

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Mon, 5 Apr 2021 16:08:26 +0000
To: Anderson, Steven (FDA/CBER); Beresnev, Tatiana (NIH) [C]; Broder, Karen (CDC/DDID/NCEZID/DHQP); Calvert, Geoffrey M. (CDC/NIOSH/WTCHP); Clark, Matthew (IHS/ALB); Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Cohn, Amanda (CDC/DDID/NCIRD/OD); Collins, Limone; [REDACTED] Daley, Matt; Destefano, Frank (CDC/DDID/NCEZID/DHQP); Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD); Edwards, Kathy; Farizo, Karen (FDA/CBER); Forshee, Richard (FDA/CBER); Gee, Julianne (CDC/DDID/NCEZID/DHQP); Helfand, Rita (CDC/DDID/NCEZID/OD); Hiers, Susan G. (CDC/DDID/NCIRD/OD); Hopkins, Bob; Jackson, Lisa; Kelman, Jeffrey A. (CMS/CM); Kulldorf, Martin; LaPorte, Kathleen (CDC/DDID/NCIRD/ID); Lee, Grace; MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD); Mullen, Jennifer (CDC/DDID/NCEZID/DHQP); Myers, Tanya R. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Patricia Whitley-Williams [REDACTED]; Riley, Laura; Rubin, Mary (HRSA); Schechter, Robert; Shanley, Edwin (CDC/DDID/NCIRD/OD); Shay, David (CDC/DDID/NCIRD/ID); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Sotir, Mark (CDC/DDID/NCIRD/DVD); Steinberg, Judith (HHS/OASH); Su, John (CDC/DDID/NCEZID/DHQP); Talbot, Keipp; Wasley, Annemarie (CDC/DDPHSIS/CGH/GID); Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Wharton, Melinda (CDC/DDID/NCIRD/ID); Wong, Hui-Lee (FDA/CBER); Woo, Jared (CDC/DDID/NCEZID/DHQP); Young, Mardia (CDC/DDID/NCEZID/DHQP) (CTR)
Subject: [EXTERNAL] VaST - Agenda for April 5 (1:30 - 3 pm ET) and presentations - CONFIDENTIAL
Attachments: Adverse events english ACIP 4_05_21.pdf, FDA VAERS data mining Baer 4_04_21.pdf, RCA results_20210405_VAST.pdf, VSD RCA Covid-19 vax - VaST methods 4-05-2021.pdf, 2021_04_05 VaST Meeting Agenda.docx

Dear all,

This email includes the VaST agenda for today (below and attached) as well as 4 slide sets. The agenda attached has more information regarding approximate times for talks and discussion.

Agenda:

Announcements, Meeting Expectations and Processes

Israel's Covid-19 vaccine safety data (Emilia Anis, Israel MOH)

FDA methods for data mining (Bethany Baer, FDA)

FDA CMS RCA (Richard Forshee, FDA)

VSD and VA RCA, overview of plans (Tom Shimabukuro, CDC and [REDACTED] VA)

The VaST call link information should be on your calendars.

Reminder - all VaST documents and communications are confidential.

Lauri Markowitz and Melinda Wharton

Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

From: Wharton, Melinda (CDC/DDID/NCIRD/ISD)
Sent: Thu, 1 Apr 2021 13:32:47 +0000
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Subject: RE: Covid-19 vaccine safety data

I agree but if we're really in a crunch that will be the best thing to postpone.

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Thursday, April 1, 2021 9:04 AM
To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Subject: RE: Covid-19 vaccine safety data

I was going to suggest the EB mining be moved to the following week, but not sure that is a good idea.

From: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Sent: Thursday, April 1, 2021 9:00 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: RE: Covid-19 vaccine safety data

Agree, I think that these points can be included in the other presentations.

But we are always going to have trouble with time!

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Thursday, April 1, 2021 8:57 AM
To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Subject: FW: Covid-19 vaccine safety data

Melinda,
See note from Israel below - I said they have 15 min and they think they need 5-10 more minutes. I'm thinking of the best approach. I wonder if we need to schedule these as separate talks? I think they can both be done together. Rich has 20 minutes for the CMS data and he should be able to cover plans in his talk.
2:35-2:40 - VSD and VA RCA (CDC & VA)
2:40-2:45 - Overview of different analyses and plans (FDA & CDC)
I will also discuss with Tom.

Lauri

This is the schedule – from Grace's slide

1:30-1:35 - Announcements, Meeting Expectations and Processes
1:35-1:50 - Israel's Covid-19 vaccine safety data (Emilia Anis, Israel MOH)
1:50-2:00 - Discussion
2:00-2:10 - FDA methods for EB data mining (Bethany Baer, FDA)
2:10-2:15 - Discussion
2:15-2:35 - FDA CMS RCA (Richard Forshee, FDA)
2:35-2:40 - VSD and VA RCA (CDC & VA)

2:45-3:00 - Discussion

From: [REDACTED] <EMILIA.ANIS[REDACTED]>
Sent: Thursday, April 1, 2021 4:24 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Cc: [REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]>
<[REDACTED]> [REDACTED] <[REDACTED]>
Subject: RE: Covid-19 vaccine safety data

Dear Laurie,

I think we will need another 5-10 minutes for our presentation.

We prefer to have these discussions by zoom. Will your invitation be by zoom or would you prefer us to send?

Regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. [REDACTED]
Fax: [REDACTED]
Mobile: [REDACTED]
E-mail: [REDACTED]

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Wednesday, March 31, 2021 7:20 PM
To: [REDACTED] <EMILIA.ANIS[REDACTED]>
Cc: [REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]> [REDACTED] <[REDACTED]>
 [REDACTED] [REDACTED] [REDACTED] [REDACTED]
Subject: RE: Covid-19 vaccine safety data

Dear Emilia,

For the VaST call next Monday, April 5, you will receive a calendar invitation from the VaST call scheduler either on Friday this week or on Monday morning.

We have several items on the agenda and would like the presentation from Israel to be first. We have scheduled 15 minutes for the presentation and 10 minutes for discussion. Will 15 minutes be enough time? It would be great if you can send slides to me before Monday, but if not, Monday morning is OK.

Regards,
Lauri

Lauri Markowitz, MD
VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, March 24, 2021 12:17 PM
To: 'D' DDDDD DDDDD' <EMILIA.ANIS [REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED] [REDACTED]>
<[REDACTED] [REDACTED]> [REDACTED] [REDACTED] [REDACTED] [REDACTED] Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
<[REDACTED]>
Subject: RE: Covid-19 vaccine safety data

Dear Emilia,

Thank you for confirming that the time will work for you to present to VaST on April 5. I want to mention again that we are interested in hearing about Israel's post-authorization safety monitoring systems and specifically any information you have on **deaths reported after vaccination**. We thought that the system there might lend itself to more complete review of deaths reported.

Regarding the information you mention below from U.S monitoring systems, all ACIP COVID-19 vaccine safety presentations are available at <https://www.cdc.gov/vaccines/acip/meetings/index.html>.

Specifically, the links to 3 recent safety presentations from March 1 are:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/04-COVID-Lee.pdf>

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf>

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/06-COVID-Lee.pdf>

In addition, safety reviews are available at:

<https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm>

<https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm>

<https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm>

<https://jamanetwork.com/journals/jama/fullarticle/2776557>

I'm also Cc'ing Dr. Tom Shimabukuro who is the vaccine safety team lead on the CDC COVID-19 Vaccine Task Force who can provide additional information, if needed.

Lauri Markowitz, MD
VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: [REDACTED] <[REDACTED]>
Sent: Monday, March 22, 2021 12:51 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]> [REDACTED] [REDACTED]
<[REDACTED]> [REDACTED] [REDACTED]; [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
Subject: RE: Covid-19 vaccine safety data

Dear Lauri,

The date you suggested works for us. We will be happy to present our data. We are interested to hear your data as well.

In addition to the general safety data, we are interested in your observations regarding the following adverse events following immunization:

- Heart inflammatory processes, e.g. myocarditis, pericarditis, pericardial effusion. Did you have reports of endocarditis?
- Cranial nerve palsy
- Female reproductive system: dysmenorrhea, vaginal bleeding, menstrual spotting
- All cause hospitalization and death
- Autoimmune diseases, e.g. MIS, multiple sclerosis
- Cardiovascular, e.g., arrhythmias, CVA
- Thrombocytopenia
- Herpes family infection (herpes simplex, herpes zoster, CMV in pregnancy)
- Significant visual or hearing disturbances
- Other topics that you think are of importance

Best regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. [REDACTED]
Fax: [REDACTED]
Mobile: [REDACTED]
E-mail: [REDACTED]

From: [REDACTED]
Sent: Saturday, March 20, 2021 4:18 PM
To: 'Markowitz, Lauri (CDC/DDID/NCIRD/DVD)' <[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]> [REDACTED] [REDACTED]
<[REDACTED]> [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
Subject: RE: Covid-19 vaccine safety data

Dear Lauri,

I will check with my colleagues and get back to you tomorrow.

Best regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. [REDACTED]
Fax: [REDACTED]
Mobile: [REDACTED]
E-mail: [REDACTED]

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Tuesday, March 16, 2021 11:48 PM
To: [REDACTED] <EMILIA.ANIS@[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]> [REDACTED] [REDACTED]
<[REDACTED]> [REDACTED] [REDACTED]; [REDACTED] [REDACTED]

Subject: RE: Covid-19 vaccine safety data

Dear Dr. Anis,

Thank you for this note and for your willingness to present to VaST. We were hoping you could present on Monday, April 5. Our calls are at 1:30 PM EDT. I know this is the early evening in Jerusalem, so let me know if this will work of you.

Warm regards,
Lauri

*Lauri Markowitz, MD
VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention*

From: "*****" <EMILIA.ANIS@*****>
Sent: Tuesday, March 16, 2021 9:28 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <*****>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <*****>
<*****> *****; ***** <*****>

Subject: RE: Covid-19 vaccine safety data

Dear Dr. Markowitz,

Thank you for the invitation.

We will be happy to share our data. Please let us know enough time in advance and note that there are Passover holidays from 27.3 until 3.4.

Best regards from Jerusalem,



Emilia Anis, MD, MPH
Director

Division of Epidemiology
Ministry of Health, Israel
Tel. [REDACTED]
Fax: [REDACTED]
Mobile: [REDACTED]
E-mail: [REDACTED]

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Monday, March 15, 2021 4:06 PM
To: [REDACTED] <EMILIA.ANIS@[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Subject: Covid-19 vaccine safety data

Dear Dr. Emilia Anis,

I am writing to inquire about a presentation on Israel's vaccine safety data to the ACIP COVID-19 Vaccines Safety Technical Sub-Group

(VaST). <https://www.cdc.gov/vaccines/acip/workgroups.html#vast>

I am a co-lead for this group, which was established to provide expert consultation on COVID-19 vaccine safety in the United States. Since December 2020, VaST has been meeting weekly to review data from the U.S. vaccination program. At a recent meeting, several members expressed interest in seeing data from other countries, particularly Israel - because we felt you likely had good COVID-19 vaccine safety monitoring in place. There is particular interest in hearing about deaths reported after vaccination. Based on the target population for the initial vaccine roll-out in the United States, the number of deaths is substantially below the number expected. Nevertheless, we would like to hear the experience in other countries.

Would you be able to present data from the vaccine safety monitoring in Israel? While we present data publicly to ACIP (most recently on March 1) <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html> the VaST meetings are closed, virtual, and all data presented are confidential.

Thank you and I hope all is well there,
Lauri

Lauri Markowitz, MD
VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

[REDACTED]

[REDACTED]

Phone: [REDACTED]

Cell: [REDACTED]

Email: [REDACTED]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 10 Mar 2021 12:38:12 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Destefano, Frank (CDC/DDID/NCEZID/DHQP)
Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Attachments: Myocarditis Response.docx

This is for that joint FDA-CDC to the Israeli MOH. Please let me know if you have any thoughts. Thanks.
Tom

From: Nair, Narayan <[REDACTED]>
Sent: Tuesday, March 9, 2021 9:10 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Hi Tom,
Here are some draft responses to the Israeli Ministry of Health's inquiry. They sent multiple message but in one they posed 4 questions so that is what I used as the basis for response. Steve is looking this over. I think the plan was to have a combined response. I did not have data for question 1 so not sure if you have that.

Narayan

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Sunday, February 28, 2021 3:06 PM
To: Anderson, Steven <[REDACTED]> Forshee, Richard <[REDACTED]> Nair, Narayan <[REDACTED]>
Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

FYI.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Sent: Sunday, February 28, 2021 2:28 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>

Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Seeing that Denise is out. + Susan

Susan – can you please help coordinate?

Thanks,
-d

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID)
Sent: Sunday, February 28, 2021 2:26 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [REDACTED]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) [REDACTED] CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks, Stacey.

Denise – can you help set this up via policy?

Best,
David

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:35 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [REDACTED]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks David. Do you want Tom and I to coordinate a call? This was sent to multiple units.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Sent: Sunday, February 28, 2021 11:15 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [REDACTED]
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Importance: High

Stacey and Tom,

Please see below re discussing with Israeli Vaccine FP re myocarditis in people receiving Pfizer vaccine.

Thanks,
David

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Importance: High

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Rocco Singer MD, MPH [REDACTED]

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The

Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

Summary of VAERS Reports of myocarditis, pericarditis and myopericarditis following vaccination with mRNA COVID-19 vaccines

Background:

This memo responds to questions posed from the Israeli Ministry of Health to the FDA and CDC. They are investigating a safety signal of myocarditis /myopericarditis in a younger population (16 -30 years old) following administration of Pfizer-BioNTech Covid-19 vaccine. The Ministry of Health stated they received reports of around 40 cases of this adverse event. They did not provide additional details about these cases.

Questions Posed by Israeli Ministry of Health:

1. How many doses of the vaccine were administered to this age group?

CDC to provide this data

2. How many cases of myocarditis / peri-myocarditis were reported in your country?

A search of the U.S. Vaccine Adverse Event Reporting System (VAERS) conducted on February 23, 2021 revealed 27 cases (6 cases of myocarditis, 7 cases of myopericarditis, 14 cases pericarditis).

The following Medical Dictionary for Regulatory Activities (MedDRA) preferred terms were used to conduct the search: myocarditis; eosinophilic myocarditis; hypersensitivity myocarditis; pericarditis; pericarditis adhesive; pericarditis constrictive; pleuropericarditis; pericardial disease; pericardial effusion; pericardial rub; myopericarditis. Reports with sufficient information were reviewed and categorized based on case definitions previously used for surveillance of myopericarditis after smallpox vaccine (<https://www.cdc.gov/mmwr/PDF/wk/mm5221.pdf>).

Reports were included if they contained a diagnosis by of myocarditis, pericarditis or myopericarditis. Reports with pericardial effusion and no other signs of myopericarditis were excluded. If the diagnosis in the narrative was pericarditis but the patient also had elevated troponin they were categorized as myopericarditis.

3. Could you elaborate details on these AE cases (time of diagnosis from the vaccine, first/second dose, risk factors, etc.) ?

Twelve cases occurred after dose 1, 7 cases after dose 2, and the dose was not reported for 8 cases. Four patients had comorbid conditions that could suggest alternate etiologies for the adverse event. These included:

- One patient with subacute pericarditis noted on cardiac MRI. The clinical impression was this pre-dated vaccination
- One patient had a history of recurrent pericarditis
- One patient had recent SARS CoV-2 infection
- One patient had psoriatic arthritis and was on Adalimumab

None of the cases reported other risk factors or causes such as preceding viral infections or other vaccines administered concurrently. However, due to the nature of passive surveillance reports, it is not possible to completely exclude these due to potential incompleteness of reports.

The following table displays additional information about the cases of myopericarditis.

Characteristics	Reports of Myopericarditis/Myocarditis/Pericarditis (N = 27)
Median age, years (range)*	36 (21–84)
Female (%)	10(37)
Male (%)	16 (59)
Gender not reported (%)	1(4)
Median Time to Onset in Days (range)	3 (0-20)

4. Have you assessed the causality between the AE and the vaccine for each of the cases?

During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines. We will continue to monitor this outcome in active and passive surveillance.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 4 Mar 2021 14:33:09 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Yes

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, March 4, 2021 9:29 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Tom,

Can I reply to the person who send this and copy all the other mailboxes that it was sent to let them know that CDC and FDA will respond jointly and no further action is required from them?

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, March 4, 2021 9:24 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Dua, Anamika (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks Tom

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, March 4, 2021 9:17 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Dua, Anamika (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Both FDA and CDC have received multiple requests from various Israeli public health and regulatory official re: this topic. We are working on a joint response with FDA. No action is necessary; you don't need to do anything for this.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) [REDACTED]
Sent: Thursday, March 4, 2021 8:52 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Dua, Anamika (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) [REDACTED]
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all,
I will do a VAERS search.
Is anyone able to talk to this MD from the Israel Ministry of Health?
Thanks,
Elaine

From: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management
Sent: Wednesday, March 3, 2021 8:31:15 PM (UTC-05:00) Eastern Time (US & Canada)
To: CDC IMS 2019 NCOV Response VTF Global
Cc: COVID19VaxSafety; CISA Response (CDC); CDC IMS 2019 NCOV Response VTF Communications; CDC IMS 2019 NCOV Response International Task Force
Subject: Fw: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hello VTF Global colleagues,

Please see the inquiry from the Deputy Director, Division of Epidemiology, MoH Israel below. Could you please respond?

Thank you,

Kate

Record ID: [REDACTED]

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force
CDC Coronavirus Disease 2019 (COVID-19) Response | [REDACTED]

Further CDC Resources:

[COVID-19 What's New](#)
[CDC Health Alert Network \(HAN\)](#)

CDC Vaccines

CDC Clinician Outreach and Communication Activity (COCA)

From: CDCInfoResponse <[REDACTED]>
Sent: Wednesday, March 3, 2021 1:50 PM
To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <[REDACTED]>
Subject: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events;
[CDC-1460726-X0X9M8] CRM:09092401

Please let us know if you are able to respond to this inquiry or if you would like us to forward the inquiry to another program. This inquiry is being escalated because the answer could not be found in CDC resources.

To close the case, you may reply directly to this e-mail, keeping the original subject line and historical e-mail thread in your reply. Please let us know if your group will provide the answer directly to the inquirer below, or provide a reply for us to send back.

To better serve the inquirer, please reply within 3 business days of receipt of this escalation. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Thank you for your assistance.

OO/PR#14312/17771/11109

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Message -----

Sent: 3/3/2021
From: Clinician
Subject: COVID-19 vaccine adverse events
Email Address: [REDACTED]

Question: From the Israel vaccine adverse event monitoring team:

We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC.

Optional Information

Name: Dr. Roe Singer
Title: Deputy Director, Division of Epidemiology, MoH Israel
Organization: SLHD - Israel Ministry of Health
Phone: [REDACTED]
Other Email: [REDACTED]
Address:
Jerusalem, Israel
PII Extraction:

VaST Agenda – April 5, 2021

Open session

1:30 - 3:00

1:30-1:35 - Announcements, Meeting Expectations and Processes

1:35-1:55 - Israel's Covid-19 vaccine safety data (Emilia Anis, Israel MOH)

1:55-2:05 - Discussion

2:05-2:15 - FDA methods for data mining (Bethany Baer, FDA)

2:15-2:20 - Discussion

2:20-2:40 - FDA CMS RCA (Richard Forshee, FDA)

2:40-2:45 - VSD and VA RCA, overview of plans (Tom Shimabukuro and Fran Cunningham)

2:45-3:00 - Discussion

Adverse events following vaccination COVID-19

Data updated March 31st 2021



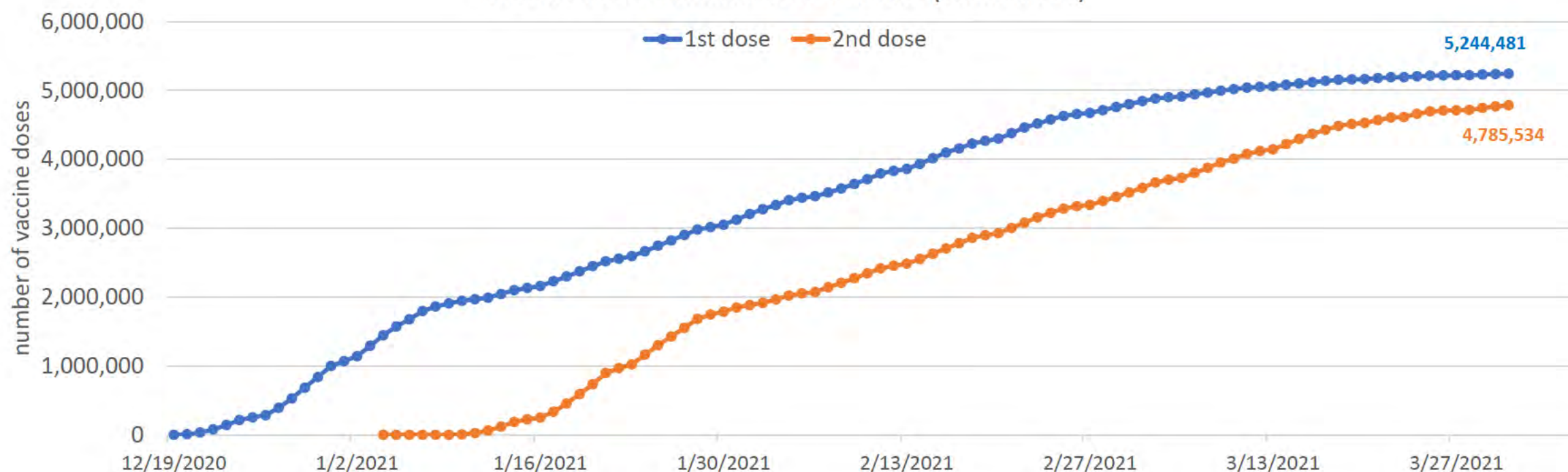
Division of Epidemiology
Public health services
Ministry of Health Israel

Sources of adverse events reports include:

- Hospitals
- HMOs
- Emergency Medical Services - MDA (for individuals who are vaccinated in nursing homes)
- The Medical Department and the Patient Safety Unit at the MoH
- Israeli Defense Forces (IDF)

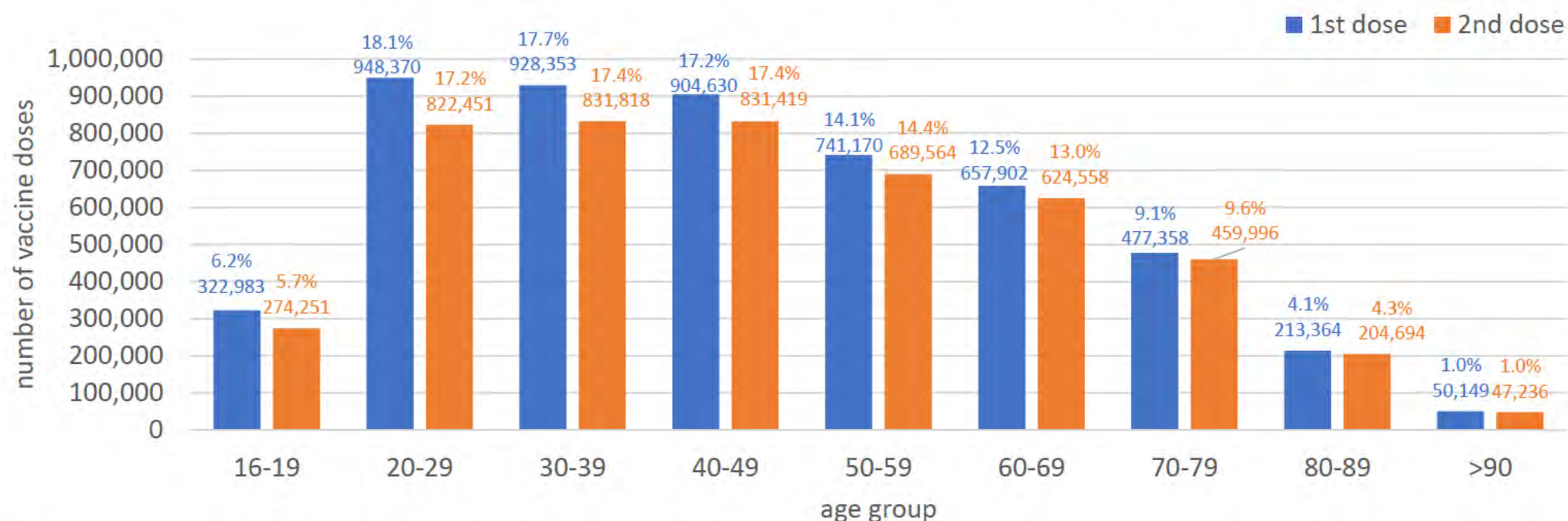
Vaccine doses administered in Israel

Vaccine doses administered in Israel (cumulative)



Distribution of vaccine recipients according to age

Distribution of vaccine recipients in Israel according to age

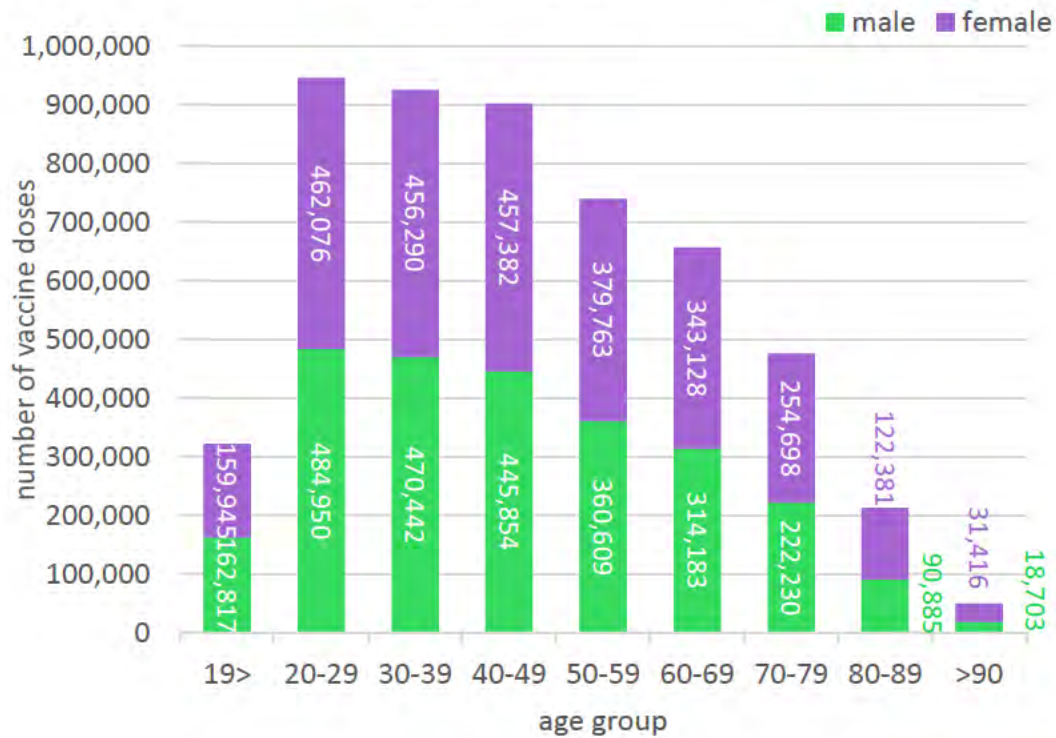


AgeGroup	16-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90<
Vaccine coverage by age group 1 st dose	55.3%	72.9%	77.6%	82.3%	87.2%	88.7%	97.3%	94.6%	97.4%
Vaccine coverage by age group 2 nd dose	47.0%	63.2%	69.5%	75.7%	81.1%	84.2%	93.7%	90.8%	91.7%

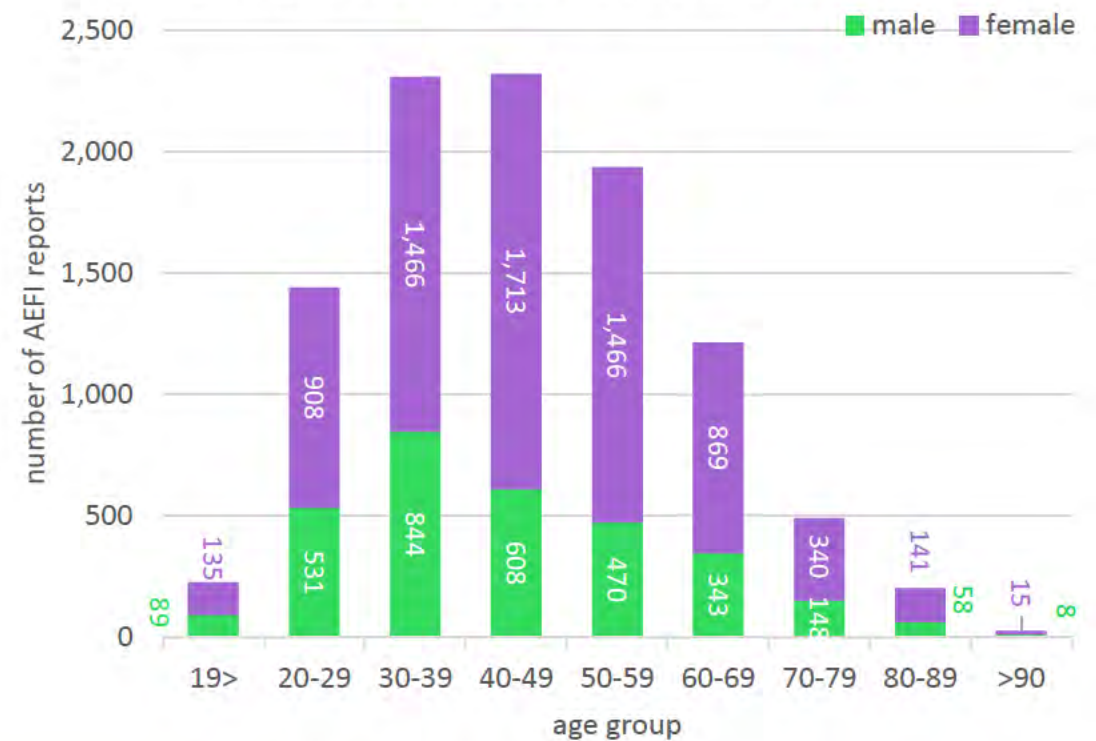
PSICOV00004381

Age and sex distribution among vaccine recipients and those who reported adverse events - FIRST DOSE

Distribution according to age group and sex among recipients of first vaccine dose.



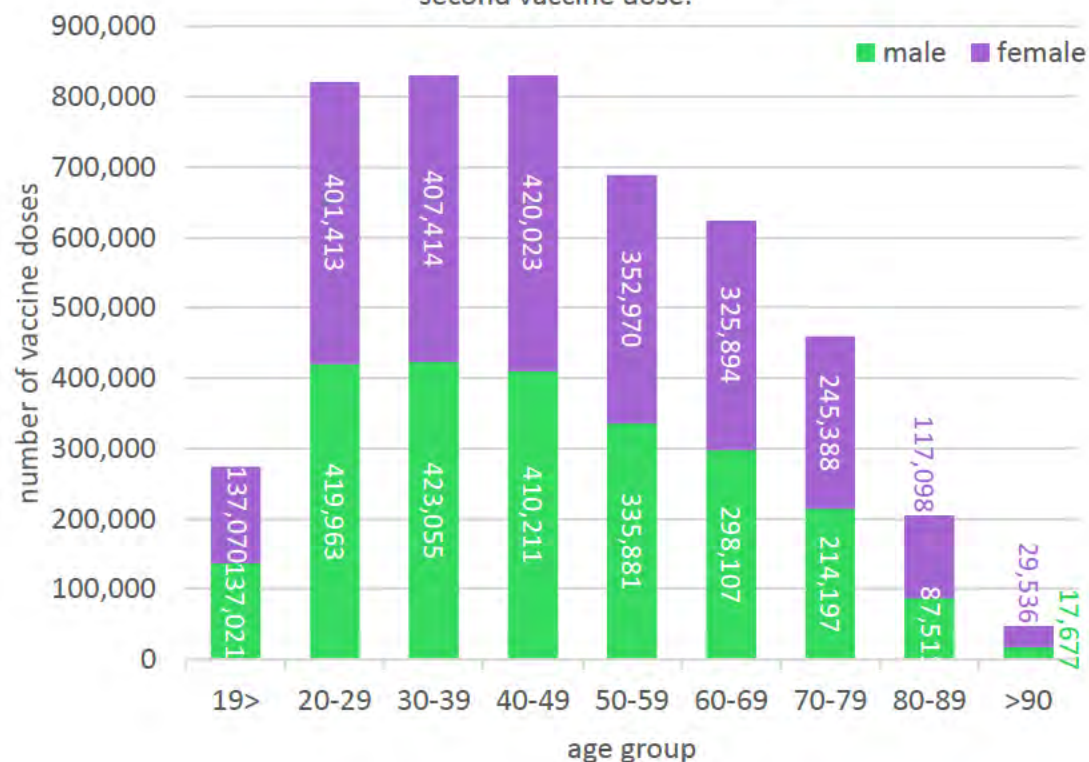
Distribution according to age group and sex among individuals reporting adverse events following first dose vaccination.



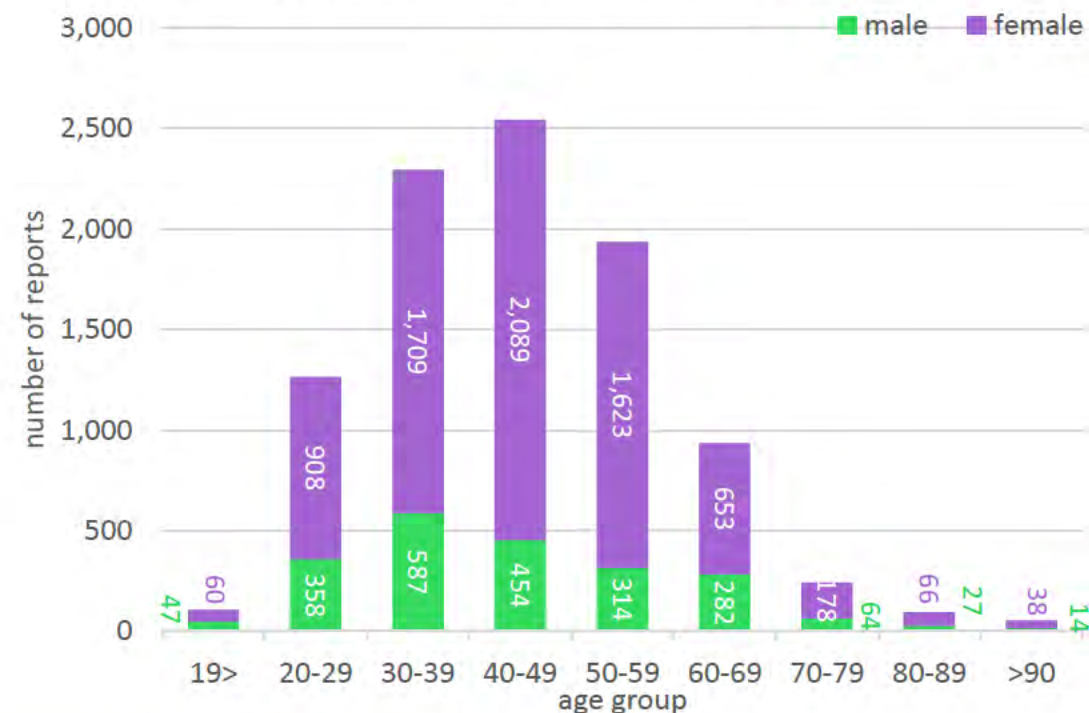
Women and younger individuals are more likely to report adverse reactions following vaccination relative to their proportion among the vaccine recipient population

Age and sex distribution among vaccine recipients and those who reported adverse events - SECOND DOSE

Distribution according to age group and sex among recipients of second vaccine dose.

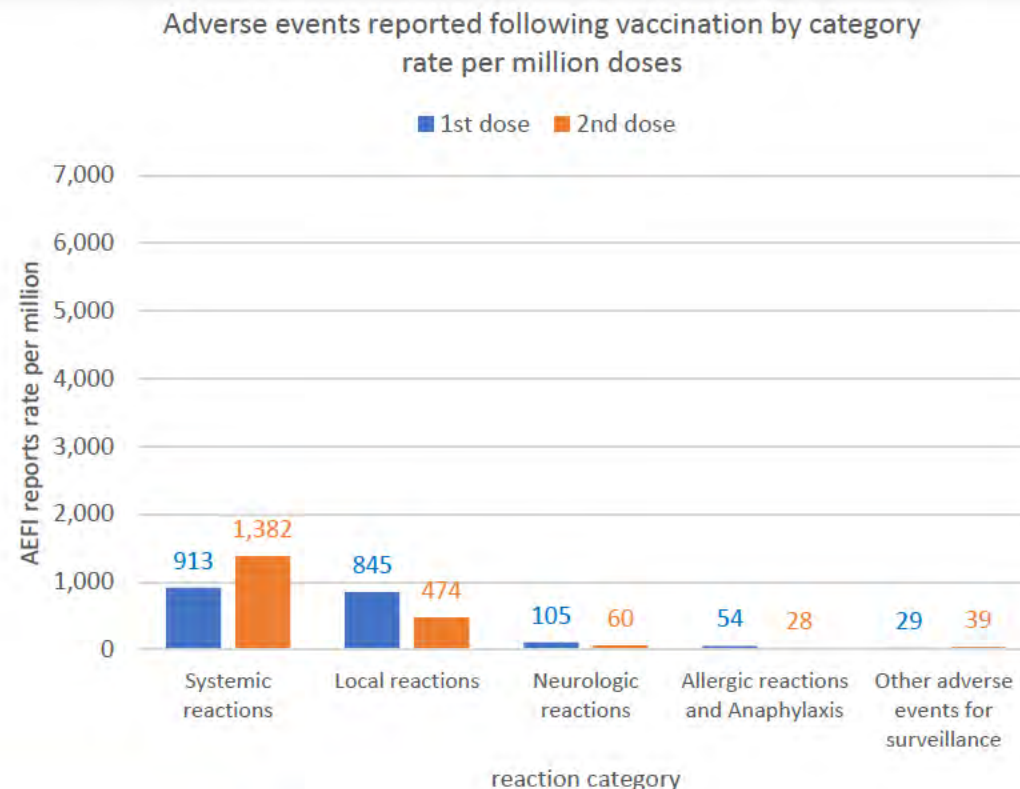
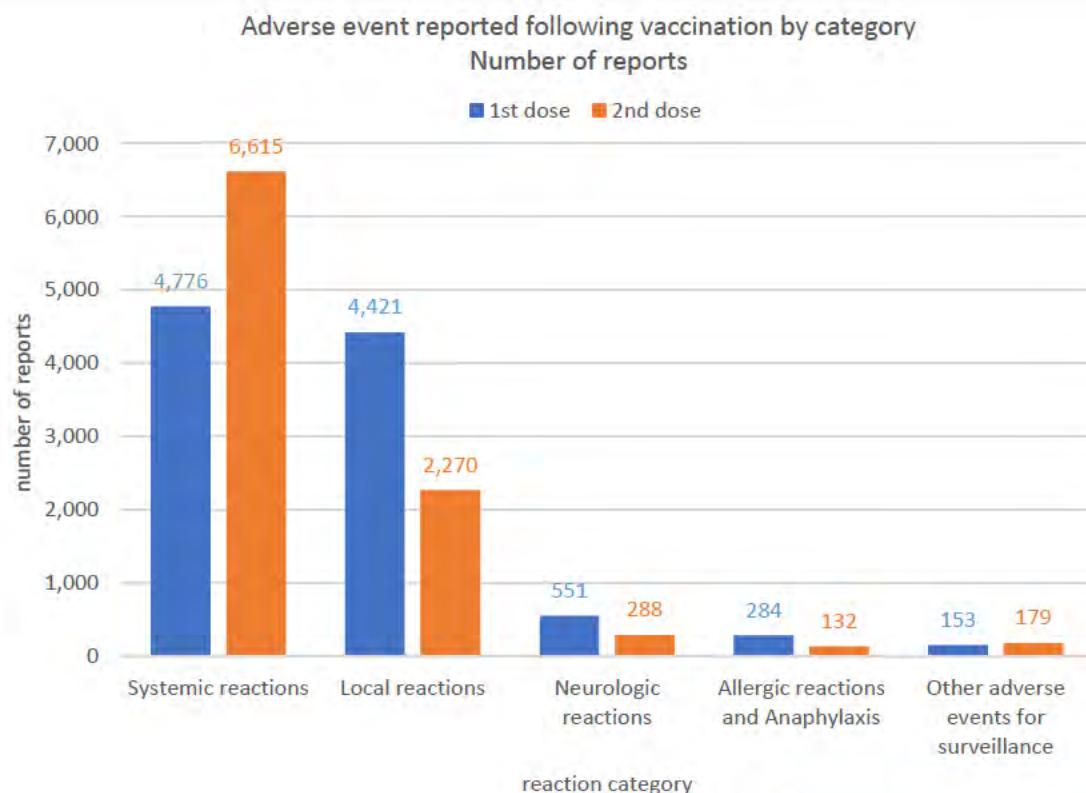


Distribution according to age group and sex among individuals reporting adverse events following second dose vaccination



Women and younger individuals are more likely to report adverse reactions following vaccination relative to their proportion among the vaccine recipient population

Adverse events following vaccination by category

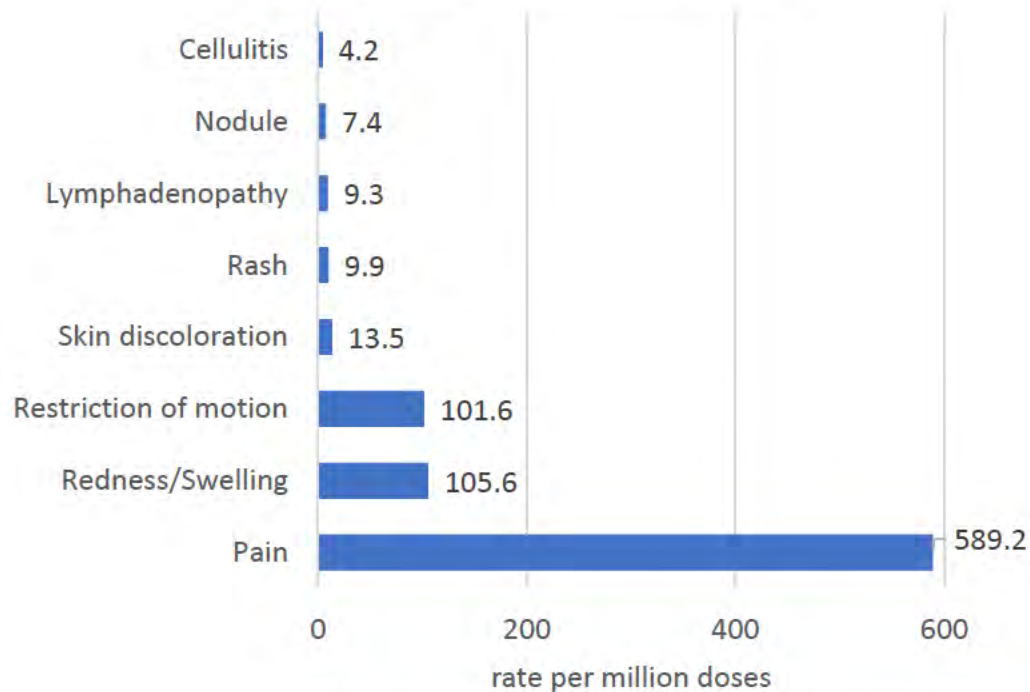


Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Updated 31/03/2021
PSICOVID_00004384

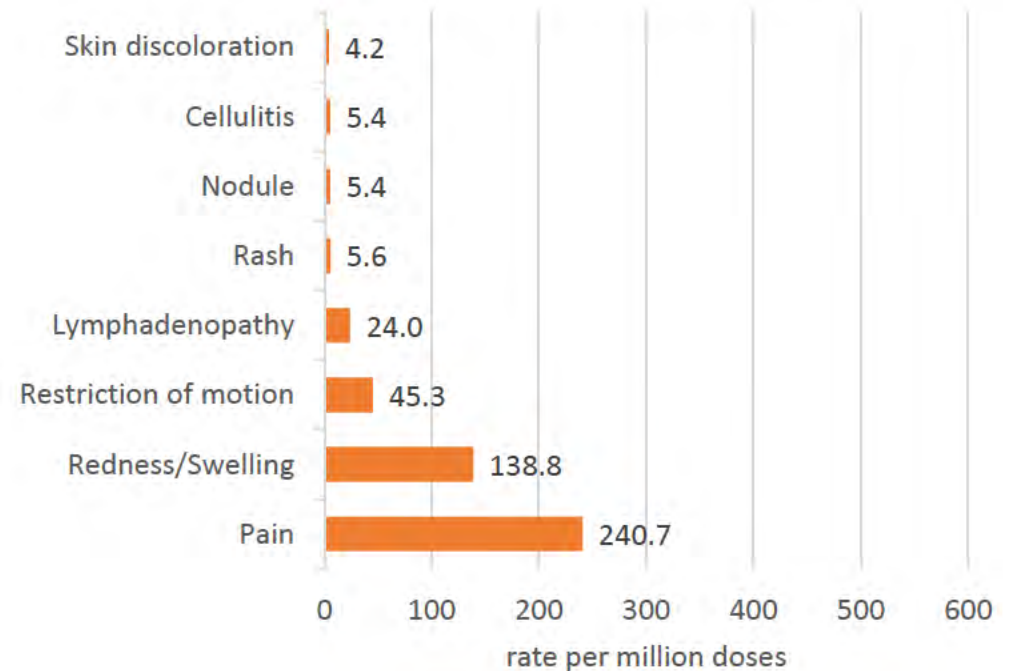
Local reactions

Local reactions (at injection site) reported following vaccination, rate per million doses- first dose



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

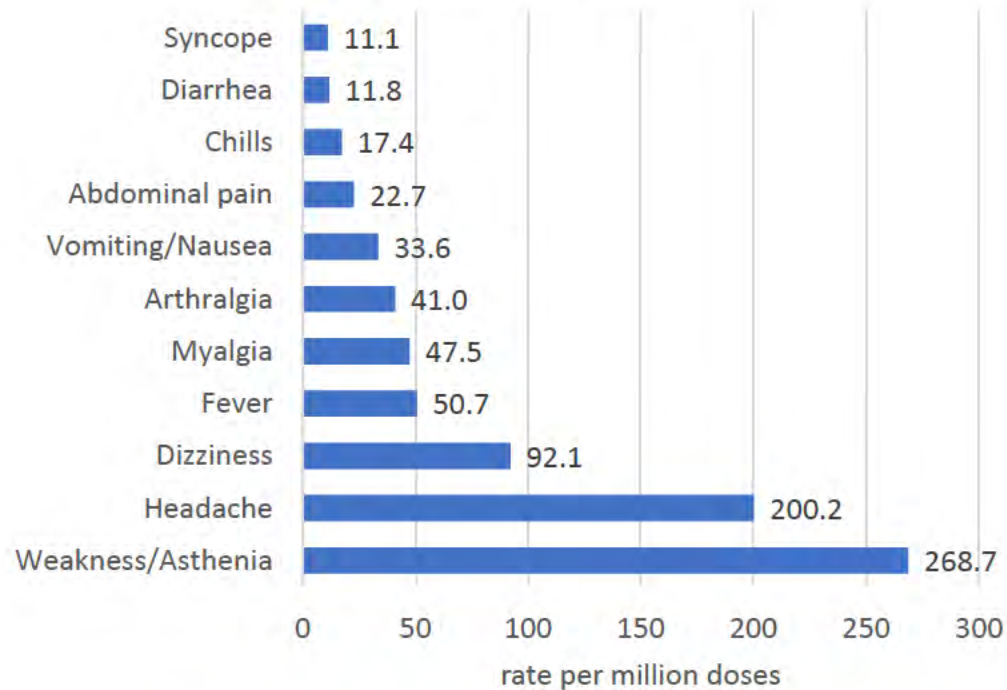
Local reactions (at injection site) reported following vaccination, rate per million doses- second dose



Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

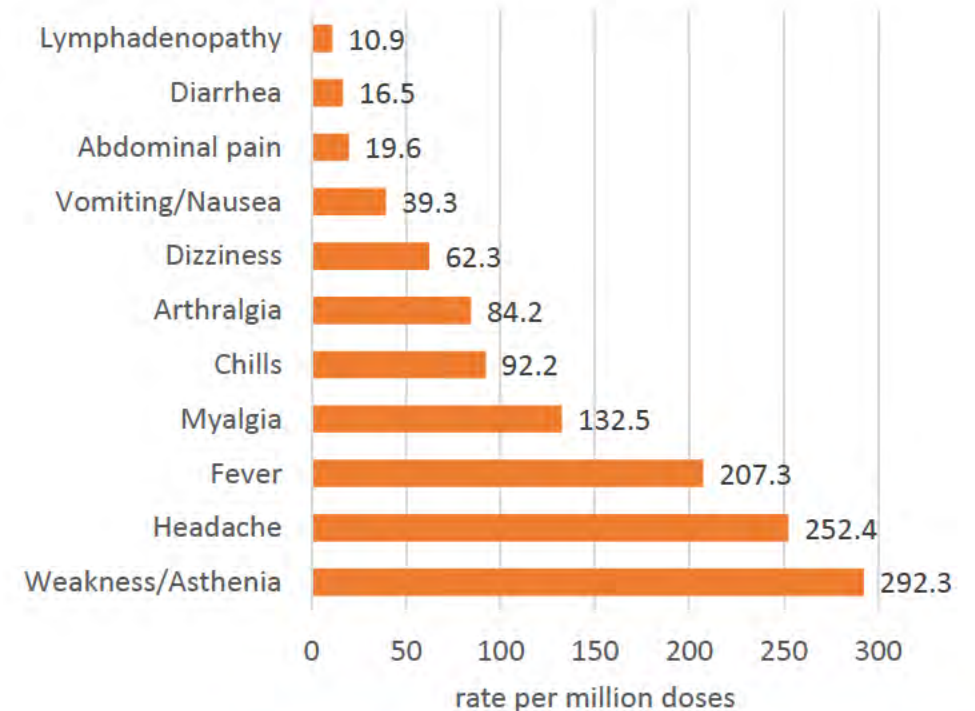
Systemic reactions

General reactions reported following immunization, rate per million doses- first dose



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

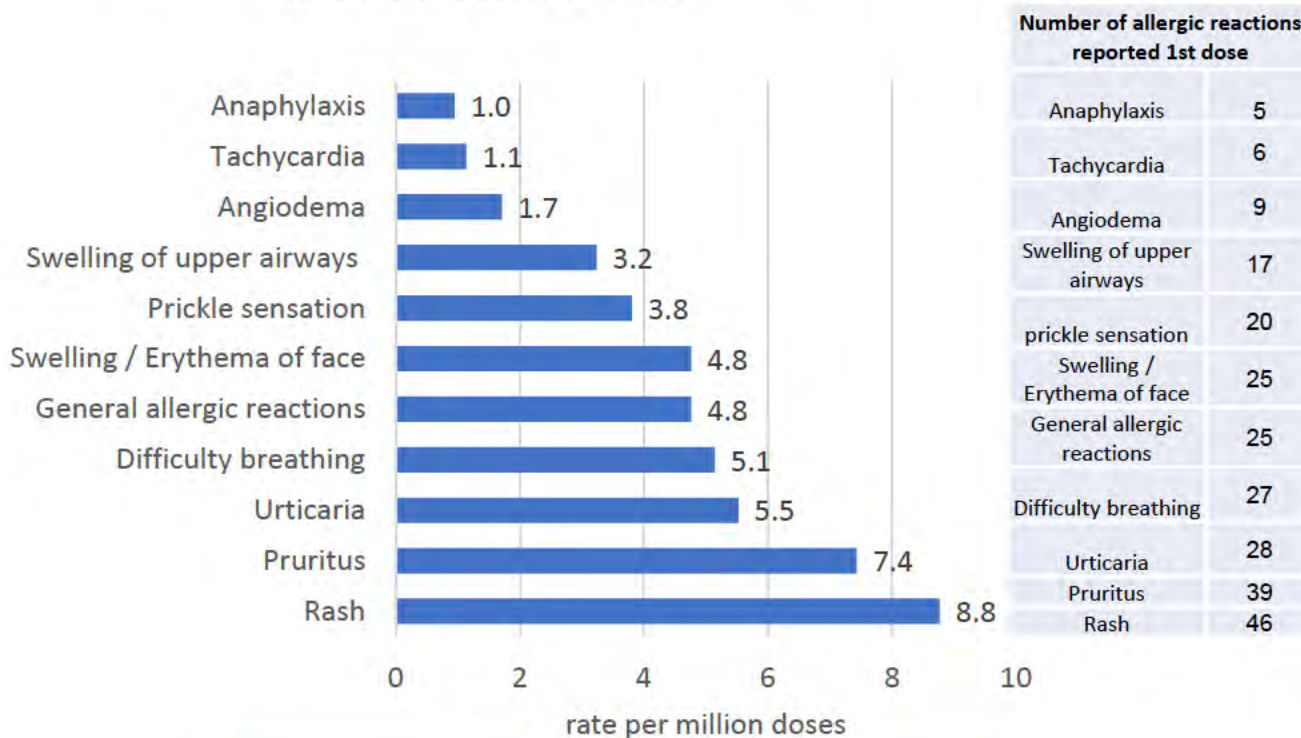
General reactions reported following immunization, rate per million doses- second dose



Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

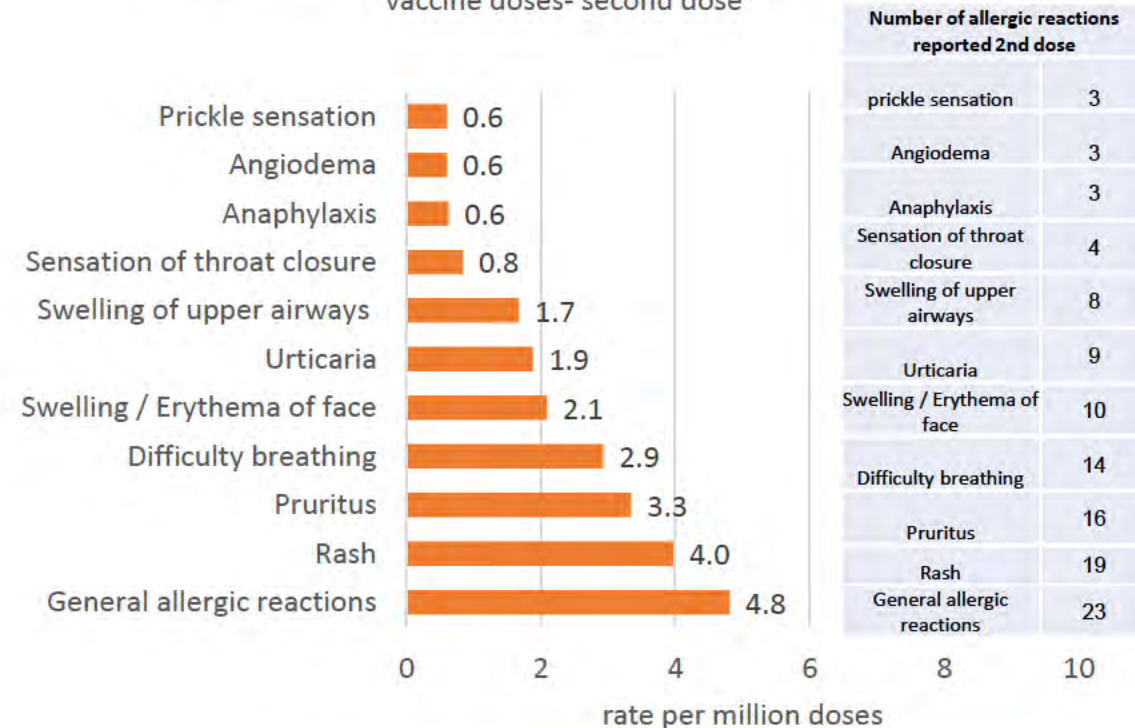
Allergic reactions

Allergic reactions reported following vaccination, rate per million vaccine doses- first dose



Rate per million vaccine doses out of 5,244,481 vaccine 1st dose recipients

Allergic reactions reported following vaccination, rate per million vaccine doses- second dose



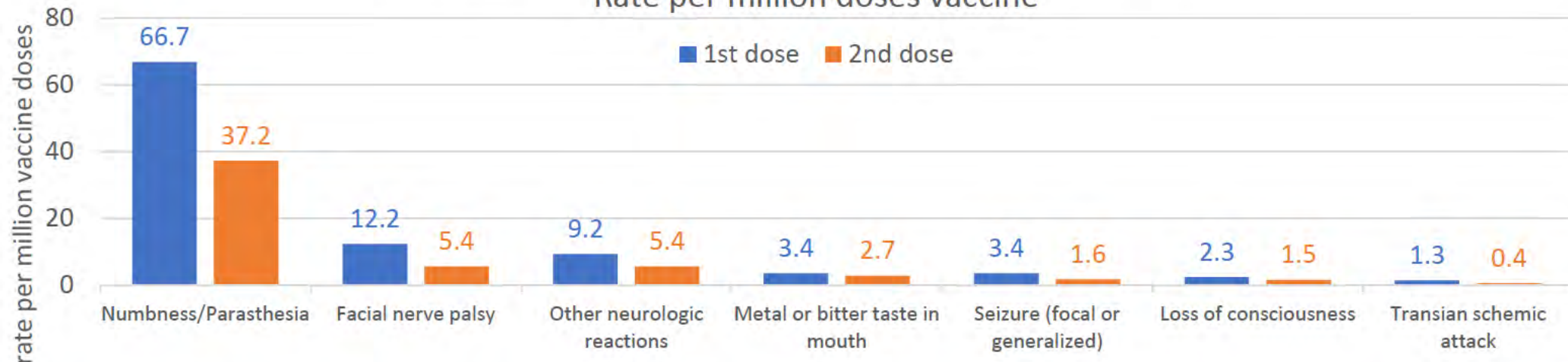
Rate per million vaccine doses out of 4,785,534 vaccine 2nd dose recipients

Neurologic reactions

Number of neurologic reactions reported

	Numbness/ Parasthesia	Facial nerve palsy	Other neurologic reactions	Metal or bitter taste in mouth	Seizure (focal or generalized)	Loss of consciousness	Transient ischemic attack
1 st dose	350	64	48	18	18	12	7
2 nd dose	178	26	25	13	8	7	2

Rate of neurological reactions reported following vaccination
Rate per million doses vaccine



Updated 31/03/2021

PSICOVID_00004388

Neurologic reactions

		Bell's palsy (1 case pregnant)		Blurred vision		Sudden sensorineural hearing loss		Abducens nerve palsy		Vertigo		Oculomotor nerve palsy		Trigeminal neuralgia		Seizures		Transient Ischemic Attack		Guillain Barré syndrome (1 case exacerbation)		Multiple sclerosis (1 case exacerbation, 1 new case)		Brachial plexitis	
Age group		1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose	1 st dose	2 nd dose
	<20	1	1													2	1								
	20-29	3	2		1	1								1		2	1	1		1					
	30-39	7	2	3		1	1									2	1								
	40-49	13	5	2	3		2			1						1	5	1				1			
	50-59	11	10	6	1	2	1				1					2				1					
	60-69	16	4	2		1	1	1	1	1	2	1				1		1		1	1			1	
	70-79	9	2			1			1							4		1	1	1		1			
	80-89	4				1	2		1							4		3							
	>90																	1							
	Total	64	26	13	5	7	7	1	3	2	3	1		1		18	8	7	2	4	1	2		1	
Follow-up second dose		38	Not relevant	10	Not relevant	5	Not relevant	1	Not relevant	0	Not relevant	1	Not relevant	1	Not relevant	12	Not relevant	6	Not relevant	1	Not relevant	2	Not relevant	1	Not relevant
Expected number of cases in population age 16 and older, for same time period of vaccination project and same population group		168	128	51	39	180	135	41	30	465	341	17	12	41	31	1372	1018	1258	920	139	110	334	260	13	9

The observed numbers are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – i.e morbidity cases following the first and second dose is compared to morbidity cases in hospitalized patients from December - March and January - March respectively.

NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected numbers cannot be presented.

Updated 31/03/2021
PSICOVID_0004389

Data is based on adverse events reported to the MoH | Some individuals reported more than one adverse event

Other adverse events of interest

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Hematological	Thrombocytopenia	0.6	26.9	0.4	21.0
	Purpura	0.2	21.2	Not reported	15.2
Infections	Sepsis	0.2	71.1	Not reported	53.5
	Herpes zoster	3.4	44.2	3.6	33.4
	Herpes simplex	1.3	15.2	1.3	10.5
	Necrotizing Fasciitis	0.2	6.5	Not reported	4.8
Neurological	Transient Ischemic Attack	1.3	201.8	0.4	147.6
	Encephalitis	0.2	1.4	Not reported	1.1
	Diplopia (double vision)	0.4	9.3	0.6	6.8
	Acute hearing loss	1.3	28.9	1.5	21.6
	Shoulder weakness and severe pain	0.2	2.1	Not reported	1.5
	Facial weakness and severe pain	0.2	6.6	Not reported	5.0
	Blurred vision	2.5	8.2	1.0	6.3
	Vertigo	0.4	59.7	0.6	43.3
	Guillain barre syndrome	0.8	22.3	0.2	17.7

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

The observed rates are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – i.e morbidity rates following the first and second dose is compared to morbidity rates in hospitalized patients from December - March and January - March respectively.

NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected rates cannot be presented.

PSICOVID_00004390

Other adverse events of interest

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Cardiovascular	Myocardial infarction	0.6	746.1	0.2	554.1
	Heart failure	0.4	859.2	Not reported	648.6
	Subarachnoid hemorrhage	0.2	19.9	Not reported	14.2
	Vasculitis	Not reported	7.3	0.2	4.5
	Pericarditis	1.0	48.7	2.1	36.6
	Myocarditis (including Perimyocarditis)	1.1	21.3	11.7	15.6
	Cardiac tamponade	0.2	3.8	Not reported	2.5
	Venous thrombosis (DVT)	Not reported	65.2	0.6	48.1
	Superficial venous thrombosis	Not reported	3.6	0.2	2.7
	Atrial Fibrillation	0.4	560.4	0.6	414.3
	Stroke	1.0	649.1	0.2	475.6
	Pulmonary embolism	0.2	78.0	0.2	56.4
	Pericardial effusion	0.4	33.9	0.2	26.8
Ophthalmological	Retinopathy	0.2	0.8	Not reported	0.5
Rheumatology	Arthritis	Not reported	252.7	0.2	191.6

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

The observed rates are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – i.e morbidity rates following the first and second dose is compared to morbidity rates in hospitalized patients from December - March and January - March respectively.

NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected rates cannot be presented.

PSICOVID_00004391

Other adverse events of interest

Other AEs of interest following vaccination (rate per million vaccine doses) compared to expected rates in the general population according to morbidity data from the corresponding periods of years 2017-2019

Other adverse events of interest	Medical diagnosis	AE rates following first dose (Dec-Mar)	Expected rates (hospitalization data Dec-Mar 2017-2019)	AE rates following second dose (Jan-Mar)	Expected rates (hospitalization data Jan-Mar 2017-2019)
Pregnant (rate calculated out of women ages 16-49 whom received the vaccine)	Missed abortion	1.3	1909.4	Not reported	1473.1
	IUFD	1.3	71.6	Not reported	53.8
	CMV	Not reported	3.8	0.7	3.2
Respiratory	Pleuritis	0.2	2.4	Not reported	1.7
	Pulmonary edema	Not reported	259.8	0.2	196.0
	Severe acute respiratory syndrome	Not reported	177.5	0.2	132.9
Organ damage	Acute liver damage	0.2	3.9	Not reported	2.8
	Acute kidney damage	0.2	227.4	Not reported	168.7
Other	Erythema Multiforme	0.2	3.4	Not reported	2.6
	Loss of smell (anosmia)/loss of taste (ageusia)	1.3	1.8	1.0	1.2
	Appendicitis	Not reported	315.9	0.2	235.3
	Acute thyroiditis	Not reported	2.4	0.2	1.9
	Multiple sclerosis (1 relapse and 1 new diagnosis)	0.4	53.6	Not reported	41.8
	Hemorrhagic cystitis	0.2	4.9	Not reported	3.9
	rhabdomyolysis	Not reported	20.6	0.2	16.0

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count morbidity within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of morbidity following vaccine administration.

The observed rates are compared to the morbidity data in hospitalized patients from 2017-2019 which includes morbidity data reported among all individuals 16 years and older from the corresponding periods – i.e morbidity rates following the first and second dose is compared to morbidity rates in hospitalized patients from December - March and January - March respectively.

NOTE: In addition to the data presented in the table, the MoH monitors other reactions for which expected rates cannot be presented.

PSICOVID_00004392

Myocarditis following vaccination

To date, 62 cases of myocarditis following vaccination have been reported

Myocarditis after first dose (N=6)

- 4 males, 2 females
- 1 case myocarditis, 5 cases of Perimyocarditis
- 4 events occurred within 10 days of receiving the vaccine, 1 event occurred within 2 weeks and 1 event occurred within 3 weeks following vaccination.
- 3 cases with comorbidities (HTN, dyslipidemia)
- All cases were discharged from the hospital and are under observation in the community
- 2 cases received a second dose with no adverse reactions reported

Myocarditis after second dose (N=56)

- 50 males and 6 females
- 37 cases of Myocarditis, 19 cases of Perimyocarditis
- 23 events occurred within 10 days of receiving the vaccine, 2 events occurred within 2 weeks, 1 events occurred within 3 weeks, 2 events occurred within 4 weeks following vaccination.
- 28 cases with comorbidities (HTN, smoking, asthma, dyslipidemia, DM, hypercholesterolemia)
- 53 cases were discharged from the hospital and are under observation at community level. 1 case is under investigation, 2 cases died (1 case fulminant myocarditis, 1 case is still under investigation)
- None of the cases reported adverse reactions after receipt of the first dose

Pericarditis following vaccination

To date, 15 cases of Pericarditis following vaccination have been reported

Pericarditis after first dose (N=5)

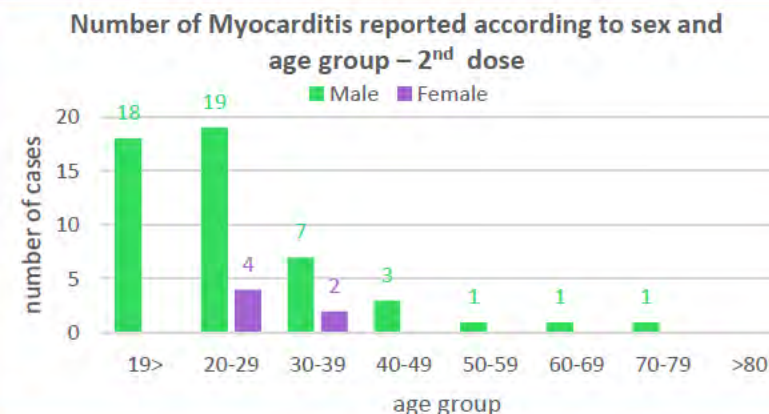
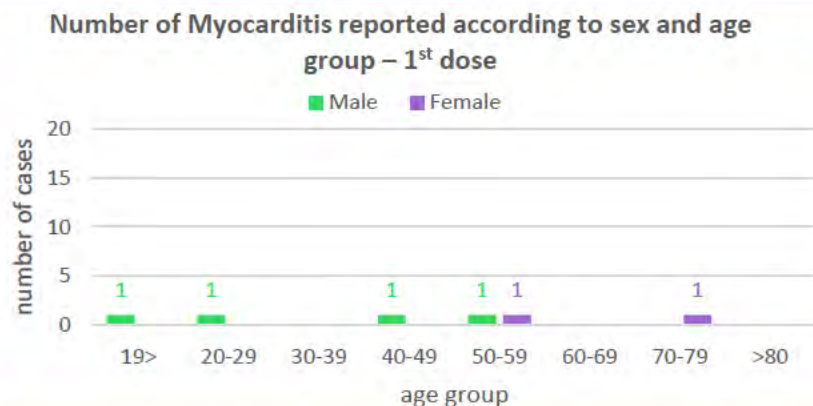
- 3 males, 2 females
- All events occurred within 4 days of receiving the vaccine.
- 2 cases with comorbidities (history of Pericarditis, heart valve)
- All cases were discharged from the hospital and are under observation in the community
- 3 cases received a second dose with no adverse reactions reported

Pericarditis after second dose (N=10)

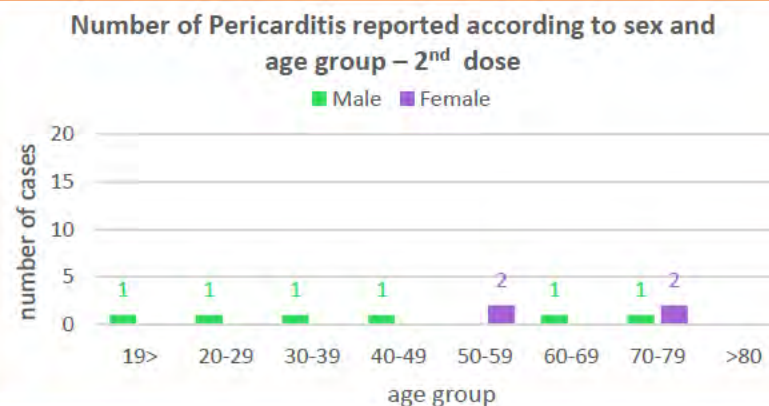
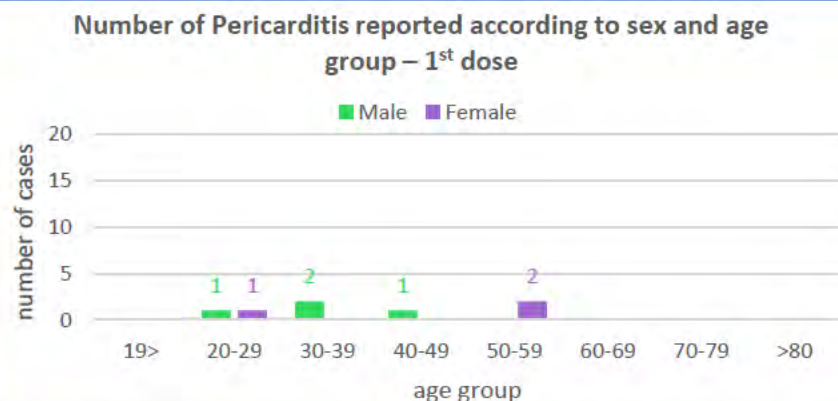
- 6 males and 4 females
- 8 events occurred within 7 days of receiving the vaccine, 1 events occurred within 3 weeks, 1 events occurred within 5 weeks following vaccination.
- 8 cases with comorbidities (HTN, obesity, hypercholesterolemia, dyslipidemia, renal disease)
- 9 cases were discharged from the hospital and are under observation at community level. 1 is under investigation.
- None of the cases reported adverse reactions after receipt of the first dose

Myocarditis / Pericarditis following vaccination

Myocarditis / Perimyocarditis

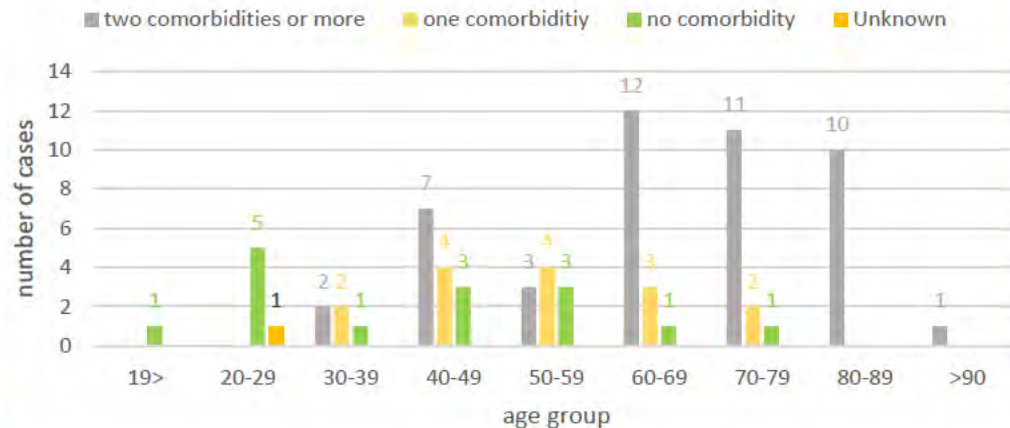


Pericarditis



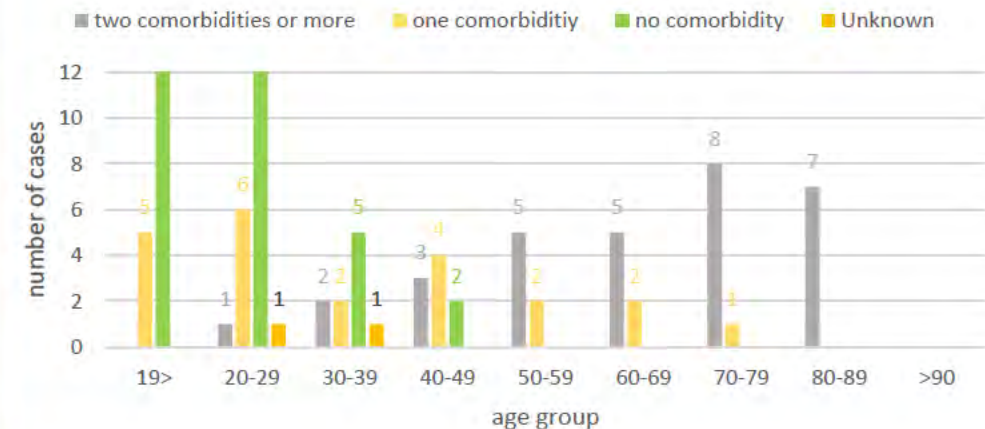
Hospitalizations reported following vaccination

Reported hospitalizations according to age and comorbidities -
First dose (N=77)



Among 77 hospitalizations following receiving the first dose, 34 cases were related to neurological diseases out of which 30 cases had comorbidities, 25 hospitalizations were related to underlying cardiovascular diseases out of which 18 had comorbidities, 6 hospitalizations were related to allergic reactions, 2 infectious and 7 hospitalizations were related to other underlying diseases. 3 hospitalizations were related to pregnancy complications.

Reported hospitalizations according to age and comorbidities -
second dose (N=95)



Among 95 hospitalizations following receiving the second dose, 75 cases were related to cardiovascular diseases and of those 38 were with significant underlying diseases. 10 hospitalizations were related to underlying neurological diseases and of those 8 were with significant underlying diseases and 4 hospitalizations were related to underlying respiratory diseases, and 8 hospitalizations were related to other underlying diseases.

Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

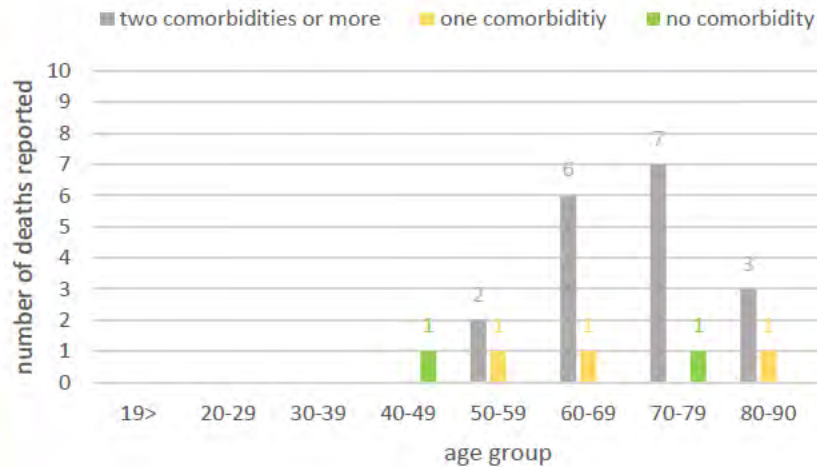
Deaths reported following vaccination

- 48 persons were reported to die in proximity to vaccination (up to 30 days following vaccination).
- 42 deaths occurred within 10 days following vaccination
- Out of 48 reported cases, 14 are <60 y old:
 - 2 were diagnosed in ER with myocarditis (1 case fulminant myocarditis, 1 case still under investigation)
 - 2 PM in cases of sudden death excluded myocarditis in one and showed blocked LAD.
 - 10 cases are under investigation: relatively young persons with sudden death.

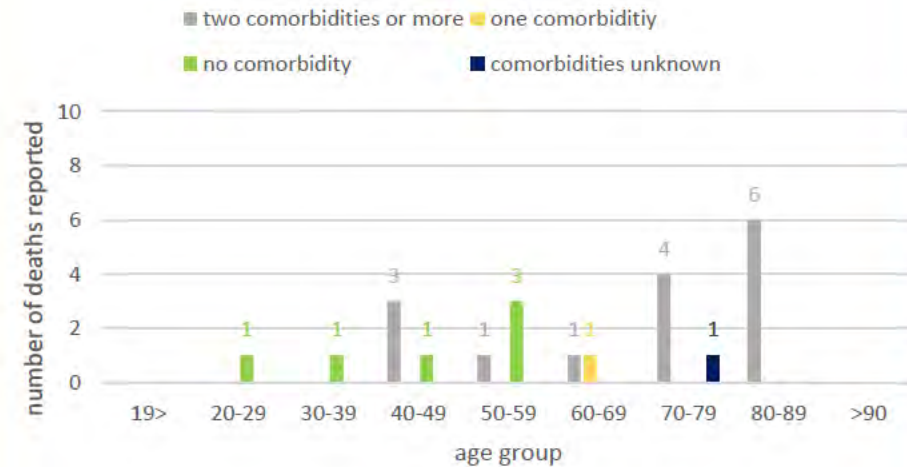
Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Deaths reported following vaccination

Deaths reported according to age and comorbidities 1st dose (N = 25)



Deaths reported according to age and comorbidities 2nd dose (N = 23)



Reports among vaccine recipients
1st dose: 5,244,481 2nd dose: 4,785,534

Deaths reported following vaccination observed and expected

Age group	Mortality cases reported following 1 st dose	Mortality cases expected all causes (Dec-Mar)	Sudden death reported following 1 st dose	Sudden death expected (Dec-Mar)	Mortality cases reported following 2 nd dose	Mortality cases expected all causes (Jan-Mar)	Sudden death reported following 2 nd dose	Sudden death expected (Jan-Mar)	Total cases reported
Male									
20-29	0	74	0	0	0	48	0	0	0
30-39	0	108	0	0	1	72	1	0	1
40-49	0	235	0	1	4	165	4	1	4
50-59	2	564	2	5	3	392	2	4	5
60-69	4	1220	1	5	2	865	0	3	6
70-79	6	2353	0	6	1	1727	0	3	7
80<	3	4349	0	9	3	3153	0	6	6
Female									
20-29	0	30	0	0	1	20	0	0	1
30-39	0	59	0	0	0	41	0	0	0
40-49	1	139	1	0	0	95	0	0	1
50-59	1	336	1	1	1	235	1	1	2
60-69	3	773	0	1	0	561	0	1	3
70-79	2	1714	1	4	4	1252	0	3	6
80<	3	5398	0	13	3	3889	0	10	6
Total	25	17,352	6	45	23	12,515	8	32	48

Note: Despite normalization to the number of vaccinees, observed and expected rates cannot be directly compared, because the observed cases are counted differently than the expected ones. The observed cases count deaths within a time window of a defined event (vaccine administration). The expected cases are calculated by the cumulative incidence over several calendar months. However, the expected cases do give a general order of magnitude for comparison of deaths following vaccine administration.

No specific signal associated with all causes of death and specifically sudden death

The overall mean of expected total deaths in the population of Israel 2015-2018, for December-March for the first dose, and January-March for the second dose, normalized for the number of vaccinated persons.

COVID-19 vaccination Israel “BACK TO LIFE”

From: [Meaney Delman, Dana M. \(CDC/DDNID/NCBDDD/DBDID\)](#)
To: [Honein, Margaret \(Peggy\) \(CDC/DDID/NCEZID/DPEI\)](#); [Rose, Dale A. \(CDC/DDID/NCEZID/DPEI\)](#)
Cc: [Walke, Henry \(CDC/DDID/NCEZID/DPEI\)](#)
Subject: Email to PH partners
Date: Friday, May 14, 2021 8:40:31 PM

All,

Here is the email going to immunization and clinical partners.

Henry and I discussed and he was in agreement to send to the key public health partners.

Website updates to follow.

Best
Dana

Dana Meaney-Delman, MD MPH

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Friday, May 14, 2021 8:35 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Cc: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)
Subject: FW: For Awareness: Monitoring Reports of Myocarditis

Amanda – this just went and is good to go to AAP, AAFP, and ACP.

Thanks,
Kristen

From: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Sent: Friday, May 14, 2021 8:34 PM
To: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Subject: For Awareness: Monitoring Reports of Myocarditis

Good evening,

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.

Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an

infection or some other trigger. While myocarditis can be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart rhythms, shortness of breath, or chest pain.

As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#).

To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#).

CDC continues to recommend COVID-19 vaccination for people 12 years and older.

Thank you

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From: [Meaney Delman, Dana M. \(CDC/DDNID/NCBDDD/DBDID\)](#)
To: [Walke, Henry \(CDC/DDID/NCEZID/DPEI\)](#)
Subject: FW: Awareness: Monitoring Reports of Myocarditis
Date: Saturday, May 15, 2021 10:31:16 AM

Exhausting- more examples of the disconnect..

Hope yesterday was ok

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)
Sent: Saturday, May 15, 2021 10:28 AM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <[REDACTED]> Greco Kone, Rebecca (CDC/DDPHSIS/OD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[REDACTED]>
Subject: RE: Awareness: Monitoring Reports of Myocarditis

Anita

Thanks so much for asking.

There is a strong contingency in NCIRD that felt there needed to be an acknowledgement of CDC's awareness of the issue and a push for formal reporting to VAERS. Myocarditis and Pericarditis has been observed in Israel and in DoD studies and EMA has put out a statement on this.

The statement is designed to:

- Promote reporting into VAERS because cardiologists and other subspecialists apparently are not aware of VAERS; we do not have a signal yet but there is some concern that this may be due to underreporting
- Address questions circulating because several academic centers are pulling together a case series and are calling around looking for cases to include in a NEJM article that will likely be a preprint
- Reiterate our recommendation to vaccinate despite awareness and investigation of this issue

The initial plan was to wait for the data to be presented at VAST on Monday and then to consider a HAN if needed. After more discussion within CDC and with FDA (particular strong feelings of Melinda, Barbara, Amanda, Sam, and the safety team), this was the agreed upon plan given the attention it was receiving and given that there may not be awareness of myocarditis and VAERS; folks were concerned that cases could be missed and that we need to ensure active reporting. Thankfully all cases in US that we know about have been mild, but there is an anecdotal report of a possible death that is being investigated.

Hope that helps.

Best

Dana

From: Patel, Anita (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Saturday, May 15, 2021 10:04 AM
To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <[REDACTED]> Greco Kone, Rebecca (CDC/DDPHSIS/OD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Subject: Re: Awareness: Monitoring Reports of Myocarditis

Realize I'm just catching up so forgive me if I'm asking a lame question here

Can someone share why are we sending this if it's anecdotal and no changes are happening (no clinician action) vs just adding this as bullet to the webpage for clinician awareness?

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <[REDACTED]>
Sent: Friday, May 14, 2021 8:43 PM
To: Patel, Anita (CDC/DDID/NCIRD/OD); Guo, Angela (CDC/DDID/NCIRD/DVD) (CTR)
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD); Fitter, David L. (CDC/DDPHSIS/CGH/GID); Greco Kone, Rebecca (CDC/DDPHSIS/OD)
Subject: Fwd: Awareness: Monitoring Reports of Myocarditis

Anita and Angela,

This went out to immunization partners through Richard and Kristen. You may want to give pharmacy partners a heads up.

Best
Dana

Dana Meaney-Delman, MD MPH

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Friday, May 14, 2021 8:35:18 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <[REDACTED]>
Cc: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <[REDACTED]>
Subject: FW: For Awareness: Monitoring Reports of Myocarditis

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To: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
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From: [CDC IMS 2019 NCOV Response VTF Policy](#)
To: [Reimels, Elizabeth \(CDC/DDNID/NCIPC/DVP\)](#); [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#)
Cc: [Walter-Garcia, Madison \(CDC/DDID/NCIRD/OD\)](#)
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 1, 2021 9:56:18 PM

Does anyone know who took this one?

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 6:48 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks for the offer, our policy group is working on coordinating a written response with FDA currently so I believe the suspense should be fine as is for now. We will reach out if we need an extension.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 5:38 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>

<[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

MaryBeth/VTF Ops,

If you need more time, I can request an extension from HHS.

Thanks for the update.

Scott F.

CDC EOC Task Tracker

[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Sent: Monday, March 1, 2021 4:13 PM

To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy

<[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer

<[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,

MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>

Sent: Monday, March 1, 2021 4:03 PM

To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [CDC IMS 2019 NCOV Response VTF Operations](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#)
Cc: [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 9:31:31 AM

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

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Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

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From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 9:33:00 AM

Stacey,
Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks
Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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2019 Novel Coronavirus Response

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Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

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Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [CDC IMS 2019 NCOV Response VTF Policy](#)
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Thursday, March 11, 2021 3:18:00 PM

CLOSED – I think we can mark this closed.

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Thursday, March 11, 2021 2:12 PM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sounds good, I think just saying we're working with FDA on it and that they're sending should be sufficient.

Thanks!
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Thursday, March 11, 2021 2:10 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Can we close out and note that we worked with FDA on a response and they are sending?

I don't have an FDA POC yet.

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Thursday, March 11, 2021 1:58 PM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon Susan,

Checking in again on this Task ID - any update from FDA? Can we close out on our end?

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:05 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Understood, thanks for the update Susan! I'll keep an eye out for further information so we can close it out on our end.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:04 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning,
Heard from the SME that they are reviewing a response and returning to FDA by COB today. I'm trying to get clarification if FDA is sending and if so a POC to provide for HHS Soc so that we can close this one out. Doesn't sound like we are sending the response to the requestor but need to confirm.

Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Wednesday, March 10, 2021 9:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Checking the progress on this RFI for the point of contact to the Israeli National Focal Point that you were working on a written response with FDA. Do you think this is on track for completion by Friday of this week?

Thanks,
MaryBeth/VTF Ops

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:22 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Heard back from Tom.

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. We don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested.

Can we ask for an extension until sometime until next week given the complexity of the response?

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to

discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [CDC IMS 2019 NCOV Response VTF Operations](#)
Cc: [CDC IMS 2019 NCOV Response VTF Policy](#)
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 15, 2021 3:03:00 PM
Attachments: [Myocarditis Response.docx](#)

I know we closed this last week thinking that FDA would provide the response but the program has sent to us. Can you share with HHS so that they can return?

Thanks
Susan McClure

Co-lead | Vaccine Task Force Policy
COVID-19 Response
Centers for Disease Control and Prevention (CDC)

[REDACTED]

www.cdc.gov/COVID19

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, March 15, 2021 11:06 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey
(CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

See attached response that includes content from both CDC and FDA. Sorry for the delay.
Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)

[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:20 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey
(CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli

National Focal Point to discuss Pfizer vaccine

Thanks. Will ask for an extension.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. I don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested. Thanks.

Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 10:55 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Since this is due at 5 pm today, let me know if we need to ask for more time. I think that is possible.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:39 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Stacey,
Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks
Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy

<[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer

<[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Sent: Monday, March 1, 2021 4:13 PM

To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy

<[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer

<[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,

MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>

Sent: Monday, March 1, 2021 4:03 PM

To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

<[REDACTED]>

Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD)

<[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra

(CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National

Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [CDC IMS 2019 NCOV Response VTF Operations](#)
To: [CDC IMS 2019 NCOV Response VCU Policy](#)
Cc: [Reimels, Elizabeth \(CDC/DDNID/NCIPC/DVP\)](#); [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#); [Cone, George Edward \(CDC/DDID/NCIRD/OD\)](#); [Gogstad, Eric \(CDC/DDID/NCIRD/ID\)](#); [Fitter, David L. \(CDC/DDPHSIS/CGH/GID\)](#); [Lubar, Debra \(CDC/DDID/NCEZID/OD\)](#); [Fox, Kimberley \(CDC/DDID/NCIRD/DBD\)](#); [Culp, MaryBeth \(CDC/DDID/NCIRD/DBD\)](#); [Petersen, Lisa \(CDC/DDID/NCIRD/OD\) \(CTR\)](#)
Subject: Fw: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 1, 2021 4:17:11 PM

Good afternoon VTF Policy,

Apologies we are late in passing this RFI along, but there's a request for contact from Israel below re: vaccine adverse effects. Perhaps someone from the Vaccine Evaluation or Global Section would be able to respond. Please triage this request and let us know when the task is complete. Internal VTF suspense of noon tomorrow 3/2 if possible. EOC suspense 3/2 1700.

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:12 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety
Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])
Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task. Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [Reimels, Elizabeth \(CDC/DDNID/NCIPC/DVP\)](#)
Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 1, 2021 9:24:00 AM

Do we have an FDA contact that we work with so that I can take this from Stacy?

I was about to reach out to the Israeli contact to set something up.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Monday, March 1, 2021 9:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

FDA has indicated they prefer to provide a written response to this inquiry. Since we aren't seeing an increase in myocarditis, should we coordinate with FDA to provide a joint written response?

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Sunday, February 28, 2021 5:48 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Yes, will do.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Sent: Sunday, February 28, 2021 2:28 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal

Point to discuss Pfizer vaccine

Seeing that Denise is out. + Susan

Susan – can you please help coordinate?

Thanks,
-d

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID)
Sent: Sunday, February 28, 2021 2:26 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks, Stacey.

Denise – can you help set this up via policy?

Best,
David

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:35 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks David. Do you want Tom and I to coordinate a call? This was sent to multiple units.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Sent: Sunday, February 28, 2021 11:15 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal

Point to discuss Pfizer vaccine

Importance: High

Stacey and Tom,

Please see below re discussing with Israeli Vaccine FP re myocarditis in people receiving Pfizer vaccine.

Thanks,
David

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Importance: High

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [Tumpey, Abbigail \(CDC/DDPHSS/CSELS/OD\)](#)
To: [Walensky, Rochelle \(CDC/OD\)](#); [Schuchat, Anne MD \(CDC/OD\)](#); [Berger, Sherri \(CDC/OCOO/OD\)](#); [Goldstein, Robert \(CDC/OD/OADPS\)](#)
Subject: Fwd: For Awareness: Monitoring Reports of Myocarditis
Date: Friday, May 14, 2021 8:36:32 PM

FYI.

Get [Outlook for iOS](#)

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Friday, May 14, 2021 8:35 PM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); McNeill, Lorrie (FDA/CBER); Sams, Ian (HHS/ASPA)
Subject: FW: For Awareness: Monitoring Reports of Myocarditis

FYI

From: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Sent: Friday, May 14, 2021 8:34 PM
To: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Subject: For Awareness: Monitoring Reports of Myocarditis

Good evening,

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.

Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. While myocarditis can be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart rhythms, shortness of breath, or chest pain.

As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#).

To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#).

CDC continues to recommend COVID-19 vaccination for people 12 years and older.

Thank you

PLEASE DO NOT RESPOND OR REPLY DIRECTLY TO THIS E-MAIL

This message has been sent to program managers and field staff. Please review the individual announcements for contact information. If you do not see any contact information and need additional information, please contact your program manager. If you need access to the ISD Awardee SharePoint site, please contact your supervisor or your CDC project officer for more information.

Summary of VAERS Reports of myocarditis, pericarditis and myopericarditis following vaccination with mRNA COVID-19 vaccines

Background:

This memo responds to questions posed from the Israeli Ministry of Health to the FDA and CDC. They are investigating a safety signal of myocarditis /myopericarditis in a younger population (16 -30 years old) following administration of Pfizer-BioNTech Covid-19 vaccine. The Ministry of Health stated they received reports of around 40 cases of this adverse event. They did not provide additional details about these cases.

Questions Posed by Israeli Ministry of Health:

1. How many doses of the vaccine were administered to this age group?

The best source of data is <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

2. How many cases of myocarditis / peri-myocarditis were reported in your country?

A search of the U.S. Vaccine Adverse Event Reporting System (VAERS) conducted on February 23, 2021 revealed 27 cases (6 cases of myocarditis, 7 cases of myopericarditis, 14 cases pericarditis).

The following Medical Dictionary for Regulatory Activities (MedDRA) preferred terms were used to conduct the search: myocarditis; eosinophilic myocarditis; hypersensitivity myocarditis; pericarditis; pericarditis adhesive; pericarditis constrictive; pleuropericarditis; pericardial disease; pericardial effusion; pericardial rub; myopericarditis. Reports with sufficient information were reviewed and categorized based on case definitions previously used for surveillance of myopericarditis after smallpox vaccine (<https://www.cdc.gov/mmwr/PDF/wk/mm5221.pdf>).

Reports were included if they contained a diagnosis by of myocarditis, pericarditis or myopericarditis. Reports with pericardial effusion and no other signs of myopericarditis were excluded. If the diagnosis in the narrative was pericarditis but the patient also had elevated troponin they were categorized as myopericarditis.

3. Could you elaborate details on these AE cases (time of diagnosis from the vaccine, first/second dose, risk factors, etc.) ?

Twelve cases occurred after dose 1, 7 cases after dose 2, and the dose was not reported for 8 cases. Four patients had comorbid conditions that could suggest alternate etiologies for the adverse event. These included:

- One patient with subacute pericarditis noted on cardiac MRI. The clinical impression was this pre-dated vaccination
- One patient had a history of recurrent pericarditis
- One patient had recent SARS CoV-2 infection
- One patient had psoriatic arthritis and was on Adalimumab

None of the cases reported other risk factors or causes such as preceding viral infections or other vaccines administered concurrently. However, due to the nature of passive surveillance reports, it is not possible to completely exclude these due to potential incompleteness of reports.

The following table displays additional information about the cases of myopericarditis.

Characteristics	Reports of Myopericarditis/Myocarditis/Pericarditis (N = 27)
Median age, years (range)*	36 (21–84)
Female (%)	10(37)
Male (%)	16 (59)
Gender not reported (%)	1(4)
Median Time to Onset in Days (range)	3 (0-20)

4. Have you assessed the causality between the AE and the vaccine for each of the cases?

During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines. We will continue to monitor this outcome in active and passive surveillance.

Myocarditis/pericarditis is a pre-specified outcome in CDC's Vaccine Safety Datalink (VSD) near real-time sequential monitoring. As of the end of February 2021, the VSD had not detected any statistically significant association or any statistical signals for myocarditis/pericarditis in VSD monitoring.

Of note, SARS-CoV-2 infection has been associated with cardiac complications, including pericarditis.

From: [Daskalakis, Demetre \(CDC/DDID/NCHHSTP/DHP\)](#)
To: [Walke, Henry \(CDC/DDID/NCEZID/DPEI\)](#); [Walensky, Rochelle \(CDC/OD\)](#)
Cc: [Berger, Sherri \(CDC/OCOO/OD\)](#)
Subject: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates
Date: Friday, May 21, 2021 9:26:49 AM

1. There is a HAN in development on Myocarditis. Haven't seen in yet
2. The Push to Pull/end of Pro-Rata proposal includes the Federal retail pharmacy program

Demetre C. Daskalakis, M.D., M.P.H.

COVID CDC Response Role: Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention

[REDACTED]

[REDACTED]

Tel: [REDACTED] | Fax: [REDACTED]

Email: [REDACTED] or [REDACTED]

Pronouns: He/His/Him

[REDACTED] Szilagyi, Peter; [REDACTED] Fink, Doran (FDA/CBER); Kelman, Jeffrey A. (CMS/CM); Kim, David (HHS/OASH); Oshansky, Christine (OS/ASPR/BARDA); Roberts, Chris (NIH/NIAID) [E]; Weiser, Thomas M (IHS/POR); Zhang, Rachel (FDA/CBER);

[REDACTED] Duchin, Jeff (CDC.kingcounty.gov);

[REDACTED] Hahn, Christine (CDC.dhw.idaho.gov);

[REDACTED] Lett, Susan (DPH);

[REDACTED] Plescia, Marcus (CDC.astho.org);

[REDACTED] Zahn, Matt (CDC.ochca.com); Zucker, Jane R. (CDC.health.nyc.gov)

Cc: Chamberland, Mary (CDC/DDID/NCIRD/OD) (CTR); Gargano, Julia Marie W. (CDC/DDID/NCIRD/DVD); Gersten, Jack (CDC/DDID/NCIRD/OD) (CTR); Hadler, Stephen (CDC/DDID/NCIRD/DBD); Lindley, Megan C. (CDC/DDID/NCIRD/ISD); Moulia, Danielle L. (CDC/DDID/NCIRD/OD); Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD); Reisman, Nicole (CDC/DDID/NCBDDD/DHDD); Scobie, Heather (CDC/DDPHSIS/CGH/GID); Shanley, Edwin (CDC/DDID/NCIRD/OD); Wallace, Megan (CDC/DDID/NCIRD/DVD); Acosta, Anna (CDC/DDID/NCIRD/DBD); [REDACTED] Carlton, Julie (CDC/DDPHSIS/CGH/GID); Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Cohn, Amanda (CDC/DDID/NCIRD/OD); Cox-Ganser, Jean (CDC/NIOSH/RHD/OD); Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD); Doss-Walker, Jillian (CDC/DDID/NCIRD/ISD); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); Fiore, Anthony (CDC/DDID/NCEZID/DHQP); Fleming-Dutra, Katherine E. (CDC/DDID/NCIRD/DBD); Freedman, Mark S. (CDC/DDID/NCIRD/ISD); Gerber, Susan I. (CDC/DDID/NCEZID/DFWED); Goldstein, Susan (CDC/DDID/NCIRD/OD); Gorwitz, Rachel (CDC/DDID/NCIRD/DBD); Graitcer, Samuel B. (CDC/DDID/NCIRD/ISD); Grohskopf, Lisa A. (CDC/DDID/NCIRD/ID); Helfand, Rita (CDC/DDID/NCEZID/OD); Hicks, Lauri (CDC/DDID/NCEZID/DHQP); Hyde, Terri (CDC/DDPHSIS/CGH/GID); Jorgensen, Cynthia (CDC/DDID/NCIRD/OD); Kennedy, Erin D. (CDC/DDPHSIS/CGH/GID); Kidd, Sarah E. (CDC/DDID/NCIRD/DVD); Koppaka, Ram (CDC/DDID/NCIRD/ISD); Lindsey, Nicole (CDC/DDID/NCEZID/DVBD); Link-Gelles, Ruth (CDC/DDID/NCIRD/DVD); MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Mahon, Barbara (CDC/DDID/NCIRD/OD); Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Martin, Stacey (CDC/DDID/NCEZID/DVBD); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD); McMorrow, Meredith (CDC/DDID/NCIRD/DVD); [REDACTED] Oduyebo, Titilope (CDC/DDID/NCCDPHP/DRH); Patel, Anita (CDC/DDID/NCIRD/OD); Routh, Janell A. (CDC/DDID/NCIRD/DVD); Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Schumacher, Bryan (CDC/OD/OCS); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Soeters, Heidi (CDC/DDPHSIS/CGH/GID); Sotir, Mark (CDC/DDID/NCIRD/DVD); Thomas, Stephanie B. (CDC/DDID/NCIRD/OD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Wasley, Annemarie (CDC/DDPHSIS/CGH/GID); Weinbaum, Cindy (CDC/DDID/NCIRD/ISD); Wharton, Melinda (CDC/DDID/NCIRD/ISD); Woodworth, Kate (CDC/DDID/NCBDDD/DBD); Yu, Patricia A. (CDC/DDID/NCEZID/DPEI); Yu, Yon C. (CDC/DDID/NCEZID/DPEI)

Subject: ACIP CV WG Updates

CAUTION: This email originated from a sender outside of the Commonwealth of Massachusetts mail system. Do not click on links or open attachments unless you recognize the sender and know the content is safe.

WG Members:

Just wanted to pass along a few updates. The CDC website has been updated to address myocarditis. Links are here:

[Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination | CDC](#)

Clinical considerations: [Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines |](#)

CDC [may not be live yet, but is coming!]

In addition, the Science Brief for COVID vaccines has been updated and is here:

[Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People \(cdc.gov\)](#)

We will send the WG call invitations for June and July soon. Of note, we plan on canceling the WG meetings on June 10th (so people can listen to the VRBPAC meeting) and June 24th (for the planned non-COVID June ACIP meeting).

Let me know if there are any other questions or issues. I hope everyone has a safe and somewhat restful Memorial Day weekend!

Sara

Sara Oliver, MD, MSPH
LCDR, U.S. Public Health Service
Lead, ACIP COVID-19 Vaccine Work Group
Vaccine Task Force
Centers for Disease Control and Prevention
phone: [REDACTED]
email: [REDACTED]

From: [Zahn, Matthew](#)
To: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
Subject: RE: ACIP CVWG Call 5/20
Date: Thursday, May 20, 2021 5:26:57 PM

As long as there is a VaST statement, that will probably suffice. As long as we have something, somewhere, to refer to.

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Thursday, May 20, 2021 2:23 PM
To: Zahn, Matthew <[REDACTED]>
Subject: RE: ACIP CVWG Call 5/20

Attention: This email originated from outside the County of Orange. Use caution when opening attachments or links.

It's my understanding that a VaST statement is going to go on the website soon (late today vs tomorrow?). When that happens, I can share broadly. I don't know that there are current plans to post the entire statement below somewhere, but things are changing quickly so I will let you know if that changes.

Sara

From: Zahn, Matthew <[REDACTED]>
Sent: Thursday, May 20, 2021 5:20 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: RE: ACIP CVWG Call 5/20

Hi Sara,
Really appreciate this communication. Is this anywhere on the CDC web site? It is SO much more helpful if/when CDC actually places something on their web site about a topic. Then we can send providers/media/the public to this site, saving countless hours of working on messaging and miscommunications.
Matt

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Thursday, May 20, 2021 2:15 PM
To: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Szilagyi, Peter
<[REDACTED]> Fink, Doran (FDA/CBER)
<[REDACTED]> Kelman, Jeffrey A. (CMS/CM) <[REDACTED]> Kim,
David (HHS/OASH) <[REDACTED]> Oshansky, Christine (OS/ASPR/BARDA)

< [REDACTED] Roberts, Chris (NIH/NIAID) [E] < [REDACTED] Weiser,
 Thomas M (IHS/POR) < [REDACTED] Zhang, Rachel (FDA/CBER)
 < [REDACTED] [REDACTED] [REDACTED]
 [REDACTED] [REDACTED] Duchin, Jeff (CDC kingcounty.gov)
 < [REDACTED] [REDACTED] [REDACTED]
 [REDACTED] Hahn, Christine (CDC dhw.idaho.gov)
 < [REDACTED] [REDACTED] [REDACTED]
 [REDACTED] [REDACTED] [REDACTED] Plescia,
 Marcus (CDC astho.org) < [REDACTED] [REDACTED]
 [REDACTED] [REDACTED] [REDACTED]
 [REDACTED] [REDACTED] [REDACTED] Zahn,
 Matthew < [REDACTED] Zucker, Jane R. (CDC health.nyc.gov) < [REDACTED]
Cc: Chamberland, Mary (CDC/DDID/NCIRD/OD) (CTR) < [REDACTED] Gargano, Julia Marie W.
 (CDC/DDID/NCIRD/DVD) < [REDACTED] Gersten, Jack (CDC/DDID/NCIRD/OD) (CTR)
 < [REDACTED] Hadler, Stephen (CDC/DDID/NCIRD/OD) < [REDACTED] Lindley, Megan C.
 (CDC/DDID/NCIRD/ISD) < [REDACTED] Moulia, Danielle L. (CDC/DDID/NCIRD/OD)
 < [REDACTED] Reisman, Nicole (CDC/DDNID/NCBDDD/DHDD) < [REDACTED] Scobie, Heather
 (CDC/DDPHSIS/CGH/GID) < [REDACTED] Shanley, Edwin (CDC/DDID/NCIRD/OD) < [REDACTED]
 Wallace, Megan (CDC/DDID/NCIRD/DVD) < [REDACTED] Acosta, Anna (CDC/DDID/NCIRD/DBD)
 < [REDACTED] [REDACTED] Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < [REDACTED]
 Cohn, Amanda (CDC/DDID/NCIRD/OD) < [REDACTED] Cox-Ganser, Jean (CDC/NIOSH/RHD/OD)
 < [REDACTED] Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD) < [REDACTED] Doss-Walker, Jillian
 (CDC/DDID/NCIRD/ISD) < [REDACTED] Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
 < [REDACTED] Fiore, Anthony (CDC/DDID/NCEZID/DHQP) < [REDACTED] Fleming-Dutra,
 Katherine E. (CDC/DDID/NCIRD/DBD) < [REDACTED] Freedman, Mark S. (CDC/DDID/NCIRD/ISD)
 < [REDACTED] Carlton, Julie (CDC/DDPHSIS/CGH/GID) < [REDACTED] Gerber, Susan I.
 (CDC/DDID/NCEZID/DFWED) < [REDACTED] Goldstein, Susan (CDC/DDID/NCIRD/OD)
 < [REDACTED] Gorwitz, Rachel (CDC/DDID/NCIRD/DBD) < [REDACTED] Graitcer, Samuel B.
 (CDC/DDID/NCIRD/ISD) < [REDACTED] Grohskopf, Lisa A. (CDC/DDID/NCIRD/ID) < [REDACTED]
 Helfand, Rita (CDC/DDID/NCEZID/OD) < [REDACTED] Hyde, Terri (CDC/DDPHSIS/CGH/GID)
 < [REDACTED] Jorgensen, Cynthia (CDC/DDID/NCIRD/OD) < [REDACTED] Kennedy, Erin D.
 (CDC/DDPHSIS/CGH/GID) < [REDACTED] Kidd, Sarah E. (CDC/DDID/NCIRD/DVD) < [REDACTED]
 Koppaka, Ram (CDC/DDID/NCIRD/ISD) < [REDACTED] Lindsey, Nicole (CDC/DDID/NCEZID/DVBD)
 < [REDACTED] Link-Gelles, Ruth (CDC/DDID/NCIRD/DVD) < [REDACTED] MacNeil, Jessica R.
 (CDC/DDID/NCIRD/OD) < [REDACTED] Mahon, Barbara (CDC/DDID/NCIRD/OD) < [REDACTED]
 Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < [REDACTED] Martin, Stacey
 (CDC/DDID/NCEZID/DVBD) < [REDACTED] Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) < [REDACTED]
 [REDACTED] [REDACTED] Oduyebo, Titilope (CDC/DDNID/NCCDPHP/DRH)
 < [REDACTED] Patel, Anita (CDC/DDID/NCIRD/OD) < [REDACTED] Routh, Janell A.
 (CDC/DDID/NCIRD/DVD) < [REDACTED] Schumacher, Bryan (CDC/OD/OCS) < [REDACTED]
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD) < [REDACTED] Shimabukuro, Tom
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 < [REDACTED] Sotir, Mark (CDC/DDID/NCIRD/DVD) < [REDACTED] Thomas, Stephanie B.
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 < [REDACTED] Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) < [REDACTED] Wasley, Annemarie

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Weinbaum, Cindy (CDC/DDID/NCIRD/ISD)
<[REDACTED]> Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]> Woodworth, Kate
(CDC/DDNID/NCBDDD/DBDID) <[REDACTED]> Yu, Patricia A. (CDC/DDID/NCEZID/DPEI)
<[REDACTED]> Yu, Yon C. (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Hicks, Lauri
(CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: ACIP CVWG Call 5/20

Attention: This email originated from outside the County of Orange. Use caution when opening attachments or links.

As promised- below is the information on myocarditis messages. I will pass things along as more information is known or additional messages are developed.

The statement:

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data. To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#). It is a requirement of the EUA that vaccine providers report adverse events to VAERS, including myocarditis and pericarditis. Without this reporting, we cannot know the scope of a potential issue, investigate it, and provide you with tools on how to communicate about it.

Melinda's message:

All,
I would like to flag a message we sent out late Friday night. I encourage you to forward this important message about vaccine safety and reporting to VAERS to providers in your jurisdiction, including those who are administering COVID-19 vaccines. As a reminder, it's a requirement of the EUA that vaccine providers report adverse events to VAERS, including myocarditis and pericarditis. Without this reporting, we cannot know the scope of a potential issue, investigate it, and provide you with tools on how to communicate about it.

Thank you,
Melinda Wharton
Melinda Wharton, MD, MPH
Director, Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

And the note that went out to the immunization programs:

Subject: For Awareness: Monitoring Reports of Myocarditis

Good evening,

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.

Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. While myocarditis can be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart rhythms, shortness of breath, or chest pain.

As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#).

To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#).

CDC continues to recommend COVID-19 vaccination for people 12 years and older.

Thank you

From: [Zahn, Matthew](#)
To: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
Subject: RE: ACIP CVWG Call 5/20
Date: Thursday, May 20, 2021 5:20:15 PM

Hi Sara,

Really appreciate this communication. Is this anywhere on the CDC web site? It is SO much more helpful if/when CDC actually places something on their web site about a topic. Then we can send providers/media/the public to this site, saving countless hours of working on messaging and miscommunications.

Matt

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Thursday, May 20, 2021 2:15 PM
To: [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] Szilagyi, Peter
<[REDACTED] [REDACTED] Fink, Doran (FDA/CBER)
<[REDACTED] Kelman, Jeffrey A. (CMS/CM) <[REDACTED] Kim,
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<[REDACTED] Roberts, Chris (NIH/NIAID) [E] <[REDACTED] Weiser,
Thomas M (IHS/POR) <[REDACTED] Zhang, Rachel (FDA/CBER)
<[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] Duchin, Jeff (CDC kingcounty.gov)
<[REDACTED] [REDACTED] [REDACTED]
[REDACTED] Hahn, Christine (CDC dhw.idaho.gov)
<[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] Plescia,
Marcus (CDC astho.org) <[REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED]
[REDACTED] [REDACTED] [REDACTED] Zahn,
Matthew <[REDACTED] Zucker, Jane R. (CDC health.nyc.gov) <[REDACTED]
Cc: Chamberland, Mary (CDC/DDID/NCIRD/OD) (CTR) <[REDACTED] Gargano, Julia Marie W.
(CDC/DDID/NCIRD/DVD) <[REDACTED] Gersten, Jack (CDC/DDID/NCIRD/OD) (CTR)
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<[REDACTED] Reisman, Nicole (CDC/DDID/NCBDDD/DHDD) <[REDACTED] Scobie, Heather
(CDC/DDPHSIS/CGH/GID) <[REDACTED] Shanley, Edwin (CDC/DDID/NCIRD/OD) <[REDACTED]
Wallace, Megan (CDC/DDID/NCIRD/DVD) <[REDACTED] Acosta, Anna (CDC/DDID/NCIRD/DBD)
<[REDACTED] [REDACTED] Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <[REDACTED]
Cohn, Amanda (CDC/DDID/NCIRD/OD) <[REDACTED] Cox-Ganser, Jean (CDC/NIOSH/RHD/OD)
<[REDACTED] Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD) <[REDACTED] Doss-Walker, Jillian
(CDC/DDID/NCIRD/ISD) <[REDACTED] Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
<[REDACTED] Fiore, Anthony (CDC/DDID/NCEZID/DHQP) <[REDACTED] Fleming-Dutra,

Katherine E. (CDC/DDID/NCIRD/DBD) <[REDACTED]> Freedman, Mark S. (CDC/DDID/NCIRD/ISD) <[REDACTED]> Carlton, Julie (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Gerber, Susan I. (CDC/DDID/NCEZID/DFWED) <[REDACTED]> Goldstein, Susan (CDC/DDID/NCIRD/OD) <[REDACTED]> Gorwitz, Rachel (CDC/DDID/NCIRD/DBD) <[REDACTED]> Graitcer, Samuel B. (CDC/DDID/NCIRD/ISD) <[REDACTED]> Grohskopf, Lisa A. (CDC/DDID/NCIRD/ID) <[REDACTED]> Helfand, Rita (CDC/DDID/NCEZID/OD) <[REDACTED]> Hyde, Terri (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Jorgensen, Cynthia (CDC/DDID/NCIRD/OD) <[REDACTED]> Kennedy, Erin D. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Kidd, Sarah E. (CDC/DDID/NCIRD/DVD) <[REDACTED]> Koppaka, Ram (CDC/DDID/NCIRD/ISD) <[REDACTED]> Lindsey, Nicole (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Link-Gelles, Ruth (CDC/DDID/NCIRD/DVD) <[REDACTED]> MacNeil, Jessica R. (CDC/DDID/NCIRD/OD) <[REDACTED]> Mahon, Barbara (CDC/DDID/NCIRD/OD) <[REDACTED]> Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <[REDACTED]> [REDACTED] Oduyebo, Titilope (CDC/DDNID/NCCDPHP/DRH) <[REDACTED]> Patel, Anita (CDC/DDID/NCIRD/OD) <[REDACTED]> Routh, Janell A. (CDC/DDID/NCIRD/DVD) <[REDACTED]> Schumacher, Bryan (CDC/OD/OCS) <[REDACTED]> Schrag, Stephanie (CDC/DDID/NCIRD/DBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Soeters, Heidi (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Sotir, Mark (CDC/DDID/NCIRD/DVD) <[REDACTED]> Thomas, Stephanie B. (CDC/DDID/NCIRD/OD) <[REDACTED]> Thornburg, Natalie (CDC/DDID/NCIRD/DVD) <[REDACTED]> Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) <[REDACTED]> Wasley, Annemarie (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Weinbaum, Cindy (CDC/DDID/NCIRD/ISD) <[REDACTED]> Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]> Woodworth, Kate (CDC/DDNID/NCBDDD/DBDID) <[REDACTED]> Yu, Patricia A. (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Yu, Yon C. (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Hicks, Lauri (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: RE: ACIP CVWG Call 5/20

Attention: This email originated from outside the County of Orange. Use caution when opening attachments or links.

As promised- below is the information on myocarditis messages. I will pass things along as more information is known or additional messages are developed.

The statement:

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data. To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#). It is a requirement of the EUA that vaccine providers report adverse events to VAERS, including myocarditis and pericarditis. Without this reporting, we cannot know the scope of a potential issue, investigate it, and

provide you with tools on how to communicate about it.

Melinda's message:

All,

I would like to flag a message we sent out late Friday night. I encourage you to forward this important message about vaccine safety and reporting to VAERS to providers in your jurisdiction, including those who are administering COVID-19 vaccines. As a reminder, it's a requirement of the EUA that vaccine providers report adverse events to VAERS, including myocarditis and pericarditis. Without this reporting, we cannot know the scope of a potential issue, investigate it, and provide you with tools on how to communicate about it.

Thank you,

Melinda Wharton

Melinda Wharton, MD, MPH

Director, Immunization Services Division

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

And the note that went out to the immunization programs:

Subject: For Awareness: Monitoring Reports of Myocarditis

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As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#).

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CDC continues to recommend COVID-19 vaccination for people 12 years and older.

Thank you

From: [Tumpey, Abbigail \(CDC/DDPHSS/CSELS/OD\)](#)
To: [Honein, Margaret \(Peggy\) \(CDC/DDID/NCEZID/DPEI\)](#); [Daskalakis, Demetre \(CDC/DDID/NCHHSTP/DHP\)](#)
Cc: [Walke, Henry \(CDC/DDID/NCEZID/DPEI\)](#)
Subject: Re: CA, WA, OR and the HAN
Date: Sunday, May 23, 2021 6:18:38 PM

Demetre or Henry should weigh in. We are going to hold and stabilize the numbers before releasing the HAN. Agree that partner calls should be part of it. Suspect we are looking at more of a Tues or Wed release, but defer to Henry and Demetre.

Get [Outlook for iOS](#)

From: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Sent: Sunday, May 23, 2021 5:46:24 PM
To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]> Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]>
Subject: Re: CA, WA, OR and the HAN

Any cdc time estimate? We can pull together core PH partners and all state epis on short notice

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From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Sent: Sunday, May 23, 2021 4:01:56 PM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]> Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Subject: FW: CA, WA, OR and the HAN

Peggy and Abbigail-

When we were on calls w WA, OR, and CA about myocarditis, the states requested that we give them a heads up if we are sending out a CDC communication. Can we try to time it so we can, if possible?

Thanks
Demetre

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Sent: Sunday, May 23, 2021 4:00 PM
To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Subject: RE: CA, WA, OR and the HAN

Yes, timing of the notification should be coordinated with Abbigail. Maybe an hour or two before. Work with Peggy also, she also needs to give the partners a heads up.

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>

Sent: Sunday, May 23, 2021 3:55 PM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[REDACTED]>

Subject: CA, WA, OR and the HAN

Can we heads up CA, WA, OR about the HAN before it hits. They all asked for a little lead time if we release a CDC communication.

Demetre

Demetre C. Daskalakis, M.D., M.P.H.

Deputy Incident Manager and Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention

Centers for Disease Control and Prevention

[REDACTED]

[REDACTED]

Tel: [REDACTED] | Fax: [REDACTED]

Email: [REDACTED] or [REDACTED]

Pronouns: He/His/Him

From: [Honein, Margaret \(Peggy\) \(CDC/DDID/NCEZID/DPEI\)](#)
To: [Walke, Henry \(CDC/DDID/NCEZID/DPEI\)](#); [Tumpey, Abbigail \(CDC/DDPHSS/CSELS/OD\)](#); [Daskalakis, Demetre \(CDC/DDID/NCHHSTP/DHP\)](#)
Subject: RE: CA, WA, OR and the HAN
Date: Sunday, May 23, 2021 7:49:41 PM
Attachments: [image001.jpg](#)

Good – that will help us in planning out the partner notice.

thx

Margaret (Peggy) Honein, PhD, MPH
State, Tribal, Local, and Territorial Support
COVID-19 Emergency Response
U.S. Centers for Disease Control and Prevention
[REDACTED]



From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Sent: Sunday, May 23, 2021 6:34 PM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]> Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Subject: RE: CA, WA, OR and the HAN

Yes tues/wed not tomorrow.

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]>
Sent: Sunday, May 23, 2021 6:19 PM
To: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Subject: Re: CA, WA, OR and the HAN

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Subject: Re: CA, WA, OR and the HAN

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Work with Peggy also, she also needs to give the partners a heads up.

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Subject: CA, WA, OR and the HAN

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Demetre

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Deputy Incident Manager and Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention

[REDACTED]

[REDACTED]

Tel: [REDACTED] | Fax: [REDACTED]

Email: [REDACTED] or [REDACTED]

Pronouns: He/His/Him

From: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
To: [Nordlund, Kristen \(CDC/DDID/NCIRD/OD\)](#)
Subject: RE: For Awareness: Monitoring Reports of Myocarditis
Date: Thursday, May 20, 2021 4:07:00 PM

Thanks. I'll send a f/ email after the call with this information. I think there's going to be a lot of interest.

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Thursday, May 20, 2021 4:06 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: FW: For Awareness: Monitoring Reports of Myocarditis

In case ACIP members want what we sent out.

From: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Sent: Wednesday, May 19, 2021 5:24 PM
To: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Subject: RE: For Awareness: Monitoring Reports of Myocarditis

All,

I would like to flag a message we sent out late Friday night. I encourage you to forward this important message about vaccine safety and reporting to VAERS to providers in your jurisdiction, including those who are administering COVID-19 vaccines. As a reminder, it's a requirement of the EUA that vaccine providers report adverse events to VAERS, including myocarditis and pericarditis. Without this reporting, we cannot know the scope of a potential issue, investigate it, and provide you with tools on how to communicate about it.

Thank you,

Melinda Wharton

Melinda Wharton, MD, MPH
Director, Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Sent: Friday, May 14, 2021 8:34 PM
To: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Subject: For Awareness: Monitoring Reports of Myocarditis

Good evening,

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.

Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. While myocarditis can be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart rhythms, shortness of breath, or chest pain.

As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the [Vaccine Adverse Event Reporting System \(VAERS\)](#) and the [Vaccine Safety Datalink \(VSD\)](#).

To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#).

CDC continues to recommend COVID-19 vaccination for people 12 years and older.

Thank you

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From: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
To: [Nordlund, Kristen \(CDC/DDID/NCIRD/OD\)](#)
Subject: RE: For Awareness: Monitoring Reports of Myocarditis
Date: Thursday, May 20, 2021 4:37:00 PM

I don't mind pulling it together. Do you have any 'media talking points' worth sharing? Or just let them pull info from all of this below?

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Thursday, May 20, 2021 4:37 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: FW: For Awareness: Monitoring Reports of Myocarditis

Here's the shorter statement we suggested. If you want me to put this all together into one email for folks to send out providers I am more than happy to do that.

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the [EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination](#). CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data. To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and [report all cases to VAERS](#). It is a requirement of the EUA that vaccine providers report adverse events to VAERS, including myocarditis and pericarditis. Without this reporting, we cannot know the scope of a potential issue, investigate it, and provide you with tools on how to communicate about it.

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Sent: Wednesday, May 19, 2021 5:24 PM
To: NCIRD Immunization Grantee Mailbox (CDC) <[REDACTED]>
Subject: RE: For Awareness: Monitoring Reports of Myocarditis

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Melinda Wharton

Melinda Wharton, MD, MPH
Director, Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

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From: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
To: [Nordlund, Kristen \(CDC/DDID/NCIRD/OD\)](#)
Subject: RE: For Awareness: Monitoring Reports of Myocarditis
Date: Thursday, May 20, 2021 5:08:00 PM

OK sounds good.

Overall- thank you! Let me know if there's anything else I can help with... it's never dull around here

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Thursday, May 20, 2021 4:55 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: RE: For Awareness: Monitoring Reports of Myocarditis

We don't yet. And it might take a hot second to put that together, but we'll see if we can get something for tomorrow (maybe that includes some of the background info that Tom S shared).

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Thursday, May 20, 2021 4:37 PM
To: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Subject: RE: For Awareness: Monitoring Reports of Myocarditis

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National Center for Immunization and Respiratory Diseases
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From: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
To: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#)
Subject: RE: Heads up
Date: Saturday, May 22, 2021 9:48:00 AM

Sure- I'll set these up. Let me know if there's a version of the HAN you want me to share. Otherwise I'll set up a meeting invitation. I'll put a few people on but feel free to forward and invite others as needed.

Sara

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Saturday, May 22, 2021 9:28 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: RE: Heads up

I have to brief on myocarditis at some IM meeting at 3:00. Could we do these at 4:00 and 4:30?

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Friday, May 21, 2021 9:03 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Heads up

OK I have their attention . They are willing to meet whenever. I am pretty open tomorrow so let me know what your schedule looks like (once you know it) and I can set something up. I imagine we can do them back-to-back since we don't typically do calls with multiple manufacturers.

Thanks-
Sara

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, May 21, 2021 6:58 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: FW: Heads up

FYI, my schedule tomorrow morning and early afternoon is a bit tenuous.

From: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Sent: Friday, May 21, 2021 6:50 PM
To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Heads up

Thanks Demetre – we appreciate the support.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, May 21, 2021 6:47 PM
To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Subject: RE: Heads up

Yes.

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Sent: Friday, May 21, 2021 6:46 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <[REDACTED]>
Subject: Heads up

We are scheduling a time with the director sometime late morning or early afternoon. I can bring one person with me. Tom are you willing and able?

Demetre

Demetre C. Daskalakis, M.D., M.P.H.

COVID CDC Response Role: Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention

[REDACTED]

[REDACTED]

Tel: [REDACTED] | Fax: [REDACTED]

Email: [REDACTED] or [REDACTED]

Pronouns: He/His/Him

From: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
To: [Barbara Kuter \(x\)](#)
Subject: RE: Publication - Myocarditis
Date: Tuesday, May 25, 2021 10:20:00 AM

Barb:

Apologies that there hasn't been more solid communication on this. Unfortunately, I still don't have a firm update to share. Things have been changing rapidly here. As we know more, I will share.

Thanks-
Sara

From: Barbara Kuter (x) <[REDACTED]>
Sent: Tuesday, May 25, 2021 9:45 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: Publication - Myocarditis

Hi Sara,

I am just checking in to see if you have decided where you will publish your statement on myocarditis. Will it be the MMWR or somewhere else please? And if you have any update on timing, that would be a big help.

We hope to send CDC the report that we are submitting to PRAC sometime this week.

Many thanks.

Barb

 **Please consider the environment before printing this email**

Confidentiality notice and disclaimer: The information in this message and any attachments is intended for the exclusive use of the addressee(s), is confidential and may be privileged or otherwise protected from disclosure. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, of any such information by persons or entities other than the intended addressee(s) is prohibited. If you have received this message in error and are not the intended addressee, please notify the sender immediately and delete this message and any attachments from your system without reading or disclosing them. If you are not the intended addressee, be advised that any use of the information in this message and any attachment is prohibited and may be unlawful, and you must not copy this message or attachment or disclose the contents to any other person.

From: [Oliver, Sara Elizabeth \(CDC/DDID/NCIRD/DVD\)](#)
To: [Barbara Kuter \(x\)](#)
Subject: RE: Publication - Myocarditis
Date: Tuesday, May 25, 2021 10:29:00 AM

I haven't heard plans for an MMWR yet. There's just not enough data yet so an MMWR wouldn't make sense at this point. I would anticipate as we have additional data and more formal analyses, there may be an MMWR, but not right now.

The pros and cons of an official HAN are what the main discussions are right now. I think it's likely to be a HAN since that is CDC's primary method of communications to clinicians and public health departments, but people don't want to appear alarmist either.

I am not trying to be vague on purpose- I really don't know. If I had to guess, I would think it's likely to be a HAN, but can't say for sure yet. I anticipate there will be firm decisions within the next 24 hours so I'll let you know.

Thanks-
Sara

From: Barbara Kuter (x) <[REDACTED]>
Sent: Tuesday, May 25, 2021 10:24 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: Re: Publication - Myocarditis

Hi Sara,

Thanks for your note. Can I just ask what are the possible options where this might be published?

Barb

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Sent: Tuesday, May 25, 2021 10:20 AM
To: Barbara Kuter (x) <[REDACTED]>
Subject: RE: Publication - Myocarditis

EXTERNAL

Barb:

Apologies that there hasn't been more solid communication on this. Unfortunately, I still don't have a firm update to share. Things have been changing rapidly here. As we know more, I will

share.

Thanks-

Sara

From: Barbara Kuter (x) <[REDACTED]>
Sent: Tuesday, May 25, 2021 9:45 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: Publication - Myocarditis

Hi Sara,

I am just checking in to see if you have decided where you will publish your statement on myocarditis. Will it be the MMWR or somewhere else please? And if you have any update on timing, that would be a big help.

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Many thanks.

Barb

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From: [Daskalakis, Demetre \(CDC/DDID/NCHHSTP/DHP\)](#)
To: [Walke, Henry \(CDC/DDID/NCEZID/DPEI\)](#); [Walensky, Rochelle \(CDC/OD\)](#)
Cc: [Berger, Sherri \(CDC/OD/OCS\)](#)
Subject: RE: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates
Date: Friday, May 21, 2021 9:31:35 AM

I think the HAN in to alert providers to reporting since there is concern that the messages have not been trickling from the vaccine programs to providers at large.

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Sent: Friday, May 21, 2021 9:30 AM
To: Walensky, Rochelle (CDC/OD) <[REDACTED]> Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Cc: Berger, Sherri (CDC/OCOO/OD) <[REDACTED]>
Subject: Re: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

Was there a trigger for starting work on HAN. Didn't think we had a safety signal yet.

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Sent: Friday, May 21, 2021 9:26:48 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Walensky, Rochelle (CDC/OD) <[REDACTED]>
Cc: Berger, Sherri (CDC/OCOO/OD) <[REDACTED]>
Subject: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

1. There is a HAN in development on Myocarditis. Haven't seen in yet
2. The Push to Pull/end of Pro-Rata proposal includes the Federal retail pharmacy program

Demetre C. Daskalakis, M.D., M.P.H.

COVID CDC Response Role: Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention

[REDACTED]

[REDACTED]

Tel: [REDACTED] | Fax: [REDACTED]

Email: [REDACTED] or [REDACTED]

Pronouns: He/His/Him

From: [CDC IMS 2019 NCOV Response VTF Policy](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#); [Reimels, Elizabeth \(CDC/DDNID/NCIPC/DVP\)](#)
Cc: [Walter-Garcia, Madison \(CDC/DDID/NCIRD/OD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 8:07:38 AM

Awesome – updated that in the tracker/email.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 5:26 AM
To: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP) <[REDACTED]>
Cc: Walter-Garcia, Madison (CDC/DDID/NCIRD/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

I am waiting to hear back from Stacey Martin who indicated that FDA wants a written response.

Susan

From: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Sent: Monday, March 1, 2021 9:56:16 PM
To: Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP) <[REDACTED]> McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Walter-Garcia, Madison (CDC/DDID/NCIRD/OD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Does anyone know who took this one?

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 6:48 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks for the offer, our policy group is working on coordinating a written response with FDA currently so I believe the suspense should be fine as is for now. We will reach out if we need an extension.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 5:38 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

MaryBeth/VTF Ops,

If you need more time, I can request an extension from HHS.

Thanks for the update.

Scott F.

CDC EOC Task Tracker

[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF

Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy
<[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer
<[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.
(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019

NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS
2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#)
Cc: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 9:39:14 AM

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Stacey,
Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks
Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief

Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations

<[REDACTED]>

Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD)

<[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra

(CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#); [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 11:15:20 AM

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. I don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested. Thanks.

Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 10:55 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Since this is due at 5 pm today, let me know if we need to ask for more time. I think that is possible.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:39 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

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Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli

National Focal Point to discuss Pfizer vaccine

Stacey,

Following up on this. Is there someone I need to connect with at FDA for the statement?

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Susan McClure

Co-lead, Vaccine Task Force Policy Unit

[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [CDC IMS 2019 NCOV Response VTF Operations](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#)
Cc: [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 11:27:39 AM

Sure thing, I'll correspond with the EOC and let them know we need an extension to the end of next week, Feb 12th. Hopefully that will be enough time.

Let me know if you need any assistance,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:22 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Heard back from Tom.

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. We don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested.

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Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

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time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

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2019 Novel Coronavirus Response

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MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Please provide an update on this request?
Thanks.
Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

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Vaccine Task Force (VTF) Operational Support

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Please provide an update on this request?
Thanks.
Scott

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Suspense: 3/2/2021 17:00:00

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Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

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From: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#); [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Wednesday, March 10, 2021 9:35:50 AM

We are reviewing a draft response that FDA send over to us. We'll get back to them by COB today, but after that it's on their timeline. Thanks.

Tom

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Wednesday, March 10, 2021 9:26 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Hi Tom,
Checking in to see if the response with FDA will be finalized this week.
Thanks
Susan

From: McClure, Susan (CDC/DDPHSIS/CGH/OD)
Sent: Tuesday, March 2, 2021 11:20 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Will ask for an extension.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 10:55 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Since this is due at 5 pm today, let me know if we need to ask for more time. I think that is possible.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:39 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Stacey,
Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks
Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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2019 Novel Coronavirus Response

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MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
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Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

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Phone #: +972-2-5080640

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Cc: [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Wednesday, March 10, 2021 10:05:35 AM

Understood, thanks for the update Susan! I'll keep an eye out for further information so we can close it out on our end.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:04 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning,
Heard from the SME that they are reviewing a response and returning to FDA by COB today. I'm trying to get clarification if FDA is sending and if so a POC to provide for HHS Soc so that we can close this one out. Doesn't sound like we are sending the response to the requestor but need to confirm.

Thanks

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<[REDACTED] CDC IMS 2019 NCOV Response VTF Chief Medical Officer

<[REDACTED]

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED] Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED] Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]

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<[REDACTED] CDC IMS 2019 NCOV Response VTF Chief Medical Officer

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Medical Officer <[REDACTED] CDC IMS 2019 NCOV Response VTF Operations

<[REDACTED]

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Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.
Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [CDC IMS 2019 NCOV Response VTF Operations](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#)
Cc: [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Thursday, March 11, 2021 1:57:40 PM

Good afternoon Susan,

Checking in again on this Task ID - any update from FDA? Can we close out on our end?

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:05 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Understood, thanks for the update Susan! I'll keep an eye out for further information so we can close it out on our end.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:04 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:22 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
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Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Vaccine Task Force (VTF) Operational Support

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Reminder-

Task due to OPS by 1700. Thanks

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Vaccine Task Force (VTF) Operational Support

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Please provide an update on this request?
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Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

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Cc: [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Thursday, March 11, 2021 2:11:39 PM

Sounds good, I think just saying we're working with FDA on it and that they're sending should be sufficient.

Thanks!
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Thursday, March 11, 2021 2:10 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Can we close out and note that we worked with FDA on a response and they are sending?

I don't have an FDA POC yet.

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Thursday, March 11, 2021 1:58 PM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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Task ID: 42633

Suspense: 3/2/2021 17:00:00

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Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

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Cc: [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 15, 2021 3:09:02 PM

Sure thing, I'll pass it along.

Thanks for sending,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Monday, March 15, 2021 3:03 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

I know we closed this last week thinking that FDA would provide the response but the program has sent to us. Can you share with HHS so that they can return?

Thanks
Susan McClure

Co-lead | Vaccine Task Force Policy
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
[REDACTED]

www.cdc.gov/COVID19

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, March 15, 2021 11:06 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey
(CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

See attached response that includes content from both CDC and FDA. Sorry for the delay.

Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:20 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey
(CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli
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Thanks. Will ask for an extension.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:15 AM
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Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>

Sent: Tuesday, March 2, 2021 10:55 AM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Since this is due at 5 pm today, let me know if we need to ask for more time. I think that is possible.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>

Sent: Tuesday, March 2, 2021 9:39 AM

To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>

Sent: Tuesday, March 2, 2021 7:34 AM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>

Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Stacey,

Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks

Susan McClure

Co-lead, Vaccine Task Force Policy Unit

[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Sent: Tuesday, March 2, 2021 9:31 AM

To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>

Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>

Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [CDC IMS 2019 NCOV Response VCU Policy](#); [Reimels, Elizabeth \(CDC/DDNID/NCIPC/DVP\)](#)
Cc: [Walter-Garcia, Madison \(CDC/DDID/NCIRD/OD\)](#)
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 5:25:00 AM

I am waiting to hear back from Stacey Martin who indicated that FDA wants a written response.

Susan

From: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Sent: Monday, March 1, 2021 9:56:16 PM
To: Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP) <[REDACTED]> McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Walter-Garcia, Madison (CDC/DDID/NCIRD/OD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Does anyone know who took this one?

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 6:48 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks for the offer, our policy group is working on coordinating a written response with FDA currently so I believe the suspense should be fine as is for now. We will reach out if we need an extension.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 5:38 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

MaryBeth/VTF Ops,

If you need more time, I can request an extension from HHS.

Thanks for the update.

Scott F.

CDC EOC Task Tracker

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [CDC IMS 2019 NCOV Response VTF Operations](#)
Cc: [CDC IMS 2019 NCOV Response VTF Policy](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 9:32:00 AM

I haven't heard back from Stacey yet. Will email her again.

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

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Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
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Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Cc: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 10:54:00 AM

Thanks. Since this is due at 5 pm today, let me know if we need to ask for more time. I think that is possible.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:39 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Stacey,
Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks
Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
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Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written

response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
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Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Thanks,
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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

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Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#); [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 11:20:00 AM

Thanks. Will ask for an extension.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 10:55 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>

Sent: Tuesday, March 2, 2021 9:25 AM

To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Sent: Monday, March 1, 2021 4:13 PM

To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>

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Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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From: CDC IMS Task Tracker (CDC) <[REDACTED]>

Sent: Monday, March 1, 2021 4:03 PM

To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

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<[REDACTED] Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED] Lubar, Debra
(CDC/DDID/NCEZID/OD) <[REDACTED]

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Tuesday, March 2, 2021 11:22:00 AM

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Can we ask for an extension until sometime until next week given the complexity of the response?

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

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Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>

<[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
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Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#); [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Wednesday, March 10, 2021 9:26:00 AM

Hi Tom,
Checking in to see if the response with FDA will be finalized this week.
Thanks
Susan

From: McClure, Susan (CDC/DDPHSIS/CGH/OD)
Sent: Tuesday, March 2, 2021 11:20 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Will ask for an extension.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. I don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested. Thanks.

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]
Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 10:55 AM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:39 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Following up on this. Is there someone I need to connect with at FDA for the statement?

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Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
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Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

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To: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#); [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Wednesday, March 10, 2021 9:51:00 AM

Thanks. Is the thinking that FDA will send out? If so, I will mark this task as complete once we send over our comments and let the HHS SOC know that FDA is sending.
Will need an FDA POC to refer HHS SOC to.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, March 10, 2021 9:36 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

We are reviewing a draft response that FDA send over to us. We'll get back to them by COB today, but after that it's on their timeline. Thanks.
Tom

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Wednesday, March 10, 2021 9:26 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
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To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>

Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Captain, U.S. Public Health Service

Deputy Director

Immunization Safety Office

Centers for Disease Control and Prevention (CDC)

[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]

Email: [REDACTED]

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Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

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To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

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To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>

Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Susan McClure

Co-lead, Vaccine Task Force Policy Unit

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Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Thanks,

MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

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Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National

Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

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Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

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To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [CDC IMS 2019 NCOV Response VTF Operations](#)
Cc: [CDC IMS 2019 NCOV Response VTF Policy](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Wednesday, March 10, 2021 10:04:00 AM

Good morning,

Heard from the SME that they are reviewing a response and returning to FDA by COB today. I'm trying to get clarification if FDA is sending and if so a POC to provide for HHS Soc so that we can close this one out. Doesn't sound like we are sending the response to the requestor but need to confirm.

Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Wednesday, March 10, 2021 9:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Checking the progress on this RFI for the point of contact to the Israeli National Focal Point that you were working on a written response with FDA. Do you think this is on track for completion by Friday of this week?

Thanks,
MaryBeth/VTF Ops

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:22 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Heard back from Tom.

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. We don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested.

Can we ask for an extension until sometime until next week given the complexity of the response?

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Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

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Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

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<[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer

<[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>

Sent: Monday, March 1, 2021 4:03 PM

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Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS

2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

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To: [CDC IMS 2019 NCOV Response VTF Operations](#)
Cc: [CDC IMS 2019 NCOV Response VTF Policy](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Thursday, March 11, 2021 2:10:00 PM

Can we close out and note that we worked with FDA on a response and they are sending?

I don't have an FDA POC yet.

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Thursday, March 11, 2021 1:58 PM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon Susan,

Checking in again on this Task ID - any update from FDA? Can we close out on our end?

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:05 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Understood, thanks for the update Susan! I'll keep an eye out for further information so we can close it out on our end.

Thanks again,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Wednesday, March 10, 2021 10:04 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning,

Heard from the SME that they are reviewing a response and returning to FDA by COB today. I'm trying to get clarification if FDA is sending and if so a POC to provide for HHS Soc so that we can close this one out. Doesn't sound like we are sending the response to the requestor but need to confirm.

Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Wednesday, March 10, 2021 9:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Checking the progress on this RFI for the point of contact to the Israeli National Focal Point that you were working on a written response with FDA. Do you think this is on track for completion by Friday of this week?

Thanks,
MaryBeth/VTF Ops

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:22 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Heard back from Tom.

FDA receive the same or a very similar request and was leaning towards providing a written response. We thought it would be best to do a joint FDA-CDC response so we send the same message. We don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested.

Can we ask for an extension until sometime until next week given the complexity of the response?

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Monday, March 1, 2021 4:13 PM
To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Monday, March 1, 2021 4:03 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [McClure, Susan \(CDC/DDPHSIS/CGH/OD\)](#)
To: [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#); [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 15, 2021 5:01:00 PM

Received.

Thank you

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, March 15, 2021 11:06 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

See attached response that includes content from both CDC and FDA. Sorry for the delay.
Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:20 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Will ask for an extension.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 2, 2021 11:15 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

FDA receive the same or a very similar request and was leaning towards providing a written

response. We thought it would be best to do a joint FDA-CDC response so we send the same message. I don't think that response will be ready until next week at the earliest; we need some additional data on doses administered, which we have requested. Thanks.

Tom

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: [REDACTED] Fax: [REDACTED]
Email: [REDACTED]

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 10:55 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks. Since this is due at 5 pm today, let me know if we need to ask for more time. I think that is possible.

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:39 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Sorry Susan. Tom was going to coordinate with you since he has been talking with FDA.

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Tuesday, March 2, 2021 7:34 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Subject: FW: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Stacey,
Following up on this. Is there someone I need to connect with at FDA for the statement?

Thanks

Susan McClure
Co-lead, Vaccine Task Force Policy Unit
[REDACTED]

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:31 AM
To: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Cc: CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: Fw: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good morning Susan,

Just checking on the RFI from Israel for which you mentioned you're working on a written response. Do you think we will have a response by 1700 today? If not we can request more time, I just wanted to follow-up to see what was needed to inform the EOC task tracker.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Tuesday, March 2, 2021 9:25 AM
To: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>
Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Reminder-

Task due to OPS by 1700. Thanks

From: CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Sent: Monday, March 1, 2021 4:13 PM

To: CDC IMS Task Tracker (CDC) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]>

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: Re: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

VTF acknowledges this task and we are working it on our end. We aim for a response by the suspense date and time.

Thanks,
MaryBeth/VTF Ops

Vaccine Task Force (VTF) Operational Support

2019 Novel Coronavirus Response

Email: [REDACTED]

From: CDC IMS Task Tracker (CDC) <[REDACTED]>

Sent: Monday, March 1, 2021 4:03 PM

To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: REMINDER:Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Good afternoon,

Please provide an update on this request?

Thanks.

Scott

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**

From: [Martin, Stacey \(CDC/DDID/NCEZID/DVBD\)](#)
To: [McClure, Susan \(CDC/DDID/NCHHSTP/DTE\)](#); [Fitter, David L. \(CDC/DDPHSIS/CGH/GID\)](#); [Shimabukuro, Tom \(CDC/DDID/NCEZID/DHQP\)](#)
Cc: [Lubar, Debra \(CDC/DDID/NCEZID/OD\)](#); [Fox, Kimberley \(CDC/DDID/NCIRD/DBD\)](#); [Beauvais, Denise \(CDC/DDID/NCIRD/OD\)](#); [CDC IMS 2019 NCOV Response VCU Policy](#)
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date: Monday, March 1, 2021 9:15:22 AM

FDA has indicated they prefer to provide a written response to this inquiry. Since we aren't seeing an increase in myocarditis, should we coordinate with FDA to provide a joint written response?

From: McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Sent: Sunday, February 28, 2021 5:48 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Yes, will do.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Sent: Sunday, February 28, 2021 2:28 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]> McClure, Susan (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Seeing that Denise is out. + Susan

Susan – can you please help coordinate?

Thanks,
-d

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID)
Sent: Sunday, February 28, 2021 2:26 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Beauvais, Denise (CDC/DDID/NCIRD/OD) <[REDACTED]> CDC IMS 2019 NCOV Response VTF Policy <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks, Stacey.

Denise – can you help set this up via policy?

Best,
David

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:35 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks David. Do you want Tom and I to coordinate a call? This was sent to multiple units.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]>
Sent: Sunday, February 28, 2021 11:15 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Importance: High

Stacey and Tom,

Please see below re discussing with Israeli Vaccine FP re myocarditis in people receiving Pfizer vaccine.

Thanks,
David

From: CDC IMS Task Tracker (CDC) <[REDACTED]>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <[REDACTED]> CDC IMS 2019

NCOV Response VTF Policy <[REDACTED]> CDC IMS 2019 NCOV Response VTF Chief Medical Officer <[REDACTED]> CDC IMS 2019 NCOV Response VTF Operations <[REDACTED]>

Cc: CDC IMS Task Tracker (CDC) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[REDACTED]> Lubar, Debra (CDC/DDID/NCEZID/OD) <[REDACTED]>

Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Importance: High

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roe Singer MD, MPH ([REDACTED])

Phone #: [REDACTED]

Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Description: The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue..

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. **The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".**