Why won't the CDC or FDA reveal the VAERS URF?

By Steve Kirsch

Summary: The VAERS underreporting factor (URF) is required information to be known for any risk-benefit of assessment of a vaccine. The fact that this number was never calculated by the FDA or CDC means that all the safety recommendations to date have been by guessing. This has resulted in the needless loss of life of well over 150,000 Americans.

VAERS is the <u>Vaccine Adverse Event Reporting System</u>. It is the official system relied upon by the FDA and CDC for adverse event tracking.

For example, if you report an adverse event in <u>V-Safe</u>, the app they told you about when you got vaccinated, you are told to file a VAERS report. It is essentially the mother of all adverse event reporting systems for vaccine events in the US. There is nothing more comprehensive than VAERS.

The most important thing to know about VAERS is that it is always underreported. This is widely known.

To properly interpret any safety data, you must know the underreporting factor (URF).

For example, the famous <u>Lazarus report</u> estimated the VAERS URF to be over 100:

"Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, **fewer than 1% of vaccine adverse events are reported**. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health."

The Baker paper, <u>Advanced Clinical Decision Support for Vaccine Adverse Event Detection and Reporting</u>, showed that "the odds of a VAERS report submission during the implementation period were 30.2 (95% confidence interval, 9.52–95.5)."

In other words, the VAERS URF was at least 30 (since the system wasn't perfect, 30 is a lower bound of the URF in that study), but they estimated that it was likely between 9.5 and 95.

The URF is normally calculated for very serious events since these are required to be reported for all vaccines by healthcare workers. That URF can then be applied to less serious events to create a conservative estimate of the true incidence rate (since less serious events would have a higher URF).

The method for calculating the URF is well known.

Sadly, the CDC has erroneously assumed that Vaccine Safety Datalink represents a fully reported comparator.

This is clearly false as can be seen from <u>slide 13 in ACIP Chair Grace Lee's presentation</u> delivered on August 30, 2021:

7	ocarditis/Pericarditis — 0-7 day risk interval							
	VAERS reporting rates per million doses administered				VSD excess cases per million doses based on chart confirmed data			
Ages (yrs)	Pfizer Dose 1	Pfizer Dose 2	Moderna Dose 1	Moderna Dose 2	Pfizer Dose 1	Pfizer Dose 2	Moderna Dose 1	Moderna Dose 2
12-15	2.6	20.9			0.7	14.4	4.9	
16–17	2.5	34.0						
18–24	1.1	18.5	2.7	20.2				19.7
25–29	1.0	7.2	1.7	10.3				
30-39	0.8	3.4	1.0	4.2				

You can clearly see that VSD estimates are below the VAERS estimates.

Therefore, calculating the URF from anaphylaxis data from a prospective targeted study, such as the <u>Blumenthal Mass General Brigham study that was published in JAMA</u> provides a more accurate estimate. There was a <u>second Blumenthal paper</u> published again in JAMA (this time an Editorial rather than a Research Letter) showing an anaphylaxis rate that was 48X lower, but that is just to mislead people into taking the vaccine.

Brian S. Hooker, Ph.D., P.E., Professor of Biology at Simpson University is one of the few scientists not afraid to speak the truth (they are hard to find nowadays). Here's what he wrote on this section (emphasis mine):

"You are correct in your analysis. The 2.4/10000 rate is based on all cases of anaphylaxis reported but the 5/1,000,000 is based only on inpatient hospital or emergency department visits. You can undergo anaphylaxis without being admitted into the hospital going to the emergency room. I also believe that the

5/1,000,000 applied the Brighton Collaboration criteria much too narrowly. The second paper is just **propaganda to get people vaccinated**."

When we do the math, we find that the URF is 41, well in line with the mean and range described in the Baker paper. It means that over 150,000 people have been killed by the vaccine so far (and we show 8 different ways in that paper, only one of which uses VAERS).

The troubling thing is this: nobody at the CDC, FDA, or on any of the outside committees will admit this. When they are asked "what is the URF for serious events in VAERS for the COVID vaccine" they are unable to respond. Not even Steven A. Anderson of the FDA can answer that. He said he was the top guy for vaccine safety at the FDA. I heard him say that on a zoom call.

He won't talk. He doesn't respond to emails, he doesn't respond to voicemails. His staff doesn't respond either.

Janet Woodcock won't tell me the URF.

The friendly people at covid19vaxsafety@cdc.gov won't tell me the URF.

Lorrie McNeill of the FDA won't tell me the URF.

Tom Shimabukuro won't tell me the URF.

John Su won't tell me the URF. He pretends in his presentations to ACIP and VRBPAC committees that the URF=1 because he never points out that VAERS is underreported or what the reporting factor is. We have all that on the record.

No member of any of the outside committees of the FDA or CDC would respond to my multiple requests.

I have tried to find someone knowledgeable to interview to ask that question, but no prominent pro-vaccine person would consent to an interview. Eric Topol doesn't respond. Monica Gandhi doesn't respond. UCSF Dean of Medicine Bob Wachter won't talk to me on camera. They are all afraid of being exposed.

None of the fact checkers I asked would help me out.

Heck, I couldn't even get Health Nerd to consent to be interviewed by me.



I thought it was just me.

To test that, I asked a former *NY Times* reporter (now working for another newspaper) to ask the question of the FDA and he was stonewalled as well. They refused to answer him. Silence as soon as he asked the question. But his paper won't let him write a story about it.

Let's be clear: you cannot do any sort of risk-benefit assessment without knowing the VAERS URF. It is impossible.

The fact that as of October 25, 2021 that nobody knows the URF for VAERS is a sign of mass incompetence and corruption at the FDA, CDC, and their external committees.

There is no other alternative.

This of course is why nobody at the FDA, CDC, or on the external committees wants to talk to me. Because I ask questions that they don't want to answer. This is why censorship is required to silence people like me.

This is the biggest cover-up in history. CDC, FDA, mainstream media, nearly the entire medical community, and all the major social media companies are pitching in to silence people like me who ask questions we aren't supposed to ask.

It's pretty sad that nobody in the mainstream media is asking those questions, isn't it?