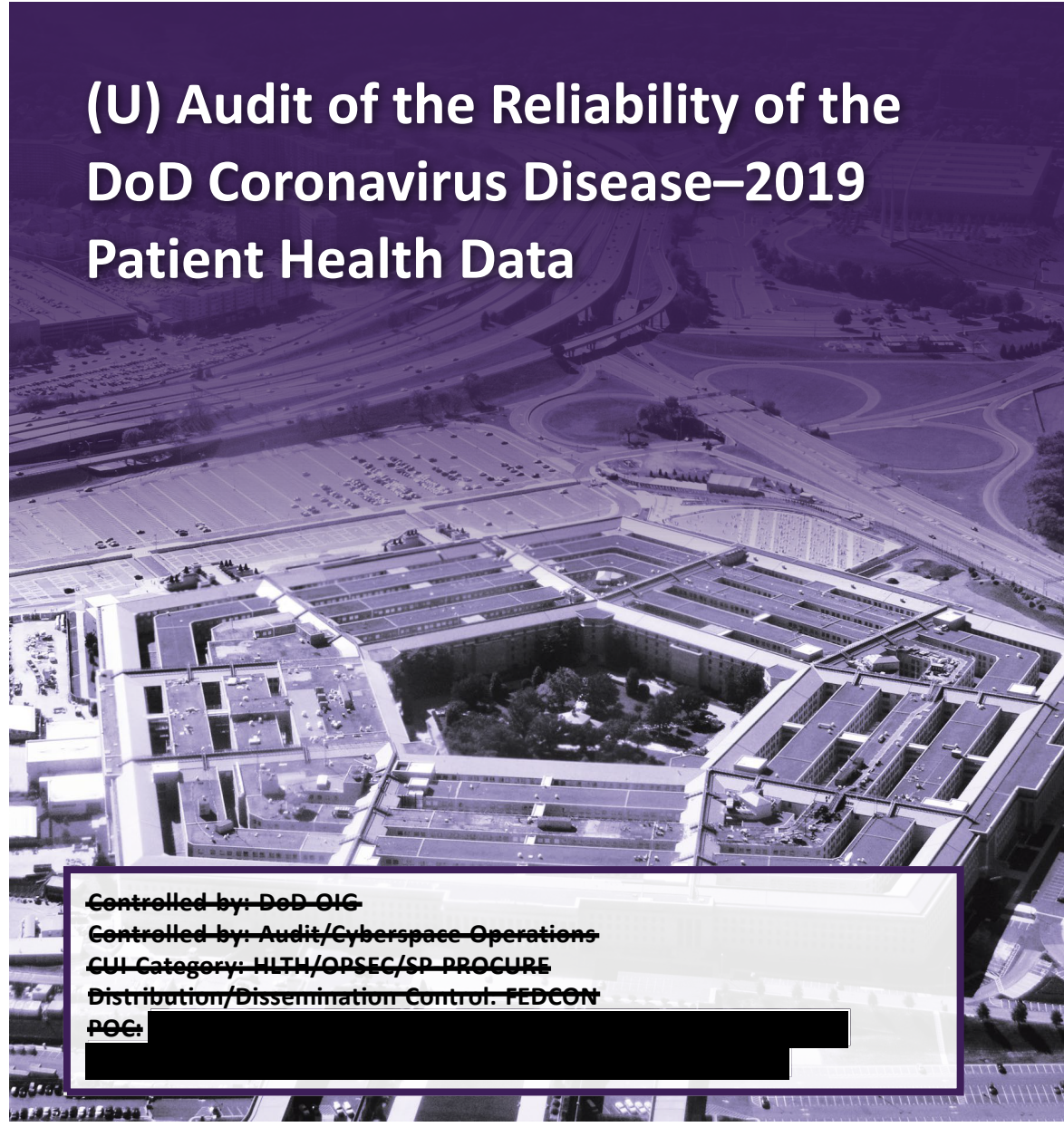


CUI

INSPECTOR GENERAL

U.S. Department of Defense

JULY 7, 2023



(U) Audit of the Reliability of the DoD Coronavirus Disease–2019 Patient Health Data

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POC: [REDACTED]

INTEGRITY ★ INDEPENDENCE ★ EXCELLENCE

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(U) Results in Brief

(U) Audit of the Reliability of the DoD Coronavirus Disease-2019 Patient Health Data

July 7, 2023

(U) Objective

(U) The objective of this audit was to determine the extent to which the DoD can rely on the patient data in its Coronavirus Disease-2019 (COVID-19) Registry to make public health and clinical care decisions.

(U) Background

(U) On July 13, 2020, the Assistant Secretary of Defense (Health Affairs) (ASD[HA]) issued a memorandum directing the Defense Health Agency Director to establish the COVID-19 Registry to collect information on all COVID-19 events within the Military Health System. The Joint Trauma System (JTS), a subordinate organization of the Defense Health Agency, was responsible for maintaining the COVID-19 Registry. The DoD hired a contractor to enter patient health data into the registry with an accuracy rate of at least 90 percent.

(U) Finding

(U) The DoD cannot rely on the data in the COVID-19 Registry to make public health and clinical care decisions concerning the COVID-19 pandemic because the data were not complete, accurate, or representative of the universe of DoD patients who had a COVID-19 event. Among other issues, we identified errors in 24 of the 25 registry records we reviewed; therefore, we are at least 90 percent confident that the accuracy rate of the data in the registry is less than the contractually required minimum of 90 percent.

(U) Finding (cont'd)

(U) The data in the Registry were not complete, accurate, or representative of the universe of DoD patients who had a COVID-19 event because the ASD(HA) lacked a process for developing and populating patient registries. As a result, any data from the COVID-19 Registry that JTS officials provided to the DoD and other stakeholders during the COVID-19 pandemic were inaccurate and potentially misleading. Additionally, the DoD incurred questioned costs of \$6.2 million for registry support services that did not meet the data accuracy requirements.

(U) Recommendations

(U) Among other recommendations, we recommend that the ASD(HA) establish and implement a policy for developing and populating patient registries, and to conduct a review of all patient registries in the Military Health System to verify the reliability of data in each registry and take corrective actions, as necessary. Additionally, we recommend that the JTS Chief conduct an analysis to determine whether the contractor complied with the terms of the contracts and recoup any of the \$6.2 million in questioned costs, if necessary.

(U) Management Comments and Our Response

(U) The Under Secretary of Defense for Personnel and Readiness responded for the DoD officials to whom we directed recommendations in this report and disagreed with 8 of our 12 recommendations. In addition, DoD officials agreed with, but did not address, the specifics of one recommendation. Therefore, 9 recommendations are unresolved. We request additional comments within 30 days in response to the final report to address the unresolved recommendations. Please see the Recommendations Table on the next page for the status of recommendations.

(U) Recommendations Table

(U) Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Assistant Secretary of Defense (Health Affairs)	5.b	5.a	None
Director of the Defense Health Agency	4.a	1, 4.b	None
Senior Contracting Official of the U.S. Army Medical Research Acquisition Activity	2	None	None
Chief of the Joint Trauma System	2, 3, 3.a, 3.b, 3.c, 3.d, 3.e	None	None (U)

(U) Please provide Management Comments by August 7, 2023.

(U) Note: The following categories are used to describe agency management’s comments to individual recommendations.

- **(U) Unresolved** – Management has not agreed to implement the recommendation or has not proposed actions that will address the recommendation.
- **(U) Resolved** – Management agreed to implement the recommendation or has proposed actions that will address the underlying finding that generated the recommendation.
- **(U) Closed** – DoD OIG verified that the agreed upon corrective actions were implemented.



OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
 4800 MARK CENTER DRIVE
 ALEXANDRIA, VIRGINIA 22350-1500

July 7, 2023

(U) MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS
 DIRECTOR, DEFENSE HEALTH AGENCY
 AUDITOR GENERAL, DEPARTMENT OF THE ARMY
 PROGRAM EXECUTIVE OFFICER, PROGRAM EXECUTIVE
 OFFICE, DEFENSE HEALTHCARE MANAGEMENT SYSTEM
 CHIEF, JOINT TRAUMA SYSTEM

(U) SUBJECT: Audit of the Reliability of the DoD Coronavirus Disease-2019 Patient Health Data (Report No. DODIG-2023-093)

(U) This final report provides the results of the DoD Office of Inspector General's audit. We previously provided copies of the draft report and requested written comments on the recommendations. We considered management's comments on the draft report when preparing the final report. These comments are included in the report.

(U) This report contains nine recommendations that are considered unresolved because management officials did not agree with or fully address the recommendations presented in the report. Therefore, as discussed in the Recommendations, Management Comments, and Our Response section of this report, the recommendations remain open. We will track these recommendations until an agreement is reached on the actions that need to be taken to address the recommendations, and management officials submit adequate documentation showing that all agreed-upon actions are completed.


(U) This report contains three recommendations that are considered resolved. Therefore, as described in the Recommendations, Management Comments, and Our Response section of this report, we will close the recommendations when we receive adequate documentation showing that all agreed-upon actions to implement the recommendations are completed.

(U) DoD Instruction 7650.03 requires that recommendations be resolved promptly. For the unresolved recommendations, within 30 days please provide us your comments concerning specific actions in process or alternative corrective actions proposed on the recommendations to audcso@dodig.mil. For the resolved recommendations, within 90 days please provide us documentation showing you have completed the agreed-upon actions. Please send your documentation as a PDF to followup@dodig.mil if unclassified or rfunet@dodig.smil.mil if classified SECRET.

(U) Responses must have the actual signature of the authorizing official for your organization.

(~~CUI~~) If you have any questions or would like to meet to discuss the report, please contact me at [REDACTED]. We appreciate the cooperation and assistance received during the audit.

FOR THE INSPECTOR GENERAL:

A handwritten signature in black ink that reads "Carol N. Gorman". The signature is written in a cursive style with a long horizontal stroke at the end.

Carol N. Gorman
Assistant Inspector General for Audit
Cyberspace Operations and Acquisition,
Contracting, and Sustainment

(U) Contents

(U) Introduction

(U) Objective.....	1
(U) Background.....	1
(U) Review of Internal Controls.....	7

(U) Finding. The DoD Cannot Rely on the Data in the COVID-19 Registry

(U) PEO DHMS Officials Did Not Identify All DoD COVID-19 Events.....	9
(U) The JTS Contractor Did Not Enter Data Accurately into the COVID-19 Registry.....	10
(U) JTS Officials Did Not Ensure the COVID-19 Registry Represented the DoD Target Population.....	13
(U) The ASD(HA) Lacks Policy for Developing and Populating Patient Registries.....	15
(U) JTS Officials Provided Inaccurate and Potentially Misleading Data and Incurred Questioned Costs.....	16
(U) Management Comments on the Finding and Our Response.....	17
(U) Recommendations, Management Comments, and Our Response.....	17

(U) Appendixes

(U) Appendix A. Scope and Methodology.....	24
(U) Internal Control Assessment and Compliance.....	27
(U) Use of Computer-Processed Data.....	27
(U) Use of Technical Assistance.....	28
(U) Prior Coverage.....	28
(U) Appendix B. Potential Monetary Benefits.....	29

(U) Management Comments

(U) Under Secretary of Defense (Personnel and Readiness).....	30
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(U) Acronyms and Abbreviations

.....	38
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(U) Introduction

(U) Objective

(U) The objective of this audit was to determine the extent to which the DoD can rely on the patient data in its Coronavirus Disease–2019 (COVID-19) Registry to make public health and clinical care decisions. See Appendix A for a discussion of the scope and methodology related to the audit objective.

(U) Background

(U) Public and private health care organizations establish patient registries to collect data about a particular disease, condition, or exposure; identify the safety and effectiveness of related treatments and outcomes; and develop best practices and performance improvements in patient care. Within the DoD, the Defense Health Agency (DHA) is responsible for establishing patient registries as directed by the Assistant Secretary of Defense (Health Affairs) (ASD[HA]). The Joint Trauma System (JTS) is a subordinate organization of the DHA that is responsible for maintaining the DoD's patient registries. The JTS's primary mission is to analyze data collected in the DoD Trauma Registry (DoDTR) to improve trauma readiness and casualty care for Service members and maximize their survivability and recovery.¹ The JTS also maintains patient sub-registries that are integrated within the DoDTR, including the traumatic brain injury, infectious disease, and military working dog sub-registries.

(U) On July 13, 2020, the ASD(HA) issued a memorandum directing the DHA Director to establish a pandemic sub-registry (known as the COVID-19 Registry) to collect information on all COVID-19 events within the Military Health System (MHS).² The memorandum also required the DHA Director to assign a functional lead for the registry to be responsible for developing a concept of operations, which explains the purpose and functional requirements of the registry. The DHA Director assigned the JTS Chief as the functional lead for management of the registry and directed the JTS to establish the COVID-19 Registry as an extension to the DoDTR's infectious disease sub-registry.

¹ (U) The DoDTR captures the demographic, injury, treatment, and outcomes for all trauma patients admitted to a military medical treatment facility.

² (U) ASD(HA) memorandum, "Guidance for Reporting and Participation in the Department of Defense Pandemic/Epidemic Registry," July 13, 2020. The MHS is responsible for providing health care to active duty, Reserve component, and retired U.S. military personnel and their dependents.

(U) COVID-19 Registry

(U) The COVID-19 Registry comprises COVID-19 events. JTS officials define a COVID-19 event as a positive lab-confirmed COVID-19 test result, or when a health care provider requires a patient to quarantine, self-isolate, or be admitted to a military medical treatment facility (MTF) because of COVID-19 symptoms. A COVID-19 event begins with the patient's initial encounter for COVID-19 with a medical provider at any MTF. The COVID-19 event ends 30 days after the patient is released from an MTF if hospitalized, tests negative for COVID-19, or dies. A patient can have multiple COVID-19 events, such as reinfections; subsequent COVID-19 events are tracked as separate COVID-19 events in the registry.

(U) COVID-19 event data are obtained from the patient's electronic health records for entry into the COVID-19 Registry. The data collected and input to the registry for each patient record have up to 187 unique data fields, which were established by a team of JTS officials, infectious disease experts from the Uniformed Services University of the Health Sciences, and health care providers from MTFs. The data fields include:

- (U) demographics,
- (U) symptoms,
- (U) past medical history,
- (U) lab and radiology tests results,
- (U) contact with known infected patients,
- (U) treatments and outcomes, and
- (U) complications.

(U) Not all 187 data fields are relevant for each patient record in the registry. For example, if a patient was not admitted to the intensive care unit, that data field would not be populated.

(U) Process for Populating the COVID-19 Registry

(U) The Program Executive Office, Defense Healthcare Management Systems (PEO DHMS) is required to initiate the process for populating the COVID-19 Registry.³ PEO DHMS personnel receive daily reports from the DHA's Armed Forces Health Surveillance Division with COVID-19 events from the Disease Reporting System Internet (DRSi). The DRSi is the system the Military Services use to log newly diagnosed incidents or reportable medical events,

³ (U) The PEO DHMS is a subordinate organization to the Office of the Under Secretary of Defense for Acquisition and Sustainment and is responsible for overseeing the acquisition, delivery, and support of information technology and services that enable data sharing and modernization of the DoD's electronic health records.

(U) such as COVID-19. PEO DHMS personnel run computer scripts on the following MHS systems that are intended to identify patient records that include a reference to COVID-19.⁴

- (U) MHS GENESIS – GENESIS is the MHS’s newest electronic health record system and is designed to provide a single, ongoing, health record for Service members, veterans, and their families. As of September 2022, DoD officials had deployed MHS GENESIS at 92 of the 721 MTFs.
- (U) Composite Health Care System (CHCS) – CHCS is the MHS’s system used to schedule patient appointments, order laboratory tests, authorize radiology procedures, and prescribe medications.

(U) Once PEO DHMS personnel identify the patient records that reference COVID-19, they add the patient data to the Combined COVID-19 Data Table (the Data Table), which is a consolidated list of all probable COVID-19 events reported in the MHS.⁵ Because the Data Table includes patient data that may not meet the definition of a COVID-19 event, such as a negative test result, JTS personnel filter the data to identify the patient records that include a probable COVID-19 event. JTS officials then export the patient records with a COVID-19 event to the JTS Manager (JTSM), which is a system JTS officials use as a workload assignment and management support application for the DoDTR.

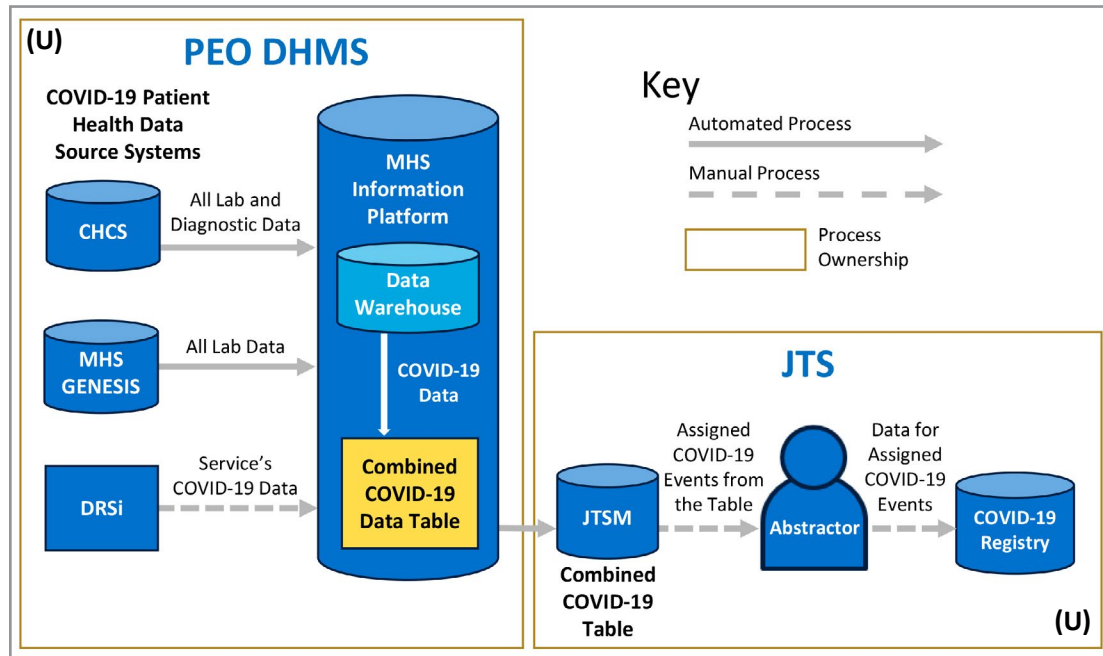
(U) The JTSM does not have an automated interface with the COVID-19 Registry; therefore, the JTS awarded a contract for abstractors and quality compliance nurses to review the patient records, validate that a COVID-19 event occurred, and enter the patient’s health data into the registry.⁶ Figure 1 illustrates the process to create the Data Table and enter COVID-19 events into the registry.

⁴ (U) A computer script is a sequence of instructions or commands for a computer to automate a task, such as assembling or sorting a set of data.

⁵ (U) A data table is an arrangement of information, typically in rows or columns, used to sort, analyze, and extract data based on user needs. Microsoft programs such as Excel and Access can store large amounts of data, run queries, perform analysis, and display data in tables.

⁶ (U) Abstractors and quality compliance nurses are contracted registered nurses with experience caring for infectious disease patients. The abstractors’ duties include reviewing source data from handwritten medical records and electronic source systems to enter patient health data into the COVID-19 Registry. Quality compliance nurses’ duties include reviewing source data against data entered into the registry.

(U) Figure 1. Process to Create the Data Table and Input Data into the COVID-19 Registry



(U) Source: The DoD OIG.

(U) COVID-19 Registry Contract Terms and Conditions

(U) In September 2020, the U.S. Army Medical Research Acquisition Activity (USAMRAA) awarded a \$2.35 million, firm-fixed-price contract on behalf of the JTS to employ abstractors and quality compliance nurses to populate the COVID-19 Registry and conduct quality assurance audits of the data entered in the registry.⁷ The contract included a base year and one option year, which USAMRAA exercised in September 2021, increasing the cumulative contract cost to \$4.75 million. Of the \$4.75 million, \$3.9 million was to employ abstractors and quality compliance nurses to support the COVID-19 Registry. USAMRAA assigned a JTS official to serve as the contracting officer's representative (COR) to monitor the contractor's performance for the duration of the contract.

(U) In September 2022, when the original COVID-19 Registry contract expired, USAMRAA awarded a new firm-fixed-price contract on behalf of the JTS for COVID-19 Registry support services.⁸ USAMRAA awarded the new \$2.3 million contract to the same contractor, on behalf of the JTS, for registry data abstraction and quality assurance services. USAMRAA assigned the same JTS official to serve as the COR for the new registry contract.

⁷ (U) Contract W81XWH-20-P-0197. A firm-fixed-price contract is a fixed-price contract that provides for a price that is not subject to change based on the contractor's incurred costs in performing the contract. The contractor assumes full responsibility for all costs and resulting profit or loss in the performance of a firm-fixed-price contract.

⁸ (U) Contract W81XWH-22-C-0151 expires in September 2025 if all options are exercised. The contract includes a base-year and two 1-year option periods, with a total contract ceiling of \$7.1 million.

~~(CUI)~~ The abstractors are responsible for evaluating COVID-19 events using the JTS COVID-19 Registry “inclusion criteria” to determine the eligibility of the COVID-19 event.⁹ To validate the event, the abstractors are required to compare the data in the JTSM to the initial recording of the COVID-19 event in the patient’s electronic health record. If the COVID-19 event met the inclusion criteria, the abstractors are required to create a record for each eligible event in the registry and populate the relevant data fields. As of March 2022, the abstractors had input data [REDACTED] [REDACTED] DoD patients who had a COVID-19 event.

(U) The abstractors are to maintain an accuracy rate of at least 90 percent for the data entered into the COVID-19 Registry. The quality compliance nurses are responsible for conducting quality assurance reviews of the patient health data that the abstractors entered into the registry, and for ensuring that the abstractors maintained an overall accuracy rate of at least 90 percent. The compliance nurses are required to record the results of their quality assurance reviews in the JTSM, which calculates the accuracy rate of the abstractors’ data entry by averaging the correct entries by the total number of data fields populated. On a monthly basis, JTS officials use the JTSM to calculate a monthly accuracy rate for the registry, which averages the accuracy rate for each abstractor. The JTSM produces a scorecard, which reports the monthly accuracy rate for each abstractor.¹⁰

(U) Health Care Best Practices for Patient Registries

(U) The Department of Health and Human Services (HHS) is the Nation’s lead agency for protecting the health of all Americans. The HHS established health care best practices for planning and interpreting patient registries and recommends several initial steps for those tasked with planning a patient registry.¹¹ These steps include:

- (U) identifying key stakeholders;
- (U) assessing the feasibility and sustainability of a registry as it relates to funding;
- (U) building a registry team with the knowledge, skills, and expertise necessary to implement the registry;
- (U) establishing a governance and oversight plan to provide formal management of the registry, guide decision making, and ensure that the registry goals are achieved;

⁹ (U) JTS, “COVID-19 Infectious Disease Module Screen Elements,” Version 1.0 (as of February 10, 2022).

¹⁰ (U) The JTSM scorecard is prepared by the contractor and includes each abstractor’s accuracy rate for a given patient health record in the COVID-19 Registry.

¹¹ (U) HHS, Agency for Healthcare Research and Quality, “Registries for Evaluating Patient Outcomes: A User’s Guide,” Fourth Edition, September 2020.

- (U) defining the scope of the registry;
- (U) defining the target population;
- (U) developing a study plan or protocol that documents the design, objectives, inclusion and exclusion criteria, data collection procedures, and desired outcomes for the registry; and
- (U) developing a project plan that serves as a roadmap for the registry, including a communication plan and a timeline for deliverables.

(U) Data Reliability Testing

(U) Data reliability comprises two components—completeness and accuracy.¹² HHS best practices state that most patient registries will only include a subset of the target population in a registry for budgetary or practicality reasons. The COVID-19 Registry would be complete if PEO DHMS officials identified all DoD patients who had a COVID-19 event for potential input into the registry. To determine completeness, we developed our own computer scripts that searched MHS GENESIS and CHCS for COVID-19 positive patient health records and compared our data to the data identified by PEO DHMS officials. The data in the registry are accurate if data the abstractors entered match the source data in the MHS electronic health record systems. To determine accuracy, we selected a sample of patient records that were in the registry as of February 2022, and compared data recorded in 39 data fields in the registry to the data posted in the patients' electronic health records.

(U) According to the HHS's health care best practices, a registry should contain data that are representative of the target population. The target population for the COVID-19 Registry is all DoD patients in the MHS who had a COVID-19 event.¹³ Data in the registry are representative if the data portray the population of DoD patients who had a COVID-19 event. For example, if approximately 1 percent of DoD COVID-19 patients were hospitalized, then the registry data should include similar hospitalization rates. To determine whether the registry represented the total MHS population who had a COVID-19 event, we interviewed JTS officials and examined their process for selecting COVID-19 events for entry into the registry.

¹² (U) For the purpose of this audit, we relied on the Government Accountability Office's definition of data reliability as published in the Government Accountability Office, Applied Research and Methods Publication 20-283G, "Assessing Data Reliability," December 2019.

¹³ (U) For the purpose of this audit, DoD patients in the MHS include DoD Service members (active duty, retired, and Reserve) and their dependents and beneficiaries.

(U) Review of Internal Controls

(U) DoD Instruction 5010.40 requires DoD organizations to implement a comprehensive system of internal controls that provides reasonable assurance that programs are operating as intended and to evaluate the effectiveness of the controls.¹⁴ We identified internal control weaknesses related to the process to identify and collect MHS COVID-19 patient health data, ensure the accuracy of data entered into the COVID-19 Registry, and provide quality assurance and oversight of the registry. We will provide a copy of the report to the senior official responsible for internal controls in the Office of the ASD(HA), USAMRAA, the PEO DHMS, the DHA, and the JTS.

¹⁴ (U) DoD Instruction 5010.40, "Managers' Internal Control Program Procedures," May 30, 2013, (Incorporating Change 1, June 30, 2020).

(U) Finding

(U) The DoD Cannot Rely on the Data in the COVID-19 Registry

(U) The DoD cannot rely on the data in the COVID-19 Registry to make public health and clinical care decisions concerning the COVID-19 pandemic because the data were not complete, accurate, or representative of the universe of DoD patients who had a COVID-19 event.

- (U) PEO DHMS officials did not identify at least 7,213 DoD patients in the MHS who had a COVID-19 event for entry into the COVID-19 Registry. PEO DHMS officials excluded these patients because the officials used computer scripts that did not search for all variations of COVID-19 laboratory results in relevant data fields in the MHS's electronic health record systems. Furthermore, PEO DHMS officials did not update their scripts to reflect changes in diagnostic coding and laboratory tests.
- (U) We identified errors in 24 of the 25 registry records we reviewed, including errors in the demographics, symptoms, and pre-existing conditions data fields. We also identified similar errors in all of the 10 records we tested that quality compliance nurses validated as accurate. Therefore, we are at least 90 percent confident that the accuracy of the data in the registry is less than the contractually required minimum of 90 percent. The data in the registry were inaccurate because Army and JTS contracting officials did not design or implement an adequate quality assurance surveillance plan (QASP) to ensure the contractor met the accuracy rate of at least 90 percent.
- (U) JTS officials did not ensure that the patient health data selected for entry into the COVID-19 Registry were representative of the universe of DoD patients in the MHS who had a COVID-19 event because the JTS officials did not develop a standardized selection process.

(U) Furthermore, all of these conditions occurred because the ASD(HA) does not have a policy that provides a consistent and repeatable process for developing and populating patient registries. As a result, any data from the COVID-19 Registry that JTS officials provided to the DoD and other stakeholders during the COVID-19 pandemic are inaccurate and potentially misleading. Additionally, the DoD incurred questioned costs of \$3.9 million, and may incur an additional \$2.3 million, for accepting services from a contractor that did not enter accurate data into the COVID-19 Registry.

(U) PEO DHMS Officials Did Not Identify All DoD COVID-19 Events

(U) PEO DHMS officials did not identify at least 7,213 DoD patients in the MHS who had a COVID-19 event for entry into the COVID-19 Registry. PEO DHMS officials were responsible for identifying DoD patients in the MHS who had a COVID-19 event and adding their data—such as social security number, demographics, and medical history—to the Data Table. As of May 2021, PEO DHMS officials identified 182,159 DoD patients in the MHS who had a COVID-19 event and added their health data to the Data Table.

(U) To determine whether the data in the Data Table were complete, we designed our own computer scripts to search the electronic health records in the MHS GENESIS and CHCS systems for all DoD patients in the MHS who had a COVID-19 event. Our scripts identified 189,372 DoD patients in the MHS, 7,213 DoD patients more than the number of patients identified by the PEO DHMS.

(U) PEO DHMS officials did not identify the 7,213 DoD patients in the MHS because the computer scripts the PEO DHMS officials developed did not search the MHS for variations in how medical providers entered laboratory results and diagnoses or search all relevant data fields in the MHS's electronic health record systems. Variations in text cases include words that may be all capitalized or all lowercase, or minor typing errors in patient records. For example, the PEO DHMS scripts did not capture COVID-19 events if medical practitioners recorded the diagnosis as "covid" instead of "covid-19" in the electronic health record systems. In addition, the scripts did not search text fields in which medical practitioners entered additional data for the patient, such as lab results or patient diagnoses. For example, if a medical practitioner manually entered "pneumonia due to Coronavirus" or its shorthand "pncv19" in a text field, the scripts would not capture the COVID-19 event.

(U) Furthermore, PEO DHMS officials did not update the scripts to reflect changes in diagnostic coding and laboratory tests. For example, PEO DHMS officials did not update their scripts in January 2021 when the World Health Organization released a new diagnostic code for persons diagnosed with pneumonia because of COVID-19.¹⁵ We identified the 7,213 COVID-19 events because our scripts allowed for variations in text cases and included updated diagnostic codes and laboratory tests. In addition, we used text analysis techniques to identify laboratory data concerning COVID-19 results in text fields.

¹⁵ (U) The World Health Organization is a United Nations agency that directs and coordinates the world's response to health emergencies.

(U) During the audit, PEO DHMS officials updated their computer scripts to include variations in text cases and additional laboratory and diagnostic codes based on our feedback. Therefore, we did not make a recommendation to PEO DHMS officials to update their scripts. However, PEO DHMS officials need to establish quality assurance standards to ensure their computer scripts are consistently incorporating future updates to laboratory and diagnostic codes, as needed. Therefore, the DHA Director should work with the PEO DHMS Program Executive Officer to document and implement the process for identifying and collecting patient health data of DoD patients in the MHS in current and future registries within their purview in a written document, such as a standard operating procedure.

(U) The JTS Contractor Did Not Enter Data Accurately into the COVID-19 Registry

(U) We are at least 90 percent confident that the accuracy rate of the data in the registry is less than the contractually required minimum of 90 percent. To determine whether the patient health data in the COVID-19 Registry were accurate, we compared 39 data fields in 25 patient registry records to the source data in the patient's electronic health record. Of the 25 records we reviewed, 24 records had errors, such as errors in the demographics, symptoms, and pre-existing conditions data fields. For example, we identified that the data in ethnicity field were incorrect for 6 of 25 records, and the data in the symptoms field were incorrect or incomplete for 15 of 25 records.

(U) The contract also required the contractor to perform quality assurance reviews of completed registry records in accordance with the JTS standard operating procedures. This required the contractor's quality compliance nurses to:

- (U) randomly sample 10 percent of the records completed by each abstractor for the month prior;¹⁶
- (U) validate the patient health data entered into the registry against the source data recorded in the electronic source system; and
- (U) score the accuracy of the sampled patient records using the quality assurance scorecard built into the JTSM.

(U) We determined that the quality compliance nurses did not perform these duties in accordance with the JTS standard operating procedure. For instance, the quality compliance nurses selected COVID-19 Registry records to review based on their opinion (known as judgmental sampling), rather than randomly selecting patient

¹⁶ (U) Random sampling is a statistical sampling technique that ensures all records within a population have an equitable chance of selection for testing.

(U) records as required in the JTS standard operating procedure. Judgmental sampling was inappropriate because the JTS standard operating procedure required random sampling and it did not give all records in the registry an equal chance of selection, which created bias in the accuracy of the results. Additionally, the quality compliance nurses did not accurately record the results of their quality assurance reviews in the JTSM scorecards. JTS and contracting officials use the JTSM scorecards to validate the accuracy of patient registry records, and monitor contractor performance.

(U) We reviewed 10 records that the quality compliance nurses validated as accurate in the JTSM, and we identified errors in all 10 records. For example, we identified errors in the ethnicity field in 4 of the 10 records. For instance, an abstractor entered a patient’s ethnicity as “unknown” in the registry, and the quality compliance nurses annotated the entry as accurate. However, when we reviewed the source electronic health systems, we determined the abstractor should have recorded the patient’s ethnicity as “not Hispanic or Latino.” In another example, we identified errors in the pre-existing conditions field in 4 of the 10 records. For instance, an abstractor did not include high cholesterol as a pre-existing condition in one registry record, and the quality compliance nurse annotated the entry as accurate.

(U) The data in the COVID-19 Registry were not accurate because Army and JTS contracting officials did not design or implement an adequate QASP to ensure that the contractor met the accuracy rate of at least 90 percent. The JTS COR developed the QASP, which documented the COR’s methodology for monitoring the contractor to ensure that the contractor complied with the contract requirements. However, the QASP permitted the COR to assess the contractor’s performance using JTSM system-generated quality assurance reports that summarized the results of the contractor-prepared JTSM scorecards.¹⁷ The Army contracting officer, who was responsible for approving the QASP, acknowledged that the COR relied on the quality assurance reports and scorecards to assess the contractor’s performance without validating the information.

~~(CUI)~~ By relying on the inaccurate quality assurance reports and JTSM scorecards, the COR [REDACTED] [REDACTED] The COR’s assessment of the contractor factored into the contracting officer’s decision to exercise the option

¹⁷ (U) The JTSM scorecard is prepared by the contractor and includes each abstractor’s accuracy rate for a given patient health record in the COVID-19 Registry. The quality assurance reports are prepared by the contractor and include accuracy rates for the records reviewed by the quality compliance nurses from the JTSM scorecard.

[REDACTED]

~~(CUI)~~ year for the registry contract in September 2021. This decision increased the total payments made to the contractor to \$3.9 million for data abstraction and quality services that did not meet the accuracy requirements in the contract. We are questioning the \$3.9 million that the DoD paid to the contractor for COVID-19 Registry services because the contractor did not comply with the terms of the contract. In addition, when the original COVID-19 Registry contract expired in September 2022, USAMRAA awarded \$2.3 million to the same contractor to continue entering and reviewing data in the registry. Therefore, the DoD may incur an additional \$2.3 million in questioned costs if DoD contracting officials do not implement immediate corrective action to improve the oversight of the contractor's performance for entering and reviewing COVID-19 Registry data. Therefore, the USAMRAA Senior Contracting Official and the JTS Chief should work with the COR to revise the QASP to include an appropriate sampling methodology for selecting patient health records from the COVID-19 Registry to verify that the contractor is achieving the contract-required accuracy rate for entering patient data, and submit the revised QASP to the contracting officer. Additionally, the JTS Chief should conduct an analysis to determine whether the patient data entered into the COVID-19 Registry met the 90 percent accuracy rate requirement for contract W81XWH-20-P-0197 and contract W81XWH-22-C-0151. If the contractor did not meet the 90 percent requirement, then the JTS Chief should work with the USAMRAA Senior Contracting Official to:

- (U) update the contractor's rating in the contractor's performance assessment reports for contract W81XWH-22-C-0151 and contract W81XWH-20-P-0197, when feasible;
- (U) if feasible, recoup any of the \$3.9 million in questioned costs paid for services that did not comply with the terms of contract W81XWH-20-P-0197;
- (U) recoup any of the \$2.3 million in questioned costs paid for services that did not comply with the terms of contract W81XWH-22-C-0151;
- (U) consider all available contract remedies for contract W81XWH-22-C-0151, including modifying and, if necessary, terminating and re-competing the contract, and take action to ensure that the Department receives full value for the funds it expends for contract W81XWH-22-C-0151; and
- (U) delegate an official to review the findings identified in this report, including the actions of the contracting officials, and take administrative actions, as necessary.

(U) JTS Officials Did Not Ensure the COVID-19 Registry Represented the DoD Target Population

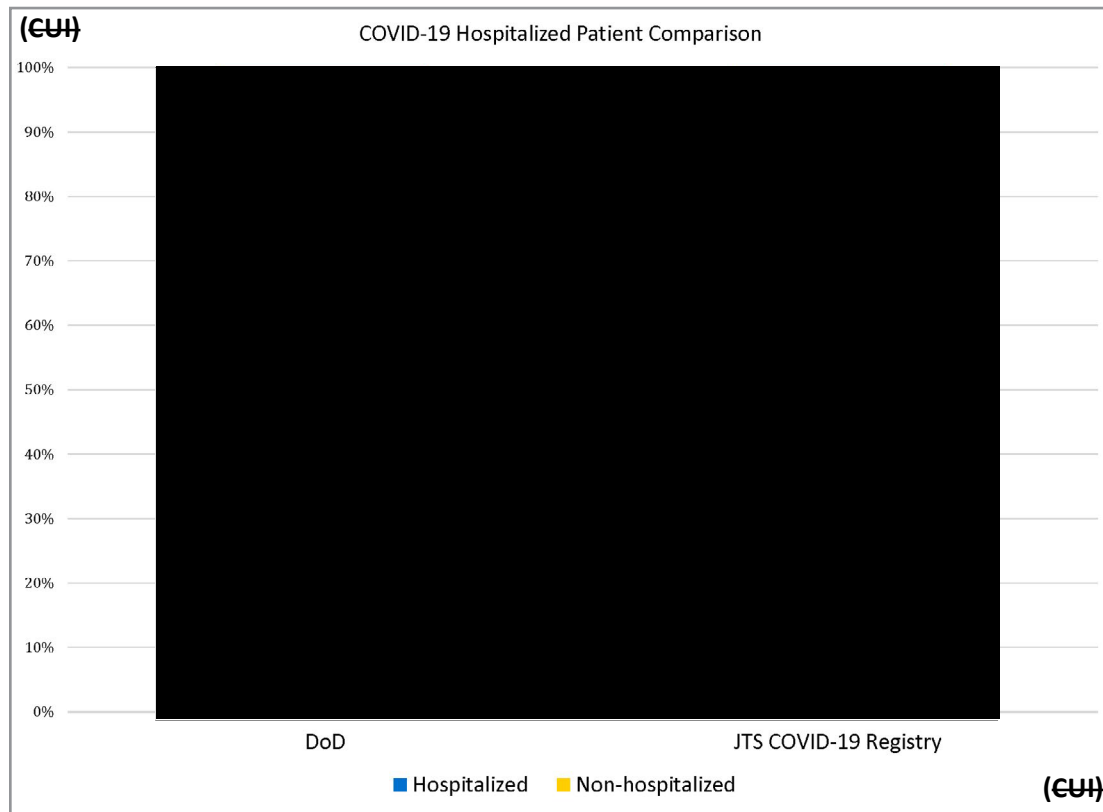
(U) JTS officials did not ensure that the COVID-19 Registry data selected for entry into the COVID-19 Registry were representative of the universe of DoD patients in the MHS who had a COVID-19 event. According to HHS best practices for patient registries, the data in the registry must be representative of the target population to obtain an accurate account of clinical care from the registry and to avoid selection bias.¹⁹ Selection bias occurs when a registry team does not randomly choose an eligible patient's data for entry in a patient registry. The target population for the COVID-19 Registry is all DoD patients in the MHS who had a COVID-19 event.

~~(CUI)~~ To determine whether the data in the COVID-19 Registry represented the total population of DoD COVID-19 patients in the MHS, we interviewed JTS officials to gain an understanding of their process for selecting patient data for entry into the registry. During those interviews, JTS officials explained that they were not randomly selecting COVID-19 events to enter into the registry, as recommended by HHS best practices. JTS officials stated that in some instances, they selected COVID-19 events for entry into the registry from specific patient groups, such as patients who received convalescent plasma treatment, or patients that required hospitalization. However, prioritizing patients in these groups is not representative of the total number of DoD patients who had a COVID-19 event. For example, we determined that the data in the registry reported [REDACTED] DoD patients required hospitalization. Conversely, the DoD reported on its COVID Registry Dashboard that [REDACTED] DoD patients required hospitalization.²⁰ Figure 2 illustrates the comparative COVID-19 patient hospitalization rates between the DoD and the JTS's COVID-19 Registry.

¹⁹ (U) HHS, Agency for Healthcare Research and Quality, "Registries for Evaluating Patient Outcomes: A User's Guide," Fourth Edition, September 2020.

²⁰ (U) The JTS created a COVID Registry Dashboard that displays data from the COVID-19 Registry in charts and graphs to show trends among DoD COVID-19 patients in the MHS. Anyone with a common access card can access the COVID Registry Dashboard and analyze the information presented on the dashboard.

(U) Figure 2. DoD COVID-19 Patient Hospitalization Rates



(U) Source: The DoD and the JTS.

(U) In other instances, JTS officials assigned COVID-19 patient health data to abstractors for entry into the COVID-19 Registry on a “first in, first out” basis, meaning that abstractors entered the data from the oldest events into the registry first. For example, if the abstractors finished entering data for all burn pit registrants who tested positive for COVID-19 into the registry, the abstractors would continue entering data from patient records in the order that the COVID-19 events occurred. Because abstractors entered the oldest data first rather than a combination of old and new data, health care providers may not have data that properly represent the total population of COVID-19 patients to make broad public health determinations regarding COVID-19.

(U) The COVID-19 Registry data were not representative of all DoD patients in the MHS because JTS officials did not develop a standardized selection process to select COVID-19 events for entry into the registry, such as those outlined in HHS best practices. When we discussed the JTS process for entering patient data into the registry with officials from the Office of the ASD(HA), they agreed that the data were biased and not representative of the total population of DoD patients in the MHS who had a COVID-19 event. During the audit, JTS officials added a disclosure notice to the registry dashboard that stated, “These abstracted data are a very

(U) small subset of the total COVID-19 population that has been reviewed in great detail. Due to abstraction priorities, data may be skewed and not represent the entire population.” However, JTS officials did not include the disclosure when briefing officials from the Office of the ASD(HA) or when providing data from the registry to DoD and congressional stakeholders, therefore implying that the data were representative. The DHA Director should work with the JTS Chief to:

- (U) establish and implement a process for selecting COVID-19 events for entry into the COVID-19 Registry to limit selection bias; and
- (U) include a bias disclosure notice on all reports generated from the COVID-19 Registry until the registry data are representative of the population of DoD patients who had a COVID-19 event.

(U) The ASD(HA) Lacks Policy for Developing and Populating Patient Registries

(U) The data in the COVID-19 Registry were not complete, accurate, or representative of the universe of DoD patients in the MHS who had a COVID-19 event because the ASD(HA) does not have a policy that provides a consistent and repeatable process for developing and populating patient registries. The HHS provides best practices that the DoD could use as a baseline for planning, developing, maintaining, and evaluating policy and registries designed to collect data about patient outcomes. Among other best practices, the HHS recommends that registry development teams establish a governance and oversight plan to provide formal management of the registry, guide decision making, and ensure that the registry goals are achieved.

(U) By issuing policy that aligns with HHS best practices, the ASD(HA) could ensure that the process for establishing patient registries in the MHS is consistent, with clear oversight and established procedures for ongoing evaluation of the data to achieve its goals. The ASD(HA) should:

- (U) establish and implement a policy for developing and populating patient registries that aligns with the HHS best practices, “Agency for Healthcare Research and Quality, Registries for Evaluating Patient Outcomes: A User’s Guide,” current edition; and
- (U) conduct a review of all patient registries in the MHS to verify the reliability of data in each registry and implement corrective actions, as necessary.

(U) JTS Officials Provided Inaccurate and Potentially Misleading Data and Incurred Questioned Costs

(U) As a result of incomplete, inaccurate, and non-representative patient health data in the COVID-19 Registry, any data from the registry that JTS officials provided to the DoD and other stakeholders during the COVID-19 pandemic were inaccurate and potentially misleading. Since the DHA authorized the COVID-19 Registry, JTS officials have used the data in the registry to:

- (U) respond to various requests for information from stakeholders, such as Members of Congress; and
- (U) launch a COVID-19 dashboard to allow users with a valid common access card to filter registry data for specific information, such as the number of patients that received certain treatments and the location of the MTFs where certain treatments were administered.

(U) Without complete and accurate data that represent the DoD patients in the MHS who had a COVID-19 event, health care providers may not be able to properly assess and improve COVID-19 treatment and more effectively track the epidemiology of the disease. A properly designed and executed registry can provide the DoD with real-time information on patient outcomes and can contribute to the research and development of treatments. Furthermore, according to the ASD(HA), the DoD's long-term strategic goal is to use the data in the COVID-19 Registry to conduct performance improvement and disease prevention data analysis, and incorporate lessons learned into plans for readiness and pandemic response. Without complete, accurate, and representative data, the DHA may not accomplish this goal.

(U) Additionally, the DoD incurred questioned costs of approximately \$3.9 million for registry abstraction and quality assurance services from a contractor that did not enter, review, or correct data in the COVID-19 Registry accurately as required by the contract terms. In addition, the DoD awarded an additional \$2.3 million contract to the same contractor for the same COVID-19 registry abstraction and quality assurance services. Therefore, if the DoD does not implement immediate corrective actions, the DoD could incur an additional \$2.3 million in questioned costs.

(U) Management Comments on the Finding and Our Response

(U) Under Secretary of Personnel and Readiness Comments

(U) The Under Secretary of Defense for Personnel and Readiness (USD[P&R]), responding for the DHA Director and the JTS Chief, disagreed that the data entered in the COVID-19 Registry were inaccurate. In addition, the USD(P&R) disagreed with our finding that the contractor did not meet the required minimum accuracy rate of 90 percent. The USD(P&R) stated that the JTS calculated accuracy rates of registry records by dividing the total number of correct responses in the health record by the total number of fields reviewed in the record. According to the USD(P&R), USAMRAA awarded the contractor the option year because the JTSM reports demonstrated the contractor met the 90 percent accuracy requirement.

(U) Our Response

(U) We acknowledge in this report that the contracted compliance nurses recorded the results of their quality assurance reviews in the JTSM, which averages the accuracy rate of each abstractors' data entry. However, we determined that the compliance nurses did not follow the quality assurance process outlined in the JTS standard operating procedure, did not always accurately record the results of their quality assurance reviews in the JTSM scorecards, and did not identify all errors made by the abstractors. In addition, the compliance nurses did not randomly select records to review as required by the JTS standard operating procedure, which created a bias in the accuracy computation. As stated in this report and outlined in Appendix A, we are at least 90 percent confident that the accuracy of the data in the COVID-19 registry is less than the contractually required 90 percent accuracy rate.

(U) Recommendations, Management Comments, and Our Response

(U) Revised and Renumbered Recommendations

(U) As a result of management comments, we renumbered:

- (U) Recommendations 1.a and 1.b as Recommendation 1;
- (U) Recommendation 2.a as Recommendation 2;
- (U) Recommendation 2.b as Recommendation 3;
- (U) Recommendations 2.b.1 through 2.b.4 as Recommendations 3.a through 3.d;
- (U) Recommendation 2.c as Recommendation 3.e;

- (U) Recommendation 3 as Recommendation 4; and
- (U) Recommendation 4 as Recommendation 5.

(U) Additionally, we changed the language in Recommendation 2 to request the USAMRAA Senior Contracting Official and the JTS Chief work with, rather than require, the JTS COR to revise the QASP. Furthermore, we removed the USAMRAA Senior Contracting Official as the responsible management official for determining whether the patient health data entered into the COVID-19 Registry were accurate.

(U) Recommendation 1

(U) We recommend that the Director of the Defense Health Agency work with the Program Executive Officer of the Program Executive Office, Defense Healthcare Management Systems to document and implement the process for identifying and collecting patient health data of DoD patients in the Military Health System in current and future registries within their purview in a written document, such as a standard operating procedure. The procedure should identify, at a minimum, the internal controls throughout the process, the relevant data sources, data fields, and diagnostic codes used in the computer scripts, and should be reviewed and approved when updates occur.

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the DHA Director, agreed, stating that the DHA partially implemented the recommendation in September 2021. In addition, the USD(P&R) stated that PEO DHMS officials are currently documenting the methodology for identifying and collecting patient health data for registries, among other actions. The USD(P&R)'s comments also included a standard operating procedure that discussed the DoDTR data abstraction procedures.

(U) Our Response

(U) Comments from the USD(P&R) addressed the recommendation; therefore, the recommendation is resolved but open. We reviewed the standard operating procedure and determined the document was not sufficient to close the recommendation. Specifically, the standard operating procedure did not list the diagnostic codes used in the computer scripts or the internal controls established throughout the process of identifying and collecting patient health data. We will close the recommendation once the DHA Director provides documentation that details the process for identifying and collecting patient health data for all current and future DoD registries to include the relevant diagnostic codes and internal controls.

(U) Recommendation 2

(U) We recommend that the Senior Contracting Official of the U.S. Army Medical Research Acquisition Activity and the Chief of the Joint Trauma System work with the Joint Trauma System contracting officer's representative to revise the quality assurance surveillance plan. The plan should include an appropriate sampling methodology for selecting patient health records from the Coronavirus Disease-2019 Registry to verify that the contractor is achieving the contract-required accuracy rate for entering patient data, and submit the revised quality assurance surveillance plan to the contracting officer.

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the USAMRAA Senior Contracting Official and the JTS Chief, disagreed, stating that USAMRAA, as the contracting activity, is not responsible for the technical performance requirements and does not possess the technical knowledge to monitor the contract's quality assurance program. The USD(P&R) stated that the JTS, as the requiring activity, is responsible for prescribing the technical and contract requirements, which includes developing the QASP to monitor the contractor's performance. USAMRAA can request, but cannot require, that the JTS revise the QASP to include a sampling methodology for contract W81XWH-22-C-0151.

(U) Our Response

(U) Based on management comments, we revised the recommendation to state that the USAMRAA Senior Contracting Official and the JTS Chief should work with, rather than require, the JTS COR to revise the QASP. We directed the recommendation to the USAMRAA Senior Contracting Official because USAMRAA is the contracting activity. According to the Defense Federal Acquisition Regulation Supplement Part 246, "Quality Assurance," Subpart 246.1, "General," Section 103, "Contracting Office Responsibilities," USAMRAA, as the contracting activity, must coordinate with the JTS, the requiring activity, before changing any contract quality assurance requirements.

(U) During the audit, we determined that 34 of the 35 records we reviewed had errors because the surveillance method included in the QASP was ineffective to ensure that the contractor met the accuracy rate of at least 90 percent. For example, the QASP allowed the COR to rely on reports that contained information entered by the contractor and the information was not validated by the COR. Had the COR independently selected and reviewed a sample of registry records, the

(U) COR may have identified the issues highlighted in this report. The USD(P&R) acknowledged that USAMRAA can modify the QASP if JTS personnel determine that including a sampling methodology in the QASP is appropriate. However, the USD(P&R) did not state whether the JTS would revise the QASP to address the recommendation. Therefore, the recommendation is unresolved, and we request that the USAMRAA Senior Contracting Official and the JTS Chief provide a response to the final report within 30 days explaining their plans for revising the QASP.

(U) Recommendation 3

(U) We recommend that the Chief of the Joint Trauma System conduct an analysis to determine whether the patient data entered into the Coronavirus Disease-2019 Registry met the 90 percent accuracy rate requirement for contract W81XWH-20-P-0197 and contract W81XWH-22-C-0151. If the contractor did not meet the 90 percent accuracy requirement, work with the Senior Contracting Official of the U.S. Army Medical Research Acquisition Activity to take the following actions.

- a. **(U) Update the contractor's rating in the contractor's performance assessment reports for contract W81XWH-22-C-0151 and contract W81XWH-20-P-0197, when feasible.**
- b. **(U) If feasible, recoup any of the \$3.9 million in questioned costs paid for services that did not comply with the terms of contract W81XWH-20-P-0197.**
- c. **(U) Recoup any of the \$2.3 million in questioned costs paid for services that did not comply with the terms of contract W81XWH-22-C-0151.**
- d. **(U) Consider all available contract remedies for contract W81XWH-22-C-0151, including modifying and, if necessary, terminating and re-competing the contract, and take action to ensure that the Department receives full value for the funds it expends for contract W81XWH-22-C-0151.**
- e. **(U) Delegate an official to review the concerns identified in this report, including the actions of the contracting officials, and take administrative actions, as necessary. The review should include a determination on whether the contractor's performance assessment reports were accurate and make updates as necessary.**

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the USAMRAA Senior Contracting Official and the JTS Chief, disagreed, but stated that they support the JTS Chief conducting an analysis to determine whether the patient data entered into the COVID-19 Registry met the 90 percent minimum accuracy rate for contracts W81XWH-20-P-0197 and W81XWH-22-C-0151. Additionally, the USD(P&R) stated that the USAMRAA Senior Contracting Official would consider all contract remedies for contracts W81XWH-20-P-0197 and W81XWH-22-C-0151 if the JTS Chief determines that the contractor did not meet the 90 percent accuracy rate requirement.

(U) Our Response

(U) Based on management comments, we renumbered Recommendation 2.b to Recommendation 3 and removed the USAMRAA Senior Contracting Official as the management official responsible for assessing the contractor's performance. However, those revisions do not affect our response to the USD(P&R)'s comments, which is that the USD(P&R) did not fully address the specifics of the recommendation. Therefore, the recommendation is unresolved. It is unclear why the USD(P&R) disagreed with the recommendation given that they agreed with the JTS Chief conducting an analysis and the USAMRAA Senior Contracting Official taking action to resolve any findings. Additionally, the USD(P&R) did not explain what actions the JTS Chief will take to analyze the accuracy rate of the COVID-19 Registry records. Therefore, we request that the JTS Chief provide a response to the final report within 30 days explaining their plans to address the recommendation.

(U) Recommendation 4

(U) We recommend that the Director of the Defense Health Agency work with the Chief of the Joint Trauma System to:

- a. **(U) Establish and implement a process for selecting Coronavirus Disease-2019 events for entry into the Coronavirus Disease-2019 Registry to limit selection bias.**

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the DHA Director, disagreed but did not provide support for the disagreement or propose alternative actions to address the recommendation.

(U) Our Response

(U) Comments from the USD(P&R) did not address the recommendation; therefore, the recommendation is unresolved. As stated in this report, JTS personnel did not randomly select COVID-19 events for entry into the registry in accordance with HHS best practices. Instead, JTS personnel selected events based on specific patient groups, such as patients who received convalescent plasma treatment, or patients who required hospitalization. Prioritizing patients in these groups is not representative of the total number of DoD patients who had a COVID-19 event. We request that the DHA Director provide additional comments within 30 days in response to the final report detailing their plan to establish and implement a standardized process for selecting and entering events into the COVID-19 registry.

- b. (U) Include a bias disclosure notice on all reports generated from the Coronavirus Disease–2019 Registry until the Coronavirus Disease–2019 Registry data represent the population of DoD patients who had a Coronavirus Disease–2019 event.**

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the DHA Director, agreed, stating that the DHA updated the disclosure notice.

(U) Our Response

(U) The USD(P&R) addressed the recommendation; therefore, the recommendation is resolved but open. We will close the recommendation once the DHA Director provides copies of COVID-19 Registry-generated reports that include the bias disclosure notice.

(U) Recommendation 5

(U) We recommend that the Assistant Secretary of Defense (Health Affairs):

- a. (U) Establish and implement a policy for developing and populating patient registries that aligns with the Department of Health and Human Services best practices, “Agency for Healthcare Research and Quality, Registries for Evaluating Patient Outcomes: A User’s Guide,” current edition.**

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the ASD(HA), agreed, stating that the ASD(HA) will coordinate with HHS and other Federal agencies to develop policies that provide oversight of the MHS patient registries.

(U) Our Response

(U) Comments from the USD(P&R) addressed the recommendation; therefore, the recommendation is resolved but open. We will close the recommendation once the ASD(HA) provides the policy for developing and populating patient registries that aligns with HHS best practices.

- b. (U) Conduct a review of all patient registries in the Military Health System to verify the reliability of data in each registry and implement corrective actions, as necessary.**

(U) Under Secretary of Defense for Personnel and Readiness Comments

(U) The USD(P&R), responding for the ASD(HA), agreed, stating that the ASD(HA) will assess the feasibility of verifying the reliability of data in each registry once they develop the policy described in Recommendation 5.a.

(U) Our Response

(U) Comments from the USD(P&R), responding for the ASD(HA), partially addressed the recommendation; therefore, the recommendation is unresolved. A properly designed and executed registry can provide the DoD with real-time information on patient outcomes and can contribute to the research and development of treatments. Therefore, it is critical that the ASD(HA) assess the reliability of data in MHS patient registries. We request that the ASD(HA) provide additional comments within 30 days in response to the final report detailing their plan to assess the reliability of data in each MHS registry.

(U) Appendix A

(U) Scope and Methodology

(U) We conducted this performance audit from February 2021 through January 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

(U) To achieve our audit objective, we reviewed the ASD(HA)'s memorandum that assigned roles and responsibilities and identified requirements for reporting and participating in the COVID-19 Registry.²¹ We also reviewed the HHS health care best practices for planning and interpreting patient registries to gain an understanding of what steps the DoD should have taken to establish the registry.

(U) We interviewed officials from the Office of the ASD(HA), DHA, PEO DHMS, JTS, and U.S. Army Medical Research Acquisition Activity to:

- (U) determine the roles and responsibilities for identifying, collecting, and managing the DoD COVID-19 patient health data;
- (U) understand how DoD COVID-19 patient health data flow from the MHS to the COVID-19 Registry; and
- (U) understand the oversight process the contracting officer and the COR used to ensure that the contractor complied with the contract requirements.

(U) Completeness Testing

(U) To determine whether the data in the COVID-19 Registry were complete, we worked with personnel from the Office of the DHA Chief Information Officer to obtain access to the Data Table. We also extracted the Data Table that included a universe of 1,204,727 probable COVID-19 events reported in the MHS from CHCS, MHS GENESIS, and DRSi, which equated to 572,401 individual patient identifications from December 2019 to May 2021. The total universe of COVID-19 events used for our completeness test included 182,159 individual patient identifications with COVID-19 positive laboratory test results included in both the COVID-19 positive analytic lab data and the Data Table. Next, we developed

²¹ (U) ASD(HA) memorandum, "Guidance for Reporting and Participation in the Department of Defense Pandemic/Epidemic Registry," July 13, 2020.

(U) and used our own computer scripts to search the electronic health records in the MHS GENESIS and CHCS systems for all patients in the MHS who had a COVID-19 event. We compared the 572,401 patient identifications in the Data Table to the 182,159 individual COVID-19 positive laboratory test results from CHCS and MHS GENESIS to determine positive lab results not already included in the shared universe. We determined that there were 7,213 positive lab tests in the MHS missing from the Data Table.

(U) Accuracy Testing

(U) To determine whether the patient health data in the COVID-19 Registry were accurate, we requested that JTS officials provide us with all of the records within the registry. We determined that there were 14,249 patient health records in the registry as of February 2, 2022. Additionally, we requested that JTS officials provide the audit team with the universe of records within the registry that were subject to a quality assurance review by the quality compliance nurses. We determined that as of February 2, 2022, the quality compliance nurses conducted a quality assurance review of 1,114 of the 14,249 registry records.

(U) We selected a statistical sample of 105 of the 14,249 COVID-19 Registry records. The statistical sample was representative of the entire registry population, containing completed records that had been through the quality assurance process, and records that had not. We designed our control test to review the first 50 sampled records, in sequential order, with a 90 percent confidence level and a 10 percent tolerable rate of deviation, to determine whether the registry was at least 90 percent accurate. Based on this approach, our test would be complete when we identified 11 registry errors, or reviewed the first 50 records, whichever came first.²² We defined an error as any instance in which the data entered into the registry did not match the source data and would affect the accuracy of the record. We nonstatistically selected 39 of 187 data fields in each record to assess for accuracy. We based our selection on data fields used in the JTS standard operating procedure and data fields used as metrics on the JTS's Abstracted COVID-19 Registry Dashboard. The fields we selected included demographics, symptoms, pre-existing conditions, complications, and treatments. We compared patient health data the abstractors entered in the 39 data fields in the registry against data in the electronic source systems and documented

²² (U) The DoD OIG Data Analytics Team used guidance from section 450 of the Government Accountability Office/ Council of the Inspectors General on Integrity and Efficiency, "Financial Audit Manual," Volume 1, June 2018 (Updated April 2020) to develop the COVID-19 Registry sample size for review. Additionally, the Data Analytics Team applied methods from Jacob Cohen's Statistical Power Analysis for the Behavioral Sciences (1988) to determine the number of allowed errors we would use to conclude whether the error rate was greater than the tolerable rate of deviation. We identified 11 errors in the first three COVID-19 Registry records we reviewed. We performed additional work to ensure due diligence in the review process and as a result reviewed an additional 22 records. We reviewed 25 registry records from the sample of the entire COVID-19 Registry.

(U) the results. Of the sample of 50 records, we tested 25 registry records and identified that 24 of 25 registry records contained at least one error throughout 26 of 39 data fields we tested. In total, we identified at least 81 errors at the data field level in the sample of records we reviewed.

(U) Additionally, because of our results from the accuracy test, we tested the JTS's quality assurance process to determine whether the control in place was working. We selected a statistical sample of 105 of the 1,114 COVID-19 Registry records that had been through the quality assurance review process. The statistical sample was representative of all registry records that had been through the quality assurance process. Given this test was to assess the accuracy of quality assurance review process, we designed our control test to review the first 25 sampled records, in sequential order, with a 95 percent confidence level and a 3 percent tolerable rate of deviation. Based on the statistical approach we used, the accuracy assessment for the patient records subject to a quality assurance review would be complete when we identified four registry errors, or reviewed the first 25 records, whichever came first.²³ We defined an error as any instance in which the data entered into the registry did not match the source data and would affect the accuracy of the record. We followed the same procedures to conduct testing that we used to test the accuracy of the registry. Of the sample of 25, we tested 10 registry records, and identified that all 10 of the registry records contained at least one error throughout 17 of 39 data fields we tested. In total, we identified at least 32 data field-level errors in the sample of records we reviewed. Furthermore, we compared the 10 registry records to the corresponding JTSM scorecard. We identified that 10 of the 10 scorecards did not correctly reflect the errors contained in the corresponding registry record.

(U) Target Population Testing

(U) To determine whether the patient health data in the COVID-19 Registry were representative of the DoD patients in the MHS with a qualifying COVID-19 event, we compared the DHA COVID-19 Registry Dashboard to the JTS Abstracted COVID-19 Dashboard.

(U) Stakeholder Coordination

(U) We provided an opportunity to the contractor for contracts W81XWH-20-P-0197 and W81XWH-22-C-0151 to comment on relevant portions of the discussion draft report. The contractor for the subject contracts provided comments. Any comments were considered in preparing the final report.

²³ (U) Although we identified four errors in the first two records we reviewed, we continued our due diligence and reviewed eight additional records from the subset of the COVID-19 Registry subject to a quality assurance review.

(U) This report was reviewed by the DoD Components associated with this oversight project to identify whether any of their reported information, including legacy FOUO information, should be safeguarded and marked in accordance with DoD CUI guidance. We considered comments submitted by the DoD Components about the CUI treatment of their information. If the DoD Components failed to provide any or sufficient comments about the CUI treatment of their information, we marked the report based on our assessment of the available information.

(U) Internal Control Assessment and Compliance

(U) We assessed internal controls and compliance with laws and regulations necessary to satisfy the audit objective. In particular, we assessed control activities and monitoring and found deficiencies in the underlying principles of implementing control activities and performing monitoring activities. Specifically, we identified several internal control deficiencies related to the process to identify and collect MHS COVID-19 patient health data, ensuring the accuracy of data entered into the COVID-19 Registry, and providing quality assurance and oversight of the registry. However, because our review was limited to these internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

(U) Use of Computer-Processed Data

(U) We relied on computer-processed data to conduct our completeness testing. We used data from the PEO DHMS-managed COVID-19 Data Table. Our original universe consisted of 1,204,727 probable COVID-19 events from December 2019 through May 2021. PEO DHMS officials collected this data from various source systems in the MHS Information Platform, including MHS GENESIS, CHCS, and DRSi. To assess the reliability of the data, we performed our own search for electronic health records in the MHS GENESIS and CHCS systems for all patients in the MHS who had a COVID-19 event and identified a positive universe of 189,372 cases. This universe included 182,159 COVID-19 positive shared events included in the Data Table and the 7,213 positive COVID-19 lab tests results excluded from Data Table but included in CHCS and MHS GENESIS lab data. We determined that the PEO DHMS data were sufficiently reliable for the purposes of the DoD OIG Data Analytics Team's comparison to analytical lab data.

(U) We also relied on the data in the COVID-19 Registry to conduct our accuracy testing. As of February 2, 2022, the universe of registry records was 14,249. JTS officials provided us with these data. We determined that the COVID-19 Registry data were sufficiently reliable for the purposes of testing the accuracy of patient health data in the registry.

(U) Use of Technical Assistance

(U) We received assistance from the DoD OIG Data Analytics Team during the audit to determine whether the DoD could rely on the patient health data in the COVID-19 Registry. The Data Analytics Team assisted us with:

- (U) extracting the Data Table from the MHS Information Platform;
- (U) developing and running computer scripts to identify missing COVID-19 events; and
- (U) developing and selecting two statistical samples to test for accuracy.

(U) We provided the Data Analytics Team with our findings, which it used to develop projections on the accuracy of the records within the COVID-19 Registry.

(U) Prior Coverage

(U) No prior coverage has been conducted on data reliability of COVID-19 patient health data during the last 5 years.

(U) Appendix B

(U) Potential Monetary Benefits

(U) The following table identifies the total questioned costs of contracts W81XWH-20-P-0197 and W81XWH-22-C-0151 for COVID-19 Registry support services.

(U) Table. COVID-19 Registry Contracts Questioned Costs

(U) Recommendation	Type of Benefit	Amount of Benefit	Account
2, 3.b	Questioned Costs*	\$3,882,393.60	97-2020/2021-0130
3.c, 3.d	Questioned Costs*	\$2,292,020.80	97-2022-0130
	Total	\$6,174,414.40	(U)

* (U) The Inspector General Act of 1978, as amended, defines a questioned cost as a cost that is questioned by the Office of Inspector General because of an alleged violation of a provision of a law, regulation, contract, grant, cooperative agreement, or other agreement or document governing the expenditure of funds; a finding that, at the time of the audit, such cost is not supported by adequate documentation; or a finding that the expenditure of funds for the intended purpose is unnecessary or unreasonable.

(U) Source: The DoD OIG.

(U) Management Comments

(U) Under Secretary of Defense (Personnel and Readiness)



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

APR 28 2023

MEMORANDUM FOR INSPECTOR GENERAL OF THE DEPARTMENT OF DEFENSE

SUBJECT: Review of Department of Defense Inspector General Draft Report, "Audit of the Reliability of the DoD Coronavirus Disease-2019 Patient Health Data" (Project No. D2021-D000CT-0096.000)

This is the response to the DoD Inspector General Draft Report, "Audit of the Reliability of the DoD Coronavirus Disease-2019 Patient Health Data" (Project No. D2021-D000CT-0096.000).

I concur with Recommendations 1, 3b, and 4. I non-concur with Recommendations 2 and 3a (attached). The attachment also provides the views of the U.S. Army Medical Research Acquisition Activity.

Briefly, the Defense Health Agency (DHA) has partially implemented Recommendation 1. Corrective actions were implemented in September 2021 to update the way filters and reference data were used in the code process flow. Regarding Recommendation 3b, DHA has already updated the disclosure notice. The Assistant Secretary of Defense for Health Affairs (ASD(HA)) will engage with the Agency for Healthcare Research and Quality and other Federal agencies to develop policies for oversight of developing and populating patient registries. Once policy is developed, the ASD(HA) will review patient registries and determine the feasibility of verifying the reliability of data in each registry.

My point of contact for this effort is [REDACTED] or [REDACTED]

A handwritten signature in black ink, appearing to read "Gilbert R. Cisneros, Jr.", written in a cursive style.

Gilbert R. Cisneros, Jr.

Attachment:
As stated

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

**DOD IG DRAFT REPORT DATED MARCH 15, 2023
D2021-D000CT-0096.000**

**“AUDIT OF THE REALIABILITY OF THE DOD CORONAVIRUS DISEASE-2019
PATIENT HEALTH DATA”**

DEFENSE HEALTH AGENCY RESPONSE TO THE DOD IG RECOMMENDATIONS

RECOMMENDATION 1: (U) That the Director of the Defense Health Agency (DHA) work with the Program Executive Officer of the Program Executive Office, Defense Healthcare Management System:

- a. (U) Document and implement the process for identifying and collecting patient health data of Department of Defense (DoD) patients in the Military Health System (MHS) who had a Coronavirus Disease-2019 event in a written document such as a standard operating procedure. The procedure should identify, at a minimum, the internal controls throughout the process, the relevant data sources, data fields, and diagnostic codes used in the computer scripts and should be reviewed and approved when updates occur.
- b. (U) Document their process for developing and updating computer scripts for all current and future DoD registries within their purview in a written document such as a standard operating procedure.

DHA RESPONSE: DHA concurs and has already partially implemented these recommendations.

(U) Enterprise Intelligence & Data Solutions PMO: Corrective actions were implemented in September 2021 to update the way filters and reference data were used in the code process flow. These changes focused on two major areas: 1) reworking the views that were created to resolve changes in processing and result in the desired output exactly as the requirement stated, and 2) creating lookup tables of the variables that are referenced within the code instead of hard coding those variables into the code itself, resulting in a viewable, auditable, and easily maintainable location to ensure future tests are captured as they are added to the lookup table. All methodology for registries is currently being documented based upon the data requirements provided to us by the Registry functional owner, attached is the functional owners Data Abstraction standard operating procedure process. The Chief Health Informatics Officer provides functional and technical oversight on all updates to the registry platform.

RECOMMENDATION 2: (U) We recommend that the Senior Contracting Official of the U.S. Army Medical Research Acquisition Activity (USAMRAA) and the Chief of the Joint Trauma System (JTS):

(U)USAMRAA is an Army Agency, accordingly USAMRAA response is captured below. DHA will continue to work with COR.

- a. (U) Require the JTS contracting officer's representative to revise the quality assurance surveillance plan to include an appropriate sampling methodology for selecting patient

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

health records from the Coronavirus Disease-2019 (COVID-19) Registry to verify that the contractor is achieving the contract-required accuracy rate for entering patient data and submit the revised quality assurance surveillance plan (QASP) to the contracting officer (COR).

- b. (U) Conduct an analysis to determine whether the patient data entered into the COVID-19 Registry met the 90 percent accuracy rate requirement for contract W81XWH-20-P-0197 and contract W81XWH-22-C-0151. If the contractor did not meet the 90 percent accuracy requirement, take the following actions.
 1. (U) Update the contractor's rating in the contractor's performance assessment reports for contract W81XWH-22-C-0151 and contract W81XWH-20-P-0197, when feasible.
 2. (U) If feasible, recoup any of the \$3.9 million in questioned costs paid for services that did not comply with the terms of contract W81XWH-20-P-0197.
 3. (U) Recoup any of the \$2.3 million in questioned costs paid for services that did not comply with the terms of contract W81XWH-22-C-0151.
 4. (U) Consider all available contract remedies for contract W81XWH-22-C-0151, including modifying and, if necessary, terminating and re-competing the contract, and take action to ensure that the Department receives full value for the funds it expends for contract W81XWH-22-C-0151.
- c. (U) Delegate an official to review the concerns identified in this report, including the actions of the contracting officials, and take administrative actions, as necessary. The review should include a determination on whether the contractor's performance assessment reports were accurate and make updates as necessary.

DHA RESPONSE: DHA non-concurs with the DoD OIG's recommendation.

USAMRAA RESPONSE: The USAMRAA non-concurs with the DoD OIG's recommendation.

(U) Joint Trauma System:

The COVID-19 registry is constantly evolving as the public health sector gains more information and understanding of the prevalence and best practices, the JTS will continue to improve on our data monitoring process and will update our requirements supporting the COVID-19 registry, as required. The OIG report states the COR was permitted by QASP to rely on the "contractor prepared quality assurance reports and contractor prepared JTSM scorecards." Within JTS, the Quality Assurance (QA) reports and JTSM manager (JTSM) scorecards are all government created products generated as the record is abstracted (scorecard) or audited (QA reports) and provided to the contractor to assist in monitoring their own personnel's quality, productivity, and areas for improvement. The JTSM reports can be generated for individuals or aggregated for the entire COVID registry abstractor or auditor staff. The COR has full reporting rights in the JTSM and can customize reports and request updates to the program/reporting options as needed.

These JTSM reports demonstrated [REDACTED] in the 90 percent accuracy standard, frequently exceeding 90 percent with the more experienced abstractors.

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

[REDACTED] therefore [REDACTED]

Accuracy rates are calculated based on a comprehensive review of the entire registry record against current definitions and business rules using all available source data at the time of abstraction. The calculated accuracy is generated based on the number of correct responses divided by the total number of audited field values. While total number of fields do not change, the denominator can fluctuate based on one-to-many field value relationships. Calculation for fields such as Symptoms, Pre-Existing Conditions, or Treatments will be different between records relative to number of Symptom, Pre-Existing Condition, or Treatment findings within each record. As an example, Record A has one Symptom and 201 audited data points. Record B has the same data except for 10 Symptoms accounting for 210 audited data points.

The OIG Audit Team limited review to 39 of 187 Data Points, reviewed 0.17 percent (25/14,249) of abstracted records, 0.9 percent (10/1114) of audited records to make their assessment and did not report on source of findings with the JTS team to support inter-rater reliability of their review process. OIG Audit Team reviewed available resources, including validation screenshots provided by QA team, and did not communicate handling of discrepancies within source records, registry variables, or methods used to determine inaccurate data capture. Source applications used for comprehensive abstraction include the following: AHLTA (Armed Forces Health Longitudinal Technology Application) AHLTA-T (Armed Forces Health Longitudinal Technology Application-Theater) AVHE (Application Virtualization Hosting Environment) CHCS (Composite Health Care System); DEERS (Defense Enrollment Eligibility Reporting System) ESSENTRIS/CLINICOMP (Inpatient Electronic Health Record) HAIMS (Healthcare Artifact and Image Management Solution HALO (Health Assessment Light Operations) JLV (Joint Legacy Viewer) MHS Genesis: System Integration Wave EHR- Project through 2023 (Transition from facility Based Essentris Model) TC2: Theater Medical Information Program Joint-Composite Health Care System-Cache TMDS (Theater Medical Data Store) and TRAC2ES (Transcom Regulating and Command & Control Evacuation System).

(U) U.S. Army Medical Research Acquisition Activity (USAMRAA):

DHA acknowledges USAMRAA non-concur noted below.

USAMRAA disagrees with the report's characterization that USAMRAA, as the contracting activity, is responsible for technical performance requirements. Contracting is a complementary effort between the program office and the contracting activity. Through collaboration, in complex and technical environments, each party plays a distinct role in a successful contract.

The contracting activity is responsible for managing the solicitation, award, administration and closing of contracts. Programmatic and technical performance aspects of an acquisition remain the responsibility of the program office from pre-award contract technical requirements' development through the entire lifecycle of the contract. This includes the quality assurance portion that was created in coordination with the statement of work (SOW), or performance work statement (PWS) developed by the program office.

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

Federal Acquisition Regulation (FAR) 46.103(a), “Contracting offices are responsible for (a) Receiving from the activity responsible for technical requirements any specifications for inspection, testing, and other contract quality requirements essential to ensure the integrity of the supplies or services (the activity responsible for technical requirements is responsible for prescribing contract quality requirements, such as inspection and testing requirements or, for service contracts, a quality assurance surveillance plan)...”

Defense Federal Acquisition Regulation Supplement (DFARS) 246.103, “(1) The contracting office must coordinate with the quality assurance activity before changing any quality requirement. (2) The activity responsible for technical requirements may prepare instructions covering the type and extent of Government inspections for acquisitions that are complex, have critical applications, or have unusual requirements....”

The USAMRAA provides responses to the recommendations with the understanding that they, as the contracting activity, do not possess the programmatic technical knowledge necessary for the referenced contract’s quality assurance. These contracts require knowledge, skills, and training in healthcare fields with active healthcare licenses, expertise in infectious disease and pandemics, and access to patient health data. The contracting activity relies on the expertise of the program office as indicated by the FAR and DFARS references above.

USAMRAA RESPONSE: The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.a

In accordance with the FAR 46.103(a) and DFARS 246.103, and as explained above, the activity responsible for technical requirements is responsible for prescribing contract quality requirements, such as a quality assurance surveillance plan (QASP). USAMRAA can request, but cannot require, that Joint Trauma System (JTS) to revise the QASP for contract W81XWH-22-C-0151 to include revising the sampling methodology for selecting patient health records from the Coronavirus Disease-2019 (COVID-19) Registry.

Furthermore, the purpose of a contract QASP is to describe the systematic methods used to monitor performance and to identify the required documentation and the resources to be employed. The QASP provides a means for evaluating whether the contractor is meeting the performance standards/quality levels identified in the SOW or PWS, and to ensure the Government pays only for the level of services received. FAR 46.401(a) states that the QASP should specify, “(1) All work requiring surveillance; and (2) the method of surveillance.” It does not require any specific type of method be used. When developing QASPs, the DoD Guidebook for Acquisition of Services lists options for surveillance such as 1) 100 percent Inspection, 2) Random Sampling, 3) Periodic Sampling, 4) Customer Feedback, 5) Mix of Contractor Metrics, and 6) Third Party Audits, among others. On page 24 of contract W81XWH-22-C-0151, the methods of Quality Assurance Surveillance used in the administration of the QASP were 1) Direct Observation, 2) Management Information Systems, and 3) Periodic Inspection. The contract QASP has nine performance areas of the PWS that are to be surveyed and meets all requirements identified in FAR 46 regarding QASPs. A QASP is not required to include a surveillance method of sampling. If the JTS determines that a surveillance method of sampling

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

is appropriate for this contract, the Contracting Officer can modify the contract to change the QASP.

Contract W81XWH-20-P-0197 had a period of performance that ended in September 2022. To the extent the recommendation includes contract W81XWH-20-P-0197, that contract is no longer active and the QASP cannot be modified.

USAMRAA RESPONSE: The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.b.

The Senior Contracting Official of the USAMRAA supports the Chief of the JTS conducting an analysis to determine whether the patient data entered the COVID-19 Registry met the 90 percent accuracy rate for contract W81XWH-20-P-0197 and W81XWH-22-C-0151 and informing USAMRAA. As stated above, the USAMRAA, as the contracting activity, does not possess the technical expertise needed to determine the validity of patient data nor do its personnel have access to the COVID-19 Registry, which would require specific authorization to access protected patient health data. Therefore, the USAMRAA must rely on the technical expertise of JTS in conducting the analysis of the accuracy rate.

USAMRAA RESPONSE: The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.b.1.

The DoD IG Draft Report Dated March 15, 2023, D2021-D000CT-0096.00 includes findings that a series of Government errors from Assistance Secretary of Defense (Health Affairs) (ASD(HA)), Program Executive Office, Defense Healthcare Management Systems (PEO DHMS), the DHA, the JTS, and the USAMRAA contributed to a lack of reliability of the JTS COVID-19 database. The Senior Contracting Official of the USAMRAA agrees with the recommendation to the extent that if the contractor did not comply with terms of the contract as drafted when signed and as modified during administration then the contractor's performance assessment report will reflect their performance. Contract W81XWH-22-C-0151 is currently six months into the first year of performance. Contractor's performance assessment reports are an annual requirement. If the analysis from JTS determines that the contractor did not meet the 90 percent accuracy requirement due to poor contractor performance, it will be reflected in the contractor's rating in the contractor's annual performance assessment report.

USAMRAA RESPONSE: The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.b.2.

The Senior Contracting Official of the USAMRAA disagrees with this recommendation. Contract W81XWH-20-P-0197 ended September 2022. The Contracting Officer relied on the inspection and acceptance performed by the JTS when performance was accepted, and payment approved. Additionally, the DoD IG Draft Report Dated March 15, 2023, D2021-D000CT-0096.00 includes findings that a series of Government errors from ASD(HA) through the PEO DHMS and DHA JTS to USAMRAA contributed to a lack of reliability of the JTS COVID-19 database. Pending the results of the analysis by JTS and how that may impact the contract as

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

agreed to by the parties, the Contracting Officer will evaluate remedies for contract W81XWH-20-P 0197.

USAMRAA RESPONSE: The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.b.3

The Senior Contracting Official of the USAMRAA disagrees with this recommendation. The Contracting Officer relied on the inspection and acceptance performed by the JTS when performance was accepted, and payment was approved.

Additionally, the DoD IG Draft Report Dated March 15, 2023, D2021-D000CT-0096.00 includes findings that a series of Government errors from ASD(HA), the PEO DHMS, the DHA, the JTS, and the USAMRAA contributed to a lack of reliability of the JTS COVID-19 database. Pending the results of the analysis by JTS and how that may impact the contract as agreed to by the parties, the Contracting Officer will evaluate remedies for contract W81XWH-22-C-0151.

The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.b.4.

The Senior Contracting Official of the USAMRAA non-concurs with this recommendation. The DoD IG Draft Report Dated March 15, 2023, D2021-D000CT-0096.00 includes findings that a series of Government errors from ASD(HA), the PEO DHMS, the DHA, the JTS, and the USAMRAA contributed to a lack of reliability of the JTS COVID-19 database. If the JTS determines that the contractor did not meet the 90 percent accuracy requirement due to the company's lack of performance, the Contracting Officer will consider all available contract remedies for W81XWH-22-C-0151 including modifying and, if necessary, terminating and recompeting the contract. Per contract W81XWH-22-C-0151, if the contractor does not meet any of the Acceptable Quality Levels of PWS Tasks, the contractor is allowed time for correction. Otherwise, the USAMRAA will pursue any other remedies available under the law.

The Senior Contracting Official of USAMRAA, non-concurs with Recommendation 2.c.

As explained, these contracts require knowledge, skills, and training in healthcare fields with active healthcare licenses, expertise in infectious disease and pandemics, and access to patient health data. USAMRAA personnel do not possess the programmatic knowledge necessary to review and competently evaluate the contractor's technical performance. Those who do are in the JTS and the USAMRAA Senior Contracting Official cannot assign JTS personnel to conduct such a review.

USAMRAA RESPONSE: The Senior Contracting Official is unable to address the recommendation to consider administrative actions as that phrase is ambiguous.

RECOMMENDATION 3: (U) We recommend that the Director of the Defense Health Agency work with the Chief of the Joint Trauma System to:

- a. (U) Establish and implement a process for selecting Coronavirus Disease-2019 events for entry into the Coronavirus Disease-2019 Registry to limit selection bias.

(U) Under Secretary of Defense (Personnel and Readiness) (cont'd)

- b. (U) Include a bias disclosure notice on all reports generated from the Coronavirus Disease-2019 Registry until the Coronavirus Disease-2019 Registry data represent the population of DoD patients who had a Coronavirus Disease-2019 event.

DHA RESPONSE: DHA non-concurs with the DoD OIG's recommendation 3a and concurs with recommendation 3b and has already updated the disclosure notice.

(U) Joint Trauma System:

The auditors may have misunderstood the inclusion criteria for the registry or may have misunderstood the relationship between the two levels of detail within the registry. The COVID-19 registry inclusion criteria are all DoD beneficiaries who received a positive COVID test result. In addition, those who were inpatients or had additional risk factors had additional details collected by manual chart abstraction that were not available through automated data feeds. Those patients who conducted home COVID tests and some who were tested outside of an Military Medical Treatment Facility may not have been identified by the registry. Additional challenges identifying all COVID tests have been updated per the auditors' recommendation. Data caveats are included in all formal registry reports which identify the source of data and potential bias. Per the investigator's recommendation, we have expanded the use of data caveats to all requests for information used internally.

RECOMMENDATION 4: (U) We recommend that the Assistant Secretary of Defense (Health Affairs):

- a. (U) Establish and implement a policy for developing and populating patient registries that aligns with the Department of Health and Human Services best practices, "Agency for Healthcare Research and Quality, Registries for Evaluating Patient Outcomes: A User's Guide," current edition.
- b. (U) Conduct a review of all patient registries in the Military Health System to verify the reliability of data in each registry and implement corrective actions, as necessary.

ASD(HA) RESPONSE: The ASD(HA) concurs with the DoD OIG's recommendations. The ASD(HA) will meet with Agency for Healthcare Research and Quality and other Federal agencies to develop policies that provide oversight of the MHS registries. Once the ASD(HA) develops policies to oversee the MHS patient registries and reviewed it patient registries, it will determine the feasibility of verifying the reliability of data in each registry.

(U) Acronyms and Abbreviations

- (U) ASD(HA)** Assistant Secretary of Defense (Health Affairs)
- (U) CHCS** Composite Health Care System
- (U) COR** Contracting Officer's Representative
- (U) COVID-19** Coronavirus Disease–2019
- (U) DHA** Defense Health Agency
- (U) DoDTR** Department of Defense Trauma Registry
- (U) DRSi** Disease Reporting System Internet
- (U) HHS** Department of Health and Human Services
- (U) JTS** Joint Trauma System
- (U) JTSM** Joint Trauma System Manager
- (U) MHS** Military Health System
- (U) MTF** Medical Treatment Facility
- (U) PEO DHMS** Program Executive Office, Defense Healthcare Management Systems
- (U) QASP** Quality Assurance Surveillance Plan
- (U) USAMRAA** U.S. Army Medical Research Acquisition Activity
- (U) USD(P&R)** Under Secretary of Defense for Personnel and Readiness

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