

**From:** Walensky, Rochelle, M.D., M.P.H.  
**Sent:** Tue, 25 May 2021 09:59:10 +0000  
**To:** Walensky, Rochelle (CDC/OD)  
**Subject:** Fwd: Write up on signals

Sent from my iPhone

Begin forwarded message:

**From:** "Marks, Peter" <Peter.Marks@fda.hhs.gov>  
**Date:** May 24, 2021 at 4:46:01 AM EDT  
**To:** "Walensky, Rochelle, M.D., M.P.H." (b) (6)  
**Cc:** "Walinsky, Sarah" <Sarah.Walinsky@fda.hhs.gov>  
**Subject:** FW: Write up on signals

**External Email - Use Caution**

Dear Rochelle,

Just wanted you to be aware that the CMS database has signaled for PE and ITP (see below, RR about 1.5). We will be initiating inferential studies to work on eliminating confounders, but it would be good to discuss this and to circle back on the myocarditis issue. Do you want to try to schedule something for our teams to meet either for early in the day (?8:00 AM) or late in the day (?5:00 PM) on Tuesday? Thanks.

Best Regards,  
Peter

**From:** Anderson, Steven <Steven.Anderson@fda.hhs.gov>  
**Sent:** Sunday, May 23, 2021 11:10 AM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Cc:** Forshee, Richard <Richard.Forshee@fda.hhs.gov>  
**Subject:** FW: Write up on signals

Dear Peter,

Here is the summary that we have put together including myself, Rich and our OBE Surveillance Team.

**As a note – myocarditis and pericarditis, as the combined outcome, myopericarditis, has not signaled in the Medicare population.**

We calculated unadjusted relative risk (RRs) of <sup>(b) (5)</sup> pre-specified AESI as the claims data accumulates in United States (US) Centers for Medicare & Medicaid Services (CMS) database to identify unexpected associations for further evaluation in epidemiology studies.

CMS Medicare Shared Systems Data (SSD) claims from December 11, 2020 through May 1, 2021. Weekly sequential hypothesis testing of unadjusted RR of AESI after vaccination compared to historical rates prior to COVID-19 vaccination. **Results:** As of May 1, 2021, 7,830,545 million Pfizer-BioNTech, 8,111,462 million Moderna and 252,569 Janssen vaccine doses were administered. No associations were flagged for the pre-specified cardiac, neurological, gastrointestinal AESI and some vascular AESI. RRs following Pfizer-BioNTech vaccination for pulmonary embolism (PE) and immune thrombocytopenia (ITP) met the statistical threshold for investigation.

On further pre-specified evaluation the RRs for acute myocardial infraction (AMI), disseminated intravascular coagulation (DIC) no longer met the statistical threshold for investigation after seasonality adjustment.

**Conclusion and relevance:** During the subsequent association verification stage, rigorous epidemiology studies will be conducted for PE and ITP to fully account for confounding. In a nationwide surveillance of persons aged  $\geq 65$  years, the US Food and Drug Administration and CMS are assuring the safety of COVID-19 vaccines in a high-risk population by rapidly detecting possible AESI as early alerts for more indepth follow-up.

Let us know if you have any questions.

Steve

Steve Anderson, Ph.D., M.P.P.  
Director  
Office of Biostatistics and Epidemiology  
Center for Biologics Evaluation and Research  
U. S. Food & Drug Administration  
10903 New Hampshire Ave.  
Bldg 71, Room 1220  
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email: [steven.anderson@fda.hhs.gov](mailto:steven.anderson@fda.hhs.gov)



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**From:** Marks, Peter  
**Sent:** Tue, 25 May 2021 10:58:30 +0000  
**To:** Walensky, Rochelle (CDC/OD)  
**Cc:** Walinsky, Sarah (FDA/CDER)  
**Subject:** RE: Write up on signals

Dear Rochelle,

Sorry about the wrong address last time.

Best Regards,  
Peter

---

**From:** Marks, Peter  
**Sent:** Monday, May 24, 2021 4:46 AM  
**To:** Rochelle Walensky MD (b) (6)  
**Cc:** Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>  
**Subject:** FW: Write up on signals

Dear Rochelle,

Just wanted you to be aware that the CMS database has signaled for PE and ITP (see below, RR about 1.5). We will be initiating inferential studies to work on eliminating confounders, but it would be good to discuss this and to circle back on the myocarditis issue. Do you want to try to schedule something for our teams to meet either for early in the day (?8:00 AM) or late in the day (?5:00 PM) on Tuesday? Thanks.

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Peter

---

**From:** Anderson, Steven <[Steven.Anderson@fda.hhs.gov](mailto:Steven.Anderson@fda.hhs.gov)>  
**Sent:** Sunday, May 23, 2021 11:10 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Forshee, Richard <[Richard.Forshee@fda.hhs.gov](mailto:Richard.Forshee@fda.hhs.gov)>  
**Subject:** FW: Write up on signals

Dear Peter,

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Let us know if you have any questions.

Steve

Steve Anderson, Ph.D., M.P.P.  
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Phone: 240-402-8577

email: [steven.anderson@fda.hhs.gov](mailto:steven.anderson@fda.hhs.gov)



**From:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)  
**Sent:** Thu, 27 May 2021 23:02:38 +0000  
**To:** Walensky, Rochelle (CDC/OD)  
**Cc:** Berger, Sherri (CDC/OCOO/OD)  
**Subject:** RE: Updated myocarditis documents

This is handled.

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**From:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>  
**Sent:** Thursday, May 27, 2021 6:51 PM  
**To:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); Nordlund, Kristen (CDC/DDID/NCIRD/OD); Caccomo, Stephanie (FDA/OC)  
**Cc:** Schindelar, Jessica (CDC/DDID/NCEZID/DHQP); Coffin, Nicole (CDC/DDID/NCEZID/DHQP); Stryker, Jo Ellen (CDC/DDID/NCHHSTP/DHPIRS); Holton, Kelly (CDC/DDNID/NCIPC/OD)  
**Subject:** RE: [EXTERNAL] RE: Updated myocarditis documents

Hi all – thanks for sharing this, we’ve reviewed (including Dr. Marks), and this addresses our concerns. We appreciate the discussion earlier to work this through.

Best –

Lorrie

**From:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>  
**Sent:** Thursday, May 27, 2021 6:25 PM  
**To:** Nordlund, Kristen (CDC) <hok4@cdc.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>  
**Cc:** Schindelar, Jessica A (CDC) <ghq1@cdc.gov>; Coffin, Nicole (CDC) <ndc3@cdc.gov>; Stryker, Jo (CDC) <gux6@cdc.gov>; Holton, Nora Kelly (CDC) <nfh5@cdc.gov>  
**Subject:** [EXTERNAL] RE: Updated myocarditis documents

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Stephanie, Lorrie,

Since Dr. Marks and Woodcock have called Dr. Walensky directly on this, just want to make sure we got to a good place. Want to make sure you see the **highlighted** question below and that landed in the correct spot. Can you confirm?

Regards,

Abbigail

**From:** Walensky, Rochelle (CDC/OD)  
**Sent:** Thu, 27 May 2021 20:07:07 +0000  
**To:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)  
**Cc:** Berger, Sherri (CDC/OCOO/OD)  
**Subject:** RE: [EXTERNAL] Materials on myocarditis

Got it...please keep me posted.

r

**From:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>  
**Sent:** Thursday, May 27, 2021 4:06 PM  
**To:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>  
**Cc:** Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>  
**Subject:** RE: [EXTERNAL] Materials on myocarditis

Yes, for about 10 mins, but it was pulled down. Team was under the impression that FDA staff were in agreement with the language. They are regrouping with the SMEs to discuss.

Cc'ing Sherri as FYI.

**From:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>  
**Sent:** Thursday, May 27, 2021 3:24 PM  
**To:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>  
**Subject:** RE: [EXTERNAL] Materials on myocarditis

Thank you – had it already been posted?

R

**From:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>  
**Sent:** Thursday, May 27, 2021 3:06 PM  
**To:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>  
**Subject:** RE: [EXTERNAL] Materials on myocarditis

Rochelle,

Spoke to the team and they are pausing on the clinical considerations language. They are regrouping with the FDA team.

I have asked for Dr. Denise Cardo and others to speak with Dr. Marks and team.

Regards,

Abbigail

**From:** Walensky, Rochelle (CDC/OD) <[aux7@cdc.gov](mailto:aux7@cdc.gov)>  
**Sent:** Thursday, May 27, 2021 2:52 PM  
**To:** Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[aws8@cdc.gov](mailto:aws8@cdc.gov)>  
**Subject:** FW: [EXTERNAL] Materials on myocarditis

**From:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Sent:** Thursday, May 27, 2021 2:03 PM  
**To:** Walensky, Rochelle (CDC/OD) <[aux7@cdc.gov](mailto:aux7@cdc.gov)>  
**Cc:** Woodcock, Janet (FDA/CDER) <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Materials on myocarditis

Dear Rochelle,

I need to ask for your patience with me. We still have concerns here if (b) (5)  
(b) (5)  
(b) (5) Can you help me understand why we are doing this when pediatricians and others in the community already seem to be aware?

Happy to jump on a call.

Best Regards,  
Peter

**From:** McNeill, Lorrie <[Lorrie.McNeill@fda.hhs.gov](mailto:Lorrie.McNeill@fda.hhs.gov)>  
**Sent:** Thursday, May 27, 2021 10:37 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Subject:** FW: [EXTERNAL] Materials on myocarditis

Hi Peter –

These materials just arrived. As noted below, CDC has decided not to issue the HAN and go with the web posting only. Of note, they've modified the web posting from the version we saw on Tuesday to include language on the amount of time until patients should wait to return to competitive sports (this was in the HAN). I've attached the previous version for comparison (dated 5/25/2021).

Let me know if you'd like me to push back on this.

Thanks –

Lorrie

**From:** Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[hok4@cdc.gov](mailto:hok4@cdc.gov)>  
**Sent:** Thursday, May 27, 2021 10:17 AM  
**To:** Caccamo, Stephanie <[Stephanie.Caccamo@fda.hhs.gov](mailto:Stephanie.Caccamo@fda.hhs.gov)>; McNeill, Lorrie <[Lorrie.McNeill@fda.hhs.gov](mailto:Lorrie.McNeill@fda.hhs.gov)>



**Cc:** Tumpey, Abbigail J (CDC) <[aws8@cdc.gov](mailto:aws8@cdc.gov)>; Hoffman, Katherine T (CDC) <[ltd0@cdc.gov](mailto:ltd0@cdc.gov)>  
**Subject:** [EXTERNAL] Materials on myocarditis

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Stephanie and Lorrie,

Thank you for all the help over the last week on this issue. As I mentioned yesterday, we decided to nix the HAN and instead publish clinician considerations (which will go online here:<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html>) and web content for the public and parents (which will go here: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>). Attached are the near final versions, pending anything from the higher ups.

As mentioned in the reactive/tough QA document, we plan (b)(5)

(b)(5)

Please let me know if you have any issues/concerns.

Thanks,  
Kristen

**Kristen Nordlund**  
CDC Public Affairs  
p. 404.639.7387 | c. 404.956.0336 | e. [hok4@cdc.gov](mailto:hok4@cdc.gov)

**From:** Walensky, Rochelle (CDC/OD)  
**Sent:** Wed, 26 May 2021 18:07:56 +0000  
**To:** Woodcock, Janet  
**Subject:** RE: [EXTERNAL] RE: Rochelle, do you know that (b) (5)  
(b) (5) as written? jw

Are you able to call me at 404-426-2086, please?  
R

**From:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Sent:** Wednesday, May 26, 2021 2:04 PM  
**To:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>  
**Subject:** RE: [EXTERNAL] RE: Rochelle, do you know that (b) (5)  
(b) (5) as written? jw

Thanks so much. I just learned that this was about to go out, despite our concerns. jw

**From:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>  
**Sent:** Wednesday, May 26, 2021 2:00 PM  
**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Subject:** [EXTERNAL] RE: Rochelle, do you know that (b) (5)  
(b) (5) as written? jw

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

Hi Janet,  
Just coming from a hearing and trying to get up to speed. Will hold until we chat.  
R

**From:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Sent:** Wednesday, May 26, 2021 1:52 PM  
**To:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>  
**Subject:** Rochelle, do you know that (b) (5) as  
written? jw