From:	Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP)
To:	McClure, Susan (CDC/DDID/NCHHSTP/DTE)
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 10:40:24 AM

I heard Madison's response. Let me know if you need anything else.

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

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. Roee 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); CDC IMS 2019 NCOV Response VCU Policy
Cc:	Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP); 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:	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 4:41:29 PM

Understood, thanks for the information Susan! If you could let us know when the written response has been sent we can close out the task with EOC.

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: Monday, March 1, 2021 4:39 PM
To: CDC IMS 2019 NCOV Response VTF Operations <[redacted] CDC IMS 2019 NCOV Response VTF Policy [redacted]
Cc: Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP) <[redacted] Cone, George Edward (CDC/DDID/NCIRD/OD) <[redacted] Gogstad, Eric (CDC/DDID/NCIRD/ID) <[redacted] Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[redacted] Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted] Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[redacted] Culp, MaryBeth (CDC/DDID/NCIRD/OD) (CTR) <[redacted] Petersen, Lisa (CDC/DDNID/NCCDPHP/DOH) [redacted]
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thank you.

I'm following up. FDA prefers a written response to this inquiry.

Susan McClure

From: CDC IMS 2019 NCOV Response VTF Operations [redacted]
Sent: Monday, March 1, 2021 4:17 PM
To: CDC IMS 2019 NCOV Response VTF Policy [redacted]
Cc: Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP) <[redacted] McClure, Susan (CDC/DDPHSIS/CGH/OD) <[redacted] Cone, George Edward (CDC/DDID/NCIRD/OD) <[redacted] Gogstad, Eric (CDC/DDID/NCIRD/ID) <[redacted] Fitter, David L. (CDC/DDPHSIS/CGH/GID) <[redacted] Lubar, Debra (CDC/DDID/NCEZID/OD) <[redacted]

Fox, Kimberley (CDC/DDID/NCIRD/DBD) < [redacted] Culp, MaryBeth (CDC/DDID/NCIRD/OD) (CTR) < [redacted] Petersen, Lisa (CDC/DDNID/NCCDPHP/DOH) [redacted]
Subject: Fw: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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. Roee 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:	Fitter, David L. (CDC/DDPHSIS/CGH/GID)
To:	Martin, Stacey (CDC/DDID/NCEZID/DVBD); 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; McClure, Susan (CDC/DDID/NCHHSTP/DTE)
Subject:	RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Date:	Sunday, February 28, 2021 2:27:48 PM

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. Roee 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:	Fitter, David L. (CDC/DDPHSIS/CGH/GID); Martin, Stacey (CDC/DDID/NCEZID/DVBD); 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 VTF 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:	Sunday, February 28, 2021 7:47:00 PM

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]

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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.

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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. Roee 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

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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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Cc:	Lubar, Debra (CDC/DDID/NCEZID/OD); Fox, Kimberley (CDC/DDID/NCIRD/DBD); Beauvais, Denise (CDC/DDID/NCIRD/OD); CDC IMS 2019 NCOV Response VTF 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 10:04:00 AM

HI Stacey,
If FDA would like to provide a written response, I think that is fine.
Perhaps we could provide the written response and then the POC for FDA?

Am happy to facilitate if you would like to connect me. Please let me know.

Thanks
Susan

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,
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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. Roee 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:	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 10:49:00 AM

Thanks. Followed up with Stacey. Am awaiting her response.

From: Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP) [redacted]
Sent: Monday, March 1, 2021 10:40 AM
To: 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

I heard Madison's response. Let me know if you need anything else.

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

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

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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. Roee 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; CDC IMS 2019 NCOV Response VTF Policy
Cc:	Reimels, Elizabeth (CDC/DDNID/NCIPC/DVP); 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/OD) (CTR); Petersen, Lisa (CDC/DDNID/NCCDPHP/DOH)
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 4:39:00 PM

Thank you.

I'm following up. FDA prefers a written response to this inquiry.

Susan McClure

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

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. Roee 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

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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: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: WG call Thurs
Date: Tuesday, May 18, 2021 6:37:00 PM

Well I was told in vague terms that this was happening, but wanted to reach out and confirm. Thanks for being willing to do this. I guess I didn't mean communication as in coms (although agree it may be helpful to have them on- good idea), but if there's going to be any HAN around this. But potentially not.

Thanks!

Sara

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, May 18, 2021 6:26 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: RE: WG call Thurs

Hi Sara – I was asked by the VaST leadership to give a 5 minute high-level verbal update on the WG call on Thursday and take questions. I guess you didn't get the memo on that one. I can talk about the communications strategy in broad terms; we are working with AAP on messaging. Beyond that, the communications isn't really an ISO issue. It might help to have the VTF communications and media folks on the call to discuss that. Thanks.

Tom

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Tuesday, May 18, 2021 5:55 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: WG call Thurs

Tom:

I think you guys may have talked about this on the VaST planning call already- but curious to know if you would be willing to give an overview of myocarditis at the WG call Thursday. I was thinking it would be helpful to discuss both the current investigation and plans for communications moving forward.

Speaking of- what are the overall communication plans? Are you thinking that there may be a HAN or other public communications from CDC? Just trying to be prepared!

Thanks!

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: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: WG call Thurs
Date: Tuesday, May 18, 2021 7:14:00 PM

The whole thing has been a bit odd, but as always- happy to work with you on everything. Lauri actually called me just now and filled me in on some of the communication challenges, so I understand that better.

Thanks again- I know you get stuck in the middle of a lot with these issues, and appreciate everything you are doing! We actually have a fairly light agenda for the WG- maybe 10 minutes at the beginning of the call as an overview of upcoming policy issues, then I'll turn it over to you. Once you've given the update and have questions, we're briefly going to highlight the variant talk from ACIP that got cut off because of the HHS live feed issue. And then that's it. So take as long as you need.

Thanks!
Sara

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, May 18, 2021 6:46 PM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]
Subject: RE: WG call Thurs

I didn't mean it that way. It sounded to me like nobody had bothered to tell you that I would be presenting on the call. The communications piece has been an bit challenging. Our office doesn't typically lead this type of communications, but we have been having to do a lot of coordination. I'm hoping once AAP puts out its statement things will calm down a bit.

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Tuesday, May 18, 2021 6:37 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: WG call Thurs

Well I was told in vague terms that this was happening, but wanted to reach out and confirm. Thanks for being willing to do this. I guess I didn't mean communication as in coms (although agree it may be helpful to have them on- good idea), but if there's going to be any HAN around this. But potentially not.

Thanks!

Sara

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, May 18, 2021 6:26 PM
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Tom

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <[redacted]
Sent: Tuesday, May 18, 2021 5:55 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: WG call Thurs

Tom:

I think you guys may have talked about this on the VaST planning call already- but curious to know if you would be willing to give an overview of myocarditis at the WG call Thursday. I was thinking it would be helpful to discuss both the current investigation and plans for communications moving forward.

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Thanks!
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:	Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To:	Snow, Vincenza T; Cane, Alejandro
Cc:	MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD)
Subject:	update on myocarditis
Date:	Thursday, May 27, 2021 11:16:00 AM

Vinnie and Ale:

Wanted to let you know an update on myocarditis. The (current) plan is to release web content describing the reports of myocarditis/pericarditis and clinical considerations, but not a formal HAN. This will be combined with targeted clinician outreach as well. The goal is to have these web updates posted this afternoon. I'll send them on when they are posted.

The language is still being finalized, but a few highlights are below (language is still draft until it's posted, but wanted you to have an idea of what it may say).

- More than 165 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- In April and May of 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.

As all things CDC, this may change, but I wanted to let you know what our current understanding of the communications plan is.

Thanks-
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:	Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To:	Barbara Kuter (x)
Cc:	MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD)
Subject:	update on myocarditis
Date:	Thursday, May 27, 2021 11:16:00 AM

Barb:

Wanted to let you know an update on myocarditis. The (current) plan is to release web content describing the reports of myocarditis/pericarditis and clinical considerations, but not a formal HAN. This will be combined with targeted clinician outreach as well. The goal is to have these web updates posted this afternoon. I'll send them on when they are posted.

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Thanks-
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: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Monday, April 5, 2021 12:08 PM
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 < Cunningham, Fran < 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 (< 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/ISD) < Wong, Hui-Lee (FDA/CBER) < Woo, Jared (CDC/DDID/NCEZID/DHQP) < Young, Mardia (CDC/DDID/NCEZID/DHQP) (CTR) <
Subject: VaST - Agenda for April 5 (1:30 - 3 pm ET) and presentations - CONFIDENTIAL

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 Fran Cunningham, 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
Centers for Disease Control and Prevention

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: WG call Thurs
Date: Tuesday, May 18, 2021 5:55:00 PM

Tom:

I think you guys may have talked about this on the VaST planning call already- but curious to know if you would be willing to give an overview of myocarditis at the WG call Thursday. I was thinking it would be helpful to discuss both the current investigation and plans for communications moving forward.

Speaking of- what are the overall communication plans? Are you thinking that there may be a HAN or other public communications from CDC? Just trying to be prepared!

Thanks!
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: Wakana, Benjamin L. EOP/WHO
Sent: Tue, 25 May 2021 03:21:11 +0000
To: Walensky, Rochelle (CDC/OD); Fauci, Anthony (NIH/NIAID) [E]; Slavitt, Andrew M. EOP/WHO; Collins, Francis (NIH/OD) [E]; Murthy, Vivek (HHS/OASH); Smith, Marcella N. EOP/OSTP
Cc: Rowe, Courtney M. EOP/WHO; Berner, Kate EOP/WHO; Munoz, Kevin EOP/WHO; Sams, Ian (HHS/ASPA); Billet, Courtney (NIH/NIAID) [E]; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); Hall, Bill (HHS/ASPA); Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Lesko, Max (HHS/OASH); Cheema, Subhan N. EOP/WHO; Saez, Mariel S. EOP/WHO; Webb, Cameron C. EOP/WHO; Beckman, Adam (HHS/OASH); Sanchez-Velasco, Marissa EOP/WHO; Beckman, Adam (HHS/OASH); McDonald, Jason (CDC/OD/OADC); Allen, Kirsten (HHS/ASPA); Perry, Sherice (OS/IEA)
Subject: RE: COVID Tough QA
Attachments: Tough QA 5.24.21 11PM.docx

Hi, attached please find the latest tough QA. New topics include:

- Myocarditis
- Wuhan Lab Leak
- Payments for Vaccinations (lotteries, etc)
- Global

Hope this helps,
Ben

+++
Ben Wakana
Deputy Director for Strategic Communications and Engagement
White House COVID Response Team
[redacted]

Tough QA

Myocarditis

Toplines

- There have been rare reports of myocarditis and pericarditis occurring after vaccination.
- Reported cases appear to be mild and often go away without requiring treatment.
- These reports are rare given the number of vaccine doses administered, and CDC and FDA will continue to monitor and evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination.
- CDC continues to strongly recommend COVID-19 vaccination for individuals 12 years of age or older given the risk of COVID-19 illness and related, potentially severe, complications.
- Getting vaccinated is the best way to protect you and your family from COVID-19.

Is there a direct link to vaccination?

- CDC and its partners are actively investigating these reports to assess whether there is a relationship to vaccination. Most reported cases have been mild and individuals have responded to treatment. CDC strongly recommends people 12 and older get vaccinated as soon as possible to protect against COVID-19 and the related, potentially severe, complications that can occur.

How many cases have been found so far?

- CDC and FDA are investigating cases reported to VAERS and they will have more details soon.

Is there a certain age group this impacts?

- Reported cases have mostly been in people under 30 years of age. Reported cases have been mild and treatable. We will continue to monitor the situation closely. CDC strongly recommends people 12 and older get vaccinated as soon as possible to protect against COVID-19 and the related, potentially severe, complications that can occur.

Should there be a pause as we learn more?

- CDC strongly recommends people 12 and older get vaccinated as soon as possible to protect against COVID-19 and the related, potentially severe, complications that can occur. Given the potential risks associated with COVID-19 infection in adolescents, and the rarity and mildness of the cases of myocarditis and pericarditis reported following vaccination, CDC and FDA continue to strongly recommend use of this vaccine. Myocarditis and pericarditis are side effects that can be seen following a viral infection and other types of vaccination. Reported cases have been mild and often go away without requiring treatment. We will continue to monitor the situation closely and provide more information as it becomes available.

Are you afraid these reports will impact your vaccination efforts?

- CDC continues to transparently communicate with the American people. Our independent vaccine working group published data online about this issue late last week. As the CDC has made clear, these occurrences are rare, and the reported cases have been mild and often go away without requiring treatment. CDC does not have cause for concern and strongly recommends that people get vaccinated as soon as possible to protect against COVID-19 and the related, potentially severe, complications that occur.

COVID Origins

Wuhan Lab Leak

- For months, we have conveyed our serious questions about the earliest days of the COVID-19 pandemic, including its origins within China.

- We are working within the WHO to support an expert-driven evaluation of the pandemic's origins that is free from interference or politicization.

- When the phase 1 results came, we were first to make clear that the WHO needed a more transparent, independent phase 2 investigation.

    - That means China finally stepping up and allowing the access needed to determine the origins. We were encouraged by other countries following suit and WHO Director General Tedros echoing our call for a real phase 2 investigation.

- *If pushed on "isn't this a lab leak confirmation":* We're not going to make pronouncements that prejudge an ongoing WHO study into the source of COVID, but we've been clear that sound and technically credible theories should be thoroughly evaluated by international experts.

January 15 State Department Fact sheet

Note: The Trump Administration Fact sheet announced that "The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses."

- A factsheet issued by the previous Administration on January 15 did not draw any conclusions regarding the origins of the coronavirus. Rather, it focused on the lack of transparency surrounding the origins.

- As a matter of policy we do not comment on intelligence issues.

Gain of Function

- NIH has never approved any grant that would have supported "gain-of-function" research on coronaviruses.

- NIH supports the need for further investigation by the World Health Organization into the origins of the coronavirus. NIH urges the WHO to begin the second phase of their study without delay.

Payments for Vaccinations

- States may recipients use funds to pay for vaccine incentive programs such as:
  - Lottery Programs
  - Cash or in-kind transfers
  - other incentives for individuals who get vaccinated

- In general, programs that provide incentives reasonably expected to increase the number of people vaccinated are an allowable --

  - So long as such costs are reasonably proportional to the expected public health benefit.

Isn't this a waste of money?

- In this phase of vaccinations, local leaders will take new, creative approaches to getting more shots in arms. And we want to be supportive of those efforts to the greatest extent possible.

- Every week, this pandemic costs our economy billions of dollars. So if these financial incentives end the pandemic just ONE day early, it will be worth it.

- Not to mention in the lives saved and communities improved from healthier outcomes.

Treasury says the amount of funds used for incentives have to be "reasonably proportional" to the expected public health benefits. What does reasonably proportional mean? Is [state]'s proposal reasonably proportional? ***Is there a particular dollar amount that wouldn't be reasonably proportional?***

- Given the high expected public health benefit of ensuring additional people get vaccinated or that people get vaccinated sooner, states and localities making use of Fiscal Recovery Funds for purposes of vaccine incentive programs will have a lot of flexibility in designing their particular approaches.

- However, states and localities should design their incentive programs with a reasonable expectation that they provide public health benefits commensurate with the costs of providing the incentives. This expectation helps to ensure that funds being used for vaccine incentive programs are addressing the public health emergency.

- The expected public health returns depend on specific conditions in states and localities, so I am not going to comment on any specific plan.

- It is worth emphasizing that the expected public health benefit of vaccinating additional people sooner is quite high.

- So, if a state or locality is making use of Fiscal Recovery Funds, its incumbent that they document the anticipated costs and expected public health returns to their vaccine incentive approaches but, generally, we anticipate that there may be many different approaches that meet the necessary standard.

Global
Global Strategy

Topline: A key pillar of the President's comprehensive strategy to defeat COVID-19 focused on helping to end the pandemic around the world. That's why the U.S. is executing a three-part strategy to address this global pandemic: 1) We are becoming an arsenal for vaccines by sharing surplus U.S. vaccines and increasing vaccine manufacturing here at home and around the world, 2) We are supporting other countries respond to outbreaks by surging supplies and offering other assistance, and 3) We are leading on the international stage by marshalling a multilateral effort with our global partners.

Becoming an arsenal for vaccines and boosting manufacturing abroad:

- *Donating surplus U.S. vaccine supply.* We have secured enough supply for the U.S. and we will share 80 million surplus doses by the end of June. That's 5 times more doses than any other country in the world has shared. Importantly:
    - We will not use its vaccines to secure favors from other countries.
    - We will work with COVAX and others to ensure these vaccines are delivered in a way that is equitable and follows the science and public health data.
    - We will continue to donate from our excess supply as that supply is delivered to us.

- *That's why we are taking steps to increase manufacturing and production capabilities here at home and around the world.*
    - *Increasing U.S. manufacturing capacity*. Driven by the aggressive actions we have taken to accelerate manufacturing and production lines in the U.S., Pfizer and Moderna have already increased their capacity to produce vaccines for the world.
    - *Increasing global manufacturing capacity*. We are working to expand global manufacturing of safe and effective vaccines. For example, we launched the Quad Initiative to manufacture at least 1 billion doses of vaccine in India, including J&J. Our Development Finance Corporation provided financing and is looking at additional ways to spur production.
    - *Relieving supply bottlenecks*: Pre-COVID, the world produced 4 billion doses of vaccine each year. Amid the pandemic, the world is trying to make 14 billion more doses just for COVID. It is not surprising, therefore, that raw materials and other items needed to manufacture are in short supply. The U.S. is working with international partners, for example diverting our filters to India so that they could make 20 million doses for their domestic needs. The U.S. is also is investing to expand the pool of available supplies.

Surge Supplies Globally

- We know that in addition to vaccine, there are areas of the world that need additional supplies to battle this pandemic, particularly when cases spike. We are sending emergency assistance to partners like India – where we recently sent six flights and up to $100 million of assistance – with more help on the way to partners in Latin America and South Asia as countries experience surges.

- We've also provided $11.5 billion in new funding in the American Rescue Plan to support countries in battling and recovering from COVID-19.

Leading on the world stage to end this pandemic.

- Donating surplus U.S. doses, medicines, oxygen and PPE are vital steps to support the global community. But ending the pandemic everywhere requires a multilateral effort, and marshaling a multilateral effort requires American leadership.
- That's why the President and his Administration–
    - Re-engaged with the World Health Organization and committed to strengthening and reforming the organization.

- Expanded funding to support global response efforts, including a total of $11.5B from ARP and $4 billion to COVAX – the most funding to COVAX of any other country in the world.
- And supports taking extraordinary measures, like supporting the TRIPS Waiver, during these extraordinary times.

- In the coming days and weeks, the U.S. will continue demonstrating its leadership by working with the G7, the E.U., COVAX and others to lead a multilateral effort to end the pandemic.

When will you give away excess doses?

- We're committed to sharing vaccine and we already have.
  - 4M to Mexico and Canada
  - 60M AstraZeneca doses

- We've only vaccinated about 59 percent of the country with one shot, and millions of people only became eligible for vaccinations on April 19th.
  - We also have millions of kids and adolescents left to vaccinate.

- As the President has said, this virus knows no borders, and we'll do everything we can do to end this pandemic at home and abroad, but it is critical that we make it as easy and accessible as possible for Americans to get vaccinated now.

India

How are you helping India/Why not share doses?

- Our national security team is working with Indian officials, and we will provide any assistance we can.
  - We've already provided:
    - Oxygen – more than 1,000 cylinders
    - PPE – 15 million N95 masks
    - Vaccine manufacturing supplies – this will allow India to make over 20 million doses of COVID-19 vaccine.
  - American experts from CDC have conducted pandemic training for Indian state and local health officials.
  - In addition, we've made vaccine cooperation a big priority, including with our Quad partners – of which India was one.
  - And we've provided $4 billion to COVAX – the most of any country.

- We'll continue to monitor the situation closely.

TRIPS Waiver

- This is a once in a century pandemic.

- Extraordinary circumstances call for extraordinary measures.

- We know that a waiver alone won't result in the scale and speed we need to make enough vaccines to end the pandemic.

- That's why we will continue to ramp up our efforts - working with the private sector and all possible partners -- to expand vaccine manufacturing and distribution around the world and increase the raw materials needed to produce those vaccines.

- The right thing to do is to support a waiver - we are in an unprecedented pandemic, and that's why we're supporting the waiver.

- *If pushed:* The US is the most innovative country in the world. Pharmaceutical companies will continue to invest, make lifesaving breakthroughs, and lead the world

Why give patents to China and Russia?

- Our aim is to get this to the countries that need the help, not to get it to China or Russia.

- U.S. companies would still have to be involved in order to provide know-how to countries that want to make vaccines.

- There will be a lot of work and details ahead, and we will actively participate in text-based negotiations.

Progress Report

How are you doing in the fight against COVID?

- We're much further along than anyone expected. We launched a whole-of-government effort to get vaccine to the American people.
  - 60% of adults have at least one shot.
  - 85% of seniors have at least one shot. We've seen an 80% drop in deaths. 70% drop in hospitalization in that age group.
  - 150 million people have rolled up their sleeve to date.

- Cases, deaths, hospitalizations are on the decline. And it's never been easier to get vaccinated.
  - Anyone 16 years or older is eligible.
  - We have 80,000 sites and thousands of vaccinators now online.
  - 90% of Americans live within 5 miles of a vaccine.

- We have a lot more work left to do. We set a new goal of getting 70% of adults with at least one shot by July 4th.

- To reach that goal – we're focused on:
  - Making it easier to get vaccinated:
  - Increasing vaccine confidence:
  - Ensuring equity:

- To book an appointment
  - visit Vaccines.gov,
  - text your zip code to 438829 (GETVAX),
  - Call 1-800 number (1800-232-0233) for assistance in 150+ other languages.

Vaccine Verification

- If you're vaccinated, you're protected. But if you're unvaccinated and choose not to wear a mask, you're putting yourself at risk.

- There will not be a federal vaccinations database or a federal mandate requiring everyone to obtain a single vaccination credential

- Because we believe the reasons for getting vaccinated are clear.
    - It protects you from serious disease or death from COVID.
    - And it protects your family, friends, and neighbors.
    - Studies estimate that over 90% of doctors have been vaccinated.
    - It is our ticket back to normal.

Confidence

Toplines

- Confidence is increasing.
    - In January, just 47% of people had either received a vaccine or wanted to get vaccinated as soon as they can.
    - Today, that number is 64%, according to Kaiser.
- People still have questions
- Getting vaccinated is a personal decision.
    - Talk to your doctor, family, faith leader, pharmacist, health care provider.
    - 90% of doctors have been vaccinated
- Getting vaccinated gets us back to normal.
    - The best way to get back to safely gathering with friends, indoor dining, weddings, sporting events, concerts, and dates is to join the more than 150 million Americans
- Vaccines are available to everyone in the U.S. 12 and older.
    - It's free
    - You don't need an ID. You don't need health insurance
    - Uber and Lyft

Young People

- Many of them recently became eligible.
- We want to make it really easy for young people.
- We know people have questions. We're working to provide facts. That's local, it's doctors, it's trusted messengers.

Conservatives

- More than 83% of seniors have received at least one dose – that includes many conservatives.
- In order to reach populations that still have questions, we're meeting conservatives where they are. That's why we're engaged with:
    - Faith Leaders
    - Rural Leaders
    - Doctors
    - Media and Entertainment Industry: We're engaged with NASCAR and Country Music TV.

Misinformation

- It's unfortunate that we live in a society where there is misinformation. We combat misinformation with facts.
- We're empowering the local, trusted people with the facts so they can answer questions.
- People should talk to their doctor.

Schools

Will schools be 100% in person by fall?

- The President wants all schools open in the fall, consistent with what Secretary Cardona has said.
- We've made a lot of progress. At the end of March, 54% of schools offered 5 days a week of in person instruction.
- We've provided funding for schools – more than $122 billion in ARP funding – that carries throughout summer and info fall.
- Teachers are vaccinated – 80% thanks to the push we made.
- As Secretary Cardona has said, we're not going to rest until every school is offering in person instruction 5 days a week.
- FYI on Full Cardona Quote: "I want all students to have the opportunity to learn in person in the spring, but I expect it in the fall. I need all students to have the opportunity to learn in the school house."

Booster shots

- As Dr. Fauci has said, we know the vaccines are effective for 6 months and likely for a considerably longer amount of time.
- Any decision about boosters will be made by our health and medical experts at CDC and FDA.
- As always, we will plan for a range of scenario, be prepared for any scenario, and ensure we have more than enough supply for the American people.

Mask Guidance Toplines

- For fully vaccinated people, life can begin to return to normal.
- If you're vaccinated, you're protected from those who may not be. But if you're unvaccinated and choose not to wear a mask, you're putting yourself at risk.
    - Vaccines work in the real world
    - Vaccines stand up to the variants
    - Vaccinated people are less likely to transmit the virus. That's how they came to this decision.

Masks and Travel

Can people travel now?

- CDC guidance is clear that vaccinated people are safe to travel and can resume travel.
- People are still required to wear a mask on planes, buses, trains, and other forms of public transportation.
- Travelers are encouraged to treat transportation operators with respect and note that civil penalties are still in effect for violating the mask mandate and there is a zero tolerance policy in place for unruly passengers on airlines.

Why are masks required for travel?

- Public transportation is unique in several ways. It is:
    - A necessary mode of transportation for people's livelihoods.
    - A small and confined space.
    - Densely populated.
- Those three factors make public transportation different from other settings.
- Given those distinctions, the CDC recommendation at this time is to still require to wear masks on planes, buses, trains, and other forms of public transportation and in transportation hubs such as airports and stations.

Masks and States

Should states drop mask mandates?

- When it comes to decisions about reopening and what communities should do, each community is going to have to make the decisions that are right for them, based on the situation in their own community. Those factors include:
    - Vaccination levels
    - Cases
    - Transmission
- We have a responsibility to tell people what activities are safe for them.
- Based on the CDC's latest science, fully vaccinated people can safely participate in most activities, indoor or outdoor, without wearing a mask or social distancing.

Should states keep masks? Variants are still dangerous.

- There is real world evidence that the vaccines work -- studies confirming they are 90+ percent effective.

- Vaccines have proven to be effective against the current variants.
    - The U.S. is now sequencing ~10% of all virus in the country, which gives a good picture of the variants that are circulating here.
    - Data shows that the vaccines we have available are effective against the current variants.

- The data shows vaccinated people are far less likely to spread the virus.
    - Given these facts, the science is clear: if you are fully vaccinated, you are protected, and you can start doing the things you stopped doing because of the pandemic

- If you're unvaccinated and choose not to wear a mask, you're putting yourself at risk.
    - The best way to protect against COVID is to get vaccinated.

Mask for Specific Populations

Kids

What does this mean for people who have unvaccinated little kids?

- The CDC guidance is for fully vaccinated people.
- The CDC guidance for people who are not fully vaccinated – such as kids – has not changed.
- Protecting kids is the most important thing we can do and there is no authorized vaccine yet for kids under 12 years of age.
- The camp guidance applies to certain settings that are unique to camps – such as bunks or if there are 10 kids on a field, all in front of the same soccer ball.
- But for spread-out activities like walks or biking, the outdoor mask guidance for unvaccinated people – where masks are not required – would apply.

People of Color

Does this put people of color at greater risk since they have lower vaccination rates?

- Dr. Walensky' announcement made clear that vaccinated people are protected from the dangers of COVID-19 and was further proof of why we need to get everyone vaccinated.
- And we're working to do just that—we're increasing access and making it easier than ever to get a shot, we're encouraging businesses to give paid time off, increasing our education and outreach efforts.

Equity Progress

- **Toplines**: Deaths are down dramatically since January—down over 80% among seniors, which includes a drop among Hispanics of over 80% and among African Americans of about 70%.
  - In the past 2 weeks, 55% of the people vaccinated were white and 45% were non-white. That compares to a general population that's about 60% white and 40% non-white.
  - The proportion of seniors who have been vaccinated is essentially equal between white seniors and seniors of color
- Hispanic Americans are leading the charge.
  - In the past four weeks, they make up 20% of those newly vaccinated while representing 17% of the overall population.
  - Latino confidence increased by 22 points since January – up to 64%
- We are trending in the right direction.
  - FEMA sites: Are all in hard hit communities across the nation and approximately 60% percent of shots were to people of color
  - Community Health Centers: About 70 percent of shots through the federal CHC program have been administered to people of color
  - Pharmacies: 40% of stores are located in high-risk areas. Over the past two weeks, 47% of pharmacy doses have been administered to people of color.
- **We have more work to do**
  - **Eligibility**: Many people of color recently became eligible because people of color skew younger and millions weren't eligible previously. We're providing new resources like Vaccines.gov / Text 438829 / 1800 Number

    - **Outreach**: Our Administration recently announced $250 million to hire community health workers to increase vaccine access for the hardest-hit and highest-risk communities. This funding will prioritize hiring workers who live in the communities they serve.
    - **Access**: As we move into the next phase, we're expanding access:
        - More pop up and mobile units.
        - The majority of our 40,000 pharmacies are now accepting walk-in appointments.
        - We're shipping a new allocation of vaccine directly to rural health clinics
        - Covering paid time off
        - Free transportation
- **Progress:** In January, only 17 states publicly reported data on race/ethnicity. Now, 48 states publicly report.
- **Closing**: The vaccines are free, every adult in America is eligible, and they're in 80,000 locations across the country. We know we have more work to do, but we are keeping equity at the center of this response, and we will not leave anyone behind.

Masks in Businesses

- We will continue to encourage fully vaccinated people to abide by state and local rules and regulations, including local business and workplace guidance.
- When it comes to decisions about more fully reopening, each business will have to make its own decisions about the timeline and process based on a variety of factors. Those factors include:
    - Vaccination levels
    - Cases
    - Transmission

Can workplaces reopen?

- Fully vaccinated people can participate in indoor and outdoor activities – large or small – without wearing a mask or physically distancing.

- Existing guidance allows workplaces to reopen.
    - But businesses must give reasonable accommodations to people with disabilities.

- When it comes to decisions about more fully reopening, each business will have to make its own decisions about the timeline and process based on a variety of factors. Those factors include:
    - Vaccination levels
    - Cases
    - Transmission

- Over the coming days and weeks, CDC will review its guidances, but keep in mind CDC guidance is typically broad and businesses will need to make decisions based on vaccination rates within an organization and local transmission.

What about bringing customers back?

- These decisions are done at the community level and depend on local conditions – vaccination levels, cases, transmission, and the prevalence of the disease.

- We will continue to encourage fully vaccinated people to abide by state and local rules and regulations, including local business and workplace guidance.

- We're saying fully vaccinated people can participate in indoor and outdoor activities – large or small – without wearing a mask or physically distancing.

Employer Vaccine Verification

- Employers can ask about vaccination status.
- There will be no federal vaccinations database and no federal mandate requiring everyone to obtain a single vaccination credential, because we believe the reasons for getting vaccinated are clear.

Employer Mandates

- Ultimately, these decisions are up to employers.
- We encourage everyone to get vaccinated, and we are doing everything we can to make it even easier for people to get vaccinated.
- Right now, we are focused on getting everyone a shot who wants one.

Vaccine Mandates / Military / Colleges

Will you mandate vaccines

- Ultimately, getting a vaccine is an individual choice. But let's be clear about the benefits.
    - It protects you from serious disease or death from COVID.
    - And it protects your family, friends, and neighbors.
    - Studies estimate that over 90% of doctors have been vaccinated.
- I can tell you this – I got vaccinated and I would recommend everyone get vaccinated as soon as possible. It's never been easier or more convenient.

School Mandates

- Ultimately, these are local decisions.
- We're working to make sure parents have all the facts and have conversations with their kid's pediatricians.

Military Mandates

- As the President has said, he will leave that to the military.
- Everyone is eligible and it's never been easier to get a shot.

College Mandates

- We encourage everyone to get vaccinated, and we are doing everything we can to make it even easier for people to get vaccinated.
- Right now, we are focused on getting everyone a shot who wants one.

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Publ c ea t rvice Act (PHS t f r COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, M i G rma y u der t e p o of se i 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indi ted f r active immunization pr vent corona isease 2019 (COVID-19) caused by severe ɔute r sp rat ry yndrome coronav 2 (SARS-CoV-2) in individuals 6 a o ge and older.

The review of this product wa assoc at d with he llowing National Clinical Trial (NCT) numbers: N 0436 2 d NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., [redacted] and at Fresenius Kabi USA, LLC, [redacted].

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 mon hs from the da e o manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF). The dat of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at Pharmacia & Upjohn Company LLC in Kalamazoo, Mich gan, the date of manufacture is defined as the date of sterile filtration f r h i al dru product; at Pfizer Manufacturing Belgium NV in Puurs, Belgium, t s f n as he date of the [redacted] Following the final sterile filtration, [redacted], no reprocessing/r ing is allowed without prior approval from the Agency. The dating period for your drug substance shall be [redacted] hen stor t [redacted]. We have approved the stability protocols n yo r cense pp'catin r u e of xt d g the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with proto ols showing results of all applicable tests You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If t dev t on v l istri ut r ct ma a f th afe y, u or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but n l m ted to, he m ufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, r in t e anu a u ng faci..itie

LABELING

We hereby approve the draft content of labeling ncl di g Package l .sert, submitted under amendment 74, dated August 21, 2021, an f ca o . and co ne l be s submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the automate ru reg stration and listing ystem, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling ust e ident cal t the Package Insert submitted on August 21, 2021. nfo i on su t.ng SPL l us ng ma be o n the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at mo. t' ly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, p a refe to t e gu da e for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-doc ents/providing-su.Jn'ssi s-electronic-format-postmarketing-safety-reports-vaccines. For information on distri ution r porting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketAc i ies/L tPe eases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 t evaluate the sa ety nd e,fective ss of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: O o r 1, 023

2. Deferred pediatric S udy 4 to ·.aluate the safety and effectiveness of COMIRNATY in infants and c l en 6 mon h o <12 years of age.

   Final Protocol Submission: ebruar , 1

   Study Completion: November 30, 20

   Final Report Submission: May 31, 2024

3. Deferred p diatric S udy 4 23 to evaluate the safety and effectiveness of COMIRNATY in i fan s months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: S p er . 0, 20 4

6. Study C4591021 substudy to describe he n t al h st y of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: January 31, 2022

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021

Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively a s th incidence of sub in cal myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 1, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June , J22

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were sub tt to h IN . Please refer to the PMR seque l numbe for ea study/clin a ial and the su m ssion number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmar eting stu s on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post m rketin h l Co m d f ul t .

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided hat you includ th element list d in section 505(o) and 21 CFR 601.70. We remind you th to co ly wit t o you u ep t must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post- mer nc U Au h i atio', A' f t Surveillance Study Among Individuals in the et ra s Affa,rs H l h System Receiving Pfizer-BioNTech o vi s e se 20 '9 (CO' -19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 20^3

13. Study C4591014, entitled " i ,r-B oN" CO -19 BNT162b2 Vaccine Effectiveness Study - se Per.na' en e o ern C i o a."

    Final Protocol Submission: March 22, 2021

    Study Completion: D ,ce' be 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 1257" explaining that these protocols were submitted to the IND. Please refer to the PMC seque ial n e f a tud linic l trial and e sub is io number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to schedule a meeting, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

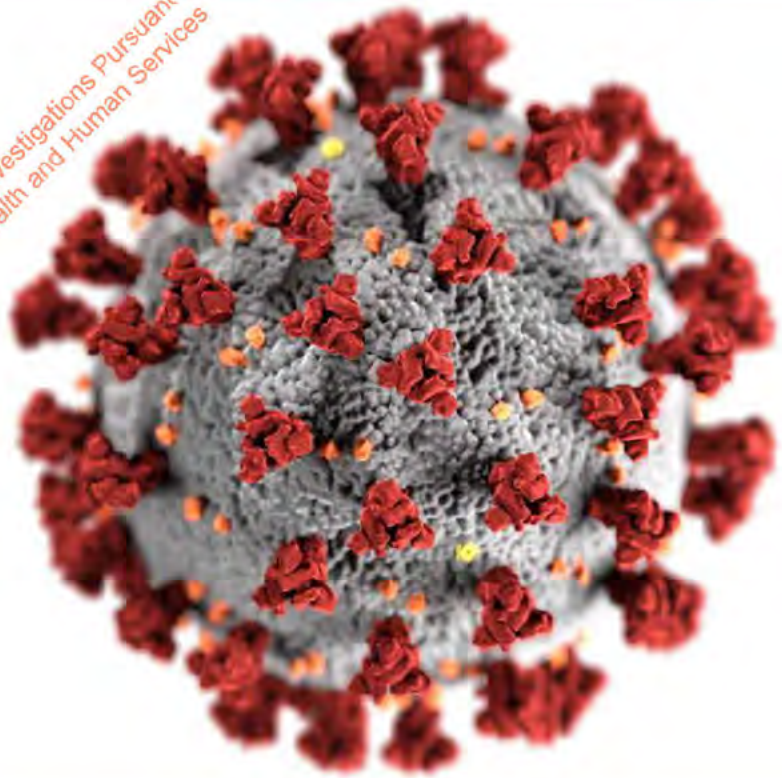
Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Update on myocarditis following mRNA COVID-19 vaccination

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

June 14, 2022

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Coordination Unit



cdc.gov/coronavirus

Topics

- Background on classic myocarditis and myocarditis associated with mRNA COVID-19 vaccination
- Update on myocarditis following mRNA COVID-19 vaccination with a focus on children ages 5–17 years*
  - Findings from the Vaccine Adverse Event Reporting System (VAERS)
  - Findings from the Vaccine Safety Datalink (VSD)
- Comparative risk for myocarditis between the two available mRNA COVID-19 vaccines, Moderna and Pfizer-BioNTech

* Analyses focus on children ages 5–11 years for the 2-dose (10 µg) primary series separated by at least 3 weeks, and children ages 12–17 years for the 2-dose (30 µg) primary series separated by at least 3 weeks followed by a booster dose at least 5 months after completion of the primary series; data outside of these authorizations and recommendations (e.g., off authorization use, vaccination errors, special population authorizations/recommendations) are not included in these analyses

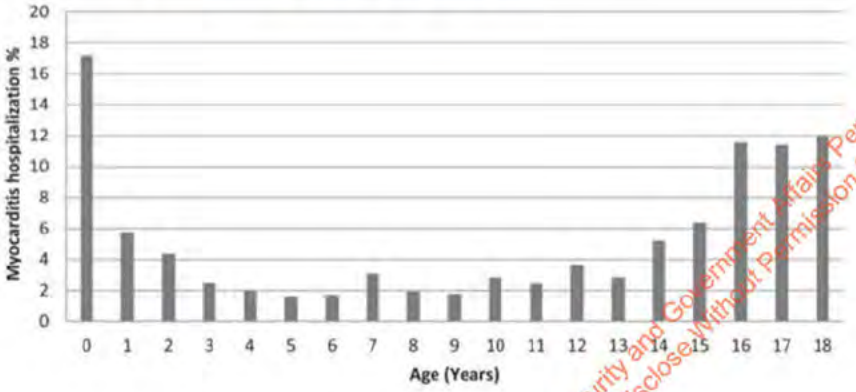
Epidemiology of classic myocarditis in children (excluding infants)

- Usually an infectious cause, typically viral or presumed to be viral, although infection with a pathogen is frequently not identified (only ~40% of time a pathogen is identified)[1,2,3]
- Can be due to direct microbial infection of myocardial cells and/or ongoing inflammatory response, with or without clearance of pathogen[4,5,6]
  - Can also be toxin-mediated or in setting of systemic infection or infection of non-cardiac tissue
- Rarer causes include autoimmune, hypersensitivity, and giant cell myocarditis
- Incidence in males > females starting after age 5 years[7]
- Previously unrecognized myocarditis was identified as cause of death in 8% of cases of sudden, unexplained death in 1–17-year-olds[8] and 9% of sudden death in athletes[9]
- It is common to not identify a pathogen or possible infectious etiology for myocarditis
  - Based on case series, where autopsy tissues were examined and tissue-based infectious disease testing was performed, a specific infectious cause was only identified in 13%–36% of cases across age groups[6,10,11]
  - For a case series where endomyocardial biopsy tissues were tested, viral nucleic acids were detected in heart tissues in ~38% (adults and children combined)[1]

[1]Bowles et al. J Am Coll Cardiol. 2003;42:466-72. [2]Simpson et al. J Am Coll Cardiol. 2013;61:(10_Supplement) E1264. [3]Park et al. J Korean Med Sci. 2021;36:e232. [4]Caforio et al. Eur Heart J. 2013;34:2636-48, 2648a-2648d. [5]Feldman et al. N Engl J Med. 2000;343:1388-98. [6]Guarner et al. Hum Pathol. 2007;38:1412-9. [7]Arola et al. J Am Heart Assoc. 2017;6:e005306. [8]Burns et al. J Pediatr X. 2020;2:100023. [9]Maron et al. Circulation. 2009;119:1085-92. [10]Weber et al. Arch Dis Child. 2008;93:594-8. [11]Ilina et al. Pediatrics. 2011;128:e513-20.

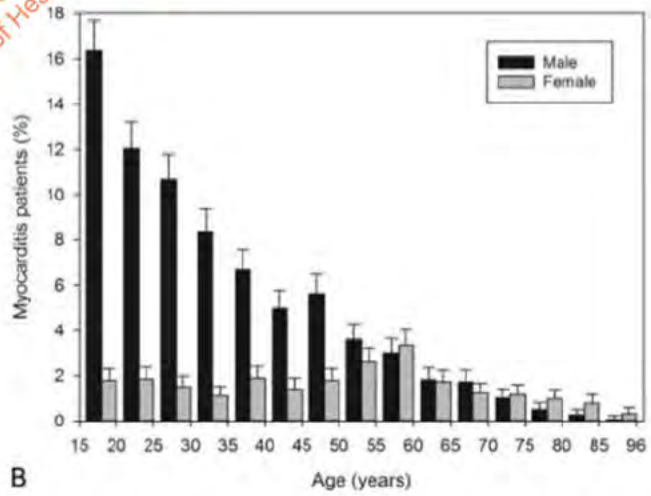
Epidemiology of myocarditis

- Children
  - Annual incidence 0.8 per 100,000
    - In 15-18yo, 1.8 per 100,000 in 2015-2016
  - 66% male
  - Median LOS 6.1 days



Vasudeva et al. *American J Cardiology*. 2021.

- Adults
  - Gradual decrease in incidence with age
  - 76% male



Kyto et al. *Heart*. 2013.

Previously presented at the June 23, 2021, ACIP meeting: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf

LOS = Length of hospital stay

Characteristic	Myocarditis associated with mRNA COVID-19 vaccination*,†	Viral myocarditis‡
Inciting exposure	mRNA COVID-19 vaccination • Dose 2 > Dose 1	Viral illness • 30–60% with asymptomatic viral course
Demographics	Most cases in adolescents and young adults, males > females	Males > females, male incidence peaks in adolescence and gradually declines
Symptom onset	A few days after vaccination, most within a week	1–4 weeks after viral illness
Fulminant course	Rare¶	23%
ICU level support	~2%	~50%
Mortality/transplant	Rare¶	11–22%
Cardiac dysfunction	12%	60%
Recovery of cardiac function	Nearly all	~75%
Time to recovery of cardiac function (ejection fraction on cardiac echo), if initially poor	Hours to days	Days to weeks to months

* https://www.cdc.gov/vaccines/acip/meetings/index.html, https://www.cdc.gov/vaccinesafety/research/publications/index.html
† Oster et al. JAMA. 2022;327:331-340.
‡ Law et al. Circulation. 2021;144:e123-e135. Ghelani et al. Circ Cardiovasc Qual Outcomes. 2012;5:622-7. Kim et al. Korean Circ J. 2020;50:1013-1022. Messroghli et al. Am Heart J. 2017;187:133-144. Patel et al. J Am Heart Assoc. 2022;11:e024393.
¶ There are rare reports in the literature, especially from other countries, but it is unclear to what extent such cases were investigated

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

VAERS

VAERS accepts reports from everyone (healthcare professionals, patients, parents, caregivers, manufacturers, etc.) regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

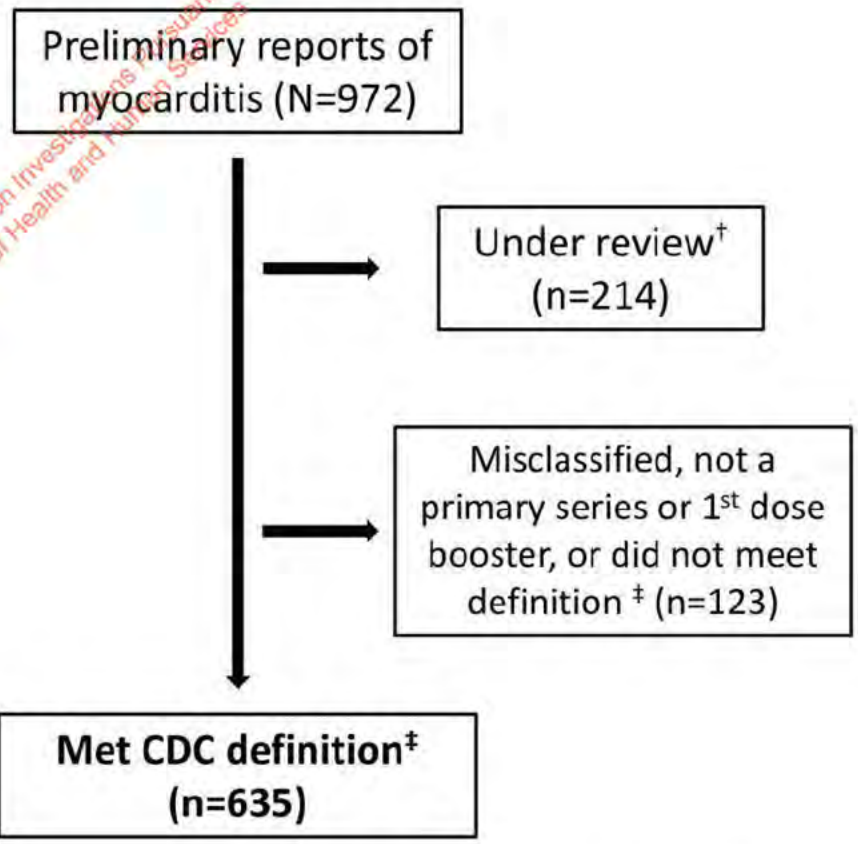
- Rapidly detects potential safety problems
- Can detect rare adverse events

Key limitations

- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

Reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–17 years (as of May 26, 2022)*

- 54.8 million total Pfizer-BioNTech doses administered to children ages 5–17 years in the United States
  - 27.7 million dose 1
  - 23.3 million dose 2
  - 3.8 million 1st booster dose (ages 12–17 years)



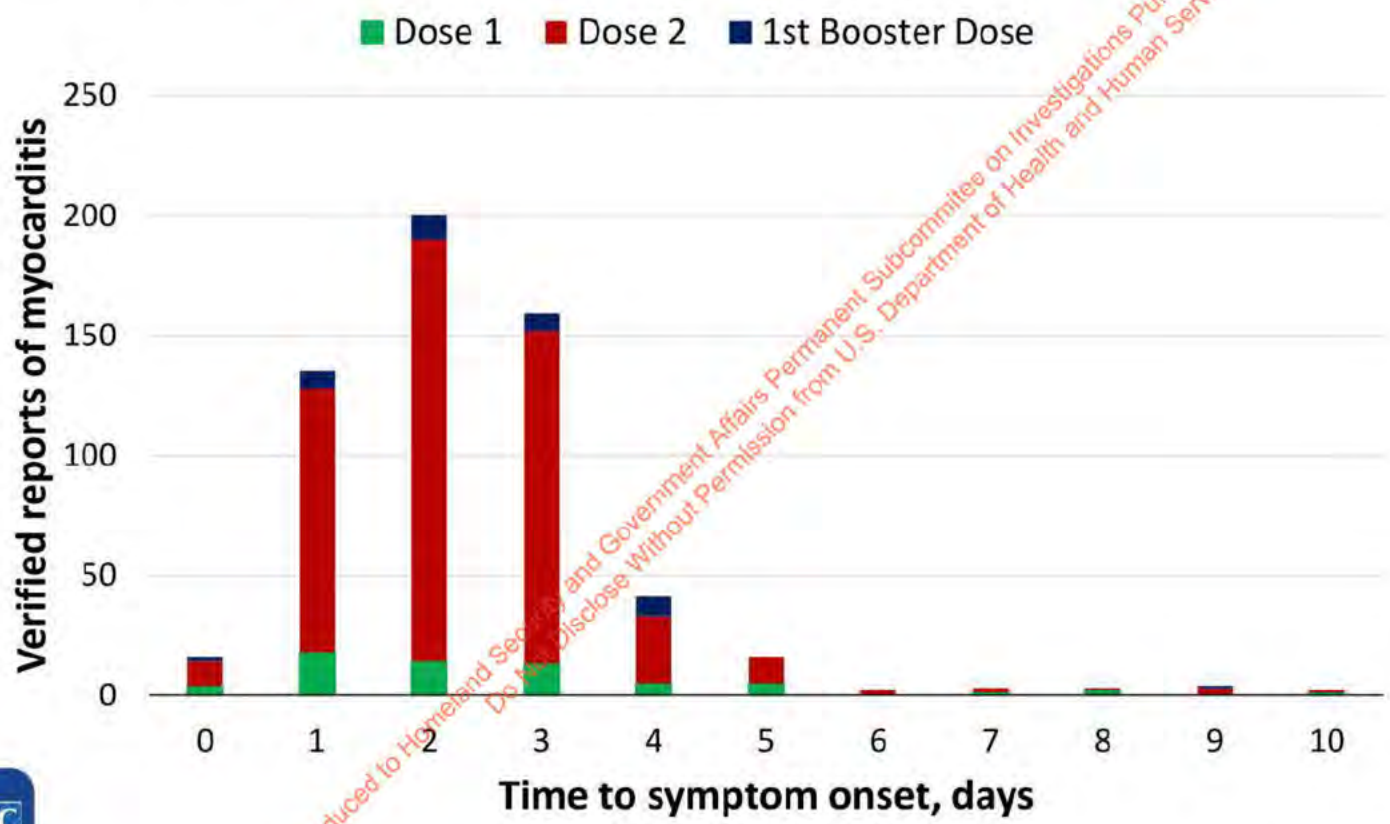
* As of May 26, 2022, primary series vaccination among children ages 16–17 years since Dec 14, 2020; children ages 12–15 years since May 10, 2021; children ages 5–11 years since Nov 3, 2021; 1st dose booster vaccination among children ages 16–17 years since Dec 9, 2021; children ages 12–15 years since Jan 5, 2022.

† Awaiting medical records and/or healthcare provider interview; some still processing

‡ Adjudicated after healthcare provider interview and/or medical record review; CDC myocarditis case definition available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

Verified* U.S. reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–17 years, by time to symptom onset† and dose number

(N=630, as of May 26, 2022)



† 630 of 635 (99%) with known time to symptom onset; 49 (8%) reports with time to symptom onset >10 days

*Verified according to CDC myocarditis case definition available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

VAERS reporting rates of myocarditis (per 1 million doses administered) after mRNA COVID-19 vaccination, days 0–7 and 8–21 post-vaccination*,†

		0–7 days			8–21 days			0–7 days			8–21 days		
		Males			Males			Females			Females		
	Age (yrs)	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster
Pfizer-BioNTech	5–11	0.2	2.6	0.0	0.6	0.0	0.0	0.2	0.7	0.0	0.2	0.0	0.0
	12–15	5.3	46.4	15.3	1.2	1.2	0.9	0.7	4.1	0.0	0.4	0.2	0.9
	16–17	7.2	75.9	24.1	1.7	3.2	1.3	0.0	7.5	0.0	0.7	0.4	0.0
Pfizer-BioNTech and Moderna	18–24	4.2	38.9	9.9	1.1	2.2	0.4	0.6	4.0	0.6	0.2	0.7	0.0
	25–29	1.8	15.2	4.8	0.4	1.1	0.5	0.4	3.5	2.0	0.2	0.0	0.8
	30–39	1.9	7.5	1.8	0.4	0.8	0.2	0.6	0.9	0.6	0.3	0.2	0.0
	40–49	0.5	3.3	0.4	0.2	0.5	0.0	0.4	1.6	0.6	0.2	0.2	0.0
	50–64	0.5	0.7	0.4	0.2	0.3	0.1	0.6	0.5	0.1	0.2	0.5	0.1
	65+	0.2	0.3	0.6	0.3	0.2	0.1	0.1	0.5	0.1	0.1	0.2	0.1

* As of May 26, 2022; reports verified to meet case definition by provider interview or medical record review; primary series and 1st booster doses only

† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 and 8–21 risk intervals, this estimated background is **0.2 to 2.2 per 1 million person-day 0–7 risk interval and 0.4 to 3.8 per 1 million person-day 8–21 risk interval**
(peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years*

- **Purpose**: Assess functional status and clinical outcomes among individuals reported to have developed myocarditis after COVID-19 mRNA vaccination
- **Methods**: A two-component survey conducted at least 90 days after the onset of myocarditis symptoms
  - **Patient or parent survey**: Focused on ascertaining functional status, clinical symptoms, quality of life, and need for medication or other medical treatment
  - **Healthcare provider (e.g., cardiologist) survey**: Gather data on cardiac health and functional status

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myo-outcomes.html; surveillance project includes two separate cohorts, children ages 5–11 years and people ages 12–29 years

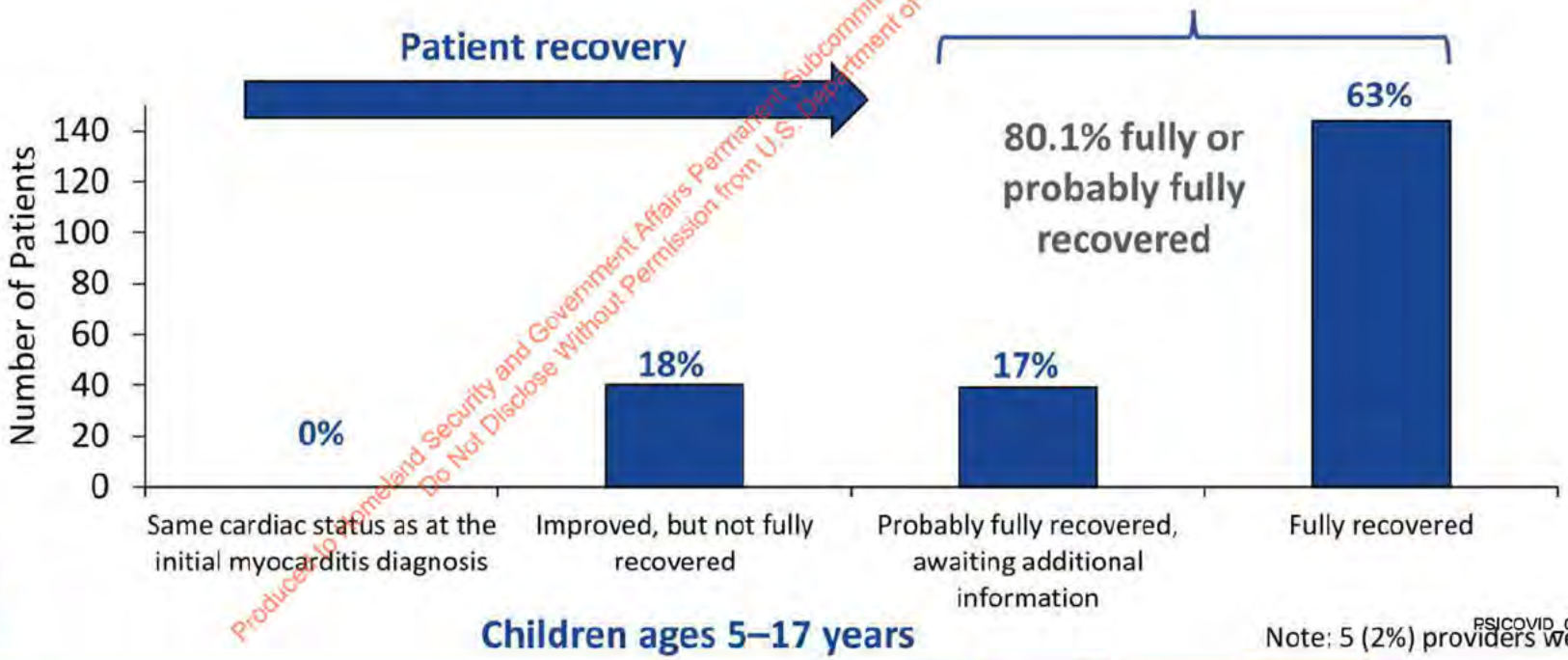
CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years

- During the surveillance periods (through November 2021 for 12–17 years and April 2022 for 5–11 years), VAERS received 430 reports of myocarditis or myopericarditis after mRNA COVID-19 vaccination in children ages 5–17 years that met CDC case definition* and were at least 90 days post-myocarditis diagnosis
  - **190 completed the patient or parent survey**, 128 were unreachable on multiple attempts, 98 had no telephone contact information in the report, and 7 declined to participate
  - **226 cardiologists or other healthcare providers (HCP) completed a survey**, 120 were unreachable on multiple attempts, and 65 had no telephone contact information in the report

* https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years

- Based on the cardiologists or healthcare provider assessment, most patients appear to have fully or probably fully recovered from their myocarditis
  - 226 patients received a follow-up assessment by a cardiologist or other healthcare provider regarding their myocarditis recovery



Note: 5 (2%) providers were unsure

CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years

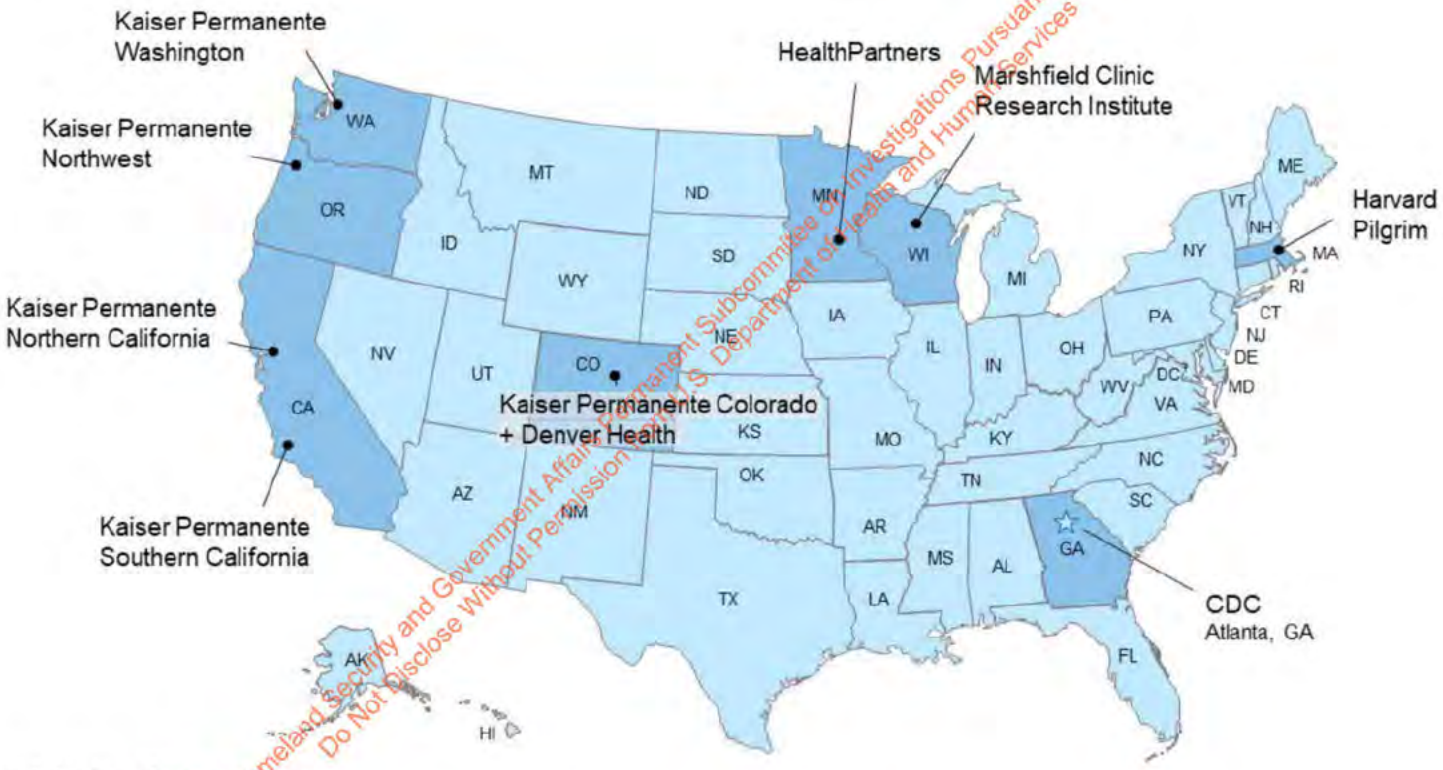
Key findings

- At least 90 days after myocarditis diagnosis, most patients who were reached reported no impact on their quality of life, and most did not report missing school or work
- Most (80.1%) healthcare providers who completed surveys indicated the patient was fully recovered or probably fully recovered
  - There was substantial heterogeneity in initial and follow-up treatment and testing
  - There did not appear to be a single test that was indicative of recovery

Next steps

- Additional follow-up with patients who were not yet recovered at time of the 90+ day survey (and their healthcare providers) to further assess recovery status at 12+ months

Vaccine Safety Datalink (VSD)



- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations

VSD Rapid Cycle Analysis (RCA)

Aims:

- To monitor the safety of COVID-19 vaccines weekly using prespecified outcomes of interest among VSD members
- To describe the uptake of COVID-19 vaccines over time among eligible VSD members overall and in strata by age, site, and race/ethnicity

VSD COVID-19 vaccine RCA prespecified surveillance outcomes

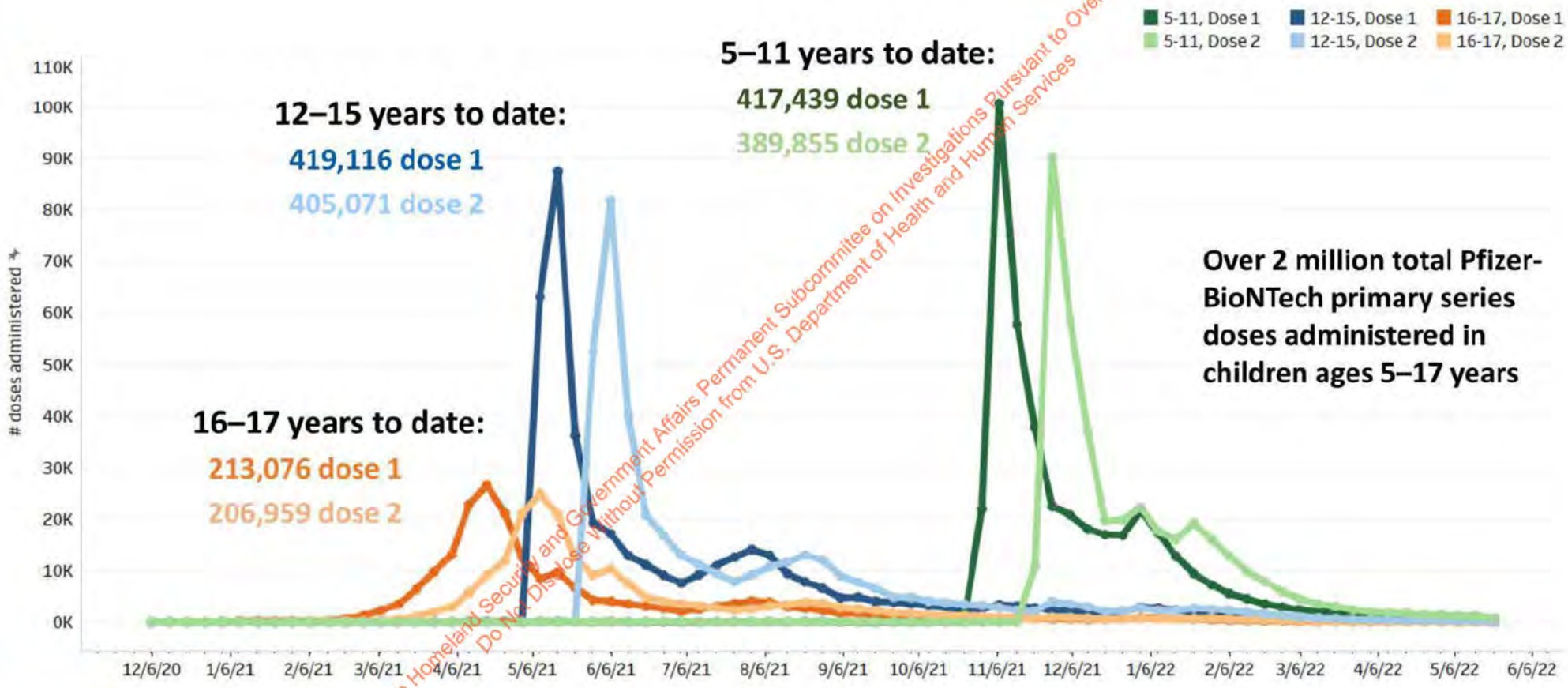
Prespecified outcomes	Settings
Acute disseminated encephalomyelitis	Emergency dept, Inpatient
Acute myocardial infarction – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Acute respiratory distress syndrome (descriptive monitoring only)	Emergency dept, Inpatient
Anaphylaxis – **First in 7 days in EHR in ICD-10 era** (descriptive monitoring only)	Emergency dept, Inpatient
Appendicitis	Emergency dept, Inpatient
Bell's palsy – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient, Outpatient
Cerebral venous sinus thrombosis	Emergency dept, Inpatient
Disseminated intravascular coagulation	Emergency dept, Inpatient
Encephalitis / myelitis / encephalomyelitis	Emergency dept, Inpatient
Guillain-Barré syndrome	Emergency dept, Inpatient
Immune thrombocytopenia	Emergency dept, Inpatient, Outpatient
Kawasaki disease (descriptive monitoring only)	Emergency dept, Inpatient
Multisystem inflammatory syndrome in children/adults (MIS-C/MIS-A) (descriptive monitoring only)	Emergency dept, Inpatient
Myocarditis / pericarditis – **First in 60 days in EHR in ICD-10 era**	Emergency dept, Inpatient
Narcolepsy / cataplexy (descriptive monitoring only)	Emergency dept, Inpatient, Outpatient
Pulmonary embolism – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Seizures	Emergency dept, Inpatient
Stroke, hemorrhagic	Emergency dept, Inpatient
Stroke, ischemic	Emergency dept, Inpatient
Thrombosis with thrombocytopenia syndrome – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Thrombotic thrombocytopenic purpura	Emergency dept, Inpatient
Transverse myelitis	Emergency dept, Inpatient
Venous thromboembolism – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient, Outpatient

EHR = Electronic health record

VSD Rapid Cycle Analysis (RCA) analytic strategy

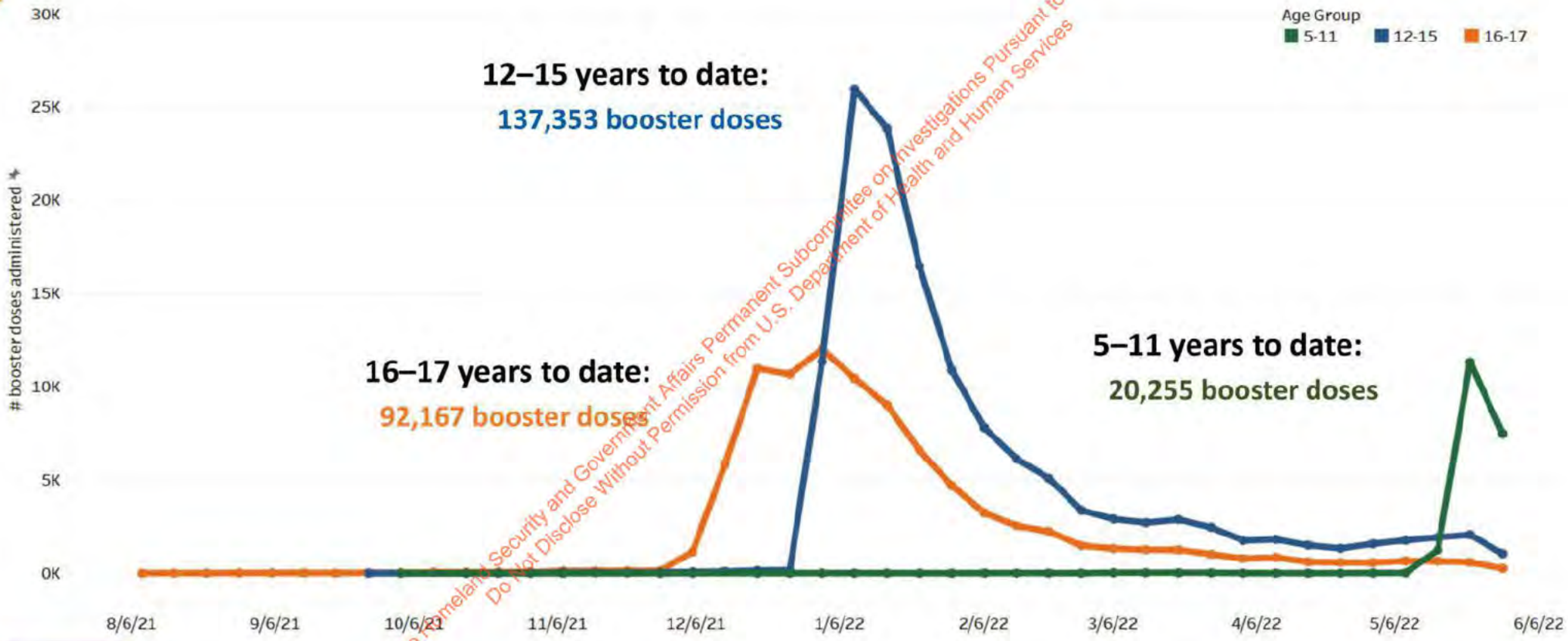
- For the primary analysis, the number of outcomes observed in the risk interval after COVID-19 vaccination were compared to the number expected
- The expected was derived from "vaccinated concurrent comparators" who were in a comparison interval after COVID-19 vaccination
- On each day that an outcome occurred, vaccinees who were in their risk interval were compared with similar vaccinees who were concurrently in their comparison interval
  - Comparisons were adjusted for age group, sex, race/ethnicity, VSD site, as well as calendar date
- For the pre-specified outcome myocarditis/pericarditis, cases were verified using the CDC case definition (https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm)

Pfizer-BioNTech vaccine doses administered* in VSD in pediatric age groups



* Pfizer-BioNTech was the only authorized vaccine in these ages during the surveillance period

Pfizer-BioNTech vaccine booster doses administered* in VSD in pediatric age groups



* Pfizer-BioNTech was the only authorized vaccine in these ages during the surveillance period

No statistical signals for pre-specified outcomes in 21-day risk interval after Pfizer-BioNTech primary series vaccination for children ages 5–11 years

- ~871,217 children ages 5–11 years in VSD
  - 42% have completed the Pfizer-BioNTech primary series
- All prespecified VSD RCA surveillance outcomes are being monitored
  - **No statistical signals** in the 21-day risk interval for any outcomes identified to date

VSD RCA prespecified outcome event*	Pfizer-BioNTech		
	Dose 1	Dose 2	Both Doses
Appendicitis	No	No	No
Bell's palsy	No	No	No
Encephalitis / myelitis / encephalomyelitis	No	No	No
Stroke, hemorrhagic	No	No	No
Stroke, ischemic	No	-	No
Immune thrombocytopenia	No	No	No
Kawasaki disease	No	No	No
Myocarditis / pericarditis	No	No	No
Seizures	No	No	No
Thrombotic thrombocytopenic purpura	No	-	No

- = analyses not yet possible
* Only outcomes for which analyses were possible for any dose are included in the table

Based on data through May 28, 2022

Statistical signals for pre-specified outcomes in 21-day risk interval after mRNA primary series vaccines for ages ≥12 years, including adults

VSD RCA prespecified outcome event*	Moderna			Pfizer-BioNTech			Both mRNA Vaccines		
	Dose 1	Dose 2	Both Doses	Dose 1	Dose 2	Both Doses	Dose 1	Dose 2	Both Doses
Acute disseminated encephalomyelitis	-	No	No	No	-	No	No	No	No
Acute myocardial infarction	No	No	No	No	**Yes**	No	No	**Yes**	No
Appendicitis	No	No	No	No	No	No	No	No	No
Bell's palsy	No	No	No	No	No	No	No	No	No
Cerebral venous sinus thrombosis	No	No	No	No	No	No	No	No	No
Disseminated intravascular coagulation	No	No	No	No	No	No	No	No	No
Encephalitis / myelitis / encephalomyelitis	No	No	No	No	No	No	No	No	No
Guillain-Barre syndrome	No	No	No	No	No	No	No	No	No
Stroke, hemorrhagic	No	No	No	No	No	No	No	No	No
Stroke, ischemic	No	No	No	No	No	No	No	No	No
Immune thrombocytopenia	No	No	No	No	No	No	No	No	No
Kawasaki disease	No	No	No	-	-	-	No	No	No
Myocarditis / pericarditis	No	No	No	No	**Yes**	**Yes**	No	**Yes**	**Yes**
Seizures	No	No	No	No	No	No	No	No	No
Transverse myelitis	No	No	No	No	No	No	No	No	No
Thrombotic thrombocytopenic purpura	No	No	No	No	No	No	No	No	No
Thrombosis with thrombocytopenia syndrome	No	No	No	No	No	No	No	No	No
Venous thromboembolism*	No	No	No	No	**Yes**	**Yes**	No	**Yes**	**Yes**
Pulmonary embolism (subset of VTE)	No	No	No	No	No	No	No	No	No

Based on data through May 21, 2022

- = analyses not yet possible

* No cases of acute myocardial infarction or venous thromboembolism within 98 days of any mRNA COVID-19 vaccination in 12–17-year-olds

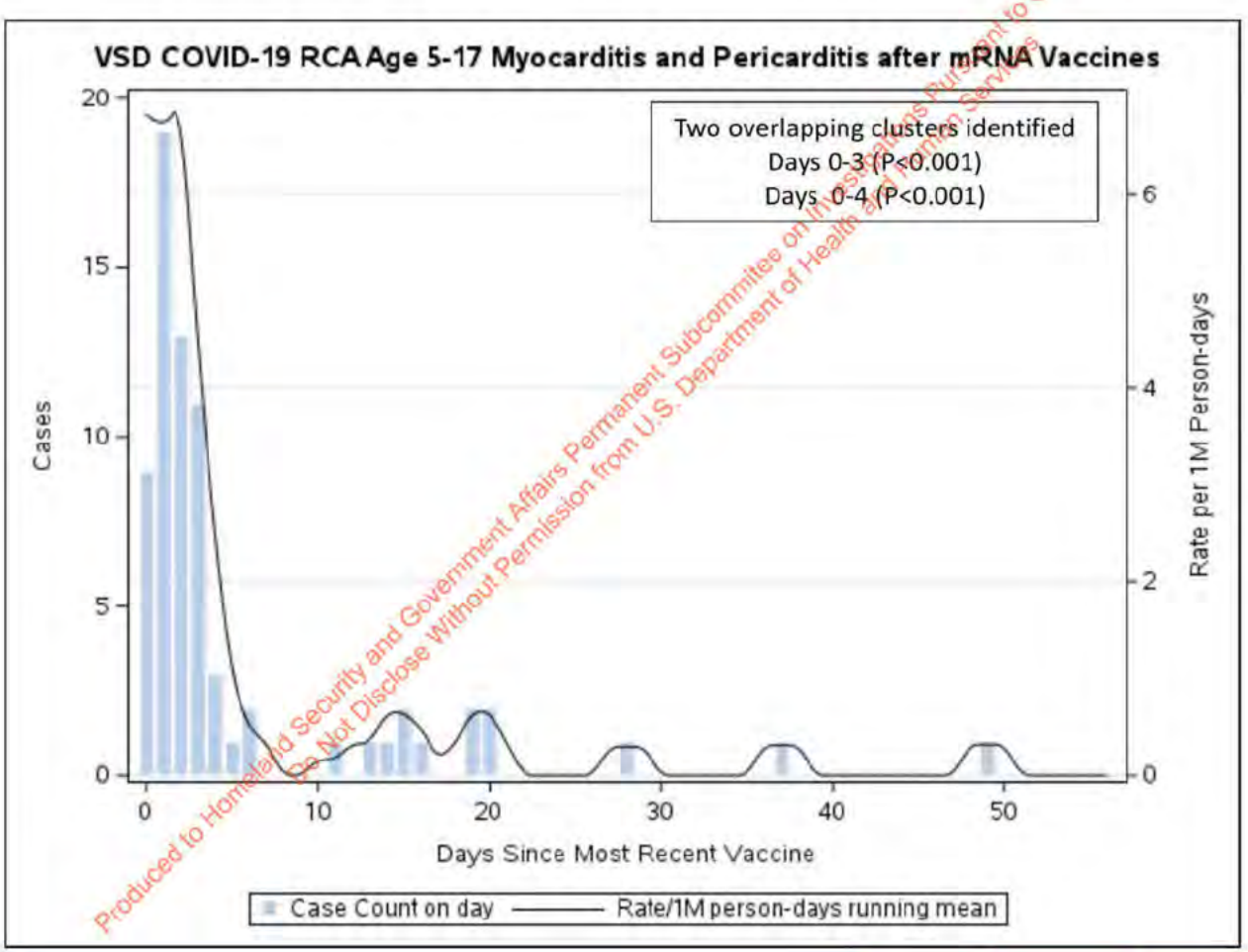
Statistical signals for pre-specified outcomes in 21-day risk interval after mRNA 1st booster vaccines for all ages above 12 years, including adults

	Primary series product:	Either mRNA	Pfizer-BioNTech	Moderna
VSD RCA prespecified outcome event*	Booster product:	Either mRNA	Pfizer-BioNTech	Moderna
Acute myocardial infarction		No	No	No
Appendicitis		No	No	No
Bell's palsy		No	No	No
Cerebral venous sinus thrombosis		No	No	No
Disseminated intravascular coagulation		No	No	No
Encephalitis / myelitis / encephalomyelitis		No	No	No
Guillain-Barre syndrome		No	No	No
Stroke, hemorrhagic		No	No	No
Stroke, ischemic		No	No	No
Immune thrombocytopenia		No	No	No
Myocarditis / pericarditis		**Yes**	No	No
Seizures		No	No	No
Transverse myelitis		No	No	No
Thrombotic thrombocytopenic purpura		No	No	No
Thrombosis with thrombocytopenia syndrome		No	No	No
Venous thromboembolism		No	No	No
Pulmonary embolism (subset of VTE)		No	No	No

Based on data through June 4, 2022

* Only outcomes for which analyses were possible are included on the table.

Day of symptom onset of verified myocarditis/pericarditis among children ages 5–17 years after either primary series dose of an mRNA COVID-19 vaccine



Based on data through May 28, 2022

Verified myocarditis and pericarditis in the 0–7-day risk interval among children ages 5-17 years in MALES by age group and dose (compared with outcome events in vaccinated comparators on the same calendar days, based on data through May 28, 2022)

Age Group	Pfizer-BioNTech dose	Events in Risk Interval	Events in Comparison Interval*	Adjusted Rate Ratio†	95% Conf Interval	2-sided P-value	Excess cases in Risk Period per million doses
5–11 Years	Dose 1	0	0	NE	NE	NE	NE
	Dose 2‡	2	0	NE	0.87 – ∞	0.061	15.2
	1st Booster	0	0	NE	NE	NE	NE
12–17 Years¶	Dose 1	3	1	**14.00**	**1.20 – 421.96**	**0.035**	**8.9**
	Dose 2	44	1	**160.52**	**30.19 – 3343.73**	**<0.001**	**147.0**
	1st Booster	9	1	**14.98**	1.39 – 484.33	0.023	**85.1**
12–15 Years subgroup	Dose 1	2	1	**13.63**	**0.94 – 433.36**	**0.056**	**8.8**
	Dose 2	28	1	**104.88**	**18.45 – 2267.59**	**<0.001**	**151.0**
	1st Booster	1	1	3.97	0.05 – 320.79	0.560	12.7
16–17 Years subgroup	Dose 1	1	0	NE	0.13 – ∞	0.285	9.6
	Dose 2	14	0	**NE**	**10.20 – ∞**	**<0.001**	**138.7**
	1st Booster	7	0	**NE**	**1.16 – ∞**	**0.038**	**200.3**

NE=not estimable

* Comparison interval is 22–42 days after either dose.

† Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date. 1st booster analyses are also adjusted for time since primary series.

‡ One case was non-informative for the risk interval analyses but was included in the excess risk calculation estimates.

¶ Subgroup events may not sum to "12–17" total due to non-informative events.

Verified myocarditis and pericarditis in the 0–7-day risk interval among children ages 5-17 years in FEMALES by age group and dose (compared with outcome events in vaccinated comparators on the same calendar days, based on data through May 28, 2022)

Age Group	Pfizer-BioNTech dose	Events in Risk Interval	Events in Comparison Interval*	Adjusted Rate Ratio†	95% Conf Interval	2-sided P-value	Excess cases in Risk Period per million doses
5-11 Years	Dose 1	0	0	NE	NE	NE	NE
	Dose 2	0	0	NE	NE	NE	NE
	1st Booster	0	0	NE	NE	NE	NE
12 – 17 Years‡	Dose 1	1	1	9.16	0.23 – 364.80	0.200	2.8
	Dose 2	5	1	**18.15**	**1.62 – 558.73**	**0.018**	**18.4**
	1st Booster	2	3	0.79	0.07 – 7.49	0.835	- 5.0
12 – 15 Years subgroup	Dose 1	0	0	NE	NE	NE	0.0
	Dose 2	4	0	**NE**	**1.01 – ∞**	**0.049**	**24.8**
	1st Booster	0	0	**NE**	NE	NE	0.0
16 – 17 Years subgroup	Dose 1	1	1	12.11	0.31 – 477.83	0.154	8.4
	Dose 2	1	1	6.10	0.16 – 239.90	0.283	7.9
	1st Booster	2	3	1.10	0.11 – 9.58	0.924	4.0

NE=not estimable

* Comparison interval is 22–42 days after either dose.

† Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date. 1st booster analyses are also adjusted for time since primary series.

‡ Subgroup events may not sum to "12–17" total due to non-informative events.

VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days following Pfizer-BioNTech vaccination, December 14, 2020–May 28, 2022

Children ages 5-17 years	Cases	Doses	Incidence rate per million doses admin.	95% Confidence Intervals
5–11 years				
Males – Dose 1	0	211,644	0.0	0.0 – 14.2
Males – Dose 2	**3**	**197,465**	**15.2**	**3.1 – 44.5**
Females – Dose 1	0	205,795	0.0	0.0 – 14.6
Females – Dose 2	0	192,380	0.0	0.0 – 15.6
12–15 years				
Males – Dose 1	2	210,622	9.5	1.2 – 34.3
Males – Dose 2	31	203,420	**152.5**	**103.6 – 216.4**
Males – 1st Booster	1	59,483	17.0	0.4 – 94.9
Females – Dose 1	0	208,494	0.0	0.0 – 14.4
Females – Dose 2	5	201,638	**24.8**	**8.1 – 57.9**
Females - 1st Booster	0	61,876	0.0	0.0 – 48.4
16–17 years				
Males – Dose 1	1	104,142	9.6	0.2 – 53.5
Males – Dose 2	14	100,980	**138.7**	**75.8 – 232.8**
Males – 1st Booster	8	40,177	**200.3**	**86.5 – 394.7**
Females – Dose 1	1	108,934	9.2	0.2 – 51.2
Females – Dose 2	1	105,929	9.4	0.2 – 52.6
Females - 1st Booster	2	45,794	**44.0**	**5.3 – 159.0**

Level of care and status of verified myocarditis and pericarditis case ages 5–17 years in the 0-7 days after primary series and 1st booster dose of mRNA COVID-19 vaccine, VSD

Level of care and status	Pfizer-BioNTech primary series (n=58)	Pfizer-BioNTech 1st booster (n=12)
Highest level of care		
Emergency department	4 (7%)	0 (0%)
Admitted to hospital	34 (59%)	6 (50%)
Admitted to ICU	20 (34%)	6 (50%)
Length of hospital stay, median (range)	2 days (0–7 days)	1 day (1–4 days)
0 – 1 days	20 (34%)	8 (67%)
2 – 3 days	28 (48%)	3 (25%)
4+ days	10 (17%)	1 (8%)
Discharged to home	58 (100%)	12 (100%)

Based on data through June 4, 2022

Comparative risk for myocarditis between the two available mRNA COVID-19 vaccines, Moderna and Pfizer-BioNTech

From: Menschik, David
Sent: Tue, 23 Feb 2021 11:47:58 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP);Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER);Zinderman, Craig E (FDA/CBER);Alimchandani, Meghna (FDA/CBER);Marquez, Paige L. (CDC/DDID/NCEZID/DHQP);Broder, Karen (CDC/DDID/NCEZID/DHQP);Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: Data mining

Hi John and Tom,

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for any EUA COVID vaccine (as of 2/18/21).

Thanks,
David

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From: Menschik, David
Sent: Tue, 12 Jan 2021 21:23:01 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining

For Thursday meeting, would be great if we could do data mining early since Bethany will only be available for the first 30 minutes and she has more experience than me...

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, January 12, 2021 1:56 PM
To: Menschik, David <[redacted] Shimabukuro, Tom (CDC) <[redacted]
Cc: Marquez, Paige L (CDC) <[redacted]; Nair, Narayan <[redacted]; Alimchandani, Meghna <[redacted] Zinderman, Craig E <[redacted]; Baer, Bethany <[redacted]
Subject: RE: Data mining

Hi David,

Awesome! Thanks for sharing.

- John

From: Menschik, David <[redacted]
Sent: Tuesday, January 12, 2021 1:51 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]; Nair, Narayan (FDA/CBER) <[redacted]; Alimchandani, Meghna (FDA/CBER) <[redacted] Zinderman, Craig E (FDA/CBER) <[redacted] Baer, Bethany (FDA/CBER) <[redacted]
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Dear John and Tom,

Our core weekly data mining run (previously refreshing monthly) called "VAERS Signals Weekly US All" was just refreshed this afternoon (as of date 1/10/21) and there are no EB05's >2 for any COVID vaccines. Attached are 3 slides providing contextual information including caveats and limitations that we can discuss at our weekly meeting on Thursday at 2pm.

Best,

David

From: Menschik, David
Sent: Tue, 12 Jan 2021 21:42:01 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining

Great and stay tuned – I will be sharing a little more info on data mining later today when I finish up a different task...

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, January 12, 2021 4:29 PM
To: Menschik, David <[redacted]
Subject: RE: Data mining

Please feel free – I think we'd all be enthusiastic to see what data mining data there is.

- John

From: Menschik, David <[redacted]
Sent: Tuesday, January 12, 2021 4:23 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: Data mining

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[redacted]; Zinderman, Craig E (FDA/CBER)
[redacted] Baer, Bethany (FDA/CBER) [redacted]
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Best,

David

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Publ c ea t rvice Act (PHS t f r COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, M i G rma y u der t e p o of se i 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indi ted f r active immunization pr vent corona isease 2019 (COVID-19) caused by severe ɔute r sp rat ry yndrome coronav 2 (SARS-CoV-2) in individuals 6 a o ɹge and older.

The review of this product wa assoc at d with he llowing National Clinical Trial (NCT) numbers: N 0436 2 d NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., Highway 301 North, Rocky Mount, North Carolina and at Fresenius Kabi USA, LLC, 3159 Staley Road, Grand Island, New York.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 mon hs from the da e o manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF). The dat of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at Pharmacia & Upjohn Company LLC in Kalamazoo, Mich gan, the date of manufacture is defined as the date of sterile filtration f r h i al dru product; at Pfizer Manufacturing Belgium NV in Puurs, Belgium, t s f n as he date of the first assignment of raw materials or intermediate from inventory to the drug product batch in the SAP system). F ll i t e ina e e f l a i w e xcep i n f e-time refiltration if an incident occurs that has co p mi h filter inte t , no reprocessing/r ing is allowed without prior approval from the Agency. The dating period for your drug substance shall be 6 months hen stor t -20ºC ± 5ºC. We have approved the stability protocols n yo r cense pplicatin r u e of xt d g the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with proto ols showing results of all applicable tests You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If t dev t on v lves a i tri ut r ct ma a f th afe y, u or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but n l m ted to, he m ufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, r in t e anu a u ng faci..itie

LABELING

We hereby approve the draft content of labeling ncl di g Package l .sert, submitted under amendment 74, dated August 21, 2021, an f ca o . and co ne l be s submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the automate ru reg stration and listing ystem, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling ust e ident cal t the Package Insert submitted on August 21, 2021. nfo i on su t.ng SPL l us ng ma be o n the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at mo. t' ly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, p a refe to t e gu da e for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-doc ents/providing-su.Jn'ssi s-electronic-format-postmarketing-safety-reports-vaccines. For information on distri ution r porting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketAc i ies/L tPe eases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 t evaluate the sa ety nd e,fective ss of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: O o r 1, 023

2. Deferred pediatric S udy 4 to ·.aluate the safety and effectiveness of COMIRNATY in infants and c l en 6 mon h o <12 years of age.

   Final Protocol Submission: ebruar , 1

   Study Completion: November 30, 20

   Final Report Submission: May 31, 2024

3. Deferred p diatric S udy 4 23 to evaluate the safety and effectiveness of COMIRNATY in i fan s months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: S p er . 0, 20 4

6. Study C4591021 substudy to describe he n t al h st y of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: January 31, 2022

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021

Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively a s th incidence of sub in cal myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 1, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June , J22

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were sub tt to h IN . Please refer to the PMR seque l numbe for ea study/clin a ial and the su m ssion number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmar eting stu s on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post m rketin h l Co m d f ul t .

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided hat you includ th element list d in section 505(o) and 21 CFR 601.70. We remind you th to co ly wit t o you u ep t must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post- mer nc U Au h i atio', A' f t Surveillance Study Among Individuals in the et ra s Affa,rs H l h System Receiving Pfizer-BioNTech o vi s e se 20 '9 (CO' -19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 20^3

13. Study C4591014, entitled " i ,r-B oN" CO -19 BNT162b2 Vaccine Effectiveness Study - se Per.na' en e o ern C i o a."

    Final Protocol Submission: March 22, 2021

    Study Completion: D ,ce' be 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 1257" explaining that these protocols were submitted to the IND. Please refer to the PMC seque ial n e f a tud linic l trial and e sub is io number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to schedule a meeting, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

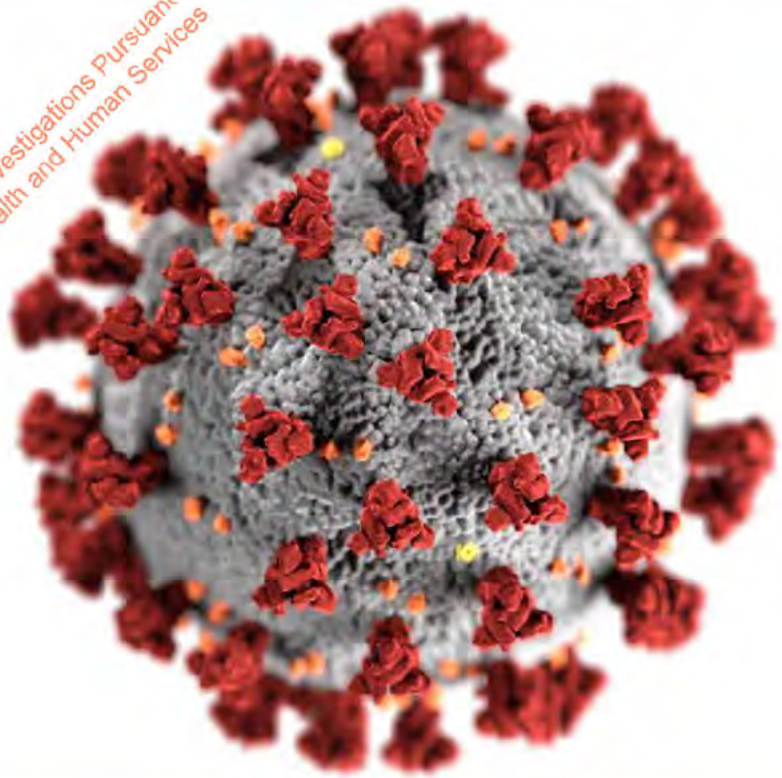
Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Update on myocarditis following mRNA COVID-19 vaccination

Vaccines and Related Biological Products Advisory Committee (VRBPAC)

June 14, 2022

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Coordination Unit



cdc.gov/coronavirus

Topics

- Background on classic myocarditis and myocarditis associated with mRNA COVID-19 vaccination
- Update on myocarditis following mRNA COVID-19 vaccination with a focus on children ages 5–17 years*
  - Findings from the Vaccine Adverse Event Reporting System (VAERS)
  - Findings from the Vaccine Safety Datalink (VSD)
- Comparative risk for myocarditis between the two available mRNA COVID-19 vaccines, Moderna and Pfizer-BioNTech

* Analyses focus on children ages 5–11 years for the 2-dose (10 µg) primary series separated by at least 3 weeks, and children ages 12–17 years for the 2-dose (30 µg) primary series separated by at least 3 weeks followed by a booster dose at least 5 months after completion of the primary series; data outside of these authorizations and recommendations (e.g., off authorization use, vaccination errors, special population authorizations/recommendations) are not included in these analyses

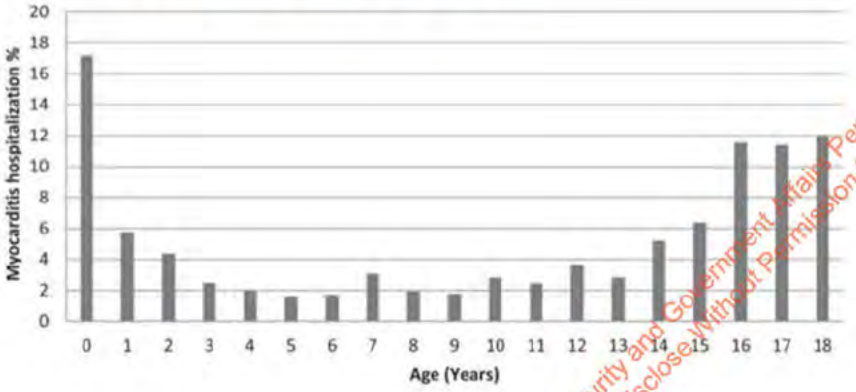
Epidemiology of classic myocarditis in children (excluding infants)

- Usually an infectious cause, typically viral or presumed to be viral, although infection with a pathogen is frequently not identified (only ~40% of time a pathogen is identified)[1,2,3]
- Can be due to direct microbial infection of myocardial cells and/or ongoing inflammatory response, with or without clearance of pathogen[4,5,6]
  - Can also be toxin-mediated or in setting of systemic infection or infection of non-cardiac tissue
- Rarer causes include autoimmune, hypersensitivity, and giant cell myocarditis
- Incidence in males > females starting after age 5 years[7]
- Previously unrecognized myocarditis was identified as cause of death in 8% of cases of sudden, unexplained death in 1–17-year-olds[8] and 9% of sudden death in athletes[9]
- It is common to not identify a pathogen or possible infectious etiology for myocarditis
  - Based on case series, where autopsy tissues were examined and tissue-based infectious disease testing was performed, a specific infectious cause was only identified in 13%–36% of cases across age groups[6,10,11]
  - For a case series where endomyocardial biopsy tissues were tested, viral nucleic acids were detected in heart tissues in ~38% (adults and children combined)[1]

[1]Bowles et al. J Am Coll Cardiol. 2003;42:466-72. [2]Simpson et al. J Am Coll Cardiol. 2013;61:(10_Supplement) E1264. [3]Park et al. J Korean Med Sci. 2021;36:e232. [4]Caforio et al. Eur Heart J. 2013;34:2636-48, 2648a-2648d. [5]Feldman et al. N Engl J Med. 2000;343:1388-98. [6]Guarner et al. Hum Pathol. 2007;38:1412-9. [7]Arola et al. J Am Heart Assoc. 2017;6:e005306. [8]Burns et al. J Pediatr X. 2020;2:100023. [9]Maron et al. Circulation. 2009;119:1085-92. [10]Weber et al. Arch Dis Child. 2008;93:594-8. [11]Ilina et al. Pediatrics. 2011;128:e513-20.

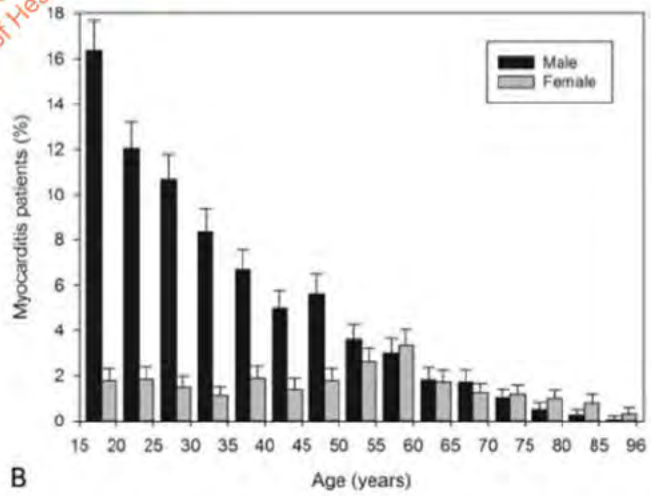
Epidemiology of myocarditis

- Children
  - Annual incidence 0.8 per 100,000
    - In 15-18yo, 1.8 per 100,000 in 2015-2016
  - 66% male
  - Median LOS 6.1 days



Vasudeva et al. *American J Cardiology*. 2021.

- Adults
  - Gradual decrease in incidence with age
  - 76% male



Kyto et al. *Heart*. 2013.

Previously presented at the June 23, 2021, ACIP meeting: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf

LOS = Length of hospital stay

Characteristic	Myocarditis associated with mRNA COVID-19 vaccination*,†	Viral myocarditis‡
Inciting exposure	mRNA COVID-19 vaccination • Dose 2 > Dose 1	Viral illness • 30–60% with asymptomatic viral course
Demographics	Most cases in adolescents and young adults, males > females	Males > females, male incidence peaks in adolescence and gradually declines
Symptom onset	A few days after vaccination, most within a week	1–4 weeks after viral illness
Fulminant course	Rare¶	23%
ICU level support	~2%	~50%
Mortality/transplant	Rare¶	11–22%
Cardiac dysfunction	12%	60%
Recovery of cardiac function	Nearly all	~75%
Time to recovery of cardiac function (ejection fraction on cardiac echo), if initially poor	Hours to days	Days to weeks to months

* https://www.cdc.gov/vaccines/acip/meetings/index.html, https://www.cdc.gov/vaccinesafety/research/publications/index.html
† Oster et al. JAMA. 2022;327:331-340.
‡ Law et al. Circulation. 2021;144:e123-e135. Ghelani et al. Circ Cardiovasc Qual Outcomes. 2012;5:622-7. Kim et al. Korean Circ J. 2020;50:1013-1022. Messroghli et al. Am Heart J. 2017;187:133-144. Patel et al. J Am Heart Assoc. 2022;11:e024393.
¶ There are rare reports in the literature, especially from other countries, but it is unclear to what extent such cases were investigated

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

VAERS

VAERS accepts reports from everyone (healthcare professionals, patients, parents, caregivers, manufacturers, etc.) regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

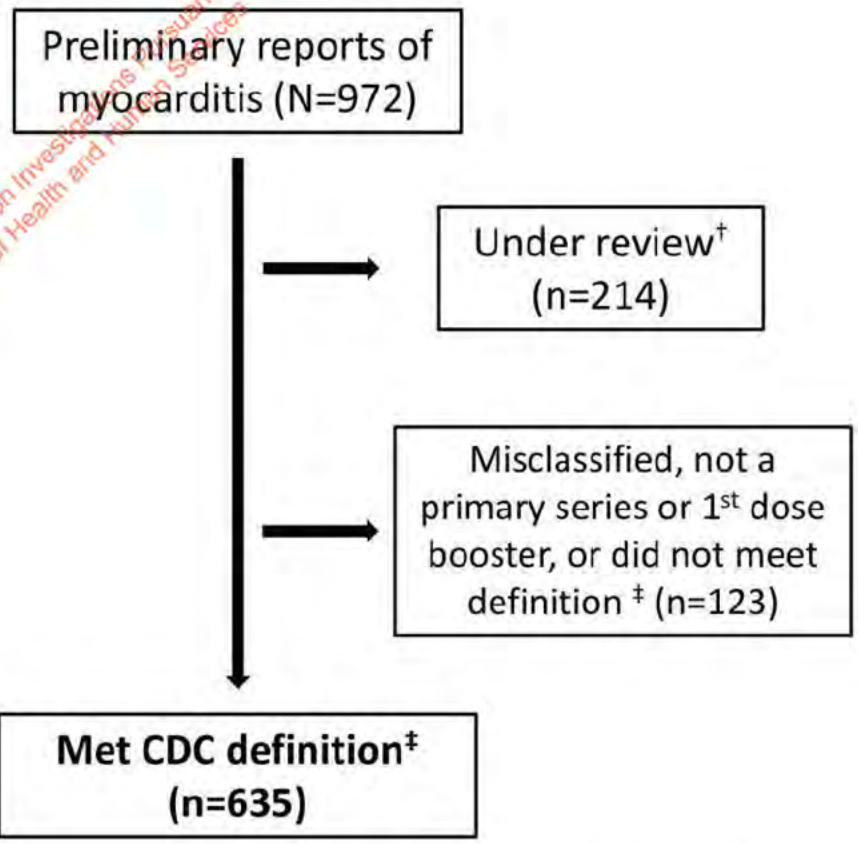
- Rapidly detects potential safety problems
- Can detect rare adverse events

Key limitations

- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

Reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–17 years (as of May 26, 2022)*

- 54.8 million total Pfizer-BioNTech doses administered to children ages 5–17 years in the United States
  - 27.7 million dose 1
  - 23.3 million dose 2
  - 3.8 million 1st booster dose (ages 12–17 years)



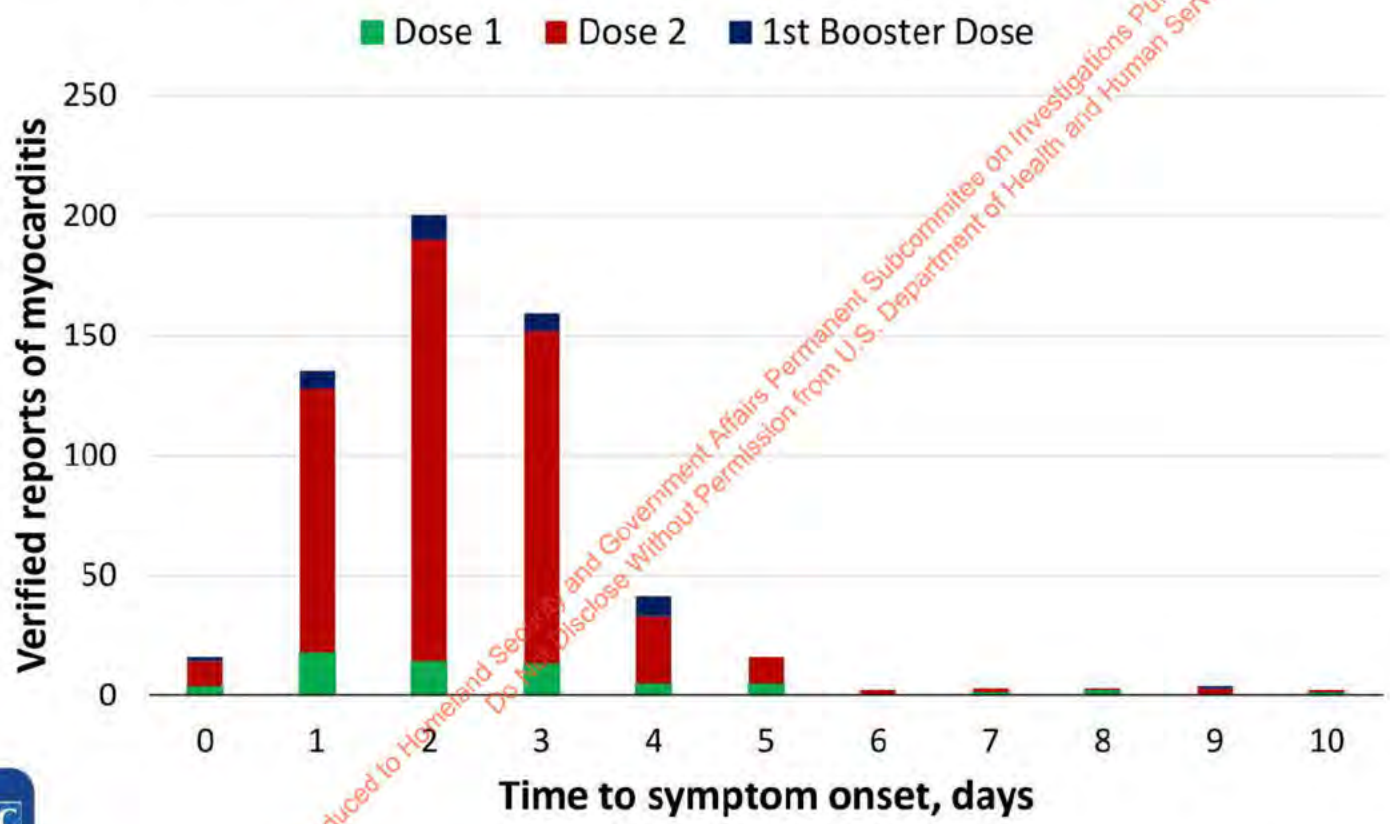
* As of May 26, 2022, primary series vaccination among children ages 16–17 years since Dec 14, 2020; children ages 12–15 years since May 10, 2021; children ages 5–11 years since Nov 3, 2021; 1st dose booster vaccination among children ages 16–17 years since Dec 9, 2021; children ages 12–15 years since Jan 5, 2022.

† Awaiting medical records and/or healthcare provider interview; some still processing

‡ Adjudicated after healthcare provider interview and/or medical record review; CDC myocarditis case definition available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

Verified* U.S. reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–17 years, by time to symptom onset† and dose number

(N=630, as of May 26, 2022)



† 630 of 635 (99%) with known time to symptom onset; 49 (8%) reports with time to symptom onset >10 days

*Verified according to CDC myocarditis case definition available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

VAERS reporting rates of myocarditis (per 1 million doses administered) after mRNA COVID-19 vaccination, days 0–7 and 8–21 post-vaccination*,†

		0–7 days			8–21 days			0–7 days			8–21 days		
		Males			Males			Females			Females		
	Age (yrs)	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster	Dose 1	Dose 2	Booster
Pfizer-BioNTech	5–11	0.2	2.6	0.0	0.6	0.0	0.0	0.2	0.7	0.0	0.2	0.0	0.0
	12–15	5.3	46.4	15.3	1.2	1.2	0.9	0.7	4.1	0.0	0.4	0.2	0.9
	16–17	7.2	75.9	24.1	1.7	3.2	1.3	0.0	7.5	0.0	0.7	0.4	0.0
Pfizer-BioNTech and Moderna	18–24	4.2	38.9	9.9	1.1	2.2	0.4	0.6	4.0	0.6	0.2	0.7	0.0
	25–29	1.8	15.2	4.8	0.4	1.1	0.5	0.4	3.5	2.0	0.2	0.0	0.8
	30–39	1.9	7.5	1.8	0.4	0.8	0.2	0.6	0.9	0.6	0.3	0.2	0.0
	40–49	0.5	3.3	0.4	0.2	0.5	0.0	0.4	1.6	0.6	0.2	0.2	0.0
	50–64	0.5	0.7	0.4	0.2	0.3	0.1	0.6	0.5	0.1	0.2	0.5	0.1
	65+	0.2	0.3	0.6	0.3	0.2	0.1	0.1	0.5	0.1	0.1	0.2	0.1

* As of May 26, 2022; reports verified to meet case definition by provider interview or medical record review; primary series and 1st booster doses only

† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 and 8–21 risk intervals, this estimated background is **0.2 to 2.2 per 1 million person-day 0–7 risk interval and 0.4 to 3.8 per 1 million person-day 8–21 risk interval**
(peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years*

- **Purpose**: Assess functional status and clinical outcomes among individuals reported to have developed myocarditis after COVID-19 mRNA vaccination
- **Methods**: A two-component survey conducted at least 90 days after the onset of myocarditis symptoms
  - **Patient or parent survey**: Focused on ascertaining functional status, clinical symptoms, quality of life, and need for medication or other medical treatment
  - **Healthcare provider (e.g., cardiologist) survey**: Gather data on cardiac health and functional status

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myo-outcomes.html; surveillance project includes two separate cohorts, children ages 5–11 years and people ages 12–29 years

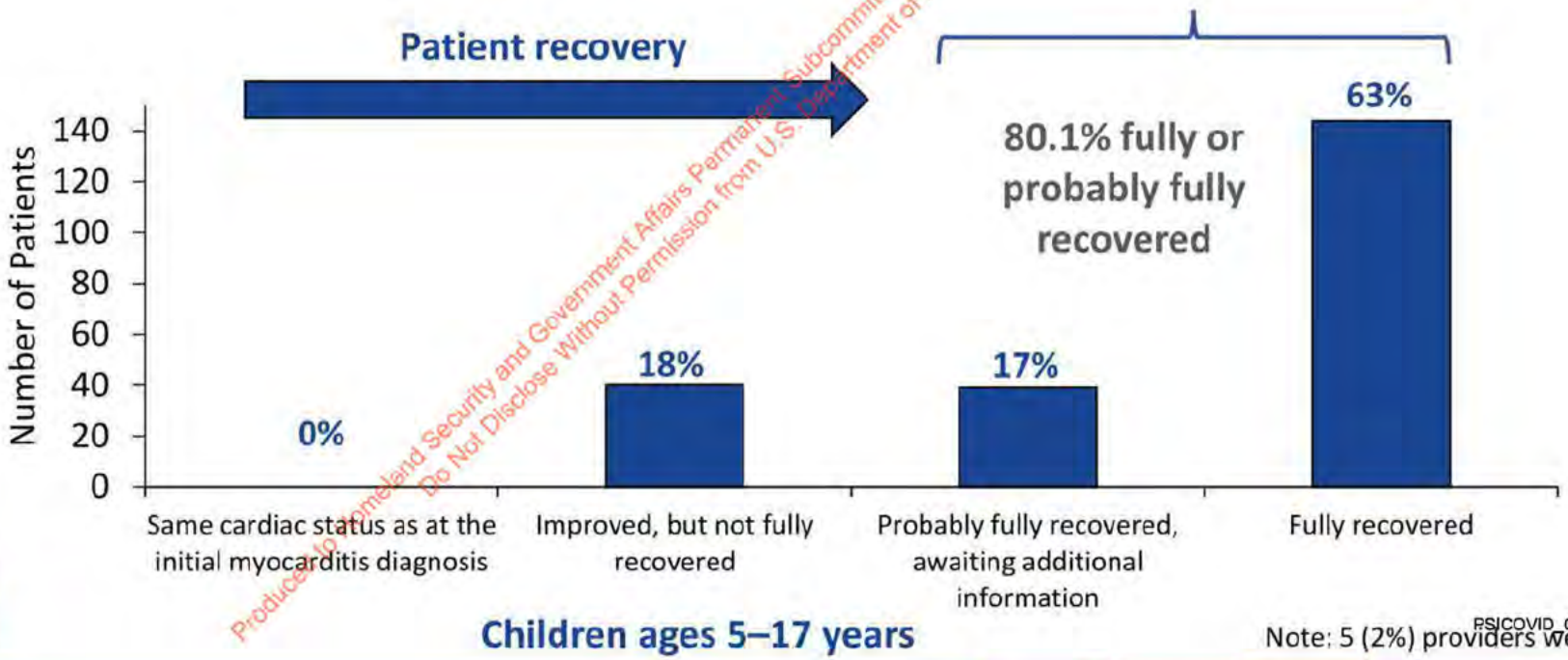
CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years

- During the surveillance periods (through November 2021 for 12–17 years and April 2022 for 5–11 years), VAERS received 430 reports of myocarditis or myopericarditis after mRNA COVID-19 vaccination in children ages 5–17 years that met CDC case definition* and were at least 90 days post-myocarditis diagnosis
  - **190 completed the patient or parent survey**, 128 were unreachable on multiple attempts, 98 had no telephone contact information in the report, and 7 declined to participate
  - **226 cardiologists or other healthcare providers (HCP) completed a survey**, 120 were unreachable on multiple attempts, and 65 had no telephone contact information in the report

* https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years

- Based on the cardiologists or healthcare provider assessment, most patients appear to have fully or probably fully recovered from their myocarditis
  - 226 patients received a follow-up assessment by a cardiologist or other healthcare provider regarding their myocarditis recovery



Note: 5 (2%) providers were unsure

CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among children ages 5–17 years

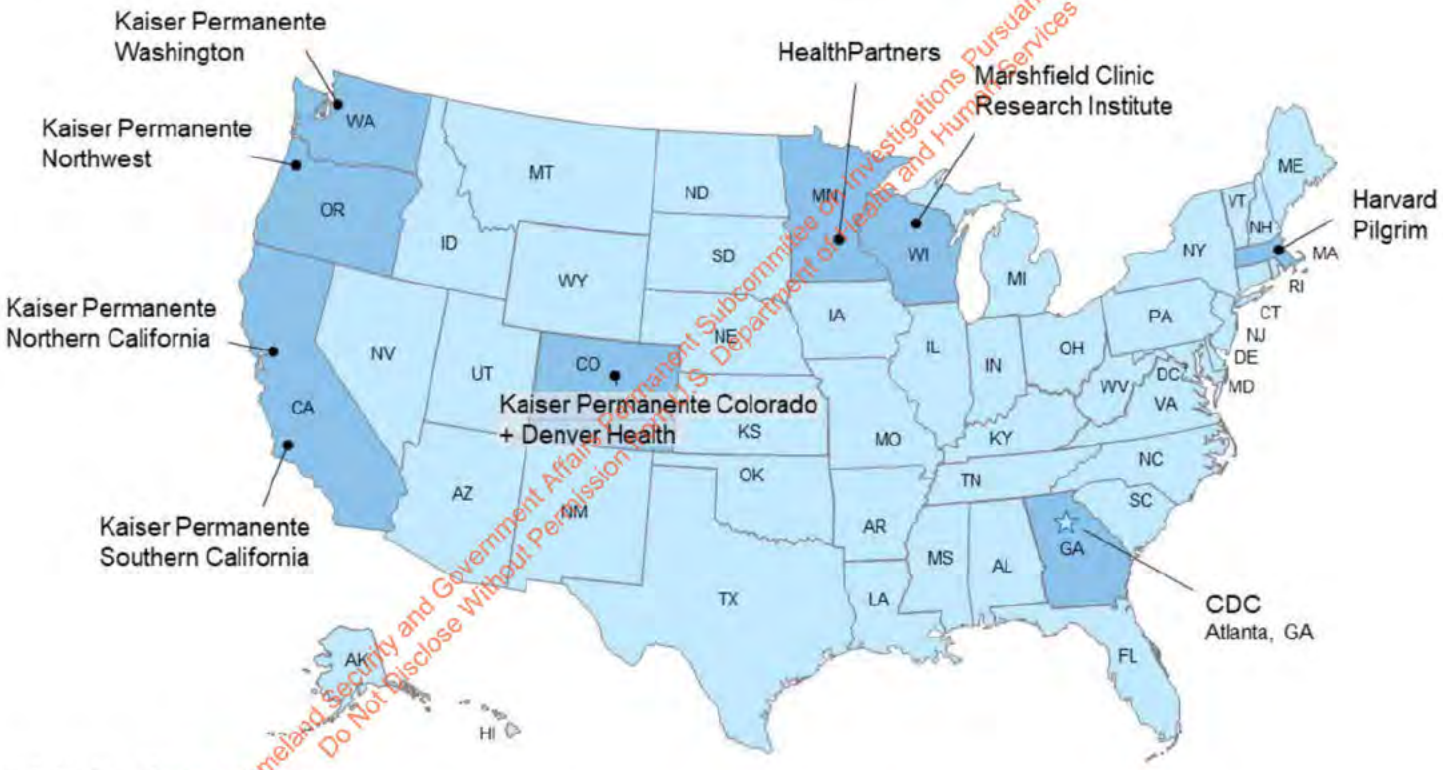
Key findings

- At least 90 days after myocarditis diagnosis, most patients who were reached reported no impact on their quality of life, and most did not report missing school or work
- Most (80.1%) healthcare providers who completed surveys indicated the patient was fully recovered or probably fully recovered
  - There was substantial heterogeneity in initial and follow-up treatment and testing
  - There did not appear to be a single test that was indicative of recovery

Next steps

- Additional follow-up with patients who were not yet recovered at time of the 90+ day survey (and their healthcare providers) to further assess recovery status at 12+ months

Vaccine Safety Datalink (VSD)



- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations

VSD Rapid Cycle Analysis (RCA)

Aims:

- To monitor the safety of COVID-19 vaccines weekly using prespecified outcomes of interest among VSD members
- To describe the uptake of COVID-19 vaccines over time among eligible VSD members overall and in strata by age, site, and race/ethnicity

VSD COVID-19 vaccine RCA prespecified surveillance outcomes

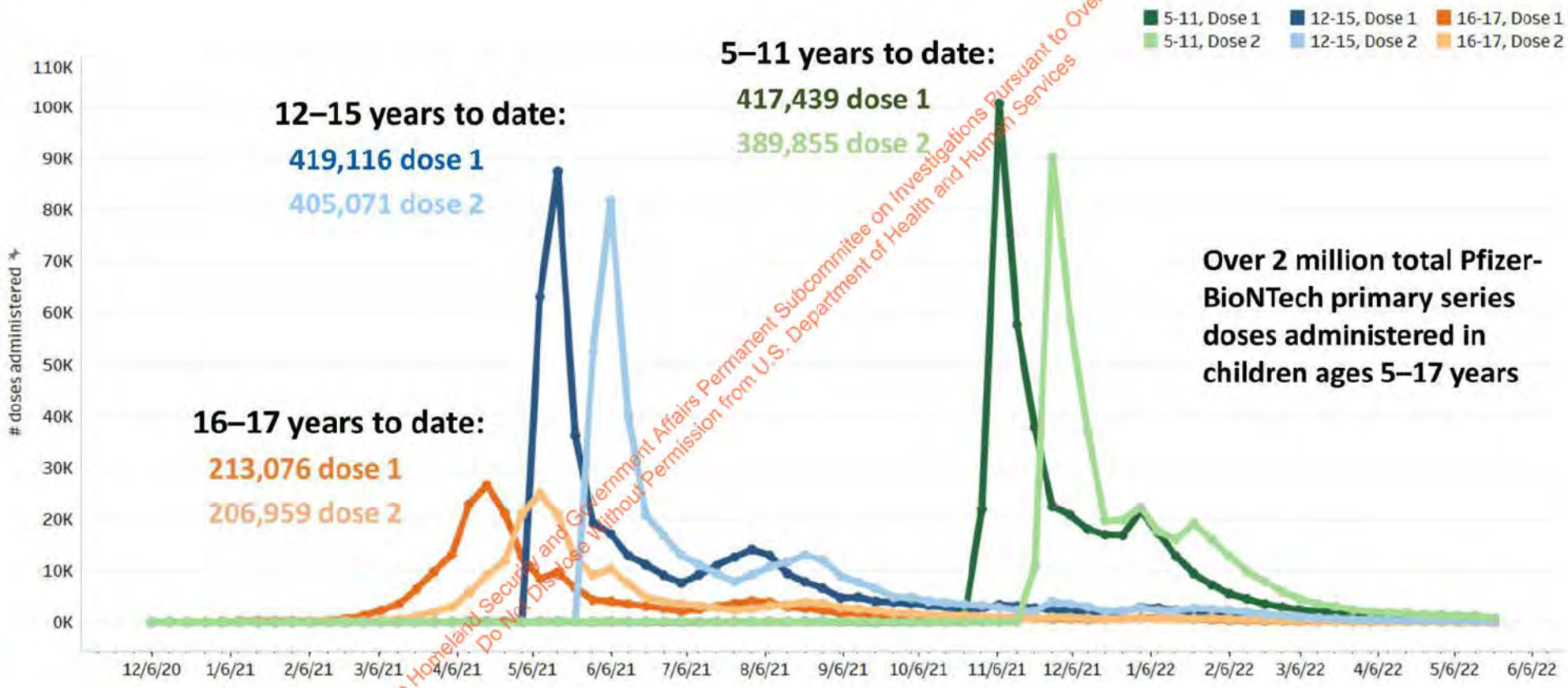
Prespecified outcomes	Settings
Acute disseminated encephalomyelitis	Emergency dept, Inpatient
Acute myocardial infarction – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Acute respiratory distress syndrome (descriptive monitoring only)	Emergency dept, Inpatient
Anaphylaxis – **First in 7 days in EHR in ICD-10 era** (descriptive monitoring only)	Emergency dept, Inpatient
Appendicitis	Emergency dept, Inpatient
Bell's palsy – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient, Outpatient
Cerebral venous sinus thrombosis	Emergency dept, Inpatient
Disseminated intravascular coagulation	Emergency dept, Inpatient
Encephalitis / myelitis / encephalomyelitis	Emergency dept, Inpatient
Guillain-Barré syndrome	Emergency dept, Inpatient
Immune thrombocytopenia	Emergency dept, Inpatient, Outpatient
Kawasaki disease (descriptive monitoring only)	Emergency dept, Inpatient
Multisystem inflammatory syndrome in children/adults (MIS-C/MIS-A) (descriptive monitoring only)	Emergency dept, Inpatient
Myocarditis / pericarditis – **First in 60 days in EHR in ICD-10 era**	Emergency dept, Inpatient
Narcolepsy / cataplexy (descriptive monitoring only)	Emergency dept, Inpatient, Outpatient
Pulmonary embolism – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Seizures	Emergency dept, Inpatient
Stroke, hemorrhagic	Emergency dept, Inpatient
Stroke, ischemic	Emergency dept, Inpatient
Thrombosis with thrombocytopenia syndrome – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Thrombotic thrombocytopenic purpura	Emergency dept, Inpatient
Transverse myelitis	Emergency dept, Inpatient
Venous thromboembolism – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient, Outpatient

EHR = Electronic health record

VSD Rapid Cycle Analysis (RCA) analytic strategy

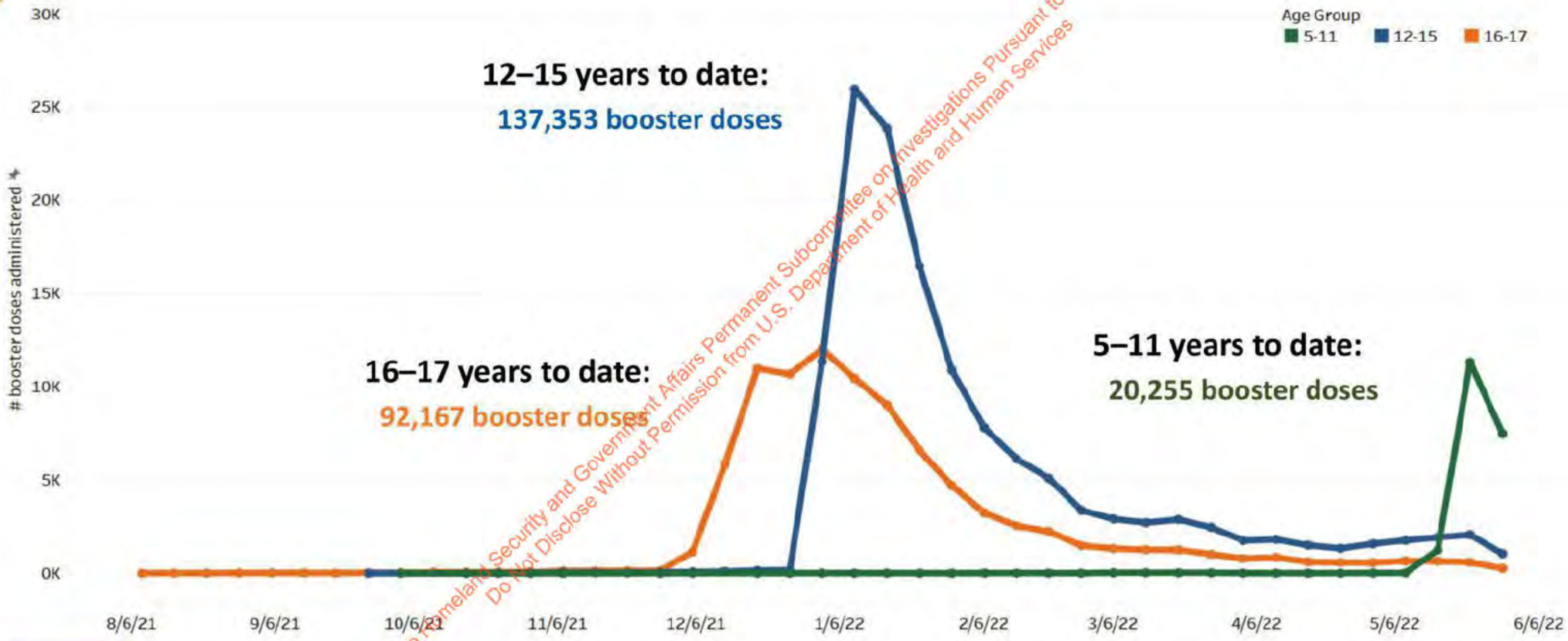
- For the primary analysis, the number of outcomes observed in the risk interval after COVID-19 vaccination were compared to the number expected
- The expected was derived from "vaccinated concurrent comparators" who were in a comparison interval after COVID-19 vaccination
- On each day that an outcome occurred, vaccinees who were in their risk interval were compared with similar vaccinees who were concurrently in their comparison interval
  - Comparisons were adjusted for age group, sex, race/ethnicity, VSD site, as well as calendar date
- For the pre-specified outcome myocarditis/pericarditis, cases were verified using the CDC case definition (https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm)

Pfizer-BioNTech vaccine doses administered* in VSD in pediatric age groups



* Pfizer-BioNTech was the only authorized vaccine in these ages during the surveillance period

Pfizer-BioNTech vaccine booster doses administered* in VSD in pediatric age groups



* Pfizer-BioNTech was the only authorized vaccine in these ages during the surveillance period

No statistical signals for pre-specified outcomes in 21-day risk interval after Pfizer-BioNTech primary series vaccination for children ages 5–11 years

- ~871,217 children ages 5–11 years in VSD
  - 42% have completed the Pfizer-BioNTech primary series
- All prespecified VSD RCA surveillance outcomes are being monitored
  - **No statistical signals** in the 21-day risk interval for any outcomes identified to date

VSD RCA prespecified outcome event*	Pfizer-BioNTech		
	Dose 1	Dose 2	Both Doses
Appendicitis	No	No	No
Bell's palsy	No	No	No
Encephalitis / myelitis / encephalomyelitis	No	No	No
Stroke, hemorrhagic	No	No	No
Stroke, ischemic	No	-	No
Immune thrombocytopenia	No	No	No
Kawasaki disease	No	No	No
Myocarditis / pericarditis	No	No	No
Seizures	No	No	No
Thrombotic thrombocytopenic purpura	No	-	No

- = analyses not yet possible
* Only outcomes for which analyses were possible for any dose are included in the table

Based on data through May 28, 2022

Statistical signals for pre-specified outcomes in 21-day risk interval after mRNA primary series vaccines for ages ≥12 years, including adults

VSD RCA prespecified outcome event*	Moderna			Pfizer-BioNTech			Both mRNA Vaccines		
	Dose 1	Dose 2	Both Doses	Dose 1	Dose 2	Both Doses	Dose 1	Dose 2	Both Doses
Acute disseminated encephalomyelitis	-	No	No	No	-	No	No	No	No
Acute myocardial infarction	No	No	No	No	**Yes**	No	No	**Yes**	No
Appendicitis	No	No	No	No	No	No	No	No	No
Bell's palsy	No	No	No	No	No	No	No	No	No
Cerebral venous sinus thrombosis	No	No	No	No	No	No	No	No	No
Disseminated intravascular coagulation	No	No	No	No	No	No	No	No	No
Encephalitis / myelitis / encephalomyelitis	No	No	No	No	No	No	No	No	No
Guillain-Barre syndrome	No	No	No	No	No	No	No	No	No
Stroke, hemorrhagic	No	No	No	No	No	No	No	No	No
Stroke, ischemic	No	No	No	No	No	No	No	No	No
Immune thrombocytopenia	No	No	No	No	No	No	No	No	No
Kawasaki disease	No	No	No	-	-	-	No	No	No
Myocarditis / pericarditis	No	No	No	No	**Yes**	**Yes**	No	**Yes**	**Yes**
Seizures	No	No	No	No	No	No	No	No	No
Transverse myelitis	No	No	No	No	No	No	No	No	No
Thrombotic thrombocytopenic purpura	No	No	No	No	No	No	No	No	No
Thrombosis with thrombocytopenia syndrome	No	No	No	No	No	No	No	No	No
Venous thromboembolism*	No	No	No	No	**Yes**	**Yes**	No	**Yes**	**Yes**
Pulmonary embolism (subset of VTE)	No	No	No	No	No	No	No	No	No

Based on data through May 21, 2022

- = analyses not yet possible

* No cases of acute myocardial infarction or venous thromboembolism within 98 days of any mRNA COVID-19 vaccination in 12–17-year-olds

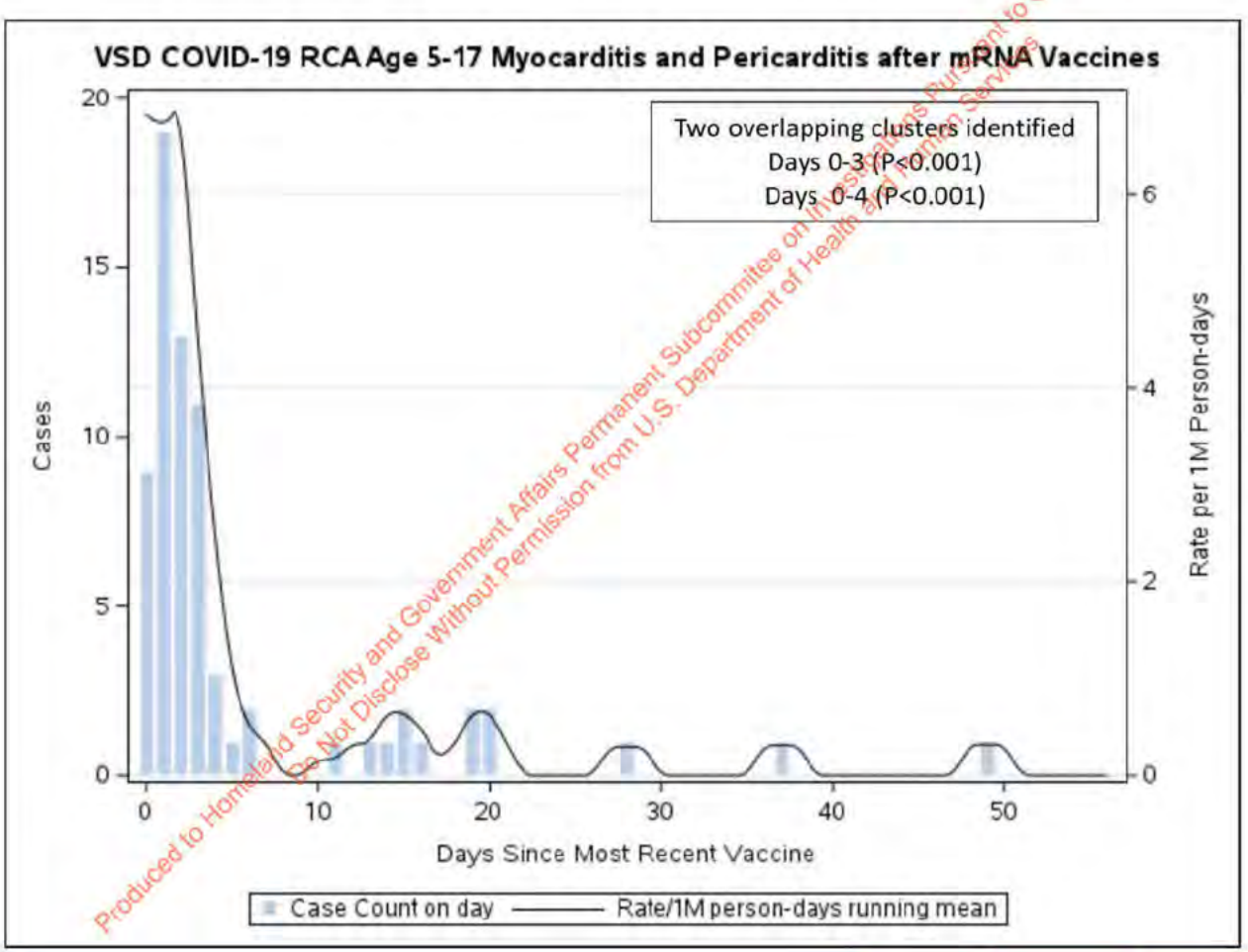
Statistical signals for pre-specified outcomes in 21-day risk interval after mRNA 1st booster vaccines for all ages above 12 years, including adults

	Primary series product:	Either mRNA	Pfizer-BioNTech	Moderna
VSD RCA prespecified outcome event*	Booster product:	Either mRNA	Pfizer-BioNTech	Moderna
Acute myocardial infarction		No	No	No
Appendicitis		No	No	No
Bell's palsy		No	No	No
Cerebral venous sinus thrombosis		No	No	No
Disseminated intravascular coagulation		No	No	No
Encephalitis / myelitis / encephalomyelitis		No	No	No
Guillain-Barre syndrome		No	No	No
Stroke, hemorrhagic		No	No	No
Stroke, ischemic		No	No	No
Immune thrombocytopenia		No	No	No
Myocarditis / pericarditis		**Yes**	No	No
Seizures		No	No	No
Transverse myelitis		No	No	No
Thrombotic thrombocytopenic purpura		No	No	No
Thrombosis with thrombocytopenia syndrome		No	No	No
Venous thromboembolism		No	No	No
Pulmonary embolism (subset of VTE)		No	No	No

Based on data through June 4, 2022

* Only outcomes for which analyses were possible are included on the table.

Day of symptom onset of verified myocarditis/pericarditis among children ages 5–17 years after either primary series dose of an mRNA COVID-19 vaccine



Based on data through May 28, 2022

Verified myocarditis and pericarditis in the 0–7-day risk interval among children ages 5-17 years in MALES by age group and dose (compared with outcome events in vaccinated comparators on the same calendar days, based on data through May 28, 2022)

Age Group	Pfizer-BioNTech dose	Events in Risk Interval	Events in Comparison Interval*	Adjusted Rate Ratio†	95% Conf Interval	2-sided P-value	Excess cases in Risk Period per million doses
5–11 Years	Dose 1	0	0	NE	NE	NE	NE
	Dose 2‡	2	0	NE	0.87 – ∞	0.061	15.2
	1st Booster	0	0	NE	NE	NE	NE
12–17 Years¶	Dose 1	3	1	**14.00**	**1.20 – 421.96**	**0.035**	**8.9**
	Dose 2	44	1	**160.52**	**30.19 – 3343.73**	**<0.001**	**147.0**
	1st Booster	9	1	**14.98**	1.39 – 484.33	0.023	**85.1**
12–15 Years subgroup	Dose 1	2	1	**13.63**	**0.94 – 433.36**	**0.056**	**8.8**
	Dose 2	28	1	**104.88**	**18.45 – 2267.59**	**<0.001**	**151.0**
	1st Booster	1	1	3.97	0.05 – 320.79	0.560	12.7
16–17 Years subgroup	Dose 1	1	0	NE	0.13 – ∞	0.285	9.6
	Dose 2	14	0	**NE**	**10.20 – ∞**	**<0.001**	**138.7**
	1st Booster	7	0	**NE**	**1.16 – ∞**	**0.038**	**200.3**

NE=not estimable

* Comparison interval is 22–42 days after either dose.

† Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date. 1st booster analyses are also adjusted for time since primary series.

‡ One case was non-informative for the risk interval analyses but was included in the excess risk calculation estimates.

¶ Subgroup events may not sum to "12–17" total due to non-informative events.

Verified myocarditis and pericarditis in the 0–7-day risk interval among children ages 5-17 years in FEMALES by age group and dose (compared with outcome events in vaccinated comparators on the same calendar days, based on data through May 28, 2022)

Age Group	Pfizer-BioNTech dose	Events in Risk Interval	Events in Comparison Interval*	Adjusted Rate Ratio†	95% Conf Interval	2-sided P-value	Excess cases in Risk Period per million doses
5-11 Years	Dose 1	0	0	NE	NE	NE	NE
	Dose 2	0	0	NE	NE	NE	NE
	1st Booster	0	0	NE	NE	NE	NE
12 – 17 Years‡	Dose 1	1	1	9.16	0.23 – 364.80	0.200	2.8
	Dose 2	5	1	**18.15**	**1.62 – 558.73**	**0.018**	**18.4**
	1st Booster	2	3	0.79	0.07 – 7.49	0.835	- 5.0
12 – 15 Years subgroup	Dose 1	0	0	NE	NE	NE	0.0
	Dose 2	4	0	**NE**	**1.01 – ∞**	**0.049**	**24.8**
	1st Booster	0	0	**NE**	NE	NE	0.0
16 – 17 Years subgroup	Dose 1	1	1	12.11	0.31 – 477.83	0.154	8.4
	Dose 2	1	1	6.10	0.16 – 239.90	0.283	7.9
	1st Booster	2	3	1.10	0.11 – 9.58	0.924	4.0

NE=not estimable

* Comparison interval is 22–42 days after either dose.

† Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date. 1st booster analyses are also adjusted for time since primary series.

‡ Subgroup events may not sum to "12–17" total due to non-informative events.

VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days following Pfizer-BioNTech vaccination, December 14, 2020–May 28, 2022

Children ages 5-17 years	Cases	Doses	Incidence rate per million doses admin.	95% Confidence Intervals
5–11 years				
Males – Dose 1	0	211,644	0.0	0.0 – 14.2
Males – Dose 2	**3**	**197,465**	**15.2**	**3.1 – 44.5**
Females – Dose 1	0	205,795	0.0	0.0 – 14.6
Females – Dose 2	0	192,380	0.0	0.0 – 15.6
12–15 years				
Males – Dose 1	2	210,622	9.5	1.2 – 34.3
Males – Dose 2	31	203,420	**152.5**	**103.6 – 216.4**
Males – 1st Booster	1	59,483	17.0	0.4 – 94.9
Females – Dose 1	0	208,494	0.0	0.0 – 14.4
Females – Dose 2	5	201,638	**24.8**	**8.1 – 57.9**
Females - 1st Booster	0	61,876	0.0	0.0 – 48.4
16–17 years				
Males – Dose 1	1	104,142	9.6	0.2 – 53.5
Males – Dose 2	14	100,980	**138.7**	**75.8 – 232.8**
Males – 1st Booster	8	40,177	**200.3**	**86.5 – 394.7**
Females – Dose 1	1	108,934	9.2	0.2 – 51.2
Females – Dose 2	1	105,929	9.4	0.2 – 52.6
Females - 1st Booster	2	45,794	**44.0**	**5.3 – 159.0**

Level of care and status of verified myocarditis and pericarditis case ages 5–17 years in the 0-7 days after primary series and 1st booster dose of mRNA COVID-19 vaccine, VSD

Level of care and status	Pfizer-BioNTech primary series (n=58)	Pfizer-BioNTech 1st booster (n=12)
Highest level of care		
Emergency department	4 (7%)	0 (0%)
Admitted to hospital	34 (59%)	6 (50%)
Admitted to ICU	20 (34%)	6 (50%)
Length of hospital stay, median (range)	2 days (0–7 days)	1 day (1–4 days)
0 – 1 days	20 (34%)	8 (67%)
2 – 3 days	28 (48%)	3 (25%)
4+ days	10 (17%)	1 (8%)
Discharged to home	58 (100%)	12 (100%)

Based on data through June 4, 2022

Comparative risk for myocarditis between the two available mRNA COVID-19 vaccines, Moderna and Pfizer-BioNTech

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 4/27/2021 3:50:15 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: Myocarditis re: Pfizer and Moderna

Perfect, thanks!

From: McNeill, Lorrie <[redacted]
Sent: Tuesday, April 27, 2021 3:48 PM
To: Capobianco, Abigail <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Will get back to you before the deadline.

Lorrie

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 3:33 PM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Hi Lorrie,

I just wanted to check back in here. Do you want me to share the cleared language from yesterday with CBS, or would CBER like something else? Alex's deadline is 5:30 pm.

Thanks!
Abby

From: Capobianco, Abigail
Sent: Tuesday, April 27, 2021 10:55 AM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: Myocarditis re: Pfizer and Moderna

Hi Lorrie,

We're starting to get more inquiries on myocarditis. Please see the email below from CBS.

Stephanie also wanted me to flag for you the way that the Military is responding to these:

Upfront Statement

We applaud Military Health System (MHS) medical professionals for considering cardiac evaluations in otherwise healthy, fit, and young individuals presenting with chest discomfort or shortness of breath following COVID-19 vaccination, given their familiarity of cardiac risk associated with the ACAM2000, a U.S. Food and Drug Administration-approved smallpox vaccine. Following diagnosis, these adverse events temporally associated with immunization were submitted to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) and subsequently have been brought to the attention of the CDC's COVID-19 vaccine Safety Technical Sub-Group. Subject Matter Expert discussions are ongoing.

The DHA-Immunization Health Division clinical support center and the CDC's VAERS program and COVID-19 vaccine Safety Technical Sub-Group are fulfilling their intended purpose - monitoring for an unexpected adverse event signal and consulting with other clinical specialists if a signal is identified. It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved. As is true for all vaccines, DoD and other nationwide health care professionals will continue to monitor for any updates to Advisory Committee on Immunization Practices (ACIP), CDC, manufacturer, and FDA recommendations.

Although several cardiac events temporally associated with COVID-19 vaccination have been identified, it is important to remember that COVID-19 disease can also effect multiple organ systems in your body - including the heart - even in those without significant symptoms or who were asymptomatic during COVID-19 infection. Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

Questions

Q: Can you confirm the number or provide an accurate number at Walter Reed, and are there any others in the military health system also being monitored for this condition following their vaccines?

A: DoD has been tracking cases of myocarditis temporally associated with COVID-19 vaccine across the MHS.

As it stands now, this is our current response (I took CDC out until I can check that with them and Kristen is out this week):

To date, FDA has not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified through this safety surveillance, that information will be communicated to the public.

Let me know if CBER wants to add anything here.

Thanks!
Abby

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:11 AM
To: Caccomo, Stephanie <[redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: [EXTERNAL] Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Lemar, Naweed (OS/ASPA) [redacted]
Sent: 4/27/2021 6:40:22 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; OS - Interviews [redacted] OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; Nordlund, Kristen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fdfd41389a645ca9fa28bed63d860c8-HHS-hok4-cd]
Subject: Re: //FOR APPROVAL//FDA Media Inquiry- COVID vaccine and myocarditis, NBC

Ok

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct: [redacted]
Mobile: [redacted]
Email: [redacted]

On Apr 27, 2021, at 6:19 PM, Caccomo, Stephanie [redacted] wrote:

+ CBS

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Lemar, Naweed (OS/ASPA) <[redacted]
Sent: Monday, April 26, 2021 4:04 PM
To: Capobianco, Abigail <[redacted]
Cc: OS - Interviews <[redacted] OC OEA OMA-Press <[redacted] Nordlund, Kristen (CDC) [redacted]
Subject: Re: //FOR APPROVAL//FDA Media Inquiry- COVID vaccine and myocarditis, NBC

Ok

V/R,

Naweed Lemar
U.S. Department of Health and Human Services

Direct: [redacted]
Mobile: [redacted]
Email: [redacted]

On Apr 26, 2021, at 3:59 PM, Capobianco, Abigail <[redacted] wrote:

****
Media Inquiry Request
****

Reporter: Alexandra Galante
Outlet: NBC
FDA Spokesperson: written response from FDA spokesperson Abby Capobianco
Deadline: COB today
Subject: COVID vaccine and myocarditis
Expected place of publication (print, online, broadcast): online/broadcast (no on-air appearance)
Expected date of publication/airing: TBD
Questions and Answers:

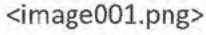
Question:
Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

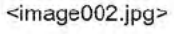
A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
According to the clinic, it has still not been confirmed that the inflammation was developed as a side effect of the vaccination. However, a number of COVID-19-related myocarditis cases have been reported, according to the US National Institutes of Health.

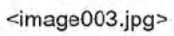
Response:
To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

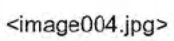
Abby Capobianco
Press Officer

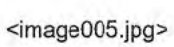
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [redacted] | Cell: [redacted]
[redacted]

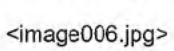












From: Tin, Alex [redacted]
Sent: 4/27/2021 6:21:00 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

Thanks for getting back to me

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Caccomo, Stephanie <[redacted]ov>
Sent: Tuesday, April 27, 2021 6:20 PM
To: Tin, Alex <[redacted] Capobianco, Abigail <[redacted]; Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]hs.gov>
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

To date, FDA has not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA through this safety surveillance, that information will be communicated to the public.

Stephanie Caccomo
Media Relations Director
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:13 PM
To: Capobianco, Abigail <[redacted] Caccomo, Stephanie <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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.

5:30 PM ET, thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 3:11 PM
To: Tin, Alex <[redacted] Caccomo, Stephanie <[redacted] Hunt, Alison
[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

Hi Alex,

What is your deadline? I will get back to you shortly.

Thanks!
Abby

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:09 PM
To: Caccomo, Stephanie [redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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.

Just checking in on this request?

Thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:10 AM
To: Caccomo, Stephanie [redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always.

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 4/27/2021 5:58:57 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: Myocarditis re: Pfizer and Moderna

Thanks for checking!

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: McNeill, Lorrie <[redacted]
Sent: Tuesday, April 27, 2021 5:38 PM
To: Capobianco, Abigail <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted] Caccomo, Stephanie <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Hi Abby –

Confirming that we would like to stick with the language provided yesterday:

To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

Peter is in agreement with using this language.

Thanks –

Lorrie

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 5:14 PM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted]; Pfaeffle, Veronika <[redacted] Caccomo, Stephanie <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Thanks so much Lorrie ☺

From: McNeill, Lorrie <[redacted]
Sent: Tuesday, April 27, 2021 5:13 PM
To: Capobianco, Abigail [redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted] Caccomo, Stephanie <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

I don't think our answer is going to change from yesterday, am waiting for Peter to weigh in. Will check with him again now.

Good luck at the vet.

L.

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 5:12 PM
To: McNeill, Lorrie <[redacted]ov>
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted] Caccomo, Stephanie <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Hi Lorrie,

If you have an answer after 5:30, can you please make sure Stephanie is included? We plan to flag for Erica and ASPA, and I need to run my cat to the vet for a 6 pm appointment.

Thanks!
Abby

From: McNeill, Lorrie <[redacted]
Sent: Tuesday, April 27, 2021 3:48 PM
To: Capobianco, Abigail [redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Will get back to you before the deadline.

Lorrie

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 3:33 PM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: Myocarditis re: Pfizer and Moderna

Hi Lorrie,

I just wanted to check back in here. Do you want me to share the cleared language from yesterday with CBS, or would CBER like something else? Alex's deadline is 5:30 pm.

Thanks!
Abby

From: Capobianco, Abigail
Sent: Tuesday, April 27, 2021 10:55 AM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: Myocarditis re: Pfizer and Moderna

Hi Lorrie,

We're starting to get more inquiries on myocarditis. Please see the email below from CBS.

Stephanie also wanted me to flag for you the way that the Military is responding to these:

Upfront Statement

We applaud Military Health System (MHS) medical professionals for considering cardiac evaluations in otherwise healthy, fit, and young individuals presenting with chest discomfort or shortness of breath following COVID-19 vaccination, given their familiarity of cardiac risk associated with the ACAM2000, a U.S. Food and Drug Administration-approved smallpox vaccine. Following diagnosis, these adverse events temporally associated with immunization were submitted to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) and subsequently have been brought to the attention of the CDC's COVID-19 vaccine Safety Technical Sub-Group. Subject Matter Expert discussions are ongoing.

The DHA-Immunization Health Division clinical support center and the CDC's VAERS program and COVID-19 vaccine Safety Technical Sub-Group are fulfilling their intended purpose - monitoring for an unexpected adverse event signal and consulting with other clinical specialists if a signal is identified. It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved. As is true for all vaccines, DoD and other nationwide health care professionals will continue to monitor for any updates to Advisory Committee on Immunization Practices (ACIP), CDC, manufacturer, and FDA recommendations.

Although several cardiac events temporally associated with COVID-19 vaccination have been identified, it is important to remember that COVID-19 disease can also effect multiple organ systems in your body - including the heart - even in those without significant symptoms or who were asymptomatic during COVID-19 infection. Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

Questions

Q: Can you confirm the number or provide an accurate number at Walter Reed, and are there any others in the military health system also being monitored for this condition following their vaccines?
A: DoD has been tracking cases of myocarditis temporally associated with COVID-19 vaccine across the MHS.

As it stands now, this is our current response (I took CDC out until I can check that with them and Kristen is out this week):

To date, FDA has not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified through this safety surveillance, that information will be communicated to the public.

Let me know if CBER wants to add anything here.

Thanks!
Abby

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:11 AM
To: Caccomo, Stephanie <[redacted]; Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: [EXTERNAL] Myocarditis re: Pfizer and Moderna

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.

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 4/27/2021 4:16:35 PM
To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: FLAGGING: RE: [Non-DoD Source] RE: Thread for today

Thanks Abby

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 4:06 PM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: FLAGGING: RE: [Non-DoD Source] RE: Thread for today

Flagging this for you!

From: Jefferson, Erica <[redacted]
Sent: Tuesday, April 27, 2021 1:58 PM
To: Caccomo, Stephanie <[redacted] Felberbaum, Michael <[redacted]
Subject: FW: [EXTERNAL] RE: [Non-DoD Source] RE: Thread for today

For awareness.

From: Ochoa, Laura C CIV OSD OSD (USA) <[redacted]
Sent: Tuesday, April 27, 2021 1:55 PM
To: Rowe, Courtney M. EOP/WHO [redacted] Jefferson, Erica <[redacted]
Sams, Ian C (OS) <[redacted] Munoz, Kevin EOP/WHO <[redacted] Waibel, Carlie S CIV (USA) <[redacted] Tumpey, Abbigail J (CDC) <[redacted]
Subject: [EXTERNAL] RE: [Non-DoD Source] RE: Thread for today

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.

All, attached is our final briefing card on this. Please let us know if you need anything more from DoD.

Mr. Kirby did not receive any questions on this today.

From: Rowe, Courtney M. EOP/WHO [redacted]
Sent: Tuesday, April 27, 2021 12:54 PM
To: Ochoa, Laura C CIV OSD OSD (USA)

Cc: Jefferson, Erica; Sams, Ian C (OS); Munoz, Kevin EOP/WHO; Waibel, Carlie S CIV (USA); Tumpey, Abbigail J (CDC)
Subject: Re: [Non-DoD Source] RE: Thread for today

This just came up on our briefing- we need to get a tight answer on this

Sent from my iPhone

On Apr 27, 2021, at 11:09 AM, Ochoa, Laura C CIV OSD OSD (USA) <[redacted] wrote:

All, Kirby is briefing at 1115 now. Below are the talking points we've cleared.

Top Lines:

- DoD is tracking 18 reports of chest pain or shortness of breath in recipients of the Pfizer and Moderna COVID-19 vaccines that have been submitted to the Vaccine Adverse Reporting System (VAERS). The overwhelming majority of these events have come within 12-96 hours after vaccination.
- Following these reports, the Defense Health Agency met with the CDC Vaccine Safety group to discuss these events, and we continue to investigate them, as we do any reaction.
- We have a very thorough vaccine safety monitoring system that is designed to notice these types of events, even if unrelated. **Important to note, just because an adverse event occurs near time of vaccination does not mean that it is caused by the vaccine.**
- We continue to believe that these vaccines are safe and we have no reason to believe otherwise. We are confident in these vaccines and encourage vaccination.
- Our military health system and defense health agency will continue to ensure the vaccine administration process remains safe for the health and wellness of our DoD population.

Talking Points:

* The Military Health System and the Defense Health Agency are always concerned about the health and wellness of our beneficiaries.

* It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved. There is not currently a higher rate with DoD vaccination population then the general population vaccinated or not and we remain extremely confident in the vaccine and continue to encourage people to take the vaccine.

* Myocarditis has a number of potential causes including bacterial, parasitic, and viral infections, including the COVID-19 virus. At this time the DoD has not established a correlation between the vaccination and identified instances of Myocarditis in DoD personnel. It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved.

* Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

* As is true for all vaccines, DoD and other nationwide health care professionals will continue to monitor for any updates to Advisory Committee on Immunization Practices (ACIP), CDC, manufacturer, and FDA recommendations.

* The department of defense is in active communication with the CDC daily to discuss any and all medical issues. In fact, one member of the Defense Health Agency sits on their daily board/ panel. DHA works daily to ensure the vaccine administration process remains safe.

* The DHA-Immunization Health Division clinical support center and the CDC's VAERS program and COVID-19 vaccine Safety Technical Sub-Group are fulfilling their intended purpose - monitoring for an unexpected adverse event signal and consulting with other clinical specialists if a signal is identified.

From: Jefferson, Erica [Erica.[redacted]
Sent: Tuesday, April 27, 2021 10:44 AM
To: Sams, Ian C (OS); Rowe, Courtney (who.eop.gov); Kevin.Munoz; Ochoa, Laura C CIV OSD OSD (USA); Waibel, Carlie S CIV (USA)
Cc: Tumpey, Abbigail J (CDC)
Subject: [Non-DoD Source] RE: Thread for today

The language on myocarditis is accurate for FDA and aligned with CDC language.

From: Sams, Ian (HHS/ASPA) <[redacted]
Sent: Tuesday, April 27, 2021 9:44 AM
To: Rowe, Courtney (who.eop.gov) <[redacted]; Kevin.Munoz <[redacted]
Ochoa, Laura (mail.mil) <[redacted]; Waibel, Carlie S CIV (USA) <[redacted]
Cc: Tumpey, Abbigail J (CDC) <[redacted]; Jefferson, Erica <[redacted]
Subject: RE: Thread for today

Adding Erica and Abbigail

Here is FDA response to media on myocarditis:
To date, FDA and CDC havenot seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

And CDC:
After 220 million doses of mRNA COVID-19 vaccine doses administered nationwide and over 5 million doses administered in the Vaccine Safety Datalink, CDC has not detected any indication of a safety problem with myocarditis or pericarditis. At this point there is no safety signal for myocarditis or pericarditis for COVID-19 vaccines in U.S. monitoring systems. Myocarditis/pericarditis is an adverse event of special interest for U.S. vaccine safety surveillance of COVID-19 vaccines and is being closely monitored in the Vaccine Adverse Event Reporting System (VAERS) and in CDC's Vaccine Safety Datalink (VSD). CDC will continue to closely monitor the safety of COVID-19 vaccines for myocarditis/pericarditis and other adverse events. Additional information is available at:

Caution->https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf< < Caution->https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf > <;
Caution->https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm< < Caution->https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm > <;

From: Rowe, Courtney M. EOP/WHO <[redacted] < Caution-mailto:[redacted] > >
Sent: Tuesday, April 27, 2021 9:28 AM
To: Kevin.Munoz <[redacted] < Caution-mailto:[redacted] > >; Ochoa, Laura (mail.mil) <[redacted] < Caution-mailto[redacted] > >; Waibel, Carlie S CIV (USA) <[redacted] < Caution-mailto[redacted] > >; Sams, Ian (HHS/ASPA) <[redacted] < Caution-mailto[redacted] > >
Subject: RE: Thread for today

Ian- could you loop the right folks at FDA and CDC on this so we can all get on the same page? I assume FDA would be getting incoming on this as well

---

From: Ochoa, Laura C CIV OSD OSD (USA) <[redacted] < Caution-mailto[redacted] > >
Sent: Tuesday, April 27, 2021 9:03 AM
To: Munoz, Kevin EOP/WHO <[redacted] < Caution-mailto:[redacted] > >; Waibel, Carlie S CIV (USA) <[redacted] < Caution-mailto[redacted] >; Rowe, Courtney M. EOP/WHO <[redacted] < Caution-mailto:Cou[redacted] > >; Sams, Ian (HHS/ASPA) <[redacted] < Caution-mailto[redacted] > >
Subject: Re: Thread for today

DHA has had 2+ meetings directly with CDC Vaccine Safety Technical subgoup to voice concerns. However, at this time there are no new recommendations coming out of CDC.

DHA is now tracking 18 cases temporarily associated with the vaccine.

From: "Ochoa, Laura C CIV OSD OSD (USA)" <[redacted] < Caution-mailto[redacted] > >
Date: Tuesday, April 27, 2021 at 8:58:40 AM
To: "Munoz, Kevin EOP/WHO" <[redacted] < Caution-mailto:[redacted] > >, "Waibel, Carlie S CIV (USA)" <[redacted] < Caution-mailto[redacted] > >, "Rowe, Courtney M. EOP/WHO" <[redacted] < Caution-mailto:[redacted] > >, "Sams, Ian (HHS/ASPA)" <[redacted] < Caution-mailto[redacted] > >
Subject: Re: Thread for today

All-

Our Health Affairs team responded to the query with the below. I think we need to add context to this.

Upfront Statement

We applaud Military Health System (MHS) medical professionals for considering cardiac evaluations in otherwise healthy, fit, and young individuals presenting with chest discomfort or shortness of breath following COVID-19 vaccination, given their familiarity of cardiac risk associated with the ACAM2000, a U.S. Food and Drug Administration-approved smallpox vaccine. Following diagnosis, these adverse events temporally associated with immunization were submitted to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) and subsequently have been brought to the attention of the CDC's COVID-19 vaccine Safety Technical Sub-Group. Subject Matter Expert discussions are ongoing.

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Although several cardiac events temporally associated with COVID-19 vaccination have been identified, it is important to remember that COVID-19 disease can also effect multiple organ systems in your body - including the heart - even in those without significant symptoms or who were asymptomatic during COVID-19 infection. Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

Questions

Q: Can you confirm the number or provide an accurate number at Walter Reed, and are there any others in the military health system also being monitored for this condition following their vaccines?

A: DoD has been tracking cases of myocarditis temporally associated with COVID-19 vaccine across the MHS.

Q: If so, how many?

A: Through March 2021, DoD is tracking 14 cases.

Q: What vaccine did they receive?

A: 11 had received the Moderna product and 3 had received the Pfizer-BioNTech product

Q: Did this condition occur after the patients' first or second vaccine?

A: One individual, who had a prior history of COVID-19 disease, presented after the 1st dose. The other 13 individuals presented after the 2nd dose. All sought medical care for chest pain 12-96 hours after vaccination.

Q: Were any of these patients diagnosed previously with COVID-19?

A: 13 did not have a history of COVID-19 disease and/or had negative testing. One was diagnosed with COVID-19 disease 3 months prior to vaccination. None had active SARS-CoV-2 infection at the time of myocarditis onset.

From: "Munoz, Kevin EOP/WHO" < [redacted] < Caution-mailto: [redacted] > >

Date: Tuesday, April 27, 2021 at 8:46:53 AM

To: "Ochoa, Laura C CIV OSD OSD (USA)" < [redacted] < Caution-mailto [redacted] > >,

"Waibel, Carlie S CIV (USA)" <[redacted] < Caution-mailto [redacted] >>, "Rowe, Courtney M. EOP/WHO" <[redacted] < Caution-mailto [redacted] >>, "Sams, Ian (HHS/ASPA)" <[redacted] < Caution-mailto [redacted] >>

Subject: Thread for today

Starting this now. Laura, keep us posted. Thanks

From: Tin, Alex [redacted]
Sent: 4/27/2021 10:10:34 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: [EXTERNAL] Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Galante, Alexandra (NBCUniversal) [redacted]
Sent: 4/26/2021 4:14:05 PM
To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: [EXTERNAL] NBC News Inquiry: Myocarditis

Hi Abigail, Alison and Veronika,

Thanks for the response.

With appreciation,

Ali Galante

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 4:08 PM
To: Galante, Alexandra (NBCUniversal) [redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] NBC News Inquiry: Myocarditis

Hi Ali,

To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

Thanks so much,
Abby

Abby Capobianco
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [redacted] | Cell: [redacted]
[redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Galante, Alexandra (NBCUniversal) <[redacted]
Sent: Monday, April 26, 2021 2:31 PM
To: Felberbaum, Michael <[redacted]
Subject: [EXTERNAL] NBC News Inquiry: Myocarditis

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.

Hi, Michael,

Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

All best,

Ali Galante

Ali Galante
Producer, *NBC Medical Unit*
W: [redacted]
C: [redacted]

A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
According to the clinic, it has still not been confirmed that the inflammation was developed as a side effect of the vaccination. However, a number of COVID-19-related myocarditis cases have been reported, according to the US National Institutes of Health.

https://www.jpost.com/health-science/19-year-old-hospitalized-with-heart-inflammation-after-pfizer-vaccination-657428

Very rare cases of pericarditis, myocarditis are being seen after mRNA vaccines. We've seen a few here in San Diego, too. It's time to get a handle on frequency and determine the mechanism.
https://twitter.com/EricTopol/status/1384133568004169734?s=20

From: Patricia Kime [redacted]
Sent: 4/26/2021 4:11:30 PM
To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

Thank you Abigail. I did report the top portion in the story.
I will add the comments. Thank you very much

Patricia Kime

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 4:09 PM
To: Patricia Kime <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

Hi Patricia,

Reports to VAERS are unverified reports; the report of an adverse event to VAERS is not documentation that a vaccine caused the event. Additional details on the limitations of VAERS data can be found here: https://vaers.hhs.gov/data/dataguide.html.

To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

Thanks very much,
Abby

Abby Capobianco
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [redacted] | Cell: [redacted]
[redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Patricia Kime <[redacted]
Sent: Monday, April 26, 2021 10:54 AM
To: Capobianco, Abigail <[redacted]
Subject: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

Can you please tell me if the FDA and the CDC are looking into this, as reported by the Jerusalem Post?
I am currently cross checking things in VAERS but there are at least 42 cases reported following vaccines, but I'm also aware that myocarditis is a complication of COVID-19.

Would you like to comment or can you refer me to the right person?

https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237

My deadline is today,

Patricia

Patricia Kime
Freelance Journalist
[redacted]
Twitter: [redacted]

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 4/26/2021 3:23:32 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: SC: Two Inquiries on myocarditis and vaccines

Will do! And I already flagged it for CBER and they asked us to let them know if we get more on this.

From: Caccomo, Stephanie <[redacted]
Sent: Monday, April 26, 2021 3:22 PM
To: Capobianco, Abigail <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: SC: Two Inquiries on myocarditis and vaccines

Fine with me! Let's flag the NBC one for ASPA. Thx!

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 3:18 PM
To: Caccomo, Stephanie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: SC: Two Inquiries on myocarditis and vaccines

Hi Steph,

We received two inquiries on myocarditis and the COVID vaccine. Please see below the inquiries and the CBER-cleared response:

Reporter: Patricia Kime, Alexandra Galante
Outlet: Military.com, NBC
Deadline: COB today
Inquiries:
Alexandra Galante, NBC: Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
According to the clinic, it has still not been confirmed that the inflammation was developed as a side effect of the vaccination. However, a number of COVID-19-related myocarditis cases have been reported, according to the US National Institutes of Health.

Patricia Kime, Military.com: Can you please tell me if the FDA and the CDC are looking into this, as reported by the Jerusalem Post?
I am currently cross checking things in VAERS but there are at least 42 cases reported following vaccines, but I'm also aware that myocarditis is a complication of COVID-19.

Would you like to comment or can you refer me to the right person?

https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237

FDA RESPONSE TO MILITARY.COM:

Reports to VAERS are unverified reports; the report of an adverse event to VAERS is not documentation that a vaccine caused the event. Additional details on the limitations of VAERS data can be found here: https://vaers.hhs.gov/data/dataguide.html.

To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

FDA RESPONSE TO NBC:
To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

Thanks!
Abby

Abby Capobianco
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [redacted] | Cell: [redacted]
[redacted]

U.S. FOOD & DRUG ADMINISTRATION

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 4/26/2021 2:52:27 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: FLAGGING: NBC News Inquiry: Myocarditis

Certainly!

From: McNeill, Lorrie <[redacted]
Sent: Monday, April 26, 2021 2:50 PM
To: Capobianco, Abigail <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: FLAGGING: NBC News Inquiry: Myocarditis

Hi Abby –

It does not change the response for now, but please keep me posted if you receive questions going forward.

Lorrie

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 2:48 PM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: FLAGGING: NBC News Inquiry: Myocarditis

Hi Lorrie,

Just flagging that we got another inquiry about myocarditis. I assume this doesn't change the response at all, but since this is from NBC, I wanted to elevate it.

Thanks!
Abby

From: Galante, Alexandra (NBCUniversal) <[redacted]
Sent: Monday, April 26, 2021 2:31 PM
To: Felberbaum, Michael <[redacted]
Subject: [EXTERNAL] NBC News Inquiry: Myocarditis

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.

Hi, Michael,

Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

All best,

Ali Galante

Ali Galante
Producer, *NBC Medical Unit*
W: [redacted]
C: [redacted]

A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
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https://www.jpost.com/health-science/19-year-old-hospitalized-with-heart-inflammation-after-pfizer-vaccination-657428

Very rare cases of pericarditis, myocarditis are being seen after mRNA vaccines. We've seen a few here in San Diego, too. It's time to get a handle on frequency and determine the mechanism.
https://twitter.com/EricTopol/status/1384133568004169734?s=20

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 4/26/2021 2:44:39 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: [EXTERNAL] NBC News Inquiry: Myocarditis

I got it! I have another inquiry on the same topic that I just got a cleared response for.

From: Felberbaum, Michael <[redacted]
Sent: Monday, April 26, 2021 2:32 PM
To: Capobianco, Abigail <[redacted] Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Cc: Caccomo, Stephanie <[redacted]
Subject: FW: [EXTERNAL] NBC News Inquiry: Myocarditis

For follow-up.

From: Galante, Alexandra (NBCUniversal) <[redacted]
Sent: Monday, April 26, 2021 2:31 PM
To: Felberbaum, Michael [redacted]
Subject: [EXTERNAL] NBC News Inquiry: Myocarditis

Hi, Michael,

Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

All best,

Ali Galante

Ali Galante
Producer, *NBC Medical Unit*
W: [redacted]
C: [redacted]

A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
According to the clinic, it has still not been confirmed that the inflammation was developed as a side effect of the vaccination. However, a number of COVID-19-related myocarditis cases have been reported, according to the US National Institutes of Health.

https://www.jpost.com/health-science/19-year-old-hospitalized-with-heart-inflammation-after-pfizer-vaccination-657428

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https://twitter.com/EricTopol/status/1384133568004169734?s=20

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 4/26/2021 2:05:31 PM
To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: Deadline today: Questions from Military.com re: vaccines and myocarditis

Hi Abby –

We recommend a slight edit (in red) below.

Reports to VAERS are unverified reports; the report of an adverse event to VAERS is not documentation that a vaccine caused the event. Additional details on the limitations of VAERS data can be found here: https://vaers.hhs.gov/data/dataguide.html.

To date, ~~we~~ FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

If you have questions about the edit, happy to explain.

Thanks –

Lorrie

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 12:03 PM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison <Alison.Hunt@fda.hhs.gov>; Pfaeffle, Veronika <[redacted]
Subject: RE: Deadline today: Questions from Military.com re: vaccines and myocarditis

Thanks, Lorrie!

From: McNeill, Lorrie <[redacted]
Sent: Monday, April 26, 2021 11:52 AM
To: Capobianco, Abigail <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: Deadline today: Questions from Military.com re: vaccines and myocarditis

Hi Abby –

Forgive me, I misread your email and missed the language in the sentence on myocarditis. So please disregard my email below.

I'll get back to you shortly.

Lorrie

From: McNeill, Lorrie
Sent: Monday, April 26, 2021 11:48 AM
To: Capobianco, Abigail <[redacted]
Cc: Hunt, Alison [redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: Deadline today: Questions from Military.com re: vaccines and myocarditis

HI Abby –

I will check with OBE. As a reminder, please don't use this language: *To date, we have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines.*

Lorrie

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 11:27 AM
To: McNeill, Lorrie <[redacted]
Cc: Hunt, Alison [redacted] Pfaeffle, Veronika <[redacted]
Subject: Deadline today: Questions from Military.com re: vaccines and myocarditis

Hi Lorrie,

We got a question from military.com regarding myocarditis and the COVID-19 vaccine. Her deadline is today, so I plan to use cleared language. Please see below and let me know if this works for you.

Question:

Can you please tell me if the FDA and the CDC are looking into this, as reported by the Jerusalem Post?
I am currently cross checking things in VAERS but there are at least 42 cases reported following vaccines, but I'm also aware that myocarditis is a complication of COVID-19.

Would you like to comment or can you refer me to the right person?

https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237

My deadline is today

Response:

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Thanks!
Abby

From: Patricia Kime <[redacted]
Sent: Monday, April 26, 2021 10:54 AM
To: Capobianco, Abigail <[redacted]
Subject: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

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.

Can you please tell me if the FDA and the CDC are looking into this, as reported by the Jerusalem Post?
I am currently cross checking things in VAERS but there are at least 42 cases reported following vaccines, but I'm also aware that myocarditis is a complication of COVID-19.

Would you like to comment or can you refer me to the right person?

https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237

My deadline is today,

Patricia

Patricia Kime
Freelance Journalist
[redacted]
Twitter: [redacted]

From: Tin, Alex [redacted]
Sent: 4/27/2021 10:10:34 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: [EXTERNAL] Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Tin, Alex [redacted]
Sent: 4/27/2021 6:21:00 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

Thanks for getting back to me

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 6:20 PM
To: Tin, Alex <[redacted] Capobianco, Abigail <[redacted] Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

To date, FDA has not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA through this safety surveillance, that information will be communicated to the public.

Stephanie Caccomo
Media Relations Director
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:13 PM
To: Capobianco, Abigail <[redacted] Caccomo, Stephanie <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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.

5:30 PM ET, thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 3:11 PM
To: Tin, Alex <[redacted] Caccomo, Stephanie <[redacted] Hunt, Alison
[redacted]
Cc: Pfaeffle, Veronika [redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

Hi Alex,

What is your deadline? I will get back to you shortly.

Thanks!
Abby

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:09 PM
To: Caccomo, Stephanie [redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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Just checking in on this request?

Thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:10 AM
To: Caccomo, Stephanie [redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always.

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

Sent: 4/27/2021 3:10:38 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: [EXTERNAL] RE: [Non-DoD Source] RE: Thread for today

Sure will. I

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 2:23 PM
To: Capobianco, Abigail <[redacted]
Subject: FW: [EXTERNAL] RE: [Non-DoD Source] RE: Thread for today

Can you flag for CBER?

Did you respond to Alex Tin?

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Jefferson, Erica <[redacted]
Sent: Tuesday, April 27, 2021 1:58 PM
To: Caccomo, Stephanie [redacted] Felberbaum, Michael <[redacted]
Subject: FW: [EXTERNAL] RE: [Non-DoD Source] RE: Thread for today

For awareness.

From: Ochoa, Laura C CIV OSD OSD (USA) <[redacted]
Sent: Tuesday, April 27, 2021 1:55 PM
To: Rowe, Courtney M. EOP/WHO <[redacted] Jefferson, Erica <[redacted]
Sams, Ian C (OS) <[redacted] Munoz, Kevin EOP/WHO <[redacted] Waibel, Carlie S CIV (USA) <[redacted] Tumpey, Abbigail J (CDC) <[redacted]
Subject: [EXTERNAL] RE: [Non-DoD Source] RE: Thread for today

All, attached is our final briefing card on this. Please let us know if you need anything more from DoD.

Mr. Kirby did not receive any questions on this today.

From: Rowe, Courtney M. EOP/WHO [redacted]
Sent: Tuesday, April 27, 2021 12:54 PM
To: Ochoa, Laura C CIV OSD OSD (USA)
Cc: Jefferson, Erica; Sams, Ian C (OS); Munoz, Kevin EOP/WHO; Waibel, Carlie S CIV (USA); Tumpey, Abbigail J (CDC)
Subject: Re: [Non-DoD Source] RE: Thread for today

This just came up on our briefing- we need to get a tight answer on this

Sent from my iPhone

On Apr 27, 2021, at 11:09 AM, Ochoa, Laura C CIV OSD OSD (USA) [redacted] wrote:

All, Kirby is briefing at 1115 now. Below are the talking points we've cleared.

Top Lines:

- DoD is tracking 18 reports of chest pain or shortness of breath in recipients of the Pfizer and Moderna COVID-19 vaccines that have been submitted to the Vaccine Adverse Reporting System (VAERS). The overwhelming majority of these events have come within 12-96 hours after vaccination.
- Following these reports, the Defense Health Agency met with the CDC Vaccine Safety group to discuss these events, and we continue to investigate them, as we do any reaction.
- We have a very thorough vaccine safety monitoring system that is designed to notice these types of events, even if unrelated. **Important to note, just because an adverse event occurs near time of vaccination does not mean that it is caused by the vaccine.**
- We continue to believe that these vaccines are safe and we have no reason to believe otherwise. We are confident in these vaccines and encourage vaccination.
- Our military health system and defense health agency will continue to ensure the vaccine administration process remains safe for the health and wellness of our DoD population.

Talking Points:

* The Military Health System and the Defense Health Agency are always concerned about the health and wellness of our beneficiaries.

* It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved. There is not currently a higher rate with DoD vaccination population then the general population vaccinated or not and we remain extremely confident in the vaccine and continue to encourage people to take the vaccine.

* Myocarditis has a number of potential causes including bacterial, parasitic, and viral infections, including the COVID-19 virus. At this time the DoD has not established a correlation between the vaccination and identified instances of Myocarditis in DoD personnel. It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved.

* Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

* As is true for all vaccines, DoD and other nationwide health care professionals will continue to monitor for any updates to Advisory Committee on Immunization Practices (ACIP), CDC, manufacturer, and FDA recommendations.

* The department of defense is in active communication with the CDC daily to discuss any and all medical issues. In fact, one member of the Defense Health Agency sits on their daily board/ panel. DHA works daily to ensure the vaccine administration process remains safe.

* The DHA-Immunization Health Division clinical support center and the CDC's VAERS program and COVID-19 vaccine Safety Technical Sub-Group are fulfilling their intended purpose - monitoring for an unexpected adverse event signal and consulting with other clinical specialists if a signal is identified.

From: Jefferson, Erica [Erica.[redacted]
Sent: Tuesday, April 27, 2021 10:44 AM
To: Sams, Ian C (OS); Rowe, Courtney (who.eop.gov); Kevin.Munoz; Ochoa, Laura C CIV OSD OSD (USA); Waibel, Carlie S CIV (USA)
Cc: Tumpey, Abbigail J (CDC)
Subject: [Non-DoD Source] RE: Thread for today

The language on myocarditis is accurate for FDA and aligned with CDC language.

From: Sams, Ian (HHS/ASPA) [redacted]
Sent: Tuesday, April 27, 2021 9:44 AM
To: Rowe, Courtney (who.eop.gov) <Courtn[redacted] Kevin.Munoz <[redacted]
Ochoa, Laura (mail.mil) <[redacted] Waibel, Carlie S CIV (USA) <[redacted]
Cc: Tumpey, Abbigail J (CDC) <[redacted] Jefferson, Erica <[redacted]
Subject: RE: Thread for today

Adding Erica and Abbigail

Here is FDA response to media on myocarditis:

To date, FDA and CDC havenot seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

And CDC:

After 220 million doses of mRNA COVID-19 vaccine doses administered nationwide and over 5 million doses administered in the Vaccine Safety Datalink, CDC has not detected any indication of a safety problem with myocarditis or pericarditis.

At this point there is no safety signal for myocarditis or pericarditis for COVID-19 vaccines in U.S. monitoring systems. Myocarditis/pericarditis is an adverse event of special interest for U.S. vaccine safety surveillance of COVID-19 vaccines and is being closely monitored in the Vaccine Adverse Event Reporting System (VAERS) and in CDC's Vaccine Safety Datalink (VSD). CDC will continue to closely monitor the safety of COVID-19 vaccines for myocarditis/pericarditis and other adverse events. Additional information is available at:

Caution->https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf< < Caution->https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf > <;
Caution->https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm< < Caution->https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm > <;

From: Rowe, Courtney M. EOP/WHO <[redacted] < Caution-mailto:Court[redacted] > >
Sent: Tuesday, April 27, 2021 9:28 AM
To: Kevin.Munoz [redacted] < Caution-mailto:[redacted] >; Ochoa, Laura (mail.mil) <[redacted] < Caution-mailto[redacted] >>; Waibel, Carlie S CIV (USA) <[redacted] < Caution-mailto[redacted] >>; Sams, Ian (HHS/ASPA) <[redacted] < Caution-mailto:[redacted] > >
Subject: RE: Thread for today

Ian- could you loop the right folks at FDA and CDC on this so we can all get on the same page? I assume FDA would be getting incoming on this as well

---

From: Ochoa, Laura C CIV OSD OSD (USA) <[redacted] < Caution-mailto[redacted] > >
Sent: Tuesday, April 27, 2021 9:03 AM
To: Munoz, Kevin EOP/WHO <[redacted] < Caution-mailto:[redacted] > >; Waibel, Carlie S CIV (USA) <[redacted] < Caution-mailto:[redacted] > >; Rowe, Courtney M. EOP/WHO <[redacted] < Caution-mailto:[redacted] >>; Sams, Ian (HHS/ASPA) <[redacted] < Caution-mailto[redacted] > >
Subject: Re: Thread for today

DHA has had 2+ meetings directly with CDC Vaccine Safety Technical subgoup to voice concerns. However, at this time there are no new recommendations coming out of CDC.

DHA is now tracking 18 cases temporarily associated with the vaccine.

From: "Ochoa, Laura C CIV OSD OSD (USA)" <[redacted] < Caution-mailto[redacted] > >
Date: Tuesday, April 27, 2021 at 8:58:40 AM
To: "Munoz, Kevin EOP/WHO" <[redacted] < Caution-mailto:[redacted] > >, "Waibel, Carlie S CIV (USA)" <[redacted] < Caution-mailto[redacted] > >, "Rowe, Courtney M. EOP/WHO" <[redacted] < Caution-mailto:[redacted] > >, "Sams, Ian (HHS/ASPA)" <[redacted] < Caution-mailto[redacted] > >
Subject: Re: Thread for today

All-

Our Health Affairs team responded to the query with the below. I think we need to add context to this.

Upfront Statement

We applaud Military Health System (MHS) medical professionals for considering cardiac evaluations in otherwise healthy, fit, and young individuals presenting with chest discomfort or shortness of breath following COVID-19 vaccination, given their familiarity of cardiac risk associated with the ACAM2000, a U.S. Food and Drug Administration-approved smallpox vaccine. Following diagnosis, these adverse events temporally associated with immunization were submitted to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) and subsequently have been brought to the attention of the CDC's COVID-19 vaccine Safety Technical Sub-Group. Subject Matter Expert discussions are ongoing.

The DHA-Immunization Health Division clinical support center and the CDC's VAERS program and COVID-19 vaccine Safety Technical Sub-Group are fulfilling their intended purpose - monitoring for an unexpected adverse event signal and consulting with other clinical specialists if a signal is identified. It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved. As is true for all vaccines, DoD and other nationwide health care professionals will continue to monitor for any updates to Advisory Committee on Immunization Practices (ACIP), CDC, manufacturer, and FDA recommendations.

Although several cardiac events temporally associated with COVID-19 vaccination have been identified, it is important to remember that COVID-19 disease can also effect multiple organ systems in your body - including the heart - even in those without significant symptoms or who were asymptomatic during COVID-19 infection. Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

Questions

Q: Can you confirm the number or provide an accurate number at Walter Reed, and are there any others in the military health system also being monitored for this condition following their vaccines?

A: DoD has been tracking cases of myocarditis temporally associated with COVID-19 vaccine across the MHS.

Q: If so, how many?

A: Through March 2021, DoD is tracking 14 cases

Q: What vaccine did they receive?

A: 11 had received the Moderna product and 3 had received the Pfizer-BioNTech product

Q: Did this condition occur after the patients' first or second vaccine?

A: One individual, who had a prior history of COVID-19 disease, presented after the 1st dose. The other 13 individuals presented after the 2nd dose. All sought medical care for chest pain 12-96 hours after vaccination.

Q: Were any of these patients diagnosed previously with COVID-19?

A: 13 did not have a history of COVID-19 disease and/or had negative testing. One was diagnosed with COVID-19 disease 3 months prior to vaccination. None had active SARS-CoV-2 infection at the time of myocarditis onset.

From: "Munoz, Kevin EOP/WHO" <[redacted] < Caution-mailto:[redacted] > >
Date: Tuesday, April 27, 2021 at 8:46:53 AM
To: "Ochoa, Laura C CIV OSD OSD (USA)" <[redacted] < Caution-mailto:[redacted] > >, "Waibel, Carlie S CIV (USA)" <[redacted] < Caution-mailto[redacted] > >, "Rowe, Courtney M. EOP/WHO" <[redacted] < Caution-mailto:[redacted] > >, "Sams, Ian (HHS/ASPA)" <[redacted] < Caution-mailto[redacted] > >
Subject: Thread for today

Starting this now. Laura, keep us posted. Thanks

Sent: 4/26/2021 2:56:13 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: Two Inquiries on myocarditis and vaccines

Hi Steph,

We received two inquiries on myocarditis and the COVID vaccine. Please see below the inquiries and the CBER-cleared response:

Alexandra Galante, NBC: Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
According to the clinic, it has still not been confirmed that the inflammation was developed as a side effect of the vaccination. However, a number of COVID-19-related myocarditis cases have been reported, according to the US National Institutes of Health.

Abby Capobianco
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [redacted] | Cell: [redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

Sent: 4/26/2021 11:19:47 AM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
Subject: Inquiry from Military.com re: vaccines and myocarditis

From: Patricia Kime <[redacted]
Sent: Monday, April 26, 2021 10:54 AM
To: Capobianco, Abigail <[redacted]
Subject: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

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.

Can you please tell me if the FDA and the CDC are looking into this, as reported by the Jerusalem Post?
I am currently cross checking things in VAERS but there are at least 42 cases reported following vaccines, but I'm also aware that myocarditis is a complication of COVID-19.

Would you like to comment or can you refer me to the right person?

https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237

My deadline is today,

Patricia

Patricia Kime
Freelance Journalist
[redacted]
Twitter: [redacted]

Sent: 4/26/2021 4:09:45 PM
To: [redacted]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: [EXTERNAL] NBC News Inquiry: Myocarditis

Hi Ali,

Tha

From: Galante, Alexandra (NBCUniversal) <[redacted]
Sent: Monday, April 26, 2021 2:31 PM
To: Felberbaum, Michael <[redacted]
Subject: [EXTERNAL] NBC News Inquiry: Myocarditis

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.

Hi, Michael,

Hope you're well. We're seeing reports of myocarditis after the mRNA vaccine. Can you confirm? Any additional insight would be greatly appreciated.

All best,

Ali Galante

Ali Galante
Producer, *NBC Medical Unit*
W: [redacted]
C: [redacted]

A 19-year-old was hospitalized with myocarditis – inflammation of the heart muscle – five days after receiving his second dose of the coronavirus vaccine, Terem emergency medical clinic reported Monday.
According to the clinic, it has still not been confirmed that the inflammation was developed as a side effect of the vaccination. However, a number of COVID-19-related myocarditis cases have been reported, according to the US National Institutes of Health.

https://www.jpost.com/health-science/19-year-old-hospitalized-with-heart-inflammation-after-pfizer-vaccination-657428

Very rare cases of pericarditis, myocarditis are being seen after mRNA vaccines. We've seen a few here in San Diego, too. It's time to get a handle on frequency and determine the mechanism.
https://twitter.com/EricTopol/status/1384133568004169734?s=20

Sent: 4/27/2021 7:03:58 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Tin, Alex [redacted] Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 6:21 PM
To: Tin, Alex <[redacted] Capobianco, Abigail <[redacted]v>; Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

To date, FDA has not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA through this safety surveillance, that information will be communicated to the public.

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:13 PM
To: Capobianco, Abigail <[redacted] Caccomo, Stephanie <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

5:30 PM ET, thank you!

Alexander Tin
[redacted]

Cell [redacted], Signal [redacted]

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 3:11 PM
To: Tin, Alex <[redacted] Caccomo, Stephanie <[redacted] Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

Hi Alex,

What is your deadline? I will get back to you shortly.

Thanks!
Abby

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:09 PM
To: Caccomo, Stephanie <[redacted]; Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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Just checking in on this request?

Thank you!

Alexander Tin
[redacted]
Cell [redacted] Signal [redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:10 AM
To: Caccomo, Stephanie <[redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]

Cc: Pfaeffle, Veronika [redacted]
Subject: Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 4/27/2021 7:04:02 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

Thank you!

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 6:21 PM
To: Tin, Alex <[redacted] Capobianco, Abigail <[redacted] Hunt, Alison <[redacted]
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Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:13 PM
To: Capobianco, Abigail <[redacted] Caccomo, Stephanie <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
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5:30 PM ET, thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Capobianco, Abigail <[redacted]
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Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

Hi Alex,

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Thanks!
Abby

From: Tin, Alex <[redacted]
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To: Caccomo, Stephanie <[redacted]>; Capobianco, Abigail <[redacted]
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Alexander Tin
[redacted]
Cell [redacted] Signal [redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:10 AM
To: Caccomo, Stephanie <[redacted] Capobianco, Abigail <[redacted]
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Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 4/27/2021 10:39:19 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Thread for today

Surely!

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 10:28 AM
To: Capobianco, Abigail <[redacted]
Subject: FW: Thread for today

Can you flag what MHS is sending to reporters?

Upfront Statement
We applaud Military Health System (MHS) medical professionals for considering cardiac evaluations in otherwise healthy, fit, and young individuals presenting with chest discomfort or shortness of breath following COVID-19 vaccination, given their familiarity of cardiac risk associated with the ACAM2000, a U.S. Food and Drug Administration-approved smallpox vaccine. Following diagnosis, these adverse events temporally associated with immunization were submitted to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) and subsequently have been brought to the attention of the CDC's COVID-19 vaccine Safety Technical Sub-Group. Subject Matter Expert discussions are ongoing.

The DHA-Immunization Health Division clinical support center and the CDC's VAERS program and COVID-19 vaccine Safety Technical Sub-Group are fulfilling their intended purpose - monitoring for an unexpected adverse event signal and consulting with other clinical specialists if a signal is identified. It's important to remember that medical events developing or worsening around the time of a vaccine does not mean that the vaccine was involved. As is true for all vaccines, DoD and other nationwide health care professionals will continue to monitor for any updates to Advisory Committee on Immunization Practices (ACIP), CDC, manufacturer, and FDA recommendations.

Although several cardiac events temporally associated with COVID-19 vaccination have been identified, it is important to remember that COVID-19 disease can also effect multiple organ systems in your body - including the heart - even in those without significant symptoms or who were asymptomatic during COVID-19 infection. Evidence available in peer-reviewed literature suggests that cardiac risk of complications are clearly higher in those with COVID-19 disease as opposed to a potential risk from the COVID-19 vaccine. Therefore, we continue to fully support FDA authorized COVID-19 vaccines and recommend obtaining a COVID-19 vaccine as soon as possible.

Questions
Q: Can you confirm the number or provide an accurate number at Walter Reed, and are there any others in the military health system also being monitored for this condition following their vaccines?
A: DoD has been tracking cases of myocarditis temporally associated with COVID-19 vaccine across the MHS.

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Jefferson, Erica <[redacted]
Sent: Tuesday, April 27, 2021 10:20 AM
To: Caccomo, Stephanie <[redacted]
Cc: Felberbaum, Michael <[redacted]
Subject: RE: Thread for today

That is curious. I wonder why.

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 10:14 AM
To: Jefferson, Erica <[redacted]
Cc: Felberbaum, Michael <[redacted]
Subject: RE: Thread for today

Yup! We confirmed yesterday as we received two inquiries on it. I'm concerned CDC and FDA are on the same page, but the military folks seem to be suggesting a causation.

Stephanie Caccomo
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Jefferson, Erica <[redacted]
Sent: Tuesday, April 27, 2021 10:00 AM
To: Caccomo, Stephanie <Steph[redacted]
Cc: Felberbaum, Michael [redacted]
Subject: FW: Thread for today

I just want to confirm that the language on myocarditis is still accurate from our end. Thanks

From: Sams, Ian (HHS/ASPA) <[redacted]
Sent: Tuesday, April 27, 2021 9:44 AM
To: Rowe, Courtney (who.eop.gov) <[redacted] Kevin.Munoz <[redacted]
Ochoa, Laura (mail.mil) <[redacted]>; Waibel, Carlie S CIV (USA) <[redacted]
Cc: Tumpey, Abbigail J (CDC) <[redacted] Jefferson, Erica <[redacted]
Subject: RE: Thread for today

Adding Erica and Abbigail

Here is FDA response to media on myocarditis:

To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

And CDC:

After 220 million doses of mRNA COVID-19 vaccine doses administered nationwide and over 5 million doses administered in the Vaccine Safety Datalink, CDC has not detected any indication of a safety problem with myocarditis or pericarditis. At this point there is no safety signal for myocarditis or pericarditis for COVID-19 vaccines in U.S. monitoring systems. Myocarditis/pericarditis is an adverse event of special interest for U.S. vaccine safety surveillance of COVID-19 vaccines and is being closely monitored in the Vaccine Adverse Event Reporting System (VAERS) and in CDC's Vaccine Safety Datalink (VSD). CDC will continue to closely monitor the safety of COVID-19 vaccines for myocarditis/pericarditis and other adverse events. Additional information is available at:

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm

From: Rowe, Courtney M. EOP/WHO <[redacted]
Sent: Tuesday, April 27, 2021 9:28 AM
To: Kevin.Munoz <[redacted] Ochoa, Laura (mail.mil) <[redacted] Waibel, Carlie S CIV (USA) <[redacted] Sams, Ian (HHS/ASPA) <[redacted]
Subject: RE: Thread for today

Ian- could you loop the right folks at FDA and CDC on this so we can all get on the same page? I assume FDA would be getting incoming on this as well

---

From: Ochoa, Laura C CIV OSD OSD (USA) <[redacted]
Sent: Tuesday, April 27, 2021 9:03 AM
To: Munoz, Kevin EOP/WHO <[redacted] Waibel, Carlie S CIV (USA) <[redacted] Rowe, Courtney M. EOP/WHO <[redacted] Sams, Ian (HHS/ASPA) <[redacted]
Subject: Re: Thread for today

DHA has had 2+ meetings directly with CDC Vaccine Safety Technical subgoup to voice concerns. However, at this time there are no new recommendations coming out of CDC.

DHA is now tracking 18 cases temporarily associated with the vaccine.

From: "Ochoa, Laura C CIV OSD OSD (USA)" <[redacted]
Date: Tuesday, April 27, 2021 at 8:58:40 AM
To: "Munoz, Kevin EOP/WHO" <[redacted] "Waibel, Carlie S CIV (USA)"

<[redacted] "Rowe, Courtney M. EOP/WHO" <[redacted] "Sams, Ian (HHS/ASPA)" <[redacted]
Subject: Re: Thread for today

All-

Our Health Affairs team responded to the query with the below. I think we need to add context to this.

Upfront Statement
We applaud Military Health System (MHS) medical professionals for considering cardiac evaluations in otherwise healthy, fit, and young individuals presenting with chest discomfort or shortness of breath following COVID-19 vaccination, given their familiarity of cardiac risk associated with the ACAM2000, a U.S. Food and Drug Administration-approved smallpox vaccine. Following diagnosis, these adverse events temporally associated with immunization were submitted to the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) and subsequently have been brought to the attention of the CDC's COVID-19 vaccine Safety Technical Sub-Group. Subject Matter Expert discussions are ongoing.

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Questions
Q: Can you confirm the number or provide an accurate number at Walter Reed, and are there any others in the military health system also being monitored for this condition following their vaccines?
A: DoD has been tracking cases of myocarditis temporally associated with COVID-19 vaccine across the MHS.

Q: If so, how many?
A: Through March 2021, DoD is tracking 14 cases

Q: What vaccine did they receive?
A: 11 had received the Moderna product and 3 had received the Pfizer-BioNTech product

Q: Did this condition occur after the patients' first or second vaccine?
A: One individual, who had a prior history of COVID-19 disease, presented after the 1st dose. The other 13 individuals presented after the 2nd dose. All sought medical care for chest pain 12-96 hours after vaccination.

Q: Were any of these patients diagnosed previously with COVID-19?
A: 13 did not have a history of COVID-19 disease and/or had negative testing. One was diagnosed with COVID-19 disease 3 months prior to vaccination. None had active SARS-CoV-2 infection at the time of myocarditis onset.

From: "Munoz, Kevin EOP/WHO" <[redacted]
Date: Tuesday, April 27, 2021 at 8:46:53 AM
To: "Ochoa, Laura C CIV OSD OSD (USA)" <[redacted] "Waibel, Carlie S CIV (USA)" <[redacted] "Rowe, Courtney M. EOP/WHO" <[redacted] "Sams, Ian (HHS/ASPA)" <[redacted]
Subject: Thread for today

Starting this now. Laura, keep us posted. Thanks

From: Tin, Alex [redacted]
Sent: 4/27/2021 6:21:00 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

Thanks for getting back to me

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Caccomo, Stephanie <[redacted]
Sent: Tuesday, April 27, 2021 6:20 PM
To: Tin, Alex <[redacted] Capobianco, Abigail <[redacted] Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

To date, FDA has not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA through this safety surveillance, that information will be communicated to the public.

Stephanie Caccomo
Media Relations Director
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: [redacted]
Cell: [redacted]
[redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:13 PM
To: Capobianco, Abigail <[redacted] Caccomo, Stephanie <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Re: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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.

5:30 PM ET, thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Capobianco, Abigail <[redacted]
Sent: Tuesday, April 27, 2021 3:11 PM
To: Tin, Alex <[redacted] Caccomo, Stephanie [redacted] Hunt, Alison
<[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

External Email [redacted]

Hi Alex,

What is your deadline? I will get back to you shortly.

Thanks!
Abby

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 3:09 PM
To: Caccomo, Stephanie <[redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: [EXTERNAL] Re: Myocarditis re: Pfizer and Moderna

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.

Just checking in on this request?

Thank you!

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Tin, Alex <[redacted]
Sent: Tuesday, April 27, 2021 10:10 AM
To: Caccomo, Stephanie <[redacted] Capobianco, Abigail <[redacted]
Hunt, Alison <[redacted]
Cc: Pfaeffle, Veronika <[redacted]
Subject: Myocarditis re: Pfizer and Moderna

Good morning!

Checking in for a statement or comment re: possible myocarditis or pericarditis following the Pfizer or Moderna vaccines? Have any hospitalizations or deaths been reported?

Reaching out because I read this story in McClatchy: https://www.mcclatchydc.com/news/coronavirus/article250965424.html

Thanks for anything you can share, as always.

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]

From: Patricia Kime [redacted]
Sent: 4/27/2021 10:53:02 AM
To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
Subject: RE: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

Thanks, Abby – greatly appreciated.
pnk

Patricia Kime

From: Capobianco, Abigail <[redacted]
Sent: Monday, April 26, 2021 4:09 PM
To: Patricia Kime <[redacted]
Cc: Hunt, Alison <[redacted] Pfaeffle, Veronika <[redacted]
Subject: RE: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

Hi Patricia,

Reports to VAERS are unverified reports; the report of an adverse event to VAERS is not documentation that a vaccine caused the event. Additional details on the limitations of VAERS data can be found here: https://vaers.hhs.gov/data/dataguide.html.

To date, FDA and CDC have not seen any new safety signals for myocarditis following administration of any of the authorized COVID-19 vaccines. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. Should any new safety signals be identified by FDA and CDC through this safety surveillance, that information will be communicated to the public.

Thanks very much,
Abby

Abby Capobianco
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [redacted] Cell: [redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Patricia Kime <[redacted]
Sent: Monday, April 26, 2021 10:54 AM
To: Capobianco, Abigail <[redacted]
Subject: [EXTERNAL] Questions from Military.com re: vaccines and myocarditis

Can you please tell me if the FDA and the CDC are looking into this, as reported by the Jerusalem Post?
I am currently cross checking things in VAERS but there are at least 42 cases reported following vaccines, but I'm also aware that myocarditis is a complication of COVID-19.

Would you like to comment or can you refer me to the right person?

https://www.jpost.com/health-science/covid-19-israel-finds-possible-link-between-vaccine-myocarditis-cases-666237

My deadline is today,

Patricia

Patricia Kime
Freelance Journalist
[redacted]
Twitter: [redacted]

From: Tin, Alex [redacted]
Sent: 4/27/2021 10:10:34 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]
CC: Pfaeffle, Veronika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a299f2d320c143f79ba87e09b21ec5e5-Veronika.Pf]
Subject: [EXTERNAL] Myocarditis re: Pfizer and Moderna

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Thanks for anything you can share, as always,

Alexander Tin
[redacted]
Cell [redacted], Signal [redacted]