

## Elizabeth Brehm

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**From:** Elizabeth Brehm  
**Sent:** Tuesday, May 25, 2021 9:37 AM  
**To:** Elizabeth Brehm  
**Subject:** FW: High level VAERS reporting concern/covid vaccines

----- Forwarded Message -----

**From:** [REDACTED] >  
**To:** [paul.richards@fda.hhs.gov](mailto:paul.richards@fda.hhs.gov) <[paul.richards@fda.hhs.gov](mailto:paul.richards@fda.hhs.gov)>  
**Sent:** Thursday, April 15, 2021, 07:25:23 AM CDT  
**Subject:** High level VAERS reporting concern

To whom it may concern,

I am writing this email with high level importance regarding what I believe is gross under reporting of possible covid 19 vaccine related adverse events/side effects/possible immune mediated adverse events. I work in a small community hospital in Upstate New York and as a medical provider and professional have taken on the responsibility for my hospital of reporting to VAERS the significant influx of patients we are seeing in our emergency room and hospital wards in the past few months with new medical problems or sudden worsening of medical problems following covid 19 vaccination. In the last 4 weeks I have reported 50 cases to VAERS and 4 possible deaths. These are only the patients I have taken care of or who were brought to my attention by ER providers or some of my colleagues and I'm sure are not all. The only reason we are starting to capture these cases is I brought awareness to our hospital that the question needs to be asked of patients when they are coming in the ER if they have recently had their covid 19 vaccination and I have volunteered to be the person for now who reports cases to VAERS. I do not feel that hospital systems were prepared or adequately notified of this possibility or how we should be managing it. There was no notification or training about who should be reported, what should be reported and how far out post vaccination that possible immune mediated adverse events would be seen. Pfizers EUA recommends a minimum of 6 weeks post vaccination to capture this data. VAERS notes that ANY hospitalization post vaccination, infection with covid 19, inability to perform daily functions, vaccine administration errors, deaths should be reported and that reporting is MANDATORY. If it is mandatory then why was no education sent out to hospital systems and administrators??? I've contacted the FDA, Moderna, Pfizer, our DNV/hospital accrediting body, our state health department and many hospital system leaders and physicians in my state with either no answer in regards to how we deal with this issue or a complete unawareness that this is even necessary or mandatory. Had I not taken on this task none of these cases would of been reported to VAERS. Just yesterday we had a pt in the hospital for covid 19 infection despite being 3 weeks out from both vaccines and had a nurse not contacted me her case would of gone unreported. The safety of these vaccines for the public lies with a passive reporting system that is in place, but if hospital systems and medical providers are not educated on the importance of reporting, especially an EUA product, very large volumes of problems will go unreported and the vaccines could be fully licensed for use without complete and accurate information on possible immediate and long term side effects. I reported 5 patients with deep vein thrombosis/pulmonary emboli following vaccination with Pfizer/Moderna which is the same condition the pause is currently for with the J and J vaccine. I'm sure there are many more out there I am unaware of. I have contacted 2 large tertiary hospitals within 1 hr from us and there is no system for reporting in either. A colleague of mine is seeing the same thing in her hospital and cases upon cases of patients with acute strokes, myocardial infarction, blood clots, covid 19 infection, new autoimmune conditions, arrhythmia, seizures/neurological conditions and bleeds are not being reported to VAERS or the drug companies. Every case of covid 19 is being recorded in the state but the question if infection is following vaccination is not even on the questionnaire, so the data will never be captured.

This is NOT true transparency and puts all Americans health and possible future health at risk. Most physicians and nurses, health care staff don't even know that they should be asking patients who are getting admitted about their covid 19 vaccines and patients don't know that there possibly could be a link to their current acute medical problem and the vaccine. We will never know unless the data is captured. This issue must be addressed ASAP and I am pleading with the FDA to bring awareness of this to hospital systems as the FDA is responsible for protecting public health by ensuring the safety,

efficacy and security of human and veterinary drugs, vaccines and other biological products for human use.

Thank you and I hope to hear a response soon,

Anonymous writer