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November 1, 2022

Mr. Steve Kirsch
13930 La Paloma Rd.,
Los Altos Hills, CA

Re: Request for Information on Why N-95s are not a Solution for Protecting Individuals from the COVID-19 Virus

Dear Steve:

Based on your request for information to help convince Dr. Pierre Kory that N-95-type respirators are not a viable solution to protect the public from virus infectious diseases, including the COVID-19 virus, I have put together this quick letter as I am preparing for a benzene exposure deposition later this week. It will draw on materials I have presented on this issue in dozens of forums over the past two years. The main arguments against N-95s for protecting the public are:

- Poor performance in the real-world (theoretical vs real world performance or efficacy).
- N-95s are "Not Intended for Use with Children" according to manufacturers' such as 3M.
- Standard of Care (SOC) is a 90% relative risk reduction (protect the vast majority of the public; a little protection does not meet the Industrial Hygiene (IH) SOC.
- Inappropriate public response or solution (N-95 is a respirator and must follow the respiratory protection standard and is worst solution from the Hierarchy of Controls construct first published by the National Safety Council (NSC) in 1950).
- Harms from long-term usage of N-95s.
- KN-95s (China) vs N-95s – Usage and Confusion.

As a 40-year practicing Industrial Hygienist (IH), I will simply start by stating that N-95s are not the solution and never have been the solution, based on IH sciences in place since at least 1950. Proving this is more complicated that may be obvious because of the differences between *theoretical* constructs or arguments and *real world/practical* experience regarding respiratory protection over the decades. The untrained are looking for a simple solution or data set, this is not possible in the IH world as I will try to illustrate.

Asbestos Illustration:

To first illustrate this point, let's consider asbestos particles, which are on average ~50x larger than COVID-19 virus particles. Theoretically, one could use an N-95 half-face respirator with a 10x protection factor based on theoretical data. However, as illustrated in Figure 1 [ASTM F3502-21 – Standard Specification for Barrier Face Coverings (BFCs)], these types of studies ensure no gaps between the mask or N-95 respirator as the devices are literally glued onto a board or mannequin.

Figure 1: Mask Test Setup from ASTM Mask Standard – Glued to Board [ASTM F3502-21 – Standard Specification for Barrier Face Coverings (BFCs)]

Thus, the gap is critical if a respirator is to be effective; this requires sizing and fit-testing by a professional and then compliance in wearing it by the user. As I have shown for masks based on the literature (based on Drewnick et al.,), a gap of ~3% of the mask area reduces its effectiveness to ~0% (Figure 2):

Figure 2: Loss of Mask Effectiveness Due to Gaps – From Drewnick et al, 2021)

My own surgical mask has a 9% gap area, so it was essentially useless.

Back to the asbestos example, thus for much larger particles, an N-95 respirator could theoretical be utilized, yet the requirements and SOC is to use a much higher-grade respirator called a PAPR (Powered Air Purifying Respirator) to account for real world gaps and leakage.

This requirement to use a PAPR for asbestos workers is not only the IH SOC, but also the legal statute (https://www.epa.gov/asbestos/safe-work-practices). Specifically, they US EPA states that for respiratory PPE:

“Do not use single use, disposable paper dust masks when dealing with asbestos” and options used include:

“A half or full facepiece, negative pressure, air-purifying respirator with replaceable high-efficiency filters” or “A half or full facepiece powered air purifying respirator (PAPR) with replaceable high-efficiency filters. This has a battery powered pump which assists breathing and provides positive pressure in the facepiece.”

Note the following from Cal-OSHA:

Thus, even for much larger asbestos particles, N95s are explicitly not to be used – real world/gaps/fit/etc. vs theoretical data. No reputable IH would ever use N-95s for COVID-19 particles that are an order of magnitude smaller than asbestos particles.

Gaps and fitness for purpose are the keys – if gaps are present all bets are off. Simple engineering argument, flow occurs through the path of least resistance – or effectively no resistance for the gaps. Thus, the need for professional selection and fit testing of respirators. Even the 2021 ASTM Face Covering Standard recognized this issue:

<u>N-95 Efficacy Data:</u>

The most recent data explicitly available for N-95s and COVID particles comes from work by Shah, et. al., [https://aip.scitation.org/doi/full/10.1063/5.0057100?fbclid=IwAR28W8OPjvRdf4jHX4pXF67bjqmy-UZUGnZjb5K5As-9IRpXdJABS6bQ0N4& - Table III] as summarized and referenced in Figure 3 below:

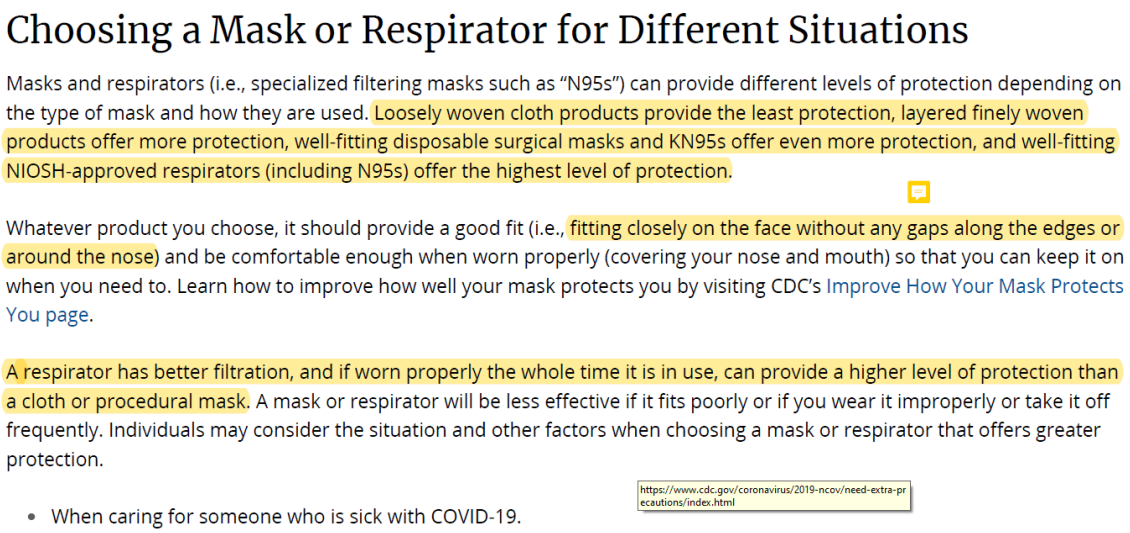
Figure 3: Loss of KN-95 Effectiveness Due to Gaps – From Shah et al, 2021)

Note that the effectiveness drops by >90% with a gap present - from 46.3% to 3.4%. These results are conservative since this study used 1-micron (larger) particles, not 0.1-micron particles. Thus, the real-world effect illustrated by Shah, et. al.

This is one of the last of many studies demonstrating that poorly selected and/or fit tested N-95s are not effective (another example - 2021, O'Kelly et. al., Comparing the fit of N95, KN95, surgical, and cloth face masks and assessing the accuracy of fit checking - https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0245688). The authors conclude by stating the obvious:

> "Fit check responses had poor correlation with quantitative fit factor scores. KN95, surgical, and fabric masks achieved low fit factor scores, with little protective difference recorded between respiratory protection options. In addition, small facial differences were observed to have a significant impact on quantitative fit"
>
> and
>
> "Fit is critical to the level of protection offered by respirators. For an N95 respirator to provide the promised protection, it must fit the participant. Performing a fit check via NHS self-assessment guidelines was an unreliable way of determining fit."

Cleverly, in their February 2022, guidance, CDC states N95s work when "no gap" is present (Figure 4).



Choosing a Mask or Respirator for Different Situations

Masks and respirators (i.e., specialized filtering masks such as "N95s") can provide different levels of protection depending on the type of mask and how they are used. Loosely woven cloth products provide the least protection, layered finely woven products offer more protection, well-fitting disposable surgical masks and KN95s offer even more protection, and well-fitting NIOSH-approved respirators (including N95s) offer the highest level of protection.

Whatever product you choose, it should provide a good fit (i.e., fitting closely on the face without any gaps along the edges or around the nose) and be comfortable enough when worn properly (covering your nose and mouth) so that you can keep it on when you need to. Learn how to improve how well your mask protects you by visiting CDC's Improve How Your Mask Protects You page.

A respirator has better filtration, and if worn properly the whole time it is in use, can provide a higher level of protection than a cloth or procedural mask. A mask or respirator will be less effective if it fits poorly or if you wear it improperly or take it off frequently. Individuals may consider the situation and other factors when choosing a mask or respirator that offers greater protection.

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html

- When caring for someone who is sick with COVID-19.

Figure 4: CDC Guidance – N95s Work Without Any Gaps

This is not reality!

Note that most of the public do not understand the much greater requirements for providing and using a respirator vs a mask. Use of, or providing a respirator requires one to follow the Respiratory Protection Standard (RPS) – 29 CFR 1910.134 and the PPE Standard 29 CFR 1910.134. Under 1910.132 a Hazards Analysis must be completed to ensure proper PPE is selected and under 1910.134 monitoring must effectively be completed or one must use higher level IDLH (Immediately Dangerous to Life and Health) protection. IDLH conditions would require moon suites (Level A protections), etc., so in almost all cases monitoring is completed to determine PPE requirements and avoid IDLH PPE. All these require an IH professional to complete these activities; the public can't be expected to know these requirements let alone complete them. For example, a partial comparison of mask vs respirator requirements is illustrated in Figure 5:

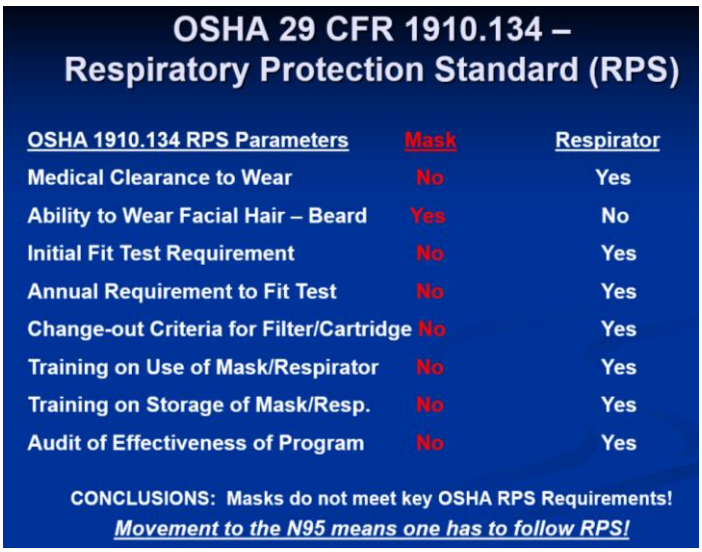


Figure 5: Petty – Mask vs Respirator Requirements – Partial List of Differences

Some may argue that these are OSHA requirements, and the public doesn't have to follow OSHA. However, labels from the N-95 manufacturers suggest that the user to follow the RPS.

CDC, N95s and Children:

Finally, as illustrated in our 28-page letter to CDC, Dr. Fauci and others (https://drive.google.com/file/d/1lbu5zCR6HfuPhaGdE4_YChwgPZetNGqb/view?usp=drivesdk), N-95s are not recommended for use by children! Yet CDC still recommended them for children – see Figure 6, 7 and 8 below:

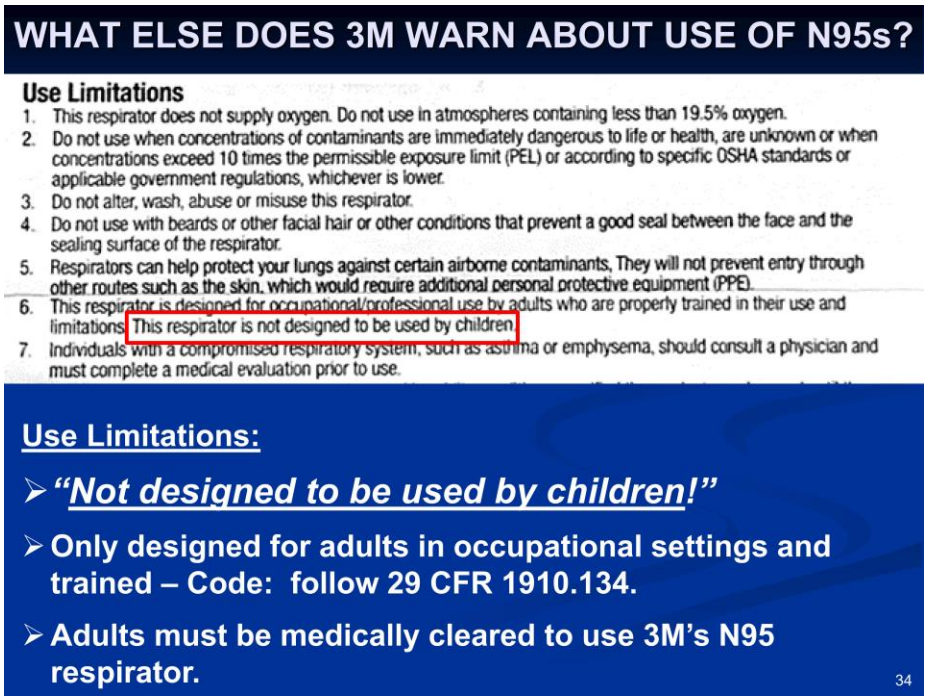


Figure 6: 3M N-95 Label Limitations – Not Designed to be Used by Children

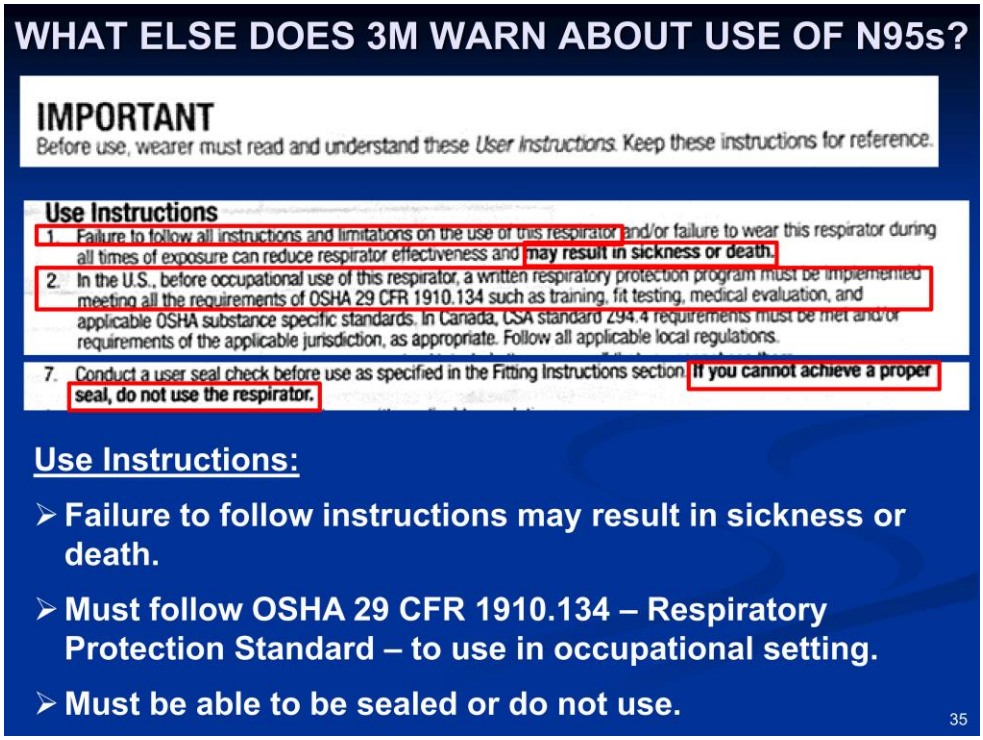
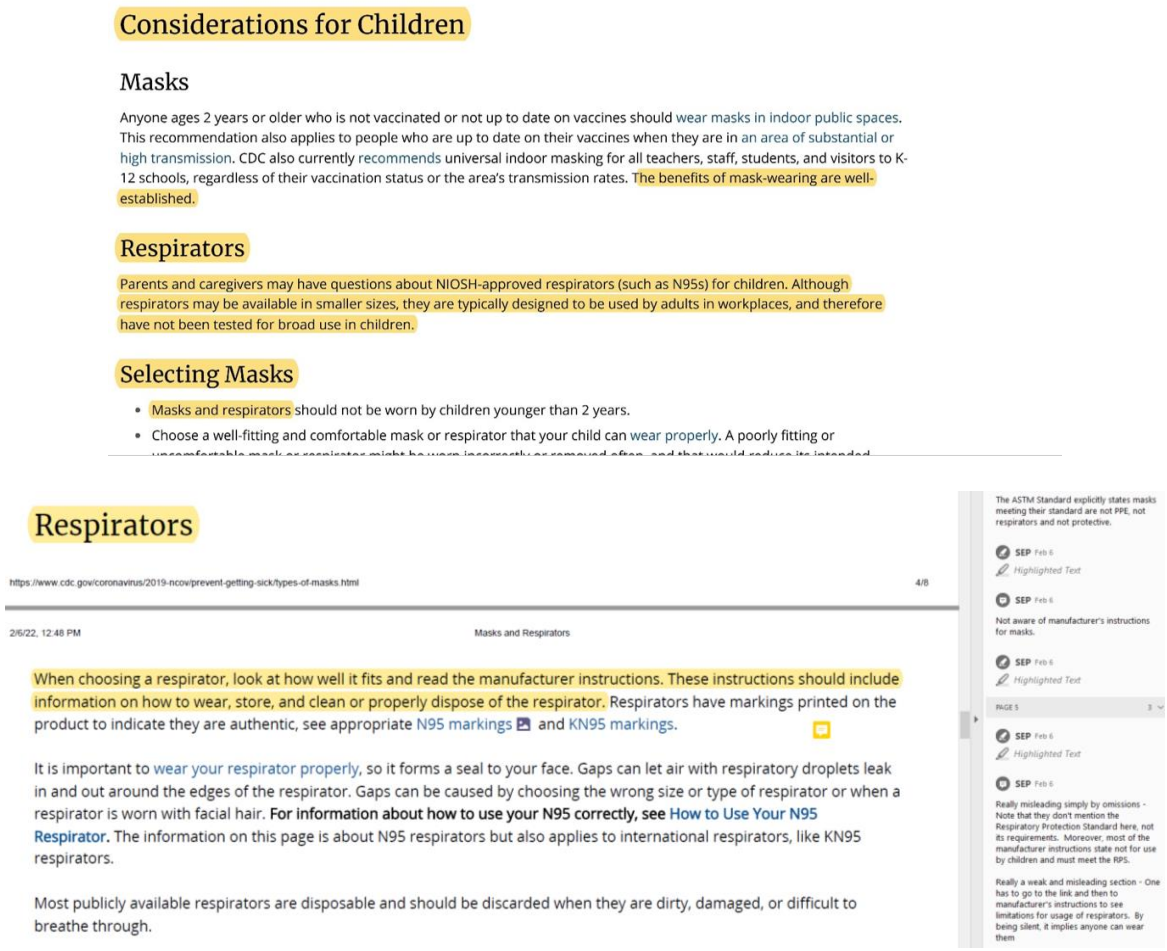


Figure 7: 3M N-95 Label Limitations – Follow RPS –

Failure May Result in Sickness or Death



Considerations for Children

Masks

Anyone ages 2 years or older who is not vaccinated or not up to date on vaccines should wear masks in indoor public spaces. This recommendation also applies to people who are up to date on their vaccines when they are in an area of substantial or high transmission. CDC also currently recommends universal indoor masking for all teachers, staff, students, and visitors to K-12 schools, regardless of their vaccination status or the area's transmission rates. The benefits of mask-wearing are well-established.

Respirators

Parents and caregivers may have questions about NIOSH-approved respirators (such as N95s) for children. Although respirators may be available in smaller sizes, they are typically designed to be used by adults in workplaces, and therefore have not been tested for broad use in children.

Selecting Masks

- Masks and respirators should not be worn by children younger than 2 years.
- Choose a well-fitting and comfortable mask or respirator that your child can wear properly. A poorly fitting or

Respirators

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html 4/8

2/6/22, 12:48 PM Masks and Respirators

When choosing a respirator, look at how well it fits and read the manufacturer instructions. These instructions should include information on how to wear, store, and clean or properly dispose of the respirator. Respirators have markings printed on the product to indicate they are authentic, see appropriate N95 markings and KN95 markings.

It is important to wear your respirator properly, so it forms a seal to your face. Gaps can let air with respiratory droplets leak in and out around the edges of the respirator. Gaps can be caused by choosing the wrong size or type of respirator or when a respirator is worn with facial hair. **For information about how to use your N95 correctly, see How to Use Your N95 Respirator.** The information on this page is about N95 respirators but also applies to international respirators, like KN95 respirators.

Most publicly available respirators are disposable and should be discarded when they are dirty, damaged, or difficult to breathe through.

The ASTM Standard explicitly states masks meeting their standard are not PPE, not respirators and not protective.

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Not aware of manufacturer's instructions for masks.

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Really misleading simply by omissions - Note that they don't mention the Respiratory Protection Standard here, not its requirements. Moreover, most of the manufacturer instructions state not for use by children and must meet the RPS.

Really a weak and misleading section - One has to go to the link and then to manufacturer's instructions to see limitations for usage of respirators. By being silent, it implies anyone can wear them

Figure 8: CDC Recommendations – N-95s or KN-95s for Children [CDC's January 28, 2022 webpage language misleadingly implies respirators are acceptable for children yet knows that this is not the case simply based on manufacturer instructions, they link the reader to https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html]

<u>Masks and N-95s May Do Some Good Argument:</u>

An often-heard argument is that masks or an N-95 might do some good; but this does not meet the IH (Figure 9) SOC needed to help the vast majority of the public:

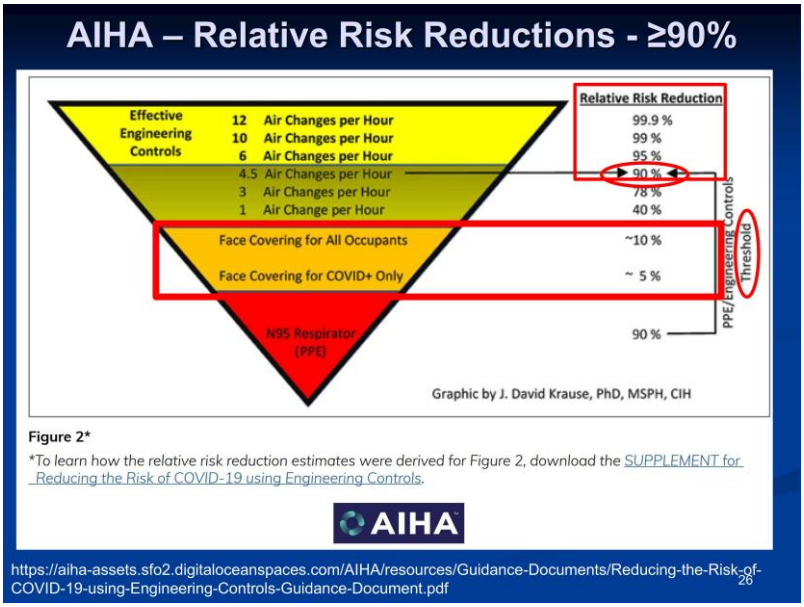


Figure 9: AIHA 90+% Relative Risk Requirement

Note that the N-95 argument assumes a perfect fit which does not occur in the real world and especially where they are given to the public with no sizing or fit testing.

The real solutions to reducing COVID exposures are engineering controls consisting of increased fresh air (ventilation), filtration and destruction first provided to the IH community by at least 1950 by the National Safety Council (NSC) (Figure 10):

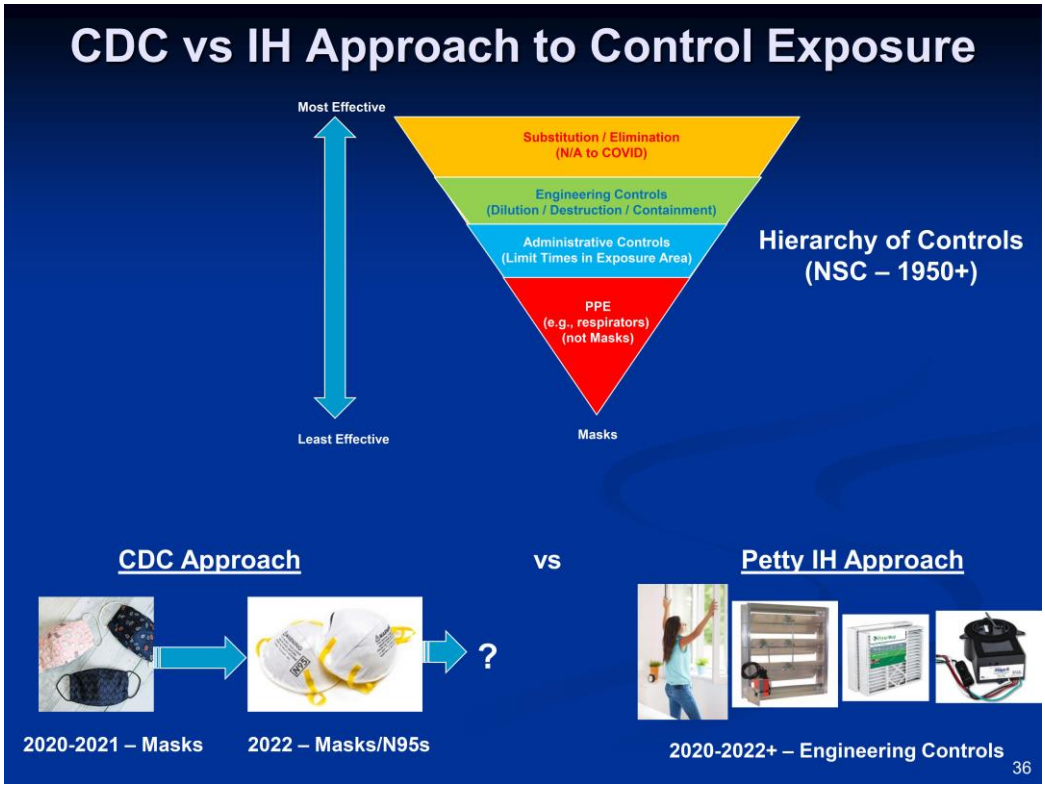


Figure 10: IH Hierarchy of Controls

Masks are not an option under this Hierarchy of Controls and N-95s would be the least

desirable option assuming they would work in a public health setting.

N-95s vs KN-95s:

One of the big issues regarding use of these low-grade respirators is that the vast majority are KN-95s made in China. This is mostly because they are low-cost. Yet while CDC recommends their usage, they oddly note that a high percentage (60%) have been found with low efficacy. Moreover, CDC/NIOSH will not vouch for their performance (Figure 11):

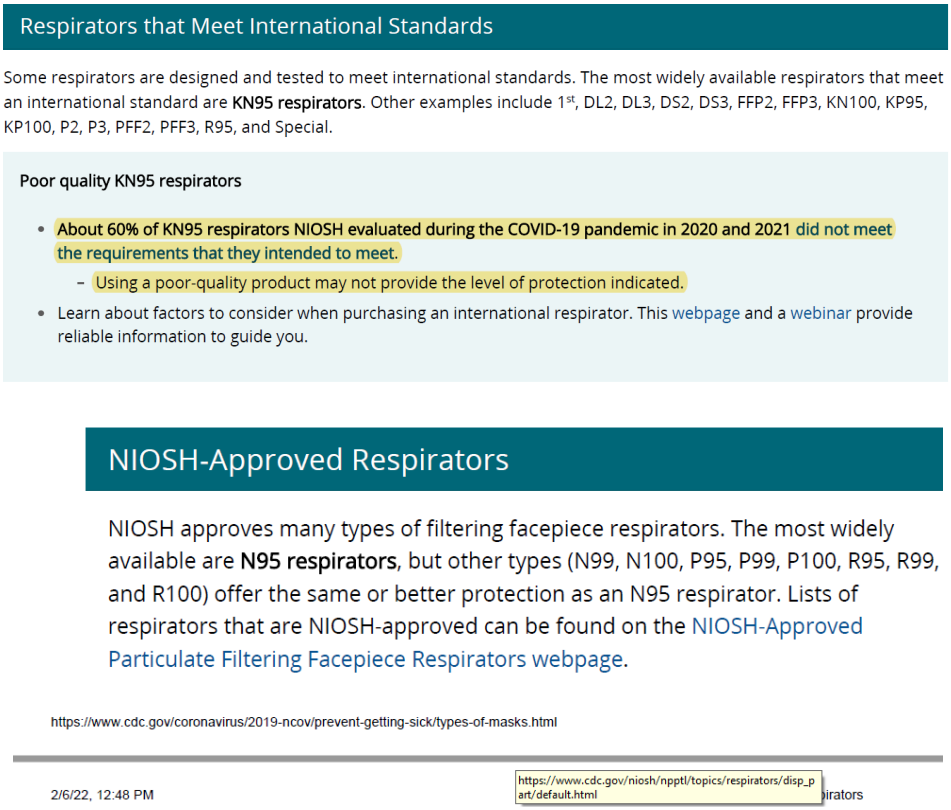


Figure 11: CDC Recommended Wearing N-95 or KN-95 Respirators Yet Admit 60% Didn't Work – Even with No Edge Leaks & Won't Vouch for KN-95 Respirators - https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

These nuances would be confusing to the public, assuming they even knew about the differences between an N-95 and KN-95.

Harms from Wearing N-95s and/or KN-95s:

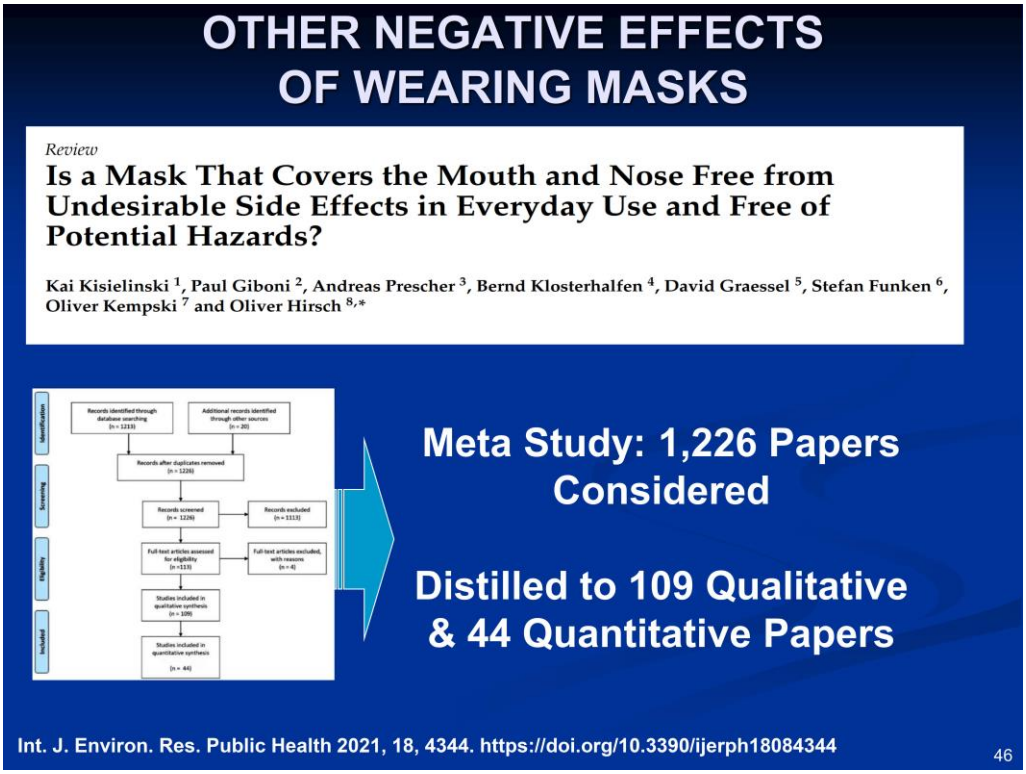
As indicated above, even manufacturers of these products (e.g., 3M) state that if not used properly (selected properly for hazard, fit-tested, cleaned and stored properly, etc.) the user can become sick or even die. Respirators of any kind, including low-end N-95s were never intended for the general public without selection, fit-testing, and training by a professional.

Other issues are:

- Physical,
- Emotional
- Psychological

➢ Development Harms

Kisielinski et al., 2021 completed a meta study of harms from masking. They reviewed 1,226 papers, reduced them to 109 qualitative and 44 quantitative papers (Figure 12) resulting in 27 quantitative effects.



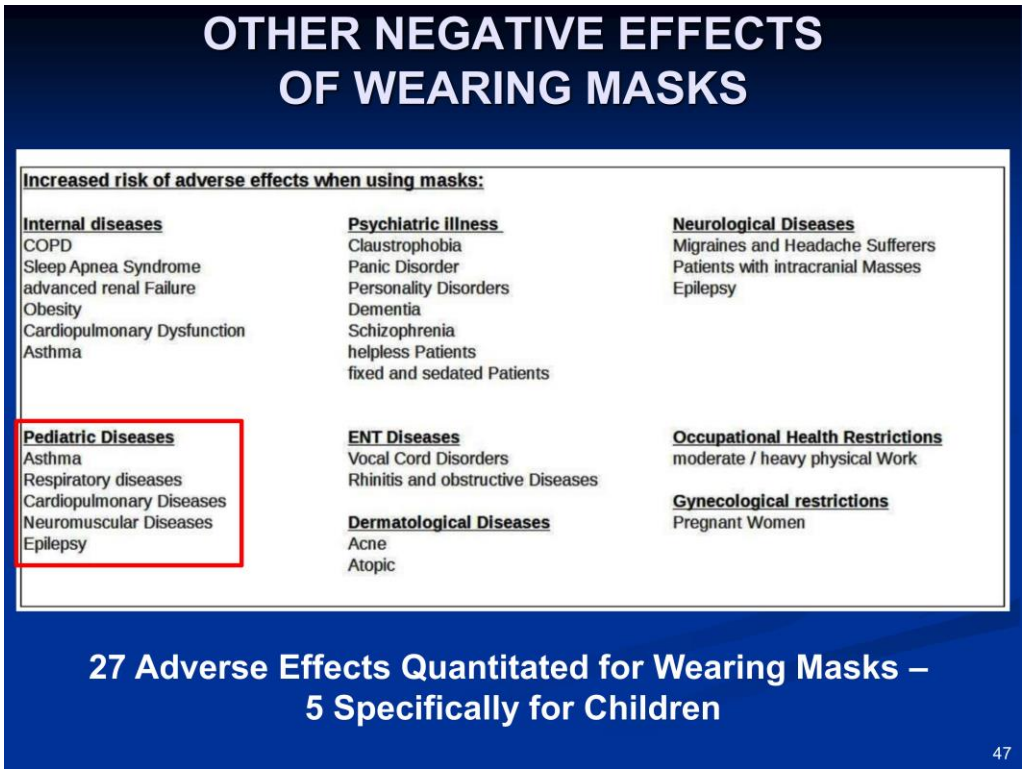


Figure 12: Harms from Masking – Kisielinski et al., 2021

While this topic could be written about for dozens of pages, one effect often not discussed is

that the mask/N-95 materials are perfect breeding grounds (e.g., temperature and humidity) for amplification of opportunistic biological materials (mold, bacteria and viruses). For instance, visible mold has spore counts >1,000,000 spores/square inch whereas non-visible levels are <10,000 spores/square inch. Thus, once amplified, these substances are rebreathed into the body at levels orders of magnitude above at which they were exhaled.

My apologies for the quick write-up; let me know if you find mistakes, need clarifications or have questions.

Best regards

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