



April 2018

DOD HEALTH CARE

Defense Health Agency Should Improve Tracking of Serious Adverse Medical Events and Monitoring of Required Follow-up

Accessible Version

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Why GAO Did This Study

Adverse medical events are unintended incidents that may harm a patient. Serious adverse medical events, called sentinel events, have specific follow-up requirements. The National Defense Authorization Act for Fiscal Year 2017 (NDAA 2017) requires DHA to assume the military services' administrative responsibilities, such as adverse medical event reporting, for all MTFs beginning October 1, 2018.

The NDAA 2017 included a provision for GAO to examine the reporting and resolving of adverse medical events in the military health system. Among other objectives, this report reviews (1) the extent to which sentinel events and RCA reports are tracked and DHA ensures it has received complete information, and (2) the extent to which DHA ensures it has received MOS reports. GAO examined relevant policies; analyzed the most current available data on sentinel events from 2013 through 2016; and interviewed officials with DHA, the military services, and four MTFs selected for variety in military service, size, and geographic location.

What GAO Recommends

GAO recommends that the Assistant Secretary of Defense (Health Affairs) ensure DHA (1) improve tracking of sentinel events and RCA reports, and (2) clarify its requirements for submitting reports on the implementation of corrective actions and consistently track and reconcile individual reports. DOD agreed with these recommendations.

View [GAO-18-378](#). For more information, contact Debra Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

GAO found that the process for tracking the most serious adverse medical events, called sentinel events, and their root cause analysis (RCA) reports are fragmented, impeding the Defense Health Agency's (DHA) ability to ensure that it has received complete information. Unlike other adverse medical events, sentinel events—which may result in severe harm or death—have additional reporting requirements that must be met within specified time frames. For example, military treatment facility (MTF) officials must develop RCA reports, which identify causal factors and corrective actions for sentinel events. However, because the database that DHA uses to collect information on adverse medical events does not currently have the capability to track this information, the military services (Army, Navy, and Air Force) and DHA each maintain their own tracking records for sentinel events and RCA reports. Due to these fragmented tracking efforts, DHA reconciles its information on sentinel events and RCA reports through monthly emails to the military services—a time-consuming, inefficient process. DHA officials emphasized that this process relies on the military services' cooperation because DHA does not currently have the authority to compel their responses. Moreover, despite DHA's reconciliation efforts, GAO identified discrepancies and missing information in DHA's tracking record. As a result, DHA lacks critical information about why a sentinel event may have occurred and what actions, if any, MTFs should take to prevent similar incidents in the future. Recently, DHA replaced its previous system of emails with a new tracker tool that can be accessed on the military health system website. However, the new tracker does not allow the military services to make edits, and as a result, any corrections or additional information must be submitted to DHA via email, which may perpetuate previous inefficiencies.

GAO found that DHA cannot ensure that it is receiving all reports on the implementation of corrective actions identified in RCA reports as required by a March 2015 memo. DHA officials stated that MTFs could meet this requirement by submitting copies of their measures of success (MOS) reports, which may be required by the Joint Commission, a hospital accrediting organization. As of September 2017, DHA had received 27 MOS reports for the 319 sentinel events that were reported in 2016. However, DHA does not know how many reports it is missing because MOS reports are not required for every sentinel event, and DHA did not begin reconciling its information for these reports until January 2018, when it implemented its new tracker tool. Furthermore, GAO found that the new tracker tool documents the aggregate number of MOS reports received and does not indicate whether individual sentinel events have an MOS report, impeding DHA's ability to identify which reports are missing. This issue is compounded by the fact that the military services either track MOS reports in different ways or not at all, and military service officials said that DHA's requirement for MOS report submission is not clear. DHA officials stated that they expect to clarify this requirement in their update to the patient safety policy. Because it is unable to ensure it has received all reports on the implementation of corrective actions, DHA could be missing important information that could be used to help inform broader, system-wide patient safety improvement efforts.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
DHA	Defense Health Agency
DOD	Department of Defense
JPSR	Joint Patient Safety Reporting
MHS	Military Health System
MOS	Measures of Success
MTF	military treatment facility
NDAA 2017	National Defense Authorization Act for Fiscal Year 2017
NCR	National Capital Region
RCA	root cause analysis
SERCA	Sentinel Event and Root Cause Analysis

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

April 26, 2018

The Honorable John McCain
Chairman
The Honorable Jack Reed
Ranking Member
Committee on Armed Services
United States Senate

The Honorable Mac Thornberry
Chairman
The Honorable Adam Smith
Ranking Member
Committee on Armed Services
House of Representatives

One of the key patient safety responsibilities within the Department of Defense's (DOD) Military Health System (MHS) is the reporting and tracking of adverse medical events—unintended health care incidents, such as administering incorrect medication or treatment to a patient, that may or may not result in harm. DOD's Assistant Secretary of Defense for Health Affairs sets policies—including patient safety policies—for the MHS, and the Defense Health Agency (DHA) oversees the implementation of these policies.¹ The military services (Army, Navy, and Air Force) and the National Capital Region (NCR) currently manage their own hospitals and clinics, referred to as military treatment facilities (MTF). In doing so, they develop policies that must align with DOD's policies, including policies for reporting adverse medical events that occur in their facilities.² However, the National Defense Authorization Act for Fiscal Year 2017 (NDAA 2017) requires the transfer of administrative control of MTFs, including the reporting of adverse medical events, to DHA, beginning October 1, 2018.

¹DHA supports the delivery of health care services to beneficiaries of the MHS, and executes responsibility for shared services, functions, and activities of the MHS and other common clinical and business processes in support of the military services.

²The Department of the Navy administers health care for the Marine Corps. NCR is the entity within DOD that manages MTFs within the Washington D.C., area, including Walter Reed National Military Medical Center, Fort Belvoir Community Hospital, and their supporting clinics.

Information gleaned from the reporting and tracking of adverse medical events provides the military services, NCR, and DHA with critical information that can be used to make improvements in the way health care is delivered across the MHS. MTF officials are required to report all adverse medical events in DHA's Joint Patient Safety Reporting (JPSR) system, which captures information on the factors—such as medication or equipment—that may have contributed to the event. The most serious type of adverse medical event is called a sentinel event, which can result in unexpected death or serious physical or psychological harm to the patient. For every sentinel event, MTF officials are required to prepare a root cause analysis (RCA) report, which is intended to identify the factors that caused or contributed to the sentinel event, as well as corrective actions needed to prevent future incidents. For most sentinel events, an additional report—a Measures of Success (MOS) report—may be required by the Joint Commission, a hospital accrediting organization that reviews sentinel events and assigns follow-up activities to accredited MTFs for these events.³ This MOS report includes the determination of whether the implementation of identified corrective actions was successful.

In 2014, news articles highlighted concerns about medical errors and lapses in patient safety at MTFs, including staff's reluctance to report these errors.⁴ In August 2014, DOD released a review of the MHS that addressed patient safety, among other issues.⁵ While DOD's review found that the culture of safety within the system was comparable to that found in the civilian sector, the report made a number of recommendations that included the clarification of policy on the definitions

³The Joint Commission is an independent, not-for-profit organization that accredits and certifies health care organizations and programs. MTFs that are accredited by the Joint Commission must report sentinel events that occur in their facilities and submit RCA reports for these events to the Joint Commission. The Joint Commission also typically assigns the MTF a follow-up activity for each reported sentinel event and RCA report, such as an MOS report.

⁴Sharon LaFraniere, "Military Hospital Care Is Questioned; Next, Reprisals," *The New York Times*, December 20, 2014, accessed March 9, 2017, https://www.nytimes.com/2014/12/21/us/military-hospital-care-is-questioned-next-reprisals.html?_r=1 Sharon LaFraniere and Andrew Lehren, "In Military Care, A Pattern of Errors but Not Scrutiny" *The New York Times*, June 28, 2014, accessed March 9, 2017. <https://www.nytimes.com/2014/06/29/us/in-military-care-a-pattern-of-errors-but-not-scrutiny.html>.

⁵Department of Defense, *Final Report to the Secretary of Defense MHS Review* (Washington, D.C.: Aug. 29, 2014).

for sentinel events to reduce variation in interpretation. In December 2017, the DOD Inspector General released a follow-up report focused on patient safety, which found that DOD had established courses of action to resolve all relevant patient safety findings identified in the 2014 review.⁶

The NDAA 2017 included a provision for us to examine several issues related to DOD's delivery of health care, such as reporting and resolving adverse medical events.⁷ In this report, we examine

1. the extent to which the military services' and NCR's policies align with DOD's policies for reporting adverse medical events;
2. the extent to which the military services, NCR, and DHA track sentinel events and RCA reports, and the extent to which DHA ensures it has received complete information;
3. the extent to which DHA ensures it has received MOS reports; and
4. how DHA uses information about adverse medical events to make improvements in its health care system.

To examine the extent to which the military services and NCR have policies that align with DHA's policies for reporting adverse medical events, we reviewed and compared the military services' and NCR's policies with DHA's policies. We also reviewed relevant documents related to these policies, including updated memorandums. In addition, we interviewed officials from the military services' medical commands and NCR's medical directorate to determine how they manage patient safety efforts pertaining to reporting adverse medical events throughout their MTFs and how the future transfer of this authority to DHA may affect these efforts.⁸ We also conducted site visits to a non-generalizable sample of four MTFs—Dwight. D. Eisenhower Army Medical Center (Fort Gordon, Ga.), Robert E. Bush Naval Hospital (Twentynine Palms, Calif.), Mike O'Callaghan Federal Medical Center (Nellis AFB, Nev.), and Walter Reed National Military Medical Center (Bethesda, Md.)—to better understand how the military services and NCR report adverse medical

⁶Department of Defense, Office of Inspector General, *DOD's Response to the Patient Safety Elements in the 2014 MHS Review*, DODIG-2018-036 (Washington, D.C.: Dec. 14, 2017).

⁷Pub. L. No. 114-328, § 751, 130 Stat. 2000, 2244-2245 (2016).

⁸Throughout this report, we refer to the military services' medical commands as the military services and NCR's medical directorate as NCR.

events in their facilities. Our site selection criteria included one MTF from each of the military services and NCR with a range of hospital sizes, geographic diversity, and numbers of reported adverse medical events. We also interviewed DHA officials, including officials from DHA's Patient Safety Program and the Patient Safety Analysis Center, and reviewed relevant documentation about their patient safety policies, their plans to update these policies, and how the future transfer of MTF administrative responsibilities to DHA will impact the reporting of adverse medical events.⁹

To determine the extent to which the military services, NCR, and DHA track sentinel events and RCA reports, we reviewed relevant military service, NCR, and DHA policies to identify requirements for sentinel events and RCA reports. We interviewed officials from the military services, NCR, and DHA about their tracking processes for sentinel events and RCA reports. We also interviewed officials during our site visits to the four MTFs about how they transmit information about sentinel events and their required RCA reports to their respective military service or NCR. We evaluated our findings against the GAO *Fragmentation, Overlap, and Duplication: An Evaluation and Management Guide* to identify any potential fragmentation.¹⁰

To determine how DHA ensures it has complete information, we reviewed relevant DHA policies, interviewed DHA officials, and obtained documents outlining DHA's monitoring process. We obtained the most current data available on reported sentinel events and RCA reports from 2013 through 2016 from tracking records maintained by each of the military services, NCR, and DHA, and we compared the data to assess DHA's monitoring efforts.¹¹ We interviewed military service, NCR, and DHA officials about

⁹Throughout this report, we refer to officials from the Patient Safety Program and Patient Safety Analysis Center as DHA officials.

¹⁰GAO, *Fragmentation, Overlap, and Duplication: An Evaluation and Management Guide*, GAO-15-49SP (Washington, D.C.: Apr. 14, 2015) and GAO, 2017 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits, GAO-17-491SP (Washington, D.C.: Apr. 26, 2017).

¹¹We collected data beginning in 2013 because DHA was established in 2013, and we could not verify how these data were tracked prior to this date. We collected data through 2016 because it was the most currently available at the time of our review. Though DHA requires RCA reports to be completed only for sentinel events, DHA, Navy, and Air Force officials told us RCA reports may also be conducted on adverse events that are not classified as sentinel events for learning purposes. We only examined the number of RCA reports that were required to be prepared for reported sentinel events.

how these data are collected and documented, as well as the steps taken to ensure that the data are complete, and on this basis we determined that these data were sufficiently reliable for the purposes of our audit objective.

To determine the extent to which DHA ensures that it has received MOS reports, we reviewed relevant military service, NCR, and DHA policies to identify requirements for completing and tracking these reports. We also reviewed documentation on requirements for MOS reports from the Joint Commission.¹² We interviewed officials from the four MTFs we visited about how they transmit MOS reports to their respective military services or NCR. To determine how DHA monitors this information, we obtained data from DHA's tracking record on total MOS reports for reported sentinel events from 2016, the first full year that such reports were required to be submitted to DHA. We interviewed military service, NCR, and DHA officials about how these data are collected and documented as well as steps to ensure that these data are complete, and we determined that these data were sufficiently reliable for the purposes of our audit objective. We also assessed efforts to monitor MOS reports against federal standards for internal controls.¹³

To determine how DHA uses information about adverse medical events to make improvements in its health care system, we reviewed documentation on DHA's patient safety initiatives, relevant DHA publications, such as the Patient Safety Annual report, and the MHS website. We also interviewed military service, NCR, and MTF officials about the patient safety initiatives implemented by DHA, including how these initiatives are communicated to them and how the information is used to make improvements in their facilities.

We conducted this performance audit from February 2017 to April 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

¹²DOD requires a report on the implementation of corrective actions. DHA officials told us that MTFs could submit their MOS reports to meet this requirement.

¹³GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Adverse Medical Events

DHA requires the military services and NCR to categorize adverse medical events by severity, using seven categories defined by the Agency for Healthcare Research and Quality (AHRQ), ranging from unsafe condition to death.¹⁴ (See table 1.)

Table 1: Adverse Medical Event Harm Scale Used by the Defense Health Agency

Harm scale category	Description of category
Unsafe Condition	Any circumstance that increases the probability of a patient safety event.
Near Miss	Event occurred but did not reach patient.
No Harm	Event reached patient, but no harm was evident.
Mild Harm	Bodily or psychological injury resulting in minimal symptoms or loss of function, or injury limited to additional treatment, monitoring and/or increased length of stay.
Moderate Harm	Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.
Severe Harm	Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life.
Death	Dead at the time of the assessment.

Source: Agency for Healthcare Research and Quality. | GAO-18-378

MTF personnel must enter all adverse medical events in DHA's JPSR system, which was implemented in June 2011 in response to a statutory mandate for the MHS to establish a patient care error reporting and management system.¹⁵ The JPSR system is intended to provide ways to facilitate the self-reporting, collection, and aggregation of adverse medical event data across the MHS. The system includes prompts for information about factors that may have contributed to the event, such as medication or equipment, as well as the assignment of a severity category.

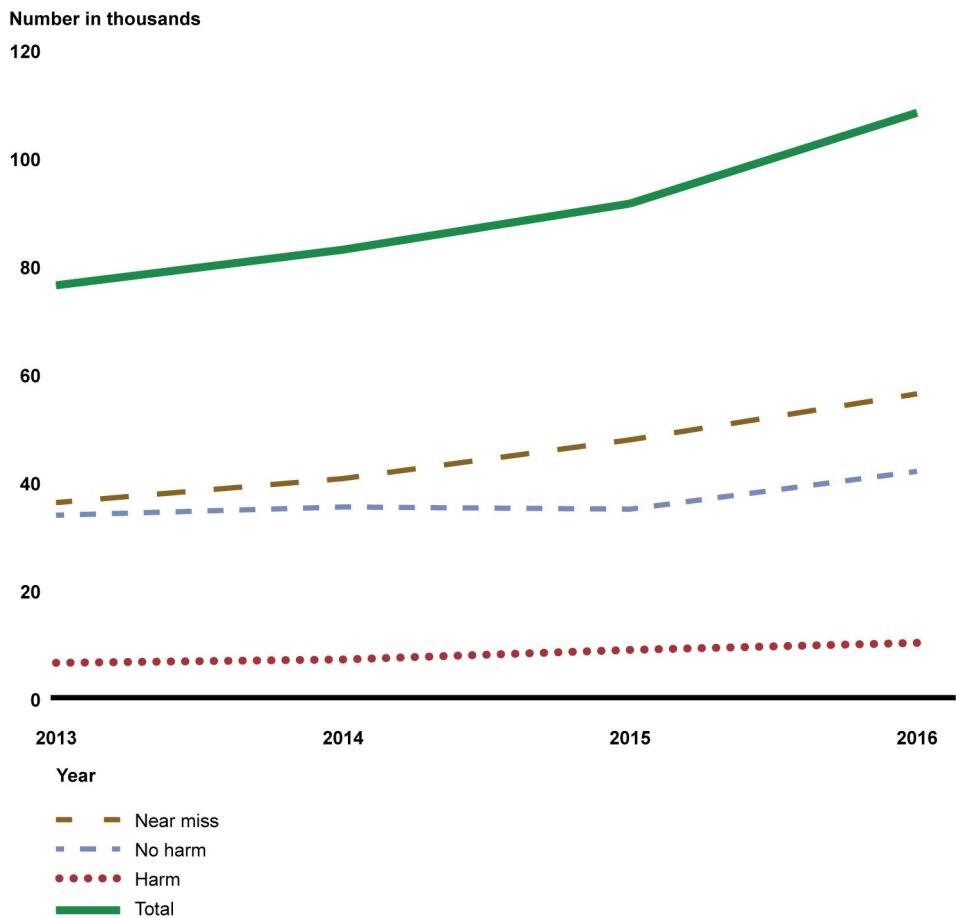
¹⁴AHRQ is a federal agency within the Department of Health and Human Services that is responsible for improving the safety and quality of America's health care system.

¹⁵The JPSR system was originally called the Patient Safety Reporting system. In 2016, the Patient Safety Reporting system became the JPSR system when the Department of Veterans Affairs also began using it to record adverse medical events for its facilities.

From 2013 through 2016, the total number of reported adverse medical events in the JPSR system increased from over 76,000 to about 108,000. When analyzing adverse medical events, DHA groups the data into three categories—near miss, no harm, and harm.¹⁶ The highest increase was in the near miss category (about 36,000 to 56,000) while the other two categories increased to a lesser extent. According to an internal DHA publication, a higher increase in near miss events alongside a decrease in harm and no harm events is considered a positive trend because it shows that more potential adverse medical events are being detected before they reach the patient. (See fig. 1.)

¹⁶The near miss category includes both unsafe condition and near miss events in the AHRQ severity scale. The no harm category includes no harm events from the AHRQ severity scale. The harm category includes mild harm, moderate harm, severe harm, and death from the AHRQ severity scale.

Figure 1: Number of Harm, Near Miss, and No Harm Adverse Medical Events Reported to the Defense Health Agency (DHA), 2013 through 2016



Source: GAO analysis of Joint Patient Safety Reporting system data. | GAO-18-378

Notes: Our data trend begins in 2013 because DHA was established in 2013, and we cannot confirm how these data were tracked prior to this time.

DHA's near miss category includes both unsafe condition and near miss events from the adverse medical event harm scale. DHA's no harm category includes only no harm events from the harm scale. Its harm category includes mild harm, moderate harm, severe harm, and death.

Sentinel Events

The most severe types of adverse events are called sentinel events. In March 2015, DOD issued a memo that revised its previous definition of a sentinel event, which was an unexpected occurrence involving death or serious physical or psychological injury or risk. The revised definition states that a sentinel event is a patient safety event (not primarily related

to the natural course of the patient's illness or underlying condition) that results in death, permanent harm, or severe temporary harm.¹⁷ The revised definition also added a list of events outlined by the Joint Commission and the National Quality Forum that go beyond those that result in unexpected death or serious physical or psychological harm to the patient.¹⁸ (See app. I for the revised definition of sentinel events.)

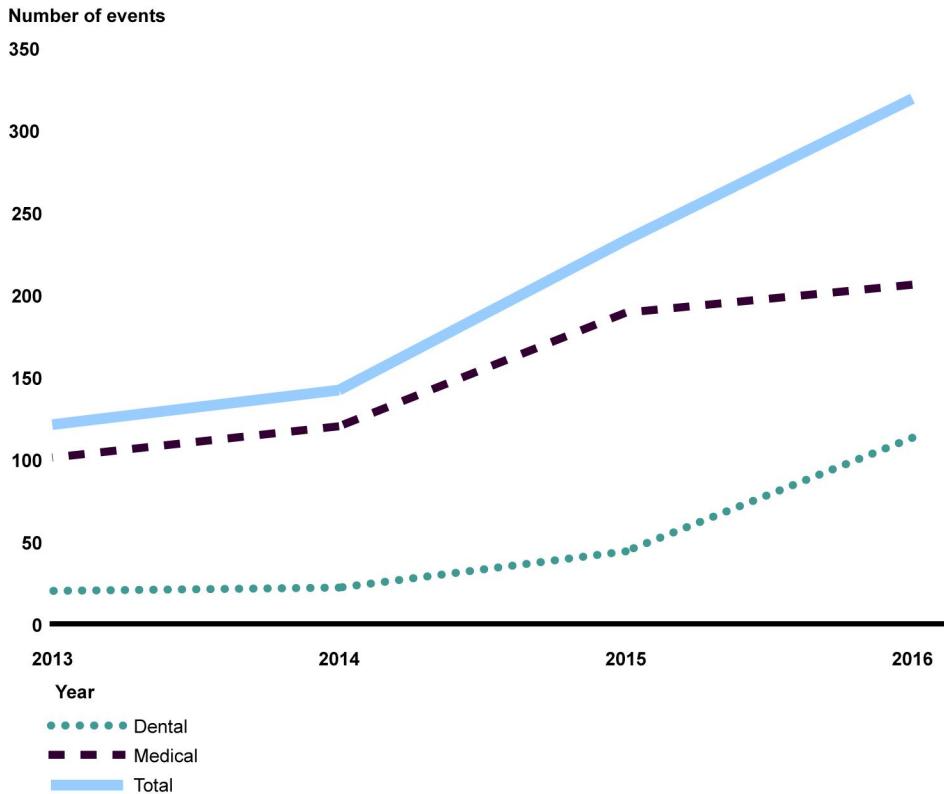
From 2013 through 2016, DHA's data showed an increase in the total number of reported sentinel events—both medical and dental—from 121 to 319. Medical sentinel events approximately doubled from 101 to 206, while dental sentinel events increased more than fivefold from 20 to 113. (See fig. 2.) The sharp increase in events in 2015 may have been influenced by DHA's revised definition of sentinel events as well as the Army's inclusion of dental events that meet sentinel event criteria.¹⁹ A DHA internal publication also noted that a culture shift in patient safety reporting could have contributed to this increase.

¹⁷Severe temporary harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual effect, but requires transfer to a higher level of care or monitoring or both for a prolonged period of time; transfer to a higher level of care for a life-threatening condition; or additional major surgery, procedures, or treatment to resolve the condition.

¹⁸The National Quality Forum is a not-for-profit independent organization that evaluates health care performance measures for multiple areas including patient safety.

¹⁹According to Army officials, the Army began including dental events that meet sentinel event criteria in 2015. The other military services and NCR have always reported dental sentinel events.

Figure 2: Sentinel Events (Medical and Dental) Reported to the Defense Health Agency (DHA), 2013 through 2016



Source: GAO analysis of DHA data. | GAO-18-378

Notes: Our data trend begins in 2013 because DHA was established in 2013, and we could not confirm how these data were tracked prior to this time.

In 2015, DHA revised its definition of sentinel events, and the Army began to include dental events that meet sentinel event criteria, which may have influenced the trend of reported events between 2014 and 2015. The other military services and NCR have always reported dental sentinel events in their reporting of sentinel events.

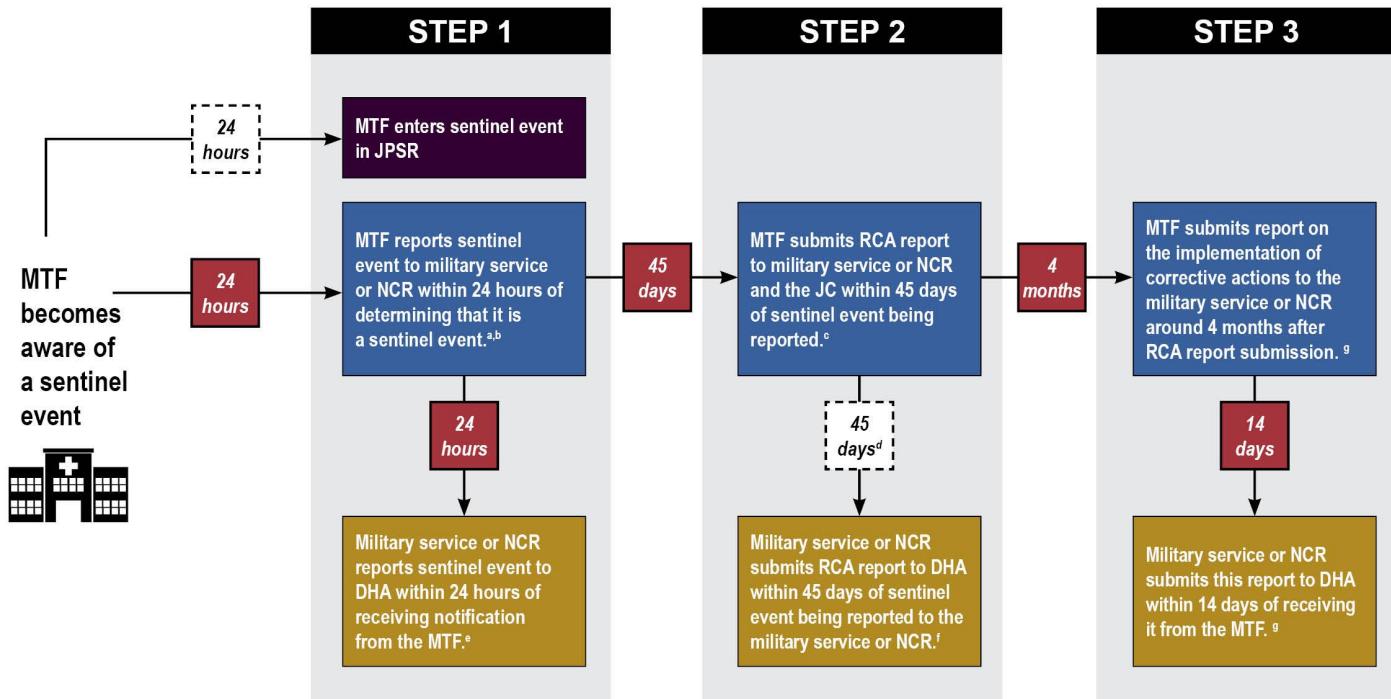
As with all adverse medical events, MTF personnel must enter sentinel events into the JPSR system; however, sentinel events have additional reporting requirements that must be met within specified time frames. For example, DHA policy requires MTF officials to report sentinel events to their respective military service or NCR within 24 hours after they become aware of the event. (See fig. 3, step 1.) MTFs also must report to and comply with sentinel event reporting requirements established by the Joint Commission. These requirements include the development and submission of an RCA report for each sentinel event to identify the causal and contributory factors associated with the event as well as the corrective actions needed to prevent future incidents. The military

services and NCR submit copies of their RCA reports to DHA, which rates the corrective actions included in each RCA report as stronger, intermediate, or weaker based on an estimation of their effectiveness.²⁰ (See fig. 3, step 2.) DHA uses commercial process improvement software called TapRooT to assist with the development of RCA reports, and DHA requires all MTFs to use a methodology for its RCA reports that is currently supported by this software.

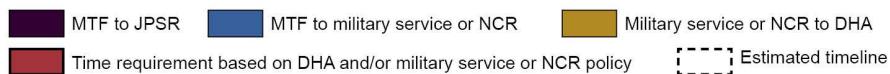
Additionally, once the Joint Commission approves an RCA report and its associated corrective action plan, it may require the preparation of an MOS report that assesses the corrective actions 4 months after an RCA report is submitted to determine whether the implementation of corrective actions and outcome measures was successful. Unlike RCA reports, these reports are only required for selected sentinel events as determined by the Joint Commission. DOD's March 2015 memo that revised the definition of sentinel events contained an additional requirement for the military services and NCR to submit copies of reports on the implementation of corrective actions to DHA. (See fig. 3, step 3.) DHA officials told us that MTFs could submit their MOS reports to meet this requirement. For this report we use the term MOS report when referring to this requirement.

²⁰According to DHA officials, they review and provide feedback on the RCA submitted by the military services and NCR, and they rate the corrective actions based on a framework developed by the Department of Veterans Affairs. An example of a stronger corrective action is purchasing new equipment to reduce risk. An example of a weaker corrective action is education or training.

Figure 3: Military Health System Process for Reporting of Sentinel Events, Root Cause Analysis Reports, and Reports on the Implementation of Corrective Actions, as of September 2017



Legend: DHA= Defense Health Agency; JC= Joint Commission ; JPSR= Joint Patient Safety Reporting System; MTF= Military Treatment Facility; RCA= root cause analysis.



Sources: GAO analysis of Defense Health Agency's, military services', and National Capital Region's policies and interviews with officials. | GAO-18-378

Note: Each box represents a separate time requirement for an action. For example, in step 1, the MTF has 24 hours to report a sentinel event to the military service or NCR. In the next 24 hours, the military service or NCR must report the sentinel event to DHA. Therefore, DHA must receive the report within 48 hours of the MTF becoming aware of the event.

^aJoint Commission-accredited MTFs also may report sentinel events to the Joint Commission.

^bArmy and Navy MTFs also send sentinel event initial notification to their regional health commands.

^cDHA's definition of a sentinel event is broader than the Joint Commission's—therefore, DHA would require RCA reports for some events for which the Joint Commission would not.

^dSome military services and NCR told us they often submit the RCA report to DHA prior to the 90 day (45+45 days) requirement.

^eMilitary service and NCR formats for reporting sentinel events vary, but contain mostly consistent information.

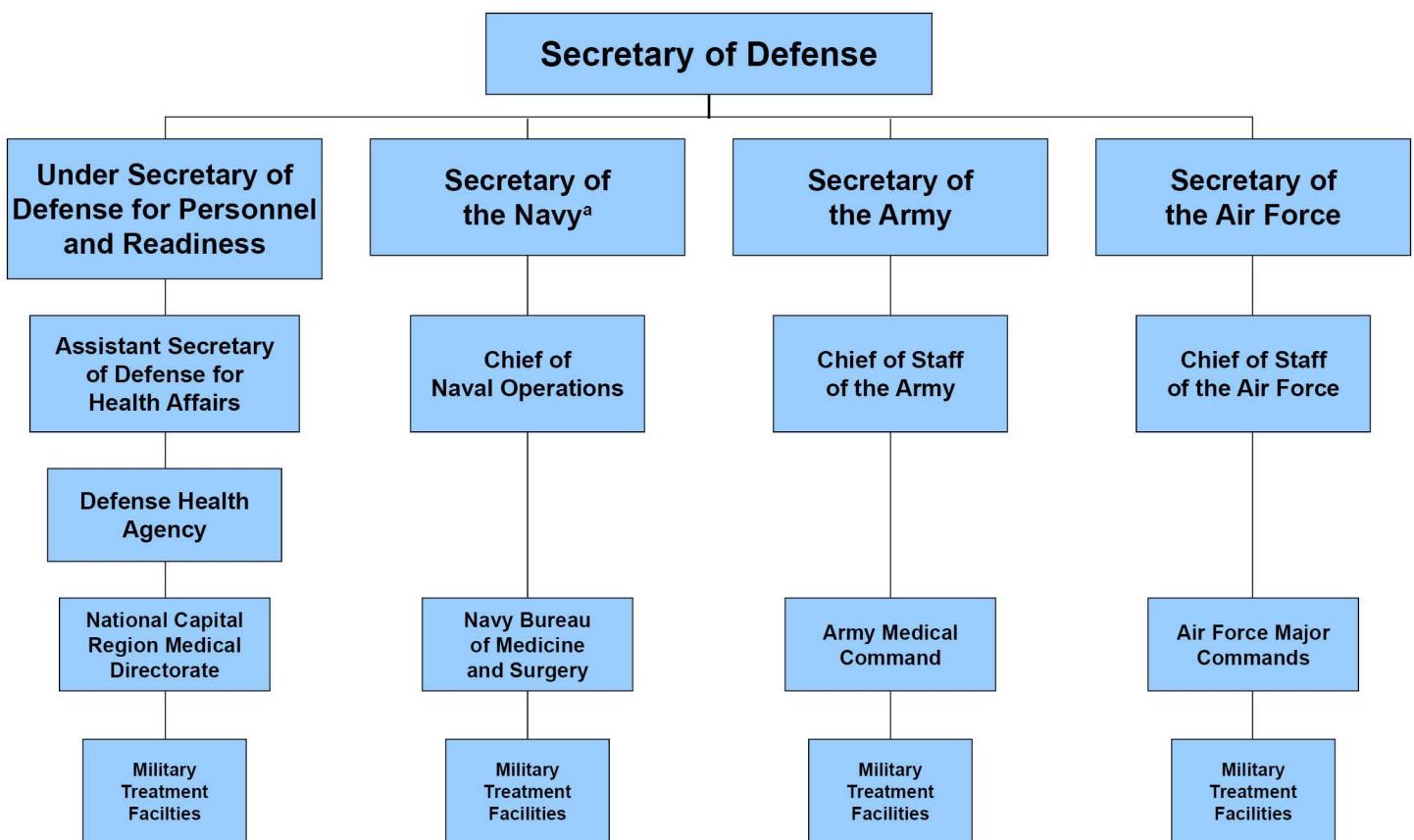
^fAccording to DOD's 2015 memo on sentinel event and RCA report process improvements, the services must submit the RCA report within 90 days of the sentinel event notification.

^gDOD requires a report on the implementation of corrective actions. DHA officials told us that MTFs could submit their MOS reports to meet this requirement.

Transition of MTF Administrative Responsibilities to DHA

Responsibility for the delivery of care in the MHS is shared among the Office of the Assistant Secretary of Defense (Health Affairs), DHA, the military service medical commands, and NCR's medical directorate. MTFs are currently under the direction and control of the Army Medical Command, the Navy Bureau of Medicine and Surgery, and the Air Force Major Commands. MTFs within the NCR are under the direction and control of the NCR medical directorate, which reports to DHA. (See fig. 4.)

Figure 4: Military Health System Organizational Structure, as of September 2016



Source: Department of Defense. | GAO-18-378

^aThe Department of the Navy administers health care for the Marine Corps.

The NDAA 2017 included a provision that requires the Director of DHA to be responsible for the administration of every MTF beginning October 1,

2018.²¹ This responsibility includes budgetary matters, patient safety activities, information technology, and health care administration and management, among other things. As part of the patient safety activities, DHA officials will assume responsibility for adverse medical event reporting. As required, DHA submitted initial plans to Congress in both March and June 2017 about how it plans to implement its new responsibilities. In September 2017, we reported that DHA's plans summarize its new roles and responsibilities at a high level and that a significant amount of work remained to complete the implementation plan.²² On March 30, 2018, DOD submitted an additional implementation plan and stated that its final implementation plan will be completed by June 30, 2018.

The Military Services' and NCR's Adverse Medical Event Policies Do Not Consistently Align with DOD's Policies, but Transition to DHA's Policies Is Planned

Policies established by the military services and NCR for reporting adverse medical events are developed to implement DOD's policies—which tend to be broad—and may include additional requirements specific to their branch of military service. However, we found that aspects of these policies do not consistently align with DOD's policies, including the definitions for adverse medical events and sentinel events, as well as requirements for entering events into the JPSR system. (See table 2.)

²¹Pub. L No. 114-328, § 702(a)(1), 130 Stat. 2000, 2193 (2016), codified, as amended, at 10 U.S.C. § 1073c.

²²GAO, *Defense Health Reform: Steps Taken to Plan the Transfer of the Administration of the Military Treatment Facilities to the Defense Health Agency, but Work Remains to Finalize the Plan*, GAO 17-791R (Washington, D.C.: Sept. 29, 2017).

Table 2: Alignment of Military Service and National Capital Region (NCR) Adverse Medical Event Policies with Department of Defense (DOD) Policies

Element of DOD's adverse medical event policies	Aligned with DOD policies?			
	Army	Navy	Air Force	NCR
Definition of adverse medical event	No ^a	Yes	No	No
Policy on entering events into the Joint Patient Safety Reporting (JPSR) system	No ^a	No	No	Yes
Policy on reviewing adverse medical events for harm to the patient	No ^a	No ^b	Yes	Yes
Memorandum that revised the definition of a sentinel event	Yes ^c	No	No	No
Memorandum that requires the military services and NCR to submit copies of their reports on the implementation of corrective actions to DHA ^d	Yes ^c	No	No	No

Sources: DOD, the military services, and NCR. | GAO-18-378

^aIn March 2018, Army officials provided us with a copy of their draft policy revision, which aligned with DOD's policy for the definition of an adverse medical event, for entering events into the JPSR system, and for reviewing adverse medical events for harm to the patient.

^bThe Navy's policy requires the review of an event based on severity and recurrence. Navy officials told us that reviewing an event for severity includes an assessment of harm to the patient. However, this is not clearly stated in the policy.

^cThe Army has developed a draft policy that includes these revisions. Army officials expect the draft policy to become official in early 2018.

^dDHA officials told us that MTFs could submit their MOS reports to meet this requirement.

- **Definition of adverse medical event.** The Navy uses DOD's definition of an adverse medical event—which includes events that may or may not result in harm to the patient. However, the Army, Air Force, and NCR defined this term more narrowly, to include only an event that causes actual harm to the patient.²³ While the difference in these definitions could potentially result in the underreporting of events, officials from all four of the MTFs we visited told us that the discrepancy does not have much of an impact because the individuals who report these events—MTF personnel—are unlikely to be aware of the difference and likely follow the broader DOD definition.
- **Policy on entering events in the JPSR system.** Only NCR's policy states that adverse medical events should be entered into the JPSR

²³In February 2018, the Air Force provided a copy of its draft revised policy, which included an updated definition of adverse medical events. In March 2018, Army officials provided a copy of their draft policy revision, which included an updated definition of adverse medical events.

system. However, Army, Navy, and Air Force officials as well as officials from one MTF we spoke with stated that they record all adverse medical events in the JPSR system even though their policies do not require it.²⁴

- **Policy on reviewing adverse medical events.** NCR and Air Force policies, which align with DOD's policy, require a review of an adverse event that is based on whether there is harm to the patient. In contrast, Army and Navy policies do not require that an adverse medical event be reviewed on the basis of whether there is harm to the patient, but they do require the event to be reviewed for the level of severity and probability of recurrence.²⁵ However, Navy officials told us that reviewing an event for severity includes an assessment of harm to the patient even though this is not clearly stated in their policy. Additionally, all of the MTF officials we interviewed said that the JPSR system requires them to review an adverse medical event on the basis of whether there is harm to the patient and to assign a harm scale category.
- **Memorandum that revised the definition of a sentinel event.** Only the Army's draft policy aligned with DOD's March 2015 revised definition of sentinel events. However, MTF officials from the other military services and NCR told us that even though the revised definition was not in their policies, they were aware of the memo and were using this definition.
- **Memorandum that requires the military services and NCR to submit copies of their reports on the implementation of corrective actions to DHA.** The Army's draft policy that aligned with DOD's revised definition of sentinel events also included a section requiring the submission of these reports to DHA. The policies of the other military services and NCR do not include this requirement. However, officials from the other military services we interviewed told us that they are aware of this requirement and are submitting MOS reports to meet this requirement. NCR officials told us that they are aware of this requirement but have not begun submitting these reports.

²⁴In March 2018, Army officials provided a copy of their draft policy revision, which stated that all adverse medical events should be entered into the JPSR system.

²⁵In March 2018, Army officials provided a copy of their draft policy revision, which required the review of an adverse medical event based on harm to the patient.

In March 2017, DOD's senior military medical leadership published operating principles to guide the implementation of specific MHS requirements outlined in the NDAA 2017. One of the operating principles to guide the transition of MTF administrative responsibilities to DHA requires DHA to create all health care policies for the direct care system (the MTFs) to ensure greater consistency and eliminate duplicative governance. As a result, the military services and NCR will no longer be establishing their own policies. According to DHA officials, the transition for DHA to be the single policy writer for MTFs will take time, and policies issued by the military services and NCR will remain in place until they are superseded by revised DHA policies. DHA officials are in the process of updating the department's patient safety policy through the Patient Safety Improvement Collaborative, a working group that includes patient safety representatives from all of the military services, NCR, and DHA.²⁶ However, as of January 2018, DHA officials were uncertain as to when this effort would be complete.

Fragmented Process for Tracking Sentinel Events and RCA Reports Impedes DHA's Ability to Ensure It Has Received Complete Information

Process Used by the Military Services, NCR, and DHA to Track Sentinel Events and RCA Reports Is Fragmented

Sentinel Event Tracking

We found that the process used by the military services, NCR, and DHA to track sentinel events is fragmented.²⁷ (See fig. 5.) Similar to all other

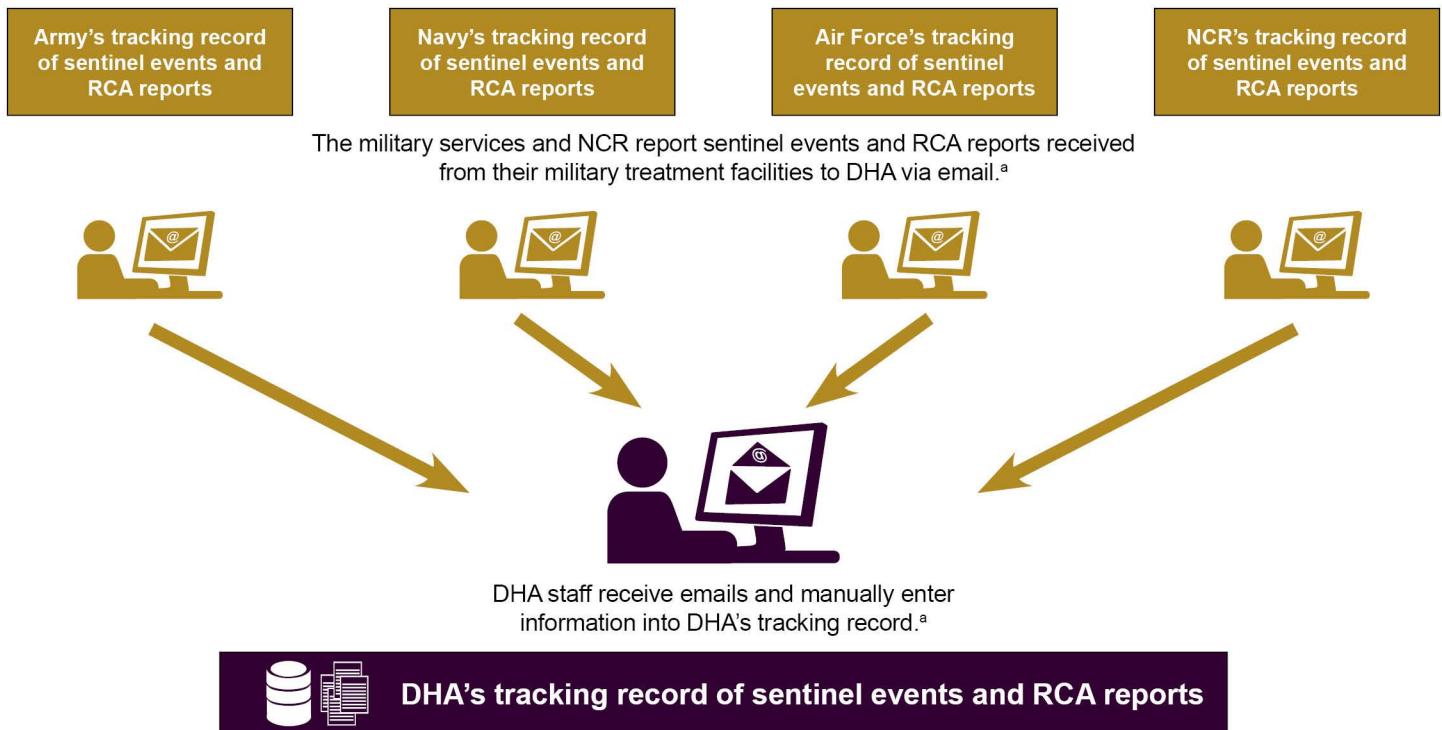
²⁶The Patient Safety Improvement Collaborative intends to coordinate the development, validation, and dissemination of patient safety activities across the MHS and foster interagency collaboration in the implementation of the patient safety program.

²⁷[GAO-15-49SP](#). Fragmentation refers to those circumstances in which more than one federal agency (or more than one organization within an agency) is involved in the same broad area of national need, and opportunities exist to improve service delivery.

types of adverse events, DHA requires that sentinel events be recorded in the JPSR system. However, DHA officials told us there are additional follow-up reports and associated deadlines for sentinel events that go beyond the JPSR system's current tracking capabilities, and as a result, officials from each of the military services and NCR told us they track sentinel events in their own tracking record outside of the JPSR system. Officials told us the military services and NCR receive reports about sentinel events from their MTFs via email, which are then entered in their respective internal tracking records and reported to DHA via email. DHA then enters and tracks the sentinel events in its own internal tracking record. DHA officials told us that they do not believe that all sentinel events are being entered in the JPSR system, and that the JPSR system does not currently have the capability to pull sentinel event data for tracking purposes.²⁸ As a result, the same sentinel events are entered and tracked in two separate tracking records—DHA's tracking record and the tracking records maintained by the military services or NCR.

²⁸NCR officials told us they do not require their MTFs to enter sentinel events into the JPSR system because these events are reported to NCR directly. Further, DHA officials told us that the contract to obtain the JPSR system did not include the requirement for the system to track sentinel events.

Figure 5: Fragmented Process for Tracking Sentinel Events and Root Cause Analysis (RCA) Reports in the Military Health System



Sources: GAO analysis of information from the Defense Health Agency (DHA), military services, and National Capital Region (NCR). | GAO-18-378

^aInstead of emailing the RCA, Air Force officials told us that they upload the RCA to a secure website and send DHA a notification to view the RCA when it has been uploaded.

RCA Report Tracking

In a similarly fragmented process, MTFs email RCA reports—a requirement for sentinel events—separately to their respective military services or NCR, which then emails them to DHA.²⁹ Although DHA requires MTFs to use a methodology currently supported by the TapRooT system to complete their RCA reports, DHA officials told us the TapRooT software is not compatible with most MTFs' computer systems, and as a result, MTFs do not share RCA reports through this system. Instead, they told us MTFs use the methodology from the TapRooT system to prepare

²⁹Two of the military services and the NCR email DHA a copy of the RCA report. One military service told us they post the RCA reports on a secure website and send a link to DHA to view the reports on the website.

the RCA report as a standalone document. Officials told us MTFs then email the RCA reports to their military service or NCR, which notates the RCAs in their respective internal tracking record. The military services and NCR email the RCA reports to DHA, which notates the reports in its own internal tracking record.

Fragmented Tracking Impedes DHA's Ability to Ensure That It Has Complete Information on Sentinel Events and RCA Reports

Because the process used by the military services, NCR, and DHA to track sentinel events and RCA reports is fragmented, DHA officials told us they must rely on their reconciliation process to ensure they have complete information. Specifically, on a monthly basis, DHA officials email separate spreadsheets of DHA's sentinel event records to each of the military services and NCR requesting confirmation of reported sentinel events and the status of overdue RCA reports, among other information.³⁰ DHA officials acknowledged that their reconciliation process is inefficient and told us that their full-time employees and contractors spend an average of 80 hours per month working on it. Additionally, officials told us that sometimes information about sentinel events and RCA reports is lost or not effectively communicated due to complexities related to routing the email submissions and to turnover in the contract staff who track and reconcile this information. The cooperation of the military services and NCR is key to this process because officials told us that DHA currently has no authority to compel a response from these entities, although this may change with the transition of MTF administrative responsibilities to DHA. DHA officials told us they sometimes do not receive a response to their emails, and in these cases, DHA assumes concurrence.

In an effort to improve the reconciliation process and compliance with RCA report submission requirements, DHA officials told us that they developed a new tool called the Comprehensive Analysis Progress Tracker for all three military services and NCR. DHA officials told us this tracker shows the full cycle of each sentinel event, including which RCAs

³⁰DHA also reconciles for missing JPSR system numbers associated with reported sentinel events. JPSR system numbers are assigned by the system when the MTF enters the sentinel event in the JPSR system.

are overdue, and is available on the MHS internal website.³¹ DHA officials told us that this tracker, launched in October 2017, replaced the previous system of separate monthly reconciliation emails with individual spreadsheets for each military service and NCR. In January 2018, DHA officials told us they began using this tracker at monthly Patient Safety Improvement Collaborative meetings and will use it during monthly check-ins with the military services and NCR to discuss delayed or missing items. However, the military services and NCR cannot directly edit the Comprehensive Analysis Progress Tracker. As a result, DHA officials told us that the military services and NCR will continue to use email to submit their sentinel events and RCA reports as well as any corrections or additional information needed for the tracker, which may perpetuate previous inefficiencies.

Despite Reconciliation Efforts, DHA Does Not Have Complete Information on Sentinel Events and RCA Reports

Despite DHA's efforts to reconcile its information on sentinel events and RCA reports, we identified discrepancies and missing information in its tracking record.

Sentinel Event Discrepancies

We found that the sentinel events in all of the military service and NCR tracking records matched DHA's tracking record except for those of the Navy. Specifically, DHA had a record of 19 sentinel events that the Navy did not have for 2013 through 2016. DHA officials were not sure of the reason for the discrepancy between their tracking record and the Navy's, but told us that sometimes sentinel events are reported to DHA and later determined to not be reportable, and DHA is not given the updated status of the event. Navy officials told us that although they initially reported these 19 events as sentinel, the Joint Commission informed the Navy that it did not consider these events to be sentinel after reviewing the Navy's submission. Navy officials told us that they determined these events also

³¹DHA will populate the Comprehensive Analysis Progress Tracker with data from its internal tracking record.

did not meet other sentinel event criteria per DHA's revised definition, which goes beyond the definition used by the Joint Commission. Further, Navy officials told us they informed DHA that these events had been deemed non-sentinel by the Joint Commission, and DHA's tracking record subsequently noted this. However, DHA did not remove the events from its tracking record.

RCA Report Discrepancies

We found discrepancies in the number of RCA reports when comparing DHA's internal tracking record to the military services' and NCR's internal tracking records. In some instances, we found that DHA had more RCA reports in its tracking record than the military services or NCR for reported sentinel events, and in other instances, DHA had fewer RCA reports in its tracking record than the military services or NCR:

- DHA had more RCA reports in its internal tracker than in the Army's internal tracker for 2015 (2 more) and 2016 (1 more).
- DHA had fewer RCA reports than the Air Force in 2013 (3 less), 2014 (2 less), 2015 (13 less), and 2016 (1 less).
- Additionally, DHA had fewer RCA reports for reported sentinel events for NCR in 2015 (1 less) and 2016 (18 less).

Officials with the military services and NCR told us they did not know why there were differences between their tracking records and those of DHA. However, Army and NCR officials offered potential reasons for these differences.

- Army officials told us that they may have fewer RCA reports than DHA because they recently transitioned their sentinel event and RCA tracking record from a spreadsheet format to a database, and some reports may not have been copied into the database.
- NCR officials told us their tracking record may not match DHA's tracking record because an MTF may submit only one RCA report to DHA that covers multiple similar sentinel events, so DHA may have fewer reports documented in its internal tracking record.

Missing RCA Reports

For some reported sentinel events, we found that the required RCA reports had not been recorded in any tracking record for the Army, NCR, or DHA. (See table 3.)

Table 3: Number of Root Cause Analysis (RCA) Reports Missing in Tracking Records, 2013 through 2016

Agency combination	Number of RCAs both the Defense Health Agency (DHA) and the Military Services or National Capital Region (NCR) Are Missing			
n/a	2013	2014	2015	2016
DHA and Army	0	0	14	55
DHA and Navy	0	0	0	0
DHA and Air Force	0	0	0	0
DHA and NCR	1	3	0	2
Total	1	3	14	57

Sources: GAO analysis of DHA's, military services', and NCR's data. I GAO-18-378

Army and NCR officials told us that they did not know why they did not have a record of an RCA report for every sentinel event in their internal tracking record. However, these officials explained that there are a number of potential reasons that RCA reports could be missing, including insufficient MTF staff to carry out these activities, and MTF officials' confusion about the revised definition of a sentinel event.

DHA officials told us that they did not know the reasons for the discrepancies between the tracking records for the military services, NCR, and DHA or for the missing RCA reports. Specifically, DHA officials did not know whether these reports were completed but not submitted to DHA or were not completed at all. They told us that they rely on the cooperation of the military services and NCR to submit these reports and cannot enforce the requirement, although this may change with the transition of MTF administrative responsibilities to DHA. Because of these discrepancies and missing RCA reports, DHA lacks critical information about why a sentinel event may have occurred and what actions, if any, MTFs should take to prevent similar incidents in the future.

We have previously reported that when fragmentation or overlap exists, there may be opportunities to increase efficiency.³² In particular, our prior work identified management approaches that may improve efficiency and effectiveness, including implementing process improvement methods and

³²In 2010, Congress directed us to identify programs, agencies, offices, and initiatives with duplicative goals and activities within departments and government-wide and report to Congress annually. For more information on our work on fragmentation, overlap, and duplication in the federal government, see the most recent annual report, [GAO-17-491SP](#).

technology improvements.³³ As MTF patient safety responsibilities are transitioned to DHA, the fragmented tracking process may hamper DHA's ability to efficiently and effectively monitor sentinel events and RCA reports, potentially leading to missed opportunities for systemic improvements.

³³GAO, *Streamlining Government: Opportunities Exist to Strengthen OMB's Approach to Improving Efficiency*, [GAO-10-394](#) (Washington, D.C.: May 7, 2010).

DHA's Efforts to Ensure It Receives MOS Reports Are Limited and Impeded by Inconsistent Report Tracking and Unclear Requirements about Report Submission

DHA's Efforts to Ensure It Receives MOS Reports Are Limited and Impeded by Inconsistent Report Tracking

As of September 2017, DHA had received 27 MOS reports for the 319 sentinel events that were reported in 2016. However, DHA does not know how many reports it is missing because its efforts to reconcile information for these reports have been limited. Prior to January 2018, DHA did not include MOS reports as part of its reconciliation process for sentinel events and RCA reports. However, in January 2018, DHA officials told us they added MOS reports to their new monthly reconciliation process using the Comprehensive Analysis Progress Tracker. While this tracker displays the total number of MOS reports DHA has received, it does not display whether individual reported sentinel events have an associated MOS report. Without this information, DHA may be unable to identify which MOS reports are missing. DHA officials told us that they may revise the Comprehensive Analysis Progress Tracker to follow up on MOS reports associated with specific sentinel events in the future.

DHA's efforts to identify which MOS reports are missing are further impeded by the military services' and NCR's inconsistent tracking efforts. Specifically, the military services and NCR have been tracking the submission of their MOS reports in different ways or not at all.

- Army officials had told us that the completion of MOS reports was noted in their internal tracking record for sentinel events and RCAs. Army officials subsequently told us that as of January 2018, they began tracking whether MOS reports were submitted to DHA in the notes section of their internal tracking record.
- Navy officials told us they indicated the due date of the MOS report and the date of its submission to DHA in their internal tracking record for sentinel events and RCA reports.
- Air Force officials told us they indicated in their internal tracking record for sentinel events and RCA reports the date that the MOS report was sent to DHA. However, they told us the Air Force's process for

tracking and submitting MOS reports to DHA has been inconsistent, and they plan to revise it in the future.

- NCR officials told us they did not track the completion of MOS reports or their submission to DHA.³⁴

Because of these issues, DHA may not be able to fully reconcile its information for individual MOS reports or identify the reports it is missing, impeding its ability to obtain complete information on the effectiveness of MTFs' corrective action plans. This is inconsistent with federal internal control standards, which require management to identify and respond to risks to achieve its objectives, and for management to use quality information to achieve its objectives.³⁵

DOD's Requirement to Submit Reports on the Implementation of Corrective Actions Is Unclear

The requirement in DOD's memo to submit reports on the implementation of corrective actions is unclear, which may also impact DHA's ability to ensure that it is receiving these reports for all sentinel events. DHA officials told us that MTFs could meet this requirement by submitting copies of their MOS reports.³⁶ According to the Joint Commission's guidance, the Joint Commission assigns MOS reports on an ad hoc basis, depending on the sentinel event, RCA report, and corrective actions, and as a result, an MOS report is not necessarily required for each sentinel event.³⁷

DHA officials told us that they intended to obtain a report on the implementation of corrective actions for every sentinel event, and they believed that an MOS report was required and thus would be reported for every sentinel event, similar to RCAs. However, DHA officials told us that

³⁴NCR officials told us that they discuss these reports during routine management meetings with their MTFs.

³⁵[GAO-14-704G](#).

³⁶DHA officials told us that they do not have guidance on reports about the implementation of corrective actions. These officials said that they tell MTFs to use the Joint Commission MOS guidance for developing these reports.

³⁷For example, Navy officials told us an MOS report might not be required if there were no causal factors identified in the RCA report. An MTF official also told us that an MOS report might not be required if the MTF could prove the corrective action was already completed by the time the MTF discussed the RCA and corrective actions with the Joint Commission.

they learned from the military services and NCR at the January 2018 Patient Safety Improvement Collaborative meeting that an MOS report was not required for every sentinel event and that DHA's requirement for submitting reports on the implementation of corrective actions was unclear. Specifically, DHA officials told us the military services and NCR told DHA that the 2015 memo did not state when the reports on the implementation of corrective actions are required by DHA. For example, the memo did not state whether DHA requires this report for a reported sentinel event and RCA when the Joint Commission does not.

DHA's unclear requirement is inconsistent with internal control standards, which require management to review policies for continued relevance and effectiveness in achieving the entity's objectives.³⁸ Under the current policy, DHA cannot be sure it is receiving all reports on the implementation of corrective actions—such as MOS reports—as it intended, and therefore, it may be missing important information on the effectiveness of MTFs' implementation of their corrective actions that could be used to help inform broader system-wide improvements. DHA officials told us that they expect to clarify this requirement in DHA's update to its patient safety policy.

DHA Uses Information about Adverse Medical Events to Inform System-wide Patient Safety Improvement Initiatives

We found that DHA has introduced several system-wide patient safety improvement initiatives informed by data on adverse medical events from the JPSR system and data on sentinel events from DHA's tracking database, including the following:

DHA's Partnership for Improvement. In January 2015, DHA established an MHS-wide information technology system called the Partnership for Improvement. The Partnership for Improvement collects data from MTFs and assesses MTF performance on approximately 38 health care measures that were established by a committee of MHS officials and designed to improve readiness, population health, and quality of care as well as control costs. Three of these measures focus on

³⁸ GAO-14-704G.

patient safety—central line-associated bloodstream infection, unintended retained foreign object, and wrong site surgery.³⁹ To track these measures, DHA officials told us that they created an associated performance dashboard, including acceptable ranges for each measure, to provide visibility into MHS, military service-, and NCR-level performance. The dashboard is available to all MHS users on the system website and allows MTF leaders and staff to review MTF-level performance data. DHA officials conduct quarterly system-wide performance assessments on these measures. DHA officials told us they use the data on this dashboard to determine what is improving and where to make changes. Officials from each of the military services, NCR, and each of the MTFs we visited told us they are aware of the Partnership for Improvement and its associated dashboard and that they review the data to assess their performance.

Publications on Patient Safety. DHA produces several types of publications using adverse medical event and sentinel event data that officials told us are generally distributed to MTFs through the military services and NCR, including the following.

- **Patient Safety Data Snapshot.** This monthly publication contains an overview of adverse medical event and sentinel event data, trends across the MHS, and short descriptions of sentinel events that have been reported in the system in the same month. Additionally, this publication may include reports of medical product deficiencies, or materials that have been determined to be or are suspected of being harmful, defective, deteriorated, or unsatisfactory because of malfunction or design.
- **Annual patient safety report.** This yearly publication provides a retrospective status update on MHS patient safety initiatives and in-depth adverse event and sentinel event trend analysis, system-wide and by military service. Content includes trends in adverse events reported in JPSR, sentinel events, and RCAs, including information on weaker, intermediate, and stronger corrective actions. This report also describes progress on Partnership for Improvement measures system-wide and by military service and NCR, the culture of patient safety, and collaboration across DHA, the military services, and NCR. The report also details online resources for MHS officials.

³⁹Central line-associated bloodstream infections occur when a catheter tube is not inserted correctly or kept sterile.

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- **Focused review.** According to officials, focused review publications are produced three times a year, and the topics are related to adverse medical events and associated follow-up data provided to DHA as determined by data and performance trends.⁴⁰ For example, in September 2016, the publication included an explanation of the basic components of an RCA, including their associated corrective actions and factors DHA considers when determining if they are stronger, intermediate, or weaker. This publication included 2013 through 2016 system-wide data, such as the number of RCAs submitted, the most common root cause categories, and the proportion of RCAs with stronger, weaker, or no corrective actions. The publication also included an example of a decrease in occurrences of wrong-site surgery accompanied by an improvement in RCAs with stronger corrective actions, common pitfalls in conducting high-quality RCAs, and recommendations to conduct better RCAs.
 - **Patient safety alerts.** DHA uses these publications to inform the MHS about immediate hazards, and officials told us they produce these publications on an as-needed basis. For example, a July 2016 report was focused on unintended retained foreign objects during surgery, specifically, pieces of gloves. The publication described recent occurrences of retained pieces of gloves, glove selection best practices, tips for preventing unintended retention, and corrective actions when retention occurs.

Global Trigger Tool. The Global Trigger Tool is a new tool for collecting adverse medical event data by selecting a sample of medical charts that was implemented MHS-wide as of September 2017. Unlike traditional methods to detect adverse events, the Global Trigger Tool does not focus on voluntary reporting and tracking of adverse medical events. Instead, a team of three reviewers managed by DHA uses the tool methodology to retrospectively examine a random selection of patient medical charts at a facility over time to identify “triggers” (or clues) that may lead to an adverse medical event.⁴¹ The 53 triggers include events such as a patient fall or readmission to the emergency department within 48 hours of treatment. If a trigger is discovered, the medical chart is further reviewed to determine if an adverse event occurred. After the Global Trigger Tool

⁴⁰DHA officials told us that the topics of focused reviews were determined by a vote of military service, NCR, and DHA officials in 2016, but after 2016 were determined by data performance and trends.

⁴¹The team consists of two primary medical record reviewers who have a clinical background, such as experience as a nurse or pharmacist, and one physician.

review is complete, the contractor is able to provide facility leaders with rates of harmful adverse events per 1,000 patient days and per 100 admissions. Results from the tool are intended to aid MTFs in understanding the true frequency of harm events and in identifying systemic issues that contribute to patient safety events. All inpatient MTFs across the MHS will use the tool, and implementation began in 2017. The Global Trigger Tool has just begun to provide data to the MTFs, and DHA officials told us that 6 to 12 months of data is recommended before the tool can be used to make improvements.

Sentinel Event and Root Cause Analysis (SERCA) tool. In October 2017, DHA released a dashboard called the SERCA tool, which DHA officials told us will allow all MTF patient safety leaders to share lessons learned in the course of sentinel event follow-up in real time. The SERCA tool displays sentinel event and RCA data from DHA's internal tracking record reported by the military services and NCR. It is intended to provide quick, online access to sentinel event trends MHS-wide and at the military service, NCR, and MTF levels. The SERCA tool is also intended to facilitate sharing of lessons learned and best practices based on sentinel events and RCAs in a single platform. DHA officials told us that individuals with access to the system will be able to see a breakdown of corrective actions submitted by other MTFs for a particular type of sentinel event and whether these corrective actions were rated as stronger, intermediate, or weaker by DHA. DHA officials told us that for now, they will allow the military services and NCR to determine who has access to the system. Officials from two military services and NCR told us that they have access to this tool and are responsible for granting access to their MTFs. One MTF we visited told us they have access to this tool. However, it is too early to evaluate how the SERCA tool will be used to make improvements.

Conclusions

Each year, thousands of adverse medical events are reported at MTFs. Tracking and conducting follow-up on these events is crucial for officials to learn from and prevent these events in the future. As DHA assumes administrative responsibility for all MTFs, its role in ensuring that sentinel events—the most serious type of adverse medical events—are reported and tracked and that required follow-up is conducted will become increasingly critical. However, the current fragmented and inconsistent tracking process across the military services and NCR has impeded the efficiency of DHA's efforts to ensure DHA has complete information about

sentinel events and RCA reports. Furthermore, DHA cannot ensure that it is receiving all reports on the implementation of corrective actions, such as MOS reports, and does not know how many reports it is missing for a number of reasons, including those related to policy, tracking, and reconciliation efforts. Collectively, all of these information gaps impair DHA's ability to fully understand the types of sentinel events that are occurring in its MTFs, the corrective actions that have been implemented, and whether these actions have been effective. This information is essential to prevent adverse medical events from occurring in the future and to ensure that the care provided by MTFs is safe and effective.

Recommendations for Executive Action

We are making the following two recommendations to the Assistant Secretary of Defense (Health Affairs):

- Ensure DHA improves as appropriate the systems and processes used by the military services, NCR, and DHA to track sentinel events and RCA reports and require the military services and NCR to communicate with DHA the reasons RCA reports are not completed for reported sentinel events. (Recommendation 1)
 - Ensure DHA clarifies its requirement that reports on the implementation of corrective actions, such as MOS reports, should be completed and submitted to DHA, and to work with the military services and NCR to develop a standard system to help DHA consistently track and reconcile information about individual reports. (Recommendation 2)
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Agency Comments

DOD provided written comments on a draft of this report, including technical comments, which we incorporated as appropriate. In its written comments, which are reprinted in appendix II, DOD concurred with both of our recommendations. In response to our first recommendation, DOD acknowledged that its current tracking efforts for sentinel events and RCAs are fragmented, inefficient, and unreliable. DOD stated that in the future, it envisions a single system to track and monitor sentinel events, RCAs, and corrective action implementation plan reports. A single system would eliminate the fragmentation associated with tracking these reports and the need for a cumbersome reconciliation process, potentially

improving the completeness and reliability of DHA's patient safety data as well as its ability to identify and implement system-wide improvements.

In response to our second recommendation, DOD stated that it will clarify the difference between an MOS report, which may be required by the Joint Commission, and a corrective action implementation plan report, which will always be required by DOD for reported sentinel events. DOD explained that when an MOS report is required by the Joint Commission, this report will satisfy DOD's requirement. However, when the Joint Commission does not require an MOS report for a sentinel event, DOD will require a corrective action implementation plan report. DOD stated that it expects the revised policy to be signed in late summer 2018 and in effect by October 1, 2018—the date that DHA is to assume responsibility for the administration of all MTFs.

We are sending copies of this report to the Secretary of Defense and appropriate congressional committees. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.



Debra A. Draper
Director, Health Care

Appendix I: Department of Defense's (DOD) Revised Definition of a Sentinel Event

In a March 2015, the Assistant Secretary of Defense for Health Affairs issued a memorandum about improving the sentinel event and root cause analysis (RCA) reporting processes. This memorandum also revised DOD's definition of sentinel events, which previously stated that a sentinel event is an unexpected occurrence involving death or serious physical or psychological injury or risk. The revised sentinel event definition is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm.¹ This revised definition also includes additional types of events outlined by the Joint Commission and the National Quality Forum.² (See table 4.)

DOD described the following sentinel events that are outlined by the Joint Commission:

- Suicide of any patient receiving care, treatment, and services in a staffed around-the clock care setting or within 72 hours of discharge, including from the hospital's emergency department.
- Unanticipated death of a full-term infant or discharge of an infant to the wrong family.
- Abduction of any patient receiving care, treatment, and services.
- Any elopement (unauthorized departure) of a patient from a staffed around-the-clock care setting (including the emergency department),

¹Severe temporary harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual effect, but that may require transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

²The Joint Commission is an independent, not-for-profit organization that accredits and certifies health care organizations and programs. The National Quality Forum is a not-for-profit independent organization that evaluates health care performance measures for multiple areas, including patient safety.

leading to death, permanent harm, or severe temporary harm to the patient.

- Destruction of red blood cells transfusion reaction involving administration of blood or blood products that have major blood group incompatibilities.
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital.
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure.
- Unintended retention of a foreign object in a patient after an invasive procedure.
- Severe neonatal excess of bilirubin (bilirubin >30 milligrams/deciliter).
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25 percent above the planned radiotherapy dose.
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care.
- Any maternal death or severe maternal or morbidity occurring during or after birth (24 hours).

Table 4: National Quality Forum Sentinel Events Outlined by the Department of Defense (DOD)

Category of event	Description of event
Surgical or invasive procedure events	Surgery or other invasive procedure performed on the wrong site or wrong patient or wrong surgical or other invasive procedure performed on a patient
Surgical or invasive procedure events	Unintended retention of a foreign object in a patient after surgery or other invasive procedure
Surgical or invasive procedure events	Intraoperative or immediately postoperative/post-procedure death of a patient classified as fit for surgery
Product or device events	Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting
Product or device events	Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
Product or device events	Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting
Patient protection events	Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
Patient protection events	Patient death or serious injury associated with patient elopement (disappearance)

**Appendix I: Department of Defense's (DOD)
Revised Definition of a Sentinel Event**

Category of event	Description of event
Patient protection events	Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a health care setting
Care management	Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
Care management	Patient death or serious injury associated with unsafe administration of blood products
Care management	Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting
Care management	Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
Care management	Patient death or serious injury associated with a fall while being cared for in a health care setting
Care management	Any stage 3, stage 4 ^a , and unstageable pressure ulcers acquired after admission to a health care setting
Care management	Artificial insemination with the wrong donor sperm or wrong egg
Care management	Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
Care management	Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results
Environmental events	Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a health care setting
Environmental events	Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances
Environmental events	Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting
Environmental events	Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting
Radiologic events	Death or serious injury of a patient or staff associated with the introduction of a metallic object into the magnetic resonance imaging area
Potential criminal events	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
Potential criminal events	Abduction of a patient/resident of any age
Potential criminal events	Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting
Potential criminal events	Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting

Source: GAO analysis of DOD document. | GAO-18-378

^aStages 3 and 4 of pressure ulcers are the most severe, in which skin and/or tissue is lost.

Appendix II: Comments from the Department of Defense

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of Defense**



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 02 2018

Ms. Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington DC 20548

Dear Ms. Draper:

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Thank you for the opportunity to provide management comments on the draft report recommendations. We appreciate the in-depth review and findings related to the processes for monitoring and tracking patient safety events to drive safe care for patients. Attached is the DoD's management comments in response to the subject report. The DoD concurs with both of the GAO's recommendations focused on improving processes to track sentinel events and root cause analysis reports, providing clarity on reporting of corrective action implementation reports, and developing standard processes to reconcile information on these reports.

We sincerely thank the GAO team members for developing this report and for the steadfast commitment to protecting the health and wellness of our Service members, civilian workforce, and beneficiaries. Should you need any additional information, my point of contact is Ms. Heidi King. Ms. King may be reached at Heidi.B.King.civ@mail.mil or at (703) 681-0064.

Sincerely,

A handwritten signature in black ink, appearing to read "TOM McCaffery".

Tom McCaffery

Attachment:
As stated

**GAO DRAFT REPORT DATED FEBRUARY 28, 2018
GAO-18-378 (GAO CODE 101685)**

**"DOD HEALTH CARE: DEFENSE HEALTH AGENCY SHOULD IMPROVE
TRACKING OF SERIOUS ADVERSE MEDICAL EVENTS AND MONITORING OF
REQUIRED FOLLOW-UP"**

**DEPARTMENT OF DEFENSE (DOD) COMMENTS
TO THE GOVERNMENT ACCOUNTABILITY OFFICE (GAO) RECOMMENDATIONS**

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DoD RESPONSE: The Department concurs with the recommendation.

The DHA will improve the systems and processes for tracking adverse events and monitoring Root Cause Analysis (RCA) reports (and the improvements identified within the Corrective Action Implementation (CAI) Plan reports) by:

1. Clearly codifying terms and requirements within the Clinical Quality Management (CQM) DHA-Procedural Instruction (DHA-PI) in development, which will replace Department of Defense Manual (DoDM) 6025.13 policy (dated October 2013).
2. Continuing to utilize and refine the two tools--Sentinel Events and Root Cause Analysis (SERCA) tool and Comprehensive Analysis Progress Tracker (CAPT)—developed in 2016 and 2017.
3. Developing an education strategy aligned with the new DHA-PI specifically targeting reporting, investigating, and analyzing of safety events, as well as actions to be implemented in response to safety events.

Standard procedures will be critically important as the DHA transitions to assume responsibility for administration of military medical treatment facilities (MTFs) under section 702 of the National Defense Authorization Act for Fiscal Year 2017 (NDAA for FY17). The DHA is coordinating with Health Affairs (HA), the Services and NCR on revisions to the Department of Defense Instruction (DoDI) 6025.13 on CQM and to establish a DHA-PI to replace the DoDM 6025.13 (CQM Manual) for the purpose of managing and administering the medical treatment facilities (MTFs). The Patient Safety enclosure in the DHA-PI will address program structure, roles and responsibilities, and codify definitions, requirements, processes, and accountability. A key section will be on reporting, investigating, and analyzing patient safety events, as well as actions implemented in response to safety events, including associated CAI Plan reports. Included will be management direction for Patient Safety Reports, Adverse Events and SEs and methodologies to ensure information from these events is integrated into the Military Health System (MHS) healthcare learning system. It is anticipated that the final policy will be signed late summer, and in effect on October 1, 2018.

Appendix II: Comments from the Department of Defense

The current process for the submission and tracking of SEs and RCAs from the Services/NCR is fragmented, inefficient, and not completed reliable. The DHA developed the SERCA tool in 2016 to enable quicker, real-time, system-wide safety data trending and provide an easy platform for sharing of lessons learned from RCAs. In doing so, DHA moved forward from monthly and annual data sharing to real-time, interactive, self-serve patient safety data available 24/7. SERCA enables visibility of the same data across all Services/NCR. DHA facilitates regular patient safety data deep dives to clinical work groups/communities as they prioritize improvement efforts on trending safety events as indicated through real-time data collection.

The DHA Chief, Patient Safety Program, regularly tracks and monitors all submitted SEs and their accompanying RCAs and CAI Plan Reports. An enterprise-level view and Service/NCR-level view of patient safety trends in reported events is provided to the Services/NCR and multiple stakeholders through regular publications and work products, which show cumulative SE trends, degree of harm and SE categories. Currently, the Patient Safety Improvement Collaborative (PSIC) and clinical work groups use the data to identify and prioritize patient safety focus areas and targeted approaches. To complement the Services/NCR patient safety improvement efforts, the Patient Safety Program (PSP) designs integrated guides and solutions, which the Services/NCR may disseminate and implement. The PSP and PSIC continually evaluate the impact of these solutions.

As an additional measure to counteract these issues, DHA developed and implemented the CAPT tool in late 2017. This is a web-enabled tool hosted on a secure site that tracks all SEs and RCAs received by DHA. The tool is available to authorized personnel 24 hours a day and is updated each week. This tool enables the Services/NCR to reconcile what DHA has received against what is in their own records. For example, users can review SEs received by DHA, and obtain notification of any information missing in the SE report, such as Patient Safety Reporting number, outcome, or event type. Missing information is flagged for follow up. Users can also use the tool to easily see when DHA records indicate a missing or overdue RCA. The Services can then track down that RCA and send it to DHA. The SERCA and CAPT tools continue to be refined through Service and NCR feedback, and their development is eliminating unwarranted duplication and reducing non-value added activities such as the time consuming emails.

In the future, we envision a single reporting system that will allow for entry of both SEs, RCAs and CAI Plan reports. This system would be used by both the Services/NCR and DHA to access SE and RCA data, ensuring that all parties involved have access to the same information. The entry system would use mandatory fields to ensure that SE, RCA, and CAI Plan report submissions are complete. In addition, this future system would have the ability to automate email notifications to appropriate parties to meet policy requirements.

A robust education strategy is paramount to the success of the DHA PSP mission - to promote a culture of safety to end preventable patient harm by engaging, educating, and equipping. This education strategy must be incorporated into DHA-PI policy changes. DHA will revise and/or design educational materials and offerings, as needed, in support of policy changes, specific to reporting, investigating, and analyzing of safety events, as well as actions implemented in response to safety events. This strategy will align with the revised DoDI 6025.13 and the new

DHA-PI for CQM enclosure on Patient Safety. Learning events and regularly scheduled office-assist consultation hours are currently available on a weekly basis, and will continue.

RECOMMENDATION 2: The GAO recommends that the Secretary of Defense direct the DHA to clarify its policy regarding when Measures of Success (MOS) reports should be completed and submitted to DHA, and work with the military services and NCR to develop a standard system to help it consistency track and reconcile information about individual MOS reports.

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Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to those named above, key contributors to this report were: Bonnie Anderson, Assistant Director; Danielle Bernstein, Analyst-in-charge; Jacquelyn Hamilton; Elizabeth T. Morrison; Vikki Porter; and Helen Sauer.

Appendix IV: Accessible Data

Data Tables

Accessible Data for Figure 1: Number of Harm, Near Miss, and No Harm Adverse Medical Events Reported to the Defense Health Agency (DHA), 2013 through 2016

Year	No harm (number in thousands)	Near miss (number in thousands)	Harm (number in thousands)	Total (number in thousands)
2013	33.757	36.096	6.443	76.296
2014	35.284	40.542	7.065	82.891
2015	34.883	47.707	8.837	91.427
2016	41.873	56.217	10.14	108.23

Accessible Data for Figure 2: Sentinel Events (Medical and Dental) Reported to the Defense Health Agency (DHA), 2013 through 2016

Year	Medical (number of events)	Dental (number of events)	Total (number of events)
2013	101	20	121
2014	120	22	142
2015	189	44	233
2016	206	113	319

Agency Comment Letter

Accessible Text for Appendix II: Comments from the Department of Defense

Page 1

HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON

WASHINGTON, DC 20301-1200

APR 02 2018

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U.S. Government Accountability Office

441 G Street, NW

Washington DC 20548

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