

United States Senate

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

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

December 5, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

The Honorable Robert Califf
Commissioner
Food and Drug Administration

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention

Dear Secretary Becerra, Commissioner Califf, and Director Cohen:

You have, once again, failed to respond to my oversight requests for documents and information relating to COVID-19 vaccine adverse events. Most recently, on November 19, 2024, I wrote to you requesting unredacted records, previously released through Freedom of Information Act (FOIA) requests, regarding your agencies' detection of and response to myocarditis and pericarditis in post-vaccinated individuals.¹ The response deadline for that letter was December 3, 2024 and, to date, my office has not received any of the requested information. It appears that even in the waning days of the Biden administration, your agencies will remain defiant in providing the public with complete information about the COVID-19 vaccines.

Nevertheless, as I made clear in my November 19 letter, my oversight work must continue. If it becomes necessary to subpoena these and other requested records in the next Congress when I become chairman of the Permanent Subcommittee on Investigations, I will do so.

As a follow-up to my November 19 letter requesting unredacted FOIA records relating to COVID-19 vaccine adverse events, I write today to highlight another example of your agencies' response to concerning reports of myocarditis and pericarditis in post-vaccinated individuals. The timeline below details how, in early 2021, officials at the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) were made aware of "a large number of reports" based on Israeli health data that showed "myocarditis, particularly in young people, following the administration of the Pfizer vaccine."²

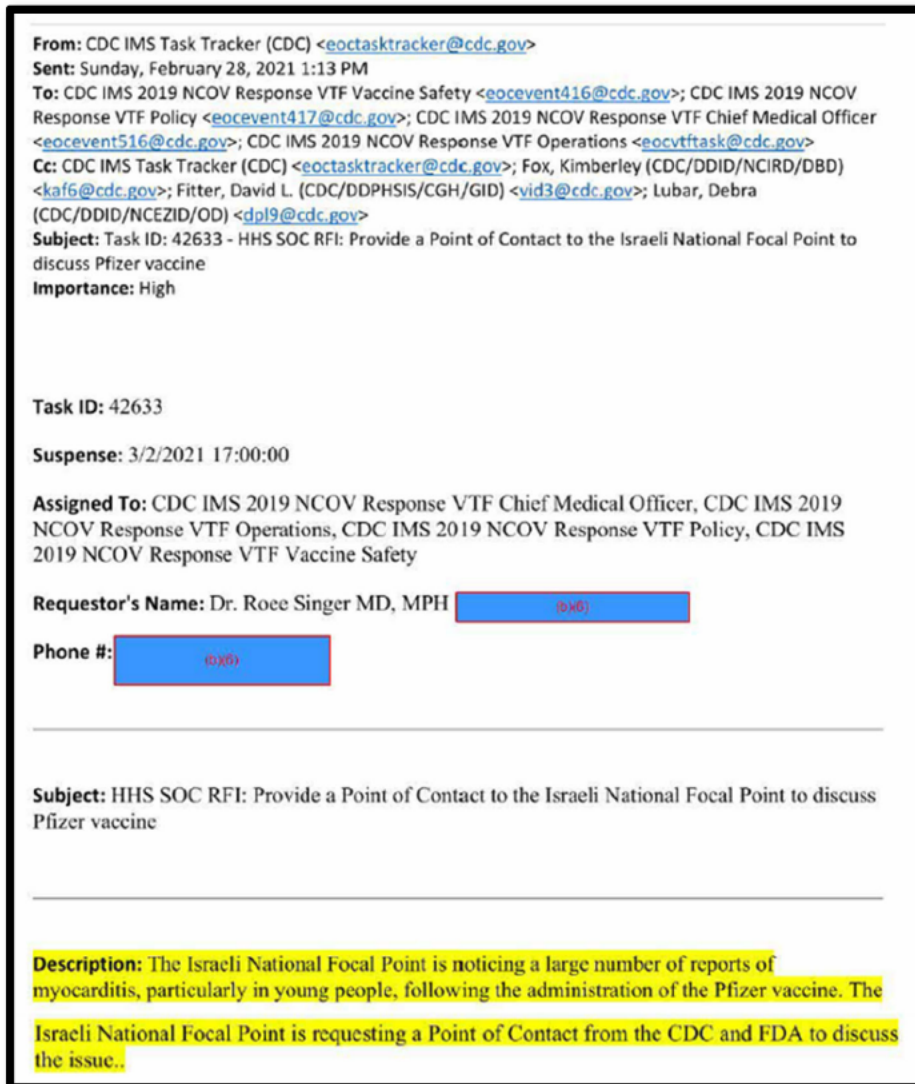
¹ Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et. al, Nov. 19, 2024, <https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D>.

² FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 712.

February 28, 2021

CDC, and eventually FDA officials, were notified about an apparent request from an Israeli Ministry of Health official to obtain a CDC and FDA point of contact to discuss reports of myocarditis in young people after receiving the Pfizer COVID-19 vaccine.³

Snapshot of Feb. 28, 2021 email⁴



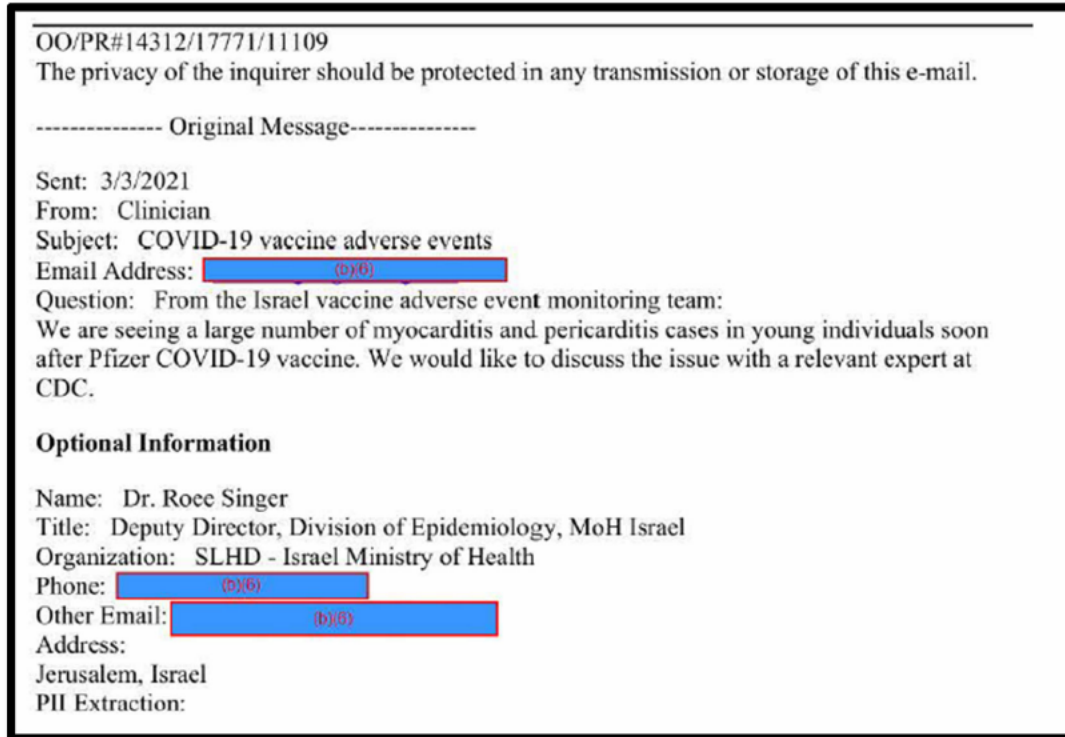
³ FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 710-713; Ed Berkovich and Amy Kelly, FOIA'd CDC Emails Reveal Disturbing Myocarditis Timeline Warranting Investigation: Different Messaging Internally Vs. Publicly About COVID-19 Vaccines and Myocarditis, Daily Clout, Nov. 2, 2023, <https://dailyclout.io/foiad-cdc-emails-reveal-disturbing-myocarditis-timeline-warranting-investigation/>.

⁴ *Id.* at 712-713; FOIA code (b)(6) is used to protect information involving matters of personal privacy. *What information is available under the FOIA?* Dep't of Health & Hum. Servs., <https://www.hhs.gov/foia/faqs/what-information-is-available-under-the-foia/index.html> (last visited Nov. 19, 2024).

March 3, 2021

CDC was notified once again about the Israeli Ministry of Health's request to discuss reports of "a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccination."⁵

Snapshot of March 3, 2021 request from Israeli Ministry of Health to CDC to discuss adverse events associated with Pfizer COVID-19 vaccine⁶



March 4, 2021

The Israeli Ministry of Health's request to speak with a CDC expert about cases of myocarditis and pericarditis in post-vaccinated individuals was eventually forwarded to CDC's vaccine safety team lead in the COVID-19 Vaccine Task Force, Dr. Tom Shimabukuro.⁷ However, due to heavy redactions in the FOIA documents, it is unclear what Dr. Shimabukuro communicated to his colleagues regarding the ministry's "Priority HIGH" request.

⁵ FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 668; Ed Berkovich and Amy Kelly, FOIA'd CDC Emails Reveal Disturbing Myocarditis Timeline Warranting Investigation: Different Messaging Internally Vs. Publicly About COVID-19 Vaccines and Myocarditis, Daily Clout, Nov. 2, 2023, <https://dailyclout.io/foiad-cdc-emails-reveal-disturbing-myocarditis-timeline-warranting-investigation/>.

⁶ *Id.*

⁷ Biography, Tom Shimabukuro, M.D., Centers for Disease Control and Prevention, <https://blogs.cdc.gov/safehealthcare/bios/tom-shimabukuro/>.

Snapshot of March 4, 2021 heavily-redacted email⁸

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

Yes

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Thursday, March 4, 2021 9:29 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <lt8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Tom,
[REDACTED]
[REDACTED]?

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, March 4, 2021 9:24 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Dua, Anamika (CDC/DDID/NCEZID/DHQP) <qtv2@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <lt8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks Tom

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, March 4, 2021 9:17 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Dua, Anamika (CDC/DDID/NCEZID/DHQP) <qtv2@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <lt8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

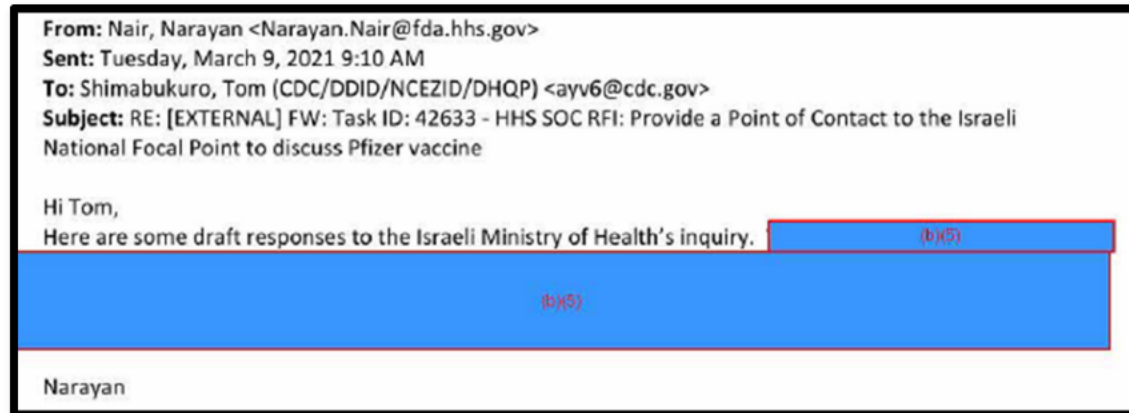
[REDACTED]

⁸ FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 668; FOIA code (b)(5) is used to protect inter-agency or intra-agency communications that are protected by legal privileges. *What information is available under the FOIA?* Dep't of Health & Hum. Servs., <https://www.hhs.gov/foia/faqs/what-information-is-available-under-the-foia/index.html> (last visited Nov. 19, 2024).

March 9, 2021 – March 10, 2021

Documents show that FDA and CDC officials began drafting “responses to the Israeli Ministry of Health’s inquiry.”⁹ On March 9, 2021, an FDA official emailed his “draft responses” to Dr. Shimabukuro, however, the email itself is almost completely redacted.

Snapshot of March 9, 2021 heavily-redacted email¹⁰



The next day, Dr. Shimabukuro emailed his CDC colleagues a document with the file name, “Myocarditis Response,” and wrote, “This is for that joint FDA-CDC to the Israeli [Ministry of Health]. Please let me know if you have any thoughts.”¹¹ Based on FOIA records, it appears that the document Dr. Shimabukuro shared with his colleagues was titled, “Summary of VAERS Reports of myocarditis, pericarditis and myopericarditis following vaccination with mRNA COVID-19 vaccines.”¹² The background section of the two-page document stated that it:

[R]esponds to questions posed from the Israeli Ministry of Health to the FDA and CDC. They are investigating a safety signal of myocarditis/myopericarditis in a younger population (16-30 years old) following administration of Pfizer-BioNTech Covid-19 vaccine. The Ministry of Health stated they received reports of around 40 cases of this adverse event. They did not provide additional details about these cases.¹³

The document included responses to four questions posed by the Israeli Ministry of Health and appears to be based on data obtained from “a search of the U.S. Vaccine Adverse Event Reporting System (VAERS) conducted on February 23, 2021[.]”¹⁴ That search apparently

⁹ *Id.* at 710.

¹⁰ *Id.*

¹¹ *Id.*; Ed Berkovich and Amy Kelly, FOIA’d CDC Emails Reveal Disturbing Myocarditis Timeline Warranting Investigation: Different Messaging Internally Vs. Publicly About COVID-19 Vaccines and Myocarditis, Daily Clout, Nov. 2, 2023, <https://dailyclout.io/foiad-cdc-emails-reveal-disturbing-myocarditis-timeline-warranting-investigation/>.

¹² FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 714.

¹³ *Id.*

¹⁴ *Id.*

revealed six cases of myocarditis, seven cases of myopericarditis, and 14 cases of pericarditis.”¹⁵
The document noted:

During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines. We will continue to monitor this outcome in active and passive surveillance.¹⁶

The document itself can be viewed in Enclosure 1. It remains unclear whether this document or another version of it was shared with the Israeli Ministry of Health. It is also unclear which FDA and CDC officials contributed to the document and when Israeli health officials shared that “they received reports of around 40 cases” of myocarditis/myopericarditis.¹⁷

March 15, 2021 – March 31, 2021

A collection of heavily-redacted FOIA records shows that on March 15, 2021, a CDC official who co-lead the Vaccine Safety Technical (VaST) Work Group began corresponding with an Israeli Ministry of Health official regarding “Covid-19 vaccine safety data.”¹⁸ On March 16, 2021, the Ministry official wrote, “[w]e will be happy to share our data” and later that day, the CDC official responded “[t]hank you for this note and for your willingness to present to VaST. We were hoping you could present on Monday, April 5.”¹⁹ Documents indicate that the Ministry official confirmed availability to present on April 5 and, on March 31, 2021, the CDC official requested that the Ministry official “send slides” ahead of the presentation.²⁰

According to a public report, the slides that the Israeli Ministry of Health provided to the CDC showed that “by the end of March 2021, 5.2 million Israelis received the first dose of the vaccine and 4.8 million received the second dose. The incidence of myocarditis following dose 1 was 1.1 per million, and 11.7 per million following dose 2 — a 964% increase in incidence between the two.”²¹ The slide deck can be viewed in Enclosure 4.

¹⁵ *Id.*

¹⁶ *Id.* at 715.

¹⁷ *Id.* at 714.

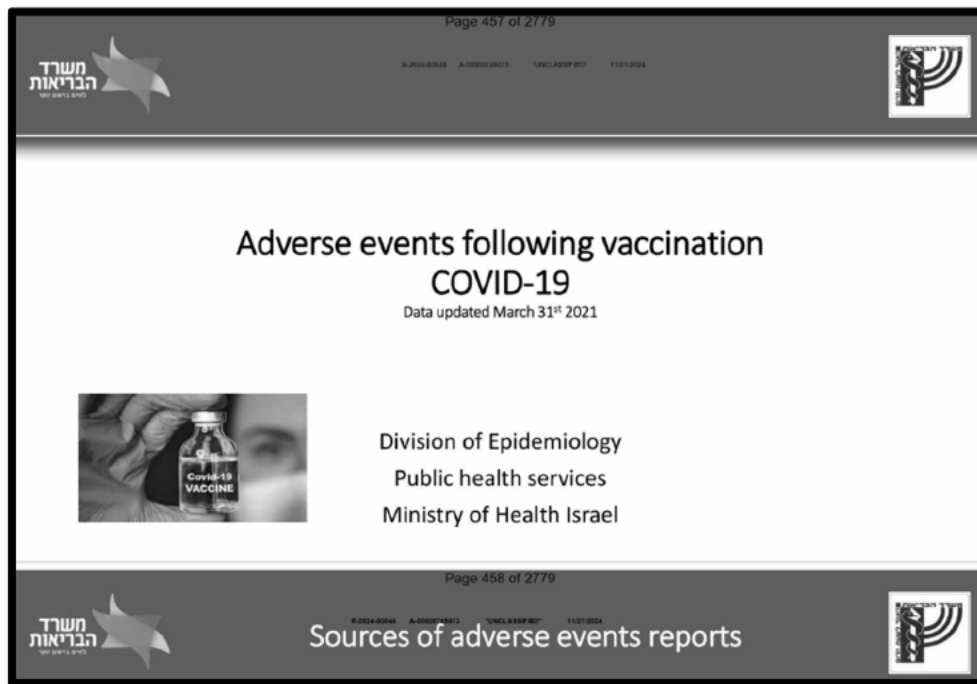
¹⁸ *Id.* at 726; Ed Berkovich and Amy Kelly, FOIA’d CDC Emails Reveal Disturbing Myocarditis Timeline Warranting Investigation: Different Messaging Internally Vs. Publicly About COVID-19 Vaccines and Myocarditis, Daily Clout, Nov. 2, 2023, <https://dailyclout.io/foiad-cdc-emails-reveal-disturbing-myocarditis-timeline-warranting-investigation/>.

¹⁹ FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 725.

²⁰ *Id.* at 721-722.

²¹ Brenda Baletti, Mounting Evidence Suggests CDC Hid Data on COVID Vaccines and Myocarditis, The Defender, Nov. 27, 2024, <https://childrenshealthdefense.org/defender/mounting-evidence-cdc-hid-data-covid-vaccines-myocarditis/>.

Snapshot of cover page of March 31, 2021 slide deck by Israeli Ministry of Health²²



April 5, 2021

Public reporting asserts that the slide deck from the Israeli Ministry of Health was included as an attachment in the CDC's April 5, 2021 agenda for the VaST meeting.²³ As shown below, the attachments and agenda for the meeting are heavily redacted:

²² FOIA production: <https://drive.google.com/file/d/1ywgzcxfpQI86lqslZPpYxylPuVnlgKfw/view> at 1.

²³ Brenda Baletti, Mounting Evidence Suggests CDC Hid Data on COVID Vaccines and Myocarditis, The Defender, Nov. 27, 2024, <https://childrenshealthdefense.org/defender/mounting-evidence-cdc-hid-data-covid-vaccines-myocarditis/>.

Snapshot of CDC's April 5, 2021 VaST meeting agenda

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Mon, 5 Apr 2021 16:08:26 +0000
To: Anderson, Steven (FDA/CBER); Beresnev, Tatiana (NIH) [C]; Broder, Karen (CDC/DDID/NCEZID/DHQP); Calvert, Geoffrey M. (CDC/NIOSH/WTCHP); Clark, Matthew (IHS/ALB); Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Cohn, Amanda (CDC/DDID/NCIRD/OD); Collins, Limone; [REDACTED] Daley, Matt; Destefano, Frank (CDC/DDID/NCEZID/DHQP); Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD); Edwards, Kathy; Farizo, Karen (FDA/CBER); Forshee, Richard (FDA/CBER); Gee, Julianne (CDC/DDID/NCEZID/DHQP); Helfand, Rita (CDC/DDID/NCEZID/OD); Hiers, Susan G. (CDC/DDID/NCIRD/OD); Hopkins, Bob; Jackson, Lisa; Kelman, Jeffrey A. (CMS/CM); Kuldorf, 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 (whitlepn@rwjms.rutgers.edu); 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: [EXTERNAL] VaST - Agenda for April 5 (1:30 - 3 pm ET) and presentations - CONFIDENTIAL

Attachments: [REDACTED] (b)(5)
[REDACTED] (b)(5)
2021_04_05 VaST Meeting Agenda.docx

Dear all,

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

Agenda:
[REDACTED] (b)(5); (b)(6)

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

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As a result of your agencies' excessive redactions and incomplete productions, the complete account of how your agencies reviewed and analyzed the concerning health information from the Israeli Ministry of Health remains unclear. Furthermore, my office has been informed that CDC completely redacted the March 31, 2021 slide deck in its FOIA production and that the slides were made available to the public through a State Department FOIA response.²⁴ Your agencies' lack of transparency is completely unacceptable. The public

²⁴ Brenda Baletti, Mounting Evidence Suggests CDC Hid Data on COVID Vaccines and Myocarditis, The Defender, Nov. 27, 2024, <https://childrenshealthdefense.org/defender/mounting-evidence-cdc-hid-data-covid-vaccines->

deserves the complete truth about your agencies' awareness of and lack of response to the glaring health risks associated with the COVID-19 vaccines. Accordingly, I request you provide the following information by no later than December 19, 2024:

1. An unredacted version of Enclosure 1.
 - a. All records²⁵ referring or relating to the drafting, review, and distribution of the attached document included and referenced in Enclosure 1.
2. An unredacted version of Enclosure 2.
3. An unredacted version of Enclosure 3.
4. All records referring or relating to Enclosure 4 including communications between and among agency employees regarding data from the Israeli Ministry of Health on adverse events following COVID-19 vaccination.
5. An unredacted version of Enclosure 5.

Thank you for your attention to this matter.

Sincerely,



Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

Enclosures

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services

myocarditis/; Letter from Brian Hooker, Chief Scientific Officer, Children's Health Defense, to Sen. Ron Johnson, Dec. 2, 2024 (on file with Subcomm.).

²⁵ "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

Enclosure 1

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

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

From: Nair, Narayan <Narayan.Nair@fda.hhs.gov>
Sent: Tuesday, March 9, 2021 9:10 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Hi Tom,

Here are some draft responses to the Israeli Ministry of Health's inquiry.

(b)(5)

(b)(5)

Narayan

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Sunday, February 28, 2021 3:06 PM
To: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>
Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

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

FYI.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>
Sent: Sunday, February 28, 2021 2:28 PM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <zmt0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eocevent417@cdc.gov>; McClure, Susan (CDC/DDPHSIS/CGH/OD) <zur1@cdc.gov>

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) <zmt0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eocevent417@cdc.gov>
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.

(b)(5) ?

Best,
David

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <zmt0@cdc.gov>
Sent: Sunday, February 28, 2021 1:35 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>
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

(b)(5) ?

(b)(5)

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>
Sent: Sunday, February 28, 2021 11:15 AM
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <zmt0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>
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) <eoctasktracker@cdc.gov>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <eocevent416@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eocevent417@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocevent516@cdc.gov>; CDC IMS 2019 NCOV Response VTF Operations <eocvtftask@cdc.gov>
Cc: CDC IMS Task Tracker (CDC) <eoctasktracker@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>
Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine
Importance: High

Task ID: 42633

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

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

Requestor's Name: Dr. Roe Singer MD, MPH (b)(6)

Phone #: (b)(6)

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

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

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

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

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

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

Background:

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

Questions Posed by Israeli Ministry of Health:

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

CDC to provide this data

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

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

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

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

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

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

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

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

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

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

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

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

Enclosure 2

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

Yes

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Thursday, March 4, 2021 9:29 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltld8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Tom,

(b)(5)

(b)(5)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, March 4, 2021 9:24 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Dua, Anamika (CDC/DDID/NCEZID/DHQP) <qtv2@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltld8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks Tom

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, March 4, 2021 9:17 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Dua, Anamika (CDC/DDID/NCEZID/DHQP) <qtv2@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltld8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

(b)(5)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Thursday, March 4, 2021 8:52 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Dua, Anamika (CDC/DDID/NCEZID/DHQP) <gtv2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all,

(b)(5)

Is anyone able to talk to this MD from the Israel Ministry of Health?

Thanks,
Elaine

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

Hello VTF Global colleagues,

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

Thank you,

Kate

(b)(5)

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force
CDC Coronavirus Disease 2019 (COVID-19) Response | eocevent168@cdc.gov

Further CDC Resources:

[COVID-19 What's New](#)

[CDC Health Alert Network \(HAN\)](#)

[CDC Vaccines](#)

[CDC Clinician Outreach and Communication Activity \(COCA\)](#)

From: CDCInfoResponse <cdcinforesponse@cdcinqury.onmicrosoft.com>

Sent: Wednesday, March 3, 2021 1:50 PM

To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eocevent168@cdc.gov>

Subject: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

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

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

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

Thank you for your assistance.

OO/PR#14312/17771/11109

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

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

Sent: 3/3/2021

From: Clinician

Subject: COVID-19 vaccine adverse events

Email Address: (b)(6)

Question: From the Israel vaccine adverse event monitoring team:

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

Optional Information

Name: Dr. Roe Singer

Title: Deputy Director, Division of Epidemiology, MoH Israel

Organization: SLHD - Israel Ministry of Health

Phone: (b)(6)

Other Email: (b)(6)

Address:

Jerusalem, Israel

PII Extraction:

Enclosure 3

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

(b)(5)

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Thursday, April 1, 2021 9:04 AM
To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: RE: Covid-19 vaccine safety data

(b)(5)

From: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Sent: Thursday, April 1, 2021 9:00 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Subject: RE: Covid-19 vaccine safety data

(b)(5)

(b)(5)

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Thursday, April 1, 2021 8:57 AM
To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: FW: Covid-19 vaccine safety data

Melinda,

(b)(5)

Lauri

This is the schedule – (b)(5)

(b)(5)

(b)(5)

From: ?' ???? ???? <EMILIA.ANIS@MOH.GOV.IL>
Sent: Thursday, April 1, 2021 4:24 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Cc: ???? ???? <hadas.rotem@MOH.GOV.IL>; ?? ???? <BOAZ.LEV@MOH.GOV.IL>; ??? ???? <dana.arad@MOH.GOV.IL>; ?????? ?????? ???? <sharon.alroy@MOH.GOV.IL>
Subject: RE: Covid-19 vaccine safety data

Dear Laurie,

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

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

Regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. 972-2-5080521
Fax: 972-2-5655950
Mobile: 972-50-6242145
E-mail: emilia.anis@moh.health.gov.il

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Wednesday, March 31, 2021 7:20 PM
To: ?' ???? ???? <EMILIA.ANIS@MOH.GOV.IL>
Cc: ???? ???? <hadas.rotem@MOH.GOV.IL>; ?? ???? <BOAZ.LEV@MOH.GOV.IL>; ??? ???? <dana.arad@MOH.GOV.IL>; ?????? ?????? ???? <sharon.alroy@MOH.GOV.IL>
Subject: RE: Covid-19 vaccine safety data

Dear Emilia,

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

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

Regards,
Lauri

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

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, March 24, 2021 12:17 PM
To: 'ד"ר עמיליה אניס' <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; ד"ר חדס רותם <hadas.rotem@MOH.GOV.IL>; ד"ר בואז לזבוב <BOAZ.LEV@MOH.GOV.IL>; ד"ר דנה ארד <dana.arad@MOH.GOV.IL>; ד"ר שרון אלרוי <sharon.alroy@MOH.GOV.IL>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: Covid-19 vaccine safety data

Dear Emilia,

Thank you for confirming that the time will work for you to present to VaST on April 5.

(b)(5)

(b)(5)

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

Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: א'ר ארררר אררררררר <EMILIA.ANIS@MOH.GOV.IL>

Sent: Monday, March 22, 2021 12:51 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; ארררר ארר
<hadas.rotem@MOH.GOV.IL>; אר אררר <BOAZ.LEV@MOH.GOV.IL>; ארר אררר <dana.arad@MOH.GOV.IL>;
ארררר ארררר ארררר <sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Lauri,

(b)(5)

Best regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. 972-2-5080521
Fax: 972-2-5655950
Mobile: 972-50-6242145
E-mail: emilia.anis@moh.health.gov.il

From: א'רן רוטמן רוזנברג
Sent: Saturday, March 20, 2021 4:18 PM
To: 'Markowitz, Lauri (CDC/DDID/NCIRD/DVD)' <lem2@cdc.gov>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; אהוד רוטם
<hadas.rotem@MOH.GOV.IL>; אבנר לוי <BOAZ.LEV@MOH.GOV.IL>; דנה ארד <dana.arad@MOH.GOV.IL>;
אשר אלרואי רוזנברג <sharon.alroy@MOH.GOV.IL>
Subject: RE: Covid-19 vaccine safety data

Dear Lauri,

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

Best regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. 972-2-5080521
Fax: 972-2-5655950
Mobile: 972-50-6242145
E-mail: emilia.anis@moh.health.gov.il

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Tuesday, March 16, 2021 11:48 PM
To: א'רן רוטמן רוזנברג <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; אהוד רוטם
<hadas.rotem@MOH.GOV.IL>; אבנר לוי <BOAZ.LEV@MOH.GOV.IL>; דנה ארד <dana.arad@MOH.GOV.IL>;

????? ?????? ??????<sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Dr. Anis,

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

Warm regards,
Lauri

Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: ?' ???? ??????<EMILIA.ANIS@MOH.GOV.IL>

Sent: Tuesday, March 16, 2021 9:28 AM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; ????? ???
<hadas.rotem@MOH.GOV.IL>; ?? ???<BOAZ.LEV@MOH.GOV.IL>; ??? ???<dana.arad@MOH.GOV.IL>;
????? ?????? ??????<sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Dr. Markowitz,

Thank you for the invitation.




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

Best regards from Jerusalem,



Emilia Anis, MD, MPH
Director

Division of Epidemiology
Ministry of Health, Israel
Tel. 972-2-5080521
Fax: 972-2-5655950
Mobile: 972-50-6242145
E-mail: emilia.anis@moh.health.gov.il

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Monday, March 15, 2021 4:06 PM
To:    <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: Covid-19 vaccine safety data

Dear Dr. Emilia Anis,

I am writing to inquire

 (b)(5)

 (b)(5)

Thank you and I hope all is well there,
Lauri

Lauri Markowitz, MD
VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd MS H24-5
Atlanta, GA 30329-4027
Phone: 404-639-8359
Cell: 404-384-3767
Email: lem2@cdc.gov

Enclosure 4

Adverse events following vaccination COVID-19

Data updated March 31st 2021



Division of Epidemiology
Public health services
Ministry of Health Israel

Sources of adverse events reports



Sources of adverse events reports include:

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

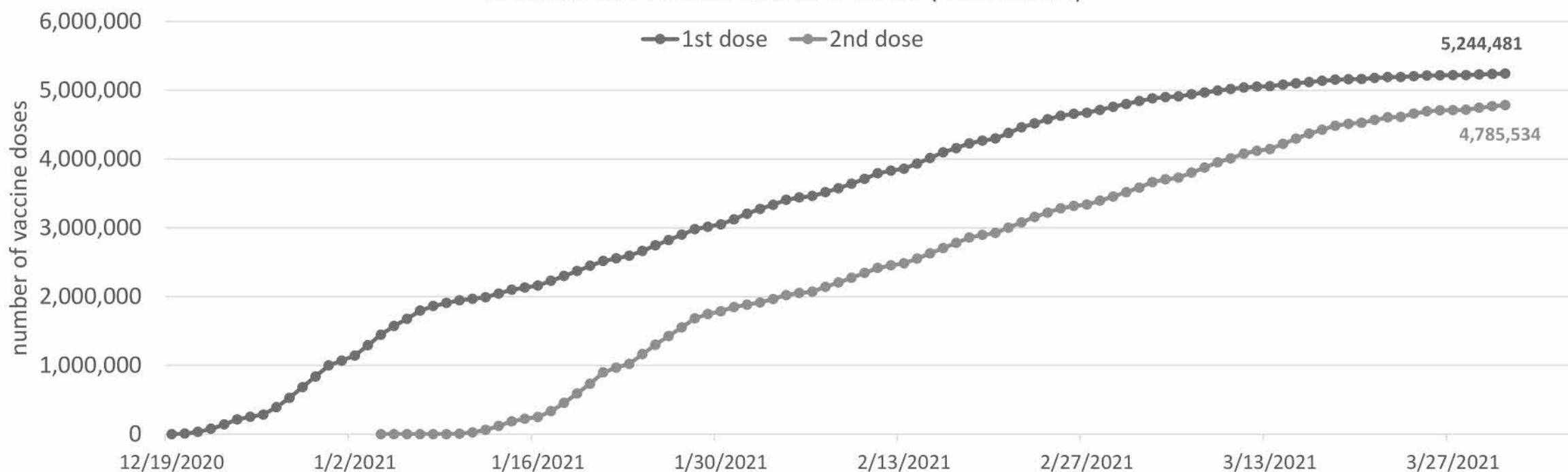


Vaccine doses administered in Israel

R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024



Vaccine doses administered in Israel (cumulative)

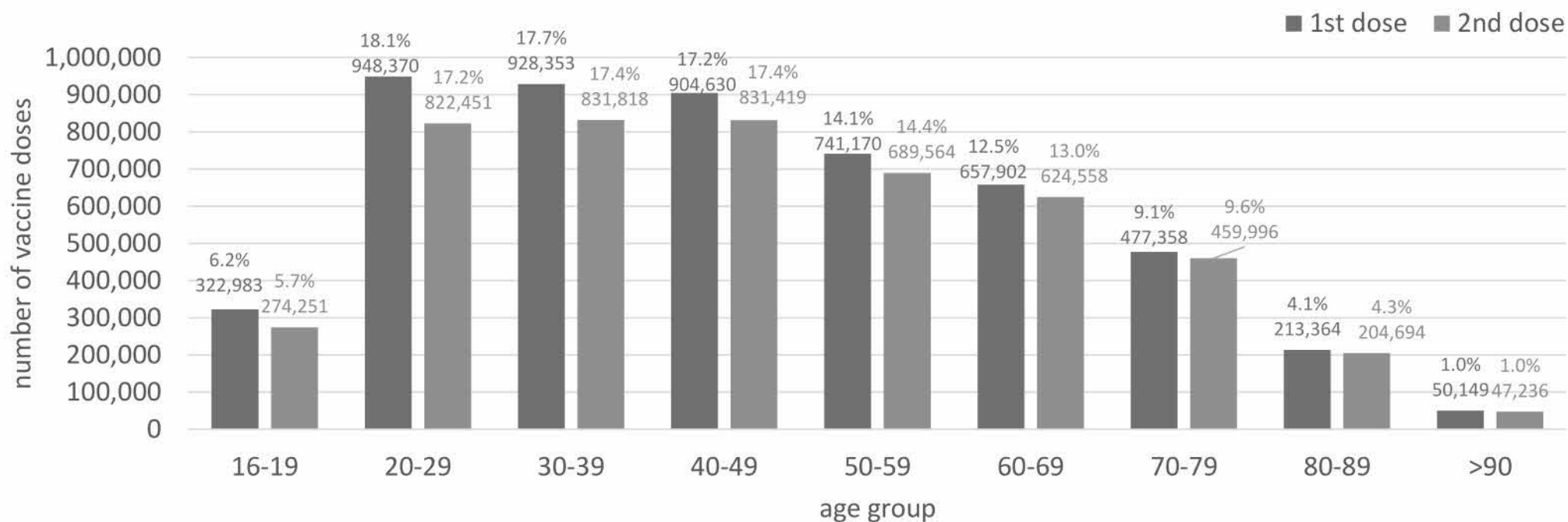




Distribution of vaccine recipients according to age



Distribution of vaccine recipients in Israel according to age



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

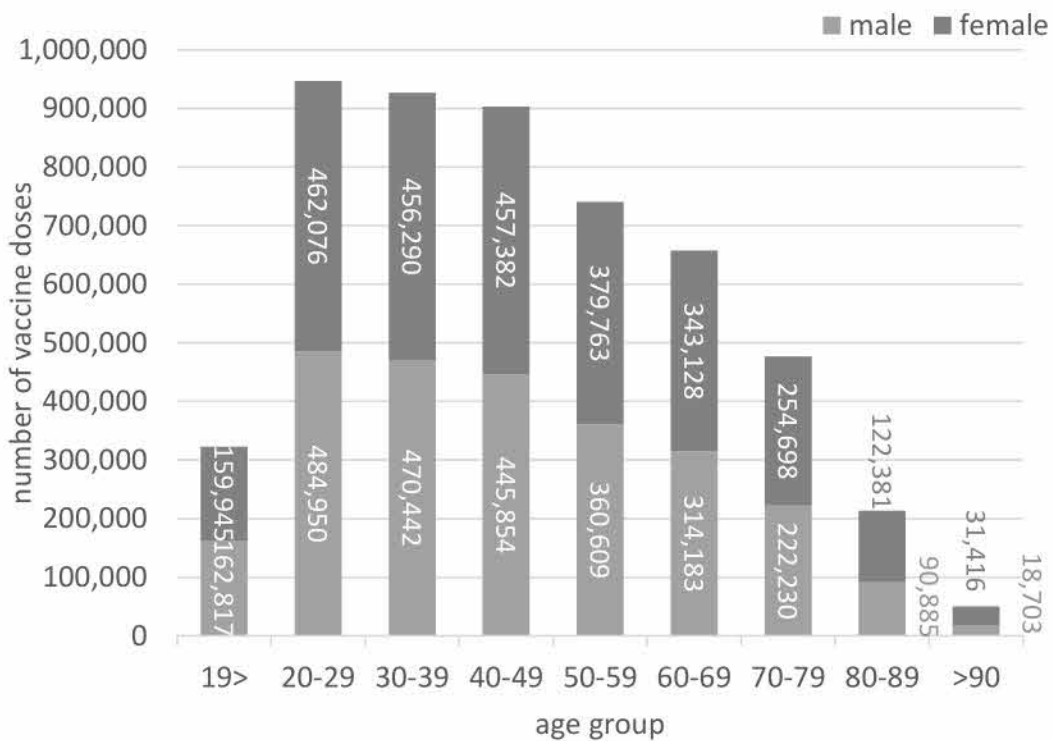


Age and sex distribution among vaccine recipients and those who reported adverse events - FIRST DOSE

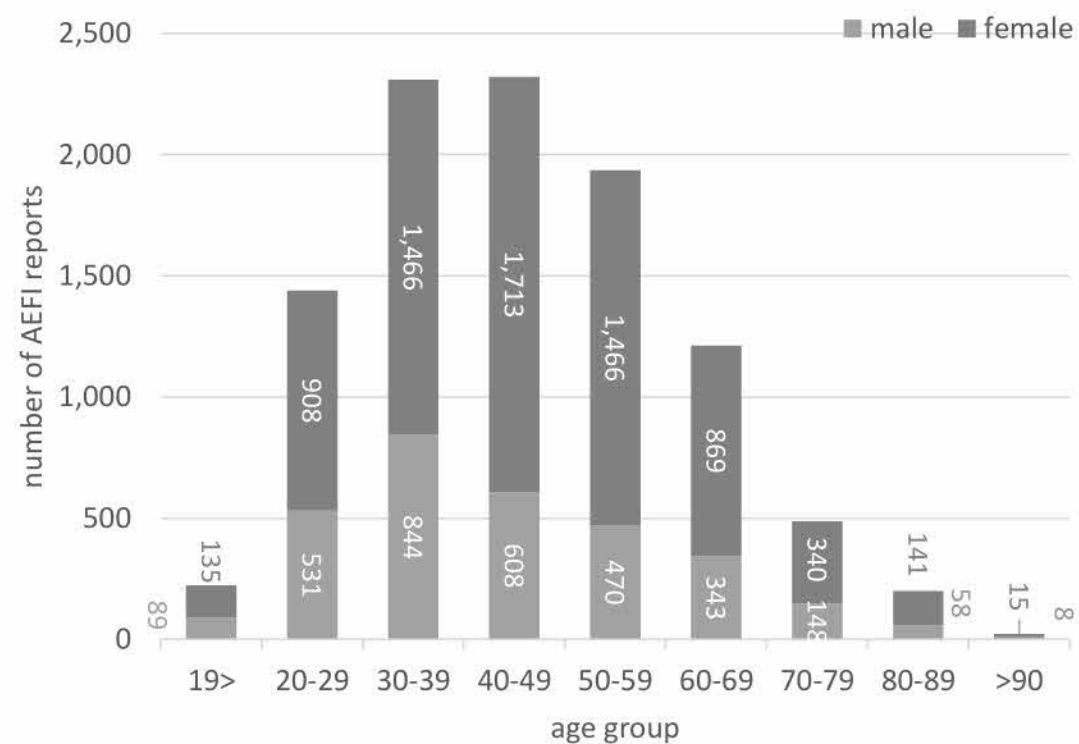


R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

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



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

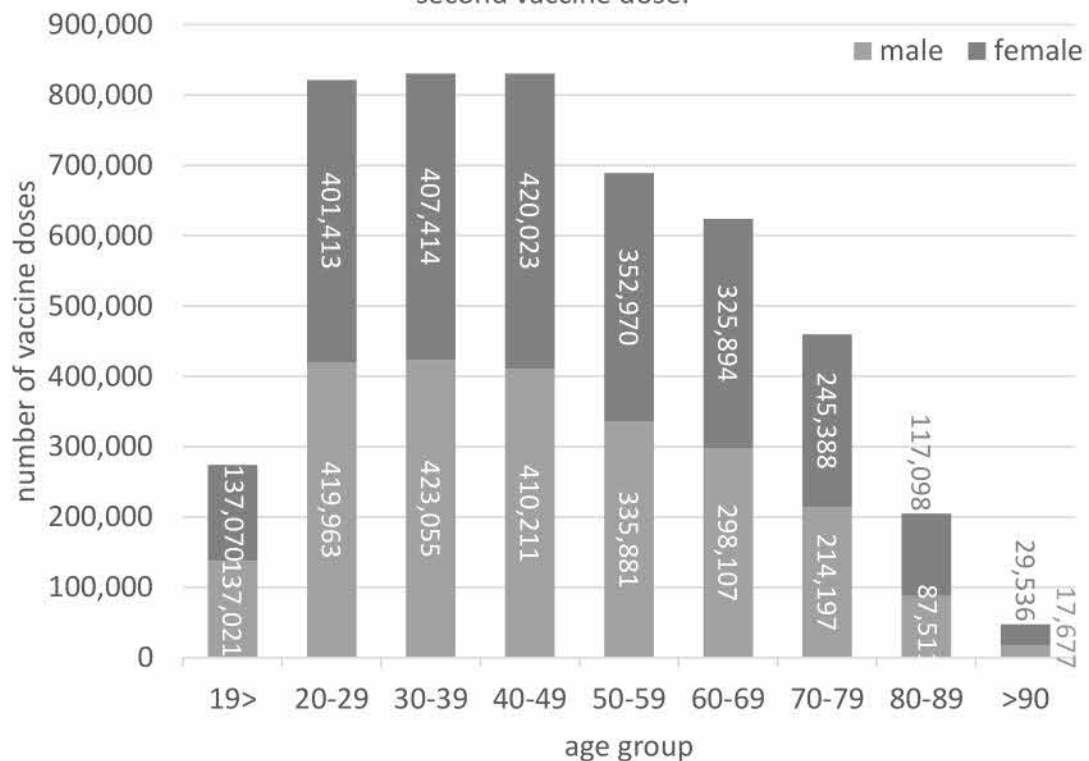


Women and younger individuals are more likely to report adverse reactions following vaccination relative to their proportion among the vaccine recipient population

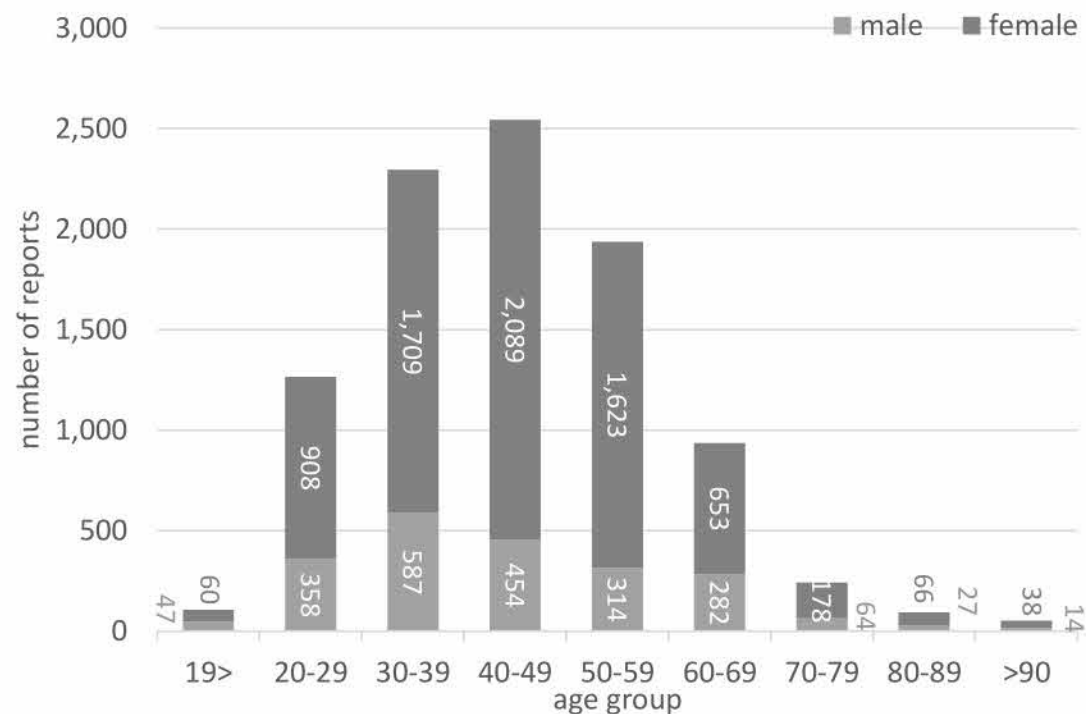


Age and sex distribution among vaccine recipients and those who reported adverse events - SECOND DOSE

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



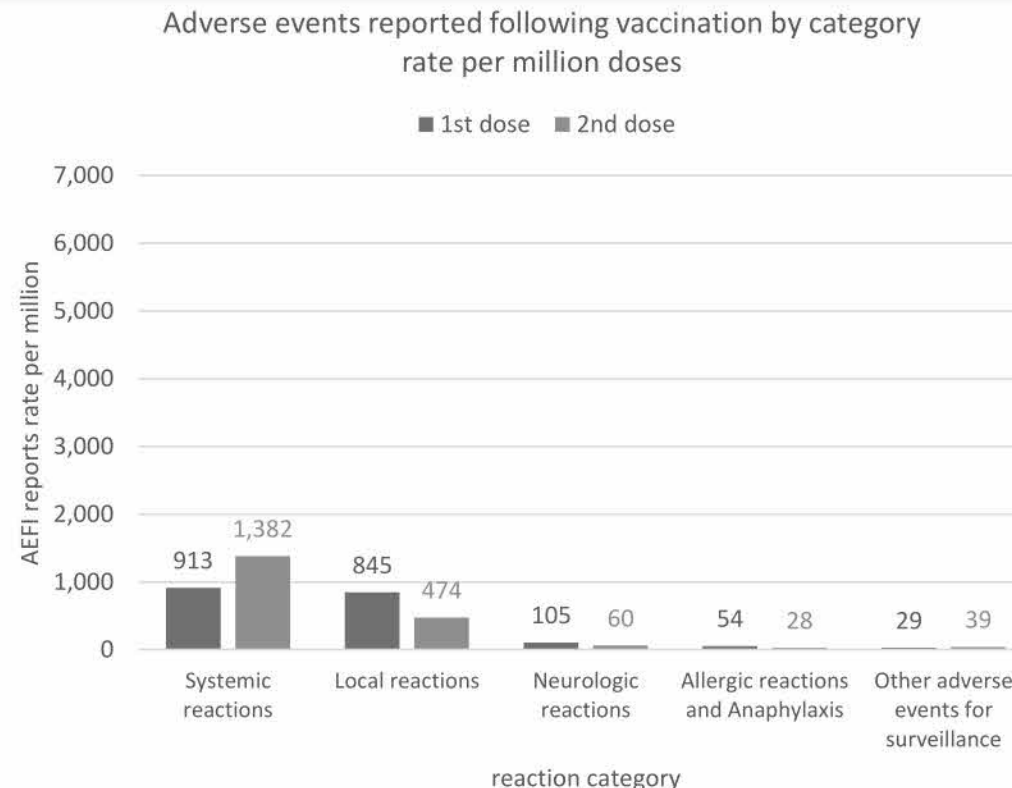
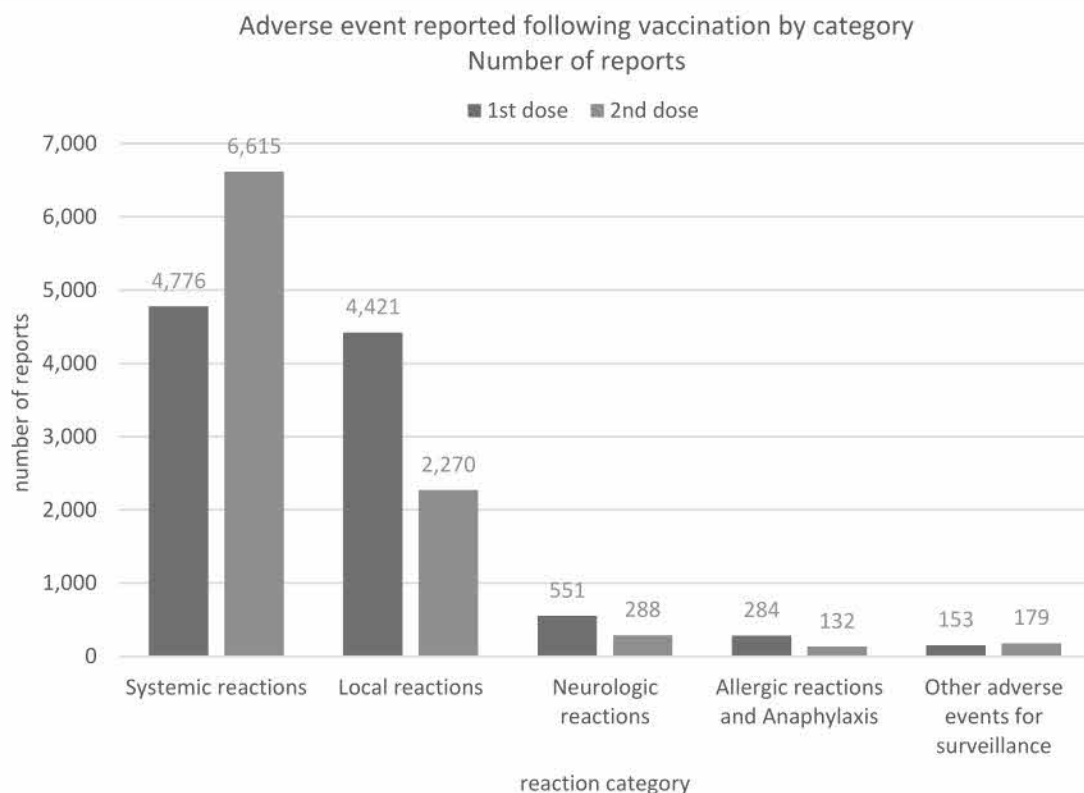
Distribution according to age group and sex among individuals reporting adverse events following second dose vaccination



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



Adverse events following vaccination by category



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

Updated 31/03/2021

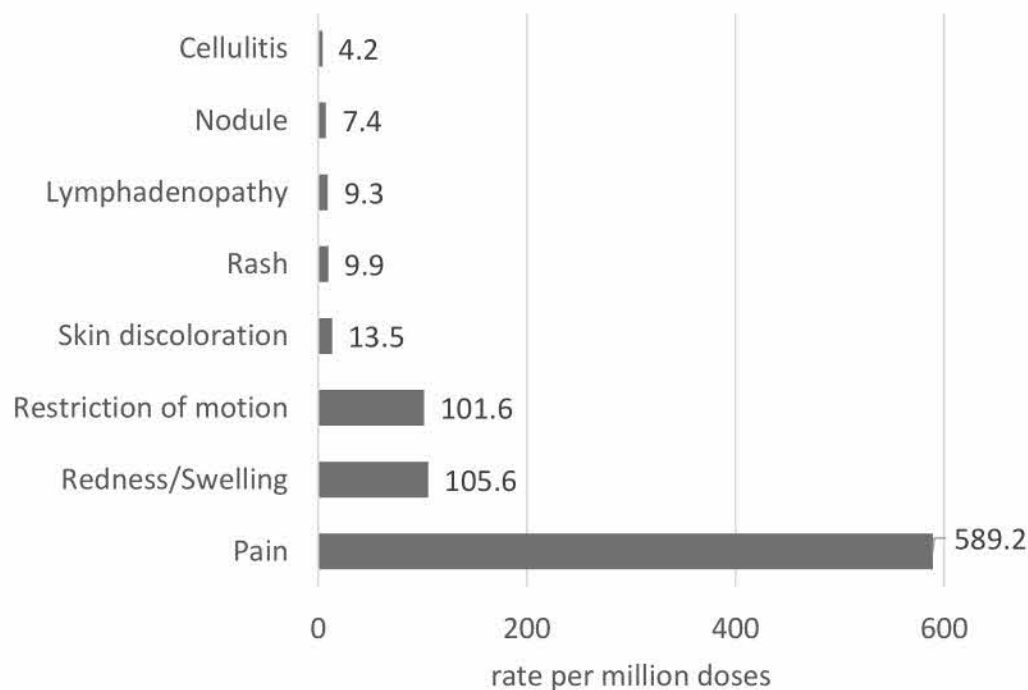


R-2024-00044 A-00000749473 "UNCLASSIFIED" 11/21/2024

Local reactions

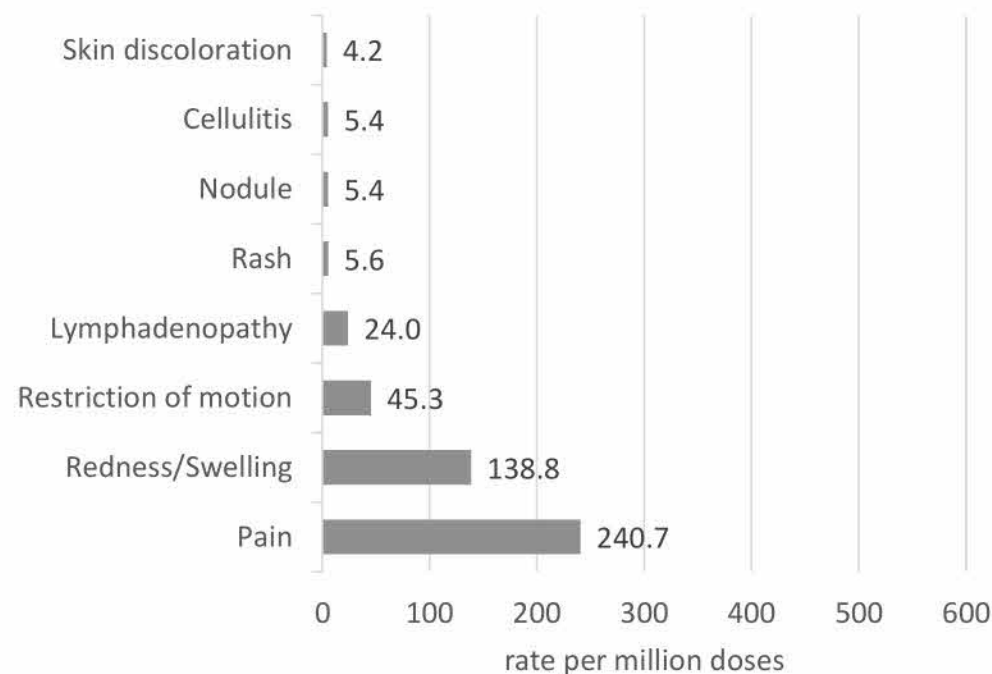


Local reactions (at injection site) reported following vaccination, rate per million doses- first dose



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

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



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

Updated 31/03/2021



R-2024-00044

A-00000749473

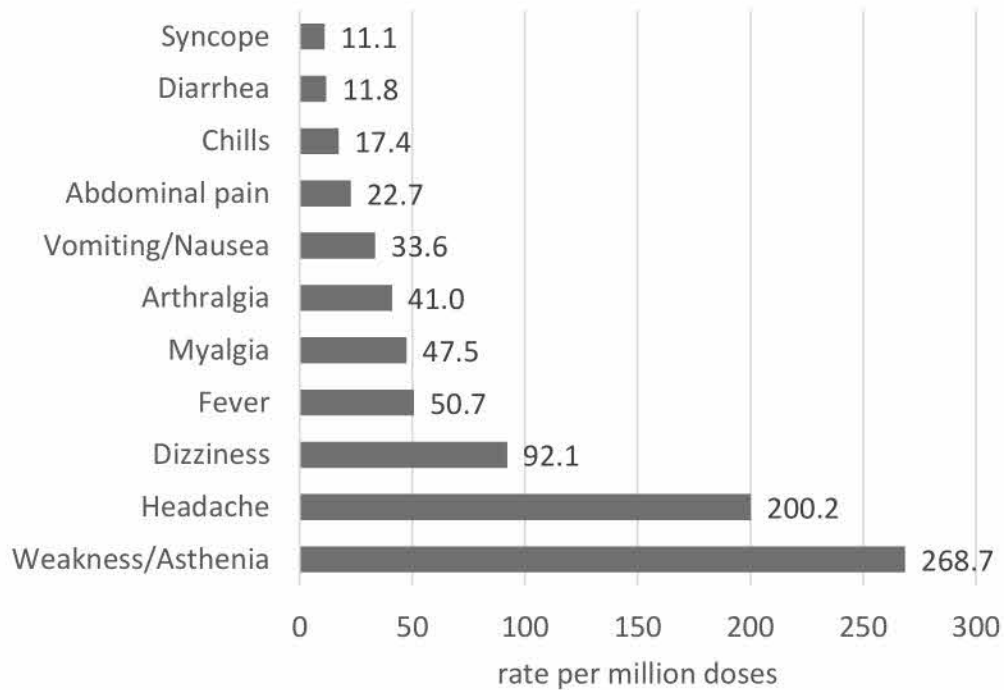
"UNCLASSIFIED"

11/21/2024

Systemic reactions

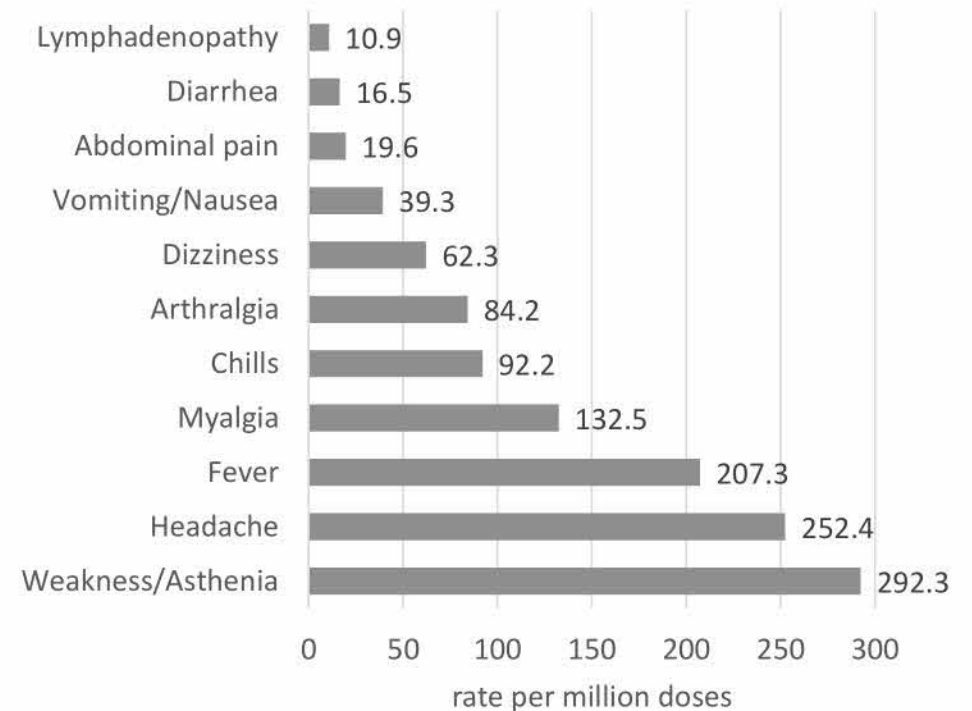


General reactions reported following immunization, rate per million doses- first dose



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

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



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

Updated 31/03/2021



R-2024-00044

A-00000749473

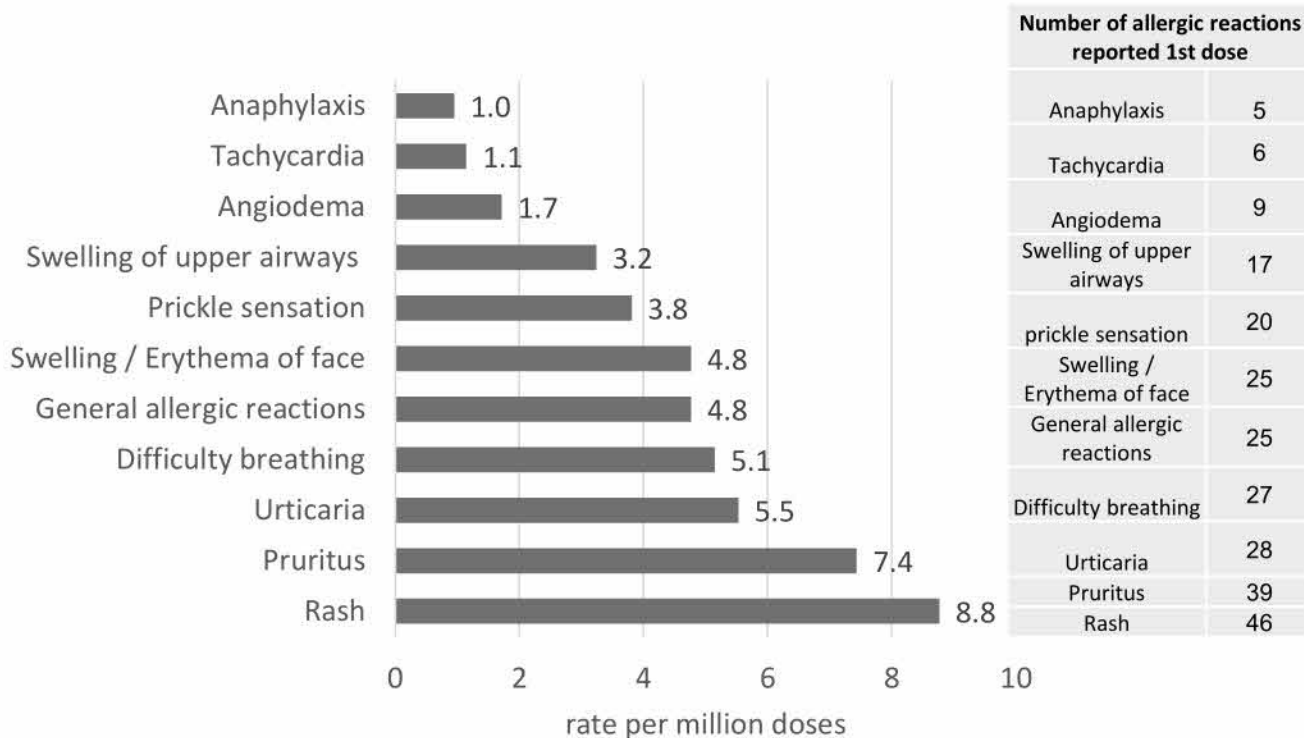
"UNCLASSIFIED"

11/21/2024

Allergic reactions

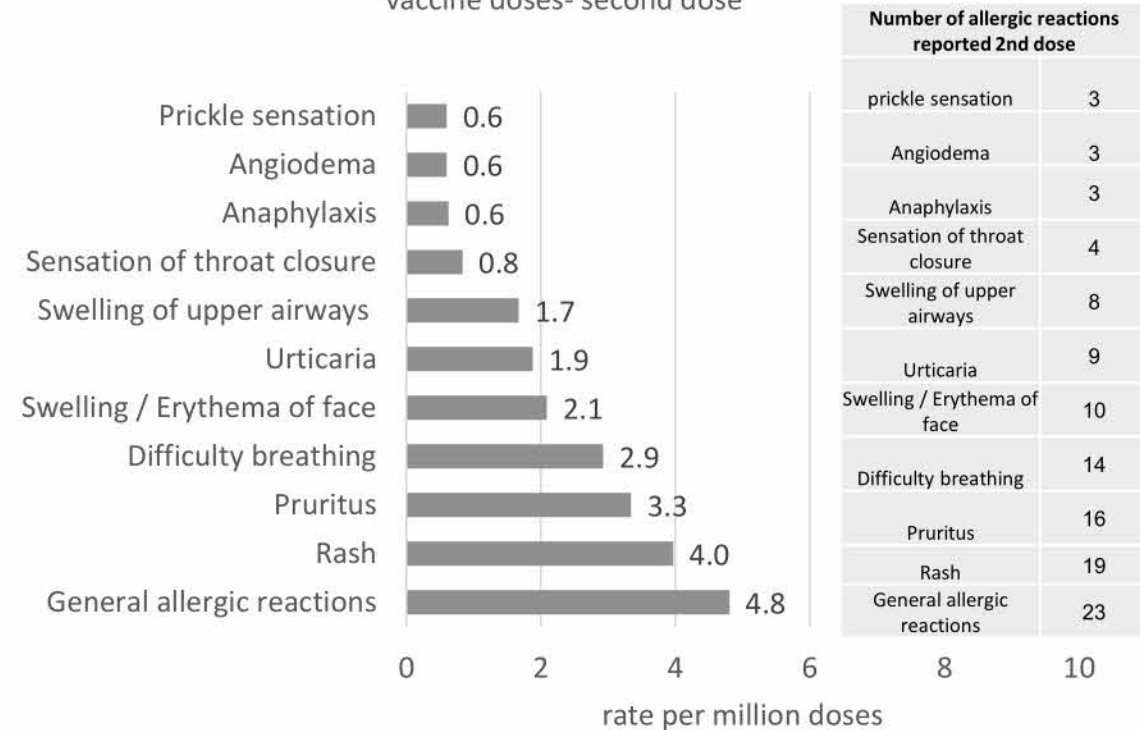


Allergic reactions reported following vaccination, rate per million vaccine doses- first dose



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

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



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

Updated 31/03/2021

Neurologic reactions

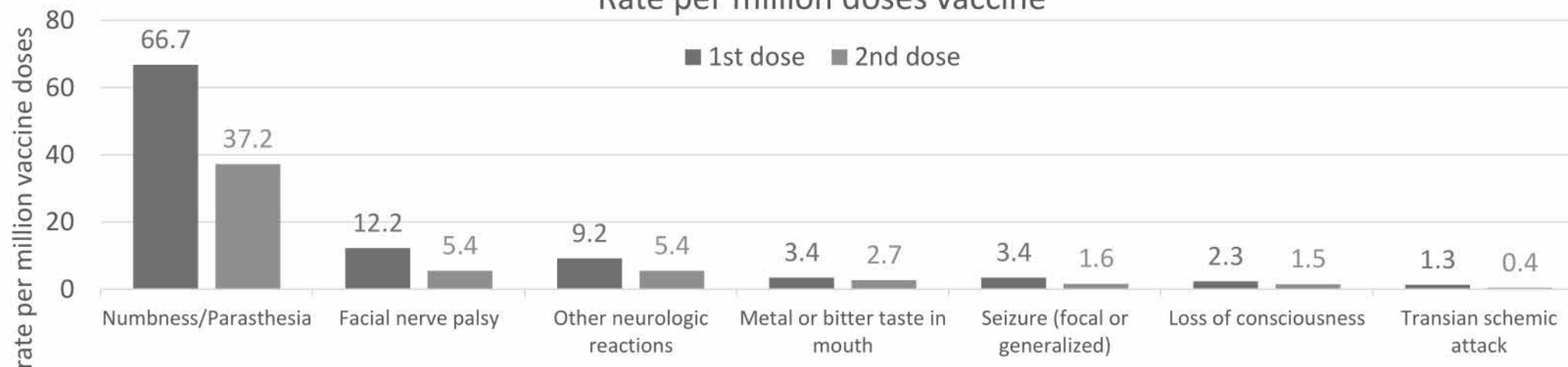


Number of neurologic reactions reported

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

Rate of neurological reactions reported following vaccination

Rate per million doses vaccine



Updated 31/03/2021

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



R-2024-00044

A-00000749473

"UNCLASSIFIED"

11/21/2024

Neurologic reactions



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

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

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

Updated 31/03/2021

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



Other adverse events of interest

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

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

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

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

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

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

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

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

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



Myocarditis following vaccination

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

Myocarditis after first dose (N=6)

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

Myocarditis after second dose (N=56)

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



Pericarditis following vaccination

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

Pericarditis after first dose (N=5)

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

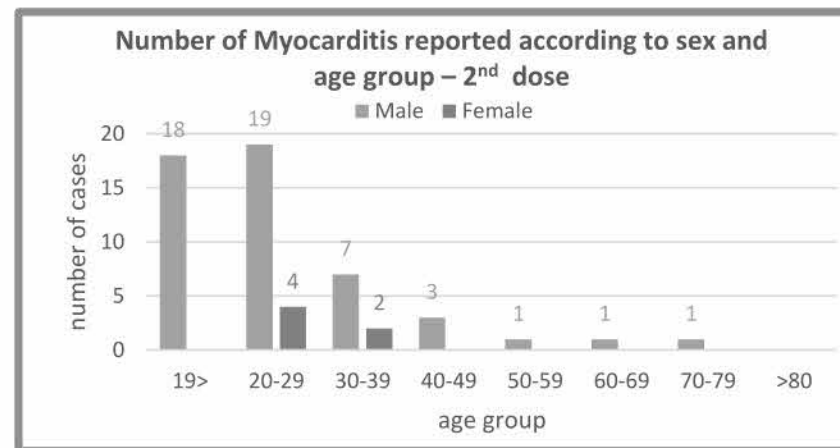
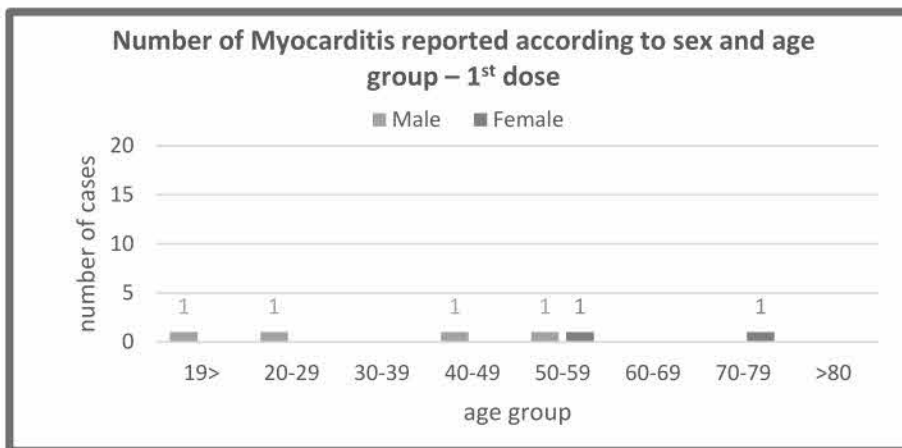
Pericarditis after second dose (N=10)

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

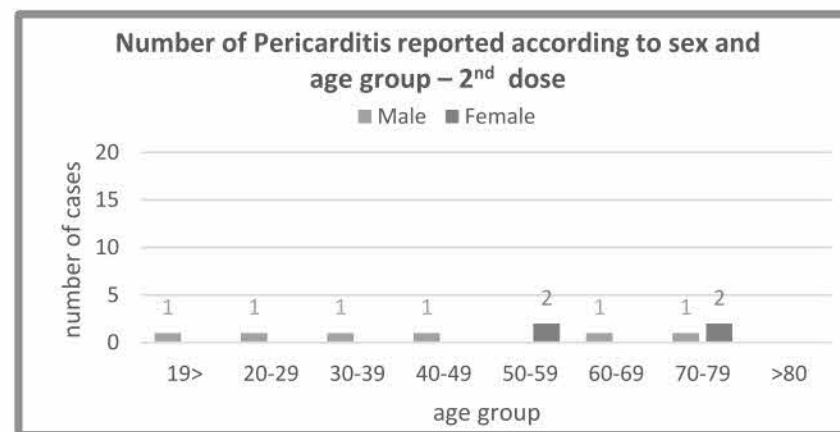
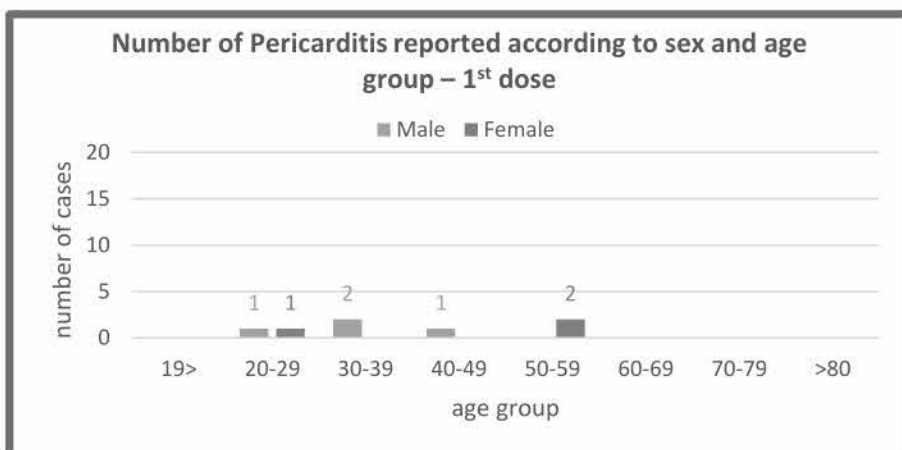


Myocarditis / Pericarditis following vaccination

Myocarditis / Perimyocarditis

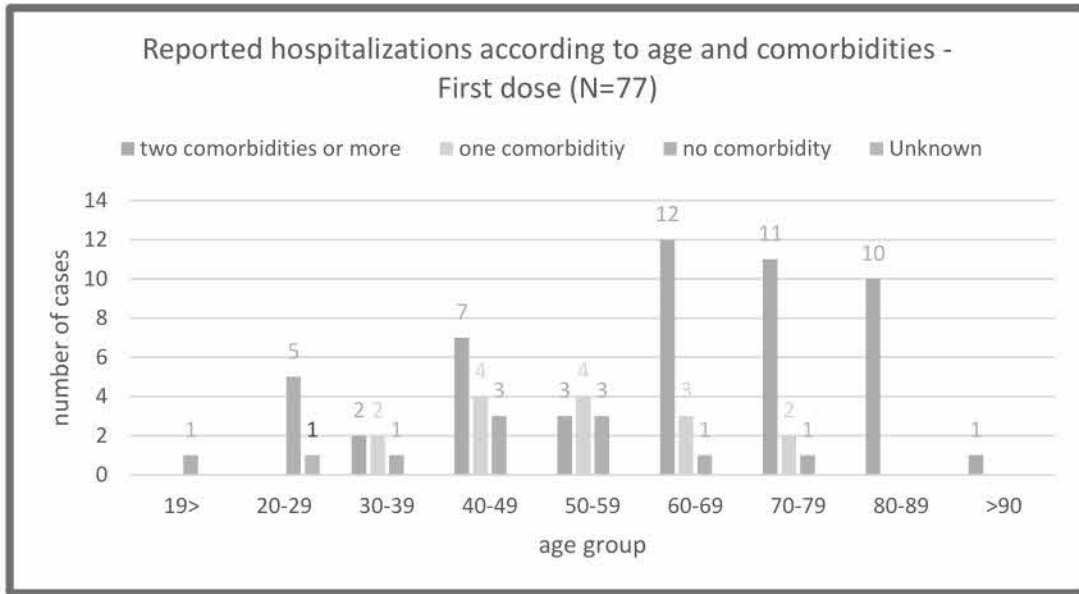


Pericarditis

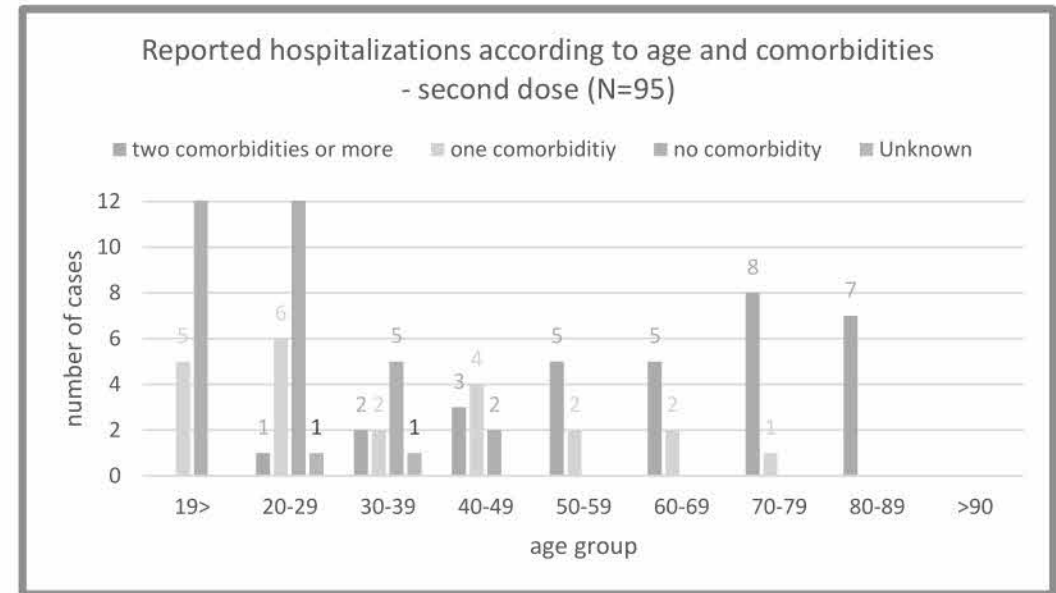




Hospitalizations reported following vaccination



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



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

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

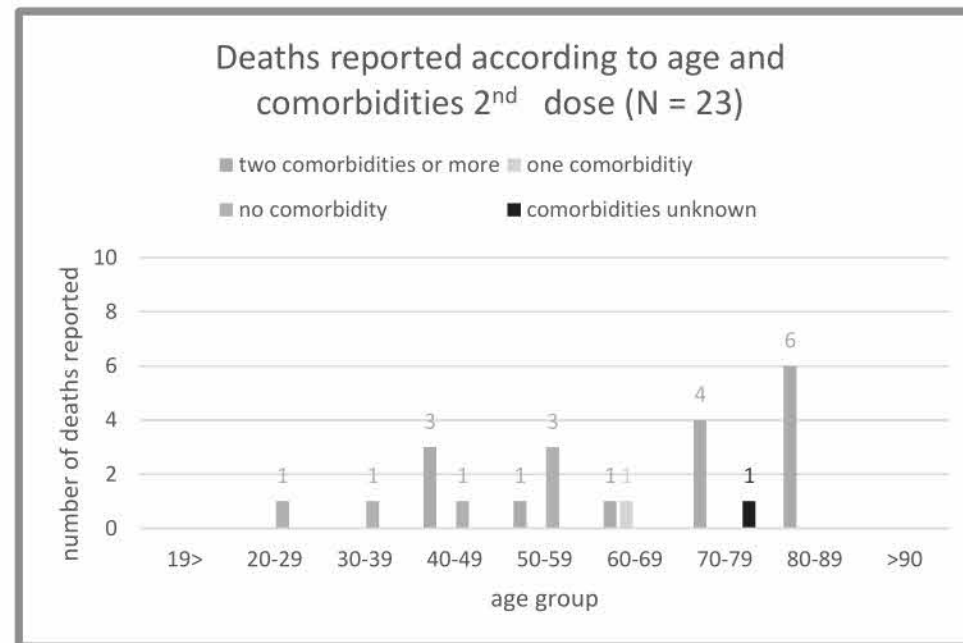
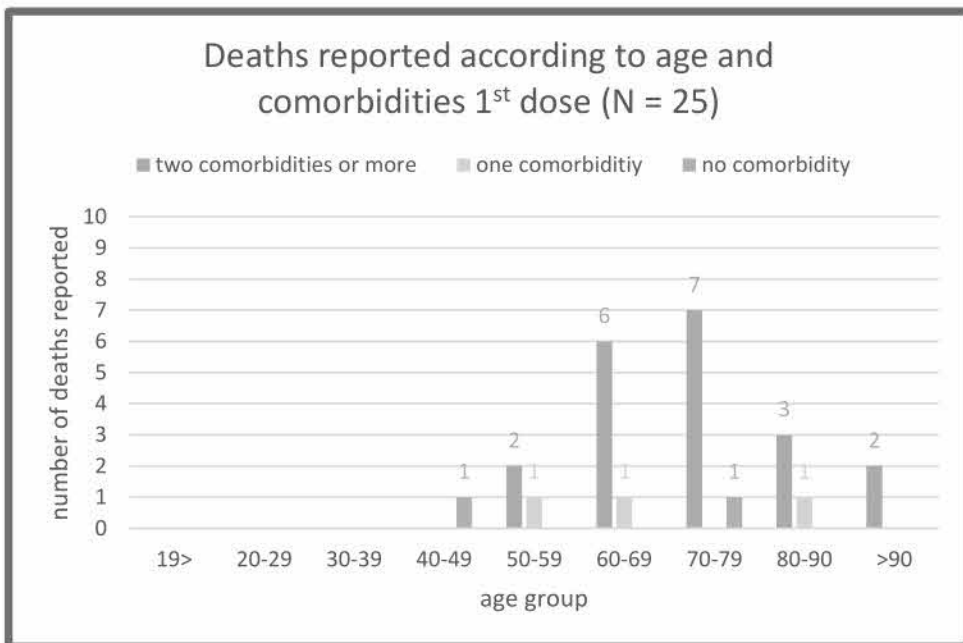
Deaths reported following vaccination

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

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



Deaths reported following vaccination



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



Deaths reported following vaccination observed and expected



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

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

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

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



R-2024-00044

A-00000749473

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11/21/2024



COVID-19 vaccination Israel "BACK TO LIFE"

Enclosure 5

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Mon, 5 Apr 2021 16:08:26 +0000
To: Anderson, Steven (FDA/CBER); Beresnev, Tatiana (NIH) [C]; Broder, Karen (CDC/DDID/NCEZID/DHQP); Calvert, Geoffrey M. (CDC/NIOSH/WTCHP); Clark, Matthew (IHS/ALB); Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Cohn, Amanda (CDC/DDID/NCIRD/OD); Collins, Limone; [REDACTED] Daley, Matt; Destefano, Frank (CDC/DDID/NCEZID/DHQP); Dooling, Kathleen L. (CDC/DDID/NCIRD/DVD); Edwards, Kathy; Farizo, Karen (FDA/CBER); Forshee, Richard (FDA/CBER); Gee, Julianne (CDC/DDID/NCEZID/DHQP); Helfand, Rita (CDC/DDID/NCEZID/OD); Hiers, Susan G. (CDC/DDID/NCIRD/OD); Hopkins, Bob; Jackson, Lisa; Kelman, Jeffrey A. (CMS/CM); Kuldorf, 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 (whitlepn@rwjms.rutgers.edu); 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: [EXTERNAL] VaST - Agenda for April 5 (1:30 - 3 pm ET) and presentations - CONFIDENTIAL
Attachments: [REDACTED] (b)(5)
[REDACTED] (b)(5)
2021_04_05 VaST Meeting Agenda.docx

Dear all,

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

Agenda:

[REDACTED] (b)(5); (b)(6)

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