Kristin

From: NICOLA P KLEIN <Nicola.Klein@kp.org>
Sent: Thursday, April 29, 2021 5:56 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQF) <e1w8@cdc.gov>; Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard <Kristin.X.Goddard@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: RE: updated VaST slideset

Eric and I revised the slides. Please use this version when updating.
Nicky

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQF) <e1w8@cdc.gov>
Sent: Thursday, April 29, 2021 6:58 AM
To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard <Kristin.X.Goddard@kp.org>; NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: updated VaST slideset

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Eric and I revised the slides. Please use this version when updating.
Nicky

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NOTICE TO RECIPIENT: If you are not the intended recipient of this e-mail, you are prohibited from sharing, copying, or otherwise using or disclosing its contents. If you have received this e-mail in error, please notify the sender immediately by reply e-mail and permanently delete this e-mail and any attachments without reading, forwarding or saving them. v.173.285 Thank you.
Will send prelim counts in AM

Thursday March 3, 2021

**COVID-19 Summary**

<table>
<thead>
<tr>
<th>Cases</th>
<th>Hospital Admissions (Confirmed)</th>
<th>Hospital Admissions (All)</th>
<th>Hospital In-Patient Beds 230% COVID-19</th>
<th>Deaths</th>
<th>Test Volume</th>
<th>Test Positivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>28,514,774</td>
<td>1,809,100</td>
<td>3,354,035</td>
<td>N/A</td>
<td>515,277</td>
<td>335,876,223</td>
<td>8.9%</td>
</tr>
<tr>
<td>54,276</td>
<td>4,533</td>
<td>9,251</td>
<td>N/A</td>
<td>2,103</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>63,938</td>
<td>5,650</td>
<td>11,372</td>
<td>0.9%</td>
<td>1,990</td>
<td>1,177,275</td>
<td>4.6%</td>
</tr>
<tr>
<td>-2.4%</td>
<td>-13.0%</td>
<td>-7.4%</td>
<td>-36.7%</td>
<td>-4.3%</td>
<td>7.0%</td>
<td>-13.5%</td>
</tr>
</tbody>
</table>

**COVID-19 Vaccinations in the United States**

<table>
<thead>
<tr>
<th>Overall US</th>
<th>Federal Pharmacy Partnership for Long-Term Care Program (Subset of Overall Numbers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Doses Allocated</td>
<td>N/A</td>
</tr>
<tr>
<td>Total Doses Delivered</td>
<td>N/A</td>
</tr>
<tr>
<td>Total Doses Administered</td>
<td>80,540,474</td>
</tr>
<tr>
<td>Number of People Receiving ≥1 Dose (% Population)</td>
<td>52,855,579 (15.9)</td>
</tr>
<tr>
<td>Number of People Receiving 2 Doses (% Population)</td>
<td>26,957,804 (8.1)</td>
</tr>
</tbody>
</table>

*These data were generated through an externally supported web-scrapping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 08:00 ET today.

**Cases:** The current 7-day average of new cases decreased by 2.4% compared to the previous week. There has been a 7-week downward trend resulting in an overall 74.4% decline since the highest peak of the 7-day moving average of new cases on January 11, 2021 (249,360 to 63,938).

- 28,514,774 COVID-19 cases reported as of Mar 2, 2021 with 54,276 new cases reported.
- The 7-day average number of new cases decreased by 2.4% to 63,938 new cases per day compared to the previous 7-day period.
- During the 7 days ending March 1, 2021, regarding cases:
- 26 (46.4%) jurisdictions are decreasing
- 30 (53.6%) jurisdictions are increasing

*The current 7-day average of new cases is impacted by a historical correction of 2,990 and 1,840 cases reported by Texas on February 27, 2021 and March 1, 2021, respectively. The 7-day average number of new cases (excluding historical cases reported in the past two weeks) decreased by 3.4% to 63,248 new cases per day compared to the previous 7-day average of 65,485.

- Testing: RT-PCR test volume appears to be increasing. RT-PCR test positivity continues to decline (7-day average now 4.6%); 1 jurisdiction remains >=10% positivity (TX).
  - The national 7-day average test volume for Feb 18 – Feb 24, 2021, was 1,177,275 up 7.0% from 1,099,850 the previous 7-days
  - The national 7-day average percent positivity for Feb 22 – Feb 28, 2021, is 4.6%, down 0.7 percentage points from 5.3% the previous week
  - 7-day average positivity is high (>=10%) in 1 jurisdiction (2% of all jurisdictions): TX
  - 7-day average positivity is low (<5%) in 28 jurisdictions (55% of all jurisdictions)
  - Positivity is decreasing in 46 jurisdictions (90% of all jurisdictions)

- Hospitalizations: The new confirmed COVID-19 admissions 7-day average (5,650) has decreased 65.8% since the peak on January 9, 2021 (16,540)
  - The 7-day average number of new admissions of patients with confirmed COVID-19 decreased by 13.0% to 5,650 during the most recent week, Feb 23–Mar 1, 2021
  - The 7-day average number of hospitalized patients with confirmed COVID-19 decreased by 17.3% to 45,607 during the most recent week, Feb 23–Mar 1, 2021
  - The peak above refers to the date of the highest 7-day moving average
    - The single-day peaks are:
      - Admissions: Jan 05, 2021 – 18,009
      - Hospitalizations: Jan 05, 2021 – 125,422

- Deaths: The current 7-day average of new deaths decreased by 4.3% compared to the previous week. There has been a 7-week downward trend resulting in an overall 41.1% decline since the highest peak of the 7-day moving average of new deaths on January 13, 2021 (3,378 to 1,990).
  - 515,277 COVID-19 deaths reported as of Mar 2, 2021 with 2,103 new deaths reported.
  - The 7-day average number of new deaths decreased by 4.3% to 1,990 new deaths per day compared to the previous 7-day period.*

*The current 7-day average of new deaths is impacted by a historical correction of 806 deaths reported by California on February 25, 2021. The 7-day average number of new deaths (excluding historical deaths reported in the past two weeks) decreased by 9.8% to 1,875 new deaths per day compared to the previous 7-day average of 2,079.

- Emerging Variants: At least 48 jurisdictions with reported variant cases. CDC genomic surveillance activities continue to ramp up. There are more than 145,000 sequences in GISAID from U.S. submitters.
B.1.1.7 Variant
- Cumulative in US (AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, PR, RI, SC, TN, TX, UT, VA, WA, WI, WV, and WY)
  - 2,580* cases in 48 jurisdictions
  - As of March 3, 2021, there are two cases attributed to the B.1.1.7 variant that also contains the E484K substitution in GISAID in Oregon and New York City.

P.1 Variant
- Cumulative in U.S. (AK, FL, MD, MN, OK, and OR)
  - 11* cases in 6 jurisdictions
  - (SBU) There are two cases in New Jersey attributed to the P.1 variant that CDC is not authorized to report publicly. This case is not reflected in the total variant case numbers shown above.

B.1.351 Variant
- Cumulative in US (CA, CT, DC, FL, GA, ID, IL, MA, MD, NC, NV, NY, SC, TN, TX, VA, WA)
  - 66* cases in 17 jurisdictions
  - (SBU) There are two additional cases in New York, one additional case in Wyoming, and four additional cases in Washington attributed to the B.1.351 variant that CDC is not authorized to report publicly. These cases are not reflected in the total variant case numbers shown above.

Other Variants
- CDC is monitoring other variants in addition to the variants of concern highlighted above, including B.1.427/9, B.1.526, and P.2 variants of interest. Currently, through NS3 enhanced surveillance, state public health laboratories are asked to submit specimens that contain the E484K or N501Y substitutions or deletions in the S protein for sequencing, isolation, and further characterization at CDC.

• Vaccine: More than 52 million people or 15.9% of the population have received at least 1 dose. Just reached an average of over 2 million doses administered per day
  - Overall, 80,540,474 vaccine doses have been administered.
    - In total, 15.9% (N= 52,855,579) of the population has received 1 or more doses.
    - 8.1% of the population (N= 26,957,804) has received two doses.
    - Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 doses
      - Overall, 7,218,655 doses have been administered in LTCFs
      - 4,669,986 people in LTCFs have received 1 or more doses
  - Doses in LTCF reported since 01/20/2021 (Day 41): 5,310,399 doses
  - Daily vaccine doses administered and reported to CDC increased to an average of 2,010,790 doses reported per day over the past week (previous week: 1,454,731 doses reported per day, on average).
  - Retail Pharmacy Program: The Federal Retail Pharmacy Program is adapting to prioritize vaccinating all school staff and childcare workers during the month of March. CDC is also working with jurisdictions to prioritize this population in other delivery sites.
• Each year CDC helps distribute and administer about 80 million vaccines through its Vaccines for Children Program – we’ve now accomplished that same yearly total in 11.5 weeks. Additionally, we’re now averaging 2 million doses administered per day.

• Other Publications

*Lancet Child and Adolescent Health: Factors associated with severe outcomes in patients with multisystem inflammatory syndrome in children (MIS-C), March-October 2020.*


  • Paper describes 1,080 hospitalized patients <21 years with dates of MIS-C onset from March 11-October 10, 2020.
  • Outcomes of interest were ICU admission, decreased cardiac function, shock, myocarditis, and coronary artery abnormalities.
  • Demographic characteristics, signs and symptoms, and laboratory findings were assessed for associations with the outcomes, controlling for all pre-existing factors.
  • Primary results include:
    • Patients 6-12 years old were more likely to have severe outcomes compared to those under the age of 5 years, and these risks were even higher for patients 13-20 years old.
    • Male sex was associated with coronary artery abnormalities and myocarditis.
    • Non-Hispanic Black patients were more likely to be admitted to the ICU and experience decreased heart function.
    • Patients with shortness of breath and abdominal pain were more likely to be admitted to the ICU.
    • Elevated levels of certain lab markers (troponin, BNP, and proBNP, as well as d-dimer, CRP, and ferritin) and lower levels of lymphocytes and platelets were linked to ICU admission, shock and decreased cardiac function.

○ Manuscript being published 3/4

*MMWR Releases*

• Two *MMWR* reports related to COVID-19 are scheduled as part of the regular issue of the Weekly, with the embargo lifting on Thursday, March 4, at 1 pm. Please note that the titles, content, and timing might change.
FYI
Updated the website today on national seroprevalence from two rounds in January. See below.
https://covid.cdc.gov/covid-data-tracker/#national-lab
# CDC COVID-19 Response Update Report

**DIRECTOR’S BRIEF**

Thursday, March 4, 2021

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**Preliminary COVID-19 Case and Death Data**

<table>
<thead>
<tr>
<th>Data Through</th>
<th>Total Cases</th>
<th>New Cases</th>
<th>Total Deaths</th>
<th>New Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar 3, 2021</td>
<td>28,514,774</td>
<td>54,276</td>
<td>63,938</td>
<td>-2.4%</td>
</tr>
</tbody>
</table>

Source: State-level Aggregated Case and Death Counts (ACDC)

**COVID-19 Summary**

<table>
<thead>
<tr>
<th></th>
<th>Cumulative Total</th>
<th>Daily</th>
<th>7-Day Daily Average</th>
<th>Change from Prior 7-Day Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases²³</td>
<td>28,514,774</td>
<td>54,276</td>
<td>63,938</td>
<td>-2.4%</td>
</tr>
<tr>
<td>Hospital Admissions (Confirmed)⁴</td>
<td>1,809,100</td>
<td>4,533</td>
<td>5,650</td>
<td>-13.0%</td>
</tr>
<tr>
<td>Hospital Admissions (All)⁴</td>
<td>3,354,035</td>
<td>9,251</td>
<td>11,372</td>
<td>-7.4%</td>
</tr>
<tr>
<td>Hospital In-Patient Beds ≥30% COVID-19⁵</td>
<td>N/A</td>
<td>N/A</td>
<td>0.9%</td>
<td>-36.7%</td>
</tr>
<tr>
<td>Deaths⁶</td>
<td>515,277</td>
<td>2,103</td>
<td>1,990</td>
<td>-4.3%</td>
</tr>
<tr>
<td>Test Volume⁷</td>
<td>335,876,223</td>
<td>N/A</td>
<td>1,177,275</td>
<td>7.0%</td>
</tr>
<tr>
<td>Test Positivity⁷</td>
<td>8.9%</td>
<td>N/A</td>
<td>4.6%</td>
<td>-13.5%</td>
</tr>
</tbody>
</table>

Source: HHS Protect; DSEW

**COVID-19 Vaccinations in the United States**

<table>
<thead>
<tr>
<th></th>
<th>Total Doses Allocated</th>
<th>Total Doses Delivered</th>
<th>Total Doses Administered</th>
<th>Number of People Receiving ≥1 Dose (% Population)</th>
<th>Number of People Receiving 2 Doses (% Population)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall US</td>
<td>163,759,745</td>
<td>107,028,890</td>
<td>80,540,474</td>
<td>52,855,579 (15.9)</td>
<td>26,957,804 (8.1)</td>
</tr>
<tr>
<td>Federal Pharmacy Partnership for Long-Term Care Program (Subset of Overall Numbers)</td>
<td>N/A</td>
<td>N/A</td>
<td>7,218,655</td>
<td>4,669,986</td>
<td>2,510,471</td>
</tr>
</tbody>
</table>

Data as of Mar 3, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC_COVID Data Tracker

Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 (overall); 5,310,390 (LTCP)

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¹ These data were generated through an externally supported web-scrapping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

² Time period: Jan 22, 2020 – Mar 2, 2021; confirmed and probable cases.

³ California reported 806 historical deaths on Feb 25, and Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. This will temporarily impact rates and averages. Beginning Feb 24, 2021, South Carolina reconciles their historical data every Wednesday.

⁴ Time period: Aug 1, 2020 – Mar 1, 2021; (All) includes both confirmed and suspect cases.


⁷ Includes data for US States, DC, US Territories, and Federal entities, and pharmacies (see table on last page for details). Total doses allocated are through Mar 28, 2021.
COVID-19 Director’s Brief - Thursday, Mar 4, 2021  INTERNAL – NOT FOR FURTHER DISTRIBUTION

Daily Change in COVID-19 Cases, United States
January 22, 2020* - March 2, 2021

28,514,774
Total Cases Reported

54,276
New Cases Reported

63,938
Current 7-Day Average
Feb 24, 2021 - Mar 2, 2021

65,485
Prior 7-Day Average
Feb 17, 2021 - Feb 23, 2021

-2.4%
Change in 7-Day Average

-74.4%
Change Since Peak Average

Peaks in New Cases and Highest 7-Day Moving Average

<table>
<thead>
<tr>
<th>Highest Daily Number of New Cases</th>
<th>Highest 7-Day Moving Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Cases</td>
</tr>
<tr>
<td>Current</td>
<td>Jan 8, 2021</td>
</tr>
<tr>
<td>2nd Peak</td>
<td>Jul 17, 2020</td>
</tr>
<tr>
<td>1st Peak</td>
<td>Apr 6, 2020</td>
</tr>
</tbody>
</table>

*Figures display data for Mar 1, 2020 to date. Totals include cases reported since Jan 22, 2020. As of April 12, 2020, data include confirmed and probable cases reported from jurisdictions. On Nov 7, 2020, 33,864 probable cases were reclassified to suspect cases and removed. Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 2, 2021. These historical cases are excluded during identification of the highest peaks in new cases, but are included in the number of cumulative cases. Beginning Feb 24, 2021, counts will reflect updates to South Carolina’s historical data each Wednesday.

New Admissions of Patients with Confirmed COVID-19, United States
August 1, 2020 – March 1, 2021

1,809,100
Total New Admissions
Aug 1, 2020 – Mar 1, 2021

4,533
New Admissions
Mar 1, 2021

5,650
Current 7-Day Average

6,495
Prior 7-Day Average

-13.0%
Change in 7-Day Average

-65.8%
Change Since Peak 7-Day Average

Peaks in New Admissions and Highest 7-Day Moving Average

<table>
<thead>
<tr>
<th>Highest Daily Number of New Admissions</th>
<th>Highest 7-Day Moving Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>New Admissions</td>
</tr>
<tr>
<td>Jan 5, 2021</td>
<td>18,009</td>
</tr>
</tbody>
</table>

Based on reporting from all hospitals. (Per 243).
Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution. Data reported prior to Aug 1, 2020 are unavailable.

Last Updated: Mar 1, 2021

Data Source: Council of State and Territorial Epidemiologists COVID-19 Data Workgroup; COVID-19 Data Submission; Public Health Laboratory Information System

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Page 2 of 5
Daily Change in COVID-19 Deaths, United States  
January 22, 2020* - March 2, 2021

- 515,277
  Total Deaths Reported

- 2,103
  New Deaths Reported

- 1,990
  Current 7-Day Average
  Feb 24, 2021 – Mar 2, 2021

- 2,079
  Prior 7-Day Average
  Feb 17, 2021 – Feb 23, 2021

-4.3%
  Change in 7-Day Average

-41.1%
  Change Since Peak Average

* Graph displays data starting on Mar 1, 2020. Totals include deaths reported since Jan 22, 2020. As of Apr 12, 2020, confirmed and probable cases reported from jurisdiction.

**Various states reported historical deaths on Apr 15, 2020 (4,959 probable deaths), Apr 25, 2020 (3,824 probable deaths), Feb 8, 2021 (1,567 confirmed deaths), Feb 12, 2021 (2,559 deaths), Feb 13, 2021 (1,208 deaths), and Feb 25, 2021 (88 deaths). These historical deaths are excluded during identification of the highest peaks of new deaths, but are included in the number of cumulative cases. Beginning Feb 24, 2021, counts will reflect updates to South Carolina’s historical data each Wednesday.

Last Updated: Mar 3, 2021, 15:52

Daily SARS-CoV-2 RT-PCR Percent Test Positivity and Test Volume, United States  
March 1, 2020 – February 28, 2021

- 335,876,223
  Total Test Volume

- 1,177,275
  Current 7-Day Avg. Daily Test Volume
  Feb 16, 2021 – Feb 24, 2021

- 1,099,850
  Prior 7-Day Avg. Daily Test Volume
  Feb 15, 2021 – Feb 17, 2021

-7.0%
  Percent Change in 7-Day Avg.

- 4.6%
  Current 7-Day Avg. % Positivity
  Feb 22, 2021 – Feb 28, 2021

- 5.3%
  Prior 7-Day Avg. % Positivity
  Feb 15, 2021 – Feb 21, 2021

-13.5%
  Percent Change in 7-Day Avg.

-0.7
  Percentage Point Difference in 7-Day Averages
<table>
<thead>
<tr>
<th>State/Territory, Federal Entity, or Pharmacy</th>
<th>Doses Allocated</th>
<th>Doses Delivered</th>
<th>Doses Administered</th>
<th>People Receiving ( \geq 1 ) Dose</th>
<th>People Receiving 2 Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>2,538,105</td>
<td>2,138,365</td>
<td>1,927,225</td>
<td>1,848,475</td>
<td>1,726,277</td>
</tr>
</tbody>
</table>

---

**Notes:**

- Green shading indicates higher rates of distribution or vaccine administration relative to other states/territories. Rates calculated based on 2019 Census data for US States, DC, and PR, and 2018 Census data for all other US Territories. Population data not available for Federal Entities or pharmacies.
- **Total** doses allocated are through Mar 28, 2021. Total doses allocated includes second dose allocations that are not yet available to order.

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Page 4 of 4
<table>
<thead>
<tr>
<th>State/Territory, Federal Entity, or Pharmacy</th>
<th>Doses Allocated</th>
<th>Doses Delivered</th>
<th>Doses Administered</th>
<th>People Receiving ≥ 1 Dose</th>
<th>People Receiving 2 Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total10</td>
<td>Total</td>
<td>Rate/100K Population</td>
<td>Total</td>
<td>Rate/100K Population</td>
</tr>
<tr>
<td>FSM</td>
<td>47,400</td>
<td>30,000</td>
<td>28,946</td>
<td>15,705</td>
<td>15,153</td>
</tr>
<tr>
<td>Guam</td>
<td>87,860</td>
<td>65,500</td>
<td>39,513</td>
<td>55,402</td>
<td>33,421</td>
</tr>
<tr>
<td>Marshall Islands</td>
<td>35,600</td>
<td>21,000</td>
<td>35,951</td>
<td>11,351</td>
<td>19,432</td>
</tr>
<tr>
<td>Palau</td>
<td>14,800</td>
<td>14,600</td>
<td>81,532</td>
<td>8,185</td>
<td>45,708</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>1,470,700</td>
<td>1,055,070</td>
<td>33,067</td>
<td>554,694</td>
<td>17,368</td>
</tr>
<tr>
<td>US Virgin Islands</td>
<td>56,280</td>
<td>37,680</td>
<td>35,995</td>
<td>19,736</td>
<td>18,854</td>
</tr>
<tr>
<td>Unspecified1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>US Total</strong></td>
<td><strong>163,758,745</strong></td>
<td><strong>107,018,590</strong></td>
<td><strong>32,238</strong></td>
<td><strong>80,540,474</strong></td>
<td><strong>24,259</strong></td>
</tr>
<tr>
<td>Bureau of Prisons</td>
<td>106,670</td>
<td>65,335</td>
<td>N/A</td>
<td>62,745</td>
<td>N/A</td>
</tr>
<tr>
<td>Dept of Defense</td>
<td>2,323,995</td>
<td>1,556,605</td>
<td>N/A</td>
<td>1,017,839</td>
<td>N/A</td>
</tr>
<tr>
<td>Dept of State</td>
<td>110,870</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>FEMA</td>
<td>2,168,855</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>HRSA</td>
<td>932,280</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Indian Health Service</td>
<td>1,378,015</td>
<td>948,600</td>
<td>N/A</td>
<td>588,253</td>
<td>N/A</td>
</tr>
<tr>
<td>Veterans Health</td>
<td>4,023,750</td>
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N/A = Not available (no data)

Data as of Mar 3, 2021, 06:00 ET; Sources: Data Monitoring and Reporting Section, Vaccine Task Force; COVID Tracker; US Census

11 Includes doses delivered or administered by federal agencies outside the US or in unspecified states or territories.

12 Totals for states and territories include doses delivered to or administered by federal agencies. The overall total also includes doses delivered to or administered by federal agencies where the state or territory was not specified. The overall total of doses allocated includes data from federal agencies and pharmacies.
Tom,

Please see two considerations below.

1. Do you want to...

2. Do you want to...

Thanks,
Karen

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Wednesday, March 10, 2021 7:38 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>
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

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.

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

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

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

Thanks, Stacey.

Denise – can you help set this up via policy?

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/DHQI) <avy6@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

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) <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/DHQI) <avy6@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
Importance: High

Stacey and Tom,

Please see below re discussing with Israeli Vaccine FP

Thanks,
David

From: CDC IMS Task Tracker (CDC) <eoctaskIdTracker@cdc.gov>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <eoevent416@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eoevent417@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eoevent516@cdc.gov>; CDC IMS 2019 NCOV Response VTF Operations <eovtfTask@cdc.gov>
Cc: CDC IMS Task Tracker (CDC) <eoctaskIdTracker@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
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. Roece Singer MD, MPH

Phone #: (b)(6)

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

Description:

(b)(5)

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: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPI)
Sent: Fri, 9 Apr 2021 21:09:35 -0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQPI); Lagarde, Melanie (CDC/OCOO/OSSAM/OHC); Su, John (CDC/DDID/NCEZID/DHQPI)
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
Attachments: COVID past history.rtf, COVID past history-safety profile.rtf, COVID past history.rtf, COVID past history.rtf, COVID history-details.rtf

Please let me know your edits:

Sincerely,
Pedro
Hi Pedro,

Melanie and I discussed that if I could get back to you with a revised response soon. Thanks, Elaine

Hi Melanie,

Elaine or John, do you have any edits?

Thanks for sending this

Pedro
Sincerely,
Pedro
Sincerely,
CDC Immunization Safety Office Staff
Atlanta, GA
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)  
Sent: Thursday, April 8, 2021 1:13 PM  
To: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,
Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.
Melanie

Melanie Carmel Lagarde, DNP, MPH, RN, CHES  
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>  
Sent: Thursday, April 8, 2021 1:09 PM  
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggestions.

Thanks again

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>  
Sent: Thursday, April 8, 2021 12:56 PM  
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>  
Subject: DRAFT RE: Autoimmune dx post vaccine
Sincerely,
CDC Immunization Safety Office Staff
Atlanta, GA

Melanie Carmel Lagarde, DNP, MPH, RN, CHES
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell
Hi Melanie,

Please let me know if you can draft a response for this inquiry.

Thanks,

Elaine

---

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Sent: Wednesday, April 7, 2021 6:19 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: FW: Autoimmune dx post vaccine

Elaine,

Pedro

---

From: dale nordenberg
Sent: Wednesday, April 7, 2021 5:16 PM
To: Robert Chen
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ); Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: Re: Autoimmune dx post vaccine

Hi

Thanks!

Sent from my iPhone

On Apr 7, 2021, at 5:08 PM, Robert Chen wrote:

Dale?
On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov> wrote:
Hi Bob,

Pedro

From: Robert Chen
Sent: Wednesday, April 7, 2021 3:33 PM
To: Nordenberg, Dale (CDC gmail.com)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Subject: Re: Autoimmune dx post vaccine

Bob

On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg wrote:
Bob

Dale

Sent from my iPhone

--
Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
e-mail:
I didn’t have any comments.
Great job with the manuscript.

I hope all is well with you and you had a wonderful Thanksgiving with your family.
Regards,
Maria

-----Original Message-----
From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fcy9@cdc.gov>; Carmen Ng <ming yan [removed]@cdc.gov; M Cano @cdc.gov>
Sent: Tue, Nov 24, 2020 6:48 pm
Subject: FW: Your Submission

Hi folks,

I hope you’re staying healthy and safe during these strange times!

Please find enclosed the revised myopericarditis paper, with responses to the below reviewers comments. Please take a look, and let me know if you have any questions, concerns, or other feedback by COB next Thursday (3 Dec); if I don’t hear from you, I’ll assume you’re good with these responses. I will then resubmit our paper to Vaccine.

Thanks for your hard work!

-- John

-----Original Message-----
From: eesserver@eemail.elsevier.com <eesserver@eemail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671
Title:[(b)(5), (b)(4)]

Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
Hi folks,

I hope you’re staying healthy and safe during these strange times!

Please find enclosed the revised myopericarditis paper, with responses to the below reviewers comments. Please take a look, and let me know if you have any questions, concerns, or other feedback by COB next Thursday (3 Dec); if I don’t hear from you, I’ll assume you’re good with these responses. I will then resubmit our paper to Vaccine.

Thanks for your hard work!

-- John

-----Original Message-----
From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQIP) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671
Title: Myopericarditis paper - 11-24-2020.docx, Tables.docx, Response to Reviewers.docx

Dear John,

and
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
Hi David,

[b][b]RE: VAERS Review of Myocarditis/Myopericarditis for DoD Discussion Tomorrow[/b]

Hi all,

Any comments or suggestions for improvement are welcome. Please send any comments by 10AM 4/2 so that I have a chance to incorporate them into the presentation.

Best,
David
David McCormick, MD, MPH
LCDR, US Public Health Service
EIS Officer
Centers for Disease Control and Prevention
Bacterial Diseases Branch | Division of Vector-Borne Diseases
Fort Collins, CO
yup1@cdc.gov | Office 970-225-4272 | Cell 970-787-5036

Restricted Use /CDC FTE Only
Myopericarditis after vaccination, Vaccine Adverse Event Reporting System (VAERS), 1990–2018

John R. Su\textsuperscript{a,\textdagger}, Michael M. McNeil\textsuperscript{a}, Kerry J. Welsh\textsuperscript{b}, Paige L. Marquez\textsuperscript{a}, Carmen Ng\textsuperscript{a,\dagger}, Ming Yan\textsuperscript{a}, Maria V. Cano\textsuperscript{a}

\textsuperscript{a}Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, United States
\textsuperscript{b}Center for Biologics Evaluation and Research, Food and Drug Administration (FDA), United States

\begin{abstract}

Background: Myopericarditis after vaccination has been sporadically reported in the medical literature. Here, we present a thorough descriptive analysis of reports to a national passive vaccine safety surveillance system (VAERS) of myopericarditis after vaccines licensed for use in the United States.

Methods: We identified U.S. reports of myopericarditis received by VAERS during 1990–2018 that met a published case definition for myopericarditis or were physician-diagnosed. We stratified analysis by age group (<19, 19–49, \geq 50 years), describing reports by serious/non-serious status, sex, time to symptom onset after vaccination, vaccine(s) administered, and exposure to other known causes of myopericarditis. We used Empirical Bayesian data mining to detect disproportionate reporting of myopericarditis after vaccination.

Results: VAERS received 620,195 reports during 1990–2018: 708 (0.1%) met the case definition or were physician-diagnosed as myopericarditis. Most (79%) myopericarditis reports described males; 69% were serious; 72% had symptom onset \leq 2 weeks postvaccination. Overall, smallpox (55%), anthrax (23%), and tetanus vaccines were most commonly reported. By age, among persons aged \leq 19 years, Haemophilus influenzae type b (22%, 22%) and hepatitis B (18%, 18%); among persons aged 19–49 years smallpox (387, 79%); among persons aged \geq 50 years inactivated influenza (31, 36%) and live attenuated zoster (19, 22%) vaccines were most commonly reported. The vaccines most commonly reported remained unchanged when excluding 138 reports describing other known causes of myopericarditis. Data mining revealed disproportionate reporting of myopericarditis only after smallpox vaccine.

Conclusions: Despite the introduction of new vaccines over the years, myopericarditis remains rarely reported after vaccines licensed for use in the United States. In this analysis, myopericarditis was most commonly reported after smallpox vaccine, and less commonly after other vaccines.

Published by Elsevier Ltd.
\end{abstract}

1. Introduction

Myocarditis (inflammation of the myocardium, or heart muscle) and pericarditis (inflammation of the pericardium, or tissue overlying the heart muscle) often occur together (termed myopericarditis), and can range in severity from mild and without symptoms, to severe \cite{1}. Myopericarditis has many causes, including viral infections \cite{1}.

Although not establishing causality, myopericarditis has been reported after vaccinations. Myopericarditis is known to occur after administration of smallpox vaccine \cite{2}. Amsel et al., described myocarditis in a male aged 3 months after receiving both combined diphtheria, tetanus, and pertussis (DTP) vaccine, and oral
polio vaccine [3], de Meester et al. described pericarditis after vaccination with influenza vaccine [4], Peyriere et al. described pericarditis after hepatitis B vaccine [5], and Mei et al. have described recurrent pericarditis after inactivated influenza (IV) [6]. Except for smallpox vaccine, none of these reports described vaccines licensed for use in the United States.

Myopericarditis after live virus vaccines other than smallpox vaccine has been explored to some degree [7,8]. Reports of myopericarditis after inactivated vaccines have been scant, mostly after IV [4,9], including a recently published case report attributing myopericarditis to adjuvanted inactivated influenza vaccine (FlucelVaxVIA®, Seqirus) [9]. Further, several vaccines that are not IV – including both live attenuated and inactivated vaccines – have been licensed for use in the United States over the past several years. To better characterize myopericarditis after vaccination, we reviewed and described reports of myopericarditis received by the Vaccine Adverse Event Reporting System (VAERS).

2. Methods

2.1. Data source

VAERS is a national spontaneous reporting system for monitoring AEs after vaccination [10]. Reports of AEs following vaccines licensed for use in the United States are accepted from healthcare providers, vaccine manufacturers, vaccine recipients and other persons and entities, including the military. Reported signs and symptoms are coded using Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) [11]. MedDRA PTs are not necessarily medically confirmed diagnoses, and a VAERS report can be assigned multiple MedDRA PTs. The Code of Federal Regulations defines a report as serious if at least one of the following conditions is reported: death, life-threatening illness, hospitalization or prolongation of existing hospitalization, permanent disability, or a congenital anomaly or birth defect [12]. An AE might therefore present as an acutely severe condition, but not be classified as a serious report. For non-manufacturer serious reports, medical records are routinely requested and made available to VAERS personnel. Due to regulatory processes [13], vaccine manufacturers will request and review medical records before reporting a serious report to VAERS; as a result, serious reports from vaccine manufacturers typically do not contain medical records that VAERS personnel can review.

2.2. Descriptive analysis

We searched the VAERS database for reports of myocarditis, pericarditis, myopericarditis, and perimyocarditis following vaccination. We searched for reports containing PTs that included the words “myocarditis”, “coxsackie carditis”, “pericarditis”, and “pericardial effusion”; a complete list of PTs searched is available in the Supplemental Materials. Our search included PTs from past versions of the MedDRA browser, to capture reports using these older PTs. All identified reports were reviewed for signs and symptoms that met case definitions previously used for surveillance of myopericarditis after smallpox vaccine [14]; we also included for review reports where there was a diagnosis by a physician, regardless of if the reported case met the published case definition. Reports of cases that either met the definition for myocarditis or pericarditis, or were diagnosed by a physician, were stratified by age group (<19 years, 19–49 years, ≥50 years), in part because of age differences in recommended vaccination schedules [15,16], and the known association between smallpox vaccine, administered routinely to selected populations, and myopericarditis [2,14]. For each age group, we analyzed cases by seriousness of report (death, serious, or non-serious), sex, and time from vaccination to onset of symptoms. In addition, we analyzed by whether vaccines were given alone or concomitantly with other vaccines. Because myopericarditis is commonly viral in origin in the community [1], we conducted a secondary analysis that excluded reports in which patients exhibited signs or symptoms of influenza-like illness (including fever, malaise, upper or lower respiratory symptoms, gastrointestinal symptoms like nausea or vomiting) or had a history of such symptoms within 42 days of symptom onset for myopericarditis [14].

2.3. Estimated reporting rates

Data on doses of vaccine that were distributed or administered are difficult to obtain. Estimating reporting rates of AEs after vaccination using data from VAERS is therefore challenging. For smallpox vaccine, doses administered data were unavailable, but doses distributed data were available. We were able to estimate crude reporting rates of myopericarditis after smallpox vaccine using reports received during 2014 through 2018 as the numerator, divided by doses distributed during the corresponding time period (which included disbursements to the U.S. military) (Centers for Disease Control Prevention, Division of State and Local Readiness, personal communication) as the denominator; rates were estimated as reports per 1,000 doses distributed. For influenza vaccine, vaccine coverage data were available, and could be used to estimate doses administered. We therefore estimated annual crude reporting rates for influenza vaccine (all types), with reports received during 2014 through 2018 as the numerator, with population estimates and vaccine coverage for the corresponding year multiplied as the denominator [18,19]; rates for 2 age groups (1–17 years, ≥18 years) were estimated. From these annual crude reporting rates, median rates of reports per million doses administered were estimated for 2014 through 2018.

2.4. Disproportionality analysis

Empirical Bayesian data mining techniques [17] were used to identify MedDRA PTs related to myopericarditis that occurred among U.S. reports more often than expected following each individual U.S. licensed vaccine: AEs after a given vaccine were compared to AEs reported for all vaccines, with adjustment for age, sex, and year of report receipt. The statistic calculated for this data mining analysis was the Empirical Bayes Geometric Mean (EBGM) and its associated 90% confidence interval (EB05, EB09). An EB05 ≥ 2.0 indicates a vaccine-event pair occurs at least twice as often as assumed, assuming that vaccine-event pairs are random, and is the commonly used threshold for considering an AE as a potential signal [18]; we thus used an EB05 ≥ 2.0. Disproportionality analyses are intended to assess potential associations between a vaccine and an AE, but do not imply causality between the vaccine-event pair.

The data in this analysis resulted from routine public health surveillance activities. U.S. federal law specifies that these activities do not constitute research. This analysis was therefore exempt from institutional review.

3. Results

3.1. Descriptive analysis

During the analytic period, VAERS received a total of 620,195 reports. Of these reports, 708 (0.1%) either met the published case
definition for myopericarditis [14] or were diagnosed by a physician as myopericarditis (Table 1). Most reports described males (79%), and most reports were classified as serious (69%), with a reported time to symptom onset of 14 days or less (72%). Median reported age was 24 years (range: 0 to 90 years): among people ≤ 18 years of age, median age was 8 years (range: 0 to 18 years); among people 19 to 49 years of age, median age was 25 years (range: 19 to 49 years), with 75% of reports among people 19 to 31 years of age; among people ≥ 50 years, median age was 64 years (range: 50 to 90 years). We observed notable differences by age group: most reports (69%) were among persons 19 to 49 years of age, most of whom (90%) were males, and most of whom reported a time to symptom onset of 8 to 14 days after vaccination (whereas for other age groups, the greatest proportion of reported persons had symptom onset within 7 days of vaccination). Also, in over half of reports among persons 18 years of age and younger, the patient died. When excluding reports after smallpox vaccine, most reports still described males, were classified as serious, reported time to symptom onset of 14 days or less, with similar median ages and distribution of sex by age (data not shown).

Considering all vaccines (regardless if administered with other vaccines, or alone), the most frequently reported vaccines were smallpox (59%), anthrax (23%), and typhoid (13%) vaccines; IV was also frequently reported (11%) (Table 2). Among persons 18 years of age and younger, the most frequently reported vaccines were Haemophilus influenzae type b (22%) and hepatitis B (18%) vaccines; among persons 19 to 49 years of age, smallpox vaccine

Table 1

<table>
<thead>
<tr>
<th>Sex</th>
<th>0 to 18 years n = 99 (%)</th>
<th>19 to 49 years n = 490 (%)</th>
<th>50 + years n = 85 (%)</th>
<th>Unreported n = 34 (%)</th>
<th>Total N = 708 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>55 (56)</td>
<td>439 (90)</td>
<td>42 (49)</td>
<td>23 (68)</td>
<td>559 (79)</td>
</tr>
<tr>
<td>Female</td>
<td>44 (44)</td>
<td>51 (10)</td>
<td>43 (51)</td>
<td>7 (21)</td>
<td>145 (20)</td>
</tr>
<tr>
<td>Unreported</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (12)</td>
<td>4 (1)</td>
</tr>
<tr>
<td>Seriousness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-serious</td>
<td>5 (5)</td>
<td>183 (38)</td>
<td>13 (15)</td>
<td>19 (56)</td>
<td>221 (31)</td>
</tr>
<tr>
<td>Serious, non-death</td>
<td>40 (40)</td>
<td>294 (60)</td>
<td>63 (74)</td>
<td>15 (44)</td>
<td>412 (58)</td>
</tr>
<tr>
<td>Serious, death</td>
<td>54 (55)</td>
<td>12 (2)</td>
<td>9 (11)</td>
<td>0 (0)</td>
<td>75 (11)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both MMWR definition and MD</td>
<td>54 (55)</td>
<td>293 (60)</td>
<td>39 (46)</td>
<td>8 (24)</td>
<td>394 (56)</td>
</tr>
<tr>
<td>MMWR only</td>
<td>20 (20)</td>
<td>45 (9)</td>
<td>21 (25)</td>
<td>4 (12)</td>
<td>90 (13)</td>
</tr>
<tr>
<td>MD only</td>
<td>25 (25)</td>
<td>152 (31)</td>
<td>25 (29)</td>
<td>22 (65)</td>
<td>224 (32)</td>
</tr>
<tr>
<td>Time to onset, days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤7</td>
<td>46 (46)</td>
<td>111 (23)</td>
<td>49 (58)</td>
<td>3 (9)</td>
<td>209 (30)</td>
</tr>
<tr>
<td>8 to 14</td>
<td>15 (15)</td>
<td>263 (54)</td>
<td>8 (9)</td>
<td>14 (41)</td>
<td>300 (42)</td>
</tr>
<tr>
<td>15 to 29</td>
<td>8 (8)</td>
<td>62 (13)</td>
<td>13 (15)</td>
<td>1 (3)</td>
<td>84 (12)</td>
</tr>
<tr>
<td>≥30</td>
<td>14 (14)</td>
<td>20 (4)</td>
<td>4 (5)</td>
<td>1 (3)</td>
<td>39 (6)</td>
</tr>
<tr>
<td>unreported</td>
<td>16 (16)</td>
<td>34 (7)</td>
<td>11 (13)</td>
<td>15 (44)</td>
<td>76 (11)</td>
</tr>
</tbody>
</table>

1 Serious defined as death, life-threatening illness, hospitalization or prolongation of existing hospitalization, permanent disability, or a congenital anomaly or birth defect.

[12]

Case definition from published analysis [ref]; MD = clinical diagnosis by a physician.

Table 2

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0-18 n = 99</th>
<th>19-49 n = 490</th>
<th>≥50 n = 85</th>
<th>Not reported n = 34</th>
<th>Total N = 708</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>6 (6)</td>
<td>387 (79)</td>
<td>4 (5)</td>
<td>19 (56)</td>
<td>416 (59)</td>
</tr>
<tr>
<td>Anthrax</td>
<td>5 (5)</td>
<td>151 (31)</td>
<td>1 (1)</td>
<td>6 (18)</td>
<td>163 (23)</td>
</tr>
<tr>
<td>Typhoid</td>
<td>3 (3)</td>
<td>83 (17)</td>
<td>2 (2)</td>
<td>2 (6)</td>
<td>90 (13)</td>
</tr>
<tr>
<td>Influenza, inactivated</td>
<td>11 (11)</td>
<td>31 (7)</td>
<td>31 (36)</td>
<td>2 (6)</td>
<td>77 (11)</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>18 (18)</td>
<td>17 (3)</td>
<td>3 (3)</td>
<td>3 (9)</td>
<td>41 (6)</td>
</tr>
<tr>
<td>Influenza, not specified</td>
<td>3 (3)</td>
<td>22 (4)</td>
<td>13 (15)</td>
<td>2 (6)</td>
<td>40 (6)</td>
</tr>
<tr>
<td>Tdap</td>
<td>9 (9)</td>
<td>17 (3)</td>
<td>3 (4)</td>
<td>1 (3)</td>
<td>30 (4)</td>
</tr>
<tr>
<td>Influenza, live attenuated</td>
<td>3 (3)</td>
<td>22 (4)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>22 (3)</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>12 (12)</td>
<td>9 (2)</td>
<td>1 (1)</td>
<td>3 (9)</td>
<td>25 (4)</td>
</tr>
<tr>
<td>Varicella</td>
<td>16 (16)</td>
<td>61 (13)</td>
<td>0 (0)</td>
<td>2 (6)</td>
<td>24 (3)</td>
</tr>
<tr>
<td>Haemophilus influenza type b</td>
<td>22 (22)</td>
<td>0 (0)</td>
<td>19 (22)</td>
<td>2 (6)</td>
<td>21 (3)</td>
</tr>
<tr>
<td>Zoster, live attenuated</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>MMR</td>
<td>13 (13)</td>
<td>7 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>20 (3)</td>
</tr>
<tr>
<td>4-valent HPV</td>
<td>16 (16)</td>
<td>3 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>19 (3)</td>
</tr>
<tr>
<td>DTaP</td>
<td>14 (14)</td>
<td>2 (0)</td>
<td>1 (1)</td>
<td>1 (3)</td>
<td>18 (3)</td>
</tr>
<tr>
<td>Meningococcal conjugate</td>
<td>14 (14)</td>
<td>2 (0)</td>
<td>0 (0)</td>
<td>2 (6)</td>
<td>18 (3)</td>
</tr>
<tr>
<td>Polio, inactivated</td>
<td>11 (11)</td>
<td>4 (1)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td>16 (2)</td>
</tr>
<tr>
<td>Pneumococcal polysaccharide</td>
<td>1 (1)</td>
<td>8 (2)</td>
<td>4 (5)</td>
<td>0 (0)</td>
<td>13 (2)</td>
</tr>
<tr>
<td>Pneumococcal conjugate, 7-valent</td>
<td>12 (12)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>12 (2)</td>
</tr>
<tr>
<td>Pneumococcal conjugate, 13-valent</td>
<td>7 (7)</td>
<td>1 (0)</td>
<td>3 (4)</td>
<td>1 (3)</td>
<td>12 (2)</td>
</tr>
</tbody>
</table>

Counts not mutually exclusive; in descending order of overall reports.

Tdap = combined tetanus and diphtheria toxoid, acellular pertussis vaccine; MMR = combined measles, mumps, and rubella vaccine; HPV = human papillomavirus vaccine; DTaP = combined diphtheria and tetanus toxoid, acellular pertussis vaccine.
(7%) was most frequently reported; and among persons 50 years of age and older IV (36%) and live attenuated zoster (22%) vaccines were most frequently reported.

Of vaccines administered alone, the most frequently reported vaccines were smallpox (53%) and IV (12%) vaccines (Table 3). By age, among persons 18 years of age and younger, the most frequently reported vaccines were 4-valent human papillomavirus (HPV) (25%) and hepatitis B (13%) vaccines; among persons 19 to 49 years of age, smallpox vaccine (71%) was most frequently reported; and among persons 50 years of age and older IV (38%) and live attenuated zoster (23%) vaccines were most frequently reported.

Of the 708 identified reports of myopericarditis, 138 (19%) described signs or symptoms of influenza-like illness up to 42 days prior to symptom onset for myopericarditis. Reported median age was 24 years (range: 0 to 90 years); 101 (73%) reported persons were male, and 37 (27%) were female. Of these 138 reports, 129 reports were serious, including 31 (24%) reports where the patient died; 21 (68%) of these reported deaths had histologic evidence of myopericarditis on autopsy. Reported median time to symptom onset was 8 days after vaccination (range: 0 to 102 days). When excluding these 138 reports from consideration, the most frequently reported vaccines — both administered with other vaccines and administered alone — the order of vaccines most commonly reported did not change appreciably (Tables 4 and 5).

We identified 75 reports of myopericarditis in which the patient died. Median reported age was 7 years (range: 0 to 80 years); 40 reported patients were male, and 35 were female. Median time to onset of myopericarditis was 6 days after vaccination (range: 0 to 571 days). In 60 (80%) reports, myopericarditis could be attributed to other known causes (e.g., viral infection, disseminated bacterial infection, systemic lupus erythematosus), including 45 of 54 (83%) reported deaths among patients aged 0 to 18 years (Table 1). Of the remaining 15 reports, the reported vaccines reflected recommended vaccines for the patient’s age; among 5 reports describing patients < 1 year of age, 4 received vaccines containing diphtheria and tetanus toxoids, and acellular pertussis antigen, and 3 received pneumococcal conjugate vaccines (2 received the

### Table 3

Most frequently reported vaccines administered alone among myopericarditis reports, by age.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0-18 (n = 40)</th>
<th>19-49 (n = 307)</th>
<th>≥50 (n = 77)</th>
<th>Not reported (n = 25)</th>
<th>Total (n = 449)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza, inactivated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zoster, live attenuated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anthrax</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal conjugate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella, live attenuated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal conjugate, 13-valent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Counts in descending order of overall reports.

2 *Tdap* = combined tetanus and diphtheria toxoid, acellular pertussis vaccine; *HPV* = human papillomavirus vaccine; *MMR* = combined measles, mumps, and rubella vaccine.

### Table 4

Most frequently reported vaccines among myopericarditis reports, excluding recent illness, by age.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>0-18 (n = 63)</th>
<th>19-49 (n = 409)</th>
<th>≥50 (n = 63)</th>
<th>Not reported (n = 35)</th>
<th>Total (n = 570)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anthrax</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal conjugate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella, live attenuated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal conjugate, 13-valent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Counts not mutually exclusive; in descending order of overall reports; excludes reports describing people with documented flu-like symptoms (including gastrointestinal symptoms) prior to vaccination, and within 30 days of symptom onset.

2 *Tdap* = combined tetanus and diphtheria toxoid, acellular pertussis vaccine; *HPV* = human papillomavirus vaccine; *MMR* = combined measles, mumps, and rubella vaccine; *DTaP* = combined diphtheria and tetanus toxoid, acellular pertussis vaccine.
13-valent vaccine, 1 received the 7-valent vaccine); among 4 reports describing patients 12 to 18 years of age, 2 received meningococcal conjugate vaccines, 1 received 4-valent HPV vaccine, and another received monovalent mumps vaccine; among 6 reports describing patients 19 years of age and older, 2 received smallpox vaccine, 2 received influenza vaccine (not specified), 1 received IVI, and 1 received live attenuated zoster vaccine.

3.2. Estimated reporting rates

During 2014 through 2018, myopericarditis after smallpox vaccine was reported to VAERS at an estimated rate of 4.0 per 1,000 doses distributed. Regardless of age group, estimated median reporting rates of myopericarditis during 2014 through 2018 after influenza vaccine (all types) was < 0.1 per 1,000,000 doses administered.

3.3. Disproportionality analysis

Disproportionality analysis identified an elevated EB05 (≥2.0) for smallpox vaccine and the myopericarditis-related PTs of “Myocarditis”, “Pericardial disease”, “Pericardial effusion”, and “Pericarditis”. An EB05 ≥ 2.0 was found for anthrax vaccine and the PTs “Myocarditis”, “Pericardial disease”, and “Pericarditis”; most patients (95%) received a concomitant smallpox vaccine. An EB05 ≥ 2.0 was also identified for typhoid vaccine and the PT “Pericardial disease”; review of these typhoid vaccine reports revealed that all patients received smallpox vaccine concomitantly with typhoid vaccine. No other product-specific vaccine had an EB05 ≥ 2.0 for any myopericarditis-related PT.

4. Discussion

We performed a comprehensive review of post-licensure vaccine surveillance data on myopericarditis, using both a published case definition [14] and review of medical records to identify such reports. Smallpox vaccine remained the most commonly reported vaccine, while other reported vaccines were consistent with vaccine type recommended for the given age group of the patient and therefore might reflect relative frequencies of vaccine exposure per recommended schedules for vaccination [17,18]. Myopericarditis remained a rarely reported AE after vaccines (0.1% of reported AEs during the analytic period), and this analysis revealed no new or unexpected safety concerns.

Distribution of reports by sex was similar to previous case series among hospitalized pediatric and adult patients (Table 1). A case series describing myocarditis among children and adolescents 18 years of age and younger found a comparable proportion (57%) of cases among males [19], but a case series among adults hospitalized in a group of Finnish hospitals found a preponderance of cases among males<55 years of age [20]. A potential explanation for these differences by sex and age remains elusive, although findings in studies with BALB/c mouse models of acute coxsackievirus-induced myocarditis suggest possible biologic mechanisms [21,22]. The patients in both case series would be considered serious by definition (due to hospitalization); likewise, a large proportion of serious reports were observed in the VAERS data.

Reported case fatality after acute myocarditis among pediatric patients has been reported around 8% to 12% [23,24]. The high proportion of deaths reported among persons 18 years of age and younger in this analysis (Table 1) would seem unusual. However, biased reporting to VAERS can occur, and deaths after vaccination among otherwise healthy young people might be more prone to report compared to deaths among older or less healthy populations [10]. Conversely, younger persons (such as children) who experience mild myopericarditis might not be reported to VAERS; such lack of reporting would skew the proportion of reported deaths among this population. These and other limitations of VAERS will be discussed shortly.

The high proportion of reported myopericarditis after smallpox vaccine (Tables 2 and 3) likely reflects the known association between myopericarditis and smallpox vaccine [2,14], which is also reflected in the disproportionality analysis results. The preponderance of myopericarditis after smallpox vaccine reported among people 19 to 31 years of age (predominately male) in this analysis is consistent with smallpox vaccination among selected military personnel [25]. Indeed, during the analytic period, the military conducted active surveillance (and subsequent reporting to VAERS) of myopericarditis after smallpox vaccine [26]. Despite this potential simulated reporting, the most frequently reported vaccines, by age range, would not vary after discounting smallpox vaccine (Tables 3 and 4) (except among people 19–49 years of age). Disproportionate reporting of anthrax and typhoid vaccines and myopericarditis-related PTs likely reflect coadministration with smallpox vaccine, as was common practice in the military during the analytic period [26].

During 2009–2018, ACAM2000® was the smallpox vaccine in use (prior to 2008, D Pryx® was the smallpox vaccine used). Myopericarditis after ACAM2000 has been reported at rate of 5.7 per 1,000 doses administered [27]. A rate of 6.9 per 1,000 doses administered has been reported among people receiving their first dose of ACAM2000 [28]. The estimated reporting rate of myopericarditis we observed after smallpox vaccine during 2014–2018 (4.0 per 1,000 doses distributed) is comparable to these rates.
Other vaccines after which myopericarditis was reported largely reflect recommended vaccination schedules for people in the corresponding age groups [15,16]. Myopericarditis has not been described previously after hepatitis B, Haemophilus influenzae type b, 9-valent HPV, or live attenuated zoster vaccines that were licensed for use in the United States, and only sparse case reports describes myopericarditis after inactivated influenza and diphtheria, tetanus, and inactivated polio vaccines [9,29,30]. Myopericarditis has been reported after 4-valent HPV vaccine [31]. Of interest, myopericarditis is commonly caused by viral infections, [1] including varicella zoster virus [32]. Disabling smallpox vaccine, myopericarditis after live attenuated viral vaccines was reported infrequently (Tables 2 and 3), a result consistent with a past report describing no increased risk of myopericarditis after live attenuated virus vaccines (except smallpox vaccine) [7]. Together, these observations suggest that—aside from smallpox vaccine—myopericarditis after vaccines licensed for use in the United States is rare. As noted in the below paragraph, these reports do not establish a causal relationship between vaccines and myopericarditis.

VAERS is a passive surveillance system that gathers reports from across the United States, and can detect rare events [10], like myopericarditis, after vaccination. VAERS also shares the limitations of passive surveillance systems: under-reporting, reporting biases, inconsistent data quality and completeness, changes in reporting over time, and lack of an unvaccinated comparison group [10,13]. These limitations generally do not allow VAERS data to determine if a vaccine caused a particular adverse event, including myopericarditis or death. Also, because doses administered data were not available, we used doses distributed as the denominator in estimating reporting rates after smallpox vaccine. That our estimates (4.0 per 1,000 doses distributed) are comparable to known rates of myopericarditis after smallpox vaccine (5.7 per 1,000 doses administered) is reassuring. Also reassuring is the confirmation of the known association between smallpox vaccine and cardiac-related PTs on disproportionality analysis (EB05 > 2).

Given that smallpox vaccine continues to be administered to selected military and civilian personnel [25,33] and that new vaccines continue to be approved for use, continuing surveillance for myopericarditis after vaccination is warranted. However, this analysis revealed no unexpected safety concerns, and reports of myopericarditis after vaccines remain rare.

5. Note
This article reflects the views of the authors and should not be construed to represent FDA’s views or policies.

6. Disclaimer
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC), or the US Food and Drug Administration (FDA). Mention of a product or company name does not constitute endorsement by the CDC or FDA.

Declaration of Competing Interest
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material
Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2020.12.046.

References


From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 25 Mar 2021 18:17:00 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: WHO GACVS sub-committee - request for information
Attachments: Table 3a Daily VAW COVID19 Reports Overall Summary.pdf, Table 2 Weekly Prespecified Conditions of VAERS COVID19 Reports.pdf, Table 3a Daily VAW COVID19 Reports Overall Summary.pdf
Hi folks,

Please see below email chain. [b][/b]?

Tom,

Thanks!

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 1:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

Thanks.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 12:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information
Tom,
John is out today
Elaine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPP) <ayv6@cdc.gov>
Sent: Wednesday, March 17, 2021 12:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>
Subject: FW: WHO GACVS sub-committee - request for information

Thanks.

From: Phillips, Anastasia <Anastasia Phillips@health.wa.gov.au>
Sent: Wednesday, March 17, 2021 3:47 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPP) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis Pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvd3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia
Dear Tom,

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.
The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Sent: Monday, October 26, 2020 1:40 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Kristin Goddard, MPH (kristin.x.goddard@kp.org) <kristin.x.goddard@kp.org>
Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>
Subject: RE: RCA Outcome Questions/Recommendations

-Kayla

From: Hanson, Kayla E
Sent: Thursday, October 22, 2020 1:59 PM
To: Weintraub, Eric (CDC/DDID/NCEZID) <eiw8@cdc.gov>; Kristin Goddard, MPH (kristin.x.goddard@kp.org) <kristin.x.goddard@kp.org>
Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>
Subject: RCA Outcome Questions/Recommendations

Hi Kristin and Eric,

Jim and I have a list of outstanding questions...
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
☎ 1-715-221-6482 | ☎ 1-715-389-3880 | ✉ hanson.kayla@marshfieldresearch.org

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Myocarditis and pericarditis are rare following live viral vaccinations in adults

Jennifer Kuntz, Bradley Crane, Sheila Weinmann, Allison L. Naleway*, and Vaccine Safety Datalink Investigator Team

Center for Health Research, Kaiser Permanente Northwest, 3800 N. Interstate Ave., Portland, OR 97227, USA

Abstract

Reports of myocarditis and pericarditis following smallpox vaccination in adults suggested a need to assess inflammatory cardiac disease risk among adults who receive live viral vaccinations. From 1996 through 2007, among 416,629 vaccinated adults in the Vaccine Safety Datalink, we identified one probable pericarditis case and no cases of myocarditis in the 42 days following a live viral vaccination. Our self-controlled risk interval analysis found that, based on one case identified during the risk interval and 10 cases during the control interval, there is no increased risk of myopericarditis in the 42 days following vaccination (IRR, 0.57; 95% CI, 0.07, 4.51). Our study suggests that the occurrence of myopericarditis following live viral vaccination is rare with an estimated incidence of 0.24 per 100,000 vaccinated, which is not higher than the background rate and is much lower than the incidence rates reported following smallpox vaccination.

Keywords
Myocarditis; Pericarditis; Vaccination adverse effects

1. Introduction

Reports of cardiac complications – including myocarditis, pericarditis, and arrhythmias – following smallpox vaccination, have dated back to the 1950s in the United States, although a total of only six such cases were reported prior to 2003 [1–4]. This changed when, from December 2002 through December 2003, a campaign was held to vaccinate 540,824 U.S. military personnel against smallpox using DryVax vaccine. During this campaign, 67 cases of myocarditis or pericarditis were reported with an average period of 10 days between vaccination and symptom onset [5].

Although cardiovascular complications due to vaccination are rare, these reports of myocarditis and pericarditis following smallpox vaccination in adults have raised the issue

*Corresponding author. allison.naleway@kpchr.org (A.L. Naleway).
†The Vaccine Safety Datalink investigator team includes: Roger Baxter, Nicola Klein (Kaiser Permanente Northern California); Steven Jacobsen (Kaiser Permanente Southern California); Lisa Jackson (Kaiser Permanente Washington); Bradley Crane, Jennifer Kuntz, Allison Naleway, Sheila Weinmann (Kaiser Permanente Northwest); James Baggs, Robert Chen, Frank DeStefano, John Iskander (Centers for Disease Control and Prevention).
of assessing inflammatory cardiac disease risk following other live viral vaccinations in adults. We sought to determine the risk of myocarditis and pericarditis following the administration of non-smallpox, live viral vaccinations among adults.

2. Methods

We identified a retrospective cohort of adults 18 years and older who received a measles-mumps-rubella vaccine (MMR), varicella vaccine (VZV), oral polio vaccine (OPV), or yellow fever vaccine (YFV) between January 1, 1996 and December 31, 2007 at four integrated healthcare delivery organizations: Kaiser Permanente Northwest, Kaiser Permanente Washington (formerly Group Health), Northern California Kaiser Permanente, and Southern California Kaiser Permanente. These organizations collaborate with the Centers for Disease Control and Prevention (CDC) as the Vaccine Safety Datalink (VSD) to conduct population-based research on vaccine safety [6,7]. The cohort was restricted to patients with at least 6 months of health plan enrollment prior to their first live viral vaccination. We then identified cohort members who had a diagnosis of myocarditis or pericarditis within the study period at any point following vaccination.

Acute myocarditis was identified with the following ICD-9 codes: 422.0 (acute myocarditis in diseases classified elsewhere); 422.90 (acute myocarditis NOS); 422.91 (idiopathic myocarditis); 422.99 (other and unspecified acute myocarditis); and, 429.0 (myocarditis unspecified). Acute pericarditis was identified with ICD-9 code 420.x. We identified the earliest diagnosis during the study period and cases diagnosed prior to 1996 were excluded. We also collected information about comorbid conditions diagnosed prior to the myocarditis or pericarditis diagnosis date, including diabetes, hyperlipidemia, hypertension, coronary insufficiency, prior myocardial infarction, chronic ischemic heart disease, coronary artery disease, and connective tissue disorder.

During medical record abstraction, we confirmed that the cardiac event diagnosis was recorded in the medical record and the earliest diagnosis occurred during the study period. We excluded diagnoses that were miscoded or considered to be a ‘rule-out’ diagnosis, could not be confirmed because of a lack of information in the medical record, or occurred prior to 1996. We also collected information about cardiac symptoms, co-morbidities, and diagnostic tests (e.g., echocardiograms, chest x-rays, cardiac enzymes). A cardiology nurse and physician then further classified cases with validated diagnoses as definite, probable or possible according to surveillance case definitions for myocarditis and pericarditis developed by the U.S. Department of Defense and CDC for their smallpox vaccine program [8–10]. We defined definite pericarditis cases as those with at least two of the following criteria: presence of chest pain made worse by lying down and relieved by sitting up or leaning forward; pericardial rub or auscultatory sign with 1–3 components per beat; electrocardiogram with ST elevations, or PR depressions without reciprocal ST depressions; presence of abnormal collection of pericardial fluid on echocardiogram; or, histopathologic evidence of pericardial inflammation. Persons with elevated cardiac enzymes or evidence of myocardial inflammation plus at least two of the following criteria were considered definite myocarditis cases: presence of dyspnea, palpitations, or chest pain; electrocardiogram
(ECG) abnormalities; or evidence of focal or diffuse depressed left ventricular function identified by an imaging study.

We conducted a self-controlled risk interval analysis using conditional Poisson regression. Our analysis included possible, probable, and definite cases who were vaccinated during the study period, and we used a composite outcome of myopericarditis consistent with many of the previously published smallpox vaccine studies. We defined the risk interval as the 42-day window following YFV, VZV, OPV, or MMR vaccination; the control interval was defined as the time period 85 to 365 days following vaccination. We censored a ‘wash out’ period of 43 to 84 days after vaccination. We selected the 42-day exposure window based on prior smallpox vaccination investigations that suggested these cardiac events developed soon after vaccination at a mean onset time of 10 days [11]. We calculated an incidence rate ratio (IRR) and 95% confidence interval (CI), which compared the incidence of myopericarditis in the risk interval to incidence in the control interval.

This study was approved by the Institutional Review Boards at all participating sites.

3. Results

We identified 416,629 adults who received at least one live viral vaccine between 1996 and 2007 and met eligibility criteria (Fig. 1). Two hundred ninety-seven thousand doses of measles, mumps, or rubella-containing vaccine, 87,295 doses of VZV, 76,606 doses of YFV, and 35,291 doses of OPV were administered to this cohort during the study period. Of the 416,629 eligible vaccinated adults, 120 had a coded pericarditis diagnosis and 32 had a coded myocarditis diagnosis at any time following vaccination. After review of these potential cases, 54 (45%) had a validated pericarditis diagnosis and 18 (56%) had a validated myocarditis diagnosis. The remaining 80 potential cases were excluded because they had miscoded or rule-out diagnoses, lacked sufficient information in the medical record to confirm the diagnosis, or were diagnosed prior to 1996. Twelve (67%) of the myocarditis diagnoses occurred among 18–29-year-olds, whereas pericarditis was more evenly distributed across the age strata. Both diagnoses were more common in males than females (myocarditis: 79% male; pericarditis: 69% male). Hypertension (n = 16, 30%) and hyperlipidemia (n = 11, 20%) were common comorbid diagnoses in pericarditis cases. After adjudication, only 5 patients were classified as definite pericarditis and only 3 were classified as definite myocarditis cases according to the DoD/CDC definitions.

One probable pericarditis case occurred in the 42 days following vaccination; no myocarditis cases and no definite or possible pericarditis cases occurred in the 42-day period. The one probable pericarditis case occurred 36 days after YFV. This patient also received tetanus-diphtheria (Td) and meningococcal vaccines on the same day as YFV and inactivated polio, hepatitis A, and influenza vaccines in the four days after YFV. Thus, the incidence rate of diagnosed myopericarditis in the 42 days following vaccination with VZV, YFV, OPV, or MMR was 0.24 per 100,000 vaccinated. The remaining 71 definite, probable, and possible cases occurred at least 43 days after vaccination and were relatively evenly distributed over the course of the maximum of 10 years of follow-up after vaccination (Fig. 2). Only 10 of these cases occurred in the 85 to 365 days following vaccination control window. Based on
the one case identified during the risk interval and 10 cases that occurred during the control interval, we found no increased risk of myopericarditis in the 42 days following vaccination (IRR, 0.57; 95% CI, 0.07, 4.51).

4. Discussion

There are limited published data about cardiac events after non-smallpox vaccinations. This study evaluated myopericarditis risk after non-smallpox, live viral vaccination in a population-based cohort. Seven cases of pericarditis after hepatitis B and influenza vaccine were reported in 1980–90s [12,13]. In 2000, a case of myopericarditis in a 31-year old man was reported 2 days after diphtheria, tetanus and polio vaccination [14]. Additional research reported no detectable increase in the risk of myocardial infarction or stroke following influenza, tetanus, or pneumococcal vaccinations [15,16].

In the absence of additional incidence studies of non-smallpox vaccinations, we can only compare our rates to those from published smallpox vaccination studies [5,17]. Among U.S. military personnel, the observed incidence of myopericarditis that came to medical attention over a 30-day observation window following smallpox vaccination was 12.3 cases per 100,000 [5]. In turn, Engler et al. prospectively followed a cohort of 1081 healthy military personnel to identify cardiac symptoms, biomarkers (specifically troponin T), and ECG changes, and identified four cases of probable myocarditis and one case of suspected pericarditis in the 30 days after smallpox vaccination, resulting in a higher incidence of 463 cases per 100,000 [17]. While our study does not speak to risk related to smallpox vaccination, our results provide evidence for the lack of an association between other commonly-administered live viral vaccines and these cardiac outcomes.

Myocarditis and pericarditis are inflammatory processes with variable and unpredictable clinical presentations and course. Thus, diagnosis of these conditions is often difficult. Considering this, we acknowledge the potential for underestimation of the true occurrence of myocarditis and pericarditis, as patients may not present in the healthcare setting for these conditions or the diagnosis may not be accurately reflected in coded data. For example, the Engler et al. study reported a higher incidence of myopericarditis after vaccination through active follow up of vaccinated participants; the authors note that 3 of the 5 cases they observed would not have sought medical care for their symptoms outside of the study protocol [15]. Reducing the underestimation and misclassification of cases would require further enhancement of VSD active surveillance, an effort that would not be feasible, especially given the population size that would be needed to detect rare outcomes such as these.

Our study focused on non-smallpox, live viral vaccines recommended for previously unvaccinated adults, those without documented immunity, or those at increased risk for exposure or transmission, such as healthcare personnel or international travelers. Although a live attenuated influenza vaccine was licensed in 2003 for use in adults, we did not include it in our analysis since use of the vaccine in adults during most of the study period was limited in the VSD. A herpes zoster vaccine was licensed and recommended for adults 60 years of age and older in 2006, but also was not included in this analysis; a separate VSD study
reported no increased risk of myocarditis or pericarditis in the 1–42 days following zoster vaccination [18].

We found that the rate of myocarditis and pericarditis in the 42 days following VZV, YFV, OPV, or MMR vaccination was very low and was not statistically different than the rate of these events during unexposed, control intervals. These findings confirm that cardiovascular complications related to commonly-administered, live viral vaccination are rare in adults.

Acknowledgements

The authors thank Mindy Gramberg, RN and Stephen Fortmann, MD for their assistance with case adjudication.

Financial support for this study was provided in full by the Centers for Disease Control and Prevention (200–2002-00732), through America’s Health Insurance Plans. The manuscript was reviewed and approved through the clearance process of the Centers for Disease Control and Prevention prior to submission. The findings and conclusions in this report are those of the authors and do not necessarily represent the official positions of the Centers for Disease Control and Prevention or America’s Health Insurance Plans.

References


Fig. 1.
Identification and validation of myocarditis and pericarditis cases following live viral vaccination.
Fig. 2.
Distribution of myocarditis (n = 18) and pericarditis (n = 54) cases over time since live viral vaccination.
From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Thursday, March 4, 2021 7:12 AM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Romanik, Nikki Jo (CDC/OD/ODS) <kon6@cdc.gov>
Subject: Director’s Brief: Thursday March 4, 2021

Thursday March 4, 2021

- Cases: The current 7-day average of new cases decreased by 2.4% compared to the previous week. There has been a 7-week downward trend resulting in an overall 74.4% decline since the highest peak of the 7-day moving average of new cases on January 11, 2021 (249,360 to 63,938).
  - 28,514,774 COVID-19 cases reported as of Mar 2, 2021 with 54,276 new cases reported.
o The 7-day average number of new cases decreased by 2.4% to 63,938 new cases per day compared to the previous 7-day period.*

o During the 7 days ending March 1, 2021, regarding cases:
  - 26 (46.4%) jurisdictions are decreasing
  - 30 (53.6%) jurisdictions are increasing

*The current 7-day average of new cases is impacted by a historical correction of 2,990 and 1,840 cases reported by Texas on February 27, 2021 and March 1, 2021, respectively. The 7-day average number of new cases (excluding historical cases reported in the past two weeks) decreased by 3.4% to 63,248 new cases per day compared to the previous 7-day average of 65,485.

• Testing: RT-PCR test volume appears to be increasing. RT-PCR test positivity continues to decline (7-day average now 4.6%); 1 jurisdiction remains >=10% positivity (TX).
  - The national 7-day average test volume for Feb 18 – Feb 24, 2021, was 1,177,275 up 7.0% from 1,099,850 the previous 7-days
  - The national 7-day average percent positivity for Feb 22 – Feb 28, 2021, is 4.6%, down 0.7 percentage points from 5.3% the previous week
  - 7-day average positivity is high (>=10%) in 1 jurisdiction (2% of all jurisdictions): TX
  - 7-day average positivity is low (<5%) in 28 jurisdictions (55% of all jurisdictions)
  - Positivity is decreasing in 46 jurisdictions (90% of all jurisdictions)

• Hospitalizations: The new confirmed COVID-19 admissions 7-day average (5,650) has decreased 65.8% since the peak on January 9, 2021 (16,540)
  - The 7-day average number of new admissions of patients with confirmed COVID-19 decreased by 13.0% to 5,650 during the most recent week, Feb 23–Mar 1, 2021
  - The 7-day average number of hospitalized patients with confirmed COVID-19 decreased by 17.3% to 45,607 during the most recent week, Feb 23–Mar 1, 2021
  - The peak above refers to the date of the highest 7-day moving average
    - The single-day peaks are:
      - Admissions: Jan 05, 2021 – 18,009
      - Hospitalizations: Jan 05, 2021 – 125,422

• Deaths: The current 7-day average of new deaths decreased by 4.3% compared to the previous week. There has been a 7-week downward trend resulting in an overall 41.1% decline since the highest peak of the 7-day moving average of new deaths on January 13, 2021 (3,378 to 1,990).
  - 515,277 COVID-19 deaths reported as of Mar 2, 2021 with 2,103 new deaths reported.
  - The 7-day average number of new deaths decreased by 4.3% to 1,990 new deaths per day compared to the previous 7-day period.*

*The current 7-day average of new deaths is impacted by a historical correction of 806 deaths reported by California on February 25, 2021. The 7-day average number of new deaths (excluding historical deaths reported in the past two weeks) decreased by 9.8% to 1,875 new deaths per day compared to the previous 7-day average of 2,079.

• Emerging Variants: At least 48 jurisdictions with reported variant cases. CDC genomic surveillance activities continue to ramp up. There are more than 145,000 sequences in GISAID from U.S. submitters.
B.1.1.7 Variant
- Cumulative in US (AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, PR, RI, SC, TN, TX, UT, VA, WA, WI, WV, and WY)
  - **2,580* cases in 48 jurisdictions**
- As of March 3, 2021, there are two cases attributed to the B.1.1.7 variant that also contains the E484K substitution in GISAID in Oregon and New York City.

P.1 Variant
- Cumulative in U.S. (AK, FL, MD, MN, OK, and OR)
  - **11* cases in 6 jurisdictions**
  - (SBU) There are two cases in New Jersey attributed to the P.1 variant that CDC is not authorized to report publicly. This case is not reflected in the total variant case numbers shown above.

B.1.351 Variant
- Cumulative in US (CA, CT, DC, FL, GA, ID, IL, MA, MD, NC, NV, NY, SC, TN, TX, WA, VA)
  - **66* cases in 17 jurisdictions**
  - (SBU) There are two additional cases in New York, one additional case in Wyoming, and four additional cases in Washington attributed to the B.1.351 variant that CDC is not authorized to report publicly. These cases are not reflected in the total variant case numbers shown above.

Other Variants
- CDC is monitoring other variants in addition to the variants of concern highlighted above, including B.1.427/9, B.1.526, and P.2 variants of interest. Currently, through NS3 enhanced surveillance, state public health laboratories are asked to submit specimens that contain the E484K or N501Y substitutions or deletions in the S protein for sequencing, isolation, and further characterization at CDC.

- **Vaccine:** More than **52 million people or 15.9% of the population have received at least 1 dose.** Just reached an average of over 2 million doses administered per day
  - Overall, 80,540,474 vaccine doses have been administered.
    - In total, 15.9% (N= 52,855,579) of the population has received 1 or more doses.
    - 8.1% of the population (N= 26,957,804) has received two doses.
    - Progress towards 100M dose target (doses reported since 1/20/2021 [Day 41]): 64,015,193 doses
      - Overall, 7,218,655 doses have been administered in LTCFs
      - 4,669,986 people in LTCFs have received 1 or more doses
  - Doses in LTCF reported since 01/20/2021 (Day 41): 5,310,399 doses
  - Daily vaccine doses administered and reported to CDC increased to an average of **2,010,790 doses reported per day over the past week** (previous week: 1,454,731 doses reported per day, on average)
  - Retail Pharmacy Program: The Federal Retail Pharmacy Program is adapting to prioritize vaccinating all school staff and childcare workers during the month of March. CDC is also working with jurisdictions to prioritize this population in other delivery sites.
Each year CDC helps distribute and administer about 80 million vaccines through its Vaccines for Children Program – we’ve now accomplished that same yearly total in 11.5 weeks. Additionally, we’re now averaging 2 million doses administered per day.

Other Publications

*Lancet Child and Adolescent Health: Factors associated with severe outcomes in patients with multisystem inflammatory syndrome in children (MIS-C), March-October 2020.*

  - Paper describes 1,080 hospitalized patients ≤21 years with dates of MIS-C onset from March 11-October 10, 2020.
  - Outcomes of interest were ICU admission, decreased cardiac function, shock, myocarditis, and coronary artery abnormalities.
  - Demographic characteristics, signs and symptoms, and laboratory findings were assessed for associations with the outcomes, controlling for all pre-existing factors.
  - Primary results include:
    - Patients 6-12 years old were more likely to have severe outcomes compared to those under the age of 5 years, and these risks were even higher for patients 13-20 years old.
    - Male sex was associated with coronary artery abnormalities and myocarditis.
    - Non-Hispanic Black patients were more likely to be admitted to the ICU and experience decreased heart function.
    - Patients with shortness of breath and abdominal pain were more likely to be admitted to the ICU.
    - Elevated levels of certain lab markers (troponin, BNP, and proBNP, as well as d-dimer, CRP, and ferritin) and lower levels of lymphocytes and platelets were linked to ICU admission, shock and decreased cardiac function.

- Manuscript being published 3/4

**MMWR Releases**

- Two *MMWR* reports related to COVID-19 are scheduled as part of the regular issue of the Weekly, with the embargo lifting on Thursday, March 4, at 1 pm. Please note that the titles, content, and timing might change.
FYI
Updated the website today on national seroprevalence from two rounds in January. See below.
https://covid.cdc.gov/covid-data-tracker/#national-lab
Hi Kristin and Eric,

Jim and I have a list of outstanding questions
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
☎ 1-715-221-6482 | ☎ 1-715-389-3880 | ☐ hanson.kayla@marshfieldresearch.org

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From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Thu, 4 Mar 2021 12:11:49 +0000
To: Walensky, Rochelle (CDC/OD)
Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD); Romanik, Nikki Jo (CDC/OD/OCs)
Subject: Director’s Brief: Thursday March 4, 2021

Thursday March 4, 2021

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<tr>
<th>COVID-19 Summary</th>
<th>Cumulative Total</th>
<th>Daily</th>
<th>7-Day Daily Average</th>
<th>Change from Prior 7-Day Period</th>
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<td>Cases†,‡</td>
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<td>54,276</td>
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Source: HHS Protect; DSEW

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<th>COVID-19 Vaccinations in the United States‡</th>
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<tbody>
<tr>
<td>Overall US</td>
</tr>
<tr>
<td>Total Doses Allocated: 163,759,745</td>
</tr>
<tr>
<td>Total Doses Delivered: 107,028,890</td>
</tr>
<tr>
<td>Total Doses Administered: 80,540,474</td>
</tr>
<tr>
<td>Number of People Receiving ≥1 Dose (%) Population: 52,855,579 (15.9%)</td>
</tr>
<tr>
<td>Number of People Receiving 2 Doses (%) Population: 26,957,804 (8.1%)</td>
</tr>
</tbody>
</table>

Data as of Mar 3, 2021, 06:00 ET
Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID-19 Data Tracker
Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 (overall); 5,310,399 (LTCF)

1 These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.
2 Time period: Jan 22, 2020 – Mar 2, 2021; confirmed and probable cases.
3 California reported 806 historical deaths on Feb 25, and Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. This will temporarily impact rates and averages. Beginning Feb 24, 2021, South Carolina reconciles their historical data every Wednesday.
4 Time period: Aug 1, 2020 – Mar 1, 2021; (All) includes both confirmed and suspect cases.
7 Includes data for US States, DC, US Territories, and Federal entities, and pharmacies (see table on last page for details). Total doses allocated are through Mar 29, 2021.

- Cases: The current 7-day average of new cases decreased by 2.4% compared to the previous week. There has been a 7-week downward trend resulting in an overall 74.4% decline since the highest peak of the 7-day moving average of new cases on January 11, 2021 (249,360 to 63,938).
  - 28,514,774 COVID-19 cases reported as of Mar 2, 2021 with 54,276 new cases reported.
  - The 7-day average number of new cases decreased by 2.4% to 63,938 new cases per day compared to the previous 7-day period.*
  - During the 7 days ending March 1, 2021, regarding cases:
    - 26 (46.4%) jurisdictions are decreasing
    - 30 (53.6%) jurisdictions are increasing
The current 7-day average of new cases is impacted by a historical correction of 2,990 and 1,840 cases reported by Texas on February 27, 2021 and March 1, 2021, respectively. The 7-day average number of new cases (excluding historical cases reported in the past two weeks) decreased by 3.4% to 63,248 new cases per day compared to the previous 7-day average of 65,485.

- **Testing:** RT-PCR test volume appears to be increasing. RT-PCR test positivity continues to decline (7-day average now 4.6%); 1 jurisdiction remains >=10% positivity (TX).
  - The national 7-day average test volume for Feb 18 – Feb 24, 2021, was 1,177,275 up 7.0% from 1,099,850 the previous 7-days
  - The national 7-day average percent positivity for Feb 22 – Feb 28, 2021, is 4.6%, down 0.7 percentage points from 5.3% the previous week
  - 7-day average positivity is high (>=10%) in 1 jurisdiction (2% of all jurisdictions): TX
  - 7-day average positivity is low (<5%) in 28 jurisdictions (55% of all jurisdictions)
  - Positivity is decreasing in 46 jurisdictions (90% of all jurisdictions)

- **Hospitalizations:** The new confirmed COVID-19 admissions 7-day average (5,650) has decreased 65.8% since the peak on January 9, 2021 (16,540)
  - The 7-day average number of new admissions of patients with confirmed COVID-19 decreased by 13.0% to 5,650 during the most recent week, Feb 23–Mar 1, 2021
  - The 7-day average number of hospitalized patients with confirmed COVID-19 decreased by 17.3% to 45,607 during the most recent week, Feb 23–Mar 1, 2021
  - The peak above refers to the date of the highest 7-day moving average
    - The single-day peaks are:
      - Admissions: Jan 05, 2021 – 18,009
      - Hospitalizations: Jan 05, 2021 – 125,422

- **Deaths:** The current 7-day average of new deaths decreased by 4.3% compared to the previous week. There has been a 7-week downward trend resulting in an overall 41.1% decline since the highest peak of the 7-day moving average of new deaths on January 13, 2021 (3,378 to 1,990).
  - 515,277 COVID-19 deaths reported as of Mar 2, 2021 with 2,103 new deaths reported.
  - The 7-day average number of new deaths decreased by 4.3% to 1,990 new deaths per day compared to the previous 7-day period.*

*The current 7-day average of new deaths is impacted by a historical correction of 806 deaths reported by California on February 25, 2021. The 7-day average number of new deaths (excluding historical deaths reported in the past two weeks) decreased by 9.8% to 1,875 new deaths per day compared to the previous 7-day average of 2,079.

- **Emerging Variants:** At least 48 jurisdictions with reported variant cases. CDC genomic surveillance activities continue to ramp up. There are more than 145,000 sequences in GISAID from U.S. submitters.
  - B.1.1.7 Variant
Cumulative in US (AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, PR, RI, SC, TN, TX, UT, VA, WA, WI, WV, and WY)
- **2,580* cases in 48 jurisdictions**
  - As of March 3, 2021, there are two cases attributed to the B.1.1.7 variant that also contains the E484K substitution in GISAID in Oregon and New York City.

**P.1 Variant**
- Cumulative in U.S. (AK, FL, MD, MN, OK, and OR)
  - **11* cases in 6 jurisdictions**
  - *(SBU)* There are two cases in New Jersey attributed to the P.1 variant that CDC is not authorized to report publicly. This case is not reflected in the total variant case numbers shown above.

**B.1.351 Variant**
- Cumulative in US (CA, CT, DC, FL, GA, ID, IL, MA, MD, NC, NV, NY, SC, TN, TX, VA, WA)
  - **66* cases in 17 jurisdictions**
  - *(SBU)* There are two additional cases in New York, one additional case in Wyoming, and four additional cases in Washington attributed to the B.1.351 variant that CDC is not authorized to report publicly. These cases are not reflected in the total variant case numbers shown above.

**Other Variants**
- CDC is monitoring other variants in addition to the variants of concern highlighted above, including B.1.427/9, B.1.526, and P.2 variants of interest. Currently, through NS3 enhanced surveillance, state public health laboratories are asked to submit specimens that contain the E484K or NS01Y substitutions or deletions in the S protein for sequencing, isolation, and further characterization at CDC.

- **Vaccine:** More than 52 million people or 15.9% of the population have received at least 1 dose. Just reached an average of over 2 million doses administered per day
  - Overall, 80,540,474 vaccine doses have been administered.
    - In total, 15.9% (N= 52,855,579) of the population has received 1 or more doses.
    - 8.1% of the population (N= 26,957,804) has received two doses.
    - Progress towards 100M dose target (doses reported since 1/20/2021; Day 41):
      - 64,015,193 doses
        - Overall, 7,218,655 doses have been administered in LTCFs
        - 4,669,986 people in LTCFs have received 1 or more doses
  - Doses in LTCF reported since 01/20/2021 (Day 41): 5,310,399 doses
  - Daily vaccine doses administered and reported to CDC increased to an average of 2,010,790 doses reported per day over the past week (previous week: 1,454,731 doses reported per day, on average).
  - Retail Pharmacy Program: The Federal Retail Pharmacy Program is adapting to prioritize vaccinating all school staff and childcare workers during the month of March. CDC is also working with jurisdictions to prioritize this population in other delivery sites.
o Each year CDC helps distribute and administer about 80 million vaccines through its Vaccines for Children Program – we’ve now accomplished that same yearly total in 11.5 weeks. Additionally, we’re now averaging 2 million doses administered per day.

- Other Publications

*Lancet Child and Adolescent Health: Factors associated with severe outcomes in patients with multisystem inflammatory syndrome in children (MIS-C), March-October 2020.*

  - Paper describes 1,080 hospitalized patients <21 years with dates of MIS-C onset from March 11-October 10, 2020.
  - Outcomes of interest were ICU admission, decreased cardiac function, shock, myocarditis, and coronary artery abnormalities.
  - Demographic characteristics, signs and symptoms, and laboratory findings were assessed for associations with the outcomes, controlling for all pre-existing factors.
  - Primary results include:
    - Patients 6-12 years old were more likely to have severe outcomes compared to those under the age of 5 years, and these risks were even higher for patients 13-20 years old.
    - Male sex was associated with coronary artery abnormalities and myocarditis.
    - Non-Hispanic Black patients were more likely to be admitted to the ICU and experience decreased heart function.
    - Patients with shortness of breath and abdominal pain were more likely to be admitted to the ICU.
    - Elevated levels of certain lab markers (troponin, BNP, and proBNP, as well as d-dimer, CRP, and ferritin) and lower levels of lymphocytes and platelets were linked to ICU admission, shock and decreased cardiac function.

- Manuscript being published 3/4

*MMWR Releases*

- Two *MMWR* reports related to COVID-19 are scheduled as part of the regular issue of the Weekly, with the embargo lifting on Thursday, March 4, at 1 pm. Please note that the titles, content, and timing might change.
FYI
Updated the website today on national seroprevalence from two rounds in January. See below.
https://covid.cdc.gov/covid-data-tracker/#national-lab
From: Weintraub, Eric (CDC/DDID/NCEZID/DHQD)
Sent: Fri, 23 Oct 2020 14:22:05 +0000
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQD); Panagiotakopoulos, Lakshmi (CDC/DDID/NCEZID/DHQD); Myers, Tanya R. (CDC/DDID/NCEZID/DHQD); McNeil, Michael (CDC/DDID/NCEZID/DHQD); Kamidani, Satoshi (CDC/DDID/NCEZID/DHQD)
Subject: FW: RCA Outcome Questions/Recommendations

Fyi – see questions and comments below

From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Sent: Thursday, October 22, 2020 2:59 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQD) <eiw8@cdc.gov>; Kristin Goddard, MPH (kristin.x.goddard@kp.org) <kristin.x.goddard@kp.org>
Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>
Subject: RCA Outcome Questions/Recommendations

Hi Kristin and Eric,

Jim and I have a list of outstanding questions
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
☎ 1-715-221-6482 | ☎ 1-715-389-3880 | ✉ hanson.kayla@marshfieldresearch.org
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Hi there,

Kristin

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQ5) <eiw8@cdc.gov>
Sent: Monday, October 26, 2020 10:51 AM
To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard <Kristin.X.Goddard@kp.org>
Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>
Subject: RE: RCA Outcome Questions/Recommendations

Caution: This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.

-Kayla

From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Sent: Monday, October 26, 2020 1:40 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ5) <eiw8@cdc.gov>; Kristin Goddard, MPH (kristin.x.goddard@kp.org) <kristin.x.goddard@kp.org>
Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>
Subject: RE: RCA Outcome Questions/Recommendations

From: Hanson, Kayla E
Sent: Thursday, October 22, 2020 1:59 PM
To: Weintraub, Eric (CDC/OID/NCEZID) <eiw8@cdc.gov>; Kristin Goddard, MPH (kristin.x.goddard@kp.org) <kristin.x.goddard@kp.org>
Hi Kristin and Eric,

Jim and I have a list of outstanding questions.
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
☎ 1-715-221-6482 | ☎ 1-715-389-3880 | ✉ hanson.kayla@marshfieldresearch.org

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John,

Please see revised response and let me know if you want edits.

Thanks,

Elaine
Hi John,
Please let me know if this response needs edits.
Thanks,
Elaine
Sincerely,

From: CISA Response (CDC)
Sent: Monday, January 18, 2021 9:54:58 AM (UTC-05:00) Eastern Time (US & Canada)
To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management; COVID19VaxSafety
Cc: CISA Response (CDC)
Subject: RE: RESPONSE REQUIREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179

Hi COVID Vaccine Inquiry Management Team (Sarah),

Thank you.

Theresa

From: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eocevent168@cdc.gov>
Sent: Sunday, January 17, 2021 3:30 PM
To: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: Re: RESPONSE REQUIREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179

Hi CISA and Vaccine Safety colleagues,

Sincerely.
Sarah Reagan-Steiner
Further CDC Resources:

From: CDC IMS 2019 NCOV Response MCCM INFO <eocevent355@cdc.gov>
Sent: Friday, January 15, 2021 10:37 AM
To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eocevent168@cdc.gov>
Cc: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>
Subject: Fw: RESPONSE REQUIREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179

See the below request
Thanks

Health Systems and Worker Safety (HSWS, formerly MCCM) Task Force
CDC COVID-19 Response

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>
Sent: Thursday, January 14, 2021 10:05 PM
To: CDC IMS 2019 NCOV Response MCCM INFO <eocevent355@cdc.gov>
Subject: RESPONSE REQUIREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179

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.

Things to note about this case: Phone call being escalated about covid-19 vaccines and people who have had Thrombocytopenia

1. 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.

MD PR# 11109

----------------------- Original Message -----------------------
From: COVID-19 MCCM;
Received: Tue Jan 12 2021 12:49:13 GMT-0600 (Central Standard Time)
To: CDC Info Response; CDC Inbound Email;
Subject: Fw: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [Vaccine Side Effects] [CDC-1255677-W2H7Z7] CRM:06132319

CDC Info,

This is a vaccine-related question and should be sent to Vaccine Inquiry Management (VIM).

Thanks,
HSWS

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>
Sent: Tuesday, January 12, 2021 11:30 AM
To: CDC IMS 2019 NCOV Response MCCM INFO <eocevent355@cdc.gov>
Subject: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [Vaccine Side Effects] [CDC-1255677-W2H7Z7] CRM:06132319

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.

Things to note about this case: None

1. This inquiry is being escalated because the answer could not be found in CDC resources.
1. During the call, phone agent provided PRs #11109 to inquirer.
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.

JJ/LD PR# 11109/14312
The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

Name:  
E-mail:  
Phone:  
Date, Time ET: 1/11/2021, 10:29 AM
General Public: (My son took the covid-19 vaccine. I want to know if there's any information about people having Thrombocytopenia have there been any cases?)
Happy Monday!

**March 8, 2021, 5 Articles**

**Antibody Resistance of SARS-CoV-2 Variants**

**B.1.351 and B.1.1.7**, Nature Wang et al. (March 8, 2021)

B.1.351, which has the E484K mutation, is resistant to multiple monoclonal antibodies and threatens the protection of current mRNA vaccines.

Note: Changes in neutralization IC50 of authorized or investigational therapeutic monoclonal antibodies against B.1.1.7, WT (WA1), B.1.351 viruses.

Note: Changes in neutralization IC50 of sera from vaccinees against B.1.1.7, WT (WA1), B.1.351 viruses.
Among 192,550 adults hospitalized with COVID-19 in 555 US medical centers from March-August 2020, in-hospital mortality was high (13.6%) and increased with increasing age; there was a significant reduction in mortality from March (22.1%) to August (6.5%).

**Outcomes and Mortality Among Adults Hospitalized With COVID-19 at US Medical Centers.** JAMA Nguyen et al. (March 5, 2021)

Two doses of mRNA vaccine are needed to reach equivalently high levels of IgG and neutralization activity among seropositive, with and without history of prior COVID-19, and seronegative persons.

**Comparison of IgG and neutralizing antibody responses after one or two doses of COVID-19 mRNA vaccine in previously infected and uninfected persons.** medRxiv Demonbreun et al. (Preprint, March 8, 2021)

mRNA vaccine induced significant antibody immunological memory responses following two doses among seronegative persons and one dose among seropositive persons.

**Longitudinal Analysis Reveals Distinct Antibody and Memory B Cell Responses in SARS-CoV2 Naive and Recovered Individuals Following mRNA Vaccination.** medRxiv Goel et al. (Preprint, March 6, 2021)

Professional athletes with prior COVID-19 illness have low prevalence of inflammatory heart disease and can safely return to play with implementation of current cardiovascular risk stratification practices.

Cross-sectional study of 789 professional athletes who underwent return-to-play cardiac screening.
Prevalence of inflammatory heart disease among professional athletes with prior COVID-19 infection who received systematic return-to-play cardiac screening. JAMA Cardiology Martinez et al. (March 4, 2021)

30 (3.8%) athletes received additional testing after screening; of whom 5 (0.6%) has inflammatory heart disease: 3 with myocarditis and 2 with pericarditis.

All 5 athletes had preceding symptoms consistent with moderate COVID-19 illness (such as loss of taste and smell, nonspecific fatigue, and cough without dyspnea).
Hi folks,

Please see below email chain:

Tom: Thanks!

John

Thanks.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQD) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 12:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQD) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information
Thanks.

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia
Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I’m happy to talk when convenient. I’m Cc’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.
The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
Hi John,

Agam

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, January 14, 2021 11:41 PM
To: Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>
Subject: RE: VaST update
Hi Agam,

Please see results of a search I did a bit ago. From what I see, there are:

- John

From: Broder, Karen (CDC/DDID/NCEZID/DHQPP) <krb2@cdc.gov>
Sent: Thursday, January 14, 2021 11:24 PM
To: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPP) <ayv6@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQPP) <fxd1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQPP) <tsh3@cdc.gov>
Subject: RE: VaST update

Agam, can you and John connect?

Thanks

Karen

From: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>
Sent: Thursday, January 14, 2021 11:06 PM
To: Broder, Karen (CDC/DDID/NCEZID/DHQPP) <krb2@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPP) <ayv6@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQPP) <fxd1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQPP) <tsh3@cdc.gov>
Subject: RE: VaST update

Hi Karen,

Thanks for the heads up! Looking forward to presenting with you.

- John

From: Broder, Karen (CDC/DDID/NCEZID/DHQPP) <krb2@cdc.gov>
Sent: Thursday, January 14, 2021 10:35 PM
To: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQ) <tsh3@cdc.gov>

Subject: VaST update

John,

Hello. For the VaST meeting TUES, I was asked

Thanks,

Karen
From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)  
Sent: Sun, 18 Apr 2021 14:32:55 +0000  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)  
Subject: RE: To be sure you are aware  
Attachments: All vax_myocarditis.rtf

Tom, John:  
FYI-

Elaine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
Sent: Saturday, April 17, 2021 10:09 PM  
To: Meissner, Cody <cmeissner@tuftsmedicalcenter.org>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>  
Cc: dbalaguru@mgh.harvard.edu  
Subject: RE: To be sure you are aware

Hi Cody,

Good to hear from you and I hope you are doing well. There have been reports of myocarditis following mRNA vaccines. I'm including John Su, VAERS team lead, for his awareness. Take care.

Regards,

Tom

From: Meissner, Cody <cmeissner@tuftsmedicalcenter.org>  
Sent: Thursday, April 15, 2021 2:21 PM  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
Cc: dbalaguru@mgh.harvard.edu  
Subject: To be sure you are aware

Great presentation to ACIP yesterday,

Regards,
Cody

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Tufts Medical Center HIPAA Hotline at (617) 636-4422. If the e-mail was sent to you in error but does not contain patient information, contact the sender and properly dispose of the e-mail.

Please consider the environment and the security of the information contained within or attached to this e-mail before printing or saving to an insecure location.
From: Weintraub, Eric (CDC/DDID/NCEZID/DHQ)
Sent: Mon, 19 Apr 2021 16:06:25 +0000
To: Scotty, Erica J
Cc: Hanson, Kayla E
Subject: RE: VSD COVID19 DXIDs

Thanks for the reminder that I need to update our master list!

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Monday, April 19, 2021 12:05 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Thanks,

Erica

From: Scotty, Erica J
Sent: Monday, March 15, 2021 11:04 AM
To: 'Weintraub, Eric (CDC/DDID/NCEZID/DHQ)' <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs
Thanks,

Erica

From: Scotty, Erica J
Sent: Thursday, February 11, 2021 1:40 PM
To: 'Weinraub, Eric (CDC/DDID/NCEZID/DHQ)' <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Thanks,

Erica

From: Scotty, Erica J
Sent: Monday, January 11, 2021 11:41 AM
To: 'Weinraub, Eric (CDC/DDID/NCEZID/DHQ)' <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Here are a few more:
Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Sent: Monday, December 21, 2020 3:58 PM
To: Scotty, Erica J <SCOTTY.ERIC@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] Re: VSD COVID19 DXIDs

Crazy!!

From: Scotty, Erica J <SCOTTY.ERIC@marshfieldresearch.org>
Sent: Monday, December 21, 2020 4:54:43 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Here are new DXIDs for the week:
Thanks,

Erica

From: Scotty, Erica J
Sent: Tuesday, December 15, 2020 7:56 AM
To: 'Weintraub, Eric (CDC/DDID/NCEZID/DHQD)' <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We had an issue with our DXID and lab file refresh yesterday. They should be up-to-date now.

Thanks,

Erica

From: Scotty, Erica J
Sent: Monday, November 30, 2020 9:29 AM
Hi Eric,

Here are the new DXIDs for this week:

Thanks,

Erica

From: Scotty, Erica J  
Sent: Monday, November 16, 2020 12:36 PM  
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ); hancock@cdc.gov  
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@mcrl.mfdclin.edu>  
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are a few more:
Thanks,

Erica

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Monday, November 02, 2020 3:27 PM
To: Weinraub, Eric (CDC/DDID/NCEZID/DHQG) <ew8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We have more to add again.

Thanks,
Hi Eric,

We have a few new DXIDs.

Thanks,

Erina
From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Wednesday, September 2, 2020 11:17 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Sent: Wednesday, September 02, 2020 7:03 AM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs
Hi Eric,

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Tuesday, August 18, 2020 12:04 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs
Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Sent: Tuesday, August 11, 2020 9:24 AM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

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Do you mind sending over the text for these as well – I’ll make the changes and add them in:

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Monday, August 10, 2020 11:06 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

(b)(5)

Thanks,
Hi Eric,

Thanks,

**Erica Scotty**  
Research Programmer/Analyst Senior | Office of Research Computing & Analytics  
Marshfield Clinic Health System  
**Office:** 715-221-8066 | **Ext:** 1-8066

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, March 4, 2021 9:29 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) <gtv2@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: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPI) <erm4@cdc.gov>
Sent: Thursday, March 4, 2021 8:52 AM
To: Su, John (CDC/DDID/NCEZID/DHQPI) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQPI) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQPI) <tsh3@cdc.gov>; Dua, Anamika (CDC/DDID/NCEZID/DHQPI) <qtv2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPI) <ayv6@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQPI) <ltd8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all,

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

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force
CDC Coronavirus Disease 2019 (COVID-19) Response | eoevent168@cdc.gov

Further CDC Resources:

COVID-19 What’s New
CDC Health Alert Network (HAN)
From: CDCInfoResponse <cdcinforeponse@cdcinquiry.onmicrosoft.com>
Sent: Wednesday, March 3, 2021 1:50 PM
To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eoevent168@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: [redacted]
Question: From the Israel vaccine adverse event monitoring team:
We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC.

Optional Information

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

PII Extraction:
Yea, I’ll be updating the list this week – have a bunch to update!!!

Here are a few more:

Thanks,

Erica
To: Scotty, Erica J <SCOTTY.ERIC@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] Re: VSD COVID19 DXIDs

Crazy!!

From: Scotty, Erica J <SCOTTY.ERIC@marshfieldresearch.org>
Sent: Monday, December 21, 2020 4:54:43 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

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To: 'Weintraub, Eric (CDC/DDID/NCEZID/DHQ)' <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We had an issue with our DXID and lab file refresh yesterday. They should be up-to-date now.

Here are some new DXIDs for this week:
Thanks,

Erica

From: Scotty, Erica J  
Sent: Monday, November 30, 2020 9:29 AM  
To: 'Weintraub, Eric (CDC/DDID/NCEZID/DHQI)' <eiw8@cdc.gov>  
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>  
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are the new DXIDs for this week:

Thanks,

Erica

From: Scotty, Erica J  
Sent: Monday, November 16, 2020 12:36 PM  
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eiw8@cdc.gov>
Hi Eric,

Here are a few more:

Thanks,

Erica
Thanks,

Erica

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Monday, October 12, 2020 2:31 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQPD) <eim8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We have a few new DXIDs.
Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eiw8@cdc.gov>
Sent: Wednesday, September 02, 2020 10:20 AM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

Thanks,

Erica

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Wednesday, September 2, 2020 11:17 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eiw8@cdc.gov>
Sent: Wednesday, September 02, 2020 7:03 AM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Hi Eric,
Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eiw8@cdc.gov>
Sent: Tuesday, August 11, 2020 9:24 AM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

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From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Sent: Monday, August 10, 2020 11:06 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Thanks,

Erica

From: Scotty, Erica J
Sent: Monday, July 20, 2020 12:54 PM
To: 'Weintraub, Eric (CDC/DDID/NCEZID/DHQ)' <eiw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: VSD COVID19 DXIDs

Hi Eric,

Thanks,

Erica Scotty  
Research Programmer/Analyst Senior | Office of Research Computing & Analytics  
Marshfield Clinic Health System  
Office: 715-221-8066 | Ext: 1-8066

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Perfect – updating the list tomorrow morning!

thanks

---

Here are a couple more DXIDs:

(b)(5), (b)(8)

Thanks,

Erica

---

Here are a few more:

(b)(5), (b)(8)
Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQAP) <eiw8@cdc.gov>
Sent: Monday, December 21, 2020 3:58 PM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] Re: VSD COVID19 DXIDs

Crazy!!

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Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs

Here are new DXIDs for the week:
Hi Eric,

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Here are some new DXIDs for this week:

Thanks,

Erica
Here are the new DXIDs for this week:

(b)(5), (b)(6)

Thanks,

Erica

From: Scotty, Erica J
Sent: Monday, November 16, 2020 12:36 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eihw8@cdc.gov>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@mcrf.mldclin.edu>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are a few more:
Hi Eric,

We have more to add again.

Thanks,

Erica
Hi Eric,

We have a few new DXIDs.

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Wednesday, September 02, 2020 10:20 AM
To: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs
From: Scotty, Erica J <SCOTTY.ERIC@marshfieldresearch.org>
Sent: Wednesday, September 2, 2020 11:17 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
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Subject: RE: VSD COVID19 DXIDs

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Sent: Wednesday, September 02, 2020 7:03 AM
To: Scotty, Erica J <SCOTTY.ERIC@marshfieldresearch.org>
Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

Hi Eric,

Erica
Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>
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Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
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Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>
Subject: RE: VSD COVID19 DXIDs
Hi Eric,

Thanks,

Erica Scotty
Research Programmer/Analyst Senior | Office of Research Computing & Analytics
Marshfield Clinic Health System

Office: 715-221-8066 | Ext: 1-8066

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Thanks, Tom.

Theresa

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
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) <ltd8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks Tom

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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) <ltd8@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401
Hi all,

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

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@cdcinquiry.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

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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:
From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 12 Apr 2021 22:58:32 +0000
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: RE: April 12 VaST call - draft agenda and presentations

• John

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Monday, April 12, 2021 6:48 PM
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>
Subject: FW: April 12 VaST call - draft agenda and presentations

FYI – let me know your thoughts.

From: Jay Montgomery
Sent: Monday, April 12, 2021 6:41 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Renata Engler LC COLLINS <limone.c.collins.civ@mail.mil>
Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Dr. Markowitz,

Respectfully,
Jay Montgomery
On Monday, April 12, 2021, 11:14 AM, Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov> wrote:

Dear Jay and Renata,

Thank you again for your presentations.

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

From: Jay Montgomery
Sent: Sunday, April 11, 2021 7:14 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQI) <dzg2@cdc.gov>
Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Drs. Markowitz and Gee,
Please find attached my slide deck for Monday’s VaST presentation on Myocarditis following COVID-19 Vaccination. Please let me know if anything else is required.

I assume I will be receiving a Zoom Invite for Monday? Please be sure to send it to my civilian e-mail address, as my government laptop cannot accept ZOOM conferences. As I am on the road, I would appreciate the opportunity to call in early to be sure we have a good connection and everything works as expected.

I very much look forward to sharing with the VaST team the findings of our review.

R/

Dr. Jay Montgomery

In a message dated 4/9/2021 12:22:41 PM Eastern Standard Time, lem2@cdc.gov writes:

Dear all,

Thank you for agreeing to present to the VaST next week. Attached is the current agenda, with times.

Please send your PowerPoint presentations to me and Julianne Gee (copied here), by Monday morning at 10 am.

I will send pdfs of presentations to the VaST members and other call attendees. Our administrative assistant will advance slides for you during the call.

Thank you and let me know if you have any questions.

Lauri

Lauri Markowitz, MD
VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lcm2@cdc.gov>
Sent: Thursday, April 8, 2021 2:01 PM
To: Forshee, Richard (FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Cunningham, Fran <Fran.Cunningham@va.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Su, John R CAPT USPHS (USA) <ezu2@cdc.gov>; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) <limone.c.collins.civ@mail.mil>
Cc: Shimabukuro, Tom T CAPT USPHS (USA) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQ) <dzg2@cdc.gov>
Subject: [Non-DoD Source] April 12 VaST draft agenda and proposed times

Dear all,

Please see below the approximate times planned for your talks on the VaST call next Monday. Let me know if you feel any revisions are needed.

April 12

Thank you all for presenting to VaST.
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: JANIN, Annick <janina@who.int>  
Sent: Thursday, April 1, 2021 8:44 AM  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>  
Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; Phillips, Anastasia <anastasia.phillips@health.wa.gov.au>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>  
Subject: RE: [EXT] RE: WHO GACVS sub-committee - request for information

Dear Tom,

Thank you these data are very useful.

I have one question related to thrombotic events (I have highlighted relevant sections below):

Would it be possible ...

Kind regards
Annick
Hi Anastasia,

Could it be shared with the GACVS COVID-19 subcommittee members first and then shared with the broader GACVS if the subcommittee member think it will be helpful? Also, attached are some ACIP COVID-19 vaccine safety technical subgroup presentations. Please treat these as confidential as well. Thanks.

Tom

---

Dear Tom

Thank you for providing this information. Are you happy for this to be provided to the GACVS members in writing (in strict confidence), or would you prefer a verbal update be provided?

Many thanks again
Anastasia
Hi Anastasia – Please keep this information close hold.

Tom

From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Friday, March 19, 2021 1:01 AM
To: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQIP) <avv6@cdc.gov>
Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DPHHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DPHHSIS/CGH/GID) <lyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom
Thank you for sharing this comprehensive piece of work. I have shared it with GACVS sub-committee members only and in confidence.

I have set up a meeting via MS Teams for next week. It would be helpful to discuss what analyses CDC may be able to share with GACVS members going forward, in response to further issues identified internationally.

I have also included Kristine Macartney in the meeting request (GACVS member and NCIRS Director) as there may be a couple of other related issues to discuss. Please feel free to forward the invitation to anyone else in your organization as required. Rita, I have included you in the invitation in case you would like to join.

Many thanks again
Anastasia

From: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>
Sent: Friday, 19 March 2021 12:40 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <lyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: RE: WHO GACVS sub-committee - request for information

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

Thanks, Tom! Anastasia, I would interpret this as being that it could go to the GACVS sub-committee but not the larger group of participants.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Thursday, March 18, 2021 12:29 PM
To: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <lyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: RE: WHO GACVS sub-committee - request for information

Dear Anastasia,

I have received permission to confidentially share this draft manuscript with is under review at Vaccine. Please do not share outside of you need-to-know group. We hope it will be published soon
I have standing meetings starting at 8am, but could do 7:30am next week if that works.

Regards,

Tom

From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>  
Sent: Wednesday, March 17, 2021 3:47 AM  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>  
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>  
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>  
Sent: Wednesday, 17 March 2021 6:43 AM  
To: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>  
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>
Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I’m happy to talk when convenient. I’m CC’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Monday, March 8, 2021 10:05 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis PILllsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>
Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks
Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
Thanks to both of you for your comments. I know everyone is busy with other things at the moment.

Hi Lauri,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329
Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

FYI – let me know your thoughts.
From: Jay Montgomery
Sent: Monday, April 12, 2021 6:41 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Renata Engler
 LC COLLINS <limone.c.collins.civ@mail.mil>
Subject: Re: April 12 VaST call - draft agenda and presentations

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Respectfully,
Jay Montgomery

Sent from the all new AOL app for iOS

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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
From: Jay Montgomery

Sent: Sunday, April 11, 2021 7:14 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQI) <dzig2@cdc.gov>

Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Drs. Markowitz and Gee,

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I very much look forward to sharing with the VaST team the findings of our review.

R/

Dr. Jay Montgomery

---

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Please send your PowerPoint presentations to me and Julianne Gee (copied here), by Monday morning at 10 am.

I will send pdfs of presentations to the VaST members and other call attendees. Our administrative assistant will advance slides for you during the call.

Thank you and let me know if you have any questions.

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) <lem2@cdc.gov>
Sent: Thursday, April 8, 2021 2:01 PM
To: Forshee, Richard (FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Cunningham, Fran <Fran.Cunningham@va.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQp) <elw8@cdc.gov>; Su, John R CAPT USPHS (USA) <euz2@cdc.gov>; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) <limone.c.collins.civ@mail.mil>
Cc: Shimabukuro, Tom T CAPT USPHS (USA) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQp) <dzg2@cdc.gov>
Subject: [Non-DoD Source] April 12 VaST draft agenda and proposed times

Dear all,

Please see below the approximate times planned for your talks on the VaST call next Monday. Let me know if you feel any revisions are needed.
April 12

Thank you all for presenting to VaST.

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: 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.

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>; Beaualais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eoevent417@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.

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

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) <eocvtftrackercdc.gov>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <eocvent416@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eocvent417@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eocvent516@cdc.gov>; CDC IMS 2019 NCOV Response VTF Operations <eocvtftrackercdc.gov>
Cc: CDC IMS Task Tracker (CDC) <eocvtftrackercdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Fitter, David L. (CDC/DPHIS/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

Phone #: (b)(8)

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; pleuroperticarditis; 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](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.

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

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

During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines. We will continue to monitor this outcome in active and passive surveillance.
From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)  
Sent: Mon, 12 Apr 2021 22:44:03 +0000  
To: Wharton, Melinda (CDC/DDID/NCIRD/ISD)  
Subject: FW: April 12 VaST call - draft agenda and presentations

Something else we need to discuss.

From: Jay Montgomery  
Sent: Monday, April 12, 2021 6:41 PM  
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Renata Engler  
LC COLLINS <limone.c.collins.civ@mail.mil>  
Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Dr. Markowitz,

Respectfully,
Jay Montgomery

Sent from the all new AOL app for iOS

On Monday, April 12, 2021, 11:14 AM, Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov> wrote:

Dear Jay and Renata,

Thank you again for your presentations.  

Lauri

Lauri Markowitz, MD  
VaST Co-Lead  
Division of Viral Diseases
From: Jay Montgomery
Sent: Sunday, April 11, 2021 7:14 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dgp2@cdc.gov>
Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Drs. Markowitz and Gee,

Please find attached my slide deck for Monday's VaST presentation on Myocarditis following COVID-19 Vaccination. Please let me know if anything else is required.

I assume I will be receiving a Zoom Invite for Monday? Please be sure to send it to my civilian e-mail address as my government laptop cannot accept ZOOM conferences. As I am on the road, I would appreciate the opportunity to call in early to be sure we have a good connection and everything works as expected.

I very much look forward to sharing with the VaST team the findings of our review.

R/

Dr. Jay Montgomery

In a message dated 4/9/2021 12:22:41 PM Eastern Standard Time, lem2@cdc.gov writes:

Dear all,
Thank you for agreeing to present to the VaST next week. Attached is the current agenda, with times.

Please send your PowerPoint presentations to me and Julianne Gee (copied here), by Monday morning at 10 am.

I will send pdfs of presentations to the VaST members and other call attendees. Our administrative assistant will advance slides for you during the call.

Thank you and let me know if you have any questions.

Lauri

*Lauri Markowitz, MD*

*VaST Co-Lead*

*Division of Viral Diseases*

*National Center for Immunization and Respiratory Diseases*

*Centers for Disease Control and Prevention*

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**From:** Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
**Sent:** Thursday, April 8, 2021 2:01 PM
**To:** Forshee, Richard (FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Cunningham, Fran <Fran.Cunningham@va.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <elw8@cdc.gov>; Su, John R CAPT USPHS (USA) <ezu2@cdc.gov>; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) <limone.c.collins.civ@mail.mil>
**Cc:** Shimabukuro, Tom T CAPT USPHS (USA) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQ) <dzg2@cdc.gov>
**Subject:** [Non-DoD Source] April 12 VaST draft agenda and proposed times
Dear all,

Please see below the approximate times planned for your talks on the VaST call next Monday. Let me know if you feel any revisions are needed.

April 12

Thank you all for presenting to VaST.

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: 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

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

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

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,

Lauri

This is the schedule


From: Эмилана Анис <EMILIA.ANIS@MOH.GOV.IL>
Sent: Thursday, April 1, 2021 4:24 AM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Cc: Эхада Ротем <hadas.rotem@MOH.GOV.IL>; Бое Лев <BOAZ.LEV@MOH.GOV.IL>;
    Шора Алой <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. 972-2-5088521
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: Эмилана Анис <EMILIA.ANIS@MOH.GOV.IL>
Cc: Эхада Ротем <hadas.rotem@MOH.GOV.IL>; Бое Лев <BOAZ.LEV@MOH.GOV.IL>;
    Шора Алой <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: 'THE BIRD MESSAGES' <EMILIA.ANIS@MOH.GOV.IL>
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; 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.

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.
Dear Lauri,

Best regards,

[Logo: Ministry of Health]
Dear Lauri,

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

Best regards,
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

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
From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Monday, March 15, 2021 4:06 PM
To: Emilia Anis <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

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
Hi Kristin and Eric,

Jim and I have a list of outstanding questions...
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
☎ 1-715-221-6482 | ☎ 1-715-389-3880 | ✉ hanson.kayla@marshfieldresearch.org
The contents of this message may contain private, protected and/or privileged information. If you received this message in error, you should destroy the e-mail message and any attachments or copies, and you are prohibited from retaining, distributing, disclosing or using any information contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.
Excellent. Give me 5 minutes

Nicky – I’m ready now if you are, my evening “session” ended early. Otherwise, I can wait till 8:30 est

Yes if we do it at 5:30 PT/8:30 ET?

I’m running out right now and probably won’t be back available until around 8:30 – 9:00 est? Does that work?

I won’t be able to tomorrow. Hopefully it won’t take too long. I am available now until my next meeting at 4pm PT
Caution: This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.

Attached is the updated VaST slideset.

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From: John Auerbach  
To: John Auerbach  
Subject: TFAH’s Covid-19 News Update - April 28, 2021

PH Mitigation/Suppression

- With, by his own admission, “zero background in infectious disease modeling,” the young data scientist (he’s only 27) Youyang Gu built a Covid-19 modeling site that proved remarkably accurate, and has become an indispensable resource for scientists and government officials. On October 6, Gu posted his final death forecast, just before the fall wave. The model projected there would be 231,000 deaths in the US by November 1. The total recorded by that date: 230,995. He’s profiled [here](#).

- India on Wednesday reported another record number of coronavirus cases and deaths, nudging its official Covid-19 death toll past 200,000 as the virus coursed through urban centers and out into rural areas, leaving broken families and communities in its wake. In a new global record, Indian authorities logged 360,960 infections in a 24-hour period, bringing the total number of cases to more than 17.9 million. India also reported 3,293 deaths, even as experts warned that many virus fatalities were going uncounted.
  - Vidya Krishnan in the Atlantic: India’s experience of the pandemic will be defined by this enormous second wave. But the chamber of horrors the country now finds itself in was not caused by any one man, or any single government. It is the greatest moral failure of our generation. India may be classified as a developing or middle-income country, and by international standards, it does not spend enough on the health of its people. Yet this masks many of India’s strengths in the health-care sector: Our doctors are among the best trained on the planet, and as is well known by now, our country is a pharmacy for the world, thanks to an industry built around making cost-effective medicines and vaccines. What is evident, however, is that we suffer from moral malnutrition—none of us more so than the rich, the upper class, the upper caste of India. And nowhere is this more evident than in the health-care sector.

- In a prospective evaluation involving 3 rounds of testing in 1 nursing home, researchers compared antigen test performance (using BinaxNOW) versus virus culture and real-time reverse transcription polymerase chain reaction (RT-PCR). As expected, the antigen test performed less well in late infection than RT-PCR. Of note, however, it performed very well compared with RT-PCR and virus culture in early infection (percentage of positive agreement, 86% and 95%, respectively). These results provide additional support to the idea that antigen testing could be useful to identify people who are likely to be contagious and may transmit SARS-CoV-2, as well as the idea that rapid antigen tests can be a useful screening tool to limit infectious outbreaks. The rapid time to results, and thus public health mitigation, cannot be overstated. Once a result is obtained in less than a half hour, action can be taken to limit further contacts, and thus further spread of the virus. In the study, researchers also found that false positives were not a significant problem.
• The failure of U.S. authorities to test adult migrants for the coronavirus in jam-packed border processing centers is creating a potential for new transmissions, public health officials and shelter operators warn, even among migrants who may have arrived healthy at America’s door. More than 170,000 migrants crossed the border in March—many coming from countries still grappling with high infection rates—but the Border Patrol is conducting no testing for the coronavirus during the several days that the newly arrived migrants are in U.S. custody except in cases where migrants show obvious symptoms. The government says it has insufficient time and space to test migrants upon their arrival. So while migrants get a basic health screening, testing is being postponed until their release to local community groups, cities and counties, usually after the new arrivals have spent days confined in tight spaces with scores of strangers, often sleeping shoulder to shoulder on mats on the floor. Unaccompanied children are being tested, but only after they have spent around three days in custody, just before being loaded onto buses or planes for transport to government-run shelters. U.S. officials say the challenges to testing all the new arrivals when they are first apprehended are insurmountable. There have been no instances of mass spread at U.S. border facilities, and overall numbers of cases are relatively low, according to the Department of Homeland Security. About 5 percent of all single adults and families tested after their release since March showed a positive result, according to the agency, while among the thousands of unaccompanied minors now in custody, the rate has been about 12 percent. But local officials and shelter operators said they feared that the actual number of infections could be much higher.

• While coronavirus cases are falling in much of the United States, infections are spiking in Oregon, where a new wave is set to push a third of counties into the most severe level of restrictions. In the past two weeks, virus cases have risen 54 percent and hospitalizations are up 39 percent.

• Federal health officials said Tuesday that fully vaccinated people can go without masks outdoors when walking, jogging or biking, or dining with friends at outdoor restaurants—a milestone development for tens of millions of pandemic-weary Americans after more than a year of masking up and locking down.

  o The common six-foot social distancing guidance on its own may not be enough to protect people from contracting the coronavirus while spending time indoors, according to a report that examined the virus’s airborne transmission risk. Researchers from the Massachusetts Institute of Technology argued that not all indoor settings are the same, varying by size, ventilation, air filtration, occupancy and the nature of the activity. While the core premise of the study isn’t new, the research offers more details (and a handy online risk-assessment calculator) to help people better understand what factors in a given indoor setting may increase their risk for catching the coronavirus.

Herd Immunity
• Peter Hotez in Nature: I have a long-standing disagreement with many of my US public-health colleagues. I admire their commitment to disease prevention, but when I ask for a more direct way to counter anti-vaccine aggression, I’m told, “that’s not our approach;
confrontation gives them a platform and oxygen.” In my opinion, this attitude reflects a time when we had dial-up modems. Today, the anti-vaccine empire has hundreds of websites and perhaps 58 million followers on social media. The bad guys are winning, in part because health agencies either underestimate or deny the reach of anti-science forces, and are ill-equipped to counter it. Accurate, targeted counter-messaging from the global health community is important but insufficient, as is public pressure on social-media companies. The United Nations and the highest levels of governments must take direct, even confrontational, approaches with Russia, and move to dismantle anti-vaccine groups in the United States. Efforts must expand into the realm of cyber security, law enforcement, public education and international relations. A high-level inter-agency task force reporting to the UN secretary-general could assess the full impact of anti-vaccine aggression, and propose tough, balanced measures.

- **Thread** by Center for Countering Digital Hate: “Yesterday, tech CEOs told Congress they had acted on the Disinformation Dozen—12 people responsible for 65% of vaccine disinformation. It's not true. Our new report shows they are still online, posting lies viewed up to 29m times in the last month.” (Link to report [here](#)).

- **Thread** by Igor Bobic on the 2-minute PSA featuring Republican members of Congress who are also doctors, arguing for Americans to get vaccinated. "What we've found is if we put on our white coat, it literally moves the needle," Sen. Roger Marshall said.

- In 19 detailed steps—with photos, video, and illustrations—how Pfizer makes its Covid-19 vaccine.

- Paul Sax blogs on the decision to lift the pause on the J&J vaccine: “I confess this decision surprised me. My hunch was that they would advise limiting the vaccine in the U.S. to women older than 50, with no age criterion for men. Instead, it’s now available for all... [But now] It’s possible that [a] young healthy woman might end up getting the J&J vaccine. And while the odds are overwhelmingly in her favor that everything will be fine, in practice, this would be giving a vaccine with a recognized safety issue when two highly effective and safe alternatives exist.”

- The White House’s decision to send millions of doses of AstraZeneca’s Covid-19 vaccine overseas has split top Biden administration officials—with many arguing that the government cannot reduce its stockpile of doses on hand given recent disruptions in U.S. vaccine production.

**Health**

- The CDC has not found a link between heart inflammation and Covid-19 vaccines, the agency’s Director Rochelle Walensky said on Tuesday. "We have not seen a signal and we've actually looked intentionally for the signal in the over 200 million doses we've given," Walensky said in a press briefing. She said the CDC is in touch with the U.S. Department of Defense over its investigation of 14 cases of heart inflammation or myocarditis among people who were vaccinated through the military's health services.
• **Covid survivors are at risk from a possible second pandemic, this time of opioid addiction, given the high rate of painkillers being prescribed to these patients,** health experts say. A new study in Nature found alarmingly high rates of opioid use among covid survivors with lingering symptoms at Veterans Health Administration facilities. About 10% of covid survivors develop “long covid,” struggling with often disabling health problems even six months or longer after a diagnosis. For every 1,000 long-covid patients, known as “long haulers,” who were treated at a Veterans Affairs facility, doctors wrote nine more prescriptions for opioids than they otherwise would have, along with 22 additional prescriptions for benzodiazepines, which include Xanax and other addictive pills used to treat anxiety.

**Equity**

• In part because of their family histories, **many Tuskegee descendants are making a point of getting vaccinated and encouraging others to do the same.**

**Cross-cutting/Other**

• **This is what American health care looks like to people from other countries.** A short video.

• As vaccination rates go up, the floodgates of social life are poised to reopen. But not everyone will want to use this newfound freedom in the same way. Even before the pandemic, introverts and extroverts disagreed on the optimal size and frequency of gatherings. Post-vaccine life may breed some misunderstandings between the extroverts who want to dive headfirst into a sea of other people and the introverts who are excited to see their friends but don’t want to pack their schedules so full that they have no time to just be. **The Atlantic hosts a conversation with an introvert and an extrovert.** Quote from Katharine Wu, the self-described introvert: “I think small talk is the tax that God exacted for the privilege of human speech.”

**Some good news**

• **A new survey of native bees and the plants they need offers an encouraging sign that bees can bounce back if we throw them a lifeline in the form of carefully selected plants in our gardens.**
From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 9 Apr 2021 21:58:14 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Thanks!

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Sent: Friday, April 9, 2021 5:55 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Elaine,

Thanks

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, April 9, 2021 5:50 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Pedro,

Also, note that John asked [b] [5]

Thanks,
Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, April 9, 2021 3:35 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
Thanks!

- John

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Sent: Friday, April 9, 2021 5:32 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>; Lagarde, Melanie (CDC/OCCO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Elaine,

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Sent: Friday, April 9, 2021 5:10 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>; Lagarde, Melanie (CDC/OCCO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Please let me know your edits:

Sincerely,
Pedro
From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ)
Sent: Friday, April 9, 2021 4:13 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>; Lagarde, Melanie
(CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

Thanks,
Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Sent: Friday, April 9, 2021 4:09 PM
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R.
Hi Melanie,

Elaine or John, do you have any edits?

Thanks for sending this

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Sent: Friday, April 9, 2021 3:48 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQRP) <psm9@cdc.gov>; Miller, Elaine R.
(CDC/DDID/NCEZID/DHQRP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQRP) <ezu2@cdc.gov>
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Sincerely,
Pedro
Hi Pedro,
Thank you. Got it. Makes sense. Happy to work on this. I’ll send another draft.

Thanks again.
Melanie

Melanie Carmel Lagarde, DNP, MPH, RN, CHES
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQG) <psm9@cdc.gov>
Sent: Thursday, April 8, 2021 1:09 PM
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggestions
Thanks again

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Sent: Thursday, April 8, 2021 12:56 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Subject: DRAFT RE: Autoimmune dx post vaccine
Please let us know if you have additional questions.

Sincerely,
CDC Immunization Safety Office Staff
Atlanta, GA

Melanie Carmel Lagarde, DNP, MPH, RN, CHES
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>  
Sent: Thursday, April 8, 2021 9:15 AM
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>  
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <psm9@cdc.gov>  
Subject: RE: Autoimmune dx post vaccine

Hi Melanie,
Please let me know if you can draft a response for this inquiry.
Thanks,
Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <psm9@cdc.gov>  
Sent: Wednesday, April 7, 2021 6:19 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>  
Subject: FW: Autoimmune dx post vaccine

Elaine,

Pedro

From: dale nordenberg  
Sent: Wednesday, April 7, 2021 5:16 PM
To: Robert Chen  
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>  
Subject: Re: Autoimmune dx post vaccine

Hi
Thanks!

Sent from my iPhone

On Apr 7, 2021, at 5:08 PM, Robert Chen wrote:

Dale?

Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
e-mail: 

On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov> wrote:

Hi Bob,

Pedro

From: Robert Chen
Sent: Wednesday, April 7, 2021 3:33 PM
To: Nordenberg, Dale (CDC gmail.com)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Subject: Re: Autoimmune dx post vaccine

Bob

On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg wrote:
Bob
Dale

Sent from my iPhone

--

Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
email: (b)6
Thanks, Maria! Quiet day at home, hope you are enjoying the season, healthy and safe!

- John

I hope all is well with you and you had a wonderful Thanksgiving with your family.

Regards,

Maria

-----Original Message-----
From: Su, John (CDC/DDID/NCEZID/DHQD) <ezu2@cdc.gov>
To: McNeil, Michael (CDC/DDID/NCEZID/DHQD) <mmm2@cdc.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQD) <qv9@cdc.gov>; Carmen Ng <mingyang.cher@gmail.com>; M. Cano <bh7@cdc.gov>
Sent: Tue, Nov 24, 2020 6:48 pm
Subject: FW: Your Submission

Hi folks,

I hope you're staying healthy and safe during these strange times!

Thanks for your hard work!

- John
-----Original Message-----
From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671
Title: (b)(5) (b)(4)

Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
Hi Elaine,

Thank you so much for your response. It may be important for VTF Global to also be looped into these discussions given our global work. I am adding Laura Conklin to this thread as our POC for vaccine safety on the VTF Global Team.

Best,

Prianka Reddi, MSPH
Public Health Advisor | Presidential Management Fellow
COVID19 Vaccine Task Force – Global Team
Centers for Disease Control and Prevention (CDC)

Hi Prianka,
Tom Shimabukuro is working with FDA to respond.
There is no action required for VTF Global.

Thanks,
Elaine
Hi Elaine,

Best,

Prianka Reddi, MSPH
Public Health Advisor | Presidential Management Fellow
COVID19 Vaccine Task Force – Global Team
Centers for Disease Control and Prevention (CDC)

From: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Sent: Thursday, March 4, 2021 9:41 AM
To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eoevent168@cdc.gov>; CDC IMS 2019 NCOV Response VTF Global <eoevent445@cdc.gov>
Cc: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>; CDC IMS 2019 NCOV Response VTF Communications <eocvtfcommteam@cdc.gov>; CDC IMS 2019 NCOV Response International Task Force <eoevent223@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all,

Thanks,
Elaine

Elaine R. Miller, RN, MPH
Immunization Safety Office
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Atlanta, GA
Email: emiller@cdc.gov
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

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force
CDC Coronavirus Disease 2019 (COVID-19) Response | eoevent168@cdc.gov

Further CDC Resources:

COVID-19 What’s New
CDC Health Alert Network (HAN)

CDC Vaccines

CDC Clinician Outreach and Communication Activity (COCA)

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:

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. Roee Singer
Title: Deputy Director, Division of Epidemiology, MoH Israel
Organization: SLHD - Israel Ministry of Health
Phone:
Other Email:
Address:
Jerusalem, Israel

PII Extraction:
Thank you, Elaine.

Thanks again.
Melanie

Melanie Carmel Lagarde, DNP, MPH, RN, CHES
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

Please let me know your edits:

Sincerely,
Pedro
Hi Pedro,
Melanie and I discussed...

I will get back to you with a revised response soon.
Thanks,
Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQPI) <psm9@cdc.gov>
Sent: Friday, April 9, 2021 4:09 PM
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R.
Hi Melanie,

any edits?

Thanks for sending this

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Sent: Friday, April 9, 2021 3:48 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQPR) <psm9@cdc.gov>; Miller, Elaine R.
(CDC/DDID/NCEZID/DHQPR) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQPR) <ezu2@cdc.gov>
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Sincerely,
Pedro
Melanie Carmel Lagarde, DNP, MPH, RN, CHES  
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Lagarde, Melanie (CDC/OCO/OSSAM/OHC)  
Sent: Thursday, April 8, 2021 1:13 PM  
To: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,  
Thank you. Got it. Makes sense. Happy to work on this. I’ll send another draft.

Thanks again.  
Melanie

Melanie Carmel Lagarde, DNP, MPH, RN, CHES  
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>  
Sent: Thursday, April 8, 2021 1:09 PM  
To: Lagarde, Melanie (CDC/OCO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,  

Thanks for sending this. I have a few questions and suggestions...
Thanks again

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Sent: Thursday, April 8, 2021 12:56 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: DRAFT RE: Autoimmune dx post vaccine
From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ2P) <erm4@cdc.gov>
Sent: Thursday, April 8, 2021 9:15 AM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ2P) <psm9@cdc.gov>
Subject: RE: Autoimmune dx post vaccine

Hi Melanie,
Please let me know if you can draft a response for this inquiry.
Thanks,
Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ2P) <psm9@cdc.gov>
Sent: Wednesday, April 7, 2021 6:19 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ2P) <erm4@cdc.gov>
Subject: FW: Autoimmune dx post vaccine

Elaine,

Pedro

From: dale nordenberg
Sent: Wednesday, April 7, 2021 5:16 PM
To: Robert Chen
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ2P) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ2P) <erm4@cdc.gov>
Subject: Re: Autoimmune dx post vaccine

Hi
Thanks!

Sent from my iPhone

On Apr 7, 2021, at 5:08 PM, Robert Chen wrote:

Dale?

Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
email:

On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQ) wrote:

Hi Bob,

Pedro

From: Robert Chen
Sent: Wednesday, April 7, 2021 3:33 PM
To: Nordenberg, Dale (CDC gmail.com)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Subject: Re: Autoimmune dx post vaccine

Bob

On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg wrote:

Bob
Dale

Sent from my iPhone

--
Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
dd@dcheap.com
Great, we’ll review and discuss internally before next Wednesday.

Kristin

---

**Caution:** This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.

Hi Kristin and Eric,

Jim and I have a list of outstanding questions:

1. (b)(5)
2. (b)(5)
3. (b)(5)
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
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Sure.
Thanks!
Eric

From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Sent: Thursday, April 29, 2021 3:11 PM
To: Kristin X. Goddard <Kristin.X.Goddard@kp.org>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Cc: NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: RE: updated VaST slideset

(b)(5)

From: Kristin X. Goddard <Kristin.X.Goddard@kp.org>
Sent: Thursday, April 29, 2021 12:31 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Cc: NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: [EXTERNAL] RE: updated VaST slideset

Eric – I’ll have those slides updated to you tomorrow (offline later today, flying back to CA shortly)

Kristin

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Thursday, April 29, 2021 7:48 AM
To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Cc: Kristin X. Goddard <Kristin.X.Goddard@kp.org>; NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: RE: updated VaST slideset

**Caution:** This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.
From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>
Sent: Thursday, April 29, 2021 10:13 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQG) <eiw8@cdc.gov>
Cc: Kristin X. Goddard <Krisin.X.Goddard@kp.org>; NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: RE: updated VaST slideset

Thanks Eric,

A couple questions:

-Kayla

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQG) <eiw8@cdc.gov>
Sent: Thursday, April 29, 2021 8:58 AM
To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard <Krisin.X.Goddard@kp.org>; NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: [EXTERNAL] updated VaST slideset

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The contents of this message may contain private, protected and/or privileged information. If you received this message in error, you should destroy the e-mail message and any attachments or copies, and you are prohibited from retaining, distributing, disclosing or using any information contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.
Thank you

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, January 20, 2021 9:36 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ ref:_00Dt0CmwY_.500t0bPyvA:ref ]

Thanks!

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Wednesday, January 20, 2021 9:33 AM
To: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ ref:_00Dt0CmwY_.500t0bPyvA:ref ]

Ruth,

I suggest we send the following info to add to your response:

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>
Sent: Wednesday, January 20, 2021 9:21 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ ref:_00Dt0CmwY_.500t0bPyvA:ref ]
Thank you,
Ruth

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ2) <ayv6@cdc.gov>
Sent: Wednesday, January 20, 2021 8:58 AM
To: Su, John (CDC/DDID/NCEZID/DHQ2) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ2) <erm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQ2) <ltd8@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref: _00Dt0CmwY_.500t0bPyvA:ref ]

And there will be an ACIP presentation on Jan 27.

From: Su, John (CDC/DDID/NCEZID/DHQ2) <ezu2@cdc.gov>
Sent: Wednesday, January 20, 2021 8:30 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ2) <erm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQ2) <ltd8@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ2) <ayv6@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref: _00Dt0CmwY_.500t0bPyvA:ref ]

John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ2) <erm4@cdc.gov>
Sent: Wednesday, January 20, 2021 8:22 AM
To: Gallego, Ruth (CDC/DDID/NCEZID/DHQ2) <ltd8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQ2) <ezu2@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref: _00Dt0CmwY_.500t0bPyvA:ref ]

Ruth,

John,
From: Byrne, Jennifer (CDC/DDID/NCEZID/DPEI) <bgq0@cdc.gov>
Sent: Wednesday, January 20, 2021 7:54 AM
To: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Comms <eoevent411@cdc.gov>; CDC IMS 2019 NCOV Response STLT TF HDS Comms Section <eoevent501@cdc.gov>; CDC IMS 2019 NCOV Response VTF Communications <eocytfcommteam@cdc.gov>; Dixon, Nickell (CDC/DDID/NCEZID/DPEI) <ipj3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQD) <erm4@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0Cmwy_.500t0bPyvA:ref]

Thank you, Ruth! It was last Friday’s MMWR (1/15). Yes, I will take care of getting the response to the original sender.

Warm regards,
Jennifer

Jennifer Byrne, MPH
Task Force Liaison Officer
Health Department Section
State, Tribal, Local & Territorial Support Task Force
COVID-19 Emergency Response
US Centers for Disease Control and Prevention
Cell: (678) 575-8184
bgq0@cdc.gov
eoevent411@cdc.gov

From: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Sent: Tuesday, January 19, 2021 6:26 PM
To: Byrne, Jennifer (CDC/DDID/NCEZID/DPEI) <bgq0@cdc.gov>; COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Comms <eoevent411@cdc.gov>; CDC IMS 2019 NCOV Response STLT TF HDS Comms Section <eoevent501@cdc.gov>; CDC IMS 2019 NCOV Response VTF Communications <eocytfcommteam@cdc.gov>; Dixon, Nickell (CDC/DDID/NCEZID/DPEI) <ipj3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQD) <erm4@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0Cmwy_.500t0bPyvA:ref]

Good evening Jennifer,

Can you tell me which Friday MMWR are they referring to?
Thank you,
Ruth

Ruth Gallego RN, MPH, CHES®
Immunization Safety Office
Division of Healthcare Quality Promotion, NCEZID
Centers for Disease Control and Prevention

404.718.5084 | RGallego@cdc.gov

__________________________________

Vaccine Safety coordinators for Illinois are Sarah.Patrick@Illinois.gov and Heidi.Clark@illinois.gov; and city of Chicago is Van.Quach@cityofchicago.org

They receive weekly data on VAERS reports in their jurisdiction through EPIX. Data is presented in the format shown in the attached excel shell tables.

Unfortunately, v-safe data is not made available to jurisdictions.

To the question

1. How frequently will this national analysis be done and where will the data be located?
As stated, this data will be provided to vaccine safety coordinators on a weekly basis (saturdays).
   - The 3rd tab of this data file makes a comparison of number of VAERS on death, serious, and non-serious reports among states and nationwide.
   - The 4th tab shows data of the following adverse events of special interest
     i. Acute myocardial infarction
     ii. Anaphylaxis
     iii. Coagulopathy
     iv. COVID-19 Disease
     v. Death
     vi. Guillain-Barré syndrome
     vii. Kawasaki disease
     viii. Multisystem Inflammatory Syndrome in Children
     ix. Myocarditis / Pericarditis
     x. Narcolepsy / Cateplexy
     xi. Pregnancy and Prespecified Conditions
     xii. Seizures / Convulsions
     xiii. Stroke
     xiv. Transverse myelitis

2) Is it possible to receive state specific reports? See above response
From: Jennifer Byrne <bgq0@cdc.gov>
Sent: Tuesday, January 19, 2021 5:50 PM
To: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Cc: CDC IMS 2019 NCOV Response STLT Comms <eocvent411@cdc.gov>; CDC IMS 2019 NCOV Response STLT TF HDS Comms Section <eocvent501@cdc.gov>; CDC IMS 2019 NCOV Response VTF Communications <eocvtfcommtteam@cdc.gov>; Dixon, Nickell (CDC/DDID/NCEZID/DPEI) <ijp3@cdc.gov>
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwyY_500t0bPyvA:ref]

Dear Vaccine Safety Team:

Please note the original inquiry below, sent in error to eocvent416.

Please include the HD LNO, Nickell Dixon, on all responses.

Thank you,
Jennifer Byrne

TF LNO - Vaccine & HSWS

------------- Original Message -------------
From: Jennifer Byrne [bgq0@cdc.gov]
Sent: 1/19/2021 9:45 AM
To: eocvent416@cdc.gov
Cc: eocvent411@cdc.gov; ijp3@cdc.gov; eocvtfcommtteam@cdc.gov; eocvent501@cdc.gov
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwyY_500t0bPyvA:ref]

Dear VTF Vaccine Safety Team:

Friday's MMWR on adverse events reported in VAERS was shared with Illinois, to assist with this inquiry. They have responded with these follow up questions:

1) How frequently will this national analysis be done and where will the data be located?
2) Is it possible to receive state specific reports?
3) Will this be dis-aggregated by vaccine type going forward?

Please let us know how best to respond to Illinois' inquiry. Please include the HD LNO for IL, Nickell
Dixon, on all responses.

Thank you,
Jennifer Byrne

TF LNO - Vaccine & HSWS

------------------ Original Message ------------------
From: Jennifer Byrne [bgq0@cdc.gov]
Sent: 1/17/2021 2:42 PM
To: jpi3@cdc.gov
Cc: eocevent411@cdc.gov
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwY_500t0bPyvA:ref ]

Dear Nickell,

Friday's MMWR gives some data on adverse events reported to VAERS thus far, that could assist IDPH with their report (see transcript attached).

Warm regards,
Jennifer Byrne

TF LNO - Vaccine & HSWS

------------------ Original Message ------------------
From: Diamond Elston [qta6@cdc.gov]
Sent: 1/15/2021 12:08 PM
To: jpi3@cdc.gov
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwY_500t0bPyvA:ref ]

Thank you for your inquiry regarding the Communications Team of the Vaccine Task Force, however, the Contact Tracking Program Support (CTPS) team is not part of the Vaccine Task Force so does not provide vaccine communications, guidance or technical assistance.

------------------ Original Message ------------------
From: Jennifer Byrne [bgq0@cdc.gov]
Sent: 1/15/2021 11:55 AM
To: vtr9@cdc.gov; eocevtcommteam@cdc.gov; eocevent416@cdc.gov
Cc: eocevent441@cdc.gov; eocevent501@cdc.gov; jpi3@cdc.gov; gpu9@cdc.gov
Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwY_500t0bPyvA:ref ]

Dear Nancy/VTF Comms and VTF Vaccine Safety Teams:
We have received a request for adverse events data from Illinois. Here are the specifics:

**IDPH needs to give a presentation to stakeholders about what kind of adverse events have been reported to date in VAERS and V-Safe and compare that to Illinois.**

Thank you,
Jennifer Byrne

TF LNO - Vaccine & HSWS

---------- Original Message ----------
From: Nickell Dixon [jpi3@cdc.gov]
Sent: 1/15/2021 10:29 AM
To: eceevent441@cdc.gov
Cc: eceevent508@cdc.gov
Subject: Case 00008665 [ref:_00Dt0CmwY._500t0bPyvA:ref ]

Hello,
I just put in case#00008665. IDPH needs to give a presentation to stakeholders about what kind of adverse events have been reported to date in VAERS and V-Safe and compare that to Illinois and need us to help collect information on this for them.

ref:_00Dt0CmwY._500t0bPyvA:ref
From: Su, John (CDC/DDID/NCEZID/DHQD)  
Sent: Tue, 30 Mar 2021 22:04:21 +0000  
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQD)  
Subject: RE: WHO GACVS sub-committee - request for information  

Awesome!  

- John  

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQD) <fqv9@cdc.gov>  
Sent: Tuesday, March 30, 2021 5:52 PM  
To: Su, John (CDC/DDID/NCEZID/DHQD) <ezu2@cdc.gov>  
Subject: RE: WHO GACVS sub-committee - request for information  

From: Su, John (CDC/DDID/NCEZID/DHQD) <ezu2@cdc.gov>  
Sent: Tuesday, March 30, 2021 5:39 PM  
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQD) <fqv9@cdc.gov>  
Subject: RE: WHO GACVS sub-committee - request for information  

Hi Paige,  

- John  

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQD) <fqv9@cdc.gov>  
Sent: Tuesday, March 30, 2021 2:19 PM  
To: Su, John (CDC/DDID/NCEZID/DHQD) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <avv6@cdc.gov>  
Subject: RE: WHO GACVS sub-committee - request for information
Hi Tom,

I’ll have to check when I’m back by a computer.

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)
Hi Anastasia – Please keep this information close hold.

Tom
From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Friday, March 19, 2021 1:01 AM
To: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvy3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <lk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom,

Thank you for sharing this comprehensive piece of work. I have shared it with GACVS sub-committee members only and in confidence.

I have set up a meeting via MS Teams for next week. It would be helpful to discuss what analyses CDC may be able to share with GACVS members going forward, in response to further issues identified internationally.

I have also included Kristine Macartney in the meeting request (GACVS member and NCIRS Director) as there may be a couple of other related issues to discuss. Please feel free to forward the invitation to anyone else in your organization as required. Rita, I have included you in the invitation in case you would like to join.

Many thanks again
Anastasia

---

From: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>
Sent: Friday, 19 March 2021 12:40 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>; Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvy3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <lk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: RE: WHO GACVS sub-committee - request for information

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Thanks, Tom! Anastasia, I would interpret this as being that it could go to the GACVS sub-committee but not the larger group of participants.
Dear Anastasia,

I have received permission to confidentially share this draft manuscript with you under review at Vaccine. Please do not share outside of our need-to-know group. We hope it will be published soon starting at 8am, but could do 7:30am next week if that works.

Regards,

Tom

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe on AstraZeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.
If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc’d the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Sent: Wednesday, 17 March 2021 6:43 AM
To: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <lyk3@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

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Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I’m happy to talk when convenient. I’mCc’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Monday, March 8, 2021 10:05 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)
Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
From: Su, John (CDC/DDID/NCEZID/DHQG)
Sent: Tue, 13 Apr 2021 19:48:08 -0000
To: Woo, Jane; Nair, Narayan (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER);
Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Ahima, Ohenewaa (FDA/CDER);
Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG)
Subject: RE: [EXTERNAL] RE: Janssen - 4/13

Sounds great – thanks!

• John

From: Woo, Jane <Jane.Woo@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 3:40 PM
To: Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>; Nair, Narayan (FDA/CBER)
<Narayan.Nair@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-
Jonas@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Alimchandani,
Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Ahima, Ohenewaa (FDA/CDER)
<Ohenewaa.Ahima@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG) <ayv6@cdc.gov>
Subject: RE: [EXTERNAL] RE: Janssen - 4/13

Thanks.

From: Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>
Sent: Tuesday, April 13, 2021 3:37 PM
To: Woo, Jane <Jane.Woo@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Mba-Jonas,
Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Zinderman, Craig E
<Craig.Zinderman@fda.hhs.gov>; Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Ahima,
Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>
Subject: RE: [EXTERNAL] RE: Janssen - 4/13

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• John

From: Woo, Jane <Jane.Woo@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 3:34 PM
To: Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>; Nair, Narayan (FDA/CBER)
<Narayan.Nair@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-
Jonas@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Alimchandani,
Hi,

From: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Sent: Tuesday, April 13, 2021 3:28 PM
To: Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>; Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Woo, Jane <Jane.Woo@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>
Subject: [EXTERNAL] RE: Janssen - 4/13

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John

From: Nair, Narayan <Narayan.Nair@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 3:15 PM
To: Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Ahima, Ohenewaa (FDA/CDER) <Ohenewaa.Ahima@fda.hhs.gov>; Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Subject: RE: Janssen - 4/13

Thanks Adamma and Craig,

I think we should
Narayan
From: Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 3:06 PM
To: Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>; Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Woo, Jane <Jane.Woo@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>
Subject: Re: Janssen - 4/13

Adamma

From: Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 3:03:56 PM
To: Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Woo, Jane <Jane.Woo@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>
Subject: RE: Janssen - 4/13

Jane and others:

(b)(5)

(b)(5)

Thanks,
Craig

From: Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 1:03 PM
To: Woo, Jane <Jane.Woo@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>
Subject: RE: Janssen - 4/13

Jane, thank you

(b)(5)

Thanks
Meghna

From: Woo, Jane <Jane.Woo@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 12:59 PM
To: Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>

Subject: Janssen - 4/13

NB:
Yea, I think...

I've never worked with him, but the name has come up in discussion. Looks like he is still with the health system, but not in research.

Ha!! is Nick still at Marshfield?

Nope!
Thanks Eric.

A couple questions on anaphylaxis:

-Kayla

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP)  
Sent: Wed, 21 Apr 2021 14:54:20 +0000  
To: Moro, Pedro (CDC/DDID/NCEZID/DHQPP)  
Cc: Su, John (CDC/DDID/NCEZID/DHQPP); Shimabukuro, Tom  
(CDC/DDID/NCEZID/DHQPP)  
Subject: RE: Question re VAERS Reports Rec'd

Thanks—will send this as final

From: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <pms9@cdc.gov>  
Sent: Wednesday, April 21, 2021 10:52 AM  
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>  
Cc: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPP) <ayv6@cdc.gov>  
Subject: RE: Question re VAERS Reports Rec'd

Elaine,

I have no comments or edits

Thanks

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>  
Sent: Wednesday, April 21, 2021 10:45 AM  
To: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <pms9@cdc.gov>  
Cc: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPP) <ayv6@cdc.gov>  
Subject: FW: Question re VAERS Reports Rec'd

Pedro,
Please let me know if this response needs edits.
I am cc'ing Tom and John for awareness.

(kris)

Thanks,
Elaine

Dear Kris,

Thanks for your email.

I did not find either of these reports in VAERS yet, but due to processing delays, VAERS may have received them but not processed them yet.

To date, CDC vaccine safety monitoring systems have not found evidence of a concerning pattern of reports of myocarditis after COVID-19 vaccination.
Hello, Elaine -
Can you tell us if CDC has received any VAERS reports from Idaho regarding:

- 2\textsuperscript{nd} Pfizer COVID-19 vaccine dose administered 4/2, ED visit on 4/4, myocarditis, female in her twenties
- 2\textsuperscript{nd} Pfizer COVID-19 vaccine dose administered 3 days before 4/11 ED visit to ID, myocarditis, female in her fifties

If you have not, we will follow up with the provider to stimulate reporting.
Are you seeing any VAERS signals around second dose Pfizer and myocarditis? This is our third.
Thank you for your help,

Kris

Kris K. Carter, DVM, MPVM, DACVP
CAPT, USPHS; Career Epidemiology Field Officer, CDC
Epidemiology Program and Immunization Program
Bureau of Communicable Disease Prevention
Division of Public Health
Idaho Department of Health and Welfare
Desk Number: (208)334-5939 Fax Number: (208)332-7307
Kris.Carter@dhw.idaho.gov

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Hi all,

Thanks!

- John

---

**Melanie Carmel Lagarde, DNP, MPH, RN, CHES**

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

---

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>
Sent: Friday, April 9, 2021 4:13 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQG) <psm9@cdc.gov>; Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
Hi Pedro,

Thanks,
Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <psm9@cdc.gov>
Sent: Friday, April 9, 2021 4:09 PM
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Sent: Friday, April 9, 2021 3:48 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQPP) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQPP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.gov>
Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Dear Bob,

Sincerely,
Pedro
Hi Pedro,
Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.
Melanie

Melanie Carmel Lagarde, DNP, MPH, RN, CHES
MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell
Hi Melanie,

Thanks for sending this. I have a few questions and suggestions.

Thanks again

Pedro
From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Sent: Thursday, April 8, 2021 9:15 AM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Subject: RE: Autoimmune dx post vaccine

Hi Melanie,

Please let me know if you can draft a response for this inquiry.

Thanks,
ELaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Sent: Wednesday, April 7, 2021 6:19 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: FW: Autoimmune dx post vaccine

Elaine,

Pedro
Hi

Thanks!

Sent from my iPhone

On Apr 7, 2021, at 5:08 PM, Robert Chen wrote:

Dale?

Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
email:

On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQ) wrote:
Hi Bob,

Pedro

From: Robert Chen
Sent: Wednesday, April 7, 2021 3:33 PM
To: Nordenberg, Dale (CDC gmail.com)  
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>
Subject: Re: Autoimmune dx post vaccine
On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg wrote:
Bob

Dale

Sent from my iPhone

--
Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
e-mail:
Hi Kristin and Eric,

Jim and I have a list of outstanding questions...
Best,
Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute |  1000 North Oak Avenue (ML2), Marshfield, WI 54449
☎ 1-715-221-6482 | ✉ 1-715-389-3880 | ✉ hanson.kayla@marshfieldresearch.org

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQD) <eiw8@cdc.gov>
Sent: Monday, April 19, 2021 2:58 PM
To: Ned Lewis <Ned.Lewis@kp.org>
Cc: Berwick Chan <Berwick.Chan@kp.org>; Joan Bartlett <Joan.Bartlett@kp.org>; Arnold Yee <Arnold.Yee@kp.org>
Subject: RE: Covid-19 RCA data collection programs with minor revisions

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Thanks!

Ned

From: Ned Lewis <Ned.Lewis@kp.org>
Sent: Monday, April 19, 2021 5:48 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQD) <eiw8@cdc.gov>
Cc: Berwick Chan <Berwick.Chan@kp.org>; Joan Bartlett <Joan.Bartlett@kp.org>; Arnold Yee <Arnold.Yee@kp.org>
Subject: Covid-19 RCA data collection programs with minor revisions

Hi Eric,
-Ned

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From: Su, John (CDC/DDID/NCEZID/DHQG)
Sent: Mon, 29 Mar 2021 20:50:36 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQG); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG)
Subject: RE: WHO GACVS sub-committee - request for information

Thanks!

Tom,

John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQG) <fqv9@cdc.gov>
Sent: Monday, March 29, 2021 4:34 PM
To: Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG) <ayv6@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

Hey John,

John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQG)
Sent: Monday, March 29, 2021 2:13 PM
To: Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG) <ayv6@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information
Hi Tom,

Thanks!

- John

Hey Tom,

Thanks,
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Thursday, March 25, 2021 2:17 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information
From: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Sent: Wednesday, March 17, 2021 3:56 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQI) <fqv9@cdc.gov>; Licata, Charles (CDC/DDID/NCEZID/DHQI) <kui5@cdc.gov>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQI) (CTR) <qso2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Subject: FW: WHO GACVS sub-committee - request for information

Hi folks,

Please see below email chain.?

Tom, [DRA]

Thanks!

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 1:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

(Blanks)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Sent: Wednesday, March 17, 2021 12:26 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

(Blanks)

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Cc: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

Tom,
John is out today.
Elaine
Thanks.

From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Wednesday, March 17, 2021 3:47 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>;
Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>;
JANIN, Annick <janina@who.int>
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on AstraZeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Anick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia
Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I’m happy to talk when convenient. I’m Cc’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Monday, March 8, 2021 10:05 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

Dear Tom

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The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?
Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
Thanks!

- John

Hi Melanie,

Thanks for sending this

Pedro

Sincerely,
Pedro
Hi Pedro,
Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.
Melanie
Hi Melanie,

Thanks for sending this. I have a few questions and suggestions.

Thanks again

Pedro

---

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>
Sent: Thursday, April 8, 2021 12:56 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQO) <erm4@cdc.gov>
CC: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: DRAFT RE: Autoimmune dx post vaccine
**Melanie Carmel Lagarde, DNP, MPH, RN, CHES**  
*MVL3@cdc.gov* | 404-639-4856 office | 470-773-8733 cell

---

**From:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
**Sent:** Thursday, April 8, 2021 9:15 AM  
**To:** Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>  
**Cc:** Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>  
**Subject:** RE: Autoimmune dx post vaccine

Hi Melanie,  
Please let me know if you can draft a response for this inquiry.  
Thanks,  
Elaine

---

**From:** Moro, Pedro (CDC/DDID/NCEZID/DHQ) <psm9@cdc.gov>  
**Sent:** Wednesday, April 7, 2021 6:19 PM  
**To:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>  
**Subject:** FW: Autoimmune dx post vaccine

Elaine,
Hi

Thanks!

Sent from my iPhone

On Apr 7, 2021, at 5:08 PM, Robert Chen wrote:

Dale?

Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
e-mail: (b)(5)

On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQ) wrote:

Hi Bob,

Pedro

From: Robert Chen
Sent: Wednesday, April 7, 2021 3:33 PM
To: Nordenberg, Dale (CDC@gmail.com)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQD) <psm9@cdc.gov>
Subject: Re: Autoimmune dx post vaccine

Bob

On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg wrote:
Bob

Dale

Sent from my iPhone

--
Robert (Bob) Chen MD MA
Scientific Director, Brighton Collaboration
e-mail:
Hi all,

I have had a few email exchanges with some of you about this email. (b)(5) (b)(5)

Lauri

Questions to VaST members

• How do we communicate these RCA results to the public?
• How to address the trade-off of the uncertainty of self-controlled studies using pre-vaccination intervals versus more timely analyses?
• Any suggestions for adjustment of risk factors for cardiovascular events during PMaxRT runs? We currently are standardizing the expected rates to nursing home status, age, sex, race/ethnicity.
• Should we consider incorporating severity of the AESIs in determination of our clinical margin and if so, how do we do that? The clinical margins are currently selected based on whether the AESIs are common (signal faster) or rare

For Internal Deliberation Only; Do Not Share.

From: Lee, Grace <GMLee@stanfordchildrens.org>
Sent: Tuesday, April 6, 2021 12:56 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Hopkins, Bob <hopkinsroberth@uams.edu>; Shimabukuro, Tom (CDC/DDID/NCIRD/DHQF) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQF) <dzg2@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>
Subject: Signal eval considerations- feel free to comment/edit/share
Best
Grace
CONFIDENTIALITY NOTICE: This communication and any attachments may contain confidential or privileged information for the use by the designated recipient(s) named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or the attachments is strictly prohibited. If you have received this communication in error, please contact me and destroy all copies of the communication and attachments. Thank you.
Hi Tom,

Thanks!

- John
Hey Tom,

Thanks,
Paige

---

From: Marquez, Paige L. (CDC/ DDID/ NCEZID/ DHQP) <fqv9@cdc.gov>
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To: Su, John (CDC/ DDID/ NCEZID/ DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/ DDID/ NCEZID/ DHQP) <ayv6@cdc.gov>
Cc: Miller, Elaine R. (CDC/ DDID/ NCEZID/ DHQP) <erm4@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information
From: Su, John (CDC/DDID/NCEZID/DHQI) <pzu2@cdc.gov>
Sent: Wednesday, March 17, 2021 3:56 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQI) <fpy9@cdc.gov>; Licata, Charles (CDC/DDID/NCEZID/DHQI) <kui5@cdc.gov>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQI) (CTR) <gss2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Subject: FW: WHO GACVS sub-committee - request for information

Hi folks,

Please see below email chain.

Tom, (b)5

Thanks!

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 1:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
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Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

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To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

Tom,
John is out today.

Elaine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Sent: Wednesday, March 17, 2021 12:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>
Subject: FW: WHO GACVS sub-committee - request for information

(b)(5)

Thanks.

From: Phillips, Anastasia <Anastasia.Philips@health.wa.gov.au>
Sent: Wednesday, March 17, 2021 3:47 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rrzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
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Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQIP) <ayv6@cdc.gov>
Sent: Wednesday, 17 March 2021 6:43 AM
To: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzhr7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvy3@cdc.gov>
Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'mCc’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director

CAUTION External Communication: This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.
From: Phillips, Anastasia <Anastasia.Philips@health.wa.gov.au>
Sent: Monday, March 8, 2021 10:05 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>
Subject: WHO GACVS sub-committee - request for information

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The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
Perfect: I’ll call the teams at 7:40 est

Excellent. Give me 5 minutes

Nicky – I’m ready now if you are, my evening “session” ended early. Otherwise, I can wait till 8:30 est

Yes if we do it at 5:30 PT/8:30 ET?

I’m running out right now and probably won’t be back available until around 8:30 – 9:00 est?
Does that work?

Do you have time to over the slides today? I won’t be able to tomorrow. Hopefully it won’t take too long. I am available now until my next meeting at 4pm PT
From: Weintraub, Eric (CDC/DDID/NCEZID/DHQIP) <eiw8@cdc.gov>
Sent: Thursday, April 29, 2021 6:58 AM
To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard <Kristin.X.Goddard@kp.org>; NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>
Subject: updated VaST slideset

Caution: This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender.

NOTICE TO RECIPIENT: If you are not the intended recipient of this e-mail, you are prohibited from sharing, copying, or otherwise using or disclosing its contents. If you have received this e-mail in error, please notify the sender immediately by reply e-mail and permanently delete this e-mail and any attachments without reading, forwarding or saving them. v.173.285  Thank you.
From: McNeil, Michael (CDC/DDID/NCEZID/DHQPD)
Sent: Thu, 22 Oct 2020 17:52:25 +0000
To: Su, John (CDC/DDID/NCEZID/DHQPD); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPD); Broder, Karen (CDC/DDID/NCEZID/DHQPD)
Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD); Harrington, Theresa (CDC/DDID/NCEZID/DHQPD)
Subject: RE: AESI
Attachments: COVID-19 RCA Outcomes Draft Table & Questions.docx

This is the current draft table. 

Mike

From: Su, John (CDC/DDID/NCEZID/DHQPD) <ezu2@cdc.gov>
Sent: Thursday, October 22, 2020 1:22 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPD) <ayv6@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQPD) <krb2@cdc.gov>
Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <avt0@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQPD) <tsh3@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQPD) <mmm2@cdc.gov>
Subject: RE: AESI

Hi all,

John

• John
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Sent: Thursday, October 22, 2020 12:39 PM
To: Broder, Karen (CDC/DDID/NCEZID/DHQD) <krb2@cdc.gov>
Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <avt0@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQD) <tsh3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQD) <ezu2@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQD) <mmm2@cdc.gov>
Subject: RE: AESI

(b)(5)

From: Broder, Karen (CDC/DDID/NCEZID/DHQD) <krb2@cdc.gov>
Sent: Thursday, October 22, 2020 12:29 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <avt0@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQD) <tsh3@cdc.gov>
Subject: AESI

Tom,

(b)(5)

Thanks,
Karen
Outcome-related questions for discussion:
So it this correct now?

Hi folks,

Please let me know if you have any questions.

  • John
Subject: RE: WHO GACVS sub-committee - request for information

Hey Tom,

Thanks,
Paige

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- John

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Elaine

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Anastasia

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Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

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

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I’m happy to talk when convenient. I’m Cc’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov
From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Monday, March 8, 2021 10:05 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQD) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>
Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <lu4@cdc.gov>
Sent: Monday, April 26, 2021 12:19 PM
To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) <jjk7@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiew8@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Burns, Erin (CDC/DDID/NCIRD/ID) <eub5@cdc.gov>; Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR) <qbm9@cdc.gov>; Jordan, Douglas E.
Subject: RE: Myocarditis

FYI -

Thanks!
Thank you... sending to OADC.
Appreciate it,
Martha

Martha Sharan
Public Affairs
CDC/DIVISION OF HEALTHCARE QUALITY PROMOTION
Off.: 404-639-2683
Cell: 404-998-1787

From: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnr4@cdc.gov>
Sent: Monday, April 26, 2021 12:17 PM
To: Mullen, Jennifer (CDC/DDID/NCEZID/DHQ) <jkk7@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQ) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQ) <liu4@cdc.gov>
Cc: Desteefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>; Burns, Erin (CDC/DDID/NCIRD/ID) <eub5@cdc.gov>; Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR) <qbm9@cdc.gov>; Jordan, Douglas E. (CDC/DDID/NCIRD/ID) <fud7@cdc.gov>
Subject: RE: Myocarditis

[Message content]

tom

From: Mullen, Jennifer (CDC/DDID/NCEZID/DHQ) <jkk7@cdc.gov>
Sent: Monday, April 26, 2021 12:12 PM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQ) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnr4@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQ) <liu4@cdc.gov>
Cc: Desteefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>; Burns, Erin (CDC/DDID/NCIRD/ID) <eub5@cdc.gov>; Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR) <qbm9@cdc.gov>; Jordan, Douglas E. (CDC/DDID/NCIRD/ID) <fud7@cdc.gov>
Subject: RE: Myocarditis

The draft

[Message content]
Thanks!
Jenny

From: Mullen, Jennifer (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQ) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>
Cc: Desteefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>; Burns, Erin (CDC/DDID/NCIRD/ID) <eub5@cdc.gov>; Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR) <qbm9@cdc.gov>; Jordan, Douglas E. (CDC/DDID/NCIRD/ID) <fud7@cdc.gov>
Subject: RE: Myocarditis

+ Comms co-leads and deputy for awareness

From: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Sent: Monday, April 26, 2021 11:40 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQ) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Mullen, Jennifer (CDC/DDID/NCEZID/DHQ) <ijk7@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>
Cc: Desteefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>
Subject: RE: Myocarditis

Hi Tom,

- John
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG) <ayv6@cdc.gov>
Sent: Monday, April 26, 2021 10:55 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQG) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQG) <eiw8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Mullen, Jennifer (CDC/DDID/NCEZID/DHQG) <jjk7@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQG) <fxd1@cdc.gov>
Subject: RE: Myocarditis

Below is my first attempt.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>
Sent: Monday, April 26, 2021 10:41 AM
To: McNeil, Michael (CDC/DDID/NCEZID/DHQG) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQG) <eiw8@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQG) <ezu2@cdc.gov>
Subject: RE: Myocarditis
Importance: High

Hi all,

Please advise:
From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Sent: Monday, April 26, 2021 9:50 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
<erm4@cdc.gov>
Subject: RE: Myocarditis

(b)(5)

Thanks Eric

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, April 26, 2021 9:43 AM
To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
<erm4@cdc.gov>
Subject: RE: Myocarditis

(b)(5)

From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Sent: Monday, April 26, 2021 9:24 AM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
<erm4@cdc.gov>
Subject: RE: Myocarditis

Eric,

Thanks,
Mike
From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Monday, April 26, 2021 9:12 AM
To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: Myocarditis

Mike,

Thanks,
Elaine

From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <lju4@cdc.gov>
Sent: Monday, April 26, 2021 9:05 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) <jik7@cdc.gov>
Subject: Fwd: Myocarditis

Hi Elaine - see below ..
I’m at - should be back online by 10:30 am
Thanks
Martha

Get Outlook for iOS

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>
Sent: Monday, April 26, 2021 8:41:09 AM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) <lju4@cdc.gov>; Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) <ghq1@cdc.gov>
Cc: Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) <jik7@cdc.gov>
Subject: RE: Myocarditis

~Nicole

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>
Sent: Monday, April 26, 2021 6:03 AM
To: Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) <lju4@cdc.gov>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>; Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) <ghq1@cdc.gov>
Cc: Haynes, Benjamin (CDC/OD/OADC) <fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>

Subject: FW: Myocarditis

Kate, NCO, Jessica, Martha, -- (b)(5) (b)(5)

Regards,

Abigail

From: Beckman, Adam (HHS/OASH) <Adam.Beckman@hhs.gov>
Sent: Sunday, April 25, 2021 9:37 PM
To: Goldstein, Robert (CDC/OD/OADPS) <gyd2@cdc.gov>
Cc: Tumpey, Abigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Subject: Myocarditis

Robbie, Abigail,

Hope you got at least some rest this weekend!

Adam
Hi folks,

- John

Hey Tom,

Thanks,
Paige
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezeu2@cdc.gov>
Sent: Wednesday, March 17, 2021 3:56 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Licata, Charles (CDC/DDID/NCEZID/DHQP) <kui5@cdc.gov>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <qszq2@cdc.gov>
Hi folks,

Please see below email chain.

Tom,

(b)(5)

Thanks!

John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 1:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Sent: Wednesday, March 17, 2021 12:26 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

Thanks.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Sent: Wednesday, March 17, 2021 12:24 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information

Tom,

John is out today.

Elaine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Sent: Wednesday, March 17, 2021 12:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: FW: WHO GACVS sub-committee - request for information
From: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Sent: Wednesday, March 17, 2021 3:47 AM
To: Shimabukuuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again
Anastasia

From: Shimabukuuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Sent: Wednesday, 17 March 2021 6:43 AM
To: Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>
Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>
Subject: RE: WHO GACVS sub-committee - request for information
Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I’m happy to talk when convenient. I’m Cc’ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

**Tom Shimabukuro, MD, MPH, MBA**  
Captain, U.S. Public Health Service  
Deputy Director  
Immunization Safety Office  
Centers for Disease Control and Prevention (CDC)  
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666  
Email: TShimabukuro@cdc.gov

---

**From:** Phillips, Anastasia <Anastasia.Phillips@health.wa.gov.au>  
**Sent:** Monday, March 8, 2021 10:05 PM  
**To:** Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
**Cc:** Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>  
**Subject:** WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia
Dr Anastasia Phillips MBBS MPH FAFPHM
Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia
Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)
E: anastasia.phillips@health.wa.gov.au
Ph: +61 417 172 936
From: Destefano, Frank (CDC/DDID/NCEZID/DHQ2P)  
Sent: Wed, 10 Mar 2021 14:45:02 +0000  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ2P); Su, John  
(CDC/DDID/NCEZID/DHQ2P); Broder, Karen (CDC/DDID/NCEZID/DHQ2P)  
Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss

Frank DeStefano, MD, MPH

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ2P) <ayv6@cdc.gov>  
Sent: Wednesday, March 10, 2021 7:38 AM  
To: Su, John (CDC/DDID/NCEZID/DHQ2P) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQ2P) <krb2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQ2P) <fxd1@cdc.gov>  
Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss

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/DHQ2P) <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

Hi Tom,
Here are some draft responses to the Israeli Ministry of Health’s inquiry

Narayan

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ2P) <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

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, Kimbery (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

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, Kimbery (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

Thanks, Stacey.

Denise – can you help set this up via policy?

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, Kimbery (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

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) <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/DHQD) <ayv6@cdc.gov>
Cc: Luban, 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

Please see below re discussing with Israeli Vaccine FP

Thanks,
David.

From: CDC IMS Task Tracker (CDC) <eoc task tracker@cdc.gov>
Sent: Sunday, February 28, 2021 1:13 PM
To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <eoc event 416@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eoc event 417@cdc.gov>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <eoc event 516@cdc.gov>; CDC IMS 2019 NCOV Response VTF Operations <eoc vtf task@cdc.gov>
Cc: CDC IMS Task Tracker (CDC) <eoc task tracker@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Luban, 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

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

Phone #: (b)(6)
Subject: HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss

Description:

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: Hamburger, Tanya (CDC/DDID/NCCDPHP/DDT)  
Sent: Thu, 17 Dec 2020 23:22:49 +0000  
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)  
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Gee, Julianne (CDC/DDID/NCEZID/DHQP)  
Subject: RE: telehealth and vaccine safety

Thanks, Eric!

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>  
Sent: Thursday, December 17, 2020 5:52 PM  
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Hamburger, Tanya (CDC/DDID/NCCDPHP/DDT) <dln7@cdc.gov>  
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>  
Subject: RE: telehealth and vaccine safety
Tanya,
I am connecting you with Jonathan, Mike, and EW. Maybe they can give you info.
Thanks,
Julianne

From: Hamburger, Tanya (CDC/DDID/NCEZID/DDQP) <dln7@cdc.gov>
Sent: Thursday, December 17, 2020 5:02 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DDQP) <dzg2@cdc.gov>
Subject: FW: telehealth and vaccine safety

She is on it...mentioned I would try to get it to her tonight. Want to tell me by phone what to relay?

From: Coffin, Nicole (CDC/DDID/NCEZID/DDQP) <ndc3@cdc.gov>
Sent: Thursday, December 17, 2020 4:15 PM
To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DDQP) <dbc0@cdc.gov>; Joshi, Cecilia (CDC/DDID/NCEZID/DDQP) <any9@cdc.gov>; Bell, Michael MD (CDC/DDID/NCEZID/DDQP) <zzb8@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DDQP) <ayv6@cdc.gov>; Hamburger, Tanya (CDC/DDID/NCEZID/DDQP) <dln7@cdc.gov>; Moran, Kerri (CDC/DDID/NCEZID/DDQP) <vtyb5@cdc.gov>
Subject: RE: telehealth and vaccine safety

+Tanya Hamburger

Tanya is going to look into this further and may have more information later tonight or tomorrow.
~Nicole

From: Cardo, Denise M. MD (CDC/DDID/NCEZID/DDQP) <dbc0@cdc.gov>
Sent: Thursday, December 17, 2020 2:55 PM
To: Joshi, Cecilia (CDC/DDID/NCEZID/DDQP) <any9@cdc.gov>; Bell, Michael MD (CDC/DDID/NCEZID/DDQP) <zzb8@cdc.gov>
Cc: Coffin, Nicole (CDC/DDID/NCEZID/DDQP) <ndc3@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DDQP) <ayv6@cdc.gov>
Subject: RE: telehealth and vaccine safety

Thanks,
Denise.

From: Joshi, Cecilia (CDC/DDID/NCEZID/DDQP) <any9@cdc.gov>
Sent: Thursday, December 17, 2020 2:37 PM
To: Bell, Michael MD (CDC/DDID/NCEZID/DDQP) <zzb8@cdc.gov>; Cardo, Denise M. MD (CDC/DDID/NCEZID/DDQP) <dbc0@cdc.gov>
Subject: telehealth and vaccine safety
On a telehealth call today (a call that is done w/in the response for various TFs to connect on telehealth)

Cecilia W. Joshi, Ph.D.
LTC State Support & Coordination Unit | Infection Prevention and Control Team
Health Systems and Worker Safety Task Force (HSWSTF)
COVID-19 Response
Centers for Disease Control and Prevention (CDC)
eocvent467@cdc.gov
https://www.cdc.gov/COVID19

Associate Director for State Strategy, Division of Healthcare Quality Promotion &
Director, State Strategy and Evaluation Team
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Address: 1600 Clifton Road, Bldg 16, room 3143-B, Atlanta, Ga 30329
Phone: 404-639-7303  cjoshi@cdc.gov
I telework on Tuesdays and can be reached at 404-643-0177 (cell) or by email
Dear Colleagues,

On behalf of the CISA Project COVID-19 Team/ Vaccine Safety Team/ VTF I am writing to thank you for your service on our team. You played a valuable role during a time of expanding COVID-19 vaccination and increasing complexity of CISA inquiries. Below are some specific achievements.

- David (EISO) – You helped us with multiple special projects, including helping us close out a high priority death case following ITP, review myocarditis, and respond to multiple requests for emergency consults.
- Heather – Thanks for a third rotation with CISA! You served in one of the toughest roles on the team – Deputy CMO, responsible for managing the clinical staffing, 24/7 on-call operations (and staff morale) and partnerships. You helped us recruit talented officers and kept the service running. We can’t wait to have you back for night float later in the month.
- Elfriede – thanks for returning to CISA and jumping in during spring break to help with a staffing crunch and serving as Day supervisor. We are impressed how quickly you have learned the medical areas needed to supervise to these complicated inquiries. Thanks for volunteering for this role again in May!
- Suzanne – (rotating off this week). Thanks for coming back for this deployment. I think you had the most diverse set up duties on the team, ranging from fielding inquiries, preparing consults and taking on Deputy CMO to manage operations and staffing, after Heather left. Your ER background is super useful.
- Kathy Byrd – You served as an outstanding on-call clinician and responded to complex inquiries – from all areas of medicine. You provided expertise in allergy that was very useful, and along with Margaret is the best on the team.

The pandemic work has been hard work, but working with you guys has been a bright spot. Theresa and I have been impressed by your work ethic and we have learned a great deal from you. You are part of the CISA family and we look forward to continued collaboration. We hope you get a break before your next deployment.
Sincerely,

Karen R. Broder, MD  
Captain, United States Public Health Service  
Team Lead  
Clinical Immunization Safety Assessment (CISA) Project  
Immunization Safety Office  
Division of Healthcare Quality Promotion  
Centers for Disease Control and Prevention  
Phone: 404-498-0632  Fax: 404-498-0666  
email: Kbroder@cdc.gov
Good morning,

Thanks for the feedback! We will address the reviewers comments as soon as we can. I just wanted to acknowledge your email and explain the delay in our response. Your patience in the interim is most appreciated.

Stay healthy, and safe. Thanks!

-- John

-----Original Message-----
From: eesserver@esemail.elsevier.com <eesserver@esemail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671

Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQGP) <erm4@cdc.gov>
Sent: Tue, 13 Apr 2021 17:04:53 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQGP); Su, John (CDC/DDID/NCEZID/DHQGP)
Subject: RE: Janssen - 4/13

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQGP) <erm4@cdc.gov>
Sent: Tuesday, April 13, 2021 1:04 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQGP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQGP) <ezu2@cdc.gov>
Subject: RE: Janssen - 4/13

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQGP) <ayv6@cdc.gov>
Sent: Tuesday, April 13, 2021 1:01 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQGP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQGP) <ezu2@cdc.gov>
Subject: FW: Janssen - 4/13

From: Woo, Jane <Jane.Woo@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 12:59 PM
To: Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Ahima, Ohenewaa (FDA/CDER) <Ohenewaa.Ahima@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>; Su, John (CDC/DDID/NCEZID/DHQGP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQGP) <ayv6@cdc.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>
Subject: Janssen - 4/13

NB:
(b)(5)
Hi,

From: Alimchandani, Meghna &lt;Meghna.Alimchandani@fda.hhs.gov&gt;  
Sent: Tuesday, April 13, 2021 1:03 PM  
To: Woo, Jane &lt;Jane.Woo@fda.hhs.gov&gt;; Mba-Jonas, Adamma (CBER) &lt;Adamma.Mba-Jonas@fda.hhs.gov&gt;; Ahima, Ohenewaa &lt;Ohenewaa.Ahma@fda.hhs.gov&gt;; Nair, Narayan &lt;Narayan.Nair@fda.hhs.gov&gt;; Su, John (CDC) &lt;ezu2@cdc.gov&gt;; Shimabukuro, Tom (CDC) &lt;ayv6@cdc.gov&gt;; Zinder, Craig E &lt;Craig.Zinderman@fda.hhs.gov&gt;  
Subject: RE: Janssen - 4/13

Jane, thank you for the summary.  

Thanks  
Meghna

From: Woo, Jane &lt;Jane.Woo@fda.hhs.gov&gt;  
Sent: Tuesday, April 13, 2021 12:59 PM  
To: Mba-Jonas, Adamma (CBER) &lt;Adamma.Mba-Jonas@fda.hhs.gov&gt;; Ahima, Ohenewaa &lt;Ohenewaa.Ahma@fda.hhs.gov&gt;; Alimchandani, Meghna &lt;Meghna.Alimchandani@fda.hhs.gov&gt;; Nair, Narayan &lt;Narayan.Nair@fda.hhs.gov&gt;; Su, John (CDC) &lt;ezu2@cdc.gov&gt;; Shimabukuro, Tom (CDC) &lt;ayv6@cdc.gov&gt;; Zinderman, Craig E &lt;Craig.Zinderman@fda.hhs.gov&gt;  
Subject: Janssen - 4/13

NB:
From: COVID19VaxSafety
Sent: Tue, 27 Apr 2021 20:49:55 +0000
To: RE: Reported Pfizer adverse event not appearing in VAERS

Dear [Name]

Thank you for contacting the CDC. We are very sorry to hear that your son developed myocarditis after his COVID vaccination and we hope that he fully recovers.

We did locate your son’s report in VAERS. The permanent VAERS ID number is 1238456. The reason that the report is not in the VAERS public data is because the report must be processed before we can share it publicly. For example, we remove the patient name, address, birthday, hospital name, etc. in order to keep the patient identifying information confidential. Additionally due to the large number of reports that we are receiving at this time, processing is taking longer than usual.

Your son’s report is included in the government data used to analyze the safety of the COVID-19 vaccine and will eventually be viewable in the VAERS public data site.

Please let us know if we can be of additional assistance.

Sincerely,

CDC Immunization Safety Office staff
Atlanta, GA

---

From: [Name]
Sent: Tuesday, April 27, 2021 1:55 PM
To: CDC Wonder Customer Support <cwus@cdc.gov>; NIPINFO (CDC) <NIPINFO@cdc.gov>
Subject: Reported Pfizer adverse event not appearing in VAERS
Importance: High

I am writing because a filed report is not showing up in the VAERS system online. This is concerning to me given questions that are arising concerning heart problems associated with the Pfizer vaccine for covid.

My 16yo son was hospitalized with myopericarditis after receiving his first shot of the Pfizer BioN-Tech vaccination for covid-19. He was diagnosed with covid on Jan. 14. He complained of his heart pounding but had a normal EKG when seen by his pediatrician on March 31. He got the first Pfizer shot on Friday, April 16. On Sunday, April 18, he was admitted to the PICU at the [Name]. His troponin levels reached a high of 16.7 but it was successfully reduced with prednisone and other interventions. He was discharged on Thursday, April 22.

The hospital filed a report with VAERS on April 21 (I have a photo of the confirmation email), but all it listed was the Temporary VAERS E-Report Number. When I enter that number in VAERS, I get data for a 60yo man vaccinated in 2012.
I have requested the non-temporary report number from info@vaers.org but I am wondering why his data does not show up when I do a search?

Specifically, when I do a data request, the following parameters yield 0 total events:

- 10028650 (MYOPERICARDITIS)
- 1200 (COVID19 (COVID19 (PFIZER-BIONTECH)))
- Hospitalized

When I change the symptom to “10028606 (MYOCARDITIS)” and keep the other two parameters the same, I get 22 events, but in the 6-17 age range there are zero events.

This is very distressing amid reports that “CDC, FDA see no Pfizer vaccine link to heart problem.”

How are CDC and FDA able to monitor this situation if they don’t have the information being submitted by hospitals?

Feel free to call me at
Thank you.

-------------------------------
Call/Text Email
Thanks Jane,
Tom/John - it looks like a seventh case of CVST – just double checking that for these cases there was thrombocytopenia. It would be good to know if they had thrombocytopenia.

Narayan

NB:
From: Broder, Karen (CDC/DDID/NCEZID/DHQPs)  
Sent: Mon, 26 Apr 2021 16:04:17 +0000  
To: Su, John (CDC/DDID/NCEZID/DHQPs)  
Cc: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNESS)  
Subject: FW: question - confidential  
Attachments: CISA SBAR AB 4 24 2021.docx

Karen

From: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNESS) <srl2@cdc.gov>  
Sent: Monday, April 26, 2021 11:31 AM  
To: Broder, Karen (CDC/DDID/NCEZID/DHQPs) <krb2@cdc.gov>; Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNESS) <ydi0@cdc.gov>  
Subject: RE: question

Karen,

(b)(5)

Susan

From: Broder, Karen (CDC/DDID/NCEZID/DHQPs) <krb2@cdc.gov>  
Sent: Monday, April 26, 2021 11:19 AM  
To: Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNESS) <ydi0@cdc.gov>; Lukacs, Susan (CDC/DDPHSS/NCHS/DHNESS) <srl2@cdc.gov>  
Subject: question

(b)(5)

(b)(5)

Karen
Hi Kristen,

Let’s wait for records. Thanks!

- John

Kristen Pettrone, MD MPH
EIS Officer, Global Civil Registration and Vital Statistics Team
Division of Vital Statistics
National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Rd., MS P08
Hyattsville, MD 20782
(301) 458-4679
From: McCormick, David (CDC/DDID/NCEZID/DVBD)
Sent: Thu, 1 Apr 2021 17:53:43 +0000
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Can you please send VAERS definition of Serious to David?

Thanks Elaine and Theresa!

Best,
David

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>
Sent: Thursday, April 1, 2021 11:53 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: McCormick, David (CDC/DDID/NCEZID/DVBD) <yup1@cdc.gov>
Subject: RE: Can you please send VAERS definition of Serious to David?

Hi Elaine,

Thanks for the reply.

David

Yes, Elaine,

David, please update.

Thanks, all!

Theresa

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Thursday, April 1, 2021 1:24 PM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: McCormick, David (CDC/DDID/NCEZID/DVBD) <yup1@cdc.gov>
Subject: RE: Can you please send VAERS definition of Serious to David?

Hi Theresa,
Please see responses in red below.

Thanks,
Elaine
Hi Elaine,

(Blank page)

(Blank page)
Thank you!

Theresa

Theresa Harrington, MD, MPH&TM
CAPT, US Public Health Service
Medical Officer, Clinical Immunization Safety Assessment (CISA) Team
Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP)
Centers for Disease Control and Prevention
office: 404-639-2877
cell: 404-751-6389
e-mail: tharrington@cdc.gov
Hi Eric,
NOTICE TO RECIPIENT: If you are not the intended recipient of this e-mail, you are prohibited from sharing, copying, or otherwise using or disclosing its contents. If you have received this e-mail in error, please notify the sender immediately by reply e-mail and permanently delete this e-mail and any attachments without reading, forwarding or saving them. v.173.295 Thank you.
Sounds good.
I’ll be sending you the forms and paper first thing Tuesday morning

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Saturday, April 3, 2021 4:29:57 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Subject: RE: VSD methods advantages/limitations for vast call

Thanks. Due to time constraints I will be providing the slides as read only and Fran and I will verbally update VaST, but I’ll be briefing off these slides.

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Saturday, April 3, 2021 8:36 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: VSD methods advantages/limitations for vast call
Dear Kris,

Thanks for your email.

I did not find either of these reports in VAERS yet, but due to processing delays, VAERS may have received them but not processed them yet.

To date, CDC vaccine safety monitoring systems have not found evidence of a concerning pattern of reports of myocarditis after COVID-19 vaccination.

Best,
Elaine

---

Hello, Elaine -

Can you tell us if CDC has received any VAERS reports from Idaho regarding:

- 2nd Pfizer COVID-19 vaccine dose administered 4/2, ED visit 4/3, ID on 4/4, myocarditis, female in her twenties
- 2nd Pfizer COVID-19 vaccine dose administered 3 days before 4/11 ED visit to ID, myocarditis, female in her fifties

If you have not, we will follow up with the provider to stimulate reporting.

Are you seeing any VAERS signals around second dose Pfizer and myocarditis? This is our third.

Thank you for your help,
Kris

Kris K. Carter, DVM, MPVM, DACVPM
CAPT, USPHS; Career Epidemiology Field Officer, CDC
Epidemiology Program and Immunization Program
Bureau of Communicable Disease Prevention
Division of Public Health
Idaho Department of Health and Welfare
Desk Number: (208)334-5939 Fax Number: (208)332-7307
Kris.Carter@dhw.idaho.gov
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Hi Paige,

Excorcising CITGO demons again — will address your above comments when I’m online.

Thanks!

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQ) <fqv9@cdc.gov>
Sent: Wednesday, December 16, 2020 7:51:49 AM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: Table 2 Condition Updates- please advise
(x5)
Hi Elaine,
Thanks for the info!

— John
John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Sunday, April 18, 2021 10:32:55 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: To be sure you are aware

Tom, John:
FYI:

Elaine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Saturday, April 17, 2021 10:09 PM
To: Meissner, Cody <cmeissner@tuftsmedicalcenter.org>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: dbalaguru@mgh.harvard.edu
Subject: RE: To be sure you are aware

Hi Cody,

Good to hear from you and I hope you are doing well. There have been reports of myocarditis following mRNA vaccines. I’m including John Su, VAERS team lead, for his awareness. Take care.

Regards,
From: Meissner, Cody <cmeissner@tuftsmedicalcenter.org>
Sent: Thursday, April 15, 2021 2:21 PM
To: Shimabukuuro, Tom [CDC/DDID/NCEZID/DHQP] <ayv6@cdc.gov>
Cc: dbalaguru@mgh.harvard.edu
Subject: To be sure you are aware

Writing to be sure you are aware and to ask if myocarditis has been reported in other vaccinees?
Great presentation to ACIP yesterday,
Regards,
Cody

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Tufts Medical Center HIPAA Hotline at (617) 636-4422. If the e-mail was sent to you in error but does not contain patient information, contact the sender and properly dispose of the e-mail.

Please consider the environment and the security of the information contained within or attached to this e-mail before printing or saving to an insecure location.
Hi Kerry,

Thanks for letting me know! I bet things are getting busy at FDA. :P Keep your head above water, and good luck!

- John

Hi John,

Hope you’re also doing well. It’s busy here with the EUAs getting going. Thanks for putting all of this together!

Best,

Kerry

Hi folks,

I hope you’re staying healthy and safe during these strange times!

Thanks for your hard work!

-- John
-----Original Message-----
From: eesserver@eemail.elsevier.com <eesserver@eemail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671

Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
Thanks for your reply Tom
Everyone is so appreciative of the exemplary leadership you and your colleagues are providing during these unprecedented times.
Remember to save some time for yourself
Best regards
Cody

Sent from my iPhone

On Apr 17, 2021, at 10:08 PM, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> wrote:

EXTERNAL MESSAGE - TREAT LINKS/FILES WITH CARE

Hi Cody,

Good to hear from you and I hope you are doing well. There have been reports of myocarditis following mRNA vaccines, [0x0] I’m including John Su, VAERS team lead, for his awareness. Take care.

Regards,

Tom

---

From: Meissner, Cody <cmeissner@tuftsmedicalcenter.org>
Sent: Thursday, April 15, 2021 2:21 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: dbalaguru@mgh.harvard.edu
Subject: To be sure you are aware

Tom
Writing to be sure you are aware and to ask if myocarditis has been reported in other vaccinees?
Great presentation to ACIP yesterday,
Regards,
Cody

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Tufts Medical Center HIPAA Hotline at (617) 636-4422. If the e-mail was sent to you in error but does not contain patient information, contact the sender and properly dispose of the e-mail.

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Sure will, Mike. Thanks!

- John

Hi John,

Good news! Please let us know if we can assist in any way?

Thanks,

Mike

Hi folks,

I hope you're staying safe and well!

Thanks, and Happy Friday, all!

-- John

-----Original Message-----
From: eesserver@eemail.elsevier.com <eesserver@eemail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671
Title: (b)(5); (b)(4)

Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
Thanks, Ming! I hope you’re doing well.

- John

From: ming yan
Sent: Friday, October 16, 2020 5:07 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: Re: FW: Your Submission

Congrats John! Thanks for your hard work!

On Fri, Oct 16, 2020 at 10:39 Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> wrote:

Hi folks,

I hope you're staying safe and well!

Thanks, and Happy Friday, all!

-- John

-----Original Message-----
From: eesserver@eesmail elsevier.com <eesserver@eesmail elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671
Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

view the files

Reviewers' comments:
From: Hopkins jr., Robert H
Sent: Wed, 14 Apr 2021 12:41:45 +0000
To: 'Lee, Grace'; Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Wharton, Melinda (CDC/DDID/NCIRD/ISD)
Subject: RE: DoD and myocarditis

----

From: Lee, Grace [mailto:GMLee@stanfordchildrens.org]
Sent: Tuesday, April 13, 2021 6:48 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Hopkins jr., Robert H <HopkinsRobertH@uams.edu>
Subject: Re: DoD and myocarditis

Okay —

Thank you
Grace

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Date: Tuesday, April 13, 2021 at 3:16 PM
To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>, Lee, Grace <GMLee@stanfordchildrens.org>, Hopkins, Bob <HopkinsRobertH@uams.edu>
Subject: DoD and myocarditis

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Warning: This email originated from outside of Stanford Medicine. Do not open attachments or click on links unless you recognize the sender and know the content is safe. Remember to never provide your username or password via email. Please forward the email to spamcontrol@stanfordchildrens.org if you are unsure and would like it reviewed.

DoD has submitted manuscripts on post-COVID-19 vaccine-associated myocarditis to both JACC and JAMA Cardiology.
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Ok. Let's touch base tomorrow.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Monday, January 25, 2021 12:01 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: RE: ACIP_VaxSafety_Shimabukuro_1-27-2021_v3.pptx

I’ll just need to touch base with you before the Wednesday meeting.

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Monday, January 25, 2021 8:24 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: RE: ACIP_VaxSafety_Shimabukuro_1-27-2021_v3.pptx

Tom – do you want to chat during the 10:00 vsd meeting? If not feel free to give me a call.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Sunday, January 24, 2021 9:04 PM
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: RE: ACIP_VaxSafety_Shimabukuro_1-27-2021_v3.pptx

Thanks. I added the summary slide back in, but I need to talk to you about

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Sunday, January 24, 2021 5:43 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>
Subject: FW: ACIP_VaxSafety_Shimabukuro_1-27-2021_v3.pptx
From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Sunday, January 24, 2021 5:21 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQ)
<fxd1@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQ) <dgz2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>; Calvert, Geoffrey M. (CDC/NIOSH/WTCHP) <jac6@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQ) <fgv9@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQ) <vie9@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQ) <mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>
Subject: RE: ACIP_VaxSafety_Shimabukuro_1-27-2021_v3.pptx
Thanks for sending. Great to see these.

Lauri

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Sent: Sunday, January 24, 2021 2:48 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQ) <dzg2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>; Calvert, Geoffrey M. (CDC/NIOSH/WTCHP) <jac6@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQ) <fovg9@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQ) <vie9@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQ) <mmn2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQ) <eiw8@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>
Subject: ACIP_VaxSafety_Shimabukuro_1-27-2021_v3.pptx

Let me know what you think.
From: Montgomery, Jay R CIV DHA HEALTHCARE OPS (USA)  
Sent: Wed, 28 Apr 2021 22:23:06 +0000  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Engler, Renata J CTR (USA); Collins, Limone C Jr CIV DHA HEALTH OPNS (USA)  
Cc: Su, John (CDC/DDID/NCEZID/DHQP)  
Subject: RE: [Non-DoD Source] RE: Myocarditis cases

(b)(5)

Jay

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
Sent: Wednesday, April 28, 2021 6:22 PM  
To: Montgomery, Jay R CIV DHA HEALTHCARE OPS (USA) <jay.r.montgomery.civ@mail.mil>; Engler, Renata J CTR (USA) <renata.j.engler.ctr@mail.mil>; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) <limone.c.collins.civ@mail.mil>  
Cc: Su, John R CAPT USPHS (USA) <ezu2@cdc.gov>  
Subject: [Non-DoD Source] RE: Myocarditis cases

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)  
Sent: Wednesday, April 28, 2021 2:49 PM  
To: Montgomery, Jay R CIV DHA HEALTHCARE OPS (USA) <jay.r.montgomery.civ@mail.mil>; Engler, Renata J CTR (USA) <renata.j.engler.ctr@mail.mil>  
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>  
Subject: Myocarditis cases

Dear Dr. Montgomery and Colleagues,

(b)(5)

Thanks.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA  
Captain, U.S. Public Health Service  
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329
Phone: 404-498-0679, Fax: 404-498-0666
Email:TShimabukuro@cdc.gov < Caution-mailto:TShimabukuro@cdc.gov >
Thanks, Maria!

- John

Congratulations!

Sent from my Verizon 4G LTE smartphone

-------- Original message --------
From: "Su, John (CDC/DDID/NCEZID/DHQP)" <ezu2@cdc.gov>
Date: 10/16/20 11:14 AM (GMT-05:00)
To: "McNeil, Michael (CDC/DDID/NCEZID/DHQP)" <mmm2@cdc.gov>, "Welsh, Kerry (FDA/CBER)" <Kerry.Welsh@fda.hhs.gov>, "Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)" <fqv9@cdc.gov>, Carmen Ng <ming yan> M Cano <M Cano>
Subject: RE: Your Submission

Sure will, Mike. Thanks!

* John

From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Sent: Friday, October 16, 2020 11:00 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Carmen Ng <ming yan> M Cano <M Cano>
Subject: RE: Your Submission

Hi John,
Good news! Please let us know if we can assist in any way?
Thanks,
Mike

From: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.govmailto:ezu2@cdc.gov>>
Sent: Friday, October 16, 2020 10:40 AM
To: McNeil, Michael (CDC/DDID/NCEZID/DHQPP) <mmm2@cdc.govmailto:mmm2@cdc.gov>>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.govmailto:Kerry.Welsh@fda.hhs.gov>>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQPP) <fgv9@cdc.govmailto:fgv9@cdc.gov>>; Carmen Ng<mg@mg.govmailto:mg@mg.gov>>; ming yan<mg@mg.govmailto:mg@mg.gov>>; M Cano<mg@mg.govmailto:mg@mg.gov>>
Subject: FW: Your Submission

Hi folks,

I hope you're staying safe and well!

Thanks, and Happy Friday, all!

-- John

-----Original Message-----
From: eesserver@eemail.elsevier.commailto:eesserver@eemail.elsevier.com>
<eesserver@eemail.elsevier.commailto:eesserver@eemail.elsevier.com>>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQPP) <ezu2@cdc.govmailto:ezu2@cdc.gov>>
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671
Dear John,
Yours sincerely,

Robert T Chen, MD MA
Associate Editor
Vaccine or its open access mirror

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Reviewers' comments:
See below

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <vmo0@cdc.gov>
Sent: Tuesday, April 27, 2021 10:22 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Schuchat, Anne MD (CDC/OD)
<acs1@cdc.gov>
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD)
<ftm1@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Cardo, Denise M. MD
(CDC/DDID/NCEZID/DHQP) <dbc0@cdc.gov>
Subject: Myocarditis

Henry

I think I sent this to you yesterday. Denise C and I discussed.

Hope this is what you need.

Best

Dana

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Monday, April 26, 2021 2:43 PM
To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Cardo, Denise M. MD
(CDC/DDID/NCEZID/DHQP) <dbc0@cdc.gov>
Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>; Tumpey, Abbigail
(CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)
<vmo0@cdc.gov>
Subject: RE: Please read: Myocarditis

(3)(3) (b)(6)
From: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>
Sent: Monday, April 26, 2021 1:59 PM
To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQIP) <dbc0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQIP) <ayv6@cdc.gov>
Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQIP) <ndc3@cdc.gov>; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <vmo0@cdc.gov>
Subject: RE: Please read: Myocarditis
Thanks, Denise.

Tom

From: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQG) <dbc0@cdc.gov>
Sent: Monday, April 26, 2021 1:42 PM
To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQG) <ayv6@cdc.gov>
Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQG) <ndc3@cdc.gov>; Tumpey, Abigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <vmo0@cdc.gov>
Subject: Please read: Myocarditis

Importance: High

Tom C and Tom S,

Thanks,
Denise.

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQG) <ndc3@cdc.gov>
Sent: Monday, April 26, 2021 1:13 PM
To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQG) <dbc0@cdc.gov>; Kroop, Seth (CDC/DDID/NCEZID/DHQG) <wpw7@cdc.gov>; Moran, Kerri (CDC/DDID/NCEZID/DHQG) <vtb5@cdc.gov>; Joshi, Cecilia (CDC/DDID/NCEZID/DHQG) <any9@cdc.gov>
Cc: Schindelar, Jessica (CDC/DDID/NCEZID/DHQG) <ghq1@cdc.gov>
Subject: FW: Myocarditis

FYSA, in case asked in other channels.
Hi John, I know you are very busy, but I would appreciate your thoughts on this.

Thanks,
Elaine

Hi John,
Please let me know your edits. This question is from BETH HIBBS!
Thanks,
Elaine
-----Original Message-----
From: Beth
Sent: Friday, January 15, 2021 10:12 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQD) <erm4@cdc.gov>
Subject: Re: Covid 19 vaccine and thrombocytopenia

Hi Elaine,
Thank you so much. I tried to get through to Moderna to ask but they only had a recording to leave a message. I know it is too early to draw any conclusions about any rare AEs. But I was interested in the number of reports VAERS had about it for Pfizer and Moderna vaccines. I really appreciate it!
Beth

> On Jan 15, 2021, at 8:36 AM, Miller, Elaine R. (CDC/DDID/NCEZID/DHQD) <erm4@cdc.gov> wrote:
> 
> Hi Beth,
So sorry I didn't get back to you earlier.
We will look into VAERS and get back to you.
Best,
Elaine

-----Original Message-----
From: Beth Hibbs
Sent: Thursday, January 14, 2021 7:25 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: Covid 19 vaccine and thrombocytopenia

Hi Elaine,
When you get a chance. Just wanted to ask you about if you have heard of any unusual reporting about Moderna Covid 19 vaccine and thrombocytopenia. I know there has been a report with Pfizer's vax. Not sure if you all are seeing more reports of this. I know it is too soon but wanted to see if you had heard anything. Bob has an appointment for the Moderna vaccine and he has thrombocytopenia and I am hesitant since these vaccines are similar and so new.

Thanks millions
Beth
Great – thanks. Thank you for running this down...
R

From: Tumpey, Abigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>
Sent: Wednesday, April 28, 2021 3:13 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS) <bl8@cdc.gov>
Subject: RE: Myocarditis TPs

Rochelle,

(b)(5)

Re: (b)(5)

Please let me know if you need more.

Regards,

Abigail

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Wednesday, April 28, 2021 1:59 PM
To: Tumpey, Abigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>
Cc: McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS) <bl8@cdc.gov>
Subject: RE: Myocarditis TPs

Very helpful... Thank you!
R
Rochelle,
Regards,

Abbigail

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Wednesday, April 28, 2021 9:56 AM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>
Subject: Myocarditis TPs

We need this for the presser

Thanks!

R
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 6 Jan 2021 16:54:20 +0000
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Cc: McNeil, Michael (CDC/DDID/NCEZID/DHQP)
Subject: RE: Standing federal agency coordination meeting

(b)(5)

we should discuss on the call.

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>
Sent: Wednesday, January 6, 2021 11:41 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>
Subject: RE: Standing federal agency coordination meeting

(b)(5)
Hi Eric—Thanks.

Tom

Hi Tom,
Yes, I can go over that information.

Thanks,
--Rich

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPS) <ayv6@cdc.gov>
Sent: Wednesday, January 6, 2021 8:12 AM
To: Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Weintraub, Eric S (CDC) <eiw8@cdc.gov>; Cunningham, Fran <Fran.Cunningham@va.gov>; Hur, Kwan <Kwan.Hur@va.gov>
Subject: RE: Standing federal agency coordination meeting

I was hoping we could discuss

Thanks.

Tom

-----Original Appointment-----
From: Gee, Julianne (CDC/DDID/NCEZID/DHQPS) <dzg2@cdc.gov>
Sent: Wednesday, December 30, 2020 8:41 AM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQPS); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQPS); Weintraub, Eric (CDC/DDID/NCEZID/DHQPS); McNeil, Michael (CDC/DDID/NCEZID/DHQPS); Clark, Matthew (IHS/ALB); Destefano, Frank (CDC/DDID/NCEZID/DHQPS); Anderson, Steven (FDA/CBER); Forshee, Richard (FDA/CBER); Collins, Limone C Jr CIV (US); Cunningham, Fran; Hur, Kwan
Cc: Kenigsberg, Tat'Yana A. (CDC/DDID/NCEZID/DHQPS); Clark, Thomas A. (CDC/DDID/NCIRD/DVD)
Subject: Standing federal agency coordination meeting
When: Wednesday, January 6, 2021 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: zoom

Join ZoomGov Meeting
Meeting ID: 
Passcode: 
One tap mobile
Dial by your location
Meeting ID:
Hi Beth,

It is great to hear from you! I understand that you have questions about ITP we are seeing in VAERS and if we can receive the vaccine.

As of 1/14/21, VAERS contains 7 reports with the MedDRA codes: IMMUNE THROMBOCYTOPENIA, IMMUNE THROMBOCYTOPENIC PURPURA, THROMBOCYTOPENIA, or THROMBOCYTOPENIC PURPURA after either COVID-19 vaccination. The patient ages ranged from 25 to 56 with a median of 42 years. Five reports were after Pfizer and 2 were after Moderna. A brief summary of the reports is listed below.

1) A 56 year old male with no prior medical history received PFIZER-BIONTECH and had onset of symptoms about 4 days later and died 13 days after vaccination.
2) A 36 year old female with no reported medical problems received PFIZER-BIONTECH and has onset of symptoms about 13 days later. Hospitalized 2 days.
3) A 41 year old male with a prior history of ITP in 2014 that was in remission received PFIZER-BIONTECH and has onset of symptoms about 3 days later. Hospitalized 1 day
4) A 25 year old female with history of anti-thyroglobulin antibodies received Moderna vaccine and had onset of symptoms about 10 days later. Hospitalized 3 days.
5) A 43 year old female with history of GERD received Moderna vaccine and had onset of symptoms about 8 days later. Hospitalized.
6) A 44 year old female with no history received PFIZER-BIONTECH vaccine and had onset of nausea, vomiting, diarrhea, fever on the same day. The following day was hospitalized for chest pain and platelets found to be low. Diagnosed with myocarditis and thrombocytopenia. Hospitalized 2 days
7) A patient with unreported history received PFIZER-BIONTECH vaccine and died from thrombosenia; pulmonary embolism; neutropenia fever. There is no information to determine if this is a duplicate of the other death report or if this is a different patient.

CDC Clinical Guidance on the use of the COVID-19 vaccines is available at this link: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
It states the following:

*Persons with autoimmune conditions*
No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

Best,
Elaine

-----Original Message-----
From: Beth
Sent: Friday, January 15, 2021 10:12 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: Re: Covid 19 vaccine and thrombocytopenia

Hi Elaine,
Thank you so much. I tried to get through to Moderna to ask but they only had a recording to leave a message. I know it is too early to draw any conclusions about any rare AEs. But I was interested in the number of reports VAERS had about it for Pfizer and Moderna vaccines. I really appreciate it!
Beth

> On Jan 15, 2021, at 8:36 AM, Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov> wrote:
> Hi Beth,
> So sorry I didn't get back to you earlier.
> We will look into VAERS and get back to you.
> Best,
> Elaine
> -----Original Message-----
> From: Beth
> Sent: Thursday, January 14, 2021 7:25 PM
> To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
> Subject: Covid 19 vaccine and thrombocytopenia
> Hi Elaine,
> When you get a chance. Just wanted to ask you about if you have heard of any unusual reporting about Moderna Covid 19 vaccine and thrombocytopenia. I know there has been a report with Pfizer’s vax. Not sure if you all are seeing more reports of this. I know it is too soon but wanted to see if you had heard anything.

> Thanks millions

> Beth
Hi Team

I started drafting just what came from the closed meeting but added some thoughts below.

Best
Grace
CONFIDENTIALITY NOTICE: This communication and any attachments may contain confidential or privileged information for the use by the designated recipient(s) named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or the attachments is strictly prohibited. If you have received this communication in error, please contact me and destroy all copies of the communication and attachments. Thank you.
Hi Tina,
We will respond and cc you.
Thanks,
Elaine

From: NIPINFO (CDC) <NIPINFO@cdc.gov>
Sent: Tuesday, April 27, 2021 2:06 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQPC) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQPC) <ezu2@cdc.gov>
Cc: NIPINFO (CDC) <NIPINFO@cdc.gov>
Subject: FW: Reported Pfizer adverse event not appearing in VAERS
Importance: High

Hello,

Please see below. Of note this was also sent to Wonder Customer Support. Please let us know if you will address (or copy us when you send the response) and we can close the loop on our end.

Thanks,

Tina (for NIPINFO)

From: NIPINFO (CDC) <NIPINFO@cdc.gov>
Sent: Tuesday, April 27, 2021 1:55 PM
To: CDC Wonder Customer Support <cwus@cdc.gov>; NIPINFO (CDC) <NIPINFO@cdc.gov>
Subject: Reported Pfizer adverse event not appearing in VAERS
Importance: High

I am writing because a filed report is not showing up in the VAERS system online. This is concerning to me given questions that are arising concerning heart problems associated with the Pfizer vaccine for covid.

My 16yo son was hospitalized with myopericarditis after receiving his first shot of the Pfizer BioN-Tech vaccination for covid-19. He was diagnosed with covid on Jan. 14. He complained of his heart pounding but had a normal EKG when seen by his pediatrician on March 31. He got the first Pfizer shot on Friday, April 16. On Sunday, April 18, he was admitted to the PICU at the...
His troponin levels reached a high of 16.7 but it was successfully reduced with prednisone and other interventions. He was discharged on Thursday, April 22.

The hospital filed a report with VAERS on April 21 (I have a photo of the confirmation email), but all it listed was the Temporary VAERS E-Report Number. When I enter that number in VAERS, I get data for a 60yo man vaccinated in 2012.

I have requested the non-temporary report number from info@vaers.org but I am wondering why his data does not show up when I do a search?

Specifically, when I do a data request, the following parameters yield 0 total events:

- 10028650 (MYOPERICARDITIS)
- 1200 (COVID19 (COVID19 (PFIZER-BIONTECH)))
- Hospitalized

When I change the symptom to “10028606 (MYOCARDITIS)” and keep the other two parameters the same, I get 22 events, but in the 6-17 age range there are zero events.

This is very distressing amidst reports that “CDC, FDA see no Pfizer vaccine link to heart problem.”

How are CDC and FDA able to monitor this situation if they don’t have the information being submitted by hospitals?

Feel free to call me at (b)(6)
Thank you.

***************
From: Harrington, Theresa (CDC/DDID/NCEZID/DHQI)
Sent: Fri, 29 Jan 2021 18:16:41 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI); Su, John (CDC/DDID/NCEZID/DHQI); Broder, Karen (CDC/DDID/NCEZID/DHQI)
Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED)
Subject: RE: Please review VAERS search and give approval for pericarditis after COVID disease case

Thanks so much.

Theresa

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>
Sent: Friday, January 29, 2021 12:42 PM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQI) <tsh3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQI) <krb2@cdc.gov>
Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) <oqk3@cdc.gov>
Subject: RE: Please review VAERS search and give approval for pericarditis after COVID disease case

Hi Theresa,
I can check these searches. I will get back to you.
Thanks,
Elaine

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQI) <tsh3@cdc.gov>
Sent: Friday, January 29, 2021 12:08 PM
To: Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQI) <krb2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQI) <erm4@cdc.gov>
Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) <oqk3@cdc.gov>
Subject: Please review VAERS search and give approval for pericarditis after COVID disease case
Importance: High

Hi all,
Thank you.

Theresa

Theresa Harrington, MD, MPH&TM  
CAPT, US Public Health Service  
Medical Officer, Clinical Immunization Safety Assessment (CISA) Team  
Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP)  
Centers for Disease Control and Prevention  
office: 404-639-2877  
cell: 404-751-6389  
email: tharrington@cdc.gov
From: Harrington, Theresa (CDC/DDID/NCEZID/DHQG)<tsh3@cdc.gov>
Sent: Friday, January 29, 2021 12:08 PM
To: Su, John (CDC/DDID/NCEZID/DHQG)<ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP)<krb2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)<erm4@cdc.gov>
Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED)<oqk3@cdc.gov>
Subject: Please review VAERS search and give approval for pericarditis after COVID disease case

Importance: High

Hi all,

Theresa

On 01/29/2021 Theresa Harrington via Email:

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQG) <erm4@cdc.gov>
Sent: Friday, January 29, 2021 12:42 PM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQG)<tsh3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQG)<ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP)<krb2@cdc.gov>
Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED)<oqk3@cdc.gov>
Subject: RE: Please review VAERS search and give approval for pericarditis after COVID disease case

Hi Theresa,

I can check these searches. I will get back to you.

Thanks,

Elaine

Hi Theresa,

I can check these searches. I will get back to you.

Thanks,

Elaine
Thank you.

Theresa

Theresa Harrington, MD, MPH&TM
CAPT, US Public Health Service
Medical Officer, Clinical Immunization Safety Assessment (CISA) Team
Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP)
Centers for Disease Control and Prevention
office: 404-639-2877
cell: 404-751-6389
e-mail: tharrington@cdc.gov
Hi Geoff,

Thanks for sharing!

- John

From: Calvert, Geoffrey M. (CDC/NIOSH/WTCHP) <jac6@cdc.gov>
Sent: Wednesday, February 24, 2021 3:58 PM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQ) <erm4@cdc.gov>
Subject: (b)(6)
Geoffrey M. Calvert, MD, MPH
Vaccine Task Force
CDC COVID-19 Response
and
Associate Director for Clinical Quality
World Trade Center Health Program
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1090 Tusculum Avenue, R-12
Cincinnati, OH 45226
513-841-4448
Fax: 513-841-4489
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)  
Sent: Wed, 28 Apr 2021 14:41:01 +0000  
To: Su, John (CDC/DDID/NCEZID/DHQP)  
Subject: RE: myocarditis cases

---

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>  
Sent: Wednesday, April 28, 2021 10:35 AM  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
Subject: RE: myocarditis cases

- John

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
Sent: Wednesday, April 28, 2021 9:58 AM  
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>  
Subject: RE: myocarditis cases

We need to expedite these reviews and get ahead of the situation before it starts dictating our actions.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>  
Sent: Wednesday, April 28, 2021 9:28 AM  
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>  
Subject: RE: myocarditis cases

Hi Tom,
Please let me know if you need any other information.

- John

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <ayv6@cdc.gov>
Sent: Wednesday, April 28, 2021 8:09 AM
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>
Subject: myocarditis cases
Importance: High

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329
Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Friday, April 9, 2021 1:01 PM
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: RE: Call re: CVST cases in VAERS

Tom Shimabukuro, MD, MPH, MBA
Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329
Phone: 404-498-0679, Fax: 404-498-0666
Email: TShimabukuro@cdc.gov

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Friday, April 9, 2021 2:57 PM
To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Sotir, Mark (CDC/DDID/NCIRD/DVD) <mps6@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Anderson, Steven (FDA/CBER) <Steven.Anderson@fda.hhs.gov>; Forshee, Richard (FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQ) <avy6@cdc.gov>
Sent: Friday, April 9, 2021 2:43 PM
To: Desteefano, Frank (CDC/DDID/NCEZID/DHQ) <fxd1@cdc.gov>; Clark, Thomas A.
(CDC/DDID/NCIRD/DVD) <trn4@cdc.gov>; Sotir, Mark (CDC/DDID/NCIRD/DVD) <mps6@cdc.gov>;
Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD)
<mew2@cdc.gov>; Anderson, Steven (FDA/CBER) <Steven.Anderson@fda.hhs.gov>; Forshee, Richard
(FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>;
Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Su, John (CDC/DDID/NCEZID/DHQ)
<ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>; McNeil, Michael
(CDC/DDID/NCEZID/DHQ) <mmm2@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQ)
<dzg2@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>
Subject: RE: Call re: CVST cases in VAERS

Are folks available from 5-6pm Monday to discuss the CVST issue. I think ____

Thanks.
Hi David,

- John

Restrict Use / CDC FTE Only

From: McCormick, David (CDC/DDID/NCEZID/DVBD) <yup1@cdc.gov>
Sent: Thursday, April 1, 2021 1:59 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <euz2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayy6@cdc.gov>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>
Subject: VAERS Review of Myocarditis/Myopericarditis for DoD Discussion Tomorrow

Hi all,

Any comments or suggestions for improvement are welcome. Please send any comments by 10AM 4/2 so that I have a chance to incorporate them into the presentation.

Best,
David

David McCormick, MD, MPH
LCDR, US Public Health Service
EIS Officer
Centers for Disease Control and Prevention
Bacterial Diseases Branch | Division of Vector-Borne Diseases
From: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES)  
Sent: Mon, 26 Apr 2021 18:04:29 +0000  
To: Su, John (CDC/DDID/NCEZID/DHQ); Broder, Karen (CDC/DDID/NCEZID/DHQ)  
Subject: RE: question - confidential

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(b)(5)

Susan

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From: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>  
Sent: Monday, April 26, 2021 12:16 PM  
To: Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>  
Cc: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>  
Subject: RE: question - confidential

Thanks for sharing, Karen!

• John

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From: Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>  
Sent: Monday, April 26, 2021 12:04 PM  
To: Su, John (CDC/DDID/NCEZID/DHQ) <ezu2@cdc.gov>  
Cc: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>  
Subject: FW: question - confidential

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(b)(5)

Karen

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From: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>  
Sent: Monday, April 26, 2021 11:31 AM  
To: Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>; Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNES) <ydi0@cdc.gov>  
Subject: RE: question

Karen,

(b)(5)

Susan

---

From: Broder, Karen (CDC/DDID/NCEZID/DHQ) <krb2@cdc.gov>  
Sent: Monday, April 26, 2021 11:19 AM  
To: Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNES) <ydi0@cdc.gov>; Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>  
Subject: question
Thanks for the reminder!

- John

---

**From:** Shimabukuro, Tom (CDC/DDID/NCEZID/DHQI) <ayv6@cdc.gov>
**Sent:** Tuesday, April 6, 2021 6:44 PM
**To:** Gee, Julianne (CDC/DDID/NCEZID/DHQI) <dzg2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQI) <eiw8@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQI) <mmm2@cdc.gov>; Clark, Matthew (IHS/ALB) <Matthew.Clark@ihs.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQI) <fxd1@cdc.gov>; Anderson, Steven (FDA/CBER) <Steven.Anderson@fda.hhs.gov>; Forshee, Richard (FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Collins, Limone C Jr CIV (US <limone.c.collins.civ@mail.mil>; Cunningham, Fran <Fran.Cunningham@va.gov>; Hur, Kwan <Kwan.Hur@va.gov>; Kenigsberg, Tat’Yana A. (CDC/DDID/NCEZID/DHQI) <ynf1@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Wong, Hui-Lee (FDA/CBER) <Huilee.Wong@fda.hhs.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Martin, Stacey (CDC/DDID/NCEZID/DVBD) <zmt0@cdc.gov>
**Cc:** Su, John (CDC/DDID/NCEZID/DHQI) <ezu2@cdc.gov>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
**Subject:** USG vax safety coordination call

Agenda for tomorrow:

- General updates
- DoD myocarditis case series preview
- VSD and VA efforts for signal refinement for PE and AMI
- CDC update on CVST epi and CVST reports to VAERS
- Agency updates
Hi Karen,

I’m (supposedly) out of the office today. I’ll try to catch up offline. Thanks!

- John

From: Broder, Karen (CDC/DDID/NCEZID/DHQPR) <krb2@cdc.gov>
Sent: Friday, March 12, 2021 7:13 AM
To: Destefano, Frank (CDC/DDID/NCEZID/DHQPR) <fxd1@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQPR) <mmn2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQPR) <ezu2@cdc.gov>
Cc: Paulin, Heather N. (CDC/DDPHSIS/CGH/DGHT) <ydi2@cdc.gov>; McCormick, David (CDC/DDID/NCEZID/DVBD) <yup1@cdc.gov>
Subject: Call with DoD

Hello - Call with DoD at 10a today. Let me know if you want to be added.
Tom is on the invite.
Thanks
Karen

Get Outlook for iOS
From: Hesse, Elisabeth (CDC/DDID/NCEZID/DPEI) <nrr3@cdc.gov>
Sent: Monday, April 26, 2021 9:22 AM
To: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnv6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <euz2@cdc.gov>
Subject: (b)(5)

All,

Thanks,

-Lisa

Elisabeth Hesse, MD, MTM&H
LCDR, USPHS
CDC LNO to the Vaccine Operations Center
COVID-19 Vaccine Task Force
Centers for Disease Control and Prevention
404-498-5084
nrr3@cdc.gov
Thanks much!

Will pull together talking points on myocarditis and share. Henry

Henry Walke, MD, MPH
Incident Manager
CDC COVID-19 Response
+1-404-639-3582 (office)
+1-404-452-9624 (mobile)
hwalke@cdc.gov
DoD has submitted manuscripts on post-COVID-19 vaccine-associated myocarditis to both JACC and JAMA Cardiology.