

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

DAVID M. WEINBERG, STAFF DIRECTOR
WILLIAM E. HENDERSON III, MINORITY STAFF DIRECTOR
LAURA W. KILBRIDE, CHIEF CLERK

March 21, 2023

The Honorable Lloyd J. Austin III
Secretary
Department of Defense

Dear Secretary Austin:

Over the last year, I have been examining data integrity issues on the Defense Medical Epidemiology Database (DMED). A Department of Defense (DoD) whistleblower recently provided my office with new information showing concerning increases in certain registered diagnoses on DMED in 2021 compared to a five-year average from 2016-2020. The whistleblower downloaded the DMED data over a year after the DoD admitted that DMED data had been corrupted and was later apparently fixed.¹

Based on the whistleblower data, the most significant increases in registered diagnoses on DMED in 2021 compared to a five-year average from 2016-2020 are as follows:²

- Myocarditis, unspecified: 130.5% increase
- Malignant neoplasms of esophagus: 56.6% increase
- Pulmonary embolism: 41.2% increase
- Ovarian dysfunction: 38.2% increase
- Complications and ill-defined descriptions of heart disease: 37.7% increase

In addition to this concerning data, the whistleblower's information appears to conflict with information DoD previously provided my office regarding increases in registered medical diagnosis on DMED.

¹ On February 15, 2022, DoD informed my office that in late January 2022, it found that "the data in DMED was corrupt for the years 2016-2020 when accessed after September 2021." DoD claimed that this data corruption resulted in increases in registered medical diagnoses on DMED in 2021 compared to the five-year average from 2016-2020. DoD assured my office that as of January 29, 2022, it corrected the programming error that corrupted the data and that "DMED data via the online application was restored on January 30, 2022." See Temporary Data Inaccuracies in the Defense Medical Epidemiology Database, Dep't of Defense, Feb. 15, 2022 (enclosed).

² The whistleblower data is from January 2023 and February 2023 and is sourced from the "Ambulatory Data" contained in DMED for each medical encounter noted in this letter. For all medical encounters listed below, the whistleblower used the following criteria – Service: All; Grade: All; Data Sources: Hospitalizations Ambulatory Data Reportable Events; Gender: All; Marital Status: All; Query Type: ICD-10 Based Query Oct 2015 to present; Age: All; Time: 2016 2017 2018 2019 2020 2021; Condition: Primary Diagnosis; Race: All; Occurrence: All Occurrences. The whistleblower used the following ICD codes for each medical encounter: Myocarditis, unspecified: I51.4; Malignant neoplasms of esophagus: C15; Pulmonary embolism: I26; Ovarian dysfunction: E28; and complications and ill-defined descriptions of heart disease: I51.

On February 1, 2022, I sent you a letter based on allegations from three DoD whistleblowers who revealed significant increases in certain registered diagnoses on DMED in 2021 compared to a five-year average from 2016-2020.³ In that letter, I identified 15 registered diagnoses that, according to the three DoD whistleblowers, showed significant increases in 2021 compared to the average from 2016-2020.⁴ On February 15, 2022, DoD provided my office with a chart listing the 15 registered diagnoses I had previously identified and showed the percent change in health encounters before and after DoD fixed the data issue on DMED.⁵ However, the most recent DoD whistleblower provided my office with DMED data that showed different percent changes compared to what DoD provided last year.

The chart below shows the data DoD provided my office and the highlighted column shows the data from the recent DoD whistleblower:

Medical Encounter Conditions	<u>Before DoD Corrected DMED</u> Reported change to number of health care encounters (2021 compared to 2016-2020 average) using erroneous data⁶	<u>After DoD Corrected DMED</u> DMED query results for change to number of health care encounters (2021 compared to 2016-2020 average) following data correction⁷	<u>Recent DoD Whistleblower DMED Data</u> From 2023 showing change to number of health care encounters (2021 compared to 2016-2020 average)⁸
-------------------------------------	---	---	--

³ Letter from Ron Johnson, Ranking Member, Permanent Subcommittee on Investigations, to Lloyd Austin, Secretary, U.S. Dep’t of Defense, Feb. 1, 2022, <https://www.ronjohnson.senate.gov/services/files/FB6DDD42-4755-4FDC-BEE9-50E402911E02>.

⁴ *Id.*

⁵ Temporary Data Inaccuracies in the Defense Medical Epidemiology Database, Dep’t of Defense, Feb. 15, 2022 (enclosed).

⁶ The information contained in this column is based on information from DoD whistleblowers provided in January 2022. DoD claims that this data was based on faulty information. *Id.*

⁷ The information contained in this column shows the percent changes *after* DoD claimed it corrected the data problem in DMED. *Id.*

⁸ The information contained in this column is based on whistleblower DMED data from January 2023 and February 2023. The whistleblower data is sourced from the “Ambulatory Data” contained in DMED for each medical encounter noted above. For all medical encounters listed, the whistleblower used the following criteria – Service: All; Grade: All; Data Sources: Hospitalizations Ambulatory Data Reportable Events; Gender: All; Marital Status: All; Query Type: ICD-10 Based Query Oct 2015 to present; Age: All; Time: 2016 2017 2018 2019 2020 2021; Condition: Primary Diagnosis; Race: All; Occurrence: All Occurrences. The whistleblower used the following ICD codes for each medical encounter – Diseases of the nervous system: G00-G99; Hypertension: I10-I15; Tachycardia: I47; Testicular cancer: C62; Ovarian dysfunction: E28; Migraines: G43; Pulmonary embolism: I26; Female infertility: N97; Malignant neoplasms of thyroid and other endocrine glands: C73-C75; Breast cancer: C50; Demyelinating: G35-G37; Guillain-Barre syndrome: G61.0; Malignant neoplasms of digestive organs: C15-C26; Multiple sclerosis: G35; Malignant neoplasms of esophagus: C15.

Diseases of the nervous system	1,048% increase	5.7% decrease	9.5% increase
Hypertension	2,181% increase	1.9% increase	12.6% increase
Tachycardia	302% increase	8.3% decrease	4.9% increase
Testicular cancer	369% increase	3% increase	16.3% increase
Ovarian dysfunction	437% increase	23.9% increase	38.2% increase
Migraines	452% increase	1.6% increase	12.1% increase
Pulmonary embolism	468% increase	25.4% increase	41.2% increase
Female infertility	472% increase	13.2% decrease	4.3% decrease
Malignant neoplasms of thyroid and other endocrine glands	474% increase	16.1% decrease	4.3% decrease
Breast cancer	487% increase	1.1% increase	14.7% increase
Demyelinating	487% increase	17.7% decrease	8.3% decrease
Guillain-Barre syndrome	551% increase	17.2% decrease	3.2% increase
Malignant neoplasms of digestive organs	624% increase	0.2% increase	14.4% increase
Multiple sclerosis	680% increase	16.7% decrease	7.1% decrease
Malignant neoplasms of esophagus	894% increase	27.8% increase	56.6% increase

It remains unclear how DoD calculated the percent changes for these specific registered diagnoses after the DMED data issue was allegedly fixed. Further, the recent whistleblower data highlighted above raises additional questions as to why the whistleblower's percent changes differ from DoD's percent changes if the data source for both calculations was DMED.

To better understand the apparent differences in DMED data and DoD's response to the increases in certain registered medical diagnoses, please provide the following information as soon as possible but no later than April 4, 2023:

1. For the February 15, 2022 document DoD provided my office, how did DoD calculate the percent change for the 15 registered diagnoses listed above?
2. Do the percent changes DoD provided my office in February 2022 for the 15 registered diagnoses listed above remain unchanged? If not, why not and what are the updated percent changes?
3. Does DoD agree with the percent changes provided by a DoD whistleblower (indicated above)? If not, why not?
4. What steps has DoD taken or will DoD take to investigate whether the increases in certain registered medical diagnoses, including those above, are associated with COVID-19 vaccine adverse events?

Thank you for your attention to this matter.

Sincerely,



Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

Enclosure

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Robert Storch
Inspector General
Department of Defense

Mr. Kenneth Bonner
President and Chief Growth Officer
Unissant, Inc.

Enclosure

February 15, 2022

TEMPORARY DATA INACCURACIES IN THE DEFENSE MEDICAL EPIDEMIOLOGY DATABASE

BLUF:

- Department of Defense (DoD) officials detected and resolved a programming error in the Defense Medical Epidemiology Database (DMED) that had caused the database to inaccurately suggest that outpatient medical encounters for some conditions had significantly increased in 2021. In January 2022, Department officials found that data in DMED covering the years 2016 – 2020 had been corrupted during an August 2021 server migration, showing only 10% of the true number of medical encounters for that period. The corrupted data made it impossible to accurately compare medical encounter rates across the Military Health System (MHS) from 2021 to the 2016 - 2020 period because researchers could not correctly baseline their observations. In January 2022, Department officials resolved the programming error and adopted new auditing procedures for future server migrations. The accurate changes in medical encounters for the reported diagnoses are provided below.

ISSUE:

- On January 26, 2022, an opinion article was published suggesting that there was a large increase in outpatient medical encounters for various conditions among active component Service members when comparing the 2016-2020 annual average to 2021.
- Percent increases cited in the article included neurological issues (1,000%), myocardial infarction (269%), Bell's palsy (291%), congenital malformations (156%), female infertility (471%), and pulmonary embolisms (467%).
- The article suggested that these increases were due to adverse effects of COVID-19 vaccination.
- The authors used the DMED as their data source. The DMED is maintained by the Armed Forces Health Surveillance Division (AFHSD) in the Defense Health Agency.

BACKGROUND:

- DMED, developed in 1997, is a web-based tool to query de-identified active component personnel and medical event data contained within the Defense Medical Surveillance System (DMSS). It contains no personally identifiable information and no protected health information.
- DMSS is AFHSD's relational database that is used to conduct epidemiologic surveillance on Service members and is the underlying data source for DMED.
- DMED is available via remote access to authorized users, including U.S. military medical providers, epidemiologists, medical researchers, safety officers or medical operations/clinical support.
- The purpose of DMED is to provide quick access to summarized epidemiologic data for surveying health conditions in Service members. The ability to make inferences from the data using the available preset queries is very limited.
- DMED is more useful as a tool to generate questions rather than a tool to answer them. To address specific questions on Service members' health, a more thorough analysis is required.

DISCUSSION:

- On January 26th, the AFHSD of the Defense Health Agency created and preserved a full backup of the DMED.
- As part of a January 27, 2022 review and analysis, AFHSD found that the data in DMED was corrupt for the years 2016-2020 when accessed after September 2021. The DMED database is “refreshed” or re-created each month to stay in sync with DMSS. This refresh process was investigated and found to be the cause of the error.
- The review and analysis revealed that DMSS data contained approximately 22 million outpatient encounters for active component Service members for 2020. The same query found only 2 million outpatient encounters for active component Service members in DMED.
- The data for years 2016 through 2020 contained only approximately 10% of the true number of outpatient medical encounters for that period, which created an inaccurate appearance that diagnoses for medical conditions increased when compared to previous years.
- On January 28, 2022, AFHSD replicated the user queries of DMED that were referenced in recent media coverage, using accurate DMSS data, and found the following percent changes in outpatient medical encounters counts among Active Duty Service members when comparing the 2016-2020 annual average to 2021: Neurological issues (3.0%), myocardial infarction (1.4%), Bell’s palsy (0.8%), congenital malformations (1.0%), female infertility (-6.5%), and pulmonary embolisms (37.5%). These are changes in the number of health care encounters for that particular condition, not changes in the prevalence of the condition.
- Counts of health care encounters are not representative of new cases of these diagnoses; they are a measure of the workload for the health system regarding provision of care associated with these diagnoses. Counts of health care encounters cannot be used as a proxy for the prevalence of disease.
- On February 2, 2022, AFHSD replicated the queries to validate data post-DMED corrective actions. Updated results include the percent change in health encounters comparing available 2021 data to 2016-2020.

Medical Encounter Conditions	Reported change to number of health care encounters (2021 compared to last 5 years) using erroneous data	DMED query results for change to number of health care encounters (2021 compared to last 5 years) following data correction
Diseases of the nervous system	1,048% increase	5.7% decrease
Hypertension	2,181% increase	1.9% increase
Tachycardia	302% increase	8.3% decrease
Testicular cancer	369% increase	3% increase
Ovarian dysfunction	437% increase	23.9% increase
Migraines	452% increase	1.6% increase
Pulmonary embolism	468% increase	25.4% increase

Female infertility	472% increase	13.2% decrease
Malignant neoplasms of thyroid and other endocrine glands	474% increase	16.1% decrease
Breast cancer	487% increase	1.1% increase
Demyelinating	487% increase	17.7% decrease
Guillain-Barre syndrome	551% increase	17.2% decrease
Malignant neoplasms of digestive organs	624% increase	0.2% increase
Multiple sclerosis	680% increase	16.7% decrease
Malignant neoplasms of esophagus	894% increase	27.8% increase

- The DMED data queries presented in the tables above reflect health care utilization and include all health encounters with the related diagnostic codes. These queries capture disease screening, follow-up and even miscoded appointments for hospital stays and outpatient appointments. To determine the trend in any of the listed disease categories, DMSS must be used to refine the query and define criteria for the diagnoses (pre-existing versus new), as well the accuracy of the diagnoses with the inclusion of additional data such as procedures, medication, or related laboratory results.
- DMED is recreated every month using DMSS data, which relies on continuously refreshed medial administrative and personnel data. Fluctuations occur in the total number of personnel and health encounters. Because the denominator changes and does not remain static, rates should be used for comparison across time periods, not the number of encounters.

ROOT CAUSE ANALYSIS:

- On January 29, 2022, a programming logic error was discovered in the code used to create some of the DMED summary data tables.
- The DMED monthly refresh procedure was updated in August 2021 following a planned server migration. The programming error was introduced at that time and has affected DMED data since September 2021.
- Not all of the DMED tables were affected by the logic error and not all DMED queries were affected by the corrupt data. Quality control measures were focused on larger, more detailed DMED tables and failed to detect this error in the smaller aggregate data tables. Additional quality control measures are being implemented to mitigate the risk of this logic error occurring again.

SUMMARY:

- AFHSD will continue to support data requests using DMSS, including support to the Immunization Healthcare Division in its efforts to identify Active Duty military personnel who have encountered adverse health events after receiving COVID-19 vaccination.
- As of January 29, 2022, the programming logic error has been corrected and tested in a development environment. DMED data was re-generated and access to DMED data via the online application was restored on January 30, 2022.

- The data displayed in DMED has undergone extensive quality assurance testing by multiple analysts and has been found to be consistent with the source data in the DMSS.
- Quality control measures will be expanded to include all of the DMED tables and columns to prevent future occurrences of inaccurate data appearing in DMED. A second functional quality control check will be implemented following each monthly release of DMED data.