

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