From: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 8 Dec 2021 02:35:39 +0000
To: CISA Response (CDC)
Cc: Cortese, Margaret (CDC/DDID/NCIRD/DVD); Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR)
Subject: FW: EXT MSG Re: Personal Question [EXTERNAL]
Categories: CDC general

Anni, Allison,

Hi. Can we please assign this to a deployer tomorrow am to work with Margaret and Matt on this case. I suggest (b)(5)

Thanks,
Karen Broder, MD

From: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Sent: Tuesday, December 7, 2021 9:20 PM
To: Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Cortese, Margaret (CDC/DDID/NCIRD/DVD) <zrg1@cdc.gov>
Subject: Fw: EXT MSG Re: Personal Question [EXTERNAL]

VAERS temporary ID is (b)(6) for the case I mentioned yesterday. Question for CISA is: give 2nd dose? I think we should (b)(5)

Matt

From: (b)(6)
Sent: Tuesday, December 7, 2021 9:15 PM
To: (b)(6)
Cc: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>; (b)(6) (b)(6)
Subject: Re: EXT MSG Re: Personal Question [EXTERNAL]

Sorry, I told you wrong (b)(6) she was vaccinated at (b)(6) She has received the flu vaccine this year, sept 28.
Thanks to both of you

(b)(6)

On Dec 7, 2021, at 7:49 PM, (b)(6) wrote:

Hi Matt,

Sorry for the delay. Just filled out the VAERS data. Only had a couple of pieces missing – didn't know the site of vaccination and if she had received something else (Flu?) any time around that time as well. I'm sure (b)(6) can fill in the gaps here.

Here's the temporary Report number – (b)(6)

(b)(6)

From: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Sent: Monday, December 6, 2021 12:16 PM
To: (b)(6); (b)(6)
Subject: RE: EXT MSG Re: Personal Question [EXTERNAL]

(b)(6)

With your permission I'd like to refer this matter to CISA so that we can formally review this case. We like to do this when questions are posed to CISA as in this one: should this child receive a 2nd dose of vaccine? Please let me know if that is OK and I will get things started.

Also, when the VAERS report has been made, please send me the temporary ID so that we can expedite things.

Thanks,

Matt

Matthew Oster, MD, MPH
CDC COVID-19 Response
CDC Center on Birth Defects and Developmental Disabilities
Pediatric Cardiologist, Sibley Heart Center, Children's Healthcare of Atlanta
Emory University School of Medicine | Emory University Rollins School of Public Health
Igp8@cdc.gov

From: (b)(6)
Sent: Monday, December 6, 2021 10:58 AM
To: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>; (b)(6)
(b)(6)
Subject: Re: EXT MSG Re: Personal Question [EXTERNAL]

Sorry, here he is. I might have just forward it to him. (b)(6) this is Matt Oster.

(b)(6)

On Dec 6, 2021, at 8:55 AM, Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov> wrote:

(b)(6)

I didn't see the e-mail of the hospitalist. Can you re-send?

Also, OK if I go ahead and escalate this to get things moving?

Thanks,

Matt

Matthew Oster, MD, MPH
CDC COVID-19 Response
CDC Center on Birth Defects and Developmental Disabilities
Pediatric Cardiologist, Sibley Heart Center, Children's Healthcare of Atlanta
Emory University School of Medicine | Emory University Rollins School of Public Health
Igp8@cdc.gov

From: (b)(6)
Sent: Monday, December 6, 2021 9:52 AM
To: Matt Oster <OsterM@kidsheart.com>
Cc: (b)(6) Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Subject: Re: EXT MSG Re: Personal Question [EXTERNAL]

I am including the hospitalist who took care of (b)(6) in this email chain. I will call him and let him know. One of us will enter the VAERS

(b)(6)

On Dec 6, 2021, at 8:50 AM, Matt Oster <OsterM@kidsheart.com> wrote:

(b)(6)

Sorry to hear about this but glad to hear that your daughter is doing better. Thanks for letting me know about this. The biggest question of course, here, is whether this was truly KD or whether this was MIS-C related to the vaccine. (b)(6) as an update to Friday: we do now have a small number of cases like this one.

(b)(6) I discussed this with our CDC team and I'd like to ask you to do a few things:

1. Submit a VAERS report at https://vaers.hhs.gov/esub/index.jsp. Please include the information for contact information of a key provider who took care of your daughter (and let them know you're doing this). Please also e-mail me the temporary VAERS ID that you receive after submitting the report. (Anyone can report to VAERS – doesn't have to be healthcare provider but good to loop them in.)
2. Give me permission to escalate this to CISA, the CDC Clinical Immunization Safety Assessment group. This group will then launch an investigation to explore this further and likely arrange a call with the provider who took care of your daughter. The question of whether to give a 2nd dose will be addressed. Just a heads up: CISA policies are to have these calls with the healthcare team that took care of the patient and the health department in the jurisdiction, but not the parents. But, the final result of discussions will be relayed to you. Just please be patient as these can take time, especially with the holidays coming.
3. Hold off on further doses

BTW, cc'ing my CDC e-mail on this. Please send future correspondence on this topic to that address.

Thanks,

Matt

Matt Oster, MD, MPH
Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center)
Sibley Heart Center Cardiology, Children's Healthcare of Atlanta
Emory University School of Medicine | Emory University Rollins School of Public Health
Medical Officer, CDC Center on Birth Defects and Developmental Disabilities | CDC COVID-19 Response
2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341
o: 404-256-2593 | f: 770-488-9477
osterm@kidsheart.com | www.choa.org/heart

From: (b)(6)
Sent: Sunday, December 5, 2021 10:48 PM
To: (b)(6)
Cc: Matt Oster <OsterM@kidsheart.com>
Subject: Re: EXT MSG Re: Personal Question [EXTERNAL]

Thanks, (b)(6) I will talk with her doctor to report it. Waiting for a few more weeks is a good idea.

(b)(6)

On Dec 5, 2021, at 9:26 PM, (b)(6) wrote:

Dear (b)(6)

I am sorry to hear that your daughter had KD and very happy to hear that she is doing better.

Just this past Friday at the (b)(6) study meeting, I asked Matt Oster (who spends lots of time at the CDC on vaccine myocarditis) whether any cases of KD had been reported in association with the COVID-19 vaccine. He said no. I do think I would report this to VAERS, however. BUT it is super unlikely to have resulted from a first dose of vaccine. I've CC'ed Matt above to get his opinion.

My guess is that you could give the second vaccine dose, but maybe I would wait a little longer than three weeks since this is perfectly reasonable to do and to allow her to recover fully.

Matt- what do you think?

Cheers,

(b)(6)

(b)(6)

From: (b)(6)
Sent: Sunday, December 5, 2021 7:20 PM
To: (b)(6)
Subject: Personal Question [EXTERNAL]

*** External Email - Caution ***

Dear (b)(6)

I want to (b)(6) and your expertise in Kawasaki's Disease. I hope you don't mind.

(b)(6) was admitted last week with Kawasaki. She had the typical conjunctival erythema, swollen red lips, high fever, a rash with high ESR, CRP, mild elevation of AST/ALT and normal kidney function. She turn the corner magically after one dose of IVIG. She was discharged the next day.

She had just received the first dose of the Pfizer vaccine for COVID 2 weeks before her symptoms. (b)(6) and I are wondering what to do about the second dose. Any advice?

(b)(6)

From: CISA Response (CDC)
Sent: Wed, 23 Nov 2022 17:13:37 +0000
To: CISA Response (CDC)
Subject: FW: Received 11/23 7:55 AM. RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Sending to the box as a secure given PII

Restricted Use/Recipients Only

From: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Sent: Wednesday, November 23, 2022 7:55 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Good morning Allison,

That sounds good. Thank you for your help!

Shaeyla

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, November 22, 2022 4:30 PM
To: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Hi Shaeyla,

I spoke to the CISA leadership and we are going to reach out to one more CISA SME as a professional courtesy (to see if he knows of any projects that may be relevant to the inquirer).
We will hopefully hear back tomorrow.

Thank you for your patience,
Allison

From: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Sent: Tuesday, November 22, 2022 11:40 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Subject: Re: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Thank you!

We have not responded yet, but will copy you once we do.

-Shaeyla

Get Outlook for iOS

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, November 22, 2022 10:31:29 AM
To: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Hi Shaeyla,

If you plan to respond to this patient, please feel to include CISA language if his provider has a vaccine safety question.

That being said, (b)(5) (b)(5) I plan to discuss with CISA Leadership early this afternoon and will let you know if we have any thoughts about who he could contact.

If you've already responded, please let us know ☺

Many Thanks,
Allison L.

From: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Sent: Tuesday, November 22, 2022 9:49 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Good morning Anne,

We received the below reply from (b)(6)

Thank you,
Shaeyla

From: (b)(6)
Sent: Monday, November 21, 2022 5:44 PM
To: Vaccine Safety (CDC) vaccinesafety@cdc.gov
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Sorry, just saw this.

Yes, I am a US healthcare provider - (b)(6) (b)(6) and put in intensive care with acute pleurodynia and hypoxia. A couple weeks after discharge, the diagnosis came back, Coxsackie B3 infection (likely acquired at t (b)(6) he week before).

After each of my last two vaccinations, I had a recurrence of similar symptoms, enough so that I talked my provider into ordering a Coxsackie B3 panel, which came back elevated (but we didn't have a baseline, didn't know whether my levels had stayed high since 2000 – medical literature suggests that there may be an occult CBV viral reservoir and/or a chronic auto immunity, that ends up in some cases with the slow cardiomyopathy – enough so, that it accounts for a large fraction of the heart transplants.

(b)(6) but really hope that someone at CDC is looking at the co- occurrence and co-distribution of SCV-2 and CBV. May provide some insight into an auto-antibody mediated cardiomyopathy – and may suggest who is at higher risk of vaccine ill effects, though quite rare.

Lastly, (b)(6) I'm trying to decide if the 3 time will be even worse than the second – which was so acute (and with a fecalith as a red herring) the surgeons took out my appendix before the bradycardia and ekg changes were apparent.

But I've been careful, tested often, and appear to not have had covid so far. Don't know whether to fear another vax more or less than the risk of an infection.

Would like to know if there are any other similar reports, or any papers or studies.

Thanks,
(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, November 22, 2022 9:44 AM
To: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Good morning Vaccine Safety,

CISA wanted to follow-up and see if you have had any further correspondence from this provider. Have they responded if they and their patient are US based?
Please let us know if there has been any response, or if your team has already responded to the provider and closed this out.

Thank you,
Anne Scheffey, MPH, MS, BSN, RN
Nurse Consultant
Clinical Immunization Safety Assessment (CISA) Project
Centers for Disease Control and Prevention (CDC)
CISA

From: Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Sent: Friday, November 18, 2022 12:15 PM
To: (b)(6)
Subject: RE: RESPONSE REQUIRED; Priority HIGH; Mode Phone; Topic [mRNA Covid-19 Vaccine Relation With Coxsackievirus B3] [CDC-2712034-G2H6X1] CRM:00010028

Dear (b)(6)

Thank you for contacting the CDC.

Before we respond to your question, please let us know if you are a US healthcare provider asking this question about a patient in the United States?

Thank you,

Staff of the CDC Immunization Safety Office
Atlanta, GA

---------- Call Description ----------

Name: (b)(6)
E-mail: (b)(6)
Phone:
Date: 11/17/22, Time: 2:09 pm ET
Healthcare Provider:
(Does CDC has literature regarding the possible relationship between Coxsackievirus B3 antibodies increase and post mRNA covid-19 vaccine myocarditis?)

More info:
Incoming call from an [redacted] who has a case of a patient with history of coxsackievirus B3 who's antibodies of virus mentioned above increases after mRNA covid-19 vaccines and myocarditis symptoms post vaccination.

From: Vaccine Safety (CDC)
Sent: Fri, 18 Aug 2023 19:27:15 +0000
To: CISAeval (CDC)
Subject: FW: Response from CDC regarding: clinical question re-pt with history of Pfizer vaccine related myocarditis
Attachments: Outcomes at least 90 days since onset o...pdf

Hi CISA,
FYI-this inquiry is now closed.

Thanks,

Elaine

From: Vaccine Safety (CDC)
Sent: Tuesday, August 15, 2023 3:59 PM
To: (b)(6)
Subject: Response from CDC regarding: clinical question re-pt with history of Pfizer vaccine related myocarditis

(b)(6)

Thank you for contacting CDC. We are sorry to hear about this patient who is having a recurrence of symptoms of myopericarditis.

The available data that we have for outcomes among patients who developed myocarditis after mRNA COVID-19 vaccination is from the attached study by Kracalik and colleagues. This study was conducted on people aged 12-29 years in the United States who developed myocarditis after mRNA COVID-19 vaccination. The study surveyed both patients (or parents) and healthcare providers to assess outcomes at least 90 days after the onset of myocarditis. Data was collected on 519 (62%) of 836 eligible patients. Eighty one percent of patients who had a follow up healthcare provider survey were considered recovered from myocarditis and most patients reported overall good health. However, nearly half of patients continued to report symptoms, including chest pain, and a quarter were prescribed daily cardiac medications.

(b)(5)

(b)(5) That data will be published when it is available.

The medical literature has case reports that might be similar to your patient:
Relapsing myocarditis following initial recovery of post COVID-19 vaccination in two adolescent males - Case reports - PubMed (nih.gov)
Recurrent ventricular tachycardia in a patient with COVID-19 vaccine-associated myocarditis: a case report - PubMed (nih.gov)

Please let us know if we can provide additional assistance.

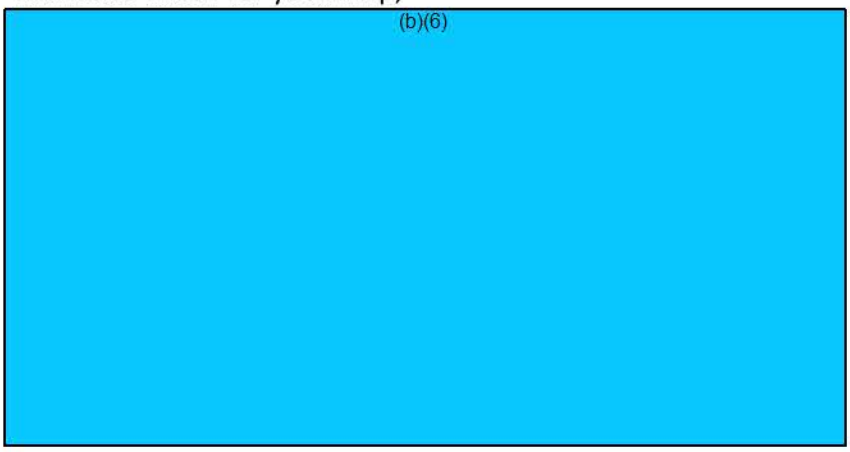
Sincerely,
Staff of the CDC Immunization Safety Office
Atlanta, GA

From: (b)(6)
Sent: Friday, August 11, 2023 1:54 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: clinical question re-pt with history of Pfizer vaccine related myocarditis

Hello,

I have a question regarding a patient of mine. He is a 17 yo healthy male who developed myocarditis 1 year ago following administration of his 3rd dose of the Pfizer mRNA Covid-19 vaccine. He has re-presented with myopericarditis without an identifiable etiology and I am wondering if this has been seen in any other patients with a history of Covid vaccine related myocarditis.

Thanks so much for your help,



From: CISAeval (CDC)
Sent: Mon, 3 Oct 2022 12:41:50 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Museru, Oidda I. (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); CISA Response (CDC)
Subject: FW: RESPONSE REQUIRED; Topic Reporting Kawasaki Disease event after 2nd Moderna vaccine (<5 years); [CDC-2670796-Q7J1H1] CRM:09451578
Importance: High
Categories: Andrea;CDC general

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>
Sent: Monday, October 3, 2022 8:41:42 AM (UTC-05:00) Eastern Time (US & Canada)
To: CISAeval (CDC) <CISAeval@cdc.gov>
Subject: RESPONSE REQUIRED; Topic Reporting Kawasaki Disease event after 2nd Moderna vaccine (<5 years); [CDC-2670796-Q7J1H1] CRM:09451578

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:

- This inquiry is being escalated because the answer could not be found in CDC resources, the A-Z List states to escalate, etc.

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.

JM/14312/17771/11109

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

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

Sent: 10/2/2022
From: Clinician
Subject: Reporting Kawasaki Disease event after 2nd Moderna vaccine (<5 years)
Email Address: (b)(6)
Question: Hi,

I'd like to request a CISA COVIDvax consultation. My name is (b)(6) and I'm a pediatric infectious disease physician practicing at (b)(6)
My cell is (0)<<PII>> .

I'm consulting on a 2 year old male child of A(b)(6)lescent who received his second COVID-19 Moderna vaccine and then 6 days later developed a week of fever with symptoms concerning for atypical Kawasaki Disease (KD). He did not present to care until after becoming afebrile, at which time an echo was done showing diffuse coronary dilation. He has been treated with IVIG, steroids and antiplatelet therapy and is very stable. Clinical picture seems most consistent with sequalae of KD, although have also considered MIS-C given sister with positive rapid COVID test the day that he first became febrile. Multiple rapid COVID tests in the patient while symptomatic have been negative, as well as PCR test on admission. SARS-CoV-2 IgM negative (pre-IVIG), IgG panel pending.

I had low suspicion for sequalae of COVID-19 vaccination given he does not have myocarditis. However, have submitted a VAERs report today, and I know that KD is one of the prespecified outcomes in the VSD, although no signal reported on data presented at ACIP CDC presentation 9/1. My question was less about management but just to bring this report to your attention so it could be noted (in a perhaps more timely manner than review of the VAERs report), give association of development of KD with severe sequalae within one week of receiving the second Moderna vaccine.

Optional Information

Name: (b)(6)
Title:
Organization: (b)(6)
Phone: (b)(6)
Other Email: (b)(6)
Address:
(b)(6)
PII Extraction: 0) (b)(6)

From: CISA Response (CDC)
Sent: Tue, 11 Jan 2022 13:25:04 +0000
To: (b)(6)
Cc: CISA Response (CDC)
Subject: Inquiry additional details
Categories: Dee;Loria

(b)(6)

Thank you for providing the history pertinent to your inquiry about the 17 year old male with hospitalization for myocarditis 2 days after receiving Dose #1 of Pfizer COVIDS-19 vaccine.

After initial discussion with the CDC vaccine safety team, we would like to ask the following additional questions:

1. Did the patient undergo nucleocapsid antibody testing for previous COVID -19 infection?
2. Was there any suspicion or work-up done for an infectious etiology (for example, Coxsackievirus)?
3. Has he received other childhood vaccines? If so, did he have any hx of any type of reaction to any other vaccines?
4. When will he turn 18?

With additional information, we plan to discuss the case with our pediatric cardiology SME.

Thank you for taking the time to provide this information. You can reply directly to this email or reach me directly at (404)277-9930

Datta Munshi, MD
Contractor, Eagle Health Analytics
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: COVID19VaxSafety
Sent: Mon, 27 Dec 2021 17:59:19 +0000
To: (b)(3):42 U.S.C. §242m(d); (b)(6)
Subject: Response from CDC RE: Non-acute req: Arrhythmia following mRNA vaccine 5-11 year old
Categories: VAERS inquiry tracking

Dear (b)(6)

Thank you for your email. Please let us know if you will send to (b)(6) or if you'd like us to.

To address your questions, we searched data from the Vaccine Adverse Event Reporting System (VAERS). As you are aware, VAERS is a national vaccine safety monitoring system managed by CDC and the Food and Drug Administration (FDA). VAERS accepts reports of possible side effects (also called "adverse events") following vaccination. The system is not designed to determine whether a reported adverse event was caused by the vaccine, but serves as an early warning system and helps CDC and FDA identify areas for further study.

As of Dec. 24, 2021, VAERS has received and processed 5702 reports for all adverse events after COVID-19 vaccine in children ages 5-11. Of those 7 are reports of arrhythmias and the reports had following codes: extrasystoles, sinus arrhythmia, sinus tachycardia, supraventricular tachycardia, ventricular extrasystoles, or ventricular tachycardia. Three of the 7 cases were "serious" since they were reported to result in hospitalization:

1) One day after vaccination a 10-year-old had chest pain and was diagnosed with premature ventricular contractions.
2) On the same day as vaccination, a 6-year-old had itching, and chest pain. EKG showed sinus arrhythmia. Patient recovered.
3) Three days after vaccination, a 6-year-old had rapid heart rate and sinus tachycardia. Treated in ER.
4) A 10-year-old had an episode of syncope and was found to be in V-tach. Required cardioversion. Hospitalized. Had a prior medical history of repaired Tetralogy of Fallot
5) A 6-year-old had supraventricular tachycardia starting 11 days after vaccination. Required treatment in PICU.
6) An 11-year-old had myocarditis with abnormal EKG, extrasystoles beginning the day after vaccination. Required hospitalization.
7) A 7-year-old had fever 1 day after vaccination that resolved and complained of chest pain. Patient and parent reported sinus arrhythmia that resolved.

VAERS data has limitations. Please keep in mind:
• VAERS generally cannot determine if the vaccine caused the reported adverse event. While some reported adverse events may be caused by vaccination, others are not and may have occurred coincidentally.
• Underreporting of adverse events may occur. However, serious adverse events are more likely to be reported than non-serious events.
• Reports vary in quality and completeness. They may lack details and contain errors.
• This VAERS data search is for personal use and not intended for scientific publication.

To read more about the strengths and limitations of VAERS, visit https://vaers.hhs.gov/data/dataguide.html.

Please let us know if we can provide additional assistance.

Sincerely,

Elaine Miller for the CDC Immunization Safety Office
Atlanta, GA

From: (b)(3):42 U.S.C. §242m(d); (b)(6)
Sent: Thursday, December 23, 2021 5:48:05 PM (UTC-05:00) Eastern Time (US & Canada)
To: CISAeval (CDC) <CISAeval@cdc.gov>
Subject: Non-acute request: Arrhythmia following mRNA vaccine 5-11 year old

From one of our colleagues in (b)(6)

Non acute (clearly – was sent to me two weeks ago).

From: (b)(6)
Date: Saturday, December 11, 2021 at 5:16 PM
To: (b)(3):42 U.S.C. §242m(d); (b)(6)
(b)(3):42 U.S.C. §242m(d); (b)(6)
Subject: post vaccine arrythmias

Hi (b)(6)
How are you? Reaching out to inquire if you have received any reports of post-vaccine arrhythmias in the 5-11 year age group? We had a 6 year old admitted to our PICU in SVT, required adenosine, 12 days post his first Covid vaccine dose. Child is otherwise healthy. Troponin elevated to 39 (our upper limit normal is 22) echo normal.
We did report to VAERS.
Thanks
(b)(6)

(b)(6)

(b)(6)

From: COVID19VaxSafety
Sent: Wed, 2 Feb 2022 12:16:40 +0000
To: (b)(6)
Subject: Response from CDC RE: Topic   CISA COVIDvax; [CDC-2373024-Y7M8N4]
CRM:04152368
Categories: VAERS inquiry tracking

Dear (b)(3):42 U.S.C. §242m(d); (b)(6)

Thank you for contacting CDC.

As policy, CDC does not offer clinical guidance, and recommends questions and decisions regarding the clinical care and management of a patient be discussed with the patient's healthcare provider. Such patient management requires familiarity with a patient's medical history, the ability to examine the patient, as well as clinical laboratory testing. These factors are beyond CDC's ability to provide, and for those reasons, we recommend you discuss your health concerns with your healthcare provider.

CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States have this information on persons with a history of myocarditis or pericarditis:

History of myocarditis or pericarditis prior to COVID-19 vaccination

There are limited data on the safety and efficacy of COVID-19 vaccines in people with a history of myocarditis or pericarditis. People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to assess cardiac recovery. Considerations for COVID-19 vaccination in people with a history of MIS-C or MIS-A are discussed here.

CDC is continuing to investigate cases of myocarditis or pericarditis after mRNA COVID-19 vaccination; this guidance may be updated as new information is obtained.

If your healthcare provider has questions about your case, including whether you should receive COVID-19 vaccination, a consultation through CDC's Immunization Safety Office, Clinical Immunization Safety Assessment (CISA) team may be requested by your physician by completing the webform on the CDC-INFO website: a CDC-INFO webform or by calling CDC-INFO [1-800-CDC-INFO (800-232-4636)] and requesting a COVIDvax consultation. Your healthcare provider should provide their contact information and indicate that the request is for a CISA COVIDvax consultation.

More information about CISA is available at this link:
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Sincerely,

Staff of the CDC Immunization Safety Office
Atlanta, GA

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

Sent: 1/31/2022
From: General Public
Subject: CISA COVIDvax
Email Address: (b)(6)
Question: I am a (b)(3):42 but contacting in regards to myself. I am 29 years old. I have an auto-inflammatory disorder/periodic fever syndrome. I also have a history of pericarditis. I have not found information online to determine if the vaccine is safe given my history of these two. Vaccines in general put me into a flare (I got a flu shot in the 19-20 season and had a fever and other associated symptoms for 12+ weeks).

Optional Information

Name: (b)(6)
Title:
Organization:
Phone: (b)(6)
Other Email:
Address:

PII Extraction:

From: COVID19VaxSafety
Sent: Tue, 1 Mar 2022 20:00:09 +0000
To: (b)(6)
Subject: Response from CDC RE: Topic Cisa covidvax consult; [CDC-2416444-M3P5M6] CRM:04152755
Categories: VAERS inquiry tracking

Dear (b)(6)

Thank you for contacting the CDC. We are very sorry to hear you experienced adverse events after receiving the COVID-19 vaccine and have been recently diagnosed with ulcerative colitis and PVCs. We did receive the VAERS report and follow up that you filed on your case.

As a policy, the CDC does not offer clinical guidance, and recommends questions and decisions regarding the clinical care and management of a patient be discussed with the patient's healthcare provider. Such patient management requires familiarity with a patient's medical history, the ability to physically examine the patient as well as clinical laboratory testing to obtain a fuller picture of the patient's clinical situation. *As you may know, the CDC does not issue exemptions from COVID-19 vaccination requirements, and hence does not make determinations for specific instances of exemption eligibility. Visit https://www.osha.gov/coronavirus/ets/faqs for information about healthcare worker requirements and exemption policies.*

At this time, data do not indicate a causal association between COVID-19 vaccines and ulcerative colitis or PVCs.

Any vaccine can cause side effects. For the most part these are minor (for example, a sore arm or low-grade fever) and go away within a few days. Possible side effects after receiving the COVID-19 vaccine include the symptoms you described of chills, body aches, and lethargy. To reduce discomfort, we encourage drinking plenty of fluids prior to vaccination.-

PVCs are a common type of irregular heartbeat and may be caused by stimulants such as caffeine or tobacco and increased levels of adrenaline due to exercise or anxiety among other causes. Please continue to get evaluated by a doctor if you are experiencing chest pain since there are a number of potential causes, some of which are very serious.

To address your concerns about ulcerative colitis, a study found that Medicare beneficiaries with ulcerative colitis were more likely to be hospitalized for COVID-19 compared with those without IBD.[13] The International Organization for the Study of Inflammatory Bowel Disease recommends that patients with IBD (ulcerative colitis or Chron's disease) get a COVID-19 vaccine.[14]

If your healthcare provider has questions about your case that is not readily addressed by ACIP guidelines or CDC's *Interim Clinical Considerations*, they can request a consultation from CDC's Clinical Immunization Safety Assessment (CISA) COVIDvax at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. Please note that CISA

does not take requests for consults from patients about their case (even if the patient is a healthcare provider). However, CISA does take consult requests from healthcare providers about their patients.

Sincerely,

Staff of the CDC Immunization Safety Office
Atlanta, GA

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

Sent: 3/1/2022
From: Clinician
Subject: Cisa covidvax consult
Email Address: (b)(6)
Question: I am a (b)(3):42 After my second Moderna vaccine on Feb 25 2021 I was lightheaded. They had me stay longer and I felt ok. That night I had the chills, body aches, insomnia, by the morning when I stood I got lightheaded and almost passed out. I had to drink 3 bottles of water and a Gatorade before I could stand so it must have caused hypotension. I had lethargy for a few days and didn't feel quite myself. Then I was dizzy with turning and my BP I checked at work was 130/80 or 90, which is high for me. After a couple days the dizziness went away. In May I started having a change in my bowels and have been diagnosed with ulcerative colitis. I am in medication for it now. In July I started having palpitations and had a heart monitor in august showing PVC's. I am going to have an echocardiogram and a stress test, I do have occasional left sided brief chest pain at times. I need to know if any of these things are a contraindication because my work is now requiring a booster. My PCP and my GI doctor say it's possible that the vaccine caused my GI problem but they don't have any data to say it's a contraindication, it's not like I had the published myocarditis that has been linked. I didn't have these problems before the vaccine so someone needs to see if it is linked for me on an individual case please. I might lose (b)(6) at my work is taking submissions for an exemption from the vaccine by the end of the week. If it doesn't get approved then (b)(6) (b)(6) I need something written definitively that I should not get the booster and this is information I hat my doctors do not have. Can someone in CDC help me please. There is no data because reactions are under reported, a case like mine is the data and needs to be listened to please.

Optional Information

Name: (b)(6)
Title:
Organization: (b)(6)
Phone: (b)(6)
Other Email: (b)(6)
Address:
(b)(6)
PII Extraction:

From: CDCInfoResponse
Sent: Fri, 14 Jan 2022 14:42:58 +0000
To: CISA Response (CDC)
Subject: RESPONSE REQUIRED: Priority Medium; Mode Phone; Topic [Adverse reaction post first dose] [CDC-2334281-Y2J8M7] CRM:04651503
Categories: Lara;Dee

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.

- This inquiry is being escalated because the answer could not be found in CDC resources, the A-Z List states to escalate, etc.
- During the call, phone agent provided PRs # 17725, 17638, 18062 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.

AW/Approver's Initials PR# 14312, 17771, 17725, 17638, 18062, 11109

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

---------- Call Description ----------

Name: (b)(6)

E-mail: (b)(6)

Phone: (b)(6)

Date, Time ET: 9:10am

Healthcare Provider:

66yo f requesting exemption from second Pfizer dose. Should patient receive the second dose of Pfizer COVID-19 vaccine? Patient has a hx of postpardem cardiomyopathy. Cancer is currently in remission. Patient received on Mar 30, 2021 the first dose of Pfizer COVID-19 vaccine. Within several days complained of heart palpitations and shortness of breath. Cardiologist determined symptoms were due to adverse reaction of vaccine. PCP suspected vaccine induced myocarditis and also advised against second dose of vaccine. No clinical information about

evaluation or treatment provided by these providers. Bylateral pulmunary embolism July 2021. Had COVID-19 Aug 2021.

From: CISA Response (CDC)
Sent: Tue, 28 Dec 2021 19:03:26 +0000
To: (b)(6)
Cc: CISA Response (CDC)
Subject: Response to your CDC CISA inquiry on COVID-19 vaccine following chest pain

Dear (b)(6)
Thank you for providing the additional information on the cardiac workup of your 30 year old patient who experienced chest pain two days after receiving COVID-19 Pfizer vaccine dose #1 in the setting of having been diagnosed with COVID-19 six months earlier. Our colleagues in NIPINFO were able to answer your question on 12/22 that "antibody testing is not recommended to assess the need for vaccination or to assess for immunity to SARS-CoV-2 following COVID-19 vaccination". This email is intended to answer your other question about the safety of this patient receiving COVID-19 vaccine dose #2 in the setting of her chest symptoms.

To answer your question, we reviewed the *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States*, section *Contraindications and precautions*. CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines.

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the COVID-19 vaccine

Given that your patient experienced chest pain following vaccination, we also discussed your patient's case with our CISA cardiology expert who advised that it would be **acceptable to proceed with further doses of COVID-19 vaccine**. The normal troponin and EKG essentially rule out myocarditis and pericarditis. Additional information can be found here: CDC Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines.

General information

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- Information about general clinical guidance for COVID-19 vaccines can be found at CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
- For the most up-to-date information, CDC will continue to post information online at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Healthcare providers are encouraged to report any clinically significant adverse events that occur after the administration of COVID-19 vaccines. To learn more about VAERS, or how to report an adverse event, you can visit their website https://vaers.hhs.gov/

We hope this information is helpful to you.

Kindly,

Loria Pollack, MD, MPH
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: (b)(6)
Sent: Thursday, December 23, 2021 12:58 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: Re: Response to your CDC CISA inquiry

1. Yes, I work in the (b)(6)
2. Troponin and CPK and EKG normal 12/18, CT pulmonary angiogram with contrast also normal the same day, echo not done
3. Pfizer/BioNTech
Thanks!

On Dec 23, 2021, at 12:34 PM, CISA Response (CDC) <cisaresponse@cdc.gov> wrote:

Dear (b)(6)

Thank you for reaching out to the CDC's Clinical Immunization Safety Assessment (CISA) team about a 30 year old female with a history of COVID-19 who developed chest pain after receiving her first COVID-19 vaccine. We have some follow up questions for you, please.

1. We will need to confirm that you are the treating physician for this patient. CISA does not provide consultation to individuals directly, even if they are health care professionals. Thank you in advance for confirming this information with the name of your medical practice. (Assuming the answer is "Yes", please see 2 and 3 below).
2. Can you please provide the information about the work up that was performed for possible myocarditis / pericarditis, including dates and results of tests performed, such as EKG, echocardiogram, troponin, BNP and any other relevant tests.
3. Which COVID-19 vaccine did the patient receive?

General information

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- Information about general clinical guidance for COVID-19 vaccines can be found at CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
- For the most up-to-date information, CDC will continue to post information online at https://www.cdc.gov/coronavirus/2019-ncov/index.html.

CISA COVIDvax is a service that CDC provides to assist healthcare providers or health departments in assessing complex COVID-19 vaccine safety questions. We work closely with CDC's Clinical Immunization Safety Assessment (CISA) Project, a national network of vaccine safety experts from the CDC's Immunization Safety Office (ISO), 7 medical research centers across the nation, and other partners, which provides consultation to healthcare providers and departments of health regarding complex adverse events following immunization.

We hope that we can be of assistance to you in your clinical care of this patient.

Kindly,

Loria Pollack, MD, MPH
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

---------- Call Description ----------

Name: (b)(6)
E-mail:
Phone:
Date, Time ET: 12/22/21 1pm EST
Healthcare Provider: 30 yr old female who had Covid in April 2021 and recovered at home on own.
Got vaccine due to work mandate on Dec 16 and developed left sided chest pain and leg twitching.
Tests did not show pericarditis or myocarditis. Currently, chest pain is better, leg twitching is gone but patient remains very anxious.
Does it make since to exempt her from the 2nd dose of the vaccine because 1) she has positive antibodies
from natural immunity she developed after getting Covid in April plus 2) now has 1 dose of vaccine - therefore,
can she be considered fully vaccinated? Additionally, should checking antibody levels influence the decision
to give 2nd vaccination or exempt patient from receiving vaccine?

From: CISA Response (CDC)
Sent: Fri, 7 Jan 2022 15:32:24 +0000
To: (b)(6)
Cc: CISA Response (CDC)
Subject: Response to your CDC CISA inquiry
Categories: VAERS inquiry tracking

Dear (b)(6)

Thank you for reaching out to CDC's Clinical Immunization Safety Assessment (CISA) Project regarding your patient who experienced cardiac issues two months after completing the Pfizer COVID-19 vaccination series on May 7, 2021.

Situation: 20-year-old male had chest pain in late July and was found to have pericardial effusion of 1.2 cm on echocardiogram that resolved on repeat echocardiogram approximately one month later. No other past medical history was provided. His cardiologist currently recommends a COVID-19 booster dose. You would like to know if it is safe to give a COVID booster vaccine dose and, if so, is there a preference for Pfizer or Moderna booster.

To answer your questions, we consulted vaccine safety subject matter experts (SMEs) in the Clinical Immunization Safety Assessment (CISA) Project. A cardiologist remarked that the interval of over two months between the vaccine and chest symptoms with a pericardial effusion is a longer time interval than reports of myocarditis/pericarditis cases occurring after either of the mRNA COVID-19 vaccine. Another expert shared that among approximately 100-120 patients in the Long-COVID Adult General (b)(3) 42 U.S.C. §242m(d); (b)(6) *none* have had symptoms of pericarditis that started > 6 weeks out from COVID infection or vaccination.

We also reviewed data presented at recent from the Advisory Committee on Immunization Practices (ACIP) meetings. Please see this link that describes reports to CDC's Vaccine Adverse Event Reporting System (VAERS) of myocarditis, pericarditis, and myopericarditis after mRNA COVID-19 vaccines. Slide #6 indicates that the onset of symptoms associated with post-COVID vaccination myocarditis/pericarditis occurs within days following vaccination, not months (data thru Oct 6, 2021). (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf). Also, during the January 5, 2021 ACIP meeting, Dr. Su presented on COVID-19 safety of booster doses among adolescent and showed on Slide #19 that among 976,882 Pfizer COVID-19 booster doses administered to persons age 16-24 years, there were 13 preliminary reports of myocarditis of which 4 met case definition. The median time to onset for these cases was 1 day (Microsoft PowerPoint - 02_COVID_Su_2022-01-05 (cdc.gov)). Additional information can be found here: CDC Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines.

The consensus among multiple subject matter experts was that **if the patient's treating cardiologist feels the pericardial effusion has resolved and is no longer an active issue, the patient can be given a booster dose.** Regarding your question on whether he should receive a Pfizer or Moderna booster, although CDC's recommendations now allow for mix and match dosing for booster shots, **there is no clear benefit to switching vaccine formulation to Moderna**. Given the complexity of the case, if there is additional pertinent information or questions from his cardiology team, we would be happy to work with the treating clinician. Information from CDC and CISA is meant to assist in decision-making, rather

than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider

General information

- Information about general clinical guidance for COVID-19 vaccines can be found at CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
- For the most up-to-date information, CDC will continue to post information online at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Healthcare providers are encouraged to report any clinically significant adverse events that occur after the administration of COVID-19 vaccines. To learn more about VAERS, or how to report an adverse event, you can visit their website https://vaers.hhs.gov/

We hope this information is helpful to you.

Kindly,

Loria Pollack, MD, MPH
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

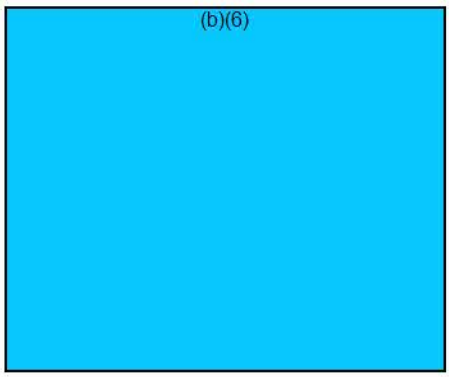
From: (b)(6)
Sent: Thursday, January 6, 2022 8:54 AM
To: CISAeval (CDC) <CISAeval@cdc.gov>
Subject: CISA COVIDvax question

Hello, my name is (b)(6) and I am a (b)(6) and the (b)(6) at The (b)(6) (b)(6) My phone number is (b)(6) I am inquiring about whether one of our patients can receive either the Pfizer or Moderna covid vaccine.

The patient is a 20 year old male who received his original Pfizer series on 4/16/21 and 5/07/21. At the end of July the patient developed mild chest pain and was evaluated by a primary care physician and then a cardiologist who performed an echocardiogram. The only thing reported to me was 1 cm of fluid around the heart that resolved in about a month based on a second echocardiogram. The patient has no lingering symptoms. The cardiologist has said he recommends the vaccination in this case but I wanted to check with you prior to giving the vaccine.

Is it recommended that this patient receive a booster dose of either mRNA? If yes should he use Moderna? If I can answer any more questions please call me on my cell phone at (b)(6) or email me back.

(b)(6)



From: CISA Response (CDC)
Sent: Sat, 14 May 2022 16:18:54 +0000
To: (b)(6)
Cc: CISA Response (CDC)
Subject: Response to your inquiry
Categories: VAERS inquiry tracking

Dear (b)(6)

Thank you for your inquiry about your 40-year-old female patient who developed numbness and weakness of her right arm and leg beginning ~5 days after receiving her first dose of Pfizer mRNA COVID-19 vaccine in July 2021. She presented to the ER 12 days after receiving the vaccine when she developed numbness on the right side of her face and loss of vision in her right eye. A brain MRI revealed nonspecific, minimal, scattered periventricular and subcortical white matter T2 FLAIR signal hyperintensities. She was discharged with diagnoses of TIA, vitamin B12 depletion, paresthesia, and nonspecific CNS demyelination. In January she began feeling pain in the MCP and proximal joints of her right hand. She also reports stress-induced palpitations. She has not received a second COVID-19 vaccine, but is undergoing evaluations with multiple subspecialists, including a neurologist, a neuro-ophthalmologist, a vascular surgeon, and a rheumatologist, on whether it would be safe to do so. You are asking if we have seen reports of similar adverse events after mRNA COVID-19 vaccines and whether a second dose of COVID-19 vaccine would be safe for her.

To answer your questions, we first reviewed the section on Contraindications and Precautions and Appendix E: Triage of people with a history of allergies or allergic reactions in CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines. In general, if the adverse event was not a severe allergic reaction, the reaction would not be a contraindication for dose 2. A history of immediate non-severe allergic reaction or a history of myocarditis/pericarditis after a dose of mRNA vaccine would be a precaution to future mRNA vaccines. We also noted that in accordance with Advisory Committee on Immunization Practices (ACIP) General Best Practices, moderate or severe acute illness, with or without fever, is a precaution to receiving all COVID-19 vaccines.

Given the clinical complexity, we also reviewed this case with vaccine safety experts in the Clinical Immunization Safety Assessment (CISA) Project Network, including a neurologist. CISA's guidance is that a patient with symptoms or findings following an immunization that are not explained by expected vaccine reactogenicity should be evaluated following whatever processes would have been followed had the patient not received a vaccine. In order to provide our best guidance on your questions, we would await the patient's completed workup. We are glad to hear that further evaluation of her symptoms and findings is currently underway. Several experts agreed that further evaluation is warranted and that follow-up neurologic evaluation, including brain MRI imaging, be performed expeditiously. Additional suggestions for possible exploration include CSF studies (with oligoclonal bands and IgG index to look for subtle signs of multiple sclerosis), and serum methylmalonic acid and homocysteine levels (before vitamin B12 repletion).

Once her clinical evaluation is complete, please reach back out to us for further guidance if you have any remaining vaccine safety questions about your patient. You can respond directly to this email, or request another CISA COVIDvax consultation via the webform on the CDC-INFO website at CDC-INFO webform.

Also, we encourage you to report this case to CDC's Vaccine Adverse Event Reporting System (VAERS) **(https://vaers.hhs.gov)** if you have not done so already. Information on how to submit a report to VAERS is available at **https://vaers.hhs.gov or by calling 1-800-822-7967.**

General information:

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- The most up-to-date general information about COVID can be found online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Thank you for contacting CDC. Please let us know if there is anything else we can do to help.

Sincerely,

Farhat Shireen MD, MPH
Brian R. Edlin, MD
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: (b)(6)
Sent: Sunday, May 8, 2022 10:28:59 PM (UTC-05:00) Eastern Time (US & Canada)
To: CISAeval (CDC) <CISAeval@cdc.gov>
Subject: RE: CISA Evaluation

To Whom It May Concern:

My name is (b)(6) and I am a (b)(6) I would like to submit a patient case to the CDC for a Clinical Immunization Safety Assessment (CISA) evaluation regarding an adverse reaction to Pfizer's COVID-19 mRNA vaccine. Please find the description of the case below.

The patient is a 40 year old female with a rare adverse reaction to her 1st COVID-19 mRNA vaccine dose (Pfizer) in July 2021 resulting in right sided numbness and weakness. She received her COVID-19 vaccine dose on 07/05/21. On July 17, 2021 the patient went to the Emergency Department at a hospital in (b)(6) (b)(6) after she started having numbness on the right side of the face and loss of vision in the right eye. She had some stuttering and short term memory issues as well and began exhibiting right-sided numbness and weakness in the arm and leg. Her symptoms had started about a week prior to presentation in the Emergency Department. The patient was admitted to the stroke unit given her symptoms. Her neurological examination on admission was as follows:

"Cranial nerve functions are unremarkable. The visual field is intact to confrontation. Pupils are equal, round, and reactive. Extraocular movements are intact without nystagmus. There is no facial asymmetry. Hearing is symmetrical. The tongue is midline. There is no focal weakness in all extremities. There is no tremor or any other abnormal involuntary movement. There is decreased sensation to pinprick over the right arm and right lower facial area, now also over the right cervical paraspinal area. DTR's are mildly diminished over the left knee and left ankle. No Babinski sign is present."

Complete blood count, chemistry, urinalysis, Lyme disease Western blot, and coagulation studies were unremarkable. The patient received an MRI of the brain on 07/18/21 with radiology reading as follows:

"No acute infarct. Minimal scattered periventricular and subcortical white matter T2 FLAIR signal hyperintensities, nonspecific and may represent chronic microvascular ischemic disease. Demyelinating disease may also be within the differential."

The patient was started on aspirin and a statin and was discharged home after a short hospital stay after her symptoms had improved. The patient was discharged with a diagnosis of:

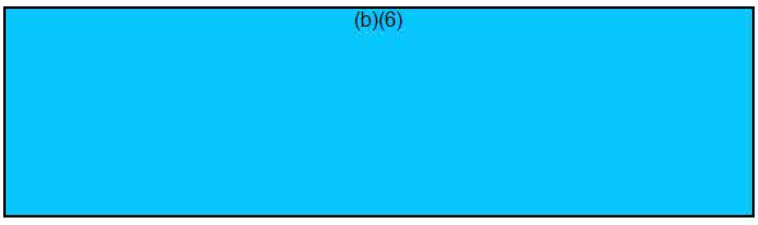
1. TIA (transient ischemic attack)
2. Vitamin B12 depletion
3. CNS demyelinating disease (HCC) - nonspecific white matter foci
4. Paresthesia of right facial area, right upper and lower extremity

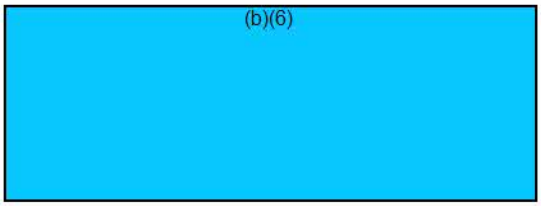
In addition, EBV reactivation was confirmed as part of the patient's evaluation during her hospital stay (positive viral capsid antigen IgG antibody with negative viral capsid antigen IgM antibody and negative nuclear antigen IgG antibody). Since the patient's hospitalization in July 2021, she has been having residual symptoms involving mostly the right side of her body such as bouts of paresthesias. She did see a neurologist as an outpatient who stated that the patient might have experienced a demyelinating event as a vaccine reaction after receiving her 1st COVID-19 mRNA vaccine dose. The patient is now working with an expanded team of medical professionals and has been advised to complete all recommended medical evaluations to determine whether she could be safely vaccinated further with a COVID-19 mRNA vaccine (or if a medical exemption is recommended) given the uncertain and unknown risk of a repeat reaction.

Besides the residual right sided symptoms that have been mentioned above, the patient has also been experiencing joint stiffness in the joints of the right hand as well as stress triggered palpitations. She is being evaluated by a team of subspecialists including rheumatology, neuro-ophthalmology, vascular surgery, and neurology given her array of symptoms. She continues to have some numbness and neuropathy on the right side with neuropathic pain (described as "nerve flicks" by patient) and "brain fog." Of note, the patient's mother had experienced the same "nerve flicks" concurrent with a GBS diagnosis after receiving the influenza vaccine in 2012. The patient's mothers symptoms only lasted a few weeks while the patient's symptoms have been episodic and varying in degree since July 2021.

I am the patient's current PCP and would like to submit her case to the CDC as a CISA evaluation given her adverse reaction to her first COVID-19 mRNA vaccine dose. If further information is required as part of the CISA evaluation process, please do not hesitate to contact me.

Sincerely,




(b)(6)

From: CISA Response (CDC)
Sent: Mon, 1 Aug 2022 21:59:03 +0000
To: CDCInfoResponse; CISA Response (CDC)
Subject: RE: 'RESPONSE REQUIRED'Priority High; Mode Phone; Topic [COVID-19 CISA] [CDC-2604267-G4Y0H9] CRM:09660016
Categories: Allison

Hi CDC Info,

CISA has responded to this inquirer.

Many Thanks,

Allison Lale, MD, MPH
CDC Clinical Immunization
Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>
Sent: Monday, August 1, 2022 2:41 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: 'RESPONSE REQUIRED'Priority High; Mode Phone; Topic [COVID-19 CISA] [CDC-2604267-G4Y0H9] CRM:09660016

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

- This inquiry is being escalated because the answer could not be found in CDC resources,
- During the call, phone agent provided PRs #14312, 17771, 17987, 17725, 11109, 17794 and 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.

JH PR#14312, 17771, 11109, 17725, 17794,17987

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

---------- Call Description ----------
Name: (b)(6)
E-mail: (b)(6)
Phone: (b)(6)
Date, Time ET: 8/1/2022, 1:59PM ET
Healthcare Provider:
I need clinical consult on patient who had pericarditis and Tamponade after receiving 2nd dose of Pfizer COVID-19, we don't know how to proceed, should we use a different COVID-19 vaccine as a 1st booster?

From: CISA Response (CDC)
Sent: Fri, 7 Oct 2022 19:19:42 +0000
To: (b)(6)
Cc: CISA Response (CDC)
Subject: RE: CISA inquiry
Categories: Andrea

Good afternoon (b)(6)

Thank you for sending the VAERS information to us.

Sincerely,
Andrea

Andrea Thames-Allen, MD, MPH
Physician Consultant, Lukos LLC- CDC COVID-19 Response
Clinical Immunization Safety Assessment (CISA) Project
E: ygt3@cdc.gov
O: 404-639-2776

From: (b)(6)
Sent: Thursday, October 6, 2022 12:49 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: Re: CISA inquiry

Hi Dr. Thames-Allen,
I very much appreciate your call earlier this week.

Just as an update, the COVID-19 IgG serology panel results returned. They show that he has robust levels of SARS-CoV-2 IgG spike protein (4,811) and RBD (10,415), consistent with recent vaccination. SARS-CoV-2 IgG nucleocapsid was not detected. Given several recent negative home COVID-19 tests, and the negative SARS-CoV-2 PCR (nasopharyngeal), IgM, and nucleocapsid IgG on admission, my suspicion for recent COVID-19 infection is low and MIS-C as an explanation for his diffuse coronary artery dilation seems unlikely.

The clinical picture continues to fit with atypical Kawasaki Disease. He received his second Moderna vaccine on 9/13 and the first symptoms consistent with atypical KD began 9/18 with right cervical lymphadenopathy and 9/19 with fever, so within the end of the first week after vaccination.

The VAERS Report Confirmation information that I received is below.

Report Confirmation

This confirmation may include updated information

VAERS ID: (b)(6)
E-Report Number: (b)(6)
Date of Report: 10/01/2022
Date of Vaccination: 09/13/2022
Patient Age at Vaccination (years): 2.00
Vaccine Information:

1. COVID19 (COVID19 (MODERNA)) / MODERNA / AR9236B

I do appreciate any updates you might have if you review the case with colleagues or have any further updates as to the likelihood that this could be vaccine-related if further cases are reported.

Thanks very much again,

(b)(6)

Tuesday, October 4, 2022 at 7:58 AM
To: (b)(6)
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: CISA inquiry

Dear (b)(6)

Thank you for speaking with me regarding your previously healthy 2 year-old male patient of (b)(6) descent with a history of fever and symptoms around two weeks following his second COVID-19 Moderna vaccine and is currently hospitalized with atypical Kawasaki Disease, status post IVIG and steroids. The patient had a recent household exposure to COVID-19 with no evidence of infection, but COVID-19 IgG serology results are pending. We understand that the patient has diffuse coronary artery dilation confirmed by Echo and CT angiogram but is clinically stable and awaiting discharge from the hospital. You stated there is no specific question related to a vaccine safety or future vaccines for this patient at this time but would like us to be aware that this patient has been reported to VAERS.
If vaccine safety guidance is desired, a **CISA COVIDvax** consultation through **CDC's Immunization Safety Office** may be requested by a treating physician on behalf of a patient via an email to CDCInfo@cdc.gov or via the webform on the CDC-INFO website: CDC-INFO webform. The healthcare provider should indicate that the request is for a **CISA COVIDvax** consultation.

General information:

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Thank you for filing a VAERS report and please share the VAERS temporary report ID number at your convenience. The VAERS team may not routinely respond to each inquiry logged into the VAERS system. We hope this information is helpful to you.

Sincerely,

Andrea Thames-Allen, MD, MPH
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

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

Sent: 10/2/2022
From: Clinician
Subject: Reporting (b)(6) event after 2nd Moderna vaccine (<5 years)
Email Address: (b)(6)
Question: Hi,

I'd like to request a CISA COVIDvax consultation. My name is (b)(6) and I'm a (b)(6) (b)(6) practicing at (b)(6) My cell is (0)<<PII>> .

I'm consulting on a 2 year old male child of (b)(3):42 descent who received his second COVID-19 Moderna vaccine and then 6 days later developed a week of fever with symptoms concerning for atypical Kawasaki Disease (KD). He did not present to care until after becoming afebrile, at which time an echo was done showing diffuse coronary dilation. He has been treated with IVIG, steroids and antiplatelet therapy and is very stable. Clinical picture seems most consistent with sequalae of KD, although have also considered MIS-C given sister with positive rapid COVID test the day that he first became febrile. Multiple rapid COVID tests in the patient while symptomatic have been negative, as well as PCR test on admission. SARS-CoV-2 IgM negative (pre-IVIG), IgG panel pending.

I had low suspicion for sequalae of COVID-19 vaccination given he does not have myocarditis. However, have submitted a VAERs report today, and I know that KD is one of the prespecified outcomes in the VSD, although no signal reported on data presented at ACIP CDC presentation 9/1. My question was less about management but just to bring this report to your attention so it could be noted (in a perhaps more timely manner than review of the VAERs report), give association of development of KD with severe sequalae within one week of receiving the second Moderna vaccine.

Optional Information

Name: (b)(6)
Title:
Organization: (b)(6)
Phone: (b)(6)
Other Email: (b)(6)
Address:
(b)(6)
PII Extraction: 0) (b)(6)

From: CISA Response (CDC)
Sent: Tue, 1 Feb 2022 15:51:39 +0000
To: CISA Response (CDC); (b)(6)
Cc: (b)(6)
Subject: RE: Covid vaccine and acute kidney injury
Categories: VAERS inquiry tracking

Dear (b)(6)

Thank you to you and (b)(6) for reporting the experience of your patient with acute kidney injury to VAERS and to the Clinical Immunization Safety Assessment (CISA) team. As we discussed, the CISA team engages in consultation with health care providers to assess if additional vaccine doses are advised. We understand that this was not your primary question and that you were more interested in whether similar cases have been reported. To summarize, your 14-year-old previously healthy patient developed mild COVID-19 illness in early November 2021 and subsequently received his first dose of Pfizer COVID-19 without any reaction (or a mild reaction per the patient's stepmother). He then had his second Pfizer COVID-19 vaccine dose and developed myalgias, flank pain, dysuria, and gross hematuria within one day. He had elevated creatinine and an elevated protein/creatinine ratio that were either stable or had begun to resolve a few days later.

To provide data regarding your question on whether gross hematuria and acute kidney injury have been reported following COVID-19 vaccination, we searched reports from the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national vaccine safety monitoring system managed by CDC and the Food and Drug Administration (FDA). VAERS accepts reports of possible side effects (also called "adverse events") following vaccination. The system is not designed to determine whether a reported adverse event was caused by the vaccine but serves as an early warning system and helps CDC and FDA identify areas for further study.

As of January 31, over 25 million children ages 5-17 years received at least one dose of a COVID-19 vaccine (https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic).

The following VAERS search terms were used: (b)(5)

(b)(5)

The following VAERS search criteria were used: (b)(5)

(b)(5)

(b)(5)

(b)(6)

(b)(5) To summarize, using broad search terms and including ages up to 21 years, there are a small number of cases reported with similar clinical presentation as your patient among the over 25 million children who received at least one dose of a COVID-19 vaccination.

We also reviewed the Vaccines and Related Biological Products Advisory Committee December 10, 2020 Meeting Briefing Document- FDA for Pfizer, Comirnaty | FDA Biologic License Application for Pfizer, Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document - FDA for Moderna. In addition, we reviewed the Fact Sheet for Healthcare Providers Administering Vaccine - Pfizer-BioNTech COVID-19 Vaccine for 12 and older - purple cap must dilute (fda.gov) and Fact Sheet for Healthcare Providers Administering Vaccine - Pfizer-BioNTech COVID-19 Vaccine for 5 - 11 Years of Age (fda.gov). There were no reports of acute kidney injury or gross hematuria.

Please note that VAERS data has limitations. Please keep in mind:
- VAERS generally cannot determine if the vaccine caused the reported adverse event. While some reported adverse events may be caused by vaccination, others are not and may have occurred coincidentally.
- Underreporting of adverse events may occur. However, serious adverse events are more likely to be reported than non-serious events.
- Reports vary in quality and completeness. They may lack details and contain errors.
- The VAERS data search conducted above is for personal use and not intended for scientific publication.

To read more about the strengths and limitations of VAERS, please visit https://vaers.hhs.gov/data/dataguide.html.

Again, we thank you for taking the time and effort to report this case to VAERS. In the future, if you would like to request consultation regarding booster vaccination for this patient, you are welcome to consult the CISA team.

General information:

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Sincerely,
Lara Akinbami, MD
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response

CISA COVIDvax

Original email inquiry:
From: (b)(6)
Sent: Monday, January 17, 2022 12:39 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6)
Subject: Covid vaccine and acute kidney injury

I was wondering if you have seen reports of acute kidney injury after covid vaccine? The nephrologist here is seeing a 13 year old previously healthy boy who developed hematuria and mild to moderate AKI 1 day after receiving the Pfizer Covid vaccine. He is cc'd on this email if you have additional questions.

Thanks,

(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, January 25, 2022 9:55 AM
To: (b)(6) CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: Covid vaccine and acute kidney injury

Good Morning (b)(6)

I'm checking in about whether you have decided you would like to proceed with a clinical consult. If so, we would begin to request medical records and schedule an initial information gathering call with you. Please let me know if you have any questions about the process.

Thank you,
Lara

From: (b)(6)
Sent: Thursday, January 20, 2022 1:00 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: Covid vaccine and acute kidney injury

Hi Lara,

The labs will be done this afternoon. I will respond to your email later.

(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Thursday, January 20, 2022 10:34 AM
To: (b)(6) CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: [EXTERNAL] RE: Covid vaccine and acute kidney injury

Hi (b)(6)

Thank you very much for the clarification of the dates. To proceed with consultation about whether this patient who developed nephritis ~12 hours after the second dose of the Pfizer vaccine should receive a booster, we will need to review medical records. You indicated that the patient's (b)(6) who is a (b)(6) may be interested in participating. Unfortunately, consultations cannot involve family members. This patient's (b)(6) has apparently been involved in some clinical decision-making, and she would be welcome to provide medical records and relevant information for you to share, but she would not be permitted to attend the actual consultation.

If you are still interested in proceeding, it would be helpful to know if the patient has a primary care provider and if they would be amenable to providing records and participating in consultation. Additionally, any update on the patient's clinical status would be helpful, including if today's evaluation shows a continued resolution of symptoms and lab abnormalities.

Regards,
Lara

From: (b)(6)
Sent: Thursday, January 20, 2022 10:31 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: Covid vaccine and acute kidney injury

Hi Lara,

I apologize for the error. In November 2020 the patient was screened for COVID. That screening was negative. On November 12, 2021 he was symptomatic and the testing was positive for COVID. I apologize for the error.

(b)(6)

TRIAGE HEALTH INFORMATION NOTE

CALLER:

(b)(6)

TELEPHONE NOTE:
COVID-19 Test Results
Date of swab: 11/12/2021
Results: Positive
Disposition: Per CDC recommendations, the patient needs to isolate until at least 24 hours have passed since resolution of fever without the use of fever reducing medications and improvement in symptoms AND at least 10 days have passed since symptoms first appeared. Symptoms were first reported on 11/12/2021. Public health may also be in contact with additional recommendations as well. Recommend quarantine for all close contacts and share community testing locations. Recommend that close contacts wait to test at day 6 or 7 after exposure.
(b)(6) continues to experience symptoms, unchanged. (b)(6) will continue to monitor symptoms, continue with homecare, and call back or seek medical care if symptoms do not improve or symptoms worsen. States understanding and denies any further questions at this time.

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Thursday, January 20, 2022 9:05 AM
To: (b)(6) CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6)
Subject: [EXTERNAL] RE: Covid vaccine and acute kidney injury

Dear (b)(6)

Thank you very much for your responses to our questions. We understand that you consider both post-streptococcal glomerulonephritis and IgA nephropathy to be unlikely given the clinical picture and laboratory results.

We would like to clarify one thing in your response. I had originally understood the COVID-19 infection to have occurred in 11/2021, that is, shortly before the first dose of the Pfizer vaccine. But in your response, the (b)(6) triage notes state that COVID symptoms were reported in **11/2020**, a full year before the first vaccination dose. However, the testing date for the positive SARS-CoV-2 test is specified as **11/12/2021**. Which is the accurate year for symptoms? Determining whether the infection occurred a year prior to vaccination or shortly before may change the line of inquiry about the possibility of SARS-CoV-2 infection as an underlying contributor to the current clinical picture.

Thank you again for the thorough information you have provided to date.
Lara

From: (b)(6)
Sent: Wednesday, January 19, 2022 1:13 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6) (b)(6)
Subject: RE: Covid vaccine and acute kidney injury

Hi Lara,

Please see my responses in red font below. I also confirm at the end of this email my willingness to discuss the case with your team. His (b)(6) and most familiar with the time line of the disease. She is willing to join the conversation if deemed appropriate by your team.

(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Wednesday, January 19, 2022 11:29 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6)
(b)(6)
Subject: [EXTERNAL] RE: Covid vaccine and acute kidney injury

Dear (b)(6)

Thank you for the information you provided yesterday during our phone conversation about your 14-year-old male patient with acute nephritis following a second dose of the Pfizer vaccine on 1/13/2022. We discussed the case briefly with vaccine safety experts from the CISA network. Some additional information would help us better understand the etiology of this patient's illness.

(b)(5); (b)(6); (b)(3):42 U.S.C. §242m(d)

Telephone Note

(b)(6) LINE TRIAGE NOTE

COVID-19 SUSPECTED
Onset/Course/Description: 11/9/2020
Pain Intensity: None
Fever: yes- 102.5
Breathing Difficulty: No
I/O: WNL
Activity/Functional Status: WNL
COVID-19 documented in community: Yes
HIGH RISK Patient: No.
COVID-19 Exposure: Unknown or possible

TRIAGE DISPOSITION: Patient will be tested for COVID-19.

Occupation/Place of Employment: Unknown

Reason for COVID-19 testing: Patient with symptoms of COVID-19:
- Fever
- Chills
- Muscle or body aches
- Headache
- Nasal congestion

(b)(6) Triage Offered: Declined.

Is this patient's first test? Yes
Is patient employed in healthcare? No
Is patient symptomatic? Yes

SYMPTOMS
- Fever- 102.5
- Chills
- Muscle or body aches
- Headache
- Nasal congestion

Date of symptom onset: 11/9/2020
Is patient hospitalized? No
Is patient in ICU? No
Resident in a (b)(6) (living in (b)(6) in order to complete activities of daily living (b)(6) this does not apply to (b)(6))? No
Pregnant? Male

Per COVID-19 Test Standing Orders, patient will present to have COVID-19 testing done. Patient instructed to self-isolate/quarantine until notified of results.

On 11/12/21 the specimen was collected and was positive based on PCR methodology.

I would be happy to discuss the case with your team in greater detail. He was not seen by his primary care provider at any time during this illness. His (b)(6) that has provided parental care for her (b)(6) She is most familiar with his disease course and is willing to join the discussion if deemed appropriate by your team.

(b)(6)

We look forward to working with you to better develop further guidance on subsequent COVID-19 vaccinations for this patient.

Regards,
Lara

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, January 18, 2022 3:50 PM
To: (b)(6)
(b)(6) CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: Covid vaccine and acute kidney injury

Thank you (b)(6)

(b)(6) I left a message just now and will call later this afternoon.

Thank you,
Lara

From: (b)(6)
Sent: Tuesday, January 18, 2022 3:32 PM
To: (b)(6) CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: Covid vaccine and acute kidney injury

Hi Lara,

Please call (b)(6) at the number he listed below. He has all the details. He submitted a VAERS report yesterday.

Thanks,

(b)(6)

From: (b)(6)
Sent: Tuesday, January 18, 2022 2:15 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6)
(b)(6)
Subject: RE: Covid vaccine and acute kidney injury

You are welcome to call me at (b)(6)

(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, January 18, 2022 12:21 PM
To: (b)(6); CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6)
Subject: [EXTERNAL] RE: Covid vaccine and acute kidney injury

CAUTION: This email originated from outside of the (b)(6)
Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good Afternoon (b)(6)

We called this afternoon to see if we could gather more information, but you were away from your office. Could you please let us know the best time to reach you to have a 15-20 minute conversation? Alternatively, if it is best to have a call with (b)(6) please let us know the best phone contact information and time. We look forward to talking at a time convenient for you.

Regards,
Lara

Lara Akinbami, MD
Clinical Immunization Safety Assessment (CISA) Project
Centers for Disease Control and Prevention
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: (b)(6)
Sent: Monday, January 17, 2022 12:39 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>

Cc: (b)(6)
Subject: Covid vaccine and acute kidney injury

I was wondering if you have seen reports of acute kidney injury after covid vaccine? The nephrologist here is seeing a (b)(3):42 U.S.C. previously healthy boy who developed hematuria and mild to moderate AKI 1 day after receiving the Pfizer Covid vaccine. He is cc'd on this email if you have additional questions.

Thanks,

(b)(6)

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.

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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.

From: CISA Response (CDC)
Sent: Tue, 22 Feb 2022 19:33:28 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); CISA Response (CDC); COVID19VaxSafety
Cc: Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: COVID VACCINE question - VAERS search
Categories: Gail

Dear Elaine,

I think it would be useful to have a call. Andrea, Eric and I will talk tomorrow after the 10 am CISA call and I will then look for a mutually agreeable time for all so we may learn more about VAERS searches.

Regards,
Gail

Gail Stennies, MD, MPH, FACPM
Captain, U.S. Public Health Service
Clinical Immunization Safety Assessment (CISA) Team
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, February 18, 2022 12:02 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Cc: Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR) <ssf1@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: COVID VACCINE question - VAERS search

Hi Gail,
We are happy to meet with you if needed.
If you decide to schedule a call, please invite me, Emma Freeborn and Amy Roberts.
If there is no need to meet, that is certainly fine too.

Thanks,

Elaine

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Friday, February 18, 2022 11:54 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>; COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Cc: Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR) <ssf1@cdc.gov>; Moro, Pedro

(CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: COVID VACCINE question - VAERS search

Dear Elaine,

Thank you for your explanation, searches, and offer to discuss. The detailed reports are much appreciated and we will review them to identify any potential information to add to a response to the provider. I think it will be useful to discuss next week when Andrea and Eric, the on-call clinicians for this case who are off today, and Gloria are available. Would you like for me to look for a mutually agreement time on your calendar? If yes, please let me know if you would like me to invite anyone else on the VAERS team.

In case of interest, we informally presented this case on the CISA call this morning and experts asked if myocarditis had been ruled out. We will seek additional information from the provider and encourage her to submit a VAERS report and records.

Regards,
Gail

Gail Stennies, MD, MPH, FACPM
Captain, U.S. Public Health Service
Clinical Immunization Safety Assessment (CISA) Team
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, February 18, 2022 8:14 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Cc: Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR) <ssf1@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: COVID VACCINE question - VAERS search

Hi Gail,
The reason you all found 10 reports is because you searched for (b)(5)

We searched for persons with a previous history of (b)(5) and our searches are attached.

This morning I ran another search using: (b)(5) (b)(5) **and found one additional report.** (b)(5)

Please let me know if you want to have a short call to discuss the search.

Thanks,

Elaine

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Thursday, February 17, 2022 6:58 PM
To: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR) <ssf1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: COVID VACCINE question - VAERS search

Dear Shaeyla,

I kindly ask that you please share the search terms you used for this summary below. While reviewing a draft response to his provider, Gloria conducted a search and found 10 cases using (b)(5) (b)(5) and COVID vaccination. I am attaching the line listing she shared. If we learn the terms you used, we can learn more about conducting searches.

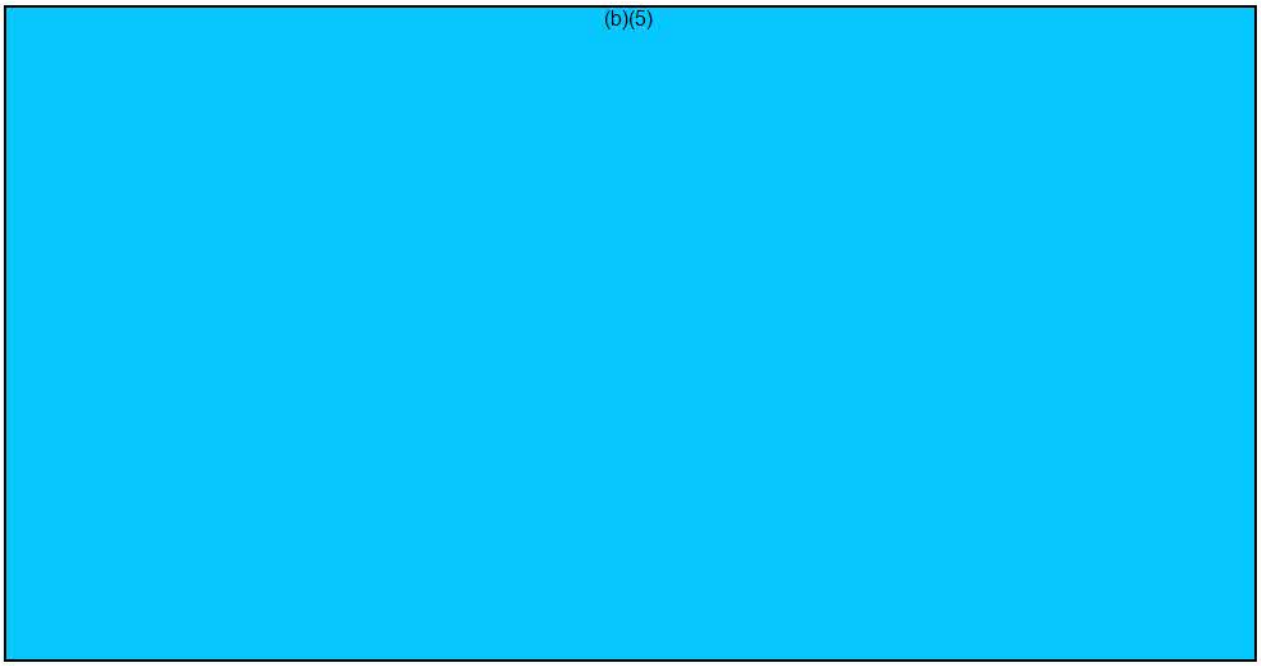
Regards,
Gail

Gail Stennies, MD, MPH, FACPM
Captain, U.S. Public Health Service
Clinical Immunization Safety Assessment (CISA) Team
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Sent: Tuesday, February 15, 2022 1:24 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR) <ssf1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: COVID VACCINE question

Good afternoon,
Below is our part of the response.
Thanks,
Shaeyla

(b)(5)



From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, February 15, 2022 11:21 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Subject: RE: COVID VACCINE question

Dear Elaine,

Since the CISA Team has initiated contact with the patient's provider (who is not (b)(6) and is awaiting her response, we would appreciate it if you would send the VAERS search results to us. The CISA clinicians, Andrea and Eric, will include it in a response to the provider.

Thank you,
Gail

Gail Stennies, MD, MPH, FACPM
Captain, U.S. Public Health Service
Clinical Immunization Safety Assessment (CISA) Team
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Monday, February 14, 2022 4:57 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Subject: RE: COVID VACCINE question

Not urgent!

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Monday, February 14, 2022 4:32 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Subject: RE: COVID VACCINE question

Hi Gail,
We can do the search. Is this urgent, or can it wait until tomorrow?

Thanks,

Elaine

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Monday, February 14, 2022 3:57 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: FW: COVID VACCINE question

Dear Elaine,

The CISA Team would appreciate it if the VAERS Team would conduct a VAERS search for any reports of COVID-19 vaccination and acute chest syndrome in (b)(3):42 U.S.C. patients, esp. children. The CISA Team has reached out to the provider to also provide a response.

Regards,
Gail

Gail Stennies, MD, MPH, FACPM
Captain, U.S. Public Health Service
Clinical Immunization Safety Assessment (CISA) Team
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Sent: Friday, February 4, 2022 1:15 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: NIPINFO (CDC) <NIPINFO@cdc.gov>
Subject: FW: COVID VACCINE question

Hi CISA,

Would you all be able to respond to this healthcare provider about a pediatric case?

Thanks,
Shaeyla

From: NIPINFO (CDC) <NIPINFO@cdc.gov>
Sent: Friday, February 4, 2022 12:50 PM
To: COVID19VaxSafety <COVID19VaxSafety@cdc.gov>
Subject: FW: COVID VACCINE question

Hello,

Could you please assist with this inquiry?

Thank you,
NIPINFO
LD

From: (b)(6)
Sent: Friday, February 4, 2022 11:49 AM
To: NIPINFO (CDC) <NIPINFO@cdc.gov>
Subject: COVID VACCINE question

To Whom It May Concern:

Is there a link of COVID vaccine in a (b)(6) girl that results in Acute Chest Syndrome?
I am curious as this occurred with one of my patients.
Please advise.
(b)(6) does not want to give her the SECOND COVID vaccine.

(b)(6)

From: CISA Response (CDC)
Sent: Wed, 5 Jan 2022 21:51:55 +0000
To: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR); CISA Response (CDC)
Subject: RE: draft email regarding patient with myocarditis history who is due for COVID booster

Thank you!

Suzanne Beavers, MD
CDR, United States Public Health Service

From: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Sent: Wednesday, January 5, 2022 16:48
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: draft email regarding patient with myocarditis history who is due for COVID booster

(b)(5)

Matthew Oster, MD, MPH
CDC COVID-19 Response
CDC Center on Birth Defects and Developmental Disabilities
Pediatric Cardiologist, Sibley Heart Center, Children's Healthcare of Atlanta
Emory University School of Medicine | Emory University Rollins School of Public Health
Igp8@cdc.gov

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Wednesday, January 5, 2022 3:45 PM
To: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: draft email regarding patient with myocarditis history who is due for COVID booster

Dear Dr. Oster,

My name is Suzanne Beavers; I am one of the deployers to CISA. We received the following inquiry from a physician asking about timing of a COVID booster for a 20 year-old patient who had developed myocarditis in November. I have a 20 yo previously healthy, admitted Nov 2021 due to severe heart and respiratory failure from Coxsackie myocarditis. He had Moderna COVID vaccine 1st dose Feb and 2nd dose March 2021. He is due for his booster dose. Our question is, is getting a booster vaccine dose risky in this immediate post-myocarditis recovery period from Coxsackie? Is he more at risk for developing myocarditis again if he gets the vaccine at this time? Should he wait weeks or months before getting thr booster?

We have drafted the below response to the physician and wanted to see if you could review it.

(b)(5); (b)(6)

General information:

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html

We hope this information is helpful to you.

Best regards,

Suzanne Beavers, MD
CDC Clinical Immunization
Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

From: CISA Response (CDC)
Sent: Fri, 16 Sep 2022 13:49:03 +0000
To: (b)(6) CISA Response (CDC)
Cc: (b)(6)
Subject: RE: Eval request
Categories: Magaret

Terrific. Thank you, (b)(6)

Sincerely,

Margaret

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Friday, September 16, 2022 9:44 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(3):42 U.S.C. §242m(d); (b)(6)
Subject: RE: Eval request

Dear Margaret,

Thank you very much for following up. I appreciate the thorough and thoughtful approach. I know the family and his other providers will also appreciate that your team reviewed his case and are providing the best available recommendations in this situation.

I will certainly reach out if other questions arise or any new events.

Best,
(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Friday, September 16, 2022 9:24 AM
To: (b)(6); (b)(3):42 U.S.C. §242m(d) CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Dear (b)(6) Thank you for your inquiry about your (b)(6) on potential listing for (b)(6) in the next 1-2 weeks because of extensive dilation and giant coronary aneurysms from Kawasaki disease. You described that you had just seen him for the first time. Your question focused on acceleration of immunizations before (b)(6) including COVID-19 vaccine.

According to the information you had available, the (b)(6) had fever temporally associated with previous immunizations and his severe inflammatory illness was temporally associated with his last set of immunizations. He is currently on prednisone 9mg BID and (b)(6) after last hospital discharge. You provided a summary of the (b)(6) past medical history, family history, and his hospitalizations for Kawasaki disease.

After your initial email to us, you determined that records from the original hospitalization indicated that the (b)(6) had tested positive for SARS-CoV-2 anti-nucleocapsid antibody (testing at ARUP) and that this 6/21/22 sample had been collected before the (b)(6) had received IVIG. You provided the subsequent information to us about (b)(6) known SARS-CoV-2 exposures (answer: none) or whether they had an illness suggestive of SARS-CoV-2 disease (no) and if either had ever tested positive by NAAT/antigen testing (b)(6) never tested (b)(6) x 2 via NP NAAT testing during initial hospitalization).

The specific question brought to CISA was whether an accelerated vaccine schedule would be appropriate, (b)(6) This includes potentially inactivated influenza vaccine, a (b)(6) nd COVID-19 vaccination. Your case was discussed with vaccine safety experts in the Clinical Immunization Safety Assessment (CISA) Project with expertise in infectious diseases, rheumatology, and allergy/immunology. I provided a summary of their suggestions to you by email on 9/9/2022.

Each of the CISA SMEs suggested that, as you planned, the (b)(3):4 receive inactivated influenza vaccine (even if not listed for (b)(6) and especially if the (b)(6) is still receiving aspirin at this time). If the (b)(6) is placed on the (b)(6) the individual viewpoints were to follow your usual plans for listed patients in providing (b)(6); (b)(5) on an accelerated schedule.

Based on the information that the (b)(6) tested positive for anti-nucleocapsid antibody, supporting that the (b)(3):42 had already been infected with SARS-CoV-2 by 6/21/22, the individual opinion of each of the SMEs was to NOT provide COVID-19 vaccine at this time; several SMEs suggested that the (b)(6) clinical course may be the result of MIS-C. The SMEs highlighted that the clinical characteristics of MIS-C and Kawasaki disease, particularly (b)(6); (b)(5) overlap considerably.

(b)(5); (b)(6)

The timing of additional vaccinations that he would be due to receive soon, including MMR and varicella vaccine, will need to be adjusted based on receipt of IVIg and whether he is, indeed, (b)(5); (b)(6); (b)(6); (b)(5) for a period of time).

You all already plan of course to maximize the protection against vaccine-preventable diseases through immunization of his close contacts.

General information:

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.

We hope this information is helpful.

Sincerely,
Margaret M. Cortese, MD
CISA

Sincerely,

Margaret

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Friday, September 9, 2022 1:08 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Margaret,

Thank you again for the quick review and response, I appreciate it and I know the family will feel better knowing that we've thoroughly considered the vaccination options for their (b)(6) in this unusual case.

Best,
(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Friday, September 9, 2022 12:47 PM
To: (b)(6); (b)(3):42 U.S.C. §242m(d) CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Hello again, (b)(6) Liz may have already reached out to you but I wanted to let you know that the individual opinions provided were just as you were thinking: agree with providing (b)(6); and inactivated influenza vaccine, and hold off on COVID-19 vaccine.

I will write this up more formally in our usual manner, and send to you, but I wanted you to have the upshot now since rather time-sensitive question.

Sincerely,

Margaret

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Friday, September 9, 2022 9:48 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

He's (b)(6)

Thanks,
(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Friday, September 9, 2022 9:46 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6); (b)(3):42 U.S.C. §242m(d)
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

This email originated from an EXTERNAL sender to (b)(6); (b)(3):42 Proceed with caution when replying, opening attachments, or clicking links in this message.

Hello again, (b)(6) Can you tell us the (b)(6) race/ethnicity? Thank you.

Sincerely,

Margaret

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Thursday, September 8, 2022 2:10 PM
To: (b)(6); (b)(3):42 U.S.C. §242m(d); CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

This is great info, (b)(6)! Thank you for filling in this info and for providing your valuable thoughts.

Sincerely,

Margaret

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Thursday, September 8, 2022 1:56 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Dr. Cortese,

Best answers that I could get from mom below. I'm never completely sure what to make of families in this era stating they haven't had any COVID-like symptoms, exposures or need for testing in the last year or so, but I take them at their word…

Without clear reason to believe that the ARUP COVID Ab was a false positive, my default position would be to interpret that as a true positive, presumably indicating that the (b)(6) had COVID at some point in the first (b)(3):42 U.S.C. of his life. (Option 1 below).

Open to any thoughts your group may have.

Thank you again,
(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Thursday, September 8, 2022 11:24 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6); (b)(3):42 U.S.C. §242m(d)
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Hi again, (b)(6) Trying to just go through the possibilities for that anti-nucleocapsid positivity results for (b)(6) Given date listed for (b)(6)) at draw pre-(b)(6), since that could impact thoughts on benefit for COVID-19 vaccine in (b)(6) As of course you are thinking. (Correct the (b)(6) date, typo below, he got that on 1 (b)(6)

Assuming that the test is a true positive re SARS-CoV-2 infection
1. (b)(6) derived, therefore (b)(6) has already been infected, vs...

2. (b)(6) antibody, ?persisting even this late in (b)(6)

It is possible folks we talk with tomorrow may have some additional questions for you...but, based on the information you already have:

Do you happen to know:

(b)(6); (b)(5)

Thanks!
Margaet

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Thursday, September 8, 2022 9:57 AM
To: (b)(6); (b)(3):42 U.S.C. §242m(d) CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Thanks so much, (b)(6) for your prompt reply and valuable information.

We are hoping to get some thoughts from a few more folks tomorrow morning ..and now that you have been able to track down the info anti-nucleocap positive that is very helpful of course.

Sincerely,

Margaret

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Thursday, September 8, 2022 9:45 AM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Dr. Cortese,

Thank you very much for the quick response!

Those are great questions and I apologize for not including them in the original email.

Here's what I learned from his presenting hospital:

(b)(6); (b)(5)

I suspect that may impact your overall thoughts on COVID vaccines for him in the future, and I'm certainly open to any suggestions.

(b)(6); (b)(5)

COVID vaccines TBD…

Thank you again for the help with this case, I appreciate it.

Best,
(b)(6)

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Wednesday, September 7, 2022 5:22 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>; (b)(6); (b)(3):42 U.S.C. §242m(d)
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

This email originated from an EXTERNAL sender to (b)(6); (b)(3):42 Proceed with caution when replying, opening attachments, or clicking links in this message.

Hello again, (b)(6) I'm sure you are working to sort this out from the other hospital....so can you let us know if that "COVID Ab positive" was indeed anti-nucleocap and if it was indeed obtained pre IVIG?

Thanks a lot

Sincerely,

Margaret Cortese, MD

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Wednesday, September 7, 2022 2:41 PM
To: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: RE: Eval request

Hello (b)(6) Thank you for providing the details in your inquiry.

We are reviewing now as a first step and realize the time-sensitive nature.

Sincerely,

Margaret

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Wednesday, September 7, 2022 2:12:06 PM (UTC-05:00) Eastern Time (US & Canada)
To: CISAeval (CDC) <CISAeval@cdc.gov>
Cc: (b)(6); (b)(3):42 U.S.C. §242m(d)
Subject: Eval request

Hello,

I am a (b)(6) and wanted to solicited suggestions on a case that I consulted on today.

Patient is a (b)(6) M, immunized, previously healthy diagnosed with incomplete Kawasaki Disease on 6/22/22. Prior to presentation he received immunizations (b)(6) on 6/14, developed fevers that evening which persisted daily through the date of his KD diagnosis. His KD was refractory (s/p IVIG x2 and ultimately required additional steroids and Infliximab). Echo findings now with extensive dilation and giant aneurysms of the coronary arteries, most severely involving the proximal RCA.

Seen today as part of initial evaluation prior to (b)(6) Remains on Pred 9mg BID.

Prior to (b)(6); I would routinely try to accelerate his immunization schedule with (b)(6); now as well as a COVID-19 series, followed by (b)(6); (b)(5) Seasonal influenza (inactivated) when available.

Based on the history of fevers with an inflammatory response temporally following his (b)(6); immunizations, do you have any suggestions with respect to immunizations going forward?

Realistically, he may be listed for (b)(6) and I would likely only have the opportunity to give him (b)(6); (b)(5) (b)(6); Would then restart immunizations at (b)(6)

More detailed history below from my clinic note.

Thank you!

(b)(6)

(b)(3):42 U.S.C. §242m(d) ; (b)(6)

From: CISA Response (CDC)
Sent: Tue, 28 Dec 2021 23:48:52 +0000
To: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR); CISA Response (CDC)
Subject: RE: Inquiry on booster in setting of steroid taper for pericardial effusion
Categories: Loria

Hi Matt,
Thank you for sharing your thinking. Understanding that you cannot make it on either call tomorrow, we'll likely present the case with the other CISA experts and include your thoughts in the discussion (I'll let the supervisors decide). There are lots of factors that make this situation not straightforward.

Hope your time on service goes well…and, congrats on your paper coming out!
--Loria Pollack

From: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Sent: Tuesday, December 28, 2021 5:10 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: Re: Inquiry on booster in setting of steroid taper for pericardial effusion

Covering clinical duties this week so hard to always respond quickly. Won't be able to join a call tomorrow due to clinic.

(b)(5)

Matt

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, December 28, 2021 4:43 PM
To: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: FW: Inquiry on booster in setting of steroid taper for pericardial effusion

Hello Matt –
I'm not sure you had a chance to read through the long email I sent earlier this afternoon. If it would be best, we want to invite you to either our 9am internal CISA call OR our 10am CISA Site call tomorrow

(Wed 12/29) to discuss the case and inquiry with a few other clinicians. Just respond to the box which time would work best for you and we will forward you the invite to join.

Thank you for your expertise.
--Loria Pollack

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Tuesday, December 28, 2021 1:59 PM
To: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: Inquiry on booster in setting of steroid taper for pericardial effusion

Dear Matt,
We recently received a CISA inquiry from a physician who works at (b)(6) Per CISA's policy to work with treating providers, his PCP, an (b)(6) submitted a CISA consult (pasted at end of the note). A summary of the case is below. I believe *much* of the HPI was provided by (b)(6) (b)(6) Therefore, we are long on symptoms and history, but short on actual labs and echo results.

The primary questions for CDC are as follows:

1. Any reason this patient should NOT get the booster? The plan is to receive a booster on 1/3/22 unless advised otherwise.
2. Any advice timing of booster given his immunocompromised state? It was recommended that he receive it once he was on the lower dose (15 mg po qd) for at least a week before booster. It is unclear at this time when he will stop the (b)(6)
3. Any specific recommendations on which specific booster he should receive given his current medical situation (i.e., though on another Pfizer dose versus Moderna). "Some physicians feel (b)(5) (b)(5)
4. (Additional information that may benefit from CISA input) The patient plans to get antibody titers before and after receiving his booster shot.

Lori A. (Loria) Pollack, MD, MPH | CAPT, U.S. Public Health Service
CDC Clinical Immunization Safety Assessment (CISA) Project
Coronavirus Disease 2019 (COVID-19) Response
CISA COVIDvax

History of Present Illness:
51 year old male (b)(6) was diagnosed with COVID in early/mid-January 2021 after mild fatigue, nasal congestion, brain fog, loss of smell and a single nighttime syncopal episode. He received 2 dose Pfizer COVID vaccination on 1/31/21 and 2/19/21 and had a second syncopal episode after dose #1 with no other notable side effects. In spring/summer 2021, felt well and was actively exercising and walking daily with a weight vest; only symptom was occasional trouble recalling information. In late August/Early September 2021, he suddenly developed intense malaise, fatigue, decrease exercise tolerance as well as a mild cough with chest discomfort and "fluttering"

multiple times a day. A self-purchased portable EKG device showed elevated resting heart rate (80-100 BPM) in normal sinus rhythm. A cardiology consultation in mid-September 2021 revealed inappropriate sinus tachycardia (IST) and a small (1.2 cm) anterior pericardial effusion, which was thought to be related to COVID. A 10-day cardiac holter monitor showed no other significant arrhythmias. Labs: Blood tests showed no cardiac damage nor any heart failure.

- Echocardiogram #1 (Sept 2021) EF was 60%; small (1.2 cm) anterior pericardial effusion. Patient was given a trial of beta blockers but could not tolerate them.
- Echocardiogram #2 (@ 3-month follow up) showed an unexpected slightly LARGER pericardial effusion. The patient developed more chest pain and difficulty breathing over the next 4 weeks.
- Echocardiogram #3 (date unknown) was stable.
-

Patient was started on a course of Prednisone due to his cardiac symptoms (not UC: 30 mg po qd x 10 days on 12/6/2021, then 20 mg qd x 7 days, and then 15 mg po qd - ongoing. Dosage will be reevaluated during the first week of January 2022 at next visit with cardiologist. It is expected taper will continue and be done over about 2-4 weeks

Currently (end of December 2021), patient reports improvement in chest discomfort and breathing and less intense fatigue. Also reports: "IST has evolved into classic POTS (postural orthostatic tachycardia syndrome)" feels this is distinct and separate from his pericardial effusion symptoms.

PCP reports cardiology stated that he is "cleared" to receive the booster because clinically his condition has improved (resolved chest pain and shortness of breath) and that the prednisone is providing some protection from possible worsening of pericarditis that could occur from the booster itself. **Plan is to receive a booster on 1/3/22 unless advised otherwise.**

Past Medical History:

- Ulcerative Colitis: Treated (until recently) with Mesalamine 1.2 g BID to QID, Patient thought that the Mesalamine was a potentially complicating factor in this cardiac condition - and subsequently stopped using the medication for 1 month. This resulted in worsening of his ulcerative colitis, 10 pound weight loss and hospital admission for hyponatremia (Dec 1-2, 2021) due to diarrhea 'from stopping the mesalamine'. During the admission he was found to have a folate deficiency anemia with elevated Vit D (70). Patient has remains off Mesalamine and his ulcerative colitis has stabilized after Dec 2021 hospitalization.
- Orthostatic Hypotension,
- Osteoporosis (via bone scan)
- Borderline anemia,
- Wandering Atrial Pacemaker (Note: unsure if diagnosed prior to covid)
- Seasonal allergies

Past Surgical History: R. Inguinal hernia repair

Labs: Available upon request - no significant abnormalities noted - other than what has been mentioned in this note. Frequent labs obtained due to q 3 month monitoring of liver and kidney function while on Mesalamine.

Imaging: See HPI for echo history

Meds: Prednisone 15 mg qd; Vit D3 2000 QOD, Vitamin K2 MK7 100 mcg, Folate 600mg qd, B12, Calcium Citrate 150 mg qd; (Mesalamine currently d/c'd)
Allergies: PCN - mild rash. Patient also reports contraindication of using Colchicine due to his ulcerative colitis history.

Social History: Does not drink, smoke, or use any drugs; Whole Food, low fat, plant-based vegan diet.

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Tuesday, December 28, 2021 10:34 AM
To: CISA Response (CDC) cisaresponse@cdc.gov
Subject: Re: [External] Additional information needed for your inquiry to CISA re COVID-19 vaccination

Thanks for following up. I have attempted to address the follow up questions below:

1. (b)(6); (b)(3):42 U.S.C. §242m(d)
2. Did the patient have myocarditis / pericarditis?
    a. Per the cardiology note, he was thought to have pericarditis based on his symptomatology and the steroid treatment was both for the pericardial effusion and pericarditis.
3. (b)(6); (b)(3):42 U.S.C. §242m(d)
4. Please confirm that the patient received Pfizer on these dates: 1/31/21 and 2/19/21
    a. This is correct, the patient received the Pfizer vaccine on 1/31/21 and 2/19/21

The pt's plan is to receive a booster on 1/3/22 unless advised otherwise. Please let me know if any advice. Thanks so much for considering the case!

From: (b)(6); (b)(3):42 U.S.C. §242m(d)
Sent: Wednesday, December 22, 2021 5:14 PM
To: CISA Response (CDC) cisaresponse@cdc.gov
Subject: COVID-19 booster guidance

Hello,

My name is (b)(6) and I am a (b)(6) I wanted to inquire to see if I could get some guidance regarding a COVID-19 booster for one of my patients. Briefly, he is a 51 yo man with a history of ulcerative colitis who had recent pericardial effusion diagnosed (thought to be due to long COVID) and is undergoing treatment with a steroid taper per his cardiologist. He initially avoided the booster due to the pericardial effusion per his cardiologist's recommendation, now has been cleared to receive the booster by the cardiologist. However, he is also still on a prednisone taper which would likely blunt his immune response to the vaccine. Please see the extended history below and let me know of any guidance regarding timing of vaccination and whether there is a recommendation on which COVID booster the patient should receive (his initial series was Pfizer).

Thanks,

(b)(6); (b)(3):42 U.S.C. §242m(d)

HPI
Dr. [Redacted] is a 51 M with a history of mild COVID in early/mid January 2021 (mild fatigue, nasal congestion, brain fog, and loss of smell - with 1 episode of syncope - at night - on route to the bathroom).
He then underwent subsequent vaccination 2 weeks later with Pfizer on 1/31/21 and 2/19/21 - with no notable side effects - other than 1 nighttime syncopal episode on route to the bathroom after the 1st dose of the Pfizer vaccine.

Over the subsequent months, other than occasional brain fog. (Issues with recalling information) he felt very well... and was very active throughout the spring and summer of 2021, exercising and walking daily with a 10-lb weight vest. Please note that the patient had a low BMI- weighing 120 lbs at 5'8"

In late August/Early September 2021, he suddenly developed a few days of intense malaise and fatigue, as well as a mild cough with chest discomfort - noting "chest fluttering" - which came and went multiple times a day. Chest discomfort was similar to eating dry food and feeling that similar esophageal discomfort.

Patient then purchased a portable EKG device, and found that his resting heart rate was in normal sinus, but in the elevated range of 80-100 BPM. Very abnormal for him. His exercise tolerance was suddenly significantly reduced.

Subsequently, in Mid September he obtained care from a cardiologist- and was found to have inappropriate sinus tachycardia (IST) and a small (1.2 cm) anterior pericardial effusion - likely related to COVID- and was told it would resolve in weeks to months. A 10-day Cardiac holter monitor showed no other significant arrhythmias. Blood tests showed no cardiac damage nor any heart failure. EF was 60% Patient was given a trial of beta blockers but could not tolerate them.

After some careful research into medication side effects, the patient thought that the Mesalamine was a potentially complicating factor in this cardiac condition - and subsequently stopped using the medication for 1 month. Though the patient did have a worsening of his ulcerative colitis, and a subsequent 10 pound weight loss - a three-month follow up cardiac echo showed an unexpected slightly LARGER pericardial effusion.

The patient developed more chest pain and difficulty breathing over the next 4 weeks. A follow up echo was then performed. Though the echo was stable on this third examination, due to his significant clinical symptoms, and a contraindication of using Colchicine due to his ulcerative colitis history - the patient was started on a course of Prednisone 30 mg po qd x 10 days, then 20 mg qd x 7 days, and then 15 mg po qd - ongoing. Dosage to be reevaluated during the first week of January 2022.

Patient's cardiac symptoms (chest discomfort, difficulty breathing, intense fatigue) have improved significantly, however his IST has evolved into classic POTS (postural orthostatic tachycardia syndrome) - and the patient understands that this may take many months to resolve - distinct and separate from his pericardial effusion symptoms.

Please note as an aside: due to the weight loss and diarrhea from stopping the mesalamine, the patient developed acute hyponatremia - and required a 2-day hospital admission on December 1st - to correct this abnormality. Also, during the admission he was found to have a folate deficiency anemia and be significantly underweight. His rapid weight loss (over 1 month), resulted in elevating his Vit D levels to 70. He was told to take 1 to 2 grams of sodium daily, use folate supplements and eat at least 2000 calories daily, and to monitor his BP and HR often. Patient has remained off Meslalamine - and his ulcerative colitis has stabilized. His sodium has normalized, and he is gradually gaining weight - though his overall stamina and energy level remain a challenge.

PMH: Ulcerative colitis treated (until recently) with Mesalamine 1.2 g BID to QID, Orthostatic Hypotension, Osteoporosis (via bone scan), Borderline anemia, cardiac history of Wandering Atrial Pacemaker, seasonal allergies
PSHx: R. Inguinal hernia repair
Labs: Available upon request - no significant abnormalities noted - other than what has been mentioned in this note. Frequent labs obtained due to q 3 month monitoring of liver and kidney function while on Mesalamine.
Allergies: PCN - mild rash
Meds: Mesalamine, Vit D3 2000 QOD, Vitamin K2 MK7 100 mcg, Folate 600mg qd, B12, Calcium Citrate 150 mg qd
Diet: Whole Food, low fat, plant-based vegan
Social History: Does not drink, smoke, or use any drugs

QUESTION TO CDC: The patient has delayed obtaining a COVID booster per the recommendation of his cardiologist, due to his active cardiac issues. However, recently, given his current treatment, his cardiologist stated that as he is currently on prednisone - he can/should get a booster given the omicron variant. However, given his immunocompromised state, it was recommended that he take it once he is on the lower dose (15 mg po qd), for at least a week. The patient plans to get antibody titers before and after receiving his booster shot. The patient is leaning towards taking another Pfizer dose - though some physicians feel that the Moderna, though with more frequent cardiac issues, might provide a stronger immune response given his current use of Prednisone, It is unclear at this time when he will stop the

prednisone - due to the recommendation of his cardiologist - that a slow taper is critical to prevent a relapse of the pericardial effusion.

OVERALL QUESTION SUMMARY: Any reason this patient should NOT get the booster? Possible exacerbation of his current cardiac issues? Any booster timing recommendations given his current use of prednisone? Any specific recommendations on which specific booster he should receive- given his current medical situation?

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 5 Oct 2022 02:21:07 +0000
To: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Allen, Andrea Thames (CDC/DDID/NCEZID/DHQP) (CTR); Vaccine Safety (CDC); CISA Response (CDC)
Subject: RE: New NIPINFO inquiry and atypical Kawasaki disease
Categories: Gloria

Very welcome 😉

From: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>
Sent: Tuesday, October 4, 2022 8:42 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Allen, Andrea Thames (CDC/DDID/NCEZID/DHQP) (CTR) <ygt3@cdc.gov>; Vaccine Safety (CDC) <vaccinesafety@cdc.gov>; CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: New NIPINFO inquiry and atypical Kawasaki disease

Thanks very much John we appreciate this!
Gloria

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, October 4, 2022 4:58 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>
Cc: Munshi, Datta (CDC/DDID/NCEZID/DHQP) (CTR) <syv2@cdc.gov>; Scheffey, Anne (CDC/DDID/NCEZID/DHQP) <uen3@cdc.gov>; Vaccine Safety (CDC) <vaccinesafety@cdc.gov>; Edlin, Brian (CDC/DDID/NCEZID/DHQP) <bxe2@cdc.gov>
Subject: RE: New NIPINFO inquiry and atypical Kawasaki disease

Hi all,

To my knowledge, we're not performing enhanced surveillance for Kawasaki's disease after COVID-19 vaccination. Kawasaki's is an AESI, so we do perform medical abstraction, but requests for medical records, etc. are per routine. Unless there's a specific ask or data need, I think we can just let our usual processes work.

- John

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Sent: Tuesday, October 4, 2022 4:56 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Munshi, Datta (CDC/DDID/NCEZID/DHQP) (CTR) <syv2@cdc.gov>; Scheffey, Anne

(CDC/DDID/NCEZID/DHQP) <uen3@cdc.gov>; Vaccine Safety (CDC) <vaccinesafety@cdc.gov>; Edlin, Brian (CDC/DDID/NCEZID/DHQP) <bxe2@cdc.gov>
Subject: RE: New NIPINFO inquiry and atypical Kawasaki disease

Elaine,

If we get a report we'll abstract it but if you mean if someone is doing a specific project, not that I know of. They are very rare

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Tuesday, October 4, 2022 4:49 PM
To: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Munshi, Datta (CDC/DDID/NCEZID/DHQP) (CTR) <syv2@cdc.gov>; Scheffey, Anne (CDC/DDID/NCEZID/DHQP) <uen3@cdc.gov>; Vaccine Safety (CDC) <vaccinesafety@cdc.gov>; Edlin, Brian (CDC/DDID/NCEZID/DHQP) <bxe2@cdc.gov>
Subject: RE: New NIPINFO inquiry and atypical Kawasaki disease

Hi John and Pedro,
Please see info highlighted in green below.
Is anyone collecting data on reports of children with Kawasaki after Covid vaccine?

Thanks,

Elaine

From: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>
Sent: Tuesday, October 4, 2022 1:49 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Amy (CDC/DDID/NCEZID/DHQP) (CTR) <ssf2@cdc.gov>
Cc: Munshi, Datta (CDC/DDID/NCEZID/DHQP) (CTR) <syv2@cdc.gov>; Scheffey, Anne (CDC/DDID/NCEZID/DHQP) <uen3@cdc.gov>; Vaccine Safety (CDC) <vaccinesafety@cdc.gov>; Edlin, Brian (CDC/DDID/NCEZID/DHQP) <bxe2@cdc.gov>
Subject: Re: New NIPINFO inquiry and atypical Kawasaki disease

Thanks Elaine! Actually we wanted to do a VAERS search and ask for your help mainly with doing an ISO RedCap search on other children who may have previously had MMVR administered before 6 months to describe how they many have fared. Can I have access to the ISO RedCap or do you need to do this piece? We're happy to set up time to discuss if needed.

There is also another cisa 'inquiry' about a child with atypical Kawasaki disease (we were told no myocarditis) that the provider reported to VAERS but wanted us to be aware of because they know CDC tracks this. For enhanced surveillance purposes do we need to let Pedro or John or anyone know? We have the reporting provider name but we don't have the temporary ID yet. Once we get it we can share it.

Thanks a lot,
Gloria

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Tuesday, October 4, 2022 1:12:55 PM
To: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>; Roberts, Amy (CDC/DDID/NCEZID/DHQP) (CTR) <ssf2@cdc.gov>
Cc: Munshi, Datta (CDC/DDID/NCEZID/DHQP) (CTR) <syv2@cdc.gov>; Scheffey, Anne (CDC/DDID/NCEZID/DHQP) <uen3@cdc.gov>; Vaccine Safety (CDC) <vaccinesafety@cdc.gov>
Subject: RE: New NIPINFO inquiry

Hi Gloria,
We can search VAERS for reports of infant who received these vaccines and share that with you. Would that work?

Thanks,

Elaine

From: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <iyo8@cdc.gov>
Sent: Tuesday, October 4, 2022 1:10 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Munshi, Datta (CDC/DDID/NCEZID/DHQP) (CTR) <syv2@cdc.gov>; Scheffey, Anne (CDC/DDID/NCEZID/DHQP) <uen3@cdc.gov>
Subject: New NIPINFO inquiry

Hi Elaine,

Thanks a lot for offering to assist with the new NIPINFO inquiry. Dee has already started working on the MMRV/Hep A vaccine safety piece and Karen had suggested a VAERS search. We would love to work with you on this inquiry (referenced in your 12:57p email). Please let us what works best.

Thanks,
Gloria

From: Guh, Alice Y. (CDC/DDID/NCEZID/DHQP)
Sent: Sat, 5 Mar 2022 03:24:51 +0000
To: CISA Response (CDC); Shireen, Farhat (CDC/DDID/NCEZID/DHQP) (CTR)
Cc: Tepper, Naomi (CDC/DDNID/NCBDDD/DBDID)
Subject: RE: Postpartum Case, Initial draft
Categories: Farhat;Alice

Thanks Farhat, and thanks so much, Naomi, for reviewing and providing your edits below (safe travels next week!).

I've also reviewed and have just some minor additional edits (in dark red).

Farhat – let's see if (b)(3):42 U.S.C. has any feedback. I can follow up with (b)(3):42 U.S.C. §242m(d); next Monday if we don't hear back from him before then.

Alice

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Friday, March 4, 2022 7:37 PM
To: Shireen, Farhat (CDC/DDID/NCEZID/DHQP) (CTR) <qwl2@cdc.gov>; Guh, Alice Y. (CDC/DDID/NCEZID/DHQP) <ggt4@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: RE: Postpartum Case, Initial draft

Hi Farhat and Alice, this is Naomi. I am making a few suggested edits to the response, in red. I will be traveling next week so I won't be able to access the CISA box, so please feel free to edit freely and move this forward without me, especially if you get additional feedback from (b)(3):4 2. Thank you so much!

(b)(5); (b)(6)

(b)(5) ; (b)(6)

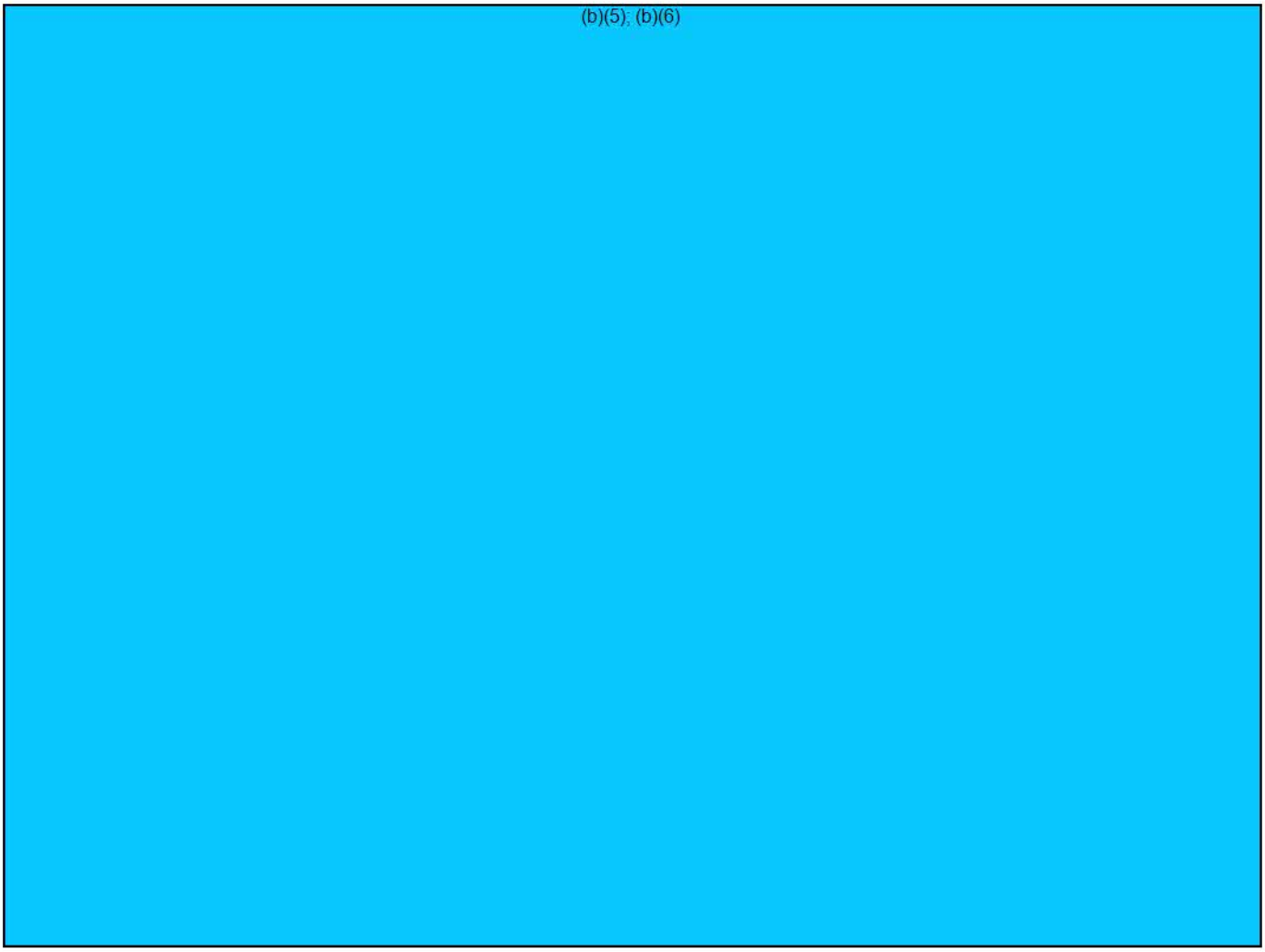
General information:

- Information from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management. Patient management decisions are the responsibility of the treating healthcare provider.
- For the most up-to-date information, CDC will continue to post information online at: https://www.cdc.gov/coronavirus/2019-ncov/index.html
- If not already done, we encourage the patient or their provider to submit a report about this adverse event to CDC's Vaccine Adverse Event Reporting System (VAERS). Here is the link to submit a report online: https://vaers.hhs.gov/

We hope this information is helpful to you.

From: CISA Response (CDC) <cisaresponse@cdc.gov>
Sent: Friday, March 4, 2022 4:09 PM
To: CISA Response (CDC) <cisaresponse@cdc.gov>
Cc: CISA Response (CDC) <cisaresponse@cdc.gov>
Subject: Postpartum Case, Initial draft

(b)(5); (b)(6)



(b)(5) ; (b)(6)

CISA COVIDvax

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

Sent: 3/2/2022
From: Clinician
Subject: re vaccine advice post possible covid related myocarditis with timing and type of vaccine
Email Address: (b)(6)
Question: 34 yo unvaccinated (b)(6) female who infected w/ covid 1/25/22 when (b)(weeks pregnant, Admitted (b)(6) hosp stay complicated by post partum hemorrhage and hypoxia from covid pneumonia. Discharged on oxygen.Readmitted 2/6 w/ seizure then cardiac arrest with v.fib.Echo EF 10% placed on ECMO given remdesivir, tocilizumab and steroids. F/u echo 2/23 EF 60%.Discharged 2/26 fully recovered .We don't know if she had cardiac issues due to pregnancy or covid(no troponins were sent). Per CDC recommendations on line- looks like we can vaccinate her(do you agree) but wondering if we should wait(like the recommendations for MIS-C) and which type of vaccine(mRNA vs J&J). Thank you so much for taking the time to look at this case. J (b)(6)

Optional Information

Name: (b)(6)
Title:
Organization: (b)(6)
Phone: (b)(6)
Other Email: (b)(6)
Address:
(b)(6)
PII Extraction: