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DEPARTMENT OF DEFENSE MONITORING OF COVID–19

HEARING

BEFORE THE

SUBCOMMITTEE ON MILITARY PERSONNEL

OF THE

COMMITTEE ON ARMED SERVICES
HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

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HOUSE OF REPRESENTATIVES,
COMMITTEE ON ARMED SERVICES,
SUBCOMMITTEE ON MILITARY PERSONNEL,
Washington, DC, Thursday, March 7, 2024.

The subcommittee met, pursuant to call, at 2:48 p.m., in room 2118, Rayburn House Office Building, Hon. Jim Banks (chairman of the subcommittee) presiding.

OPENING STATEMENT OF HON. JIM BANKS, A REPRESENTATIVE FROM INDIANA, CHAIRMAN, SUBCOMMITTEE ON MILITARY PERSONNEL

Mr. BANKS. The hearing will now come to order.

I ask unanimous consent that the Chair be authorized to declare a recess at any time. Without objection, so ordered.

And I ask unanimous consent that members may have 5 legislative days to revise and extend their remarks. Without objection, so ordered.

I want to welcome everyone to this hearing of the Military Personnel Subcommittee. Today we convene to address a matter of paramount importance: How the Department of Defense [DOD] monitoring of COVID–19 has impacted our military ranks and the implications of the COVID–19 vaccine on the health and well-being of our service men and women.

Over the past 4 years the COVID–19 pandemic has presented unprecedented challenges to our Nation and its Armed Forces. As the virus has become just another part of the yearly flu season, we need to look with clear eyes and healthy skepticism at how the Department handled the pandemic, the effects of the virus and vaccines on our service members' health, and if the Department's policies and practices actually mitigated any risk to service members and their families.

Many service members and their families are concerned with the safety and value of the COVID–19 mRNA vaccine, prompting questions about adverse reactions and unforeseen circumstances, most concerningly related to heart conditions and hypertension in a young military population. And the data is worrying.

In 2022, we saw heart rate conditions like hypertension and cardiomyopathy among service members increase by 47 percent and 94 percent respectively over DOD averages.

In addressing this pandemic there is no doubt that the Department has made mistakes and that some decisions were made for political gain rather than based on science and fact.

So today we seek clarity for the service members who took the COVID–19 vaccine, for their families, and for everyone's future health and well-being.

We seek to understand the extent to which the Department of Defense has monitored the impact of COVID–19 on our military personnel including any potential correlation between the virus itself and the development of medical conditions.

Moreover, we aim to examine the data surrounding the administration of the COVID–19 vaccine within our ranks, evaluating its safety profile and any observed trends in adverse reactions and health outcomes.

As stewards of our Nation's defense, it is incumbent upon us to ensure the well-being of those who wear the uniform. We owe it to our service members to provide them with the best possible care and support especially in times of crisis.

By convening this hearing, we demonstrate our commitment to transparency, accountability, and above all the health and safety of our military community.

I would like to welcome our witnesses; Dr. Lester Martinez-Lopez, the Assistant Secretary of Defense for Health Affairs at the Department of Defense, and Dr. Shauna Stahlman, senior epidemiologist of the Armed Forces Health Surveillance Division at the Defense Health Agency, Public Health.

Thank you for being here today. I hope this hearing provides us an opportunity for our members to have a productive exchange. Before hearing from our witnesses let me offer Ranking Member Tokuda an opportunity to make any opening remarks.

[The prepared statement of Mr. Banks can be found in the Appendix on 21.]

STATEMENT OF HON. JILL N. TOKUDA, A REPRESENTATIVE FROM HAWAII, SUBCOMMITTEE ON MILITARY PERSONNEL

Ms. TOKUDA. Thank you, Mr. Chair. Thank you to our witnesses for being here today and providing testimony regarding the Department of Defense's health surveillance efforts which includes monitoring health threats and emerging infections, biosurveillance, and epidemiological analysis, to include the impacts of infections and vaccines.

As a member of the House Select Subcommittee on the Coronavirus Pandemic I am not unfamiliar with efforts to politicize science behind vaccines to the detriment of public health and national security.

I cannot emphasize enough the importance of using a fact-driven science-based approach to this conversation today. Let's focus on the facts.

Safe and effective COVID–19 vaccine options have been readily available since 2021. According to the CDC [Centers for Disease Control and Prevention], in the first 10 months that COVID–19 vaccines were available, they saved over 200,000 lives and prevented over 1.5 million hospitalizations in the United States.

This is the purpose of these vaccines, to save lives and prevent severe illness. While the military COVID–19 vaccine requirement was rescinded in January 2023, 96 percent of the Active and Re-

serve force, over 1.9 million people, safely received one or more doses of a COVID–19 vaccine.

Vaccine requirements have longstanding precedent in our Armed Forces. Since the founding of the U.S. military, vaccine requirements have been necessary to preserve military readiness and personal safety, from General George Washington's smallpox vaccination of the Continental Army in 1777 to the flu vaccine requirement in the mid-20th century.

Today, the Department administers as many as 17 different vaccinations, and while it was in effect, the COVID–19 vaccination requirement helped ensure that our Armed Forces remained healthy and medically ready.

Service members that have received COVID–19 vaccines have done so under the most intense safety monitoring program in United States history. The CDC, the Food and Drug Administration [FDA], and other Federal partners use multiple passive and active surveillance systems and data sources to conduct comprehensive safety monitoring of COVID–19 vaccines and the Department of Defense conducts near real-time monitoring and research on the impacts of COVID–19 vaccinations and infections through the Military Health System.

Studies continue to show that the benefits of COVID–19 vaccines outweigh the risk. Yet concern and apprehension regarding the safety of COVID–19 vaccinations do still exist. This may be due in large part to a fundamental misunderstanding of the Department's COVID–19 vaccine surveillance data which has unfortunately been the subject of misleading news stories over the past year.

The Department of Defense's monitoring efforts of COVID–19 have reported a small number of increases in adverse health effects following the COVID–19 vaccine requirement. But correlation does not imply causation. Legitimate questions remain as to the root cause of these identified adverse health effects.

The overarching question for today's panel is one of paramount importance: Are there long-term effects from COVID–19 on our service members and if so, how do we discern whether any increase in reported adverse health effects are attributable to the virus itself or to the vaccine.

To address this question comprehensively we must approach today's discussion with scientific rigor, ensuring that we prioritize the health and safety of our All-Volunteer Force as a whole above all else.

As we navigate the complexities of this issue we must acknowledge the profound impact that the COVID–19 pandemic has had on the operational readiness of our Armed Forces. First and foremost, the pandemic resulted in thousands of hospitalizations across the Department and the tragic loss of hundreds of lives.

It also had far-reaching second- and third-order effects on our military including disruptions in training exercises and deployments, the mobilization of military medical personnel to support civilian pandemic response efforts, and negative impacts to military family quality of life issues like delays in moves, child care, and health care access.

At the heart of today's discussion regarding the Department's monitoring of COVID–19 lies a fundamental commitment to the

health and well-being of our service members. That must ultimately include a shared dedication to transparency and facts grounded in scientific evidence.

Mr. Chairman, I'd like to request that the Department of Defense's "Report on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine Requirement" be included in the record for today's hearing.

Mr. BANKS. Without objection.

[The information referred to can be found in the Appendix on page 37.]

Ms. TOKUDA. Thank you, Mr. Chair.

Congress required this report in fiscal year 2023 NDAA [National Defense Authorization Act] and it serves as an example of the careful and thoughtful monitoring the Department is doing.

Thank you again, Mr. Chair, for this hearing and I look forward to our witness testimony and the responses to questions that will be posed today.

I yield the balance of my time.

[The prepared statement of Ms. Tokuda can be found in the Appendix on page 23.]

Mr. BANKS. Thank you. I understand that you have one consolidated opening statement. We respectfully request that you summarize your testimony in 5 minutes or less. Your written comments and statements will be made part of the hearing record.

Following opening statements, each member will have an opportunity to question the witnesses for a very liberal 5 minutes.

With that, Dr. Martinez-Lopez, you may make your opening statement.

STATEMENT OF DR. LESTER MARTINEZ–LOPEZ, ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, OFFICE OF THE SECRETARY OF DEFENSE; ACCOMPANIED BY SHAUNA STAHLMAN, SENIOR EPIDEMIOLOGIST, ARMED FORCES HEALTH SURVEILLANCE DIVISION, DEFENSE HEALTH AGENCY, PUBLIC HEALTH

Dr. MARTINEZ-LOPEZ. Chairman Banks, Ranking Member Tokuda, distinguished members of the subcommittee, we are pleased to represent the Office of the Secretary of Defense to discuss the Department's ongoing health surveillance of the force related to COVID–19 in the aftermath of the global pandemic.

This testimony provides the committee with information on some of the key data used to track the health of service members and provides updates on some past and future studies related to the impact of COVID–19 on the health of the service members.

Service members, like all members of our Nation, experienced the effects of the global COVID–19 pandemic. However, unlike the civilian population, when service members, particularly those deployed or are on operational units, became sick with COVID–19 it impacts national security.

This is an unacceptable risk for the military and our Nation. As part of force health protection, the Department of Defense took actions to blunt the impact of the pandemic on the force and to maintain operational readiness.

This was achieved primarily through force health protection measures like vaccinations, testing, masking, symptom monitoring, and remote work.

These actions saved lives and resulted in less severe disease and fewer hospitalizations among those service members that were infected.

Nevertheless, the impact of COVID–19 lingers with some service members and veterans, just like many other Americans, are experiencing the long-term effect of COVID–19 infections including long COVID and heart-related conditions.

As we seek to keep the total force healthy and on mission, the Department monitors for infectious diseases and a range of other health threats. We do this through a dedicated staff with public health commands co-located with military units around the world.

In addition, we have a team of analysts evaluating the data for trends and investigating any signal that are identified.

One of the primary tools these health threats analysts used to answer complex epidemiological questions is a relational database called the Defense Medical Surveillance System, or DMSS.

As the central repository of medical surveillance data for the U.S. Armed Forces, DMSS contains up-to-date and historical data on diseases and medical events including inpatient and ambulatory medical encounters, immunizations, prescriptions, laboratory data, deployment health assessment, and casualty data.

To enhance our ability to identify signals in the noise of infectious disease data we have a related capability to DMSS called the Defense Medical Epidemiology Database, or DMED.

DMED, used in its proper context, is a useful tool for DOD medical and public health professionals to monitor health trends among their local populations and identify potential issues that require further inquiry or research.

The DOD's data is compelling. In looking at the impact of vaccine, the Department's data show that unvaccinated individuals with a reported COVID–19 infection were at significantly higher risk of developing three cardiac conditions—myocarditis, pericarditis, and acute myocardial infarction—compared to individuals who received a COVID vaccine.

Further, the DOD data show that among the 31 Active Duty service members who died from COVID–19, none of them were fully vaccinated.

Now, today, 4 years after the emergence of SARS–COVID–2 virus, it continues to circulate in our military communities and evolve into new variants, presenting an ongoing health threat capable of harming service members and affecting operations.

The Department remains committed to protecting the health of the force and to better understand these impacts as we prepare for future health threats.

Our ongoing studies will support the development of therapeutics and medical countermeasures. We will also continue to evaluate the relationship between COVID–19 infection or COVID–19 vaccinations and cardiac conditions through surveillance and research.

Our ongoing data surveillance will help inform future DOD policy on force health protection, improve readiness, and help prepare for and mitigate against future health threats.

Thank you for inviting us here today to speak with you about the Department's health data which enables our ongoing surveillance of the impact of the COVID–19 and the force—and the health of the force.

We look forward to answering your questions.

[The joint prepared statement of Dr. Martinez-Lopez and Dr. Stahlman can be found in the Appendix on page 25.]

Mr. BANKS. Thank you for your opening statement. I'll begin with questions and yield myself 5 minutes.

Dr. Martinez-Lopez, I find it convenient that in the report to Congress you cited in your testimony, the same report that the minority just entered into the record, that the researchers chose to use 45 days as the at-risk period following a COVID–19 infection but only 21 days for the at-risk period following the COVID–19 vaccination, especially when the administration and the—the Biden administration's CDC told everyone that you weren't considered immune immediately after the shot.

Seems to me like you were skewing the data to make it fit what you wanted the conclusion to be by doing that and to justify your use of the vaccine.

You also admitted that the sample sizes are inaccurate due to underreporting. So how are we to trust the Department and the Biden administration that you all are being honest when it reaches a conclusion that all of these medical problems were due to the infection and not the vaccine?

Dr. MARTINEZ-LOPEZ. Mr. Chairman, as a retired soldier and now given the opportunity to serve the safety and the health and the readiness of the force and the service members is most important to me.

The data is very clear, you know, that you have higher risk of developing these conditions if you got—just got the disease without the vaccine. The vaccine doesn't exempt you from getting some of these complications but it really does decrease the risk to the service members.

I will defer to Dr. Stahlman on the 45 versus the—the timeline differential.

Dr. STAHLMAN. Sure. Thank you. As an epidemiologist with the DHA [Defense Health Agency], I am concerned as well with the health and wellness of our service members and we take reports of any increase in medical conditions that are potentially due to vaccine or to the virus seriously.

In that report we worked with cardiologist specialists within DHA to determine the best risk window to use when looking at an adverse event in relation to the vaccine or to the virus.

If you're looking at an event due to a vaccine, say, 5 years later it becomes less likely that that event is actually due to the vaccine because you've accumulated much more exposures over time.

So in talking with cardiologists and SMEs [subject matter experts] and in the work that the immunizations healthcare division has done in clinically following the myocarditis and pericarditis cases within DOD we knew that most myocarditis and pericarditis cases when they occurred due to result of vaccine will occur within 21 days after the vaccine.

We also know in working with cardiologist experts within DOD that if you're going to have a myocarditis or pericarditis event following COVID–19 infection, it's most likely to show up within that 45-day period.

So we chose that period because we're using administrative data. We were not able to go in to confirm that the event was clinically ruled out due to some other condition.

So using administrative data you have to use a risk window period so that it's likely you're looking at an event that's due to your exposure.

Mr. BANKS. Okay. So on that point, either one of you, can you tell me how many new cases of myocarditis there were among Active Duty service members in 2020?

Dr. STAHLMAN. Thank you. There are around 100 to 200 cases of new myocarditis among Active Component service members each year.

Mr. BANKS. What about 2020? Obviously, you track this.

Dr. STAHLMAN. We do, but I do not have that exact number in front of me.

Mr. BANKS. Okay. So according to DOD data obtained by Senator Ron Johnson there were 275 new myocarditis cases among Active service members in 2021, which is a 151 percent more than average over the 5 years prior.

And the reason I bring that up is because I asked your office before this hearing to give me that specific number and you gave me the 20—instead of giving me the 2020 numbers you gave me the 2021 numbers.

So it's very suspicious why you wouldn't have that data available when you have the exact—you had an exact answer for me for 2021.

Dr. STAHLMAN. Thank you. We do have the number. I do not have it in front of me.

It takes our analysts time to write programming code to pull the data. It then has to be reviewed by an epidemiologist to ensure that the code is accurate, that the output is accurate, and we will get you those numbers.

Mr. BANKS. Can you at least remember if there were fewer cases of myocarditis in 2020 than what there were in 2021? I mean——

Dr. STAHLMAN. I believe they were higher in 2021 than in 2022. As the report—the duty report on cardiac and kidney issues shows there was more than a 10 times increased rate in myocarditis among Active Component service members who had a recent COVID–19 infection compared to a 2.6 increased rate among Active Component service members who had recently received the COVID–19 vaccine.

Mr. BANKS. I'm going to yield 5 minutes to Ms. Tokuda.

Ms. TOKUDA. Thank you, Mr. Chair.

Just some basic questions, perhaps, so that we get a better understanding of the research and the data that you folks have been doing.

What does DOD currently use the DMSS, the Defense Medical Surveillance System, and DMED, Defense Medical Epidemiological Database, data for?

I'm just trying to get an understanding of the regular practical uses of the data beyond research.

Dr. MARTINEZ-LOPEZ. Congresswoman, we take very seriously—I mean, data to formulate policy is critical to us, especially when it comes to clinical policy.

So I'm not the expert. I will defer. But I'll open up saying we have two systems—we have multiple systems. The two key systems is the DMSS, the Defense Medical Surveillance System—that's a relational database that encompasses pretty much all the health—many of the health care points of every service member since—I think since 1990.,

And then we have another system, it's called DMED, the Defense Medical Epidemiological Database. That's not a database. That's a web-based tool that actually can perform queries into the DMSS.

But it's really for the field. That information is not identifiable for a particular patient. So it's that it gives you—gives the people in the field an idea that something may be happening and that's what we want.

But then if you have a question about something happening then we have to do further studies using the other system, the DMSS. But I'll defer to Dr. Stahlman if she wants to expand.

Dr. STAHLMAN. Yes. Thank you.

DMED is used more as hypothesis generating. It allows users to do certain limited canned queries of the data. The default output—if you do a query on DMED looking at a certain ICD [International Classification of Diseases] diagnostic code from a drop-down list that you can choose, the default output that it will give you are—include numbers of outpatient encounters with diagnoses made in the first diagnostic position.

So it's a useful tool to get a quick idea of how common we're seeing—how commonly we're seeing encounters for certain conditions. It can also do very basic population-level queries. It does not contain any information about vaccine.

The Defense Medical Surveillance System is used by health analysts at the Armed Forces Health Surveillance Division to do comprehensive health surveillance for service members.

It's the data source that feeds the DMED. So DMED is refreshed on a approximately monthly basis with data from the DMSS but just a limited amount of those data.

Ms. TOKUDA. Thank you. That differentiation is very helpful. You know, I think part of it is while DMED seems to be more of that open source that you have it is also very—it's very limited and if people do not understand that in fact it is an aggregated—it's an aggregated data set—it's not disaggregated, you know, obviously, because you have privacy issues, although you could potentially deidentify some of that.

But because it is not disaggregated out you really can't differentiate between new encounters, followup encounters. I believe that's something that you've referenced in your testimony, that this DMED is very much limited, potentially open to misinterpretation of results for those that are using it to—you know, in the field to try to figure out if something is happening.

So my question would be given that it's subject to misinterpretation and it's very limited in its scope because it is aggregated, has

there been conversations about perhaps making DMED more of a disaggregated type of system so that you can get truer results if you're actually using it?

I mean, if not it's always going to be subject to potential misinterpretation by the users or limited by user understanding of the data that's within it.

Dr. MARTINEZ-LOPEZ. Congresswoman, I think the intent of the DMED is to have it available across the force as the first trigger. In other words, you have a question, you have a query——

Ms. TOKUDA. I guess my concern is you have it as a first trigger. But if the user is unsophisticated to understand that it's limited, what you're going to have out there is misinformation and false assumptions.

So I do feel that we have to make sure when we do have these data sets that it gives the most accurate information possible and is as user friendly as possible.

I think right now the way DMED is, you know, it is great that it's there but I think it is going to be subject to more misinformation and false assumptions being made if users are unaware of its limitations and misinterpreting the data that they're getting from it.

I know, Chair, I'm almost out of my time so I will just yield back to you.

Mr. BANKS. Thank you. I yield 5 minutes to Mr. Gaetz.

Mr. GAETZ. Dr. Martinez-Lopez, is the Department of Defense covering up vaccine injuries?

Dr. MARTINEZ-LOPEZ. Congressman, no.

Mr. GAETZ. So, who is Lieutenant Ted Macie?

Dr. MARTINEZ-LOPEZ. Congressman, I don't know the lieutenant.

Mr. GAETZ. Well, it's sort of the reason we're here.

On November 27th, 2023, Navy Medical Corps Officer Lieutenant Ted Macie shared a video on "X" where he expressed grave concern for his patients suffering after receiving the COVID–19 vaccine and according to Lieutenant Macie he tried reporting the DOD data from the DMED system to his superiors and he was subsequently silenced and punished.

He lost access to the DMED system, he's been removed from seeing his patients, and has been relegated to some broom closet somewhere to continue his service.

It seems to me that Lieutenant Macie has suffered more than the people who screwed up the DMED system. So why is this person being punished for trying to showcase data that was alarming?

Dr. MARTINEZ-LOPEZ. Congressman, I'm not prepared to talk about specifics of the lieutenant because I really don't know. But I'll be glad to entertain—answer any questions regarding the system or the vaccines and our findings.

Mr. GAETZ. But part of the system and the vaccines and how we conduct oversight is that if there are whistleblowers who say that you're not doing your job right and if there are whistleblowers concerned about a coverup, you have to—there's a process by which that has to get to the inspector general and be reviewed.

And in the case of Lieutenant Macie's concerns, those languished for, like, more than 5 months. Do you have any reason why a re-

quest made through the chain of command to view this data that could illuminate concerns over vaccine injuries was smothered?

Dr. MARTINEZ-LOPEZ. Again, Congressman, I'm not prepared to talk details on the lieutenant, I'll have to defer to the Navy.

Mr. GAETZ. Okay. Maybe let's get to what you're prepared to talk about. Let's get to the actual data that's so concerning since the people who raise concerns about the data they get punished and we don't seem to remember them.

The hypertensive diseases up 23 percent when you compare the 2016 to 2020 averages to cases in 2021. Does that sound right?

Dr. MARTINEZ-LOPEZ. That sounds right.

Mr. GAETZ. Okay. So hypertensive diseases up 23 percent. Then ovarian dysfunction up 35 percent. Does that sound right?

Dr. MARTINEZ-LOPEZ. I'm not specific—can we——

Mr. GAETZ. Does that sound right, Dr. Stahlman?

Dr. STAHLMAN. I think you're referencing something from an older document but it could be.

Mr. GAETZ. I'm referencing data from the Defense Medical Surveillance System. Is that a system that you're both familiar with?

Dr. STAHLMAN. Yes.

Mr. GAETZ. Okay. So that system says that hypertensive diseases up 23 percent; ovarian dysfunction up 35 percent; pulmonary embolisms, which as we all know can kill you, up 43 percent; myocarditis, as Chairman Banks was describing, up 151 percent.

Is it really your testimony that these massive spikes in these serious ailments are a consequence of contracting COVID? Is that your best medical opinion?

Dr. MARTINEZ-LOPEZ. Congressman, not all but, I mean, many of them, obviously ovarian dysfunction, there are other reasons; emboli, there's other reasons. But yes, there is a correlation not only from our data—for the data of CDC that, yes, correlate COVID to having higher likelihood of having some of these events.

Mr. GAETZ. Pardon me for not treating the CDC's assessment——

Dr. MARTINEZ-LOPEZ. Not the ovarian one but the other——

Mr. GAETZ. The vaccine or the virus?

Dr. MARTINEZ-LOPEZ. Both. The virus, [inaudible] like the cardiomyopathy, is a little bit higher. The risk is much higher if you just get the disease but you have an enhanced risk. Not as big as when you get the infection but you do get some risk from getting the vaccine. It's minimal but yes.

Mr. GAETZ. So there is vaccine risk associated with hypertensive diseases, right?

Dr. MARTINEZ-LOPEZ. Hypertension—help me out [looking at Dr. Stahlman]. Not that I'm aware of but——

Mr. GAETZ. Okay. Well, how about ovarian dysfunction?

Dr. MARTINEZ-LOPEZ. Not that I'm aware of.

Mr. GAETZ. And how about pulmonary embolisms?

Dr. MARTINEZ-LOPEZ. Yes.

Mr. GAETZ. Okay. So you're here giving us testimony that the vaccine increases someone's risk of pulmonary——

Dr. MARTINEZ-LOPEZ. No; pulmonary emboli, the COVID virus does increase——

Mr. GAETZ. No, I'm asking about the vaccine.

Dr. MARTINEZ-LOPEZ. No. The vaccine, no. Not that I know of.

Mr. GAETZ. No. And myocarditis you think there is a risk?

Dr. MARTINEZ-LOPEZ. Yes. A slightly higher risk, but it's much higher that—when you get the virus itself, when you get infected.

Mr. GAETZ. And to tease out those data distinctions, wouldn't it be responsible to assess these conditions in people who got the disease and were unvaccinated versus the people who got the disease and were vaccinated? Has that type of an analysis been done?

Dr. STAHLMAN. We did look at this in the DOD report on cardiac and kidney conditions. The information stratified by all the different ways—vaccinated, not vaccinated—those are not all included in the report. I do have the data on that.

When we reported the 10 times increased rate due to recent infection, that is adjusting for vaccination status; it's also adjusting for demographic risk factors including age, sex, and BMI [body mass index].

Mr. GAETZ. Right. So did that analyze ovarian dysfunction?

Dr. STAHLMAN. It did not.

Mr. GAETZ. Did it analyze pulmonary embolisms?

Dr. STAHLMAN. It did not.

Mr. GAETZ. And did it analyze hypertensive diseases?

Dr. STAHLMAN. It did not.

Mr. GAETZ. Well, I mean, we got thousands more people than the average in 2021 getting hypertensive diseases, thousands more people getting ovarian dysfunction, thousands more people—or, I'm sorry, hundreds more people getting these pulmonary embolisms.

What's the case against analyzing those conditions that have seen these increases in the vaccinated versus the unvaccinated?

Dr. STAHLMAN. We are continuing to do surveillance on these conditions and we are open to doing additional work on this. With chronic conditions it is tricky to look at that in relation to a vaccine.

Mr. GAETZ. Is a pulmonary embolism a chronic condition or is it an acute condition?

Dr. STAHLMAN. We can look at acute conditions.

Mr. GAETZ. Yeah. Well, you know, your medical knowledge goes far beyond mine but I would consider a pulmonary embolism acute, not chronic.

Dr. STAHLMAN. With hypertension it could be difficult to get causal evidence to link that to the vaccine. But yes, we can look at acute [inaudible].

Mr. GAETZ. Right. But, see, that's what—that's how you get the causal evidence. The reason there are people concerned that the DOD is engaging in a coverup here is because you seem to be willfully and purposefully ignorant to those comparisons on these ailments that are skyrocketing now for pregnant women, for people who get pulmonary embolisms, for people with hypertension.

And the one area you've looked, myocarditis, you're here giving testimony that that actually causes this increased risk factor.

And so, Mr. Chairman, I hope we continue to follow up on this because my deep concern is that there is a coverup here and that they're playing games with the data so that we can't actually assess whether it's the vaccine or the ailment that is causing these acute conditions.

And, I mean, wouldn't it be a tragic thing to have to discover that we hurt people with the vaccine more so than the virus did with the ailment, particularly in a condition where now the CDC, whose opinion I guess we treat like the gospel, is saying that you—oh, you just should quarantine for 24 hours after you're done with your fever.

So they have evolving sensibilities on this and the only way we get to the bottom of it is that data comparison.

I thank the Chair's indulgence, and I yield back.

Mr. BANKS. Thank you. I agree. That's why we asked for the 2020 figures and I didn't ask you on the record before but will you please—will you submit the 2020 figures to the committee? Can we take that for the record?

Dr. MARTINEZ-LOPEZ. Yes, sir.

[The information referred to was not available at the time of printing.]

Mr. BANKS. Okay. Mr. Moylan.

Mr. MOYLAN. Thank you, Mr. Chairman.

Dr. Martinez-Lopez, and by the way, thank you for your service in the military. I appreciate that. Our Guard unit back in Guam—Air and Army were also very responsive to the COVID–19 situation.

They played a big role in supporting our island, and our Adjutant General he has a lot of medical background, too. He's a surgeon—he's a surgeon as well. He's really concerned now we need to be ready for the next public health emergency on Guam. After all, we're INDOPACOM [U.S. Indo-Pacific Command] region. We're the most western territory. We need to protect our community and our troops.

So what I need to know is your interest in the INDOPACOM area specifically on Guam to support our National Guard and Air Force out there because they need to be properly staffed.

I need to know your interest in that and making sure their training is up to date and equipped as well so we can have—we'll be ready for the next pandemic health emergency.

Dr. MARTINEZ-LOPEZ. Congressman, we are—actually I am intimately involved with the issues of Guam. I'm very concerned about that. My concern is that we have the systems not only for Reserve or Guard, for the many Active Duty that we have in Guam and family members.

We are concerned about biosurveillance, making sure it's not just about COVID, not only about the things we know but the things that we may not know coming about and we want to make sure that, A, we detect them early and, number two, we have a response mechanism to ameliorate whatever threat comes in one way or any other way.

Mr. MOYLAN. I appreciate your concern and your continuous interest in the INDOPACOM, specifically Guam. Thank you for that.

Another question, Doctor. What do you and Admiral Valdes need to safeguard the Defense Health Agency's ability to support the military readiness if we were to enter a conflict in Indo-Pacific while ensuring patients do not experience a lapse in care?

What steps are you taking with stakeholders, doctors, hospitals on Guam to prepare for future conflicts? We're way out there. We have no support from the mainland. Time is of the essence, please.

Dr. MARTINEZ-LOPEZ. Congressman, Lieutenant General Crosland just came from the theater, went to visit Guam and visited with many of the civilian and military leadership on the island to address the medical—she's the director of the Defense Health Agency and she came back with a report, you know, trying to understand. She understood what the issues are.

Now we're working through how are we going to counter whatever gaps she found on her trip. This has to be a two-way conversation with not only the military leadership, it has to be with the civilian leadership of the island medical—in the medical aspects.

So we make sure that at least that we do our best to be in a good position to respond to any needs that in particular our service members and family members need.

Mr. MOYLAN. Very good. And final question, Doctor. Currently the U.S. Army Reserve on Guam carries out innovative readiness training mission in one of the villages, Yigo, to provide medical care to my community.

Efforts like this are important for building goodwill between the people of Guam and the military, especially as the Department plans to station increasing numbers of personnel on island. What can be done to expand efforts like this? This is very good for our community as well.

Dr. MARTINEZ-LOPEZ. Congressman, it's in our interest to—A, to, you know, have our troops ready and prepared to do the care they're going to be asked to do in combat.

The way we achieve that is by seeing patients and taking care of patients. If there is an opportunity—you know, a mutual opportunity that by providing care to the local communities we also enhance our skill sets as clinicians. That's a win-win for the Department and our neighbors.

So we are pursuing this not only in Guam. We're pursuing this across the country in those places where we can have a mutually agreeable and acceptable benefit. Then we're going to exactly go in that direction and I hope there will be many opportunities in Guam just to do that.

Mr. MOYLAN. I appreciate that and I look forward to working with you closely on how we can assist as well. So thank you for your efforts.

Thank you, Mr. Chairman.

Mr. BANKS. Mr. Mills.

Mr. MILLS. Thank you, Mr. Chairman.

I appreciate you both being here, although I must say there is a growing trend within the DOD that my colleagues recognize as well where people come here unprepared to be able to have the substantiated data that we require and that we have requested to make sure that we're able to get the answers and follow up.

This is not the first time. So I hope that in future hearings you'll actually make sure that we have the subsequent data that we're trying to ask for and all the algorithms and all the other data planning has actually gone forth.

I want to start out with the fact that—you know, kind of following along one of my colleagues Mr. Gaetz's testimony where he talks about how many people have been impacted negatively, whether it be by myocarditis, whether it be by ovarian issues, whatever the case may be, in addition to those who were unconstitutionally purged out of our military for religious and medical freedoms that they should have been afforded.

So I just want to say for the record, do either one of you have an opinion—an objective opinion on whether or not you feel that medical and religious freedoms should be a key element for all members of our Armed Forces?

Dr. MARTINEZ-LOPEZ. Congressman, DOD is committed to protect religious liberties. As you know, there's a process to request——

Mr. MILLS. Actually, I do know that process, by the way, and I got to say, if it was actually to be true, would be impressive, because on average they were able to adjudicate through six individual layers, per the Under Secretary of Readiness, who was here, in less than 5 minutes.

Imagine the ability to reach out to a minister, to a priest, to other religious figures who they actually are trying to get this counsel from or looking at their independent medical, you know, background from historical medical data from their families and being able to determine that in 5 minutes.

I can tell you, as a person who now works for the Federal Government, we are not that efficient. If anything, it would take us about 5 weeks to be able to do so. But they were adjudicating these in less than 5 minutes.

Do you think that they could adequately adjudicate a medical or religious exemption within 5 minutes or less?

Dr. MARTINEZ-LOPEZ. Congressman, I will have to defer to the services that exercise—that executed that for us.

Mr. MILLS. You know, there has been an admission to the significant errors in the Defense Medical Epidemiology Database that distorted the true numbers of medical encounters faced by service members.

How can you be certain this issue has been satisfactorily rectified as to not continue to mislead the American public?

Dr. STAHLMAN. Thank you. I can take that.

We do take data accuracy seriously. We know that data goes into making decisions about health care that's provided to service members.

When we became aware of the programming error that was done in DMED—this was in January 2022—the error, by the way, was an analyst had used a count function instead of a sum function which led to the data that existed between 2016 and 2020 to be corrupted.

That error was immediately corrected. Since then we have implemented both additional technical and functional controls. So on the technical side they're doing additional QC [quality control] steps. We have also implemented a functional team that's doing additional quality assurance checks on a periodic basis.

Mr. MILLS. So this is for both of you and I'd really like to hear your thoughts on this. Uniformed service members were expelled

from the military and punished for standing up for their personal rights.

How do we ensure that they are properly compensated for rightfully expressing these rights? How do we address the discrimination and mental drain that these individuals have faced and continue to face by things such as giving them a general discharge as opposed to honorable?

Also, the DOD forcing individuals to pay back their bonuses where they did not separate from the military at their free will—they were forced out of the military.

What would be your recommendations on how we would adequately compensate these individuals unconstitutionally purged—by the way, almost 9,000 who was unconstitutionally purged, in addition to the 41,000 recruitment deficits? Pretty significant for the largest volunteer force in the world.

Dr. MARTINEZ-LOPEZ. Congressman, as you probably know all those service members had the right to appeal their discharge to the services.

Mr. MILLS. Dr. Martinez-Lopez, we have seen where many of them had tried to appeal this and in many cases wasn't actually given any answer whatsoever.

Again, we can adjudicate things in 5 minutes whenever we're denying people their medical and freedom—religious rights—but we can't actually adjudicate something quickly where it should be a simple thing that if you did not exit the service for something which was disciplinary and reasoning—not medical and religious freedom but disciplinary and [UCMJ] [Uniform Code of Military Justice] Article 15 or above—court martialing—then I don't understand how we can't at least acknowledge the fact that this is unconstitutionally purged and at least give them the opportunity on an honorable discharge as opposed to a general where in many cases this plagues them and follows on in their careers and in future jobs.

But that still doesn't answer the bottom question, which is that these individuals in my personal opinion—I know there's others on this committee that feel the same way—should be compensated.

They should have their benefits restored. They should have their original rank reinstated for those who actually still want to serve our country, not a political agenda that is placed before us, and they should be given the rights that they were actually denied.

Would you not at least admit to the fact that these people who are trying to serve as you have served and as I have served should be denied these rights or be given these rights?

Dr. MARTINEZ-LOPEZ. Congressman, you know, we have processes in—and there are laws and processes in the system. I hope that the services will—you know, I'm confident the services are doing their best to exercise those procedures to look at each case in particular. I will have to defer to the services.

Mr. MILLS. Dr. Martinez-Lopez, I appreciate that you have the confidence. I wish that I had that and shared that same confidence levels. But under the, you know, direction of someone like Secretary Lloyd Austin I have very little when you talk about the dereliction of duty that has been placed forth and the prioritization of things that are not to the military Armed Forces' benefits.

With that, I yield back.

Mr. BANKS. Thank you. I want to thank Mr. Gaetz, who just left the room, for requesting this hearing. I think it's a really important conversation, the type of oversight that this committee should be doing more of.

It's important that we work together to differentiate between the rise of medical conditions due to COVID–19, the infection, or the COVID–19 vaccination.

This effort is vital for guiding public health responses, informing treatment and management strategies, monitoring vaccine safety and maintaining the public trust in immunization programs.

By systematically investigating and addressing these concerns, policymakers and health care professionals can effectively safeguard public health and the health of our men and women in uniform who put their lives on the line for this great country.

I want to thank both of our witnesses again and thank you for providing your testimony and answering our questions this afternoon. I want to thank the members who participated.

There being no further business, the subcommittee stands adjourned.

[Whereupon, at 3:34 p.m., the subcommittee was adjourned.]

A P P E N D I X

MARCH 7, 2024

PREPARED STATEMENTS SUBMITTED FOR THE RECORD

MARCH 7, 2024

Statement of
Chairman Jim Banks

"Department of Defense Monitoring of COVID-19"

Military Personnel Subcommittee
March 7, 2024

The hearing will now come to order.

I ask unanimous consent that the chair be authorized to declare a recess at any time.

Without objection, so ordered.

I want to welcome everyone to this hearing of the Military Personnel subcommittee.

Today we convene to address a matter of paramount importance – how ***The Department of Defense's monitoring of COVID-19*** has impacted our military ranks and the implications of the COVID-19 vaccine on the health and well-being of our servicemen and women.

Over the past three years, the COVID-19 pandemic has presented unprecedented challenges to our nation and its armed forces.

As the virus becomes just another part of the yearly flu season, we need to look with clear eyes and healthy skepticism at:

- How the Department handled the pandemic
- The effects of the virus and vaccines on our service members' health
- And if the Department's policies and practices *actually* mitigated risk to service members and their families.

Many service members and their families are concerned with the safety and value of the COVID-19 mRNA vaccine, prompting questions about adverse reactions and unforeseen consequences, most concerningly related to heart conditions and hypertension in a young military population.

And the data is worrisome: in 2022 we saw heart related conditions like hypertension and cardiomyopathy increase by 47% and 94%, respectively, over DoD averages.

In addressing this pandemic, there is no doubt that the Department has made mistakes… as the Country has made mistakes…. And that some decisions were made for political gain, rather than based on science and fact.

So today, we seek clarity for the service members who took the COVID-19 vaccine of their own free will and for those who obeyed a lawful order. For their families, and for everyone's future health and well-being. We seek to understand the extent to which the Department of Defense has monitored the impact of COVID-19 on our military personnel, including any potential correlation between the virus itself and the development of medical conditions. Moreover, we aim to examine the data surrounding the administration of the COVID-19 vaccine within our ranks, evaluating its safety profile and any observed trends in adverse reactions or health outcomes.

As stewards of our nation's defense, it is incumbent upon us to ensure the well-being of those who wear the uniform. We owe it to our service members to provide them with the best possible care and support, especially in times of crisis.

By convening this hearing, we demonstrate our commitment to transparency, accountability, and above all, the health and safety of our military community.

I would now like to introduce our Witnesses:

Dr. Lester Martinez-Lopez
Assistant Secretary of Defense for Health Affairs
Department of Defense

Dr. Shauna Stahlman
Senior Epidemiologist, Armed Forces Health Surveillance Division
Defense Health Agency Public Health

Thank you for being with us today. I hope this hearing provides an opportunity for our Members to have a productive exchange.

Before hearing from our witnesses, let me offer Ranking Member Kim an opportunity to make any opening remarks.

Hon. Jill N. Tokuda
Opening Statement (As Prepared)
for Military Personnel Subcommittee Hearing on
"Department of Defense Monitoring of COVID-19"
March 7, 2024

Thank you to our witnesses for being here today and providing testimony regarding the Department of Defense's health surveillance efforts, which include monitoring health threats and emerging infections, biosurveillance, and epidemiological analysis – to include the impacts of infections and vaccines.

As a member of the House Select Subcommittee on the Coronavirus Pandemic, I am not unfamiliar with efforts to politicize the science behind vaccines to the detriment of public health and national security. I cannot emphasize enough the importance of using fact-driven, science-based approach to this conversation today.

Let's focus on the facts. Safe and effective COVID-19 vaccine options have been readily available since 2021. According to the CDC, in the first ten months that COVID-19 vaccines were available, they saved over 200,000 lives and prevented over 1.5 million hospitalizations in the United States. This is the purpose of these vaccines: to save lives and prevent severe disease.

While the military COVID-19 vaccine requirement was rescinded in January 2023, 96 percent of the Active and Reserve Force – over 1.9 million people – safely received one or more doses of a COVID-19 vaccine.

Vaccine requirements have longstanding precedent in the armed forces. Since the founding of the U.S. military, vaccine requirements have been necessary to preserve military readiness and personnel safety—from General George Washington's smallpox vaccination of the Continental Army in 1777 to the flu vaccine requirement in the mid-twentieth century. Today, the Department administers as many as 17 different vaccinations, and while it was in effect, the COVID-19 vaccination requirement helped ensure that our armed forces remained healthy and medically ready.

Service members that have received COVID-19 vaccines have done so under the most intense safety monitoring program in U.S. history. The CDC, the FDA, and other federal partners use multiple passive and active surveillance systems and data sources to conduct comprehensive safety monitoring of COVID-19 vaccines. And the Department of Defense conducts near real-time monitoring and research on the impacts of COVID-19 vaccinations and infections through the Military Health System.

Studies continue to show that the benefits of COVID-19 vaccination outweigh the risk. Yet concern and apprehension regarding the safety of COVID-19 vaccines persists. This may be due in large part to a fundamental misunderstanding of the Department's COVID-19 vaccine surveillance data, which has, unfortunately, been the subject of misleading news stories over the past year. The Department of Defense's monitoring efforts of COVID-19 have reported a

small number of increases in adverse health effects following the COVID-19 vaccine requirement. But correlation does not imply causation. Legitimate questions remain as to the root cause of these identified adverse health effects.

The overarching question for today's panel is one of paramount importance: are there long-term effects from COVID-19 on our service members? And if so, how do we discern whether any increase in reported adverse health effects are attributable to the virus itself or a vaccine? To address this question comprehensively, we must approach today's discussion with scientific rigor, ensuring that we prioritize the health and safety of our all-volunteer Force as a whole above all else.

As we navigate the complexities of this issue, we must acknowledge the profound impact that the COVID-19 pandemic has had on the operational readiness of our armed forces. First and foremost, the pandemic resulted in thousands of hospitalizations across the Department and the tragic loss of hundreds of lives. It also had far-reaching second- and third-order effects on our military, including disruptions in training exercises and deployments, the mobilization of military medical personnel to support civilian pandemic response efforts, and negative impacts to military family quality of life issues like delays in moves, child care, and health care access.

At the heart of today's discussion regarding the Department's monitoring of COVID-19 lies a fundamental commitment to the health and well-being of our service members. That must ultimately include a shared dedication to transparency and facts grounded in scientific evidence.

Mr. Chairman, I'd like to request that the Department of Defense's "Report on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine Requirement" be included in the record for today's hearing. Congress required this report in the FY23 NDAA, and it serves as an example of the careful and thoughtful monitoring the Department is doing.

I look forward to our witnesses' testimony and their responses to our questions today.

I yield the balance of my time.

Prepared Statement

Of

Dr. Lester Martinez-Lopez

Assistant Secretary of Defense (Health Affairs)

And

Dr. Shauna Stahlman

Senior Epidemiologist
Armed Forces Health Surveillance Division

Regarding

Department of Defense Monitoring of COVID-19

Before The

House Armed Services Committee – Military Personnel Subcommittee

March 7, 2024

Not for publication until released by the Committee

Chairman Banks, Ranking Member Kim, distinguished Members of the Subcommittee, we are pleased to represent the Office of the Secretary of Defense to discuss the Department's ongoing health surveillance of the Force related to COVID-19 in the aftermath of the global pandemic.

This testimony provides the Committee with information on some of the key data used to track the health of Service members and updates on some of the past and future studies related to the impact of COVID-19 on the health of Service members.

COVID-19 Health Surveillance:

Service members, like all members of our Nation, experienced the effects of the global COVID-19 pandemic. The actions taken by the Department of Defense (DoD) to blunt the impact of the pandemic on the Force and to maintain operational readiness included force health protection measures like vaccinations, testing, masking, social distancing, and remote work. These actions saved lives and resulted in less severe disease and fewer hospitalizations among those Service members who were infected. Nevertheless, the impact of COVID-19 lingers with some Service members who, like many other Americans, are experiencing long-term effects of COVID-19 infections including Long-COVID and heart-related conditions.

Defense Medical Surveillance System (DMSS) - To answer complex epidemiological questions related to COVID-19, one source of data that can be used is the Defense Medical Surveillance System or DMSS. DMSS is a relational database that documents military and medical experiences of Service members throughout their careers. As the central repository of medical surveillance data for the U.S. Armed Forces, DMSS contains up-to-date and historical data on

diseases and medical events, including inpatient and ambulatory medical encounters, immunizations, prescriptions, laboratory data, deployment health assessments, and casualty data.

DMSS COVID-19 Studies - A DoD study published in December 2023, in the American Journal of Public Health, evaluated the degree of underreporting of SARS-CoV-2 infections within Service members.[1] This study estimated the true case count of COVID-19 cases, based on antibodies in serum, to be 1.7 to 9.3 times greater than the reported number of cases during the first year of the pandemic. This undercounting of the true number of COVID-19 cases underrepresented how SARS-CoV-2 infections contribute to adverse health circumstances such as cardiac conditions, complicating interpretation of causality for cardiac events in people with a history of COVID-19 regardless of vaccination status. This nuance is essential to interpreting causal linkages for COVID-19 seen within DOD data as well. Another example is the September 2023 DoD report to the Committee on Armed Services of the House of Representatives regarding cardiac and kidney issues in Service members prior to, and following, institution of a requirement to be vaccinated against COVID-19[2], as reflected within the DMSS. This study showed that unvaccinated individuals who had a reported SARS-CoV-2 infection were at a significantly higher risk of developing three cardiac conditions (myocarditis, pericarditis, and acute myocardial infarction) compared to individuals who received a COVID-19 vaccine.

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[1] Taylor KM, et al., Seroprevalence as an Indicator of Undercounting of COVID-19 Cases in a Large Well-Described Cohort. AJPM Focus. 2023 Aug 15;2(4):100141. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10598697/

[2] Report to the Committee on Armed Services of the House of Representatives Department of Defense Report on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine. September 2023. Requirementhttps://www.health.mil/Reference-Center/Reports/2023/09/29/DOD-Report-on-Cardiac-and-Kidney-Issues-in-Service-Members-Prior-to-and-Following-the-COVID-Vaccine-Requirement

Defense Medical Epidemiology Database (DMED) – The Defense Medical Epidemiology Database or DMED provides limited remote access to DMSS data. It is designed for military public health professionals, medical providers, safety officers, force health protection officers, and medical researchers, to get quick access to summarized epidemiologic data for surveying health conditions in groups of Service members. Unlike DMSS, DMED has access only to aggregated data, not the identifiable individual Service member data in DMSS. Because DMED provides aggregated data only, DMED cannot differentiate between a new encounter for a medical condition and a follow up encounter. For example, a Service member seeing a medical provider for trouble breathing, whether it was their first visit or their tenth visit, would be reflected identically in DMED, making the data not usable to determine rates of new versus ongoing breathing trouble among Service members. Therefore, DMED cannot be used to identify or compare rates of new cases and is more useful to generate scientific questions rather than answer them. A DMED-generated question can be further explored using DMSS data and established research methodologies. DMED, used in its proper context, is a useful tool for DoD medical and public health professions to monitor health trends among their local populations and identify potential issues that require further inquiry or research. However, when a user does not recognize the limitations of DMED as a tool to generate questions rather than answer them, misinterpretation of the resulting DMED data, combined with inaccurate assumptions, can result in incorrected conclusions regarding rates of health conditions among groups of Service members.

Future COVID-19 Surveillance and Studies –The SARS-CoV-2 virus continues to circulate and evolve into new variants, presenting an ongoing health threat capable of harming Service members and affecting operations. There is much more to be learned about the long-term health impacts of SARS-CoV-2 infection. The Department remains committed to protecting the health of the Force and to better understanding these impacts as we prepare for future health threats. Our ongoing studies will support the development of therapeutics and medical countermeasures. The relationship between SARS-CoV-2 infections or COVID-19 vaccinations and cardiac conditions is an ongoing focus of DoD surveillance and research. Multiple DoD-focused related studies are looking at long term outcomes of issues related to COVID-19, to include cardiac conditions associated with COVID-19 vaccination or illness. An example of this work is an ongoing study at Brooke Army Medical Center in San Antonio, Texas, which evaluates the "Cardiopulmonary and Cardiovascular Impact from COVID-19 among U.S. Service Members." This study is investigating whether there is an increased risk of sudden cardiac arrest or sudden cardiac death from consequential cardiovascular/cardiopulmonary disease as a result of SARS-CoV-2 infection compared to vaccination. As directed in Section 725 of the National Defense Authorization Act for Fiscal Year 2024 – "Study and Report on Health Conditions of Members of the Armed Forces Developed After Administration of COVID–19 Vaccine," the Department will develop a multi-year study to evaluate the long-term effects of COVID-19 infections and vaccinations among Service members. This study will improve understanding of both benefits and adverse health effects that may have resulted from COVID-19 vaccination by quantifying the negative health effects of SARS-CoV-2 infections in both vaccinated and unvaccinated Service members. This study, and others like it, will help inform future DoD policy, improve readiness, and help prepare for and mitigate future pandemics.

Thank you for inviting me here today to speak with you about the Department's health data, which enable our ongoing surveillance of the impact of the COVID-19 pandemic on the health of the Force. I look forward to answering your questions.

Dr. Lester Martinez-Lopez
Assistant Secretary of Defense for Health Affairs

Dr. Lester Martinez-Lopez is currently serving as the Assistant Secretary of Defense for Health Affairs. He is the principal advisor to the Secretary of Defense and the Undersecretary of Defense for Personnel and Readiness for all Department of Defense health and force health protection policies, programs, and activities.

Dr. Martinez is a family medicine physician who retired from the U.S. Army as a Major General. He was the first Latino to head the Army Medical Research and Materiel Command, where he directed the Army's worldwide medical research, acquisition, and logistics program. His experience in military medicine also includes directing a worldwide public health organization as the Commanding General of the Center for Health Promotion and Preventive Medicine, as well as command of three military hospitals. After retiring from the U.S. Army, he served as the Chief Medical Officer at the Brandon Regional Hospital in Florida and Senior Vice President and Administrator of the Lyndon B. Johnson General Hospital in Texas.

Dr. Martinez graduated from the University of Puerto Rico School of Medicine with a Doctor of Medicine degree. He earned a Master of Public Health degree from Johns Hopkins University.

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME	POSITION TITLE
Shauna Stahlman	Senior Epidemiologist Epidemiology & Analysis Branch Armed Forces Health Surveillance Division Defense Health Agency Public Health

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of California, Berkeley	BA	2009	Integrative Biology
University of California, Los Angeles	MPH	2012	Epidemiology
University of California, Los Angeles	PhD	2014	Epidemiology
Johns Hopkins University	Postdoctoral Fellow	2016	Epidemiology

EMPLOYMENT

2013 – 2014 SAS Analyst, Veterans Health Administration, Los Angeles, CA
2014 – 2016 Postdoctoral Fellow, Johns Hopkins University, Baltimore, MD
2016 – Senior Epidemiologist, Armed Forces Health Surveillance Division, Silver Spring, MD

ACADEMIC APPOINTMENTS

2018 – Adjunct Assistant Professor, Preventive Medicine and Biostatistics Department, Uniformed Services University of the Health Sciences, Bethesda, MD

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DOCUMENTS SUBMITTED FOR THE RECORD

MARCH 7, 2024

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

PERSONNEL AND
READINESS

SEP 29 2023

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Department's response to House Report 117–397, page 186, accompanying H.R. 7900, the National Defense Authorization Act for Fiscal Year 2023, "Department of Defense Report on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine Requirement," is enclosed.

The report provides a review of the overall annual crude prevalence of three cardiac conditions (myocarditis, pericarditis, and acute myocardial infarction) and two kidney conditions (acute kidney injury and chronic kidney disease) among Active Component members from January 2019 to June 2022. Additionally, the report includes a review of overall annual crude incidence stratified by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection and coronavirus disease 2019 (COVID-19) vaccination; a review of adjusted incidence rates; and adjusted rate ratios as a measure of risk. The report shows that, upon review of the Military Health System data from January 2019 to June 2022, there was an overall small increase in the myocarditis prevalence and incidence associated with both COVID-19 vaccine and SARS-CoV-2 infection. The magnitude of impact on myocarditis incidence is significantly higher from those with a recent SARS-CoV-2 infection in comparison to recent COVID-19 vaccination. All other cardiac and kidney outcomes evaluated showed mostly similar trends. The results support similar conclusions drawn by published studies that the risks for cardiac and kidney complications are higher after SARS-CoV-2 infection than they are after COVID-19 vaccine.

Thank you for your continued strong support for the health and well-being of our Service members.

Sincerely,

[redacted]

Ashish S. Vazirani
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Committee on Armed Services of the House of Representatives

Department of Defense Report on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine Requirement

September 2023

The estimated cost of this report or study for the Department of Defense is approximately $29,000 in Fiscal Years 2021 – 2022. This includes $6,470 in expenses and $23,000 in DoD labor.

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PURPOSE

This report is in response to House Report 117–397, page 186, accompanying H.R. 7900, the National Defense Authorization Act for Fiscal Year 2023, "Department of Defense Report on Cardiac and Kidney Issues in Service Members Prior to and Following the COVID Vaccine Requirement," which requests an analysis of prevalence and incidence of kidney and cardiac complications in Service members in 2019 compared to the same measures in 2021 and 2022. The report analyzes annual incidence of select kidney and cardiac conditions identified as rare adverse outcomes following identified coronavirus disease 2019 (COVID-19) vaccination among Service members in the Active Component between Calendar Years (CY) 2019 and 2022. Incidence rates for each adverse outcome (myocarditis, pericarditis, acute myocardial infarction (AMI), chronic kidney disease (CKD), and acute kidney injury (AKI)) were stratified by receipt of COVID-19 vaccine and history of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection with confounding factors identified and adjusted when possible. As a secondary analysis, the overall annual prevalence of each outcome was described and discussed.

INTRODUCTION

On December 11, 2020, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the Pfizer-BioNTech BNT162b2 vaccine. Immediately thereafter, on December 14, 2020, the Department of Defense (DoD) mobilized to begin voluntarily administering the first doses of Pfizer-BioNTech BNT162b2 vaccine to military communities with priority given to frontline health care workers at highest risk of exposure to SARS-CoV-2 infection. Two dose Moderna mRNA-1273 and single dose Johnson & Johnson JNJ-78436735 vaccines were added to the approved distribution list as they received subsequent EUAs from FDA. A year later in December 2021, over 6.4 million doses of vaccine had been distributed. The Pfizer-BioNTech and Moderna vaccines would both go on to receive full FDA approval in August 2021 and January 2022, respectively.

Eight months after DoD vaccination distribution began, on August 24, 2021, the Secretary of Defense released a memorandum requiring that all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve (including National Guard) receive a COVID-19 vaccination as part of their readiness requirements. Mandatory vaccinations are familiar to all Service members, with as many as 17 different vaccines required for military personnel in the "Joint Instruction on Immunizations and Chemoprophylaxis" as necessary to mitigate risk for various infections. Some vaccines are only required to be administered in certain special, risk-based geographical and occupational circumstances of the individual Service member. Other vaccinations, like the annual influenza vaccine, are required for all Service members regardless of the circumstances, unless the Service member is covered by an administrative (including religious) or medical exemption. All vaccination requirements, including COVID-19 when it was in effect, are in place to keep the Armed Force as a whole healthy and medically ready.

BACKGROUND

COVID-19 Vaccination Associated Cardiac Adverse Events

Severe adverse events following COVID-19 vaccinations remain rare and studies continue to support that the benefit of vaccination outweigh the risk.[1] Although extremely rare, myocarditis and pericarditis are reported following COVID-19 vaccination particularly in adolescents and young males.[2] Myocarditis is the inflammation of cardiac muscle predominantly caused by viruses including SARS-CoV-2 and other infections (e.g., influenza, hepatitis B, staphylococcus), toxins (e.g., alcohol, heavy metals, chemotherapy), and systemic immune-related diseases (e.g., sarcoidosis, celiac disease). Vaccinations such as smallpox vaccine has been causally linked to hypersensitivity myocarditis with numerous studies reporting that more than expected incidence of myocarditis and pericarditis have been found associated with COVID-19 mRNA vaccines (Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273).[3,4]

The classic clinical presentation of COVID-19 vaccine-related myocarditis is acute chest pain with an average time of onset of 3 days (range 1-28 days) after vaccination. Pericarditis, an inflammation of the pericardial sac that lines the outside of the heart, occurs most often in conjunction with myocarditis, but when observed in isolation, the onset of chest pain may be somewhat later, with an average of 5 days (range 1-28 days) after vaccination.[4,5] The incidence of myocarditis as an adverse event following COVID-19 vaccination is highly dependent on the sex and age of the patient, as well as the vaccine dose and type. As a vaccine-related safety signal, myocarditis has been most firmly established in younger (ages 18-29 years) male patients after receiving their second dose of mRNA (Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273) vaccine. A safety signal for myocarditis has not been clearly established after non-mRNA vaccines (e.g., Johnson & Johnson JNJ-78436735), after first dose of vaccine, or in patients over age 40 years.[6] Most of the clinical presentations have been mild for this very rare complication which continues to support the broader Centers for Disease Control (CDC) finding that the benefit of vaccination outweighs the risk.[7]

Myocarditis Incidence in the Vaccine Adverse Event Reporting System (VAERS) and the Military Health System (MHS)

Both the CDC and the FDA monitor for COVID-19 vaccination adverse events using a voluntary reporting system called VAERS. Anyone, including patients, can report any safety concerns related to vaccines in VAERS. A review of the VAERS safety data between December 2020 and August 2021 found a small but increased risk for myocarditis after receipt of mRNA COVID-19 vaccines. In the VAERS data review of myocarditis cases, 87 percent of those hospitalized had initial symptoms resolved by the discharge date and no cases of severe manifestation required transplant or ventricular assist device.[3]

Myocarditis occurring after administration of COVID-19 mRNA vaccines (Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273) was first noted by the U.S. military in early 2021 reporting on a case series of 23 male military members who were diagnosed with myocarditis within 4 days of receipt of COVID-19 vaccine.[8] The MHS-specific case series observed a median age of 25 with all military members who were previously healthy with no prior history of

cardiac disease. Most cases were related to second dose of mRNA vaccine, presenting within 50 hours of receiving the vaccine with no concurrent SARS-CoV-2 infection. All patients have either recovered and or were recovering at the time results were published.

Incidence of Cardiovascular Complications – Comparison between SARS-CoV-2 Infection and COVID-19 Vaccination

COVID-19 vaccination is associated with reduced risk for cardiovascular complications such as AMI after SARS-CoV-2 infection compared to those who have never been vaccinated.[9] CDC continues to recommend COVID-19 vaccination given that many more adverse outcomes related to SARS-CoV-2 infection, including death, can be avoided even among the groups at highest risk for myocarditis as an adverse event from immunization. In the highest risk group of males ages 18-29, 300 hospitalizations, 60 ICU admissions and 3 deaths due to SARS-CoV-2 infection related complications would be prevented if vaccination had been provided compared to instead preventing 22-27 COVID-19 vaccination associated myocarditis incidents should vaccination had not occured.[6]

Furthermore, data from 40 health care systems reviewing over 14 million cases from January 1, 2021 to January 31, 2022, continue to support the benefit of COVID-19 vaccination with a significantly higher cardiac complication incidence associated with SARS-CoV-2 infection than after mRNA COVID-19 vaccination for both males and females in all age groups. Analysis also confirmed the higher incidence of myocarditis or pericarditis after mRNA COVID-19 vaccination in males, with incidence of 0-35.9 per 100,000 in males compared to 0-10.9 for females across age groups. The 12-17 age group had the highest incidence of mRNA COVID-19 vaccine associated cardiac complication, with a 1.8-5.6 times higher risk for cardiac complications after SARS-CoV-2 infection than after vaccination.[10]

Kidney Complications with COVID-19 Vaccination

Serious adverse kidney events following COVID-19 vaccine are extremely rare and vaccinations continue to provide protective benefits that far outweigh the known associated kidney complications related to SARS-CoV-2 infection. Rare cases of new onset kidney disease have been reported in literature since 2020 with early complication rates reported at 0.46 percent of all adverse events in VAERS in January 2021 and most recent analysis showing kidney complication reported at incidence of 0.006 percent based on review of VAERS data.[11,12]

The majority of reported kidney disease developed de novo which would be captured under the major category of AKI, also known as acute kidney failure. There is no specific clinical presentation although edema was reported as the most common symptom in addition to hematuria and proteinuria. Various kidney pathologies have been reported with minimal change disease observed as the most common pathology.[13,14] Pathogenesis of COVID-19 vaccine associated kidney complications is unknown although T-cell mediated immune dysregulation causing podocyte damage is one of the proposed theories.[13,14]

A causal relationship between vaccine and AKI cannot be made given many confounding factors such as advanced age, underlying kidney disease, and concurrent infections that independently

predispose increased risk for AKI regardless of vaccination administration. Review of AKI cases in the self-reported VAERS from December 2020 to June 2021 showed that the majority of AKI cases potentially associated with COVID-19 vaccination was reported among individuals of advanced age (ages ranging from 59.75 to 68.41 years). Additionally, more than half of this group also had existing comorbidities such as diabetes, hypertension and heart disease. The most common cause of VAERS reported AKI was volume depletion and sepsis, which again can independently cause AKI. Most cases of AKI developed within 2 weeks of vaccination primarily related to mRNA vaccine type.[12] Fortunately, in two separate systematic reviews of kidney complications post- COVID-19 vaccination, the majority of kidney dysfunction returned to baseline within 90 days of vaccination.[13,14]

AKI is a well-recognized complication that is commonly associated with SARS-CoV-2 infection, with a wide range of incidence rate among hospitalized patients with some reports as high as 46 percent.[15,16,17] The most common cause of AKI was acute tubular necrosis associated with multi-organ failure and shock. In critically ill adults with SARS-CoV-2 infection, AKI often required renal replacement therapy (e.g., dialysis) with mortality up to 58 percent, with more than one-third having persistent need for renal replacement therapy upon discharge from the hospital.[18] Underlying CKD is also a clearly associated risk factor for severe disease with increased risk for mortality associated with SARS-CoV-2 infection. Mortality is significantly higher in those on renal replacement therapy and in kidney transplant recipients.[19]

METHODS

The primary data source for this analysis is the Defense Medical Surveillance System (DMSS), a continuously expanding relational database of personnel demographic and medical data.[20] The DMSS contains records of ambulatory encounters and hospitalizations of Active Component members of the U.S. Armed Forces when reimbursed through TRICARE. Also included are medical encounter data from the Theater Medical Data Store (TMDS), which includes diagnoses of deployed Service members. In addition, the DMSS contains immunization records for Service members from the MHS Information Platform. Due to a gap in immunization records for Air Force members identified at the time of the analysis, immunization data for Air Force members who were missing immunization records in the DMSS were extracted from the Aeromedical Services Information Management System.

The Armed Forces Health Surveillance Division maintains a list of COVID-19 infections among Service members which is updated daily. The list is comprised of reverse transcription-polymerase chain reaction and antigen test laboratory confirmed SARS-CoV-2 infections, as well as medical event reports of SARS-CoV-2 infection from Disease Reporting System Internet. For the purpose of this analysis, SARS-CoV-2 infections were also identified from the DMSS medical encounter data using the ICD-10 code U07.1. A 90-day incidence rule was applied, such that an individual could qualify as having a repeat SARS-CoV-2 infection if at least 90 days had passed since the last diagnosis or positive laboratory test.[21]

To measure obesity status, height and weight data collected from routine medical appointments were extracted from the MHS Data Repository and MHS GENESIS Vitals table in the Medical Data Repository, as well as height and weight information recorded in the electronic annual

Periodic Health Assessment data in DMSS. Individuals were categorized as obese during a given CY if they had a record Body Mass Index (BMI) greater than or equal to 30 where the height and weight measurement were taken that year.[22] If they only had records indicating a BMI less than 30 then they were classified as not obese for that year. If they had no height and weight records, then they were classified as having an unknown weight status for that year. Height and weight measurements were excluded if they occurred within 280 days of a female Service member's medical encounter that included a diagnosis for pregnancy, childbirth, and the puerperium (ICD-10 codes beginning with "O").

This study assessed three cardiac conditions that were most frequently associated with COVID-19 vaccine complications (myocarditis, pericarditis, and AMI) and two categories of kidney conditions that would broadly capture majority of COVID-19 vaccine complications (AKI and CKD). Some case definitions for each condition were referenced from a Department of Veterans Affairs study[23] comparing safety of two versions of COVID-19 vaccines: cases of myocarditis, pericarditis, AMI, and AKI were defined by having at least two medical encounters (inpatient, outpatient, or TMDS) within 60 days of each other with a qualifying diagnosis in any diagnostic position. The incident date was defined as the first qualifying encounter of which there were two within 60 days. Cases of CKD were defined by having at least two medical encounters within 730 days (2 years) of each other with a qualifying diagnosis in any diagnostic position. The incident date was defined as the date of the first-ever encounter with a diagnosis of CKD. The ICD-9 and ICD-10 codes used to define the cases are included in Appendix A, Tables A1-A5.

For each Service member, the number of days in active military service was ascertained and aggregated for each CY between 2019 and 2021. The resultant annual totals were expressed as person-years of service and used as the denominators for the calculation of annual incidence rates for each of the five outcomes. For each outcome, person time was censored at the date of the incident diagnosis and prevalent cases (i.e., cases identified prior to the start of the surveillance period in 2019) were excluded. "At risk" periods for each of the outcomes was categorized as the 45-day period following SARS-CoV-2 infection, and the 21-day period following receipt of any dose of a COVID-19 vaccine (Appendix A, Table A6). The 45-day period following SARS-CoV-2 infection was chosen to represent a general average of variable time to symptom resolution that are reported in literature. For mild acute illness, symptoms may resolve in a few days to 2 weeks whereas prolonged recovery time for months has been observed in those with severe disease. To ensure optimal inclusion of the most appropriate clinical cases and to avoid potential confounding factors, a 45-day at risk period was chosen. The 21-day at risk period following COVID-19 vaccination was chosen to be aligned with at-risk timelines that are most commonly reported in literature, federal vaccine injury compensation programs (using 0-21 day time window for smallpox vaccine associated myocarditis), and review of data from VAERS. Person time periods considered to be not at risk for the outcome due to either SARS-CoV-2 infection or vaccination with a COVID-19 vaccine were divided into two categories: infection or vaccination occurred greater than 45 days or 21 days ago, respectively, or no previous infection or vaccination. However, for CKD, the "at risk" period following SARS-CoV-2 infection and COVID-19 vaccination was categorized as 180 days instead of 45 days to ensure inclusion of all potential CKD cases. Although CKD is defined as having a decrement in kidney function that lasts for at minimum 3 months (based on references from the Kidney Disease Improving Global Outcomes and Kidney Disease Outcomes Quality Initiative), the at-

risk period for CKD was extended to 180 days to allow adequate time for follow up with a provider and to mitigate risk for exclusion of potential cases. Incidence rates were calculated per 100,000 person-years of Active Component service.

A multivariable Poisson regression model was used to calculate the adjusted incidence rate ratios for each of the five outcomes for CY 2021 by "at risk" status. Similar to the crude (i.e., unadjusted) analysis, the "at risk" periods were defined as the 45-day period following SARS-CoV-2 infection and the 21-day period following receipt of a COVID-19 vaccine dose which aligns with most published literature (except for CKD which used a 180-day period following SARS-CoV-2 infection and vaccination). These models adjusted for age, sex, race and ethnicity, obesity status, and either SARS-CoV-2 infection within the past 45 days (180 days for CKD) or COVID-19 vaccine dose received within the past 21 days (180 days for CKD). Adjusted incidence rates were calculated per 100,000 person-years of Active Component service. Due to the small number of Service members vaccinated against COVID-19 prior to 2021, these adjusted incidence rates could only be calculated in 2021.

Finally, overall crude annual prevalence was calculated for each of the five conditions. An individual was counted as a prevalent case if they had been previously identified as an incident case for that condition and had a medical encounter for that condition during the year of interest. The denominator was calculated using the number of Active Component Service members who were in service during June of that CY. Prevalence rates were calculated as the number of prevalent cases per 100,000 Service members.

RESULTS

General Explanation of Prevalence, Incidence, and Rate Ratio

Crude annual prevalence (the unadjusted rate of new and existing cases) rates were calculated for each condition of interest at the overall population level among Active Component members. It is typically best practice to use a mid-year (June) population count as denominator for this type of rate, given this population's constant fluctuation. However, numerators for this type of measure need to be able to count cases across the same amount of time for all years in order to be comparable. For this reason, a crude annual prevalence rate for CY 2022 is not able to be calculated – its numerator would be inappropriately small leading to an equally inappropriately small prevalence rate that is incomparable and otherwise easy to misinterpret.

Incidence rates (the rate of new cases in each CY) calculated for this report, both crude and adjusted, utilize a person-time (specifically person-years of military service) type of denominator that aims to better handle fluctuations in the amount of time an individual is cared for in the MHS and, thus, is not as subject to the drawbacks of the crude annual prevalence rate. While CY 2022 incidence rates are able to be calculated and compared between previous years, it is still important to practice caution when interpreting incomplete CY 2022 incidence data. Lastly, incidence rates are also likely the most appropriate measure to examine for this report given its focus on examining the likelihood of developing cardiac and kidney adverse events associated with SAR-CoV-2 infection or COVID-19 vaccination and not the general burden of these conditions on the MHS population.

Finally, adjusted incidence rate ratios were calculated for this report. A rate ratio allows for person-time incidence rates of two groups to be compared to each other, differentiated by usually a demographic feature or by exposure to a suspected causative agent and statistical significance to be tested. In this case, the rate ratios reported are differentiated by exposure to SARS-CoV-2 infection and COVID-19 vaccination separately and compared to the "Never" exposure group consistently. Interpretation of a rate ratio is straight-forward: a rate ratio of 1.0 indicates equal rates within the groups compared, a rate ratio greater than 1.0 indicates increased risk, and a rate ratio less than 1.0 indicates decreased risk or a protective effect.

Cardiac Outcomes – Overall Prevalence Data

The overall prevalence data captures the general burden of disease and causality to specific changes related to SARS-CoV-2 infection or COVID-19 vaccine cannot be made. As explained above, incidence rates are likely the most appropriate measure to examine for this report given its focus on examining the likelihood of developing cardiac and kidney adverse events associated with SAR-CoV-2 infection or COVID-19 vaccination.

Table 1. Crude Annual Prevalence Rates of Select Cardiac Conditions within Active Component Service Members

	Calendar Year								
	2019			2020			2021		
	N	Persons	Prevalence*	N	Persons	Prevalence*	N	Persons	Prevalence*
Myocarditis	205	1,313,942	15.6	189	1,320,699	14.3	326	1,339,485	24.3
Pericarditis	363	1,313,942	27.6	334	1,320,699	25.3	351	1,339,485	26.2
AMI	283	1,313,942	21.5	314	1,320,699	23.8	353	1,339,485	26.4

Abbreviations: AMI = acute myocardial infraction;
*Cases per 100,000 persons

In CY 2019, the crude prevalence (the unadjusted rate of new and existing cases) of myocarditis, pericarditis, and AMI was 15.6 cases per 100,000 persons, 27.6 per 100,000 persons, and 21.5 per 100,000 persons respectively (Table 1). By CY 2021, crude prevalence rates for myocarditis increased more than 50 percent to 24.3 cases per 100,000 persons. However, rates for pericarditis remained mostly unchanged and rates for AMI increased only modestly from 23.8 per 100,000 persons to 26.4 per 100,000 persons. Crude prevalence rates for CY 2022 could not be reported at this time, as explained above.

Cardiac Outcomes – Overall and Infection/Vaccination Exposure Incidence Data

Overall crude incidence rates (the unadjusted rate of new cases in each CY) for pericarditis and AMI remained mostly stable across the observed timespan from CY 2019 to available data in CY 2022 (Table 2). Unlike with AMI, rates for pericarditis did slightly decrease between CY 2021 and the first half of CY 2022. However, crude incidence rates for myocarditis decreased from 10.8 per 100,000 person-years (p-yrs) in CY 2019 to 8.7 in CY 2020 and then increased to 17.9 in CY 2021. While data for CY 2022 is currently only available between January and June 2022, the crude incidence rate for myocarditis during this 6-month period (13.0 cases per 100,000 p-yrs) is still above what was observed in CY 2019 (Table 2). These overall crude incidence rates include all Active Component members who experienced a new case of myocarditis, pericarditis,

or AMI during each year of interest, regardless of if they had a previous SARS-CoV-2 infection or received COVID-19 vaccine.

Table 2. Crude Annual Incidence Rates of Select Cardiac Conditions within Active Component Service Members, Overall and Stratified by SARS-CoV-2 Infection and COVID-19 Vaccine

	Calendar Year							
	2019		2020		2021		2022 (through June)	
	N	Incidence*	N	Incidence*	N	Incidence*	N	Incidence*
Myocarditis	142	10.8	116	8.7	239	17.9	84	13.0
SARS-CoV-2 Infection								
Yes, ≤ 45 days	0	0.0	13	142.8	27	152.1	16	59.1
No, > 45 days	0	0.0	7	56.5	55	41.9	16	11.6
Never	142	10.8	96	7.4	157	13.3	52	10.8
COVID-19 Vaccine								
Yes, ≤ 21 days	0	0.0	0	0.0	63	40.6	3	17.8
No, > 21 days	0	0.0	0	0.0	92	13.4	76	12.4
Never	142	10.8	116	8.8	84	17.1	5	33.9
Pericarditis	266	20.3	242	18.3	244	18.3	91	14.1
SARS-CoV-2 Infection								
Yes, ≤ 45 days	0	0.0	6	66.0	18	101.5	13	48.0
No, > 45 days	0	0.0	5	40.4	41	31.2	27	19.5
Never	266	20.3	231	17.7	185	15.6	51	10.6
COVID-19 Vaccine								
Yes, ≤ 21 days	0	0.0	1	133.9	48	30.9	5	29.7
No, > 21 days	0	0.0	0	0.0	115	16.8	82	13.3
Never	266	20.3	241	18.2	81	16.5	4	27.1
AMI	198	15.1	229	17.3	244	18.3	117	18.1
SARS-CoV-2 Infection								
Yes, ≤ 45 days	0	0.0	9	98.9	8	45.1	16	59.1
No, > 45 days	0	0.0	2	16.1	20	15.2	23	16.6
Never	198	15.1	218	16.7	216	18.2	78	16.2
COVID-19 Vaccine								
Yes, ≤ 21 days	0	0.0	0	0.0	35	22.6	0	0.0
No, > 21 days	0	0.0	0	0.0	120	17.5	115	18.7
Never	198	15.1	229	17.3	89	18.1	2	13.6

Abbreviations: AMI = acute myocardial infarction;
*Cases per 100,000 person-years of Active Component service

The overall crude incidence rates reported above were then stratified by cases that occurred within 45 days after SARS-CoV-2 (180 days for CKD) infection and cases that occurred within 21 days after COVID-19 vaccination (180 days for CKD). Given that the first laboratory confirmed case of SARS-CoV-2 in the United States occurred in January 2020 and DoD did not begin administering vaccine until December 2020, there are no cases of myocarditis, pericarditis, or AMI with previous infection or vaccine in CY 2019. In CY 2020, there were overall low number of cases related to either SARS-CoV-2 infection or COVID-19 vaccine. Specifically, in

CY 2020, there were 13, 6, and 9 cases of myocarditis, pericarditis, and AMI, respectively, which occurred within 45 days after SARS-CoV-2 infection, and only a single case of pericarditis within 21 days of receiving COVID-19 vaccine (Table 2).

In CY 2021, the crude incidence of myocarditis was 11 times higher in those with a past 45-day SARS-CoV-2 infection (152.1 per 100,000 p-yrs) compared to those with no prior SARS-CoV-2 infection (13.3 per 100,000 p-yrs) (Table 2). In contrast, the crude incidence of myocarditis was 2.4 times higher among those who received a vaccine dose within 21 days prior (40.6 per 100,000 p-yrs) compared to those who did not receive any prior dose of vaccine (17.1 per 100,000 p-yrs). The crude incidence of pericarditis was 6 times higher in those with a previous infection (101.5 per 100,00 p-yrs) compared to those without, and 1.9 times higher in those with a previous vaccination (30.9 per 100,000 p-yrs) compared to those without. Finally, incidence of AMI was 2.5 times higher in those with a recent infection and 1.2 times higher in those with a recent vaccination. For the most part, these trends continue in the 6 months available for CY 2022 at lesser magnitudes.

Cardiac outcome results showed similar patterns after adjusting for age, sex, race/ethnicity, obesity status, and either prior infection or prior vaccination (Table 3). In CY21, those with a recent SARS-CoV-2 infection had a rate ratio that showed incidence of myocarditis and pericarditis was 10.4 and 6.1 (respectively) times higher in this group compared to the incidence rates of those who were never infected. Those who were recently vaccinated had a rate ratio that showed their incidences of myocarditis and pericarditis were 2.6 and 2.0 times higher compared to those who were never vaccinated. These findings were statistically significant ($p<0.001$). In addition, those with a recent infection had a rate ratio that showed incidence for AMI was 2.4 times higher in this group compared to those who were never infected. Unlike with myocarditis and pericarditis rate ratios showing increased risk associated with vaccination, those who were recently vaccinated did not have increased incidence of AMI compared to those who were not vaccinated. The rate ratio for AMI comparing those who were vaccinated to those who were never vaccinated was at 1.1, effectively implying there was no difference between vaccination groups, although the association is not statistically significant.

Table 3: Adjusted Incidence Rates and Rate Ratios of Selected Cardiac Conditions Stratified by SARS-CoV-2 Infection and COVID-19 Vaccine, 2021

	Incidence*		Rate Ratio	
	SARS-CoV-2 Infection	COVID-19 Vaccine	SARS-CoV-2 Infection	COVID-19 Vaccine
Myocarditis				
Yes	98.2	57.2	10.4**	2.6**
No	27.8	20.3	2.9**	0.9
Never	9.5	22.2	Ref	Ref
Pericarditis				
Yes	55.5	30.8	6.1**	2.0**
No	16.3	17.5	1.8**	1.1
Never	9.1	15.3	Ref	Ref
AMI				
Yes	27.1	16.3	2.4**	1.1
No	9.9	12.1	0.9	0.8
Never	11.2	15.2	Ref	Ref

Abbreviations: AMI = acute myocardial infarction;
*Cases per 100,000 person-years in Active Component service, adjusted for age, sex, race and ethnicity, obesity status, and either COVID-19 infection within the past 45 days (180 days for CKD) or COVID-19 vaccine dose received within the past 21 days
**Statistically significant, p-value at least <0.05

Kidney Outcomes – Overall Prevalence Data

In CY 2019, the crude prevalence rates for AKI and CKD were 110.3 cases per 100,000 persons and 121.3 per 100,000 persons, respectively (Table 4). Both conditions had similar prevalence rates in both CY 2020 and CY 2021. Prevalence data for CY 2022 could not be reported as explained above.

Table 4. Crude Annual Prevalence Rates of Select Kidney Conditions within Active Component Service Members

	Calendar Year								
	2019			2020			2021		
	N	Persons	Prevalence*	N	Persons	Prevalence*	N	Persons	Prevalence*
AKI	1,449	1,313,942	110.3	1,433	1,320,699	108.5	1,533	1,339,485	114.5
CKD	1,594	1,313,942	121.3	1,547	1,320,699	117.1	1,607	1,339,485	120.0

Abbreviations: AKI = acute kidney injury; CKD = chronic kidney disease
*Cases per 100,000 persons

Kidney Outcomes – Overall and Infection/Vaccination Exposure Incidence Data

Crude annual incidence rates for AKI and CKD showed the same pattern – a slight decrease during CY 2020 followed by a return to roughly the same rate in CY 2021 as in CY 2019 (Table 5). While data for CY 2022 is only partially available at this time, the crude incidence rates for both conditions appear to be on track to end up similar to CY 2019 and CY 2021.

Table 5. Crude Annual Incidence Rates of Select Kidney Conditions within Active Component Service Members, Overall and Stratified by SARS-CoV-2 Infection and COVID-19 Vaccine

	Calendar Year							
	2019		2020		2021		2022 (through June)	
	N	Incidence*	N	Incidence*	N	Incidence*	N	Incidence*
AKI	1340	102.3	1307	98.9	1406	105.8	625	97.0
SARS-CoV-2 Infection								
Yes, ≤ 45 days	0	0.0	74	816.2	136	769.8	55	203.8
No, > 45 days	0	0.0	17	137.8	164	125.4	143	103.8
Never	1340	102.3	1216	93.5	1106	93.7	427	89.0
COVID-19 Vaccine								
Yes, ≤ 21 days	0	0.0	1	134.3	138	89.2	13	77.5
No, > 21 days	0	0.0	0	0.0	663	96.9	588	95.9
Never	1340	102.3	1306	98.8	605	123.5	24	163.2
CKD	724	55.2	648	48.9	680	51.1	230	35.6
SARS-CoV-2 Infection	0	0.0	18.0	88.2	64	88.6	42	44.4
Yes, ≤ 180 days	0	0.0	1.0	95.1	36	47.0	26	36.8
No, > 180 days	724	55.2	629.0	48.3	580	49.1	162	33.7
Never	0	0.0	18.0	88.2	64	88.6	42	44.4
COVID-19 Vaccine								
Yes, ≤ 180 days	0	0.0	1	134.1	339	51.4	85	36.2
No, > 180 days	0	0.0	0	0.0	85	46.4	137	34.2
Never	724	55.2	647	48.9	256	52.4	8	56.8

Abbreviations: AKI = acute kidney injury; CKD = chronic kidney disease
*Cases per 100,000 person-years of active component service

Once crude incidence rates were stratified by SARS-CoV-2 infection and COVID-19 vaccination, similar low case counts occur in these categories during CY 2020 for kidney conditions as they do for cardiac conditions with the exception of AKI. There was a total of 74 cases of AKI with prior SARS-CoV-2 infection within 45 days, which correlates with initial published reports of AKI complicating SARS-CoV-2 infection in as much as about 46 percent of all cases.[15] In CY 2021, the crude incidence of AKI was 8.2 times higher in those with a past 45-day SARS-CoV-2 infection (769.8 per 100,000 p-yrs) compared to those with no prior SARS-CoV-2 infection (93.7 per 100,000 p-yrs) (Table 5). In contrast, the crude incidence of AKI was reduced 28 percent among those who received a vaccine dose within 21 days prior (89.2 per 100,000 p-yrs) compared to those who did not receive any prior dose of vaccine (123.5 per 100,000 p-yrs). The crude incidence of CKD in CY 2021 was 1.8 times higher in those with an infection in the past 180 days compared to those never infected. Crude incidence rates of CKD between those with previous COVID-19 vaccination in the past 180 days (51.4 per 100,000 p-yrs) was similar to those who never had the vaccine (52.4 per 100,000 p-yrs).

Kidney outcomes again showed similar patterns after adjusting for age, sex, race/ethnicity, obesity status, and either prior infection or vaccination (Table 6). Those with a recent SARS-CoV-2 infection had a rate ratio that showed AKI incidence was 7.6 times higher among this group compared to those who were never infected. Similar for CKD, those with a recent SARS-

CoV-2 infection had a rate ratio that showed their CKD incidence was 1.8 times higher compared to those who were never infected. Those who were recently vaccinated had a rate ratio that showed they had a 20 percent reduced incidence of AKI and 20 percent reduced incidence of CKD compared to those who were never vaccinated.

Table 6: Adjusted Incidence Rates and Rate Ratios of Selected Kidney Conditions Stratified by SARS-CoV-2 Infection and COVID-19 Vaccine, 2021

	Incidence*		Rate Ratio	
	SARS-CoV-2 Infection	COVID-19 Vaccine	SARS-CoV-2 Infection	COVID-19 Vaccine
AKI				
Yes	537.8	132.8	7.6**	0.8**
No	92.5	150.4	1.3**	0.9**
Never	71.0	176.8	Ref	Ref
CKD				
Yes	64.4	44.2	1.8**	0.8**
No	36.8	34.8	1.1	0.6**
Never	35.0	54.0	Ref	Ref

Abbreviations: AKI = acute kidney injury; CKD = chronic kidney disease
*Cases per 100,000 person-years in Active Component service, adjusted for age, sex, race and ethnicity, obesity status, and either COVID-19 infection within the past 45 days (180 days for CKD) or COVID-19 vaccine dose received within the past 21 days
**Statistically significant, p-value at least <0.05

DISCUSSION

In response to the public health emergency of pandemic level spread of SARS-CoV-2 virus, DoD began administering COVID-19 vaccines in December 2020 with the full 2-dose vaccination against COVID-19 being required for all Active Component (and Ready Reserve) Service members starting in August 2021. Almost 1.5 million Active Component members have received at least one dose of the COVID-19 vaccine and the report findings suggest overall stable incidence and prevalence rates of most cardiac and kidney conditions from 2019 to 2022. Similar to numerous studies reporting an increase in myocarditis incidence as a rare complication of mRNA COVID-19 vaccination, MHS data review from January 2019 to June 2022 showed an overall small increase in myocarditis incidence and prevalence among Active Component Service members.[3-10]

The overall small increase in myocarditis incidence, which was most profound in 2021, is potentially related to the general increased incidence of SARS-CoV-2 infection that was observed nationwide and also within DoD during the surge from the Delta variant spread in summer 2021. After adjusting for confounding factors, there was a 10.4 times increased risk for myocarditis associated with recent SARS-CoV-2 infection compared to 2.6 times increased risk for myocarditis associated with COVID-19 vaccine. MHS data align with published studies acknowledging a small increase in myocarditis incidence potentially related to COVID-19 vaccine but with far worse outcomes that was potentially avoided with SARS-CoV-2 infection.[9,10]

The only other clinical outcome with a trend toward increased overall prevalence, although slight, was in AMI. To reiterate, prevalence data captures the general burden of disease and incidence rates are most appropriate to examine for this report for potential causality to changes related to SARS-CoV-2 infection or COVID-19 vaccination. Specifically, the crude prevalence rates for AMI modestly increased across the 2019-2021 time period. Conversely, the crude incidence rate for AMI started low at 15.1 cases per 100,000 p-yrs in 2019 before increasing to 17.3 in 2020 and remaining relatively stable at this increased level for 2021 and through June 2022. Both prior SARS-CoV-2 infection and receipt of COVID-19 vaccine resulted in higher crude incidence rates of AMI compared to never being infected or never receiving the vaccine. However, SARS-CoV-2 infection associated AMI crude incidence rates were markedly higher than vaccine-associated AMI crude incidence rates. Similarly, after adjusting for confounding factors, there was 2.4 times increased risk for AMI associated with recent SARS-CoV-2 infection compared to 1.1 times increased risk for AMI associated with COVID-19 vaccination. The higher and statistically significant rate ratio of 2.4 suggests that having previous SARS-CoV-2 infection had a more significant impact on AMI incidence rate than COVID-19 vaccine, the rate ratio of which was not statistically significant and nearly 1.0 (implying almost no difference in incidence rates between those who received COVID-19 vaccine and those who never received COVID-19 vaccine). At the very least, this could be a weak signal inferring that SARS-CoV-2 infection did indeed drive the moderate increase in observed AMI prevalence, but a more detailed analysis is likely needed to confirm.

The incidence and prevalence of pericarditis and both kidney outcomes (AKI and CKD) evaluated in this report remained similar or at least mostly similar in 2021 compared to previous years. The association between CKD and COVID-19 vaccine is difficult to make given multiple confounding factors and the prolonged timeline associated with CKD development. However, crude incidence rates between those with previous COVID-19 vaccination (51.4 per 100,000 p-yrs) were similar to those who never had the vaccine (52.4 per 100,000 p-yrs). Overall, our data suggests that there was a trend showing no differences in CKD incidence.

Although the incidence and prevalence of pericarditis remained stable from 2019 to 2021 with a trend toward decrease in 2022, the adjusted rate ratio of 2.0 showed a potential increase in the risk for pericarditis associated with COVID-19 vaccine. However, similar to the myocarditis findings, there was a significantly 6.1 times higher increased risk for pericarditis associated with SARS-CoV-2 infection compared to 2.0 times increased risk for pericarditis associated with the vaccine. To date and based on published clinical case reports and case series, it remains difficult to separate pericarditis from myocarditis (possible myocarditis cases) because features of myocarditis and pericarditis may overlap and commonly present as myopericarditis.[4,7] While diagnostic criteria exist for the diagnosis of pericarditis, without further review of the individual cases to confirm the clinical evaluation and diagnosis of pericarditis, it is difficult to accurately estimate the prevalence and incidence of infection or vaccine associated pericarditis as this condition may present across a spectrum of severity and symptoms that can overlap with myocarditis.

Similar to data reported in literature, the incidence of all cardiac and kidney conditions evaluated in this report were higher in those with a recent SARS-CoV-2 infection compared to without infection (rate ratios ranging from 1.8-10.4, all statistically significant).[9-10] While there was also

increased incidence for myocarditis and pericarditis in the 21 days following COVID-19 vaccination compared to those without vaccination (rate ratios of 2.6 and 2.0 respectively, both statistically significant), this increase was much lesser in magnitude compared to those observed following infection with SARS-CoV-2. Furthermore, there was no observed increase in risk for AMI, AKI, or CKD incidence following COVID-19 vaccination. In fact, rate ratios for these conditions implied either no difference in incidence rates following vaccine (AMI, though not statistically significant) or a reduced effect in incidence rates following vaccine (AKI and CKD, both statistically significant). These observations are consistent with what is reported in literature for the selected cardiac and kidney conditions.

Global studies have shown that COVID-19 vaccines are effective in protecting against SARS-CoV-2 infections and complications of infection. While vaccine effectiveness against mild infection is dependent on viral variants,[24,25] effectiveness calculations against severe disease, hospitalization, and death have been consistently estimated as high as 80-90 percent.[26,27] Vaccine effectiveness has been established in vulnerable populations as well as the relatively healthy military population.[28] The COVID-19 vaccination program in the United States has been estimated as preventing nearly 120 million infections, 18.5 million hospitalizations, and 3.2 million deaths.[29] Prevention of SARS-CoV-2 infections and complications has also been translated into substantial economic value.[29,30] Expanded understanding of post-acute sequelae of SARS-CoV-2 infection, or long-COVID, and recent research demonstrating effectiveness of vaccination in preventing long-COVID,[31] will make future calculations of vaccine value even higher than previous robust estimates. Although all vaccinations carry some risk of rare adverse events, the benefit of COVID-19 vaccination during the current pandemic has been strongly established by all international public health authorities.[32]

The findings in this report are subject to at least three limitations. First, this is a population-level evaluation of administrative data records within the MHS. Time period risk windows were used to associate outcomes with COVID-19 infection or vaccination. However, this does not necessarily mean that a case occurring during the risk window was caused by COVID-19 infection or vaccination. Detailed chart review confirmation would be needed to determine causality of the cardiac and kidney conditions included in this study. The use of administrative data for outcome definition may also result in misclassification of diagnoses due to miscoding in patient records. Furthermore, only individuals who show up for healthcare services billable to military insurance are able to be included for evaluation. While this report did focus on Active Component members, a subgroup of the MHS population that receives the majority of its health care covered by military insurance, it is still possible that cases of SARS-CoV-2 infection, myocarditis, pericarditis, AMI, AKI, and CKD were missed due to the nature of the data source. Second, this report only evaluates vaccinations administered while an Active Component member is in Military Service and may have missed vaccinations completed prior to the first date in military. Third, while the report did observe an increased risk for certain cardiac conditions after SARS-CoV-2 infection and COVID-19 vaccination, these associations are far from causal and too many factors are unable to be controlled for. Rather, the report serves as soft confirmation of trends also observed in the general population: while the COVID-19 vaccine does carry increased risk for certain cardiac conditions, the risk for those same conditions is higher still following SAR-CoV-2 infection, albeit overall a rare event in both cases.

There are no long-term outcome data available for the increased myocarditis incidence associated with both COVID-19 vaccine and SARS-CoV-2 infection globally and also within MHS. Active and continued long-term surveillance of potential incident cases with diagnosis confirmation through detailed case reviews may be pursued to assist in mitigating potential risk factors associated with increased myocarditis risk for Service members.

CONCLUSION

Review of MHS data spanning January 2019 to June 2022 demonstrates that both the prevalence and incidence of myocarditis has increased among Active Component members of the Armed Forces. All other cardiac and kidney outcomes remained mostly stable through the time period. Recent receipt of COVID-19 vaccine was shown to carry increased risk for development of both myocarditis and pericarditis, but without increased risk for AMI and with a slightly reduced risk for AKI and CKD. However, recent SARS-CoV-2 infection was associated with a significantly higher magnitude of increased risk for all observed cardiac and kidney conditions when compared to vaccine administration. While all vaccinations including COVID-19 carry some amount of risk for rare adverse events, the MHS data shows that risks for cardiac and kidney complications are higher after SARS-CoV-2 infection than they are after COVID-19 vaccine, supporting similar conclusions drawn by previous published studies.

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APPENDIX A: ICD-9, ICD-10, and CVX Codes for Case Definitions of Cardiac, Kidney, and COVID-19 Vaccination

Table A1. ICD codes for Myocarditis

ICD-10	ICD-10 Description	ICD-9	ICD-9 Description
I51.4	Myocarditis, unspecified	429.0	Myocarditis, unspecified
I40.9	Acute myocarditis, unspecified	422.90	Acute myocarditis, unspecified
I40.8	Other acute myocarditis	422.93, 422.99	Toxic myocarditis, Other acute myocarditis
I40.1	Isolated myocarditis	422.91	Idiopathic myocarditis
I40.0	Infective myocarditis	422.92	Septic myocarditis
I41	Myocarditis in diseases classified elsewhere	422.0	Acute myocarditis in diseases classified elsewhere
I01.2	Acute rheumatic myocarditis	391.2	Acute rheumatic myocarditis
I09.0	Rheumatic myocarditis	398.0	Rheumatic myocarditis

Table A2. ICD codes for Pericarditis

ICD-10	ICD-10 Description	ICD-9	ICD-9 Description
I32	Pericarditis in diseases classified elsewhere	420.0	Acute pericarditis in diseases classified elsewhere
I30.9	Acute pericarditis, unspecified	420.90	Acute pericarditis, unspecified
I30.8	Other forms of acute pericarditis	420.99	Other acute pericarditis
I30.1	Infective pericarditis	420.90	Acute pericarditis, unspecified
I30.0	Acute nonspecific idiopathic pericarditis	420.91	Acute idiopathic pericarditis
M32.12	Pericarditis in systemic lupus erythematosus	423.9	Unspecified disease of pericardium

Table A3. ICD codes for Acute Myocardial Infarction

ICD-10	ICD-10 Desc	ICD-9	ICD-9 Desc
I21.0*	ST elevation (STEMI) myocardial infarction of anterior wall	410*	Acute myocardial infarction
I21.1*	ST elevation (STEMI) myocardial infarction of inferior wall	As above	
I21.2*	ST elevation (STEMI) myocardial infarction of other sites	As above	
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site	As above	
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	As above	
I21.9	Acute myocardial infarction, unspecified	As above	
I22*	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction	As above	

*Indicates that all subsequent digits/characters are included

Table A4. ICD codes for Acute Kidney Failure

ICD-10	ICD-10 Desc	ICD-9	ICD-9 Desc
N17.0	Acute kidney failure with tubular necrosis	584.5	Acute kidney failure with lesion of tubular necrosis
N17.1	Acute kidney failure with acute cortical necrosis	584.6	Acute kidney failure with lesion of renal cortical necrosis
N17.2	Acute kidney failure with medullary necrosis	584.7	Acute kidney failure with lesion of renal medullary [papillary] necrosis

N17.8	Other acute kidney failure	584.8	Acute kidney failure with other specified pathological lesion in kidney
N17.9	Acute kidney failure, unspecified	584.9	Acute kidney failure, unspecified

Table A5. ICD codes for Chronic Kidney Disease

ICD-10	ICD-10 Desc	ICD-9	ICD-9 Desc
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease	403.01, 403.11, 403.91	Hypertensive chronic kidney disease, malignant, with chronic kidney disease stage V or end stage renal disease; Hypertensive chronic kidney disease, benign, with chronic kidney disease stage V or end stage renal disease; Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end stage renal disease
I13.1	Hypertensive heart and chronic kidney disease without heart failure		
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	404.00, 404.10, 404.90	Hypertensive heart and chronic kidney disease, malignant, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified; Hypertensive heart and chronic kidney disease, benign, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified; Hypertensive heart and chronic kidney disease, unspecified, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease	404.02, 404.12, 404.92	Hypertensive heart and chronic kidney disease, malignant, without heart failure and with chronic kidney disease stage V or end stage renal disease; Hypertensive heart and chronic kidney disease, benign, without heart failure and with chronic kidney disease stage V or end stage renal disease; Hypertensive heart and chronic kidney disease, unspecified, without heart failure and with chronic kidney disease stage V or end stage renal disease
N03.2	Chronic nephritic syndrome with diffuse membranous glomerulonephritis	582.0	Chronic glomerulonephritis with lesion of proliferative glomerulonephritis
N03.3	Chronic nephritic syndrome with diffuse mesangial proliferative glomerulonephritis	582.1	Chronic glomerulonephritis with lesion of membranous glomerulonephritis
N03.4	Chronic nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis	582.2	Chronic glomerulonephritis with lesion of membranoproliferative glomerulonephritis
N03.5	Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis	As above	
N03.6	Chronic nephritic syndrome with dense deposit disease	As above	
N03.7	Chronic nephritic syndrome with diffuse crescentic glomerulonephritis	As above	
N18*	Chronic kidney disease (CKD)	585*	Chronic kidney disease (CKD)
N19	Unspecified kidney failure	586	Renal failure, unspecified

N05.2	Unspecified nephritic syndrome with diffuse membranous glomerulonephritis	583.1	Nephritis and nephropathy, not specified as acute or chronic, with lesion of membranous glomerulonephritis
N05.3	Unspecified nephritic syndrome with diffuse mesangial proliferative glomerulonephritis	583.2	Nephritis and nephropathy, not specified as acute or chronic, with lesion of membranoproliferative glomerulonephritis
N05.4	Unspecified nephritic syndrome with diffuse endocapillary proliferative glomerulonephritis	As above	
N05.5	Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis	As above	
N05.6	Unspecified nephritic syndrome with dense deposit disease	583.89	Nephritis and nephropathy, not specified as acute or chronic, with other specified pathological lesion in kidney
N05.7	Unspecified nephritic syndrome with diffuse crescentic glomerulonephritis	As above	
N25.0	Renal osteodystrophy	588.0	Renal osteodystrophy
Z49.01, Z49.02	Encounter for fitting and adjustment of extracorporeal dialysis catheter; Encounter for fitting and adjustment of peritoneal dialysis catheter	V56.1, V56.2	Fitting and adjustment of extracorporeal dialysis catheter; Fitting and adjustment of peritoneal dialysis catheter
Z94.0	Kidney transplant status	V42.0	Kidney replaced by transplant
Z99.2	Dependence on renal dialysis	V45.11	Renal dialysis status

*Indicates that all subsequent digits/characters are included

Table A6. CVX codes for COVID-19 vaccination

Imm_type	Description	Comments
510	SARS-COV-2 COVID-19 Inactivated Virus Non-U.S. Vaccine Product (BIBP, Sinopharm)	WHO authorized pandemic vaccine. Recognized towards immunity in U.S.
511	SARS-COV-2 COVID-19 Inactivated Virus Non-U.S. Vaccine Product (CoronaVac, Sinovac)	WHO authorized pandemic vaccine. Recognized towards immunity in U.S.
502	SARS-COV-2 COVID-19 Inactivated Virus Non-U.S. Vaccine Product (COVAXIN)	Pandemic Non-U.S. Vaccine Authorized by WHO 11-3-2021, recognized toward immunity in U.S., https://extranet.who.int/pqweb/vaccines/who-recommendation-bharat-biotech-international-ltd-covid-19-vaccine-whole-virion.
212	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-Ad26, preservative free, 0.5 mL	FDA EUA 02/27/2021, 1-dose vaccine. Used to record Janssen/J&J vaccines administered in the U.S. and in non-U.S. locations
210	SARS-COV-2 (COVID-19) vaccine, vector non-replicating, recombinant spike protein-ChAdOx1, preservative free, 0.5 mL	Potential FDA EUA, 2-dose vaccine. AstraZeneca vaccine is authorized by the WHO and recognized towards immunity in the U.S. Non-U.S. WHO authorized tradenames/identifiers include VAXZEVRIA, AZD1222, ChAdOx1 nCoV-19, COVISHIELD
207	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose	FDA EUA 12/18/2020, 2-dose vaccine. Used to record Moderna vaccines administered in the U.S. and in non-U.S. locations (includes tradename Spikevax)
208	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3mL dose	FDA BLA 08/23/2021 for adult dose (16+ years). Still under EUA for adolescent doses and presentations. EUA 12/11/2020, 2-dose vaccine. Used to record Pfizer vaccines administered in the U.S. and in non-U.S. locations (includes tradename Comirnaty)

217	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 30 mcg/0.3mL dose, tris-sucrose formulation	EUA 12+ yrs, BLA 16+ yrs Pfizer tris-sucrose formulation vaccine for ages 12 and older
221	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 50 mcg/0.5 mL dose	FDA EUA 03/29/2022, Moderna booster dose 2.5mL vial presentation only
211	SARS-COV-2 (COVID-19) vaccine, subunit, recombinant spike protein-nanoparticle+Matrix-M1 Adjuvant, preservative free, 0.5mL dose	Pre-EUA Authorization - Novavax Primary Series dose
229	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, bivalent booster, preservative free, 50 mcg/0.5 mL or 25 mcg/0.25 mL dose	Pre-EUA Moderna bivalent booster, ages 6yr+ as authorized, original strain + omicron BA.4/BA.5
300	SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, bivalent booster, preservative free, 30 mcg/0.3 mL dose, tris-sucrose formulation	Pre-EUA Pfizer bivalent booster, ages adult 12+, original strain + omicron BA.4/BA.5

Note: CVX codes 207, 208, 217, 221, 229, 300 are categorized as "mRNA", 212 is "JNJ", and all others are categorized as "other"

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