed.
4. A sophisticated hazard analysis needs to be performed to identify the safety implications of the use of Millennium in the VHA context. Finding and fixing one problem at a time is not an effective strategy. Hazards need to be identified by performing proactive hazard analysis and eliminated *before* they lead to adverse events or near misses. Most hazards cannot be found in testing—analysis is required.
5. A usability analysis needs to be performed on Millennium as deployed in the VA context, particularly focusing on identifying usability problems that may affect patient safety and quality of care. The Councils are not enough, as explained later in this report.
6. An external IV&V of the product's use in the VA context, should be performed that includes more than just the current issues that the FEHRM is working on. Tamara Box and Joe Francis (VHA Office of Quality and Patient Safety, Analytics and Performance Integration) have recommended that the VA "Contract a third-party, expert systems

engineering review of the ESH and the core structural components of that database and model to ensure the implementation of Millennium EHR can scale as new VHA facilities are activated” [17]. We agree. While we have done part of an external review, we did not have the time to do a complete review.

7. For a successful deployment of a new EHR, the VA must engage end users in the design of improvements and in the testing efforts. While the Councils included many different groups, some users did not feel included, and there was inconsistent participation in the efforts by the various Councils [34].
8. Oracle Cerner must provide complete and understandable documentation of the ESH using standard information systems terminology.
9. Oracle Cerner must improve the ticketing and support system provided to the VA.⁶
10. Ensure, through sophisticated system engineering techniques (e.g., testing and analysis) that the changes made fix the identified problems before deploying the system to any more VA facilities.

While the preceding recommendations can potentially go a long way toward fixing the immediate problems with Millennium, the long-term also needs to be considered. The following recommendation focuses on this longer term and should be completed before continuing to deploy Millennium:

11. The ESH, as it exists, is not an appropriate data model for a system as complex as VA healthcare. Building a house that is expected to last a long time on an inappropriate foundation is not going to provide a robust long-term EHR solution for the VA. In addition, fixing one problem at a time as they are found is also not going to work. The VA is very likely to encounter more problems as Millennium is installed more widely at larger and different types of facilities and over time [17]. Before investing enormous resources deploying an EHR with ESH as the foundation, VA leadership needs to decide whether such an investment is worthwhile or whether a different path provides a bigger payoff. Some alternative paths are suggested in Section 6.

4.2. Veterans Administration

The problems that have occurred in the Millennium acquisition have not all been the responsibility of Oracle Cerner. VA actions and decisions contributed.

General VA Responsibilities (only those relevant to this report are included):

- Exercise overall responsibility for patient safety and quality of care.

⁶ Note that, amid all the recent contract cancellations, ticketing support was one of the contracts cancelled and not reinstated.

- With the DOD, jointly develop and implement fully interoperable EHR systems or capabilities required by the National Defense Authorization Act for Fiscal Year 2008.
- Obtain and maintain an effective and safe EHR for the VA healthcare ecosystem.
- Manage and provide oversight of the scope, schedule, risk, performance, and quality of the EHR acquisition process.
- Ensure that the product used in VA healthcare facilities either satisfies current VHA policies or create a process for policies to be changed to match the constraints on healthcare that the Cerner product imposes without sacrificing patient safety or quality of care.
- Identify the configuration changes required for Millennium to assist in the provision of safe and effective healthcare.

Councils and Workgroups:

- Identify standard workflows and best practices for the configuration of Millennium.
- Review functions available in MHS GENESIS and determine what functions need to be further developed to meet VHA's clinical and administrative requirements.

4.2.1. Actions and Decisions Contributing to the Current State

- 1. Decided to adopt a COTS product rather than develop their own perhaps through a commercial company. Did not go out for bid but acquired the same EHR system that the DOD had acquired.**

Description:

In June, 2017, former VA Secretary David Shulkin determined that a substantial investment was required to maintain and improve VistA's operational capability and to "keep pace with the improvements in healthcare information technology and cybersecurity." In addition, after many years of attempting to achieve EHR interoperability, the VA and DOD had been unable to adopt the same EHR or create a congressionally required interoperable medical record platform. He decided to adopt the same platform that the DOD had already adopted.

Several factors are involved in such a choice: big-bang vs. incremental approaches; standardization vs. customization; and COTS vs. non-COTS. There are significant differences between the VHA and the DHA that affect these choices and the ramifications that arise from them.

"Big-Bang" vs. incremental approaches to creating and installing EHR systems.

VistA was created over 30 years, with new features added slowly and carefully over time. While this process led to a slower integration of new capabilities, it also avoided the chaos that occurred during the installation of the Oracle Cerner product in the first few VA facilities. As the rollout is expanded to more facilities, the VA and Oracle Cerner will have learned to avoid some mistakes, but the differences in the new facilities will also likely create new challenges. In addition, the VA will have to ensure that Oracle Cerner has implemented changes in training, data migration, usability, safety, installation support, and the other factors that led to difficulties in the first installations.

Other industries and government agencies have found that making major changes in a short time can be more traumatic and difficult than slowly introducing capabilities, getting used to the

changes, and then determining additional needs. Transitioning to new technology may be easier if it is not done in one fell swoop. In addition, it is not always clear what is needed until the impact of prior changes is understood.

In the past, VA has been more successful in making incremental changes to VistA than in trying to upgrade the system as a whole, as was attempted in the creation of iEHR and in VistA Evolution. The VA is not alone here in finding significant challenges in the “big-bang” approach to introducing complex technology. The size and scale of the organization making the changes is a significant factor in which approach is most likely to be successful. The FAA has been attempting to make major automation upgrades to air traffic control, a nationwide and complex system, for 40 years. After several unsuccessful attempts, they have found success by upgrading incrementally.

VHA is orders of magnitude larger than any previously successful COTS EHR adoption. Previous similar attempts in several countries have not been successful as noted earlier.

Standardization vs. Customization.

While standardization of EHR systems and the workflows they impose is extremely beneficial to vendors of COTS software products and, in some respects, to their customer management, one size does not necessarily fit all when it comes to patient safety and quality of care in healthcare. Workflow design is critical to safety and quality from a human factors’ standpoint. Not being able to optimize workflow to specific unique circumstances can lead to frustration, stress, and burnout of frontline personnel. The level of frustration with seemingly “clunky” EHR systems is high among many healthcare professionals.

VistA was tailored for workflows and practices in the VA, and it does things that a commercial COTS EHR does not do because they are not things that the commercial market wanted or demanded. The DOD is more regimented and did not have a previously tailored EHR. Giving up much loved features to get some enterprise-level advantages is not an easy sell.

In addition, it is not necessarily beneficial to impose the same workflow and clinical practices on every part of a healthcare system as large and diverse as the VHA. Expecting users to adjust to non-optimal workflows and practices without increasing the risk of errors and adverse events is unreasonable. There are surely some good reasons that the 130 instances of VistA were created as well as some unjustified ones.

Decisions about where customization has important benefits over standardization and where each is most appropriate need to be made with respect to the overall system goals. As one of the VA experts we talked to said: “Sometimes the best decision you can make is to develop your own solution tailored exclusively to the needs of the organization.”

On the positive side, there are advantages in standardization from the VA perspective, such as facilitating data exchange and making it easier to collect and analyze metrics. In terms of efficiency, standardization allows repetitive, manual tasks to be more easily automated. Efficiency is different than safety, however, and these two system properties often conflict. Repeatability is important in improving overall quality in simple manufacturing assembly lines, but not in complex fields like healthcare. Consistency and repeatability do not necessarily lead to high patient safety or quality of care.

The choice is not necessarily a strict “either-or” one. Not everything needs to be standardized or customized. Decision making about what should be standardized and where

customization should be allowed needs to consider multiple dimensions, specific activities, and tradeoffs among multiple goals, and to involve experts in various domains, including application and human factors experts. It does not appear that this process was performed in the acquisition and deployment of Millennium at the VA.

Benefits and drawbacks of COTS systems.

COTS products have many potential advantages, but potential savings are often overestimated. In 2005, Cerner and other companies paid for a report by the RAND Corporation that predicted great efficiencies from electronic health records, including savings of \$81 billion a year or more [35], which RAND now says were overstated [36]. A 2013 reassessment of the 2005 RAND report said that the conversion to COTS electronic health records systems had, in fact, failed to produce savings and had led to mixed results in efficiency and patient care. This report, however, helped drive growth in the electronic health record business and billions of dollars in federal incentives to hospitals and doctors. Cerner's revenue tripled from \$1 billion in 2005 to \$3 billion in 2013.

Potential advantages of COTS do exist, however. COTS can reduce front-end acquisition or development costs in some instances, due to potential amortization of costs over a large number of users. This cost reduction, however, will depend on the number of users and on a competitive marketplace.

COTS can also compensate for a lack of technical and managerial expertise and allow for more rapid infusion of new technology. In most cases, the government does not have the expertise and sometimes the technical management skills to develop complex software systems. In this respect, the VA is unique, in comparison with other government agencies, because of its long history of EHR development. Some VA personnel have more experience with EHR than those producing commercial EHR products. Highly experienced government personnel are difficult to retain, however, in highly competitive commercial industries. Over time, the VA has lost much of its technical expertise and management skills.

A third relevant feature of COTS is that it creates new risk drivers. The government basically loses market control—in contrast to contracting with private industry to create unique tools—which leads to higher risks in terms of the commercial market not satisfying government goals over time. In a high-speed market, there can be rapid obsolescence and shortened lifetime for COTS products. EHR is not a true high-speed market, but healthcare itself is relatively dynamic: Best practices can change quickly. Innovation in technology and new discoveries (and new challenges, such as COVID-19) are arriving increasingly quickly. The new emphasis on evidence-based medicine can lead to changes as new knowledge is acquired. EHR technology must change in accordance.

The functionality provided by a COTS product, therefore, may not remain what is needed over time. Marketplace EHR systems, are built on an old and enormous code base that is very difficult, if not impossible, to change. They were not created using new software engineering technology that makes change relatively simple. It may be difficult for the VA to make desired changes as time passes and needs change, which could lead to challenges in maintaining high quality of care.

In general, COTS leads to a loss of control and a shift from a buyer's market to a seller's market. What guarantees are there that Oracle Cerner will stay in this business? How does the

VA know that Oracle will not make significant changes to future versions of Millennium that disrupt VHA (and DHA) use? Or that maintenance of old versions will continue when future versions are created?

Perhaps of greater concern to the VA relates to configurability of Millennium. While Millennium currently provides more configurability than Epic, the design of the EHR will necessarily reduce VA flexibility in workflows and in clinical and other practices. Reduced potential for flexibility will limit VA ability to make improvements over time. Needed changes to VistA fueled the continual projects to upgrade it. The same is likely to exist with Millennium, but the VA will have little ability to dictate or implement those changes as they did with VistA.

In addition, Millennium only provides part of the IT capabilities that the VA needs, so problems of interoperability and the need for Millennium to communicate and interact with other VA informatics systems in the future are not reduced but, in fact, may increase as healthcare and informatics advances and changes.

Finally, safety and quality of care are paramount in healthcare. Does Millennium conflict with VA safety and quality standards and policies? Users in the first rollouts had to grapple with the fact that they could not use Millennium as designed without compromising VA policies, leading to the need to create workarounds that led to stress and budget pressures and the need for additional personnel. Will additional workarounds be necessary in the future?

The VA has found that some VA quality and safety policies are not satisfied by the Oracle Cerner product. For example, medication management in Millennium did not align with VHA policy, which required extra work for providers in the first five installations. Was this considered in the decision to adopt Oracle Cerner and how adoption of the system was managed? Did VA reconcile the policies with the Oracle Cerner product or did they just let the people working in the healthcare facilities grapple with the discrepancies? Are the policies the same for VHA and DHA?

It is the responsibility of the VA to either ensure that the product used in VA healthcare facilities either satisfies current policies or there must be a way for those policies to be changed to match the constraints on healthcare that Millennium imposes without sacrificing patient safety or quality of care. Personnel creating workarounds, as has happened in the initial rollout, is not a long-term acceptable strategy. While many changes to the provision of healthcare by the VA required to use Millennium will have no impact on safety or quality and thus can be easily adopted, some will have significant impact in an organization with as vast a healthcare charter as the VA.

The VA decision makers may have expected that buying a commercial EHR system, which they had never done before, would simplify their processes without needing significant adjustments or customizations. They may also have underestimated the complexities involved, especially given the unique VA requirements that differ from those of most commercial healthcare organizations.

Why the Action Seemed Correct at the Time:

Mental Model Beliefs involved in the Decision Making

<p>VA: <i>To make VistA or any unique VA system interoperable with other systems would be very expensive. Using the same system as the DOD will satisfy the need to electronically exchange health records as was required by Congress.</i></p>
<p>VA: <i>There is no future in the VA being in the EHR system development business. Previous attempts by the VA (iEHR, Vista Evolution) to replace or upgrade VistA have faced significant challenges.</i></p>
<p>VA: <i>Government agencies cannot get the expertise necessary to create and maintain their own complex software systems.</i></p>
<p>VA: <i>We will save money by buying a COTS system rather than contracting out for a system developed and specifically designed to satisfy VA requirements. A COTS system will require less effort and less in-house expertise without sacrificing patient safety and quality of care.</i></p>
<p>VA: <i>Having different instances of VistA is inefficient and costly to maintain. EHR modernization cannot go the way of VistA where facilities can have differences in the EHR and the involved workflows. Clinicians can adapt to a common system without impacting safety and quality of care.</i></p>
<p>VA: <i>The VA will benefit from the DOD's deployment experience with Millennium.</i></p>
<p>VA: <i>If the COTS product satisfies the DOD's requirements, then it will satisfy the VA requirements. Both are very similar or are close enough.</i></p>
<p>VA: <i>Cerner's experience with commercial customers and with the DOD provides them with the expertise to be successful in a VA installation.</i></p>

Contextual Factors:

Dr. Shulkin, the VA Secretary who made the decision about acquiring Millennium, was fired by President Trump and replaced by Robert Wilke from the DOD who did not have a medical or VA background. He was an Air Force reservist and attorney. Wilke may not have understood the differences in culture between the VHA and DHA.

At the same time, President Trump did not fill the VHA leadership position and it remained open until President Biden filled it. Did the VHA healthcare information specialists strongly support the decision to acquire Millennium? Were they involved in the decision making?

In addition, the VA had never acquired a complex COTS product before. While there have been many successful EHR installations in commercial healthcare (as noted in the general contextual factors described in Section 3), there have also been failures, particularly for large and diverse healthcare organizations and large government projects like this one. Such difficulties are obviously not emphasized and, to be fair, perhaps are not understood by the companies selling COTS products in this market.

VA leaders may have underestimated how difficult this adoption would be and did not understand, at least at the beginning, the level of participation required of the VA enterprise. Cerner had installed Millennium in many commercial hospitals, but VA leadership (and even

Cerner) most likely did not realize that the VA requirements are significantly different than the typical Millennium customer.

The DOD adopted Millennium first (known as MHS GENESIS). The desire to use the same EHR, which was based on the belief that sharing patient records would enhance military personnel and Veterans' healthcare, led to a no-bid selection of Millennium by the VA. Only after the process was well along was there recognition that sharing of patient information would in fact be limited by DOD security constraints.

The usual process of evaluating competitive COTS products with respect to unique VA needs was therefore short-circuited in the no-bid process. While requirements obviously cannot be levied on the provider of a COTS EHR (or any COTS product), the acquisition process requires that the purchaser ensure that the product satisfies their requirements and capability needs. That would normally have happened during a competitive bid process. An assumption was made that the DOD requirements were similar enough to those of the VA that the Cerner configuration process could reconcile any differences. That assumption turned out to be not true. The incompleteness of the VA requirements process is described in Appendix C.

In fact, the VA and DOD have significantly different requirements and capability expectations that make it more difficult for the VHA to deploy a commercial EHR system than it was for the DHA. The DHA operates more like a commercial hospital and ambulatory practices. The VA scope is broader—from basic healthcare to community living centers, which are basically nursing homes for patients needing short and long stay services. There are also differences in the type of patients served: VA patients in general are older and include patients with long-term disabilities and special care needs who have been discharged from active service and transitioned into the VA system. The patients served by the VA are more similar to the larger population as a whole, although private healthcare does not try to satisfy all those needs in one organization.

Another important difference is the degree to which the VHA is based on local partnerships at the state level with academic partners and state governments. The VHA is a very different healthcare system than the DHA in terms of how it integrates with its population's care delivery.

There are also relevant cultural differences between the VHA and the DHA. VA medical personnel expect more flexibility in how they practice medicine and run their facilities while DHA personnel are expected to "adjust" to the situation provided to them.

As far as we can determine, a reconciliation of the differences was never done; the two contracts were independent. Cerner allows some configuration of their products to satisfy the customer's needs, but the DOD was several years ahead of the VA in configuring and using the Millennium system. The VA Councils and Workgroups were therefore limited in how much unique configuration of the common system was possible, although the DHA did participate to a degree. Other limitations of the Councils and Workgroups in configuring Millennium are described later.

In summary, the assumption that a common COTS EHR would be appropriate for both the DOD and the VA was not realistic. We were told that the best case for such use existed at the James A. Lovell Federal Health Care Center because VA and DOD had long worked together at that joint facility. But even that integration has not gone smoothly [37,38]. For example, Lovell has a single physical pharmacy that provides care for both the DOD and VA patients. But they have different medication costs, co-pays, billing systems, etc. In the end, the two departments

decided that using a single system was not viable. Instead, pharmacists and others are having to switch between the DOD and VA pharmacies. As a result, the clinic has two computers at each workstation so that both systems can be used simultaneously. Not only is this inefficient and frustrating for the users, but it presents a situation that is prone to error.

There are legal and policy barriers that are preventing those at Lovell from changing the workflows to be compatible with and match the commercial workflows. Similar things happened for the dental module, where it was discovered that the EHR system cannot scale at the rate that is necessary for both the DOD and the VA.

2. EHR project management was moved from VHA up to VA level

Description:

In June, 2018, the VA OEHRM was established to oversee the new EHR deployment. The OEHRM responsibilities include management of the preparation, deployment, and maintenance of the new EHR. VA OEHRM leadership includes an Executive Director, Chief Medical Officer, and Chief Technology Integration Officer. The OEHRM was headed by a Navy Veteran without a medical background. HIT (Health Information Technology) experts from the VHA were to provide “inputs,” but it is not clear how much input was requested before the first installations started to run into trouble [Interviews].

One of the major differences from the DHA adoption of the Oracle Cerner EHR system was that the DHA used Leidos as the project integrator. The VA tried to do the integration themselves. In addition, the effort was not led by the EHR experts in the VHA Office of Health Information Technology (now called the Office of Digital Health). We have been told that the VHA EHR experts were largely excluded until recently. Even if this exclusion is a misperception, it seems strange that they did not lead the effort.

The VA has a contract with Booz Allen Hamilton to serve as the program manager for the VA EHRM program. The Booz Allen role, however, was limited by government directives, and they had no authority over Oracle Cerner. We were told that Oracle Cerner constrained Booz Allen’s effectiveness in influencing the program's direction [Interviews].

Another important problem is that the safety offices were in the VHA and did not have adequate input into the VA project management effort. In fact, our examination of the official responsibilities stated for all the groups at the VA level who had responsibility for EHR modernization found that strangely none explicitly included responsibility for patient safety.

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

VA: For COTS, we do not need special expertise in EHR and information systems.
VA: The EHR experts in VHA have a conflict of interest and are not appropriate to lead the effort.

VA: The VISNs⁷ will fight centralization of decisions affecting healthcare in their facilities.

Context:

Oracle Cerner did not have sufficient government experience to play the role of integrator and systems engineering for such a large, complex federal installation as was involved here. Note that Oracle Cerner was not the prime on the DHA adoption of Millennium. Instead, the DOD contracted with Leidos, a large engineering company with extensive experience in systems engineering and the integration of technology into both government and commercial entities. We understand that the DOD contracted with Leidos because of problems in a previous deployment that involved the medical community.

The DHA adjusted course when problems arose early in their deployment. They paused for a year and a half and reorganized their approach to governance and management. This pause allowed them to get back on track and successfully continue deployment.

In addition, the DOD took more advantage of their internal healthcare experts earlier than the VA. Much of the early VA governance of the Oracle Cerner EHR acquisition was overseen by the OHI (Office of Healthcare Integration), which had limited expertise in healthcare information technology. We were told that the early OHI program manager did not get adequate input from the various healthcare facilities [Interviews].

Several reasons for moving management of the acquisition up to the VA level were suggested by the people we interviewed. One reason we heard several times is that in the VHA, VISNs have a lot of power to derail attempts to centralize decisions affecting healthcare in their facilities. The decision to move the deployment up to the VA was to control this perceived roadblock to standardizing care decisions. In addition, the VHA had had difficulty in some previous attempts to upgrade VistA and were not totally trusted to control the deployment of Millennium.

Finally, safety issues were not addressed effectively. Safety was (and still is) centered in the VHA. We do not know why it was not included in the VA offices controlling acquisition and deployment. It is likely that they thought that creating the Councils was adequate.

3. Inadequate governance and project/change management in the deployment effort.

Description:

In any large *system engineering* project, and there is no doubt that this can be classified as among the largest government system engineering projects of our time, there must be one ultimate decision maker to be successful. That decision maker must be an authority on the topic itself (healthcare and EHRs) and the politics and culture of the organization into which the system is to be introduced or must be surrounded by people with this knowledge who can assist with decision making. But ultimately, the overall decision making must lie in the hands of the

⁷ The VHA (Veteran's Health Agency) 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 Healthcare Systems within their area and are sometimes called a "network."

program manager. This governance/management structure did not exist for the VA/DOD EHR transformation.

For example, while the Councils and Workgroups may provide inputs, the ultimate responsibility for determining the configuration of the VA and DOD EHR system and its deployment has to be the program manager and, in turn, the program manager's office. Such critically important decisions as the ultimate configuration of the EHR and its deployment cannot be made by the COTS provider with assistance from Councils and Workgroups of over a thousand people. Some of these subgroups were more engaged than others and none of them seem to have been managed well except those Councils and Workgroups who created their own self-management structure] [34]. Effective management requires someone to be the ultimate decision maker. Delegation of authority to make these decisions to hundreds of people without extensive coordination and communication among them is a recipe for a failed project.

Our conclusion that governance problems existed in this project should not be a surprise to anyone. The original program manager came from DHA and had no VA experience. The original IPO, which later became the FEHRM, was assigned accountability but not responsibility and an inadequate amount of authority. We are not including a detailed analysis of the governance structure in this report as it seems to change frequently, perhaps because of perceived limitations of each of the permutations of this structure.

There have been attempts to improve the governance structure of the Millennium deployment. Despite these attempts, there still seem to be basic problems in assigning responsibilities (including overlapping or missing responsibilities), more limited roles of some groups (such as the FEHRM) that are needed for success, and so on. Most successful large projects with the scope of this one usually are driven by one or two people with a clear vision. Most failed projects can be seen, in hindsight, to lack these visionaries. Those who come in after the problems have become apparent to try to save the projects are often unable to do so.

One of the most important prerequisites for successful system engineering is establishing the desired goals and identifying any necessary tradeoffs. In a description of the goals of this project, we found that efficiency and standardization seemed to have the highest priority. Safety and quality of care are mentioned as the justification for these two primary goals without any clear explanation of exactly how efficiency and standardization are the way to improve safety and quality of care at the VA (see Appendix C). As noted earlier, the official statement of responsibilities for the offices controlling the deployment of Millennium does not mention safety and quality of care (although, curiously, security is mentioned as the responsibility of several groups). The assumption that a COTS EHR system improves safety and quality of care has never been shown to be true. COTS EHR systems may improve profits and efficiency, but more is needed to ensure safety and quality of care.

Additional Governance Problems

The following list includes some of the governance problems that have occurred in this project:

Communication: Information has not always been communicated to stakeholders, nor has it consistently been solicited from stakeholders, leading to insufficient buy-in from some critical groups. While the DOD culture may more readily accept such top-down decision making, the VA

culture is different. Those leaders from the DOD who have been involved in the VA acquisition efforts may not have understood the differences.

Unrealistic risk assessment and management: The initial decision makers did not seem to understand the difficulty of what they were attempting or at least did not take necessary steps to mitigate the risks. While the difficulty is now more apparent and appreciated by leadership, it is not clear whether the implications described in this report are still being underestimated.

Inadequate solicitation of inputs: The VA does things through Workgroups and getting a lot of people involved without clear responsibility or accountability. System engineering cannot be done by a large group of people at cross purposes and without strictly defined goals and desired outputs and a detailed management and communication plan. The Council/Workgroup process lacked proper organization. Simply getting a lot of people involved is not a recipe for success in system engineering.

At the same time, there was incomplete formal testing and analysis—including evaluation by the eventual users—before deployment was attempted. There are over 5000 configuration parameters in Millennium. Were the Councils able to understand and evaluate completely the implications of the decisions, particularly on safety?

Inputs beyond the Councils and Workgroups was sometime lacking. For example, an OIG report [31] found that OEHRM leaders did not provide scheduling staff with adequate chances to identify limitations in the new scheduling system before implementation. Soliciting input is not only important in improving usefulness and usability of the product, but it is also an effective way of getting user buy-in.

No initial determination of the information to be in the EHR. VistA and Millennium contain different information. There is also a large amount of information called “health factors,” as mentioned earlier, that does not seem to be integrated into either. Project leadership never determined what a complete record would contain. This determination should have been done by the VA before any configuration activities started.

In addition, nobody ensured that the quality of data migrated to the new EHR system sufficiently met clinicians’ quality needs. Legacy systems at the VA contain patient healthcare information (including inpatient medications from past hospitalizations, and some historical mental health and women’s health data) that did not align with any of the Millennium healthcare data domains, complicating the migration problem. Without clear guidance from the FEHRM Program Office, including definitions of the healthcare data domains that are needed for a “complete patient EHR,” problems in migration are inevitable.

No use of high-quality safety, usability, or human factors analysis. We could find no hazard analysis of the safety implications of Millennium and the process of installing and using it in VA facilities. There also did not seem to be adequate human factors and usability analysis. While Oracle Cerner seemed to be responsible for some of these activities, VA should have provided oversight and ensured that they were performed adequately. If there were such analyses performed and the people we spoke to did not know about them, then all the problems in the first installations demonstrate that what was done was inadequate.

We were told about VA safety analyses that consisted primarily of taking examples, such as a provider entering (in a simulation environment) what would be a fatal dose of a medication and determining whether an alert is generated in response [Interviews]. The VA then worked with Oracle Cerner to fix that problem. However, this type of testing is an inadequate way to determine whether a system is safe or not. At best, it provides false confidence if the few test cases run provide an acceptable result. It also provides the same false confidence if one or few unsafe behaviors are fixed and an assumption is made that these are the only unsafe behaviors in the system. In fact, finding any such unsafe behavior during testing is a very strong indication that the system design as a whole is unsafe. It is interesting that an OIG report is very critical of medication management safety during the Mann-Grandstaff rollout [39]. The bottom line that it is not possible to test for safety. Safety has to be evaluated by other means, such as hazard analysis.

It is the responsibility of the VA to conduct this type of analysis and if delegation is done, VA needs to closely oversee what is being done. Safety always depends on the context in which a system is used. Therefore, it is not possible for Oracle Cerner (or any provider of a COTS product) to determine whether their product will be safe when used by all their different customers.

Access to care was not well managed during the rollout. The VA strives to actively evaluate and manage access to care, with the goal of providing patients with care when and where they need it. The facility leaders in the first rollout, however, were not provided with written guidance on how to address access-to-care risks associated with the installation of Millennium. Facility leaders attempted to identify the risks and estimated that the new EHR implementation would result in a 30 percent decline in access to care, which might last for 12 to 24 months after going live [31]. This decline required mitigation strategies to overcome.

An OIG investigation found that the discussions between the OEHRM and the initial rollout facility leaders did not provide specific actions that the facilities could take to ensure patient safety once access to care decreased. Mann-Grandstaff leaders stated that much of the discussion focused on their local Spokane DOD colleagues' experience with the transition to the DOD version of Oracle Cerner's EHR. The DHA experienced a DHA decrease in access to care that continued 18 months following their going live with the DOD Oracle Cerner EHR system [31].

Without assistance from the VA leadership, the local VHA facility leaders developed strategies of their own to mitigate the care risks associated with installing Millennium and monitored the access to care risks. Those strategies included increasing facility staffing, extending clinic hours, and expanding use of community care. However, although they recognized the need for extra staff, hiring them was limited by budget deficits. Also, the Mann-Grandstaff facility's local medical community did not have the provider capacity to meet the clinical demand. With increased patient referrals to the community at the installation time, facility leaders and staff found themselves with inadequate staffing and facing new system requirements to manage consult referrals and claims that fall within the required care in the community care department.

Inadequate response during the pause to the rollout problems. The attempts to respond to the rollout problems appear to be incomplete. Some problems, such as orphans, are getting a lot of attention while others are not getting the attention they need. Nobody seems to be looking at the whole data model deficiencies nor at many of the problems not related to the data model. [Interviews].

There were some processes put into place to assist in the first rollouts. For example, the VA EHRM Integration Office established Change Leadership Teams at each VISN and each VA facility receiving the EHR. These teams were made up of:

- An executive sponsor, who provides overall strategic direction and promotes transformation success.
- A change lead, who executes strategies to maximize adoption and meet EHRM objectives.
- A change coordinator, who manages successful execution of change management plans and supports stakeholder communication.
- A training coordinator, who coordinates end-user training activities at their site.
- A deployment coordinator, who coordinates deployment activities at their site.

This seems like an excellent plan. We could not get any information about why these teams were not able to avoid the major problems in the initial rollout facilities. Determining the reason why they were not more successful should be useful in future deployments.

Why the Actions Seemed Correct at the Time:

Mental Model Flaws Involved

VA: <i>Cerner is experienced and knows what is necessary to install Millennium successfully in a large healthcare organization.</i>
VA: <i>Having many people involved is helpful in managing large projects, getting buy-in, and solving problems.</i>
VA: <i>The Councils and Workgroups composed of “subject matter experts” will provide all the input needed to configure the capabilities.</i>
VA: <i>The VA has the capability to do their own integration and does not need an independent integrator.</i>
VA: <i>Special system engineering expertise is not necessary when adopting a COTS product.</i>
VA: <i>HIT experts in VHA are not needed for a COTS product and they may try to sabotage the efforts because of their long history with and commitment to Vista.</i>
VA: <i>Acquiring a COTS EHR will not require any special effort on our part to ensure patient safety and quality of care.</i>

Contextual factors:

Most of the problems in governance that occurred seem to stem from lack of experience in acquiring a complex COTS product. The VA was highly experienced in using an EHR system, but they had previously created their own and had never tried to acquire and use a commercial system. In fact, the VA had never previously attempted any transformational COTS project of this size and complexity. Approaches that might have been successful in smaller projects just do not scale to what is needed here.

At the same time, no commercial EHR system has ever been successfully deployed at such a large and complex healthcare organization anywhere in the world and, in fact, several attempts to do so have failed.

Cultural and internal political factors worked against successful deployment. Some decisions that contributed to the problems, such as moving the effort out of the VHA, were made to avoid other potential problems. For example, VAMCs and VISNs tend to operate somewhat independently. It has even been suggested that when it comes to any changes, some long-term VA personnel “wait out” changes that are often modified or are even reversed when leaders are replaced. This may be particularly true when the leaders are viewed as politicians or military personnel rather than medical clinicians and when decisions are imposed by Congress or politicians.

The DOD did not run into the same problems, although their deployment was far from problem free. The AHLTA EHR system that the DOD had used previously was, according to the experts we spoke to, worse than the Oracle Cerner system to which they were transitioning. Therefore, there was less resistance to the change than at the VA. The DOD also previously had a standardized process while the VA personnel were used to the more tailorable VistA.

The VHA and its health services group also takes a holistic “whole person” health view of the veteran, including the integration of social services and long-term care. The EHR acquisition complications provided by this larger scope was not compensated by leveraging the expertise of experts at the VHA with decades of experience with VistA until problems started to occur. Probably one of the largest organizational change efforts any healthcare system undertakes is an EHR implementation—from a cost, process, and people standpoint. Failures in some past upgrade efforts for VistA, however, may have led VA leadership to conclude that VHA inputs would not have been helpful. There may have been a belief that a higher-level organization was needed to successfully drive the change efforts.

Finally, FEHRM Program Office officials limited their role to facilitating discussions when disputes arose between the DOD and the VA and only provided direction if the Departments reported a problem [Interviews]. Because the FEHRM Program Office limited its role, the DOD and the VA took separate actions to migrate patient healthcare information, develop interfaces, and grant user access to Cerner Millennium.

4.2.2. Recommendations for the VA in addition to those under Oracle Cerner above

A major decision to be made at this point is whether to continue with the Oracle Cerner adoption or to take a different path. Alternative paths are discussed at the end of this report. Here we include recommendations if the current path is continued and the recommendations listed under Oracle Cerner (Section 4.1.2) have been followed:

1. Implement the recommendation (stated earlier) by the VA's Tamara Box and Joe Francis to "Contract a third-party, expert systems engineering review of the ESH and the core structural components of the database and model to ensure the implementation of Millennium EHR can scale as new VHA facilities are activated." While we looked at the ESH database and model flaws, we did not have any detailed information about its design and could not evaluate scalability. However, we think that Box and Francis are right to be skeptical. The real problem goes far beyond fixing just the structural and semantic defects of the ESH. A lot more needs to be changed to successfully install Millennium in all the VHA facilities.
2. Establish the requirements and capabilities for a VA EHR system that satisfies the original goals (see Appendix C). This includes establishing what needs to be in a complete patient record that can be shared with the DHA. Align the VA mission and goals with those of the EHR system.
3. Obtain outside system engineering expertise, perhaps through a commercial integrator, to assist in the continued rollout of Millennium. This expertise should include healthcare EHR experience and not just general information system expertise.
4. Take control of EHR safety. Safety cannot be delegated to contractors or to COTS products. The VA has responsibility for patient safety and quality of care, not a contractor or those providing COTS products.
5. VistA does a lot more than the Oracle Cerner EHR does. Those extra operations required to run a healthcare system are not going to be included by Oracle Cerner in Millennium. Has a decision been made about how these will be handled? If both VistA and Millennium are used for the foreseeable future, planning is required.
6. Establish a structured, well-managed process for identifying the configuration parameters required for installing Millennium into the remaining VHA facilities without compromising patient safety and quality of care. The Council and Workgroup process is not appropriate for making decisions of this scope. If the required VA tailoring cannot be done, then create a solution that will satisfy basic VHA healthcare goals. Even if changes can be made that solve the problems that occurred at the first five Millennium installations, a wider rollout is very likely to identify more problems. Create a process for anticipating these and solving them before the installations are restarted.
7. In general, establish better risk and change management procedures for the project.

4.3. Congress/Executive Branch

Responsibility for the problems that have been encountered in the adoption of Millennium by the VA cannot all be traced to Oracle/Cerner and the VA.

4.3.1. Actions/Decisions Contributing to the Current State

- Congress and the Executive Branch pressured VA to procure a commercial product.
- Congress got IT moved from VHA and promoted to the department level. Many of VHA technical experts (programmers, architects) left along with institutional knowledge.

Many of the means for interaction by informatics staff, clinicians, and technical staff degraded as a result [Interviews].

Why the Action Seemed Correct at the Time:

Mental Model Flaws Involved:

Congress and Executive Branch: *Commercial companies are better at large infrastructure projects (software) than government agencies.*

Context:

There was Congressional and White House (political) pressure to outsource to private industry and for government agencies not to continue to build, maintain, and upgrade their own technology.

Congressional decisions, of course, are always influenced by the majority's political philosophy about the role of government and private enterprise, which changes over time.

5. Summary of the Causal Analysis

As in most cases of projects not working out as expected, there is nobody on which to assign blame and no real reason to do so either. Everyone did what they thought was best at the time and made reasonable decisions given the state of world, their understanding of it (mental models), and their personal experiences. It is always possible to use hindsight bias and the outcomes of decisions to second-guess the decisions and actions taken. In this report, we attempted not to do this.

Very briefly, Oracle Cerner had never attempted to install Millennium into such a large and complex healthcare system before and were unaware that the actions that had been successful in the past would not be adequate here. In fact, it is not clear that any COTS EHR system would have been successful in this case.

The VA was under pressure from Congress to provide interoperability with the DOD, which made sense as a goal. Adopting the same system as the DOD seemed like a reasonable decision before learning how difficult it would be by trying to do it. We primarily only learn from experience.

6. Potential Paths Forward

There are several approaches to addressing the challenges outlined in this report. Given the significant changes occurring in the VA under the new administration, any consideration of future approaches must be reevaluated using the most current information available at the time decisions are made.

In early March 2025, the new VA Secretary announced that nine additional VHA medical centers would go live by 2026, to bring the total medical centers using Millennium to thirteen. Additionally, the Secretary announced that all 170 VA medical centers would implement the Millennium by 2031, an average of 32 go-live implementations each year.

With the announced pending VA reduction in force of 80,000 VA employees back to 2019 levels, the challenges of successfully deploying Millennium will likely be exacerbated. This reduction represents a 15% decrease in staffing. According to the OIG, previous VA Millennium deployment sites had to recruit *additional* personnel to offset the losses in productivity experienced [40].

Rather than recommending one way to proceed, we instead provide different options and discuss their pros and cons. Decisions of Congressional and government oversight bodies may, of course, limit the actual options. We assume here that the solution is not dictated to the VA externally. Whichever path is taken, successfully upgrading EHR at the VA will require improving system engineering or no path is likely to provide the results desired.

Institute Basic System Engineering Processes

A common belief among those who have not themselves tried to implement COTS in a complex organization is that using COTS removes or reduces the need for system engineering skills. In fact, the exact opposite is true: either the organization involved needs to upgrade their internal system engineering practices or they need to obtain those skills by employing external system engineering expertise—ideally, both should be done. Many managers misunderstand COTS and think it allows them to rely on commercial companies to create, install, and operate their EHR systems. This misunderstanding has led to a lot of failed projects. Note that the DOD hired an external company, Leidos, to provide the system engineering expertise to the DOD that was necessary for successful adoption of a new EHR system.

While some of the system engineering tasks can be performed by an external company, some work must be done by the VA or a combination of VA and external experts. The most important is a basic requirements analysis. Only the VA can determine what the VA needs, which may differ from what the COTS producer can provide. For example, a COTS producer can tell the VA what information they include or can include in the EHR, but the VA must determine what information they *need* to be included in their EHR system. The authors of this report have between them decades of experience in system engineering in a variety of industries. We believe that without first determining what the VA needs and their priorities for conflicting goals, no path forward will be successful.

Appendix C shows some of the stated high-level, aspirational goals for a new VA EHR system, some of which are vague and contradictory. For example, one goal is to have standardized clinical and business processes across the VA. A second goal is to have a veteran-centric system focused on quality, safety, and patient outcomes. Standardization and efficiency, however, do not necessarily lead to achieving quality-of-care goals and safety. The same is true in the reverse, that is, efficiency may need to be sacrificed to achieve quality and safety goals. In fact, efficiency and quality goals often conflict. If tradeoff decisions are required, who should make them and how should conflicts be resolved?

Other choices also need to be considered in this system engineering effort, as described in Section 4.1.3: Big-bang vs. incremental approaches to upgrading capabilities; standardization vs. customization; and potential benefits vs. drawbacks of COTS systems in general. Only after careful consideration of these choices, along with the goals and requirements that the VA has for an EHR system, can an appropriate forward path be chosen.

One Potential Path: Continue Deploying Millennium

One seemingly easy path to choose is to continue with the acquisition and deployment of Millennium throughout the VA, which is the path chosen by current VA leadership. This path, however, will almost certainly not be successful unless the VA and Cerner adopt core system engineering principles and the lessons learned from efforts to date. Key actions VA should take to ensure a successful continuation are detailed in this report: Fix the technical root cause of the orphan codes, including providing stronger configuration control and change management along with fixing other problems with the basic underlying data model; ensure consistency between VA policies for patient care and the workflows and practices required by users of Millennium; understand and fix the Millennium usability issues that users are complaining about; perform a hazard analysis to identify potential Millennium safety issues; improve the training program; improve installation support, such as the ticketing process; and improve system documentation.

Without these recommended changes, staying the current course could lead to more unnecessary and unacceptable risk to patient safety, continuing burdens to frontline staff, losses in productivity, and escalating operating cost of system ownership.

Improvements also need to be made in VA's oversight and management of the program, as suggested in Section 4.2.2. These improvements must include better risk management processes to avoid the problems that occurred in the first rollout. Believing that all the problems have been found and fixed in the first rollout is not realistic.

In addition, more flexibility needs to be provided in terms of workflow and practices. While there are many good reasons for standardization, a healthcare system as complex and all-encompassing as the VA cannot operate in a totally standardized way. There may be unjustified reasons for all 130 instances of VistA, but there are almost surely very good reasons for many of them. A compromise goal is to standardize as much as reasonable while maintaining the flexibility to tailor the EHR design to the needs of the users where appropriate to achieve quality and safety-of-care goals as well as efficiency and productivity. Standardizing healthcare in all respects will almost certainly lead to degradation in quality and safety and even efficiency. It is also likely to degrade the current culture at the VA. Healthcare is not equivalent to producing widgets on an assembly line.

Moving forward with installing Millennium without first making these improvements creates significant risks that deployment will degrade quality of care and present serious challenges to user acceptance. Not taking the time to do this installation right from the beginning will not save time in the end because each rollout phase is going to lead to discovering more problems that will need to be solved. The result may even be that Congress loses confidence in the program and defunds it before the deployment is finished. Throwing good money after bad is not a reasonable long-term strategy.

The original cost of the Oracle Cerner COTS contract was \$10 billion over 10 years. When the deployment was paused, \$16 billion had been spent. The contract cost is estimated to increase to \$50 billion over the next 10 years [41]. This cost increase is likely to continue to rise at a similar rate due to the unknown challenges, delays, and other risks that may not have been adequately anticipated within the current restart plan.

Even if the VA was able to achieve the accelerated Millennium implementation goals recently announced by the VA Secretary, the VA would be left with an EHR system based on 30-

year-old technology, such as the flawed data model (ESH). Other EHR COTS systems use similar basic technology. Therefore, pursuing a different COTS vendor contract is not likely to achieve better results, especially with the planned reduction in force of skilled VA employees to support an accelerated Millennium implementation.

We recognize that it is very difficult to make major changes when a program runs into serious problems, as has occurred with the Millennium deployment. Decisions are often based on the Sunk Cost Fallacy and the belief that investing more effort, time, and money will make the technological system workable. The long history of technological failures does not argue for the correctness of this belief. While a short time solution with lots of compromises may be possible, will it lead to serious problems over the long term?

A Second Option: Create a New EHR for the VA

The commercial EHR systems available are all based on very old data models and rely on old software code. As healthcare progresses, these old data models and software may impede progress in healthcare quality and safety. Changing to another COTS EHR system is not going to solve the problems being encountered.

While we do not believe that the VA should try to create their own new EHR system, partnering with industry to provide one could require less effort and resources than trying to upgrade and install Millennium. It could also extend the potential for upgrading EHR capabilities in the future. Such a system could be based on a more modern data model and separate the data model completely from the workflows and practices supported so that more customization, where justified, will be possible. At the same time, the design can emphasize the needs of clinicians to provide high-quality and safe care over the convenience of software engineers.

The VA might even partner with Oracle Health Systems, which inherited the old Millennium system when they purchased Cerner. Together they could create a new EHR design that will be viable over a longer period of time and use modern software engineering methods to allow upgrades and improvement over time. This partnership could be a clear win for both. The VA gets a modern EHR system, and Oracle gets a new COTS product at least partly funded by the government.

This second option may be a lower-risk path than proceeding with the Millennium rollout with respect to avoiding additional preventable patient harm, prolonged losses of staff productivity (and higher costs to compensate for reduced productivity), additional provider burnout, and rising costs due to more veterans opting for community care due to excessive waiting times.

The VA was the first to develop and deploy an EHR system successfully across a large, integrated healthcare system. The existing VA expertise and leadership in health information technology, data standards, terminology, and health informatics would create an ideal incubator for development of the next generation of EHR for the American healthcare system.

It is unlikely that the current EHR modernization program based on Millennium will perform much better than it performs today due to the known system deficiencies highlighted in this report. Changing course should not be viewed as defeat, but rather a temporary retreat to prepare for a bold new approach to health data management—an approach that uses lessons

learned from the past and rapidly advancing technologies to create a new health IT future for veterans, clinicians, community care partners, and our nation.

A Third Potential Path: Contract with industry to create a modern new EHR system that satisfies the unique needs of VA healthcare.

An important difference between this path and the second one is that there is no need to generate a COTS product useful for all of healthcare and to make the compromises required by such a COTS system. The VA healthcare system is much more complex and comprehensive than most other healthcare systems using EHR technology, including the DOD. As described in this report, other countries have struggled to adopt COTS EHR systems, the U.S. VA is not unique here. One COTS product for different users may simply not be practical or consistent with providing high quality healthcare.

A major problem, in common with the second path forward is that the interoperability problem between the DOD and VA is not solved (unless the DOD adopts the same system). However, enhancing the interoperability of VHA health data with the DHA and Community Care partners could be realized through an expansion of CHDR (Clinical Data Health Repository) or through existing health information exchanges such as the Qualified Health Information Network and emerging integrated knowledge exchange environments.

In fact, the need to exchange healthcare data may be more limited than originally thought and primarily occurs at the specific point when Servicemembers transition from DHA to VHA. Even at places like Lovell, where DHA and VHA healthcare workers work closely together, serious problems have arisen with the deployment of Millennium. VHA processes need to differ in significant ways from those of the DHA. In addition, there is no need for identical workflows and practices to be used by DHA and VHA, any more than within all parts of the VHA. There may be simpler solutions for data interoperability than requiring the EHRs to be the same.

As with the second path, the VA would need to engage private industry to create the system as the technical expertise required no longer exists in the VA. At the same time, modern software engineering processes, such as providing an interface between the form and operations on the data and the uses of that data, could be employed to separate the patient record from the functions that use it. That is, separate:

1. The optimal design of the data storage to minimize duplication and optimize location and retrieval from the
2. Optimization and usability of the EHR data to assist healthcare personnel in obtaining the information they need to provide a high standard of care.

This separation also makes it easier to change the data information system format over time (including adding new types of healthcare data and tests) without negatively impacting the users. At the same time, it is possible to make changes to how the users see and process the data as more experience is obtained from use over time and medical science advances without requiring changes in the format of the stored data.

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Prof. Leveson has worked in the field of system safety for over 40 years. She is currently Jerome C. Hunsaker Professor of Aeronautics and Astronautics at MIT and a founding member of the MIT Engineering Systems Lab.

Prof. Leveson conducts research on all aspects of system safety including modeling and analysis, design, operations, management, and human factors. Her research results are used in a wide variety of safety-critical industries including aerospace, transportation, healthcare, chemicals, nuclear power, and many others. One common element throughout all her work is an emphasis on applying systems thinking and systems theory to complex systems.

Prof. Leveson has received many honors and awards for her achievements, most recently the 2020 IEEE Medal for Environmental and Safety Technologies. She was elected to the U.S. National Academy of Engineering in 2000.

Dr. Leveson has published over 300 research papers, delivered nearly 500 keynote and invited presentations at professional meetings, and authored three books on system safety engineering: *Safeware: System Safety and Computers* (1995), *Engineering a Safer World* (2012), and *An Introduction to System Safety Engineering* (2023). She consults extensively in many different industries on the ways to prevent accidents. Dr. Leveson has served on numerous national and international committees and accident investigations including the Presidential Commission on Deepwater Horizon, the Baker Panel on the Texas City explosion, and a Navy committee investigating one of the V-22 Osprey accidents as well as lesser-known accidents. She also served as an expert consultant for the Columbia Spacecraft Accident Investigation Board.

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Dr. Powell is the CEO and founder of Synensys, a safety management company and industry leader in safety, quality, risk management, and performance improvement, having led programs within the healthcare and other high-risk industries for more than 40 years. His most recent experience includes patient safety, health data quality, and patient-centered care improvements, system safety, learning systems, safety management systems, informatics, care coordination, safety auditing, threat and error management, and team training. Dr. Powell currently leads system safety research teams on contracts with the FDA, VA, DHA, and DOD. His current research focus includes data quality improvement, error reduction, reducing preventable patient harm, and safety management systems using human factors and safety engineering methods.

Dr. Powell provides assessment, training, strategic execution, data management, measurement, research, and implementation support for senior leaders, managers, and project teams in Federal and commercial healthcare organizations worldwide. Prior to Synensys, Dr. Powell developed and managed safety management systems for the U.S. Navy, U.S. Air Force, and the commercial airline industry. Dr. Powell has authored numerous articles, policy reports, books, and technical guidelines on topics such as human-centered design, reflective learning, global health, healthcare leadership, health data quality, teamwork, high reliability, quality improvement, patient experience, and patient safety culture.

Dr. Powell's books, including the *Patient Survival Handbook*, highlight critical needs like deeper patient engagement and activation for patient safety, system safety, and quality improvement. Dr. Powell is a leader in safety management systems, integrated health system quality improvement, and human factors engineering for safer outcomes by facilitating health system workgroups, technical expert panels, government agency collaboration, stakeholder groups, community-based organizations, leadership teams, policymakers, Congress, and advocacy groups.

Appendix A: Glossary

Advanced Medical Support Assistant (ASMA): A role within healthcare facilities responsible for administrative support, including scheduling appointments, managing patient records, and assisting with patient inquiries.

Armed Forces Health Longitudinal Technology Application (AHLTA): An electronic health record system that U.S. Department of Defense used before MHS GENESIS.

Booz Allen Hamilton: A management and information technology consulting firm that provides services to government and commercial clients.

Cerner-Based Scheduling System: A scheduling system developed by Cerner Corporation for managing appointments and other scheduling needs within healthcare facilities.

Cerner Command Language (CCL): A proprietary scripting language used within Cerner's electronic health record systems to create custom reports and automate tasks.

Cerner® Corporation: A global supplier of health information technology solutions, services, devices, and hardware.

Civilian Healthcare: Healthcare services provided to civilians, as opposed to military or Veteran healthcare services.

Clinical Data Repository (CDR): A centralized database that stores clinical data from various sources to support patient care and clinical research.

Clinical Data Repository/Health Data Repository (CHDR): A system that integrates clinical data from the Department of Defense and the Department of Veterans Affairs.

Commercial-off-the-shelf (COTS): Ready-made products that can be purchased and used under government contract, as opposed to custom-built solutions.

Computerized Patient Safety Record System: An electronic system designed to enhance patient safety by managing and tracking patient records and clinical data.

Computerized Physical Order Entry (CPOE): A system that allows healthcare providers to enter medical orders into a computer system, reducing errors and improving efficiency.

Computerized Provider Order Entry: Similar to CPOE, it refers to the process of healthcare providers entering and managing orders for patient care electronically.

Consolidated Mail Outpatient Pharmacy: A service that provides prescription medications to Veterans through the mail, consolidating pharmacy services to improve efficiency.

Corporate Data Warehouse: A centralized repository for storing and managing an organization's data, often used for reporting and analysis.

Councils: Refers to various advisory councils or committees within the VA or other organizations that provide guidance on specific issues.

Causal Analysis based on Systems Theory (CAST): A methodology for analyzing and understanding the root causes of complex system failures.

Defense Health Agency (DHA): An agency within the U.S. Department of Defense responsible for providing medical services to military personnel and their families.

Department of Defense (DOD): The federal department responsible for coordinating and supervising all agencies and functions of the government related to national security and the armed forces.

Electronic Health Record (EHR): A digital version of a patient's paper chart, containing comprehensive health information and used to improve patient care.

EHRMIO: Electronic Health Record Modernization Integration Office, responsible for overseeing the modernization of electronic health records within the VA.

Epic: A widely used electronic health record system developed by Epic Systems Corporation.

Event Set Hierarchy (ESH): A structured framework within electronic health record systems for organizing and managing clinical events and data.

Federal Electronic Health Record Modernization (FEHRM): An initiative to modernize and integrate electronic health records across federal healthcare systems.

Government Accountability Office (GAO): An independent agency that provides auditing, evaluation, and investigative services for the United States Congress.

Health Data Repository (HDR): A centralized database that stores health data from various sources to support patient care and clinical research.

Health Factors: Variables that influence an individual's health, including biological, social, and environmental factors.

Health Information Technology (HIT): The use of information technology in healthcare to store, share, and analyze health information.

Health Information Technology for Economic and Clinical Health (HITECH) Act 2009: A U.S. law enacted to promote the adoption and meaningful use of health information technology.

HealthIntent: A population health management platform developed by Cerner Corporation to aggregate and analyze health data.

Interagency Program Office (IPO): An office responsible for coordinating efforts between different government agencies, particularly in the context of health information technology.

Intermountain Health: A not-for-profit healthcare system based in Utah, known for its integrated care model and use of health information technology.

Interoperability: The ability of different information systems, devices, and applications to access, exchange, and use data in a coordinated manner.

iEHR: Integrated Electronic Health Record, a system designed to integrate health records from multiple sources to provide a comprehensive view of patient health.

Joint Health Information Exchange (joint HIE or jHIE): A secure network that enables electronic sharing of health data between the DOD, VA, and private healthcare providers.

Joint Longitudinal Viewer (JLV): A tool that provides a unified view of patient health records from the Department of Defense and the Department of Veterans Affairs.

Legacy EHR: An older electronic health record system that may be replaced or integrated with newer systems.

Leidos: A defense, aviation, information technology, and biomedical research company that provides services to government and commercial clients.

LOINC®: Logical Observation Identifiers Names and Codes, a universal standard for identifying medical laboratory observations.

Mann-Grandstaff: Refers to the Mann-Grandstaff VA Medical Center, which has been involved in the rollout of the new EHR system.

Medical Appointment Scheduling System (MASS): A system used to manage and schedule medical appointments within healthcare facilities.

Military Health System (MHS): The healthcare system that provides medical services to U.S. military personnel, retirees, and their dependents.

Millennium: A comprehensive electronic health record system developed by Cerner Corporation.

My HealthVet: An online portal that allows Veterans to access their health records, manage appointments, and communicate with their healthcare providers.

National Center for Patient Safety (NCPS): An organization within the VA focused on improving patient safety through research, education, and system improvements.

National Defense Authorization Act for Fiscal Year 2008: A U.S. law that includes provisions related to defense spending and policy, including healthcare for military personnel.

National Health Service (NHS): The publicly funded healthcare system of the United Kingdom.

National Oceanic and Atmospheric Administration (NOAA): A U.S. federal agency focused on the conditions of the oceans, major waterways, and the atmosphere.

Office of Electronic Health Record Modernization (OEHRM): An office responsible for overseeing the modernization of health electronic records within the VA.

Office of Healthcare Improvement (OHI): An office within the VA focused on improving healthcare quality and outcomes for Veterans.

Office of the Inspector General (OIG): An independent office within the VA responsible for auditing and investigating programs to prevent and detect fraud, waste, and abuse.

Office of Veterans Access to Care: An office within the VA focused on improving Veterans' access to healthcare services.

Oracle Corporation: A multinational computer technology corporation that provides database software and technology, cloud-engineered systems, and enterprise software products.

Oracle Health: A division of Oracle Corporation focused on health information technology solutions.

Orphan Event Code: An event code within an electronic health record system that is not linked to any specific patient or clinical event, potentially leading to data integrity issues.

PowerForms: A feature within Cerner's electronic health record system that allows for the creation of customizable electronic forms for data entry.

Qualified Health Information Network: A network that meets specific criteria for securely sharing health information across different systems and organizations.

RAND Corporation: A research organization that develops solutions to public policy challenges to help make communities safer and more secure.

Replacement Scheduling Application (RSA): A new scheduling application designed to replace an older system within a healthcare facility.

SNOMED®: Systematized Nomenclature of Medicine, a comprehensive clinical terminology used to code and classify medical information.

Structured Query Language (SQL): A programming language used for managing and manipulating relational databases.

TRICARE: A healthcare program of the U.S. Department of Defense Military Health System that provides health benefits to military personnel, retirees, and their dependents.

Unknown Queue: A term referring to a queue within an electronic health record system where undelivered orders are placed without feedback to the provider, potentially leading to patient safety issues.

Veterans Health Administration (VHA): The largest integrated healthcare system in the United States, providing care to Veterans through the Department of Veterans Affairs.

Veterans Health Information Exchange (VHIE): A program that enables the secure sharing of Veterans' health information between the VA and external healthcare providers.

Veterans Health Information Systems and Technology Architecture (VistA): An integrated electronic health record system developed by the VA to support patient care and administrative functions.

Veterans Integrated Service Network (VISN): A regional network of VA healthcare facilities that provides coordinated care to Veterans within a specific geographic area.

VHA Essential Medication Information Standards: Standards established by the VHA to ensure the accurate and consistent documentation of medication information within the electronic health record system.

VistA Evolution: An initiative to modernize and enhance the Veterans Health Information Systems and Technology Architecture (VistA) to improve functionality and interoperability.

VistA Scheduling Appointment (VSE): A scheduling system within the VistA electronic health record system used to manage and schedule appointments for Veterans.

Appendix B: Timeline of Major Events

The VA has been at the forefront of EHR technology and had one of the first EHR starting over 40 years ago. A complicated set of events occurred to get to where we are today. The following table tries to summarize those events.

1960-1970	MUMPS developed at VA Massachusetts General Hospital for managing patient medical records and hospital laboratory information systems
1981	VA MUMPS renamed Decentralized Hospital Computer Program (DHCP). Written into law as VA's medical-information systems development program
1981	VA began operation of an internally developed electronic health records system. One of country's first healthcare systems to implement an EHR
1990s	Upgrading of computer capacity of its medical facilities allows the VA to implement DHCP nationally
1996	DHCO renamed VistA (Veteran's Health Information Systems and Technology Architecture)
1999	CPRS (Computerized Patient Record System), a VistA application, fully implemented, including clinical data repository, data retrieval and display, problem lists, medication lists, report including radiology, health summaries, order entry for all clinical services and departments, and clinical decision support with reminders, alert systems, notification systems, order checking, and disease management features.
2000	VA initiates the Replacement Scheduling Application (RSA) project for patient scheduling.
2001	VA began its first modernization project. Its goal was to standardize VA health records by eliminating the 130 different versions of VistA. VA estimated the modernization project would be completed in 2018 and cost \$11 billion to develop and implement.
May 2002	FHIE establishes one-way transfer of data from DOD to VA
2002	All VA IT programs (functions and personnel) centralized under the CIO
2003	My HealtheVet launched; personal health record portal had over 2.5 million registered users
2004	IT staff moves from VHA to its own department, led by VA CIO
2004	VHIE enables real-time, two-way data exchange for shared patients between VA and DOD. Also added significant capability, including ability to view inpatient and outpatient notes.
2007	Office of Assistant Sec. for IT approved, centralizing IT services at the VA
2007	VA and DOD expand capabilities for prescription and drug allergy data to include semantic interoperability

2008	National Defense Authorization Act for Fiscal Year 2008 required the VA and DOD to jointly develop and implement fully interoperable EHR systems or capabilities and establish an Interagency Program Office as a single point of accountability for their efforts.
2009	RSA canceled after spending \$167 million over eight years without delivering a usable product.
2009	HITECH Act passed to increase use of EHRs by physicians and hospitals
2009	Virtual Lifetime Electronic Record (VLER) Health program introduced to share select parts of a veteran patient's medical record electronically, safely and privately with other approved healthcare facilities that are members an internet network called eHealth Exchange.
2009	VistA exceeds 1 billion shared images
2009	VA/Kaiser Permanente partnership to develop a health record pilot to allow exchange of patient records between two of the nation's largest EHR systems (HealthConnect and VistA). to connect DOD's AHLTA with the other two soon after. CDC planned to join later along with other smaller organizations in California. A pilot was done in San Diego.
2009	VA joins national eHealth Exchange
2009	95% of all VA prescriptions placed electronically through computerized physical order entry (CPOE). Regarded as a benchmark for EHR success
2009	VA introduces the Virtual Lifetime Electronic Record (VLER) Health program to share select parts of a veteran patient's medical record electronically, safely, and privately with other approved healthcare facilities that are members of a secure Internet network known as the eHealth Exchange.
2010	VRM launched as a multi-year initiative to improve veterans' access to healthcare and benefits information.
2011	Interagency Program Office (IPO) established to develop and implement a single integrated EHR capability for both VA and DOD called iEHR. iEHR was to be completed by 2017 and was estimated to have a life-cycle cost of \$29 billion through fiscal year 2029
2012	VistA Open Standardization Project ("Gold Disk") implemented across 133 sites.
2013	VA and DOD ended the iEHR project because of unmet deadlines and cost overruns.
2013	Development started on the JLV (Joint Longitudinal Viewer), a web application that provides a near real-time and chronological view of patient health information contained in the separate VA and DOD EHRs
2013	My HealthVet improves access from 16 percent to 95 percent.
2013	VistA Evolution launched to modernize VistA. Completion was estimated by the end of 2018 and cost \$4 billion through 2028. VistA Evolution was to be interoperable with the DOD EHR system.
2014	VistA scheduling enhancements deployed

Sep. 2014	VistA Evolution initial operating capability reached (first of 4 planned feature sets was delivered).
2014	VA completes migration of VistA to 25 data centers.
2014	JLV deployed
2014	Medical Appointment Scheduling Solution (MASS) delivered. Based on VistA Evolution design pattern.
2015	State Prescription Monitoring Program VistA patches deployed in phases.
Sept 2015	VistA Feature Set 2 projected release. New feature release will include improved infrastructure and clinical enhancements.
2015	DOD awards a \$3.4 billion contract to Cerner for a new electronic health record system MHS (Military Health System) GENESIS. Leidos Partnership for Defense Health (includes Cerner/Oracle) is to provide a common record of medical and dental information across all of DOD, NOAA, and private sector providers.
Feb 2017	DOD begins deployment of GENESIS in February 2017.
June 2017	VA decides to acquire the same Cerner system as DOD
May 2018	VA awards contract to Cerner to provide, host, and deploy its new EHR system. Contract includes Cerner's commercial EHR product, Millennium, as well as HealthIntent, a cloud-based software product that aggregates health data from multiple sources.
June 2018	VA creates new Office of Electronic Health Record Modernization (OEHRM)
Sept 2018	VA and DOD sign a joint commitment to coordinate on the creation of interoperable electronic health record systems. Goal was to have a single shared EHR system to enable seamless care between VA and DOD without the exchange and reconciliation of data between two separate systems. As such, the new, shared system would include records of veterans' healthcare at VA sites in addition to care received during their military service at DOD sites.
Oct 2018	VA announces plan to deploy the new system at sites in stages, based on geographical location, over a 10-year period. VA planned to begin deploying the new system in March and April 2020 at sites within VHA's Veterans Integration Service Network 20 ⁸ (VISN 20). These

⁸ The VHA (Veteran's Health Agency) 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 Healthcare 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 the state of Idaho, and one county each in Montana and California. The Puget Sound Healthcare System includes two divisions, Seattle and American Lake. VA manages the two divisions in an integrated manner.

	initial deployment sites were the Mann-Grandstaff VA Medical Center in Spokane, Washington, and the VA Puget Sound Healthcare System in Seattle, Washington.
Aug 2019	VA revises plan for initial deployment to include two phases, known as capability sets 1.0 and 2.0. Capability set 1.0 was to deploy in March 2020 at the Mann-Grandstaff VA Medical Center and capability set 2.0 was to deploy in November 2020 at the Puget Sound Healthcare System. 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.
Dec 2019	IPO re-chartered as FEHRM (Federal Electronic Health Record Modernization) Program Office.
2020	VA originally planned to roll out the new electronic record health system at three Initial Operating Capability (IOC) sites in the Pacific Northwest. VA notifies Congress on February 10, 2020 that there will be a delay in the IOC deployments. Plan to complete roll out at all VA hospitals, clinics and other facilities by 2028.
April 2020	FEHRM launchee JHIE (Joint Health information Exchange) to enhance exchange with external health providers. Allows requests by outside providers of healthcare information from DOD and VA EHR systems and vice versa.
Aug. 2020	Coast Guard begins deploying MHS GENESIS (the DOD name for the Oracle Cerner EHR system).
Oct. 2020	VA launches new system at Mann-Grandstaff VA Med. Center in Spokane and West Consolidated Patient Account Center in Las Vegas.
July 2020	VA and EHRM program office conducts a post-go-live study at Columbus. Observes slow system response, system errors, user interface issues, and inefficient workflows that affected end user experience.
2020	VA conducts a review focused on standardization, usability, and safety issues at the five deployment sites. Finds 300 issues and prioritizes 30 to address that are related to patient safety.
Mar 2021	VA pauses EHRM implementation to conduct a strategic review between March and June. Pause planned to last less than 12 weeks.
May 2021	VA National Center for Patient Safety Team identifies 60 safety concerns at Mann-Grandstaff VA Medical Center across nine core domains due to the Millennium rollout.
May 2021	Joint Health Information Exchange (HIE) connected to 70% of the nation's community providers.
July 2021	VA releases report with results of strategic review that noted deficiencies in ticket processes and proposes potential actions to address findings. Says many issues were reported through Cerner ticket system and other reporting mechanisms that were identified as potentially impacting patient safety.

Nov 2021	<p>VA issues a progress report and revises the deployment schedule: The report describes eight challenge areas for EHRM, as well as plans and progress toward addressing those challenges. Report proposes a way forward and performance measures that it expects will ensure success of EHRM while preventing and reducing issues at future deployment sites.</p> <p>The updated deployment plan includes a revised deployment schedule and outlines changes in management and governance of electronic health record modernization (EHRM) “to address previously identified organizational challenges with limited stakeholder inputs in decision-making, accountability, and information sharing transparency.” The future EHRM management structure announced by VA does not include VA OEHRM staff and identifies a new position to lead the VA’s EHRM, the Program Executive Director for EHRM Integration, working under the Deputy Secretary [40].</p>
Dec 2021	Plans to restart EHRM deployment in March 2022, beginning with the Chalmers P. Wylie VA Ambulatory Care Center in Columbus, Ohio
2022	Millennium is deployed at facilities in Walla Walla (WA), Columbus (OH) and two facilities in Oregon. Serious problems immediately surface.
Sept. 2022	VA works with contractor to conduct a survey to determine user satisfaction with Oracle Cerner System in comparison with other healthcare systems. Find users not satisfied with system or with training on new system. Users report their morale, job satisfaction, and level of burnout had worsened.
2023	Deployment of Millennium paused except for Lovell Medical Center (a joint VA-DHA facility).
2024	Several efforts begin to fix the problems found in the rollout.
2025	Plans to restart the rollout at four sites in Michigan starting in the fall of 2025

Appendix C: VA Goals and Priorities for the New VA EHR System

In System Acquisition and System Engineering, success and failure can only be defined in terms of specified goals and identified priorities among them.

The VA established some guiding principles and goals for the new EHR⁹ [42]. Have they been—and can they be—met by the Oracle Cerner system and, if not, why not? In most large projects, including this one, the reasons why goals are not achieved mostly involve unrealistic or flawed assumptions about how to achieve the goals and unrecognized and unresolved conflicts between goals.

In a VA “Industry Day” set of slides, we found the following principles and goals for the Millennium adoption. We included (in italics) questions these goals raised for us:

Guiding principles and goals:

1. Standardized clinical and business processes across the VA
2. A veteran-centric system focused on quality, safety, and patient outcomes
3. Flexible and open, single enterprise solution
4. Clinical business process reengineering, adoption, and implementation over technology
Q: The meaning of this goal is not completely clear, but can process engineering, adoption, and implementation realistically be separated from the technology?
5. Configure, not customize
Q: Is standardization over the entire VA realistic? Will it inhibit achieving some of the other goals?
6. Decisions based on doing what is best for VA’s healthcare system as a whole
Q: What does healthcare system as a whole mean? The system is composed of different components including the care provided, the healthcare providers, the Management the supporting staff, etc. Can all decisions be the “best” for all these components? How will it be determined what is best for the healthcare system as a whole? Have priorities been established? How will tradeoffs be made? Motherhood statements of this sort allow avoiding difficult decisions about priorities and how tradeoffs will be made.
7. Decision-making and design driven by front-line and clinical staff
Q: How will tradeoffs be made between this and other goals, such as goal number 8?
8. Rapid decision making to keep the program on time and on budget
Q: Is speed really the ultimate goal? Does it supersede other goals such as quality, safety, and patient outcomes or decision-making and design driven by front-line and clinical staff? How will potential tradeoffs be made between this goal and goal number 2 (quality, safety, and patient outcomes)?
9. Timely and complete communication, training, and tools to ensure a successful deployment
10. Collaborative partnerships outside the VA to advance national interoperability.

⁹ There may be a requirements statement that we could not find, but we were told that official requirements were never generated because this project involved COTS and no acquisition process. However, requirements are still needed to ensure that the product that is acquired is satisfying the needs of the VA.

11. Full veteran engagement in their healthcare enabled.

One problem that seems to be present here is that goals (such as number 2) are not separated from the principles to be used in decision making about how to achieve the goals (such as number 8).

Some of the above goals also appear to be potentially conflicting. What priority should be used if conflicts are found?

We also found a different statement of goals that were stated as potential benefits:

Primary Areas that would Benefit from the new EHR:

- Quality care and veteran experience: empower veterans to participate in their own care anytime, anywhere.
- Taxpayer savings: modern, common platform saving millions spent today on local applications and non-enterprise modifications.
Q: This assumption about savings on large technology projects rarely turn out to be true. And, of course, savings may be made by sacrificing other goals. For example, do taxpayer savings take precedent over safety and high-quality care?
- Efficiency: Standardized workflows that optimize quality, access to care, and veteran experience.
Q: Is it possible to optimize these qualities using standardized workflows? Are any potential tradeoffs involved?
- Safety: Health and wellness for servicemembers and veterans throughout their military careers and beyond.
- Innovation: driving innovation, security, and efficiency

And in another slide, the following goals were stated, some of which were stated previously along with a few new ones:

Functional Priorities:

- Involvement of user community
- Standardization of practices across VA
- Integration across modules/capabilities
- Continuity of current capabilities
- Enable more efficient and effective care
Q: If these cannot always both be achieved, what are the relative priorities?
- VA and DOD contribute to a single EHR solution enabling seamless, real-time access to health records
- Advance interoperability to improve transitions between VA and community care

Taken together, this is a long list, and some of these goals and principles appear to conflict and therefore may not be simultaneously achievable. Some, such as efficiency and safety, do not necessarily conflict but in many situations do. Was there any prioritization of the principles,

goals, and functional priorities? Was any analysis done to determine potential conflicts and requirements for tradeoffs and compromise?

Recommendation:

Most failures of large, complex system development projects stem from poor requirements engineering and inadequate concept/system analysis at the start of the project. VA leaders should:

1. Prioritize the project goals and separate the goals related to the potential impact of the EHR on VA healthcare from other goals, such as goals related to the installation process. Also, goals should be separated from decisions about how the process will be managed.
2. Perform system analysis (1) to determine whether the Oracle Cerner system satisfies the goals and principles and (2) to understand the potential conflicts between the goals. Doing this type of system analysis should help in eliminating many of the problems that have occurred during the installation as identified in this report.