SC Reported COVID-19 Adverse Events and Death Descriptions

Based on Freedom of Information Act responses (FOIA), DHEC staff did not follow-up on SC Vaccine Adverse Events Reporting System (VAERS) submissions.

Please see DHEC correspondence at the bottom of **page 1**. As well as, **Table 1** regarding the uptick in vaccine adverse events reported in SC in 2021 which coincides with the COVID-19 vaccine rollout on **page 2**.

Descriptions of COVID19 or COVID19-2 Vaccine Adverse Events Reported in South Carolina

1. **Descriptions of 90 deaths reported in South Carolina**

   https://www.medalerts.org/vaersdb/findfield.php?EVENTS=ON&PAGENO=4&VAX[]=COVID19&VAX[]=COVID19-2&DIED=Yes&STATE=SC

   *Many of these reported deaths in SC were cardiovascular in nature shortly after the vaccination was administered

2. **Descriptions of all 9,098 adverse events reported in South Carolina**

   https://www.medalerts.org/vaersdb/findfield.php?EVENTS=ON&PAGENO=2&VAX%5b%5d=COVID19&VAX%5b%5d=COVID19-2&STATE=SC

3. **Descriptions of 468 adverse events -age 6 months-18 years reported in South Carolina**

   https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&GRAPH=ON&GROUP6=AGE&EVENTS=ON&VAX%5b%5d=COVID19&VAX%5b%5d=COVID19-2&VAXTYPES=COVID-19&STATE=SC&WhichAge=range&LOWAGE=.5&HIGHAGE=18

   Some events reported in this age group were **SC providers** administering COVID-19 vaccinations to children in age-groups that were not yet approved by the FDA (purposely in many cases). * This practice warrants an ethical investigation given that providers are shielded from liability (lawsuits) if an infant or child is harmed by a vaccination.

A DHEC FOIA response was requested for DHEC staff to provide follow-up communication with the CDC and FDA related to the (at the time) over 8,000 South Carolina COVID-19 vaccine adverse events reported to the Vaccine Adverse Reporting System (VAERS) or if DHEC staff had investigated any adverse events reported directly to DHEC by providers or South Carolinians.

Freedom of Information Act response from DHEC:

"DHEC does not do follow up or investigate VAERS submissions. In fact, CDC doesn't provide us with the information on or communicate with us about entries related to SC, and they (and/or the FDA) do all of the investigating and analysis of those reports." – DHEC Staff FOIA Response

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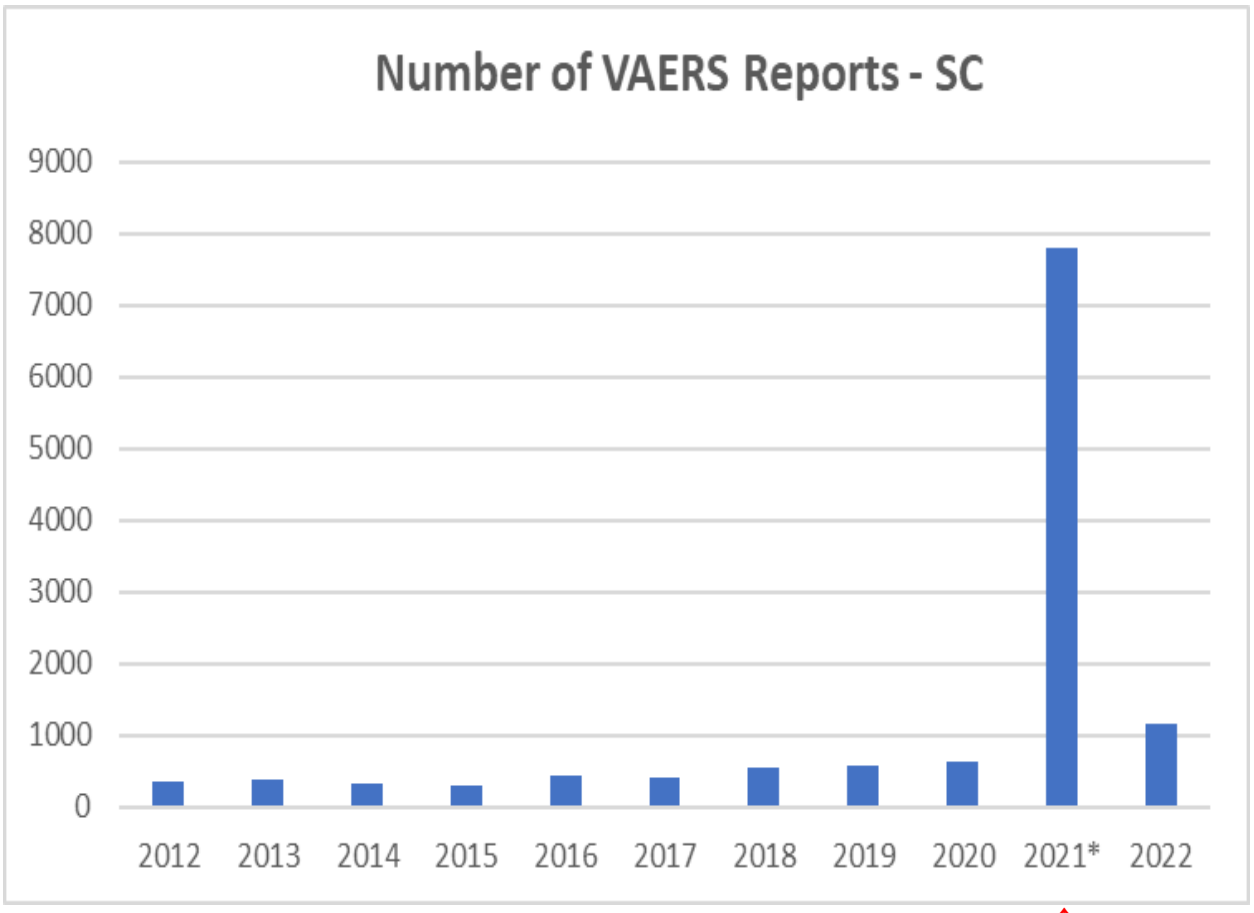
However, after corresponding with a **senior scientist at the CDC's Immunization Safety Office** it was communicated that South Carolina designated Vaccine Safety Coordinators receive weekly reports on specific South Carolinian COVID-19 vaccine adverse events reported to VAERS.

"*Currently CDC uses Epi-X to send each U.S. public health jurisdiction reports containing all of their state's VAERS reports on COVID-19 vaccine, as well as de-identified COVID-19 summary data from other jurisdictions. CDC sends this data on Epi-X weekly.*" – Immunization Safety Office (CDC) Staff

Table 1

SC Vaccine Adverse Events Reported to the Vaccine Adverse Events Reporting System (VAERS) Database by Year



*Covid-19 Vaccine Rollout

For more information of VAERS please see page 3

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The Food and Drug Administration (FDA) acknowledges that once approval is given to release a new vaccine to potentially millions of Americans, **post-marketing research and surveillance is necessary to identify potential safety issues** that may only be detected following vaccination in a much larger and more diverse population[1]. It is widely accepted that pharmaceutical products can carry potential unwanted side effects which may not be recognized in clinical trials and are difficult to predict.

The Vaccine Adverse Event Reporting System (VAERS) [2] is the primary national vaccine safety surveillance program co-monitored by the FDA and the CDC. VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences to CDC and FDA.

VAERS is not designed to determine if a vaccine caused a health problem. Rather, it is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. As such, VAERS can provide CDC and FDA with valuable information so that attention and funding may be directed to the study and evaluation necessary to further assess possible safety concerns.

A federal government funded Harvard Pilgrim study and other similar studies suggests that only between **1% -10% of vaccine adverse events are reported to VAERS.** [3] [4] Low reporting rates preclude or slow the identification of problem drugs and vaccines that endanger public health. **New surveillance methods for drug and vaccine adverse effects are urgently needed**. Barriers to reporting adverse events from pharmaceuticals for clinicians include:

- a lack of clinician awareness
- uncertainty about when and what to report, as well as
- the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative.

South Carolinians expect an ongoing objective disclosure of risks and knowledge gaps in vaccine safety from DHEC and SC providers. This is not good enough.

[1] https://www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/vaers-overview
[2] https://vaers.hhs.gov/about.html
[3] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
[4] https://academic.oup.com/cid/article/61/6/864/451758