

From: Mahon, Barbara (CDC/DDID/NCIRD/OD)
Sent: Tue, 31 Aug 2021 21:26:52 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Layden, Jennifer (CDC/DDPHSS/OS/OD); Fox, Kimberley (CDC/DDID/NCIRD/DBD); Biagioni, Mark T. (CDC/DDID/NCIRD/DBD)
Subject: RE: v-safe question

Yup, this all makes sense.

(b)(6)

was asking because I knew that VAERS and VSD would already be fine to monitor myocarditis (or appendicitis!) and the like but that v-safe was not configured for third doses in the spring.

Thanks, and thanks for all the great work you and your team have done.

Barbara

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 31, 2021 5:19 PM
To: Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>; Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Biagioni, Mark T. (CDC/DDID/NCIRD/DBD) <gld5@cdc.gov>
Subject: RE: v-safe question

Hi Barbara,

V-safe is structured to monitor 3rd dose, but v-safe will not be particularly useful for monitoring myocarditis. That will primarily be accomplished through VAERS and VSD monitoring. The questions in v-safe are pre-specified and focus on local and systemic reactogenicity and fairly general adverse health impact events. If a patient reports receiving care from a healthcare provider we would follow-up to take a VAERS report so we might capture myocarditis cases that way, but v-safe won't specifically get at myocarditis. It's just not designed to directly monitor specific adverse events outside of reactogenic AEs.

Tom

From: Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>
Sent: Tuesday, August 31, 2021 5:04 PM
To: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Biagioni, Mark T. (CDC/DDID/NCIRD/DBD) <gld5@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: v-safe question

Thanks a million. That's what I wanted to know.

Tom, I know how insanely busy you are—no need to weigh in unless you really want to.

Barbara

From: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>
Sent: Tuesday, August 31, 2021 5:02 PM
To: Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Biagioni, Mark T. (CDC/DDID/NCIRD/DBD) <gl5@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: v-safe question

Hi there-

It is. The safety team has been getting the various systems ready, and are thinking through a few items.

Adding Tom, who is the lead and guru of vaccine safety, in case he wants to provide more details.

jen

Jen Layden, MD, PhD
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From: Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>
Sent: Tuesday, August 31, 2021 4:57 PM
To: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Biagioni, Mark T. (CDC/DDID/NCIRD/DBD) <gl5@cdc.gov>
Subject: v-safe question

All,

I bet the answer is yes, but do you know if v-safe is being updated to accommodate third doses of mRNA vaccines? (b)(5)

(b)(5) I'm sure others who know more about vaccine safety than I do are already working on this....

Thanks,

Barbara

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