Edward Simmer, MD, MPH, DFAPA
Director
S.C. Dept. of Health & Environmental Contro

April 12, 2023

Re: Concerns About DHEC Freedom of Information Act (FOIA) Responses Related to COVID-19 Data and Guidance Provided to South Carolinians

Dear Dr. Simmer,

Thank you for arranging the meeting on March 30th to address concerns related to DHEC staff responses and to share what is being done to evaluate and improve methods used for the Department of Health and Environmental Control's (DHEC) public health practices and procedures.

The toll of the COVID-19 crisis has been enormous, varied and far reaching across nearly every segment of the South Carolinian population. There is no denying that in 2020 the COVID-19 pandemic brought many difficult challenges that the current State and Federal Government public health officials had never encountered. Although the initial response was led by a noble sense of urgency and crisis management, throughout the COVID-19 crisis DHEC did not consistently provide documentation of data and evidence supporting ongoing COVID-19 guidance.

In South Carolina there has been a distinct, growing mistrust of DHEC, due in part to DHEC staff adopting and encouraging certain Center for Disease Control and Prevention (CDC) recommendations without extensive scientific review, which are:

1. not supported by the body of scientific evidence.
2. not adapted as emerging scientific evidence and new information becomes available.
3. not scientifically justified to be implemented in all age groups and population.
4. detrimental due to known or unintended negative consequences in certain populations, resulting in other very serious public health problems.

As a result, South Carolinians confidence in DHEC staff to lead through future healthcare issues was compromised. Concerns regarding DHEC staff's management of the COVID-19 crisis are supported by:

- documented written correspondence from qualified DHEC staff.
- documented FOIA request responses from qualified DHEC staff.
- the known deleterious damage resulting from DHEC COVID-19 Guidance in South Carolina.

South Carolinians understandably expect excellence from DHEC staff who by law[1] are charged with being the sole public health advisors to our state. The purpose of this continued dialog is to provide transparency to South Carolinians so that trust in DHEC's public health guidance can be strengthened to support our state to heal and propel forward.

It is respectfully requested that DHEC staff provide further transparency and respond in writing to questions in the attached document on the following topics of concern:

1. **Why are DHEC staff unable to provide the data criteria used to collect South Carolinian COVID-19 hospitalizations and deaths which are published on the DHEC website?** A basic prerequisite for making informed policy decisions is to utilize accurate and reliable data, even during times of uncertainty. A need for greater diligence and transparency on data collection and reporting is urgently needed.

[1] https://www.scstatehouse.gov/code/t44c001.php

2. **Why did DHEC staff fail to provide scientific evidence supporting their recommendation of universal pediatric COVID-19 vaccination of South Carolina infants and children age 6 months to 17 years?** Parents and providers depend on ongoing rigorous review of the available scientific evidence. A thorough scientific review of COVID-19 vaccine is urgently needed.

3. **Why did DHEC staff not follow-up with the CDC and the Food and Drug Administration (FDA) regarding the almost 9,000 South Carolinian COVID-19 vaccine adverse events reported to the Vaccine Adverse Events Reporting System (VAERS)?** Vaccine adverse events rose exponentially in South Carolina after the COVID-19 vaccine roll out. To protect public health there is an urgent need for DHEC staff to closely monitor reported adverse events from COVID-19 vaccination.

4. **Why was DHEC staff unable to provide adequate scientific evidence to support DHEC's recommendation of universal masking in DHEC's K-12 COVID-19 school guidance?** DHEC staff continues to strongly encourage universal masking in schools[2]. A risk vs benefit analysis of universal masking in schools is urgently needed.

If a public health agency claims to be a trusted source of information and chooses to campaign against misinformation,[3] [4] it is important that the agency accurately presents scientific evidence and data supporting their statements and recommendations. To build trust and to ensure the best possible public health outcomes, South Carolinians depend on and expect DHEC staff to:

1. provide policy guidance using transparent, accurate data and sound scientific citations that support and justify all current and future public health recommendations on DHEC's website (not limited to COVID-19 guidance).

2. provide transparent messaging to South Carolinians on the DHEC website and through media and social media outlets that discloses an objective, independent, and rigorous review of accurate data and scientific evidence including any knowledge gaps in certain areas.

DHEC staff carry an enormous responsibility as DHEC recommendations carry significant influence and in part have resulted in mandates in certain South Carolina schools, businesses and institutions. This resulted in some South Carolinians losing their employment or their ability to receive an education.

Thank you to you and your team for your service and the time spent reviewing and responding to this document. DHEC's response will provide South Carolinians clarification on the critically important matter of current and future public health policies and practices.

Sincerely,

Denice Hilty

Denice Hilty, DC

[2] https://scdhec.gov/covid19/covid-19-proper-face-mask-usage
[3] https://www.wspa.com/news/dhec-investing-5-million-dollars-in-organizations-to-push-vaccine-fight-misinformation/
[4] https://www.greenvilleonline.com/story/news/local/south-carolina/2021/10/14/scdhec-joins-red-flag-twitter-meme-social-media-trend-vaccine-covid/8450828002/

Table of Contents

page 4 Based on DHEC correspondence and DHEC staff FOIA responses:

DHEC are staff unable to provide transparency on the data criteria used to collect South Carolinian COVID-19 hospitalizations and deaths which are published on the DHEC website. It is currently indistinguishable whether COVID-19 disease directly caused, contributed to, or was not related to a reported South Carolinian COVID-19 hospitalization or death.

page 6 Based on DHEC staff FOIA responses:

DHEC staff reported that they are unable to provide scientific evidence, data, source documents and risk vs benefit analysis supporting the safety and effectiveness of DHEC's recommendation of universal pediatric COVID-19 vaccination or various pediatric age-groups six months and up.

page 9 Based on DHEC staff FOIA responses:

DHEC staff reported that they did not perform an inquiry with CDC and FDA or independently investigate the over 8,000 COVID-19 vaccine adverse events South Carolinians reported to the Vaccine Adverse Events Reporting System (VAERS).

page 12 Based on FOIA DHEC staff responses:

DHEC staff did not provide adequate scientific evidence, data, source documents and ongoing risk vs benefit analyses to support DHEC's recommendation of universal masking in DHEC's K-12 COVID-19 school guidance and other guidance.

page 14 **Additional Questions**

page 16 **Attachment A**

page 21 **Attachment B**

DHEC correspondence related to pediatric data criteria of COVID-19 hospitalizations and deaths and DHEC Freedom of Information Act (FOIA) requests and responses are provided in two separate documents or can be found on the internal DHEC database.

- **A DHEC FOIA response was requested to provide Federal and State a) internal guidance documents and/or b) detailed instructions of specific protocols SCDHEC provided to individuals and/or hospital systems collecting and reporting South Carolina COVID-19 associated hospitalization and death data which was published on the SCDHEC website.**
- **A correspondence occurred with DHEC staff and the DHEC Director of Epidemiology regarding specific details on how pediatric COVID-19 hospitalizations and deaths were classified, collected, and reported on the DHEC website. For example, DHEC was asked to provide clarification if pediatric individuals reported on the website had a poor health outcome from COVID-19 disease or if these children had tested positive for COVID-19 and their hospitalization or death was caused by other contributing factors.**

Based on the correspondence with DHEC staff and FOIA responses provided by DHEC staff, the data collection methodology DHEC staff currently uses does not distinguish whether COVID-19 disease:

- directly caused,
-contributed to, or
-was not related to a reported South Carolinian COVID-19 hospitalization or death.

South Carolina businesses, institutions, and elected officials, such as School Board Members, depended heavily on accurate and reliable data from DHEC to assess risk and create and enact appropriate and proportional public health policies. If DHEC data is not reliable, it is DHEC's responsibility to transparently communicate this to South Carolinians.

Additionally, a recent CDC FOIA response[5] suggests that CDC COVID-19 hospital admissions data is also unreliable for a similar reason:

"The way that our data guidance defines COVID admission does not enable us to make a distinction between hospital admissions due to COVID-19 vs. hospital admissions for reasons other than COVID-19."

- CDC FOIA Response

1. Due to South Carolinians not being able to determine whether a COVID-19 hospitalization or death was a result of COVID-19 disease or if an individual had a positive COVID-19 test or other contributing illness, please explain what COVID-19 hospitalization and death data or other information DHEC staff relied on to support press releases to South Carolinians[6] and briefings to providers and elected officials such as School Boards?

(see Table 1, p2 for current DHEC COVID-19 death data by age[7]; South Carolina COVID-19 hospitalizations have been removed from the DHEC website)

[5] https://icandecide.org/wp-content/uploads/2023/01/Final-Response-No-Records-1.pdf
[6] https://scdhec.gov/covid19/dhec-news-releases-information-videos-covid-19
[7] https://scdhec.gov/covid19/covid-19-data/south-carolina-county-level-data-covid-19

Table 1

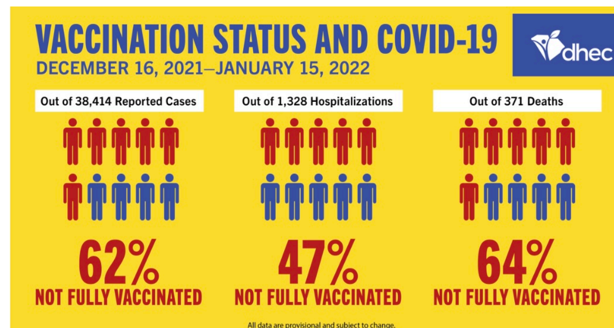
*DHEC Reported South Carolina COVID-19 Deaths by Age[8]			
Age	**Total Deaths**	**Population Estimate**	**Rate per 100K**
Under 5	12	291296	4
5 to 11	8	439755	2
12 to 17	14	391558	4
18 to 34	251	1153713	22
35 to 49	1053	944102	112
50 to 64	3637	1021241	356
65 to 84	10239	882081	1161
85 & Older	4231	94294	4487

**Based on DHEC staff FOIA responses it is unknown if a reported death was caused by or contributed to by complications from COVID-19 diseases or if COVID-19 disease was not a cause.*

2. Please explain why DHEC staff are unable to utilize and disseminate more accurate methodologies for providers to collect and report South Carolinian COVID-19 hospitalization and death data published on the DHEC website?

3. Have DHEC staff considered inquiring about and using methods from other states which would report COVID-19 hospitalizations and deaths by identifying whether COVID-19 was the primary cause, a contributing cause or not a cause?[9] This will provide transparency to South Carolinians on health outcomes from COVID-19 infection so individual risk may be better assessed.

4. Please explain why the vaccination status of South Carolina COVID-19 cases, hospitalizations and deaths were all removed from the DHEC website in early 2022?[10] (see DHEC infographic) Accurately curating and disclosing hospitalization and death data and COVID-19 vaccinated and unvaccinated hospitalization and death data will support high-risk South Carolinians to assess their risk.



[8] https://scdhec.gov/covid19/covid-19-data/south-carolina-county-level-data-covid-19
[9] https://ridoh-covid-19-response-hospital-data-rihealth.hub.arcgis.com/
[10] https://scdhec.gov/covid19/covid-19-data/cases-hospitalizations-deaths-among-not-fully-vaccinated

5. Is DHEC staff planning on providing clarification on the DHEC website of the current methodologies used to curate, collect and report COVID-19 deaths and hospitalizations? If so, when?

- **A DHEC FOIA response was requested to provide all scientific evidence, data and source documents reviewed by SCDHEC employees which determined SCDHEC's recommendation of universal COVID-19 vaccination of South Carolina children in the following age ranges: age 6 months - 4 years old, age 5-11 years old and age 12-18 years old and to further provide SCDHEC staff's risk vs benefit analysis review of universal COVID-19 vaccination for each age group.**

However, DHEC staff was unable to provide scientific evidence to support DHEC's recommendation of universal pediatric vaccination. South Carolinians depend on DHEC to rigorously review scientific evidence and make recommendations in the very best interest of each population. DHEC staff provided the following FOIA response regarding providing scientific evidence supporting DHEC's recommendation of universal pediatric vaccination in various age groups.[11].

> *"I don't know of any written risk vs benefit analysis developed by DHEC, and I can't even recall all of the data and studies and articles I read on the vaccines, their development, their trials in children, etc. I read many articles and studies on journal websites or other reputable sources of information that I didn't save. You could check with Stephen and Jonathan in Immunizations to see what stuff they might have, but I am confident no one could fully produce or recall every piece of data or information they learned on the topic."*-DHEC Staff

When DHEC was asked if they had any further information to add to the FOIA response, DHEC staff's response was the following:

> *"DHEC recommends children get vaccinated against COVID-19 in order to decrease the rare but real serious cases, including deaths, that occur in that population, as well as to decrease the risk of a child developing MIS-C or long COVID, lower the odds of transmitting the virus to high risk family members, and to reduce children missing school and other activities due to being sick. Adverse effects of the vaccine in children are rare, with myocarditis occurring in only 105.9 children per one million doses of the Pfizer vaccine given to males aged 16-17 years old, which was the highest rate among children. In addition, multiple studies have shown that the risk of myocarditis is higher after COVID-19 infection than after vaccination."*
>
> *"The CDC's analysis of the safety of the vaccines for children and teenagers, including links to the articles with the scientific studies' results that are the basis for the analysis, can be found using this link:*
> *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-safety-children-teens.html* "
>
> -DHEC Staff

Further highlighting the essential need for rigorous scientific review of COVID-19 vaccine safety, efficacy and risk vs benefit analysis, is that based on DHEC's recommendations many South Carolinians are being required to accept COVID-19 vaccinations as a condition of their employer or educational institution. Adding further complexity is that DHEC staff providing these recommendations cannot be held legally or personally accountable if injury or death results from the recommendation of universal COVID-19 vaccinations[12] [13]. This reality places the physical and legal burden of risk squarely on South Carolinians of all ages.

---

[11] https://scdhec.gov/covid19/covid-19-vaccine/covid-19-vaccines-kids-12-older
[12] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx
[13] https://www.congress.gov/bill/99th-congress/house-bill/5546

6. Why was DHEC staff unable to provide data, scientific evidence, and risk vs benefit analysis to support DHEC's recommendation of universal pediatric COVID-19 vaccination? DHEC continues to message South Carolina's parents, schools, and media outlets that COVID-19 vaccination is the best opportunity of keeping children safe and healthy from COVID-19 disease. Is DHEC staff able to provide this information currently?

7. Based on DHEC FOIA responses, can DHEC staff please provide data and scientific evidence supporting that pediatric COVID-19 vaccination achieves the following:

   - decreases the rare but real serious cases, including deaths, that occur in that population,
   - decreases the risk of a child developing MIS-C or long COVID,
   - lowers the odds of transmitting the virus to high-risk family members,
   - reduces children missing school and other activities due to being sick?

8. Please explain if DHEC staff have taken into consideration that South Carolinian infants and children age 6 months and up:

   - are at low risk to poor health outcomes from COVID-19 disease *(see Table 2)*
   -have a high rate of previous COVID-19 infection and that scientific evidence supports the efficacy of natural immunity[14]
   - COVID-19 vaccination does not prevent transmission[15]
   -there are well-established knowledge gaps in the safety profile of COVID-19 vaccinations and
   -there is potential for adverse events to COVID-19 vaccination which are difficult to predict.

Table 2

* Covid-19 Infection Death Rate by Age Group	
Age	**Infection Death Rate**
0-19	0.0027%
20-29	0.014%
30-39	0.031%
40-49	0.082%
50-59	0.27%
60-69	0.59%
70+ (non inst.)	2.40%
70+ (all)	5.50%
https://medrxiv.org/content/10.1101/2021.07.08.21260210v1	

**Assessing COVID-19 infection death rate by age group is an important part of a risk vs benefit analysis. SC DHEC data is not currently reliable to determine COVID-19 infection death rate by age group. Table 2. "Infection Death Rate" is global data curated from several countries.*

9. Do DHEC staff support providers to objectively and accurately communicate individual risks and benefits of all clinical interventions to their patients, including known knowledge gaps in the safety profile of the COVID-19 vaccines, without fear of retaliation by Medical Licensing Boards and/or the state and federal government?

[14] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)02465-5/fulltext
[15] https://www.bmj.com/content/376/bmj.o298

10. Has DHEC staff asked the FDA and CDC why COVID-19 Pfizer vaccine randomized trials[16] did not evaluate mortality, hospitalization, and transmission as primary endpoints[17]? Why were these trials terminated early?

11. Due to mortality, hospitalization and transmission, not being evaluated as primary endpoints in several the 2020 COVID-19 vaccine phase III clinical trials[18] (see Table 3) and with short and long-term vaccine effectiveness and vaccine safety being largely unknown, what information or scientific evidence did DHEC staff rely on when messaging South Carolinians about newly released COVID-19 vaccinations in January of 2021, *"I have the utmost confidence in the safety and effectiveness of the COVID-19 vaccines."*[19] - DHEC Staff?

Table 3 (Published October 21, 2020)

Table 1 | Characteristics of ongoing phase III covid-19 vaccine trials

	Moderna	Pfizer	AstraZeneca (US)	AstraZeneca (UK)	Janssen	Sinopharm*	Sinovac
Vaccine name	mRNA-1273	BNT162	AZD1222	AZD1222	Ad26.COV2.S	Sinopharm vaccine	Sinovac CoronaVac
Registration No	NCT04470427	NCT04368728	NCT04516746	NCT04400838 (UK), NCT04536051 (Brazil), NCT04444674 (South Africa)	NCT04505722	NCT04510207	NCT04456595
Target enrolment	30 000	43 998	30 000	19 330	60 000	45 000	8870
Ages eligible	18+	12+	18+	5-12, 18+	18+	18+	18+
Protocol publicly available	Y	Y	Y	N†	Y	N	N
Notable excluded populations:							
Children and adolescents	Excluded	Many excluded	Excluded	13-17 excluded	Excluded	Excluded	Excluded
Immunocompromised patients	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded
Pregnant or breastfeeding women	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded
Endpoints undergoing formal study‡:							
Prevention of symptomatic disease in vaccine recipient	Y	Y	Y	Y	Y	Presumably§	Y
Reduction in severe covid-19 (hospital admission, ICU, or death)	N	N	N	N¶	N	N	N
Interruption of transmission (person to person spread)	N	N	N	N	N	N	N

* This trial is separately randomising an inactivated SARS-CoV-2 vaccine (Vero cell) manufactured by Wuhan Institute of Biological Products Co and Beijing Institute of Biological Products Co.

† AstraZeneca has released the protocol for its stalled US trial but not its trial in UK, Brazil, and South Africa.

‡ Endpoints "undergoing formal study" include those listed as primary outcomes in ClinicalTrials.gov, publicly available study protocols, or those not listed as primary outcomes, but the company has confirmed that the study is powered sufficiently to find an effect (if one exists).

§ Sinopharm lists "incidence of COVID-19 cases" as a primary efficacy endpoint in its ClinicalTrials.gov entry.

¶ Trial registration (NCT04444674) lists the following primary endpoint: "Determine if there is a reduction of severe and non-severe COVID-19 disease in HIV-negative adults." This suggests a composite outcome that includes non-severe disease.

Parents on behalf of their children have been continually asked to accept "safe and effective" COVID-19 vaccines without qualification on safety or effectiveness[20]. When parents understand that DHEC messaging is not consistent with existing data and evidence, DHEC staff lose credibility, resulting in low pediatric uptake of COVID-19 vaccines in boosters[21].

---

[16] https://www.fda.gov/media/144246/download
[17] https://www.bmj.com/content/371/bmj.m4037
[18] https://www.bmj.com/content/371/bmj.m4037
[19] https://scdhec.gov/news-releases/south-carolina-state-epidemiologist-dr-linda-bell-receives-covid-19-vaccine-has
[20] https://scdhec.gov/covid19/covid-19-vaccine parents are being messaged through radio, media outlets and certain school systems
[21] https://scdhec.gov/covid19/covid-19-data/south-carolina-county-level-data-covid-19

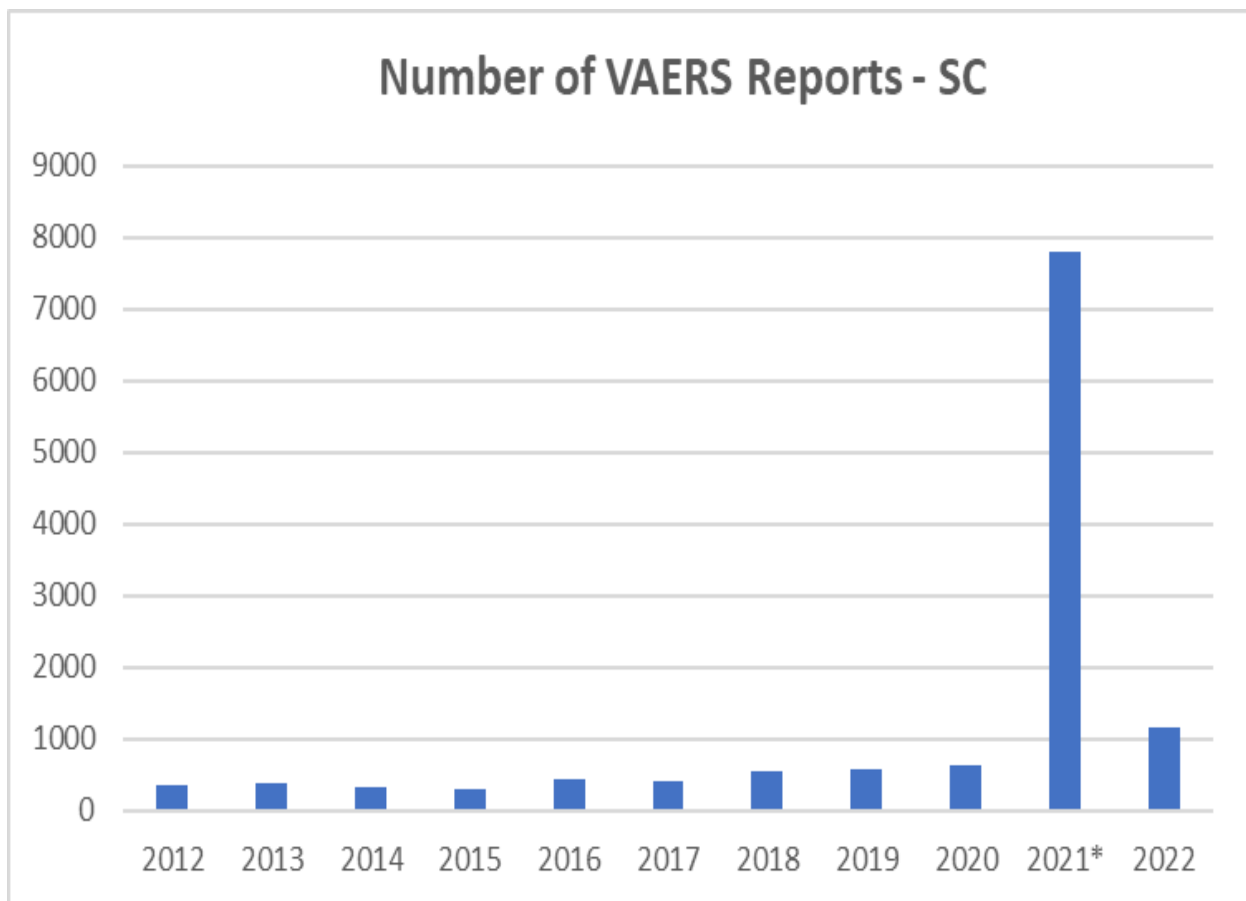
- **A DHEC FOIA response was requested to provide DHEC staff's follow-up communication with the CDC and FDA related to the over 8,000 South Carolina COVID-19 vaccine adverse events reported to the Vaccine Adverse Reporting System (VAERS) or if DHEC staff had investigated any adverse events reported directly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

DHEC staff FOIA response stated that they did not follow up on the over 8,000 reported South Carolina COVID-19 vaccine adverse events. There has been an exponential increase in South Carolinian vaccine adverse events reported since the roll out of COVID-19 vaccines[22]. *(see Table 4)*

South Carolinians depend on and expect DHEC to closely monitor the safety of COVID-19 vaccines which are universally recommended to South Carolinians age 6 months and up.

Table 4

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



[22] https://www.medalerts.org/vaersdb/index.php

The Vaccine Adverse Event Reporting System (VAERS) [23] 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.** [24] [25] 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.

DHEC staff reported in their FOIA response that:

"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

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

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[26]. 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.
(see Table 5, p8)

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

During the meeting on March 30th, we discussed limitations in understanding the short-term safety profile of new pharmaceuticals before they are released to the public (during pharmaceutical company's clinical trials). It was also discussed how it is not possible to understand the short and long-term safety profile of newly released pharmaceutical products due to the data not yet existing from the general population and therefore, the data is not available to be analyzed. Consequently, post-market data systems designed to detect safety signals require data input from providers and the public so potential serious side effects can be properly studied.

Table 5

SC COVID-19 Vaccine Adverse Events Reported to VAERS by Age[27]

Age Range	Died	Life Threat	Perm. Disabled	Hospitalized	Myo -carditis	Anaphyl -axis	Miscar -riage	Total Reports
6 mo-5 yr	0	0	0	1	0	0	0	31
5-11 yr	0	0	0	3	0	0	0	111
12-18 yr	1	6	4	24	6	0	0	393
19-30 yr	1	11	11	26	5	4	1	784
31-49 yr	7	34	51	78	18	9	11	2,266
50-64 yr	15	52	86	111	9	5	0	2,273
65-80 yr	32	59	60	152	9	5	2	2,198
81-121 yr	20	10	7	37	3	0	0	310
All Ages	**84**	**173**	**222**	**445**	**50**	**25**	**15**	**8,982**

*updated April 2023

When being encouraged by DHEC to accept a pharmaceutical product that is, "safe and effective" many South Carolinians understandably believe that the product does not carry risk and that they and their children will be protected.

It is vitally important that DHEC staff responsible for making vaccine recommendations and requirements[28] are aware that when a pharmaceutical product is authorized by the FDA to be released to the public it does not imply that these products are unequivocally safe or effective for everyone. Due to COVID-19 vaccines being messaged as "safe and effective" without qualification, potential vaccine adverse events may be minimized, dismissed or unreported which compromises public health.

12. After the FOIA correspondence, has DHEC staff reviewed South Carolinians individual COVID-19 vaccine adverse events[29] reported to VAERS?

13. Why are DHEC staff unaware of CDC's Epi-X weekly reports given that South Carolinians depend on and expect DHEC staff to be closely monitoring the safety of DHEC's recommendation of universal COVID-19 vaccination of age 6 months and up?

14. DHEC staff FOIA responses suggest that DHEC staff are not communicating with designated Vaccine Safety Coordinators in South Carolina who are in contact with federal agencies monitoring South Carolina vaccine adverse events. Why is this?

[27] https://www.openvaers.com/covid-data/states-summary
[28] https://scdhec.gov/health/vaccinations/childcare-school-vaccine-requirements
[29] https://www.openvaers.com/vaersapp/reports.php

15. Due to low adverse events reporting rates precluding or slowing the identification of problem drugs or vaccines that endanger public health, healthcare providers are being strongly encouraged by HHS to report to VAERS, "*…if any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.*"[30]

    – Health and Human Services (HHS)

    What has DHEC staff done to encourage and support South Carolina healthcare providers to report potential vaccine adverse events to VAERS?

16. Is DHEC staff willing to investigate the possibility to implement in some capacity the post market surveillance software ESP VAERS[31] to facilitate the detection and better support clinician reporting of vaccine adverse events?

17. Has DHEC staff asked the CDC and FDA why there are so few safety studies from federal agencies' vaccine safety systems? Do DHEC staff believe that there is a need for additional unbiased research to better understand the COVID-19 vaccines' short- and long-term health impacts on various populations? If so, what additional research is suggested by DHEC?

The reality that vaccine products are shielded from lawsuits if injured[32] [33] underscores the need for transparent messaging about safety and efficacy.

- **A DHEC FOIA response was requested to provide all scientific evidence, data and source documents reviewed by DHEC staff which determined the strong recommendation of universal masking of children in DHEC's COVID-19 guidance for K-12 schools. DHEC's staff was also asked to provide a risk vs benefit analysis of universal masking of children in a school setting.**

Based on the FOIA response, DHEC staff was unable to provide adequate evidence or a risk vs benefit analysis supporting universal masking in K-12 schools. DHEC staff also reported, *"The recommendations DHEC provided were based off of CDC guidelines."* -DHEC Staff

In August of 2021, DHEC staff prepared and presented a PowerPoint presentation[34] [35] rejecting concerns that universal masking in schools may have unintended harmful impacts on children.

- *"No data on impact of mask wearing on academics identified during thorough scientific literature review.*
- *Experts reject concerns about this, including the American Academy of Pediatrics: "Masks will not affect your child's ability to focus or learn in school."*
- *No evidence that masks cause delays in language development or speech"*

-DHEC staff

[30] https://vaers.hhs.gov/reportevent.html
[31] https://digital.ahrq.gov/health-it-tools-and-resources/ahrq-funded-project-resources-archives/esp-vaers-case-identification
[32] https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx
[33] https://www.congress.gov/bill/99th-congress/house-bill/5546
[34] https://scdhec.gov/sites/default/files/media/document/Evidence-For-Mask-Use-K-12-Schools.pdf
[35] https://livestream.com/accounts/10521602/events/9807526/videos/225206119

However, a growing body of scientific evidence suggests masking is not an effective public health measure in schools and that masking policies in schools carry deleterious impacts.[36] South Carolina and nation-wide data suggests universal masking policies in part contributed to children experiencing significant learning loss, developmental delays and other negative impacts.[37]

Today DHEC continues to strongly encourage universal masking in schools:

"DHEC continues to strongly encourage everyone who learns or works in a school setting to wear a well-fitted mask consistently and correctly when around others." [38] – DHEC website

Elected officials, such as School Board Members creating and enacting public policy, understandably depend on DHEC to deliver the best possible guidance to safeguard the health and safety of children and school staff to support the best possible educational outcomes.

18. Based on FOIA responses, DHEC staff acknowledge at the beginning of the 2021 school year there was no data available to understand the impact of universal masking in schools on academics and more[39] [40]. DHEC appeared to presume masking would not have a negative impact on a child's development in the absence of scientific evidence. Does DHEC staff continue to have confidence that masking in schools does not have a harmful impact on academics and childhood development?

19. Did DHEC staff ask for evidence regarding mask safety from the American Academy of Pediatrics and others to substantiate the following statement, *"Experts reject concerns about this, including the American Academy of Pediatrics: Masks will not affect your child's ability to focus or learn in school."*? If so, can you please provide it?

20. Did DHEC staff reach out to statewide educators and parents to better understand the impact of universal masking in schools? Throughout the pandemic there was real-time observation and experience of South Carolinian school children, teachers, parents, and providers that harms exist, some of which were communicated to DHEC. (please see Attachment A, p12)

21. In the video PowerPoint presentation given in August of 2021[41], why did DHEC staff rely mainly on observational studies and models,[42] which are not reliable[43], to make a strong recommendation of universal K-12 masking? At the time, did DHEC staff review the entire body of evidence including studies suggesting cloth masking is not an effective public health mitigation strategy[44]?

22. Why hasn't DHEC reconsidered masking policy recommendations[45] after the publication of more scientifically reliable randomized trials[46] [47] and the more recent published Cochrane review[48] of 78 peer-reviewed studies suggesting no or minimal efficacy of mask wearing by the public?

---

[36] https://brownstone.org/articles/studies-and-articles-on-mask-ineffectiveness-and-harms/
[37] https://www.aier.org/article/masking-children-tragic-unscientific-and-damaging/ please also see state-wide South Carolina educational outcome data
[38] https://scdhec.gov/covid19/covid-19-proper-face-mask-usage
[39] https://scdhec.gov/sites/default/files/media/document/Evidence-For-Mask-Use-K-12-Schools.pdf
[40] https://livestream.com/accounts/10521602/events/9807526/videos/225206119
[41] https://livestream.com/accounts/10521602/events/9807526/videos/225206119
[42] https://scdhec.gov/sites/default/files/media/document/Evidence-For-Mask-Use-K-12-Schools.pdf
[43] https://www.scribbr.com/methodology/reliability-vs-validity/
[44] https://brownstone.org/articles/studies-and-articles-on-mask-ineffectiveness-and-harms/
[45] https://scdhec.gov/covid19/covid-19-proper-face-mask-usage
[46] https://pubmed.ncbi.nlm.nih.gov/33205991/
[47] https://poverty-action.org/sites/default/files/publications/Mask_RCT____Symptomatic_Seropositivity_083121.pdf
[48] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub6/full

23. Given that masking has not been proven to be an effective measure to protect individuals from viral spread, are DHEC staff reconsidering the messaging, *"To protect yourself and others from COVID-19, DHEC continues to strongly encourage everyone ages two and older to wear a well-fitting mask consistently and correctly when others are around."*[49] due to potentially giving at-risk South Carolinians and their loved ones depending on masks for protection a false sense of security?

24. Has DHEC staff asked why the CDC or NIH did not fund large, randomized trials to evaluate the efficacy and potential harms of mask wearing?

Additional Questions:

25. DHEC placed much emphasis on contact-tracing efforts of young asymptomatic individuals in K-12 schools. This resulted in healthy, non-infected children losing multiple days of school. Can DHEC staff present scientific evidence supporting their recommended contact-tracing methodologies in their K-12 School Guidance, including evidence supporting the diagrams recommended for identifying close contacts in Attachment B on p17 & 18?

In South Carolina and across our nation the elderly population and individuals with comorbidities tragically and predictably experienced the most serious health complications from COVID-19 disease.

It is well established in public health that certain one-size-fits-all public health strategies have resulted in expected and unexpected negative public health consequences. Lived experiences and emerging South Carolina and national data suggests negative outcomes resulting from public health COVID-19 guidance have disproportionately impacted low risk populations such as children, especially those who are socio-economically disadvantaged. Deleterious damage impacting South Carolinians include:

- learning loss and developmental delays[50]
- an exponential increase in depression, anxiety disorders and suicidal ideation especially among the young[51]
- substantial loss of public trust in DHEC, CDC, medical institutions and medical providers[52]
- significant current and future impact on South Carolinians from economic loss [53]
- unexplained and uninvestigated excess death rates in several age groups[54]
- a false sense of security in high-risk individuals who trust in unproven measures intended to mitigate their risk.

26. Has DHEC staff investigated the deleterious impact from the COVID-19 crisis in various South Carolina populations? If not, why? If so, has DHEC staff developed strategies to help and support those specific populations impacted?

27. Based on FOIA responses and the DHEC website, it appears that DHEC staff adopted and placed emphasis on many of CDC's guidance recommendations without adequately scientifically vetting the effectiveness, safety and deleterious impacts. Why is this?

[49] https://scdhec.gov/covid19/use-cloth-face-coverings-covid-19
[50] https://www.npr.org/2022/06/22/1105970186/pandemic-learning-loss-findings
[51] https://www.cdc.gov/media/releases/2022/p0331-youth-mental-health-covid-19.html
[52] https://www.axios.com/2023/03/07/trust-in-cdc-public-health-agencies
[53]https://www.hoover.org/sites/default/files/research/docs/South%20Carolina_HESI_PaperSeries_template_Final.pdf
[54]http://phinancetechnologies.com/humanityprojects/yearly%20Excess%20Death%20Rate%20Analysis%20-%20US.htm

28. Can DHEC staff provide data supporting that vaccinated individuals have a reduced risk of hospitalization and death caused by COVID-19 disease?

29. Is DHEC staff committed to providing South Carolinians transparent documentation on the DHEC website supporting public health recommendations using accurate data, sound scientific citations and known knowledge gaps?

30. To support repairing public trust in DHEC's public health guidance, could DHEC staff please provide documentation of current and future corrective actions intended to improve DHEC's practices and procedures when implementing policy guidance?

~Thank you for your time and service~

Attachment A

Dear DHEC:

I saw your live regarding masks and psychological health.

As a psychologist and methodologist myself, I was quite shocked at some of the claims made. In particular, your comments about masks and mental health being a cultural issue raise significant concerns. Can you please send the research to support your claims on mental health? You mentioned that you had a whole bunch of data and graphs. I would like to read up on the data supporting your statements. As a scientist, I prefer the data over the story you shared.

Specifically, here are a few of my concerns:

1.As an epidemiologist, you should be well aware of the **ecological fallacy** and the risks associated with generalizing findings from population studies to the individuals within a the group that they belong. Further, we cannot compare with external validity the use of masking in Asian cultures to masking in the US. These are two different populations, and if you are basing your decisions to mask our youth is based in evidence from a different population, then the entire field of implementation science is being ignored. Best practices dictates selecting EBI that has been shown to work in the population that it will be implemented, or adaptations that reflect the cultural differences should be systematically made.

2.The other thing that surprised me was your lack of acknowledgement into the social-ecological framework and the role that schools play in the transmission of cultural risks to individuals. Bronfenbrenner's (1989) social ecological theory is not classic in social sciences and your statements were directly counter to his premises. How do cultural risks transmit to individuals? Through the proximal ecological domains – families, friends… and *schools.* You want to change the impact of culture on youth risk? That is in the purview of the schools themselves.

I have a publication on this exact issue where we tested a model of moderated mediation to understand the transmission of community level risk to youth delinquent behavior. Indeed, the "objective" risks in the community did not make a difference in the rates of delinquency, but instead the perception of the risk as moderated by the proximal ecological domains mattered. http://www.ncbi.nlm.nih.gov/pubmed/25300758

You do mention that its not the masks but the interpretation of the masks that make a difference. I agree with this contention. However, at the same time, you have ignored every reason why people interpret harm – and direct experiences wearing the masks, coupled with CDC and Denmark data showing they have no effects in community samples - make it hard to blindly obey. People have lived experiences and these need to be honored.

3. You also mentioned that masks cannot be optional because everyone needs to wear them for them to work. Can you please send that data? I had not seen any data to support this claim.

4.Last, I remind you of the dangers of making claims without substantial data to support them. Our schools are plagued with examples of programs that "sounded good" but have largely iatrogenic effects – e.g., Scared Straight, Gun Buybacks, and DARE – pop into my mind immediately.

Are you willing to stand behind the "next big thing" that *sounded good* but really did harm to our kids? Not all "good ideas" are good at all.

Here is a systematic review from a group in Germany that illustrates indeed some harms exist.
https://www.mdpi.com/1660-4601/18/8/4344

You and I both know that we never retain the null in science, and this article clearly points out that your null of mask safety is well rejected multiple times.

5.One thing that would help me understand your claims is explaining what you mean when you refer to “no psychological harm”… which outcomes are you referring to? Diagnosed mental illness? Perceived safety? Sense of control? Social connectedness? You generalizations make it hard to understand the data that you are basing your statements on. Please clarify and provide your data.

Thanks for filling in the gaps. As a scientist and advocate of children’s mental health, I value the time and effort it takes to use evidence-based policy making and I encourage you to be accountable to decisions being made.

Live Well,

Andrea

Dr. Andrea Nazarenko, PhD MA MA MAS

#1 International Best Selling Author

Researcher | Speaker | Consultant

Co-Owner, Old Mill Chiropractic & Family Wellness

711 East Main Street, Suite L2, Lexington, SC 29072

Dear Legislative Oversight Committee:

I am writing in regards to the Legislative Oversight committee meeting on 8/30. I see that a Discussion of the Study of the Department of Health and Human Services is on the agenda.

I ask that a FULL REVIEW of Dr. Bell's, Asst Epidemiologist, public claims be included as a specific item on the agenda.

Dr. Bell is respected as a health expert and is in charge of disseminating accurate and valid information based on science. Her statements are used in high-risk decision making that affects our community and state.

Unfortunately, as a PhD researcher and methodologist myself, I have identified that many of Dr. Bell's claims are not substantiated with empirical data. They are more in line with her opinion. This is a major concern.

By not speaking from an unbiased and scientific standpoint, she is misguiding the public and public institutions in the state. Making statements promoted as "science" without scientific evidence is fraudulent. This leads to non-empirically informed policy making and propagates fear and panic in the public.

I ask that you provide a full overview of her work, particularly as it pertains to the scientific validity of her public claims.

I first became aware of these concerns when Dr. Bell teamed up with Lexington One school district to promote a message of "mask safety". In a LIVE video on facebook, she advocated for mask wearing among students of all ages, even making claims about the psychological safety of mask wearing. This video was sent to every Lexington One parent, posted on their facebook page, and used to substantiate district-wide policies and procedures related to masking.

Dr. Bell shared her scientific citations with the community. She defended all her statements of mask safety based on these citations. This list was supposedly the science she used to make her recommendations of safety.

I personally reviewed each citation and have included a (very) brief summary of each paper below. They do not support the claims that she made. Additionally, I emailed her about other specific issues in her LIVE. I included a copy of this letter below. She did not respond, despite multiple emails.

Does this look like ethical behavior to you? The studies she referenced do not even mention safety – never mind being an empirical study about mask safety or the psychological harms thereof!

Of note, the issue I am raising to you here is not about masking per se. This is an EXAMPLE of one area in which I caught Dr. Bell making misconstruing data to fit her agenda.

Our health officials, especially the epidemiologist representing the state, should be unbiased and data-informed. There is no space for an agenda when people's lives are at stake – especially when it affects our children!

I ask you to hold Dr. Bell and her team accountable for her statements. Please conduct a full investigation on her public claims and ask that the scientific data to support her claims be made transparent.

I thank you for your service and commitment to keeping our state safe and healthy.

Live Well,

Dr. Andrea Nazarenko, PhD

____

SUPPORT FOR STATEMENTS ABOVE:
(For all URLS, I had to include spaces so that this message sent through the portal)

Live video for reference: https:// www. youtube. com/ watch?v=dRDLaGERh5Q

Reference list published by Dr. Bell, which she used to substantiate her claims: https: // bit.ly/ 2PLCyKM

My review of the citations (numbers refer to Dr. Bell's reference list above):

#1. This report (not an empirical study) discusses proper mask fit. No mask safety addressed.

#2. This is a review article published by the CDC about the effectiveness of masking. There is no mention of safety in the article.

#3. This paper studies the effectiveness of cloth masks in comparison surgical masks, given the shortage of surgical masks at time of publication. There is no discussion of safety.

#4. This study tests 70+ fabric combinations to test effectiveness of masks made using different materials. This is not about mask safety.

#5. This is a letter to the Editor about differences in fabrics used to make masks. The letter writer assessed different types of cloth in their filtration capacity and breathability. This is not about mask safety.

#6. In this CDC report, authors discuss the evidence to inform the use of cloth masks for prevention of respiratory infections and propose strategies for cleaning and decontamination to protect frontline healthcare workers and the general public. This is not about mask safety.

#7. This study tests different types of fabrics for effectiveness and factors that interfere with effectiveness. This is not about mask safety.

#8. This article discusses the theory of viral inoculum. Mask safety is not discussed.

#9. This study evaluated the filtration properties of natural and synthetic materials using a modified procedure for N95 respirator approval. This is not about mask safety.

#10. This article is about spread of SAR-COV2 in a nursing home in Washington March 2020. This is not about masks or mask safety.

#11. This study aimed to synthesize all available research on asymptomatic cases and transmission rates. This is not about masking or mask safety.

#12. This study assesses the proportion of SARS-CoV-2 transmissions in the community that likely occur from persons without symptoms. This is not about masks or mask safety.

#12 (she duplicated numbers in her list). This study uses experiments and simulations to quantify how exhaled air is transported in speech. This is not about masking or mask safety. It is about how spread occurs.

#13. This is a weekly report on COVID spread after choir practice and examines settings of spread. It looks at high transmissibility of SARS-CoV-2 and the possibility of superemitters contributing to broad transmission in certain unique activities and circumstances. This is not about masking or mask safety.

#14. The aim of this study was to investigate aerosol and droplet emissions during singing, as compared to talking and breathing. This is not about masking or mask safety.

#15. This study examines how SARS-COV2 spreads through small airborne droplets during singing. This is not about masking or mask safety.

#16. This study examined homemade masks as an alternative to commercial face masks. This is not about mask safety.

#17. This study is about the efficacy of surgical face masks against influenza and coronaviruses. This is not about mask safety.

#18. This study compares the relative efficacy of different fabrics used in cloth masks. This is not about mask safety.

#19. This study compares the effectiveness of different fabrics in blocking large, high-velocity droplets, using a commercial medical mask as a benchmark. This is not about mask safety.

#20. This study tests the efficacy of three types of masks and instant hand wiping using the avian influenza virus to mock the coronavirus. This is not about mask safety.

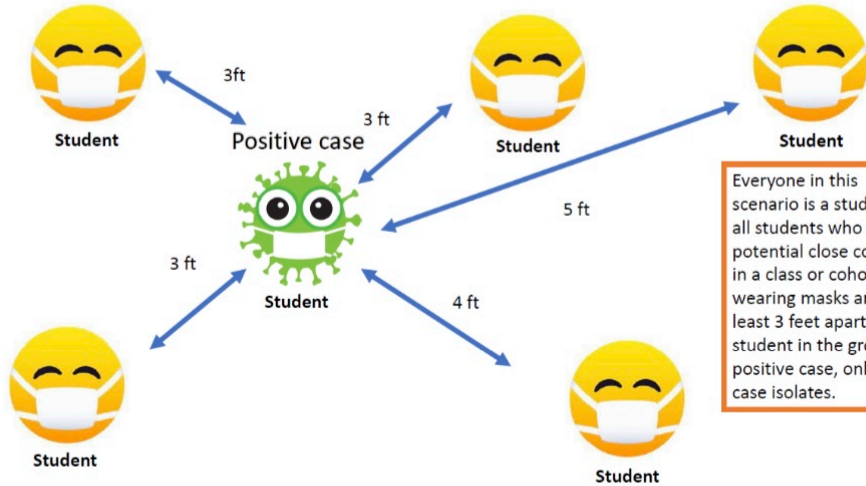
#21. This is a commentary that summarizes the evidence on face masks for COVID-19 from both the infectious diseases and physical science viewpoints and offers recommendations for most effective masks and messaging. This is not about mask safety.

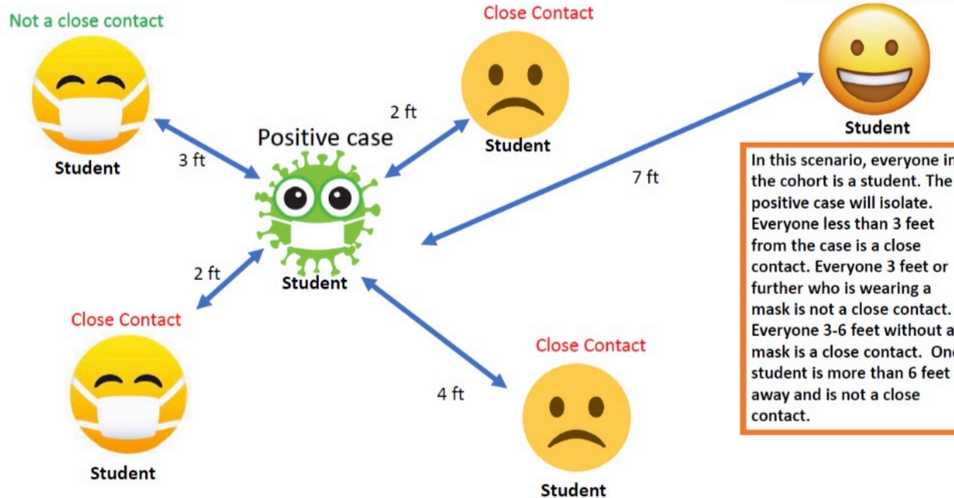
#22. This study evaluated the effectiveness of 11 face coverings for material filtration efficiency, inward protection efficiency, and outward protection efficiency. This is not about mask safety.

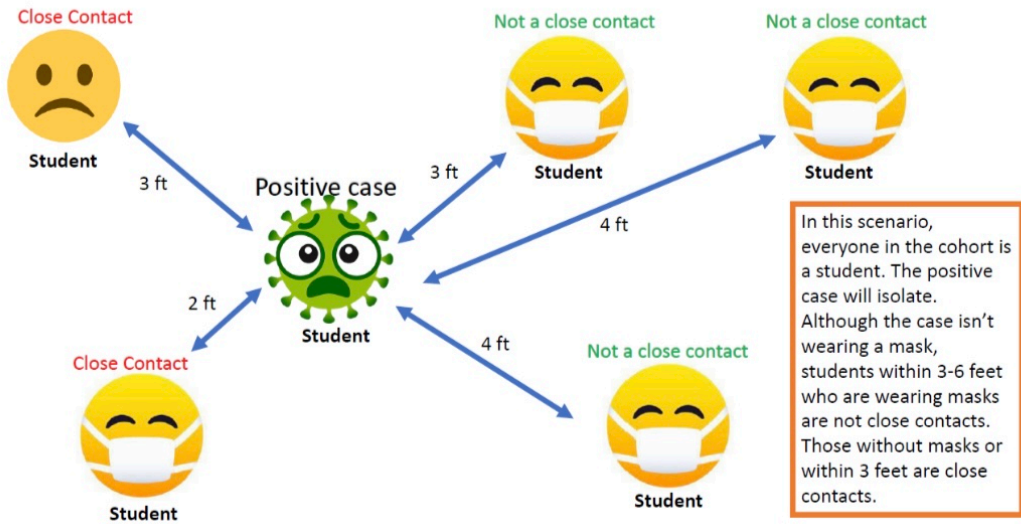
#23.This study examines the effectiveness of face shields and neck gaiters. This is not about mask safety.

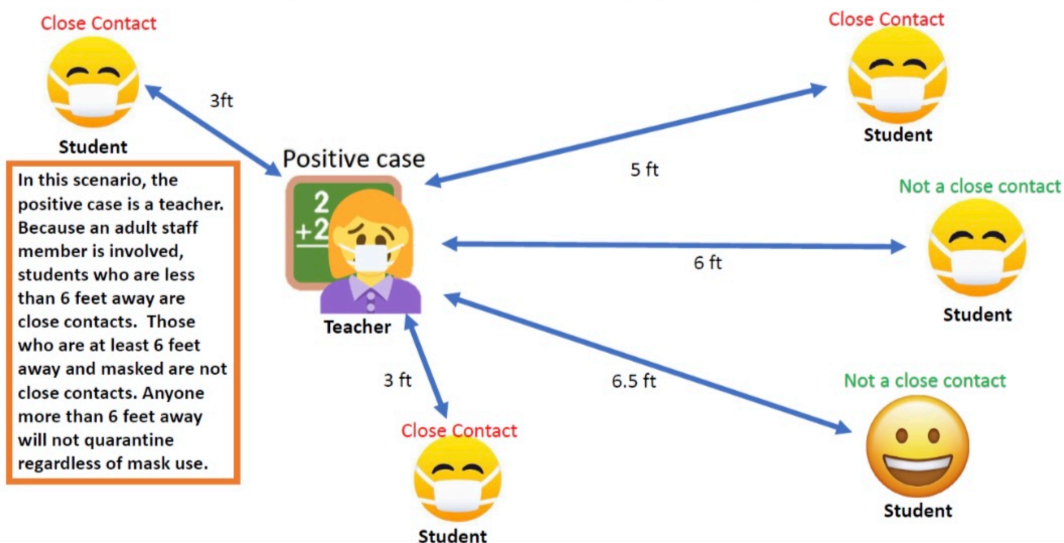
Indoor School Close Contact Scenarios

January 9, 2022









S.C. Department of Health and Environmental Control
2600 Bull Street, Columbia, SC 29201 (803) 898-3432 www.scdhec.gov