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CDC should make COVID-19 vaccine V-safe side effects self-reporting "Opt out" instead of "Opt in"

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At the moment the United States and the rest of the world are participating in an unprecedented experiment of being vaccinated for COVID-19 to end the pandemic without completely knowing long-term risks. The **Federal Drug Administration (FDA)** has authorized the emergency use for the vaccine based upon clinical trials that showing that the vaccine is highly effective in reducing or preventing COVID-19 disease and morbidity (**FDA, 2021**). Because it is an experimental procedure, it is necessary to monitor and follow-up everyone who is vaccinated in order to identify possible rare complications that could occur in the future. What has been reported is a very rare complication of anaphylaxis that may occur immediately after administration of the vaccine by **Pfizer-BioNTech** (4.7 cases per million) and **Moderna** (2.4 cases per million) (**Shimabukuro, Cole, & Su, 2021**); however, this data may under report the actual negative side effects. In the recently published prospectively study by **Blumenthal et al. (2021)** of 64,000 employees associated with Mass General Brigham (MGB) were actively followed through a multipronged approach including email, text message, phone, and smartphone application links. The complication rate of acute allergic reaction rate was 2.1% and the severe anaphylaxis reaction was 247 cases per million. This is 50 times higher than the previously reported results which depended on voluntary reporting instate of active all participants follow-up. **Nevertheless, the benefits of vaccination far outweigh the risk of anaphylaxis, which was experienced within the first 15-30 minutes after the vaccination and treatable.** What is disturbing is that at this moment, the USA does not have a systematic long-term follow up strategy for all the people who vaccinated to identify possible delayed long-term side effects since it depends upon voluntary reporting, however, rare. Thus, we are all part of an uncontrolled experiment in which I am also participating.

At the age of 76, I choose to be vaccinated after having assessed the risk-benefits reported in the published clinical studies (the possible harm caused by Covid-19 would be significantly worse than the possible harm caused by the short and long term side effects from the vaccine). It was confusing and challenging to figure out where the vaccinations were being offered. Luckily, I searched online to find a

location where I could sign up to make an appointment for the first vaccination. After having successfully navigated signing up and getting an appointment for Thursday, I contacted the older couple who live nearby and asked if they already had a vaccination appointment. When they told me that they were unable to find a location, I shared with them the information for signing up on the website.

After having received the vaccination, I installed the V-safe app in my cellphone and answered the questions on the App survey; however, to participate, I had to **opt in** instead of having to **opt out**. Later on Thursday, I received the first text message from V-safe to which I responded by answering the short symptom questions. I reported that the site of the vaccination felt sore and tight and whenever I lifted up my left arm, I felt a dull ache and stiffness. It was slightly more uncomfortable than I had experienced two years earlier from a tetanus and diphtheria (Td) vaccine injection. That night I could not sleep on my left side since the deltoid area continued to feel sore and painful to pressure. The next day, I worked and did not look at my text messages. On Saturday morning, I realized that I had not responded to Friday's check-in text message from V-safe. When I tried to response, the survey link embedded in the text message no longer worked. Thus, my discomfort that continued through Thursday night and Friday was not reported to the CDC.

As I still felt some slight tenderness, I also wondered how the older couple were doing since they had received the vaccine on the same day as I did. I called them to check on how they were doing and see if they had signed up with V-safe. They responded that they were doing well except for some soreness in the upper arm; however, they had not signed up for V-safe.

This experience brought to mind studies finding that when follow-up information depends voluntarily opting in, most people do not opt in. Thus, the follow-up data and reporting of possible negative side effects will be less reliable since it would reflect only a small subset of all the people who received the vaccine and are tech savvy. The CDC needs to revise their tracking strategy so that it is able to survey accurately the occurrence of side effects from everyone who gets vaccinated by enrolling them, unless they choose to opt out.

- Enroll people automatically unless they personally decide to opt-out. The enrollment process should be organized so that when an individual receives the vaccine, they automatically are enrolled. Automatic enrollment leads to much higher participation than a voluntary opt-in approach. The difference in participation has been demonstrated in many settings ranging from organ donations to signing up for 401K retirement plans. For example, in Austria, organ donation is the default option at the time of death, and people must explicitly 'opt out'of organ donation. "In these so-called *opt-out countries,* more than 90% of people register to donate their organs. Yet in countries such as U.S. and Germany, people must explicitly 'opt in' if they want to donate their organs when they die. In these *opt-in countries,* fewer than 15% of people register" (**Davidai, Gilovich & Ross, 2012**). Similar results have been observed in employees' enrollment in 401K saving plans (**Nash, 2007**). For example, in analyses of recent hires by Fortune 500 firms, 85.9% of new hires will participate in a 401 K retirement plan when they are automatically enrolled versus 32.4% if they have to voluntarily enroll (opt –in).

- **The V-safe app needs to allow symptom data to be reported after the deadline.** There needs to be an option to allow a delayed response. In addition, if the person did not respond to the automatic survey, the person needs to be contacted to identify the cause of the non-response.

- **Longterm follow-up to monitor for possible adverse effects needs to be implemented.** The minimum follow-up period needs to be two years to be able to monitor possible adverse effects that may be triggered by the vaccines. In theory, this could include "antibody-dependent enhancement" to another virus. This occurs when the immune response that has been previously activated makes the clinical symptoms worse when the person is infected a subsequent time with a different type of virus and that trigger an over-reaction, creating a cytokine storm. For example, when a person gets dengue fever and is infected a second time by a different strain of dengue, the person becomes much sicker the second time (**Murphy & Whitehead, 2011**). Some researchers are concerned that the vaccine in the future could cause an excessive immune reaction when exposed to another virus.

Without automatic enrollment and follow-up, the short and long-term general public safety data may be unreliable and will not accurately capture the actual frequency of side effects. The reported data may under report the actual risk. When independent researchers investigated medical procedures they often find find the complication rate three-fold higher than the medical staff reported. For example, for endoscopic procedures such as colonoscopies, doctors reported only 31 complications from 6,383 outpatient upper endoscopies and 11,632 outpatient colonoscopies. The actual rate was 134 trips to the emergency room and 76 hospitalizations. This discrepancy occurred because the only incidents reported involved patients who went back to their own doctors. The research did not capture those patients who sought help at other locations or hospitals (**Leffler et al., 2010**).

The data reported by the cellphone web-based app V-safe may represent possibly only 20% of the people vaccinate, biased to those who are healthier, more affluent, younger, and technologically adept. In order to be able to sign-up for V-safe and respond to the text messages, the person needs to be tech savvy, have a cellphone, and be able to respond to the text message during the same day the message is send.

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