February 22, 2022

Rochelle P. Walensky, MD, MPH
Director, Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30329

Anthony S. Fauci, MD
Director, National Institute of Allergy and Infectious Diseases
National Institutes of Health
31 Center Dr # 7A03
Bethesda, MD 20892

Honorable Senator Ronald H. Johnson
328 Hart Senate Office Building
Washington DC 20510

Douglas L. Parker,
Assistant Secretary of Labor for Occupational Safety and Health
Occupational Safety & Health Administration
200 Constitution Ave NW
Washington, DC 20210

Mr. Jeffrey Zients
Coordinator and Counselor to the President
COVID-19 Pandemic Response
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Sent via US Mail Certified Return Receipt and e-mail

Re: Request for Immediate Corrections to the CDC Guidance on Masks and Respirators

Dear Dr. Walensky, Dr. Fauci, Senator Johnson, Mr. Parker, and Mr. Zients:

We the undersigned, professional experts in the field of industrial hygiene, with combined experience of nearly 150 years, are highly concerned with the inaccurate and misleading guidance being promoted by the CDC on its website regarding efficacy of masking to prevent COVID-19 and now similar guidance regarding respirators and request for immediate correction to said guidance. The guidance is overly broad, inaccurate, and especially inappropriate for children and the general public.

For reference, the field of industrial hygiene is defined as:

> *"That science and art devoted to the anticipation, recognition, evaluation, and control of those environmental factors or stressors arising in or from the workplace, which may cause sickness, impaired health and well-being, or significant discomfort among workers or among of the citizens of the community" (https://www.aiha.org/about-ih/Pages/default.aspx).*

The AIHA defines an Industrial Hygienist (https://www.aiha.org/ih-careers/discover-industrial-hygiene) as:

> *"Scientists and engineers committed to protecting the health and safety of people in the workplace and the community."*

Thus, our profession is dedicated, in part, to providing controls to exposures and rely upon what is known as the hierarchy of controls. The hierarchy of controls was first developed by the National Safety Council (NSC) in 1950. This guides us as to the most effective to least effective exposure controls (see Figure 1):

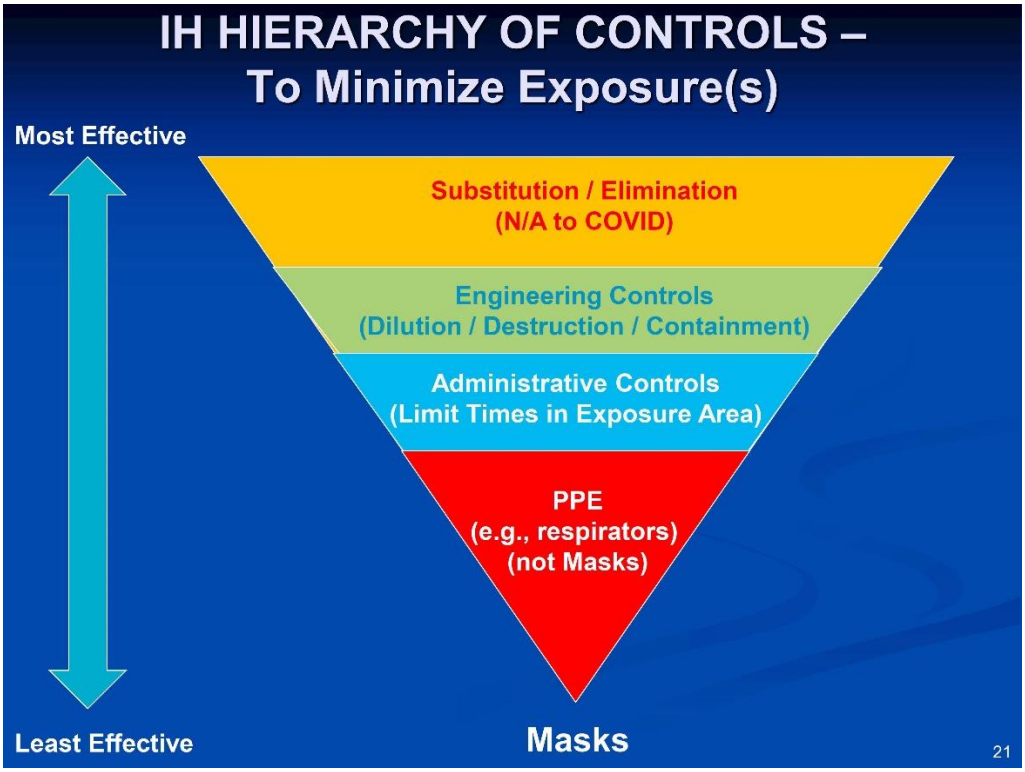
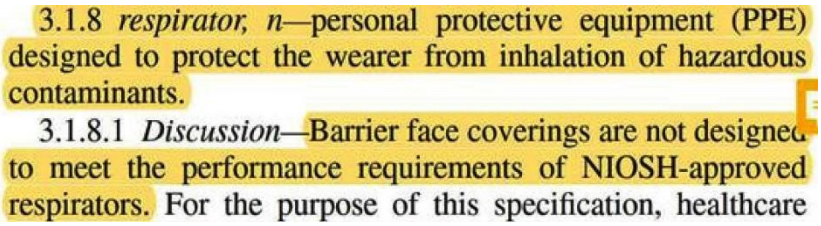


Figure 1: Hierarchy of Controls

Note that masks do not fit into the hierarchy of controls simply because they are not even personal protective equipment. This is recognized in the recent ASTM Face Covering (mask) Standard [ASTM F3502-21 – Standard Specification for Barrier Face Coverings (BFCs)] illustrated in Figure 2:



3.1.8 *respirator, n*—personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous contaminants.

3.1.8.1 *Discussion*—Barrier face coverings are not designed to meet the performance requirements of NIOSH-approved respirators. For the purpose of this specification, healthcare

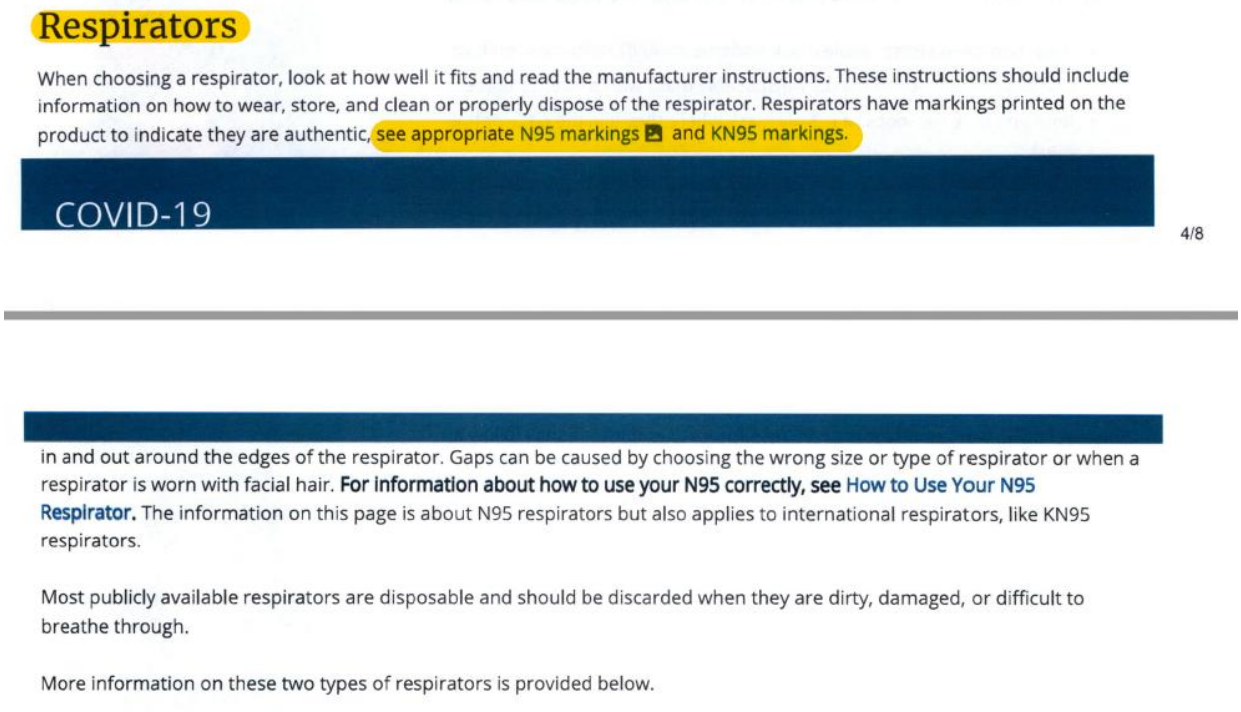
Figure 2: ASTM 2021 BFC Standard – Masks Not PPE (Respirators)

The best industrial hygiene solution has for decades been engineering controls of dilution with fresh air, filtration, and/or destruction – all of which are readily available technologies.

Given this background, we the undersigned have been increasingly concerned about the mis-information provided by the CDC to the public; often reflected by inappropriately conclusive language that *omits technical limitations and documented negative effects associated with masks and face coverings*. Examples of our concerns follow:

Issue #1: Recommending N-95 type masks is inappropriate for the general population and children:

The CDC's January 14, 2022 and January 28, 2022 webpage language have instructed people to move away from masks and toward N95-type respirators (see for example https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html), including KN95 respirators (Figure 3):



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.

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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.

More information on these two types of respirators is provided below.

Figure 3: CDC January 14 & January 28, 2022 Guidance on Respirators – pgs. 4-5

Under the topic of respirators, the CDC lists both N95 and KN95 respirators.

Moreover, as the CDC knows, persons or entities providing respirators in the workplace (unlike masks) must follow OSHA's Personal Protective Equipment Standard (OSHA 29 CFR 1910.132) to establish the nature of the hazard (Hazards Assessment) and the Respiratory Protection Standard (RPS) requirements (29 CFR 1910.134). Non-employees must also follow the RPS under the manufacturers' instructions (as we shall show later). These RPS requirements are substantial and include factors such as:

- Written RPS Plan
- Medical Clearance
- Initial Fit Test
- Annual Fit Test
- Training by a professional such as an IH on fit testing, cleaning, storage, and changeout.

As the CDC knows, or should know, movement from masks to respirators comes with significant requirements or as the manufacturers such as 3M state on their instructions, improper usage "may result in sickness or death".

In this context, we have recently been provided by the following request, and rejection by OSHA, to investigate improper usage of KN respirators by an employer (Figure 4):

U.S. Department of Labor

Occupational Safety and Health Administration
Toledo Area Office
420 Madison Ave, Suite 600
Toledo, OH 43604

February 9, 2022

[redacted]

RE: OSHA Complaint No. 1864651

Dear [redacted]

The Occupational Safety and Health Administration (OSHA) has received your notice of alleged workplace hazard(s) against notified Gun Lake Casino. After careful review we have decided not to conduct an inspection because:

On the basis of the information provided to our office during our phone conversation the employer has provided and is requiring employees to wear KN95 masks which are not NIOSH certified respirators and would not be covered by OSHA's respiratory protection standard.

If you do not agree with this decision, you may contact me for a clarification of the matter at (419) 259-7542.

Section 11(c) of the OSH Act provides protection for employees against discrimination because of their involvement in protected safety and health related activity. If you believe you are being treated differently or action is being taken against you because of your safety or health activity, you may file a complaint with OSHA. You should file this complaint as soon as possible, since OSHA normally can accept only those complaints filed within 30 days of the alleged discriminatory action.

Thank you for your concern for a safe and healthful workplace.

Respectfully,

For

Todd Jensen
Area Director

Figure 4: OSHA February 9, 2022 Response Letter to Gun Lake Casino Complaint

OSHA rejected the employee complaint on a technicality that the employer was not following the OSHA RPS because the respirator was a KN95 rather than an N95. And, as shown in Figure 5, NIOSH does not approve KN95's:

CDC Centers for Disease Control and Prevention

Promoting productive workplaces through safety and health research NIOSH

NIOSH-approved N95 Particulate Filtering Facepiece Respirators

This list is reviewed and updated weekly.

Manufacturers Listed from A to Z – L

The N95 respirator is the most common of the seven types of particulate filtering facepiece respirators. This product filters at least 95% of airborne particles but is not resistant to oil-based particles.

This web page provides a table of NIOSH-approved N95 respirators listed by manufacturer from A-Z. You can find a specific manufacturer by clicking on the first letter of their name on the index below. Web links in the table go to the NIOSH Approval Holder's website. See the Notes section for information about private labels.

NIOSH entered a Memorandum of Understanding (MOU) in 2018 with the Food and Drug Administration (FDA). This MOU granted NIOSH the authority to approve surgical N95 filtering facepiece respirators. Prior to this MOU, both NIOSH and FDA approved and cleared surgical N95s. The **Model Number/Product Line in bold text followed by (FDA)** indicates these surgical N95 respirators in the table below. NIOSH also provides a table of the surgical N95 respirators approved prior to the MOU. Surgical N95 respirators approved under the MOU do not require FDA's 510(k) clearance. These NIOSH-approved surgical N95 respirators are only on the Certified Equipment List (CEL).

A respirator labeled as a KN95 respirator is expected to conform to China's GB2626 standard. NIOSH does not approve KN95 products or any other respiratory protective devices certified to international standards. For more information, view Factors to Consider When Planning to Purchase Respirators from Another Country.

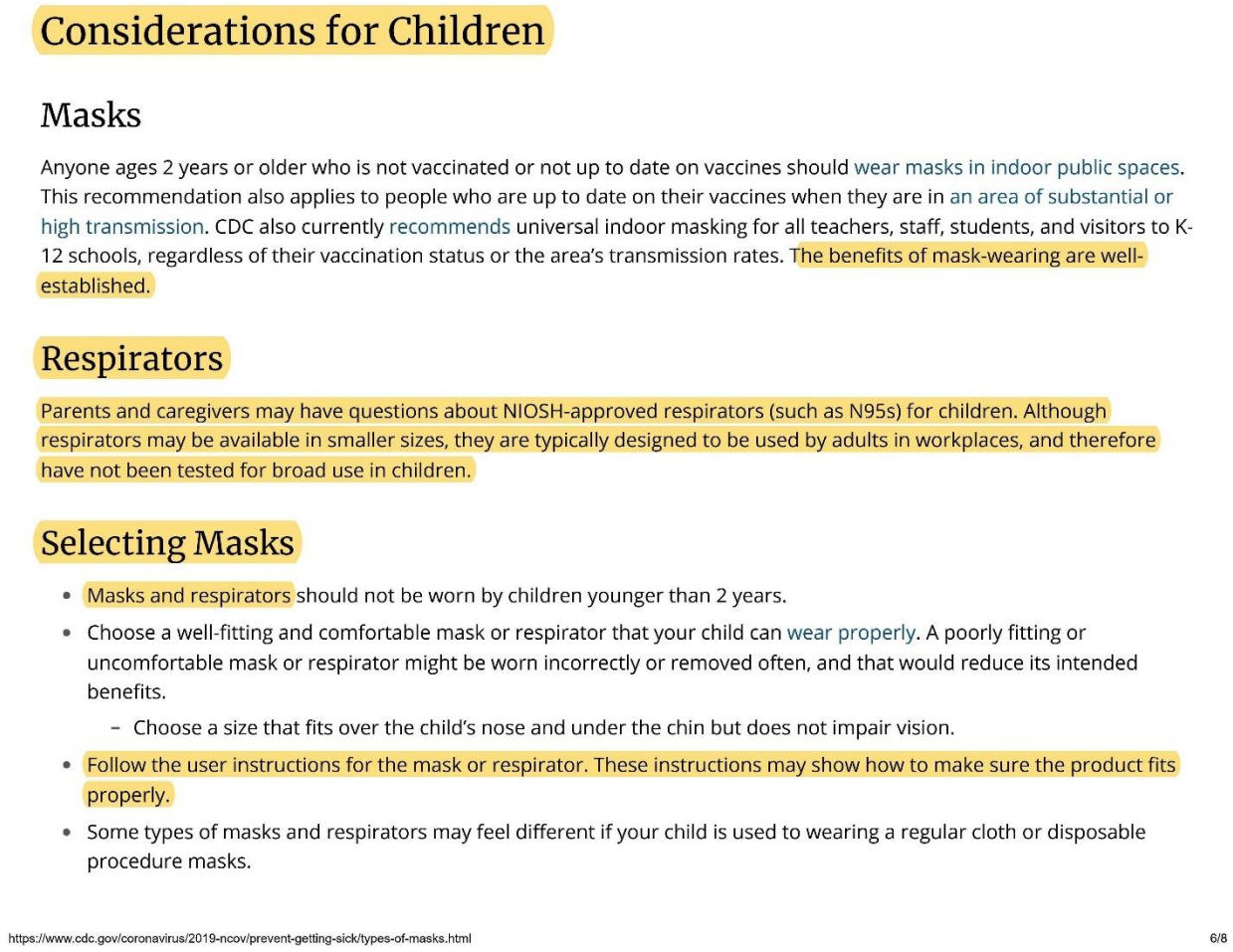
Figure 5: NIOSH Language Regarding Approval of KN95 Respirators

So, in an obvious case of deception, the CDC recommends the usage of N95 and KN95 respirators (see Figure 3) yet must know they are not approved by NIOSH and that OSHA will not enforce the RPS. The irony here is that NIOSH is part of the CDC (see Figure 5 letterhead), so the CDC clearly knows this. Note that it is known that KN95 respirators from China are known to be less expensive than those made with the N95 designation and find widespread usage; this too was known, or should have been known, by the CDC.

Thus, the CDC pushes KN95 respirators as part of the move toward respirators, knowing they are not approved by their sub-agency NIOSH, which allows employers to make employees wear respirators without the protections of OSHA's Respiratory Protection Standard (RPS). This is an unconscionable breach of the public health function and should be corrected immediately.

Issue #2: CDC has issued harmful guidance for masking children that contradicts manufacturers' recommendations, world-wide standard practice and CDC's own guidance, and without appropriate risk-benefit analysis:

The 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 – see Figure 6:



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 uncomfortable mask or respirator might be worn incorrectly or removed often, and that would reduce its intended benefits.
  - Choose a size that fits over the child's nose and under the chin but does not impair vision.
- Follow the user instructions for the mask or respirator. These instructions may show how to make sure the product fits properly.
- Some types of masks and respirators may feel different if your child is used to wearing a regular cloth or disposable procedure masks.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html 6/8

Figure 6: Misleading CDC Language Regarding Children Wearing Masks and Respirators

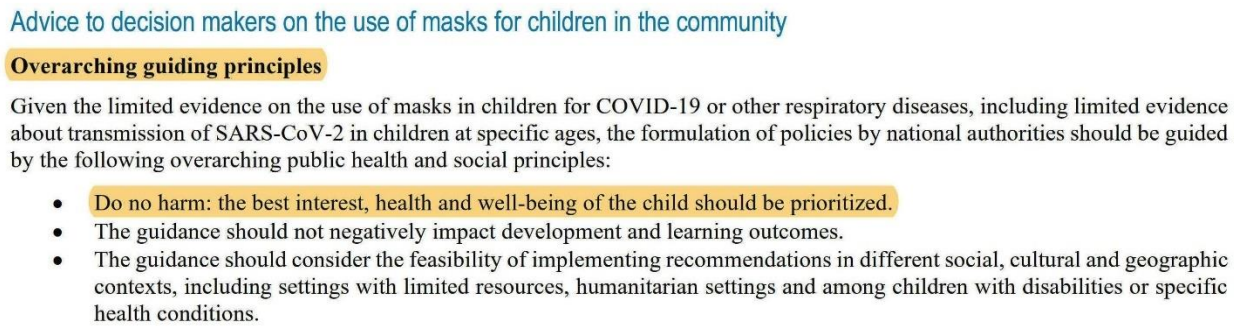
As illustrated in detail below, the CDC provided language in its January 28, 2022 guidance for children that is particularly misleading by obfuscating and omitting information readily known, or likely to have been known by the CDC.

<u>"The benefits of mask-wearing are well-established:"</u>

First, the benefits of children, or anyone for that matter, of wearing masks being well

established is simply false. A Brownstone paper by Paul Elias Alexander published December 21, 2021 (https://brownstone.org/articles/more-than-150-comparative-studies-and-articles-on-mask-ineffectiveness-and-harms/) shows both the effectiveness of masks and their harms, citing 150 studies. One of these author's testified in the Western District Court of Michigan on September 28, 2021, in a half-dozen interviews (e.g., Jeff Hayes Films: https://rumble.com/vrfoox-covid-revealed-episode-8b-bonus-video-stephen-petty.html), in his own podcasts (https://rumble.com/c/PettyPodcasts) and in the Liberty Dispatch in Canada (https://podcasts.apple.com/us/podcast/episode-99-masks-dont-work-an-interview-with-ppe/id1559570986?i=1000550149187). During this testimony it was shown that the nearly 50 studies cited by the CDC purportedly showing masks are effective did not support statements made by the CDC and most suffered from a lack of a control group (group similar to the mask study group not wearing masks) or cofounding factors (multiple factors such as changes in HVAC systems, distancing, quarantining, and masks) wherein one cannot determine the specific contribution by masking.

But the most egregious part of this statement is that it only addresses supposed benefits, not liabilities. Even the WHO - UNICEF (https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC_Masks-Children-2020.1) understands that risk-rewards analysis should be done before recommending unproven, unscientifically-supported policies before masking them. Remember – do no harm – is the overarching principle (Figures 7 & 8):



Advice to decision makers on the use of masks for children in the community

Overarching guiding principles

Given the limited evidence on the use of masks in children for COVID-19 or other respiratory diseases, including limited evidence about transmission of SARS-CoV-2 in children at specific ages, the formulation of policies by national authorities should be guided by the following overarching public health and social principles:

- Do no harm: the best interest, health and well-being of the child should be prioritized.
- The guidance should not negatively impact development and learning outcomes.
- The guidance should consider the feasibility of implementing recommendations in different social, cultural and geographic contexts, including settings with limited resources, humanitarian settings and among children with disabilities or specific health conditions.

Figure 7: WHO UNICEF Recommendations for Children and Masks

From Figure 7, the overarching guiding principle is to do no harm.

Advice on the use of masks in children

WHO and UNICEF advise decision makers to apply the following criteria for use of masks in children when developing national policies, in countries or areas where there is known or suspected community transmission[a] of SARS-CoV-2 and in settings where physical distancing cannot be achieved.

1. Based on the expert opinion gathered through online meetings and consultative processes, children aged up to five years should not wear masks for source control. This advice is motivated by a "do no harm" approach and considers:
    - childhood developmental milestones[b] [41]
    - compliance challenges and
    - autonomy required to use a mask properly.

The experts (following the methods described above) recognized that the evidence supporting the choice of the age cut-off is limited (see above, section related to transmission of COVID-19 in children), and they reached this decision mainly by consensus. The rationale included consideration of the fact that by the age of five years, children usually achieve significant developmental milestones, including the manual dexterity and fine motor coordination movements needed to appropriately use a mask with minimal assistance.

In some countries, guidance and policies recommend a different and lower age cut-off for mask use[42-45]. It is recognized that children may reach developmental milestones at different ages and children five years of age and under may have the dexterity needed to manage a mask. Based on the do no harm approach, if the lower age cut-off of two or three years of age is to be used for recommending mask use for children, appropriate and consistent supervision, including direct line of sight supervision by a competent adult and compliance need to be ensured, especially if mask wearing is expected for an extended period of time. This is both to ensure correct use of the mask and to prevent any potential harm associated with mask wearing to the child.

Children with severe cognitive or respiratory impairments who have difficulties tolerating a mask should, under no circumstances, be required to wear masks.

Other IPC, public health and social measures should be prioritized to minimize the risk of SARS-CoV-2 transmission for children five years of age and under; specifically maintaining physical distance of at least 1 meter where feasible, educating children to perform frequent hand hygiene and limiting the size of school classes. It is also noted that there may be other specific considerations, such as the presence of vulnerable persons or other local medical and public health advice that should be considered when determining if children five years of age and under need to wear a mask.

2. For children between six and 11 years of age, a risk-based approach should be applied to the decision to use of a mask. This approach should take into consideration:
    - intensity of transmission in the area where the child is and updated data/available evidence on the risk of infection and transmission in this age group;
    - social and cultural environment such as beliefs, customs, behaviour or social norms that influence the community and population's social interactions, especially with and among children;
    - the child's capacity to comply with the appropriate use of masks and availability of appropriate adult supervision;
    - potential impact of mask wearing on learning and psychosocial development; and
    - additional specific considerations and adaptions for specific settings such as households with elderly relatives, schools, during sport activities or for children with disabilities or with underlying diseases.

3. Advice on mask use in children and adolescents 12 years or older should follow the WHO guidance for mask use in adults[1] and/or the national mask guidelines for adults.

    Even where national guidelines apply, additional specific considerations (see below) and adaptions for special settings such as schools, during sport, or for children with disabilities or with underlying diseases will need to be specified.

Figure 8: WHO UNICEF Recommendations for Children and Masks by Age

Note that from Figure 8, WHO recommends against masking below age 6 and that children ages 6 to 11 may be masked upon completion of a risk assessment. England has similar guidance. But the CDC requires masks for children down to age 2 against WHO guidance and based on extensive reviews, has yet to perform any risk assessment on the net benefits of children wearing masks.

Specifically, it is well established that significant harms (i.e., reduced learning and development and physical, emotional, and social harms) have been reported in the literature (Figures 9-18):

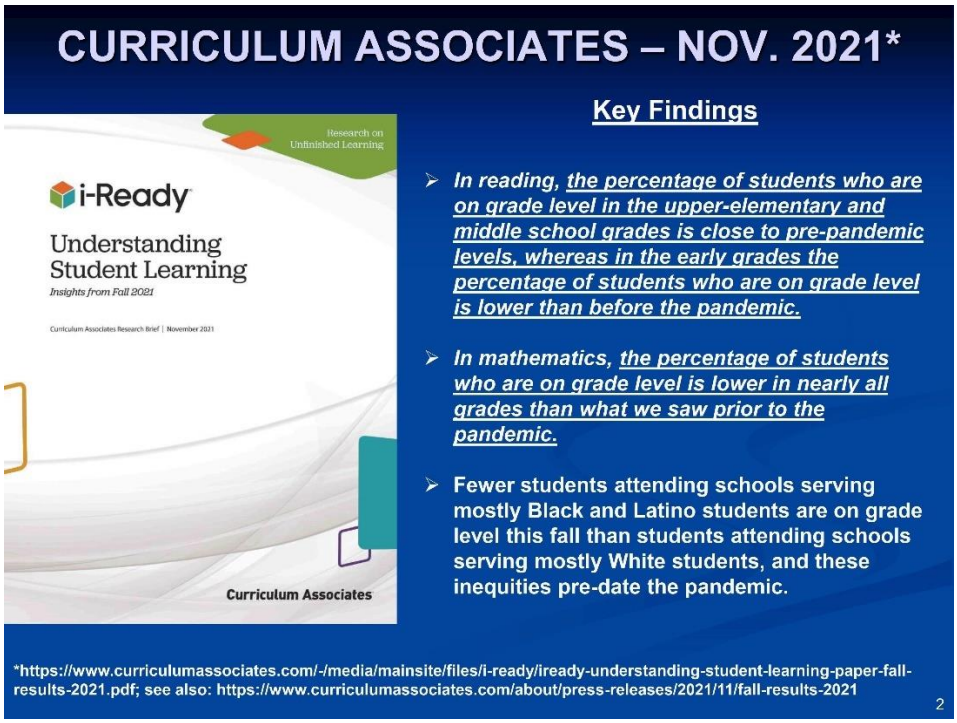


Figure 9: Curriculum Associates – Nov. 2021 – Title Page

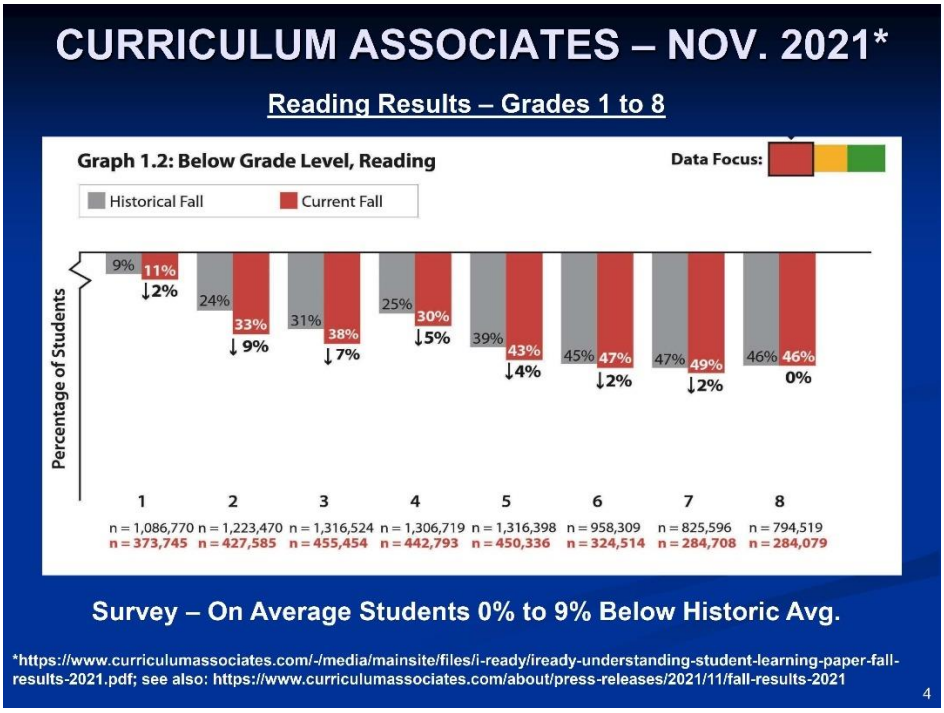


Figure 10: Curriculum Associates – Reading Deficits in 2021 vs. Prior Years

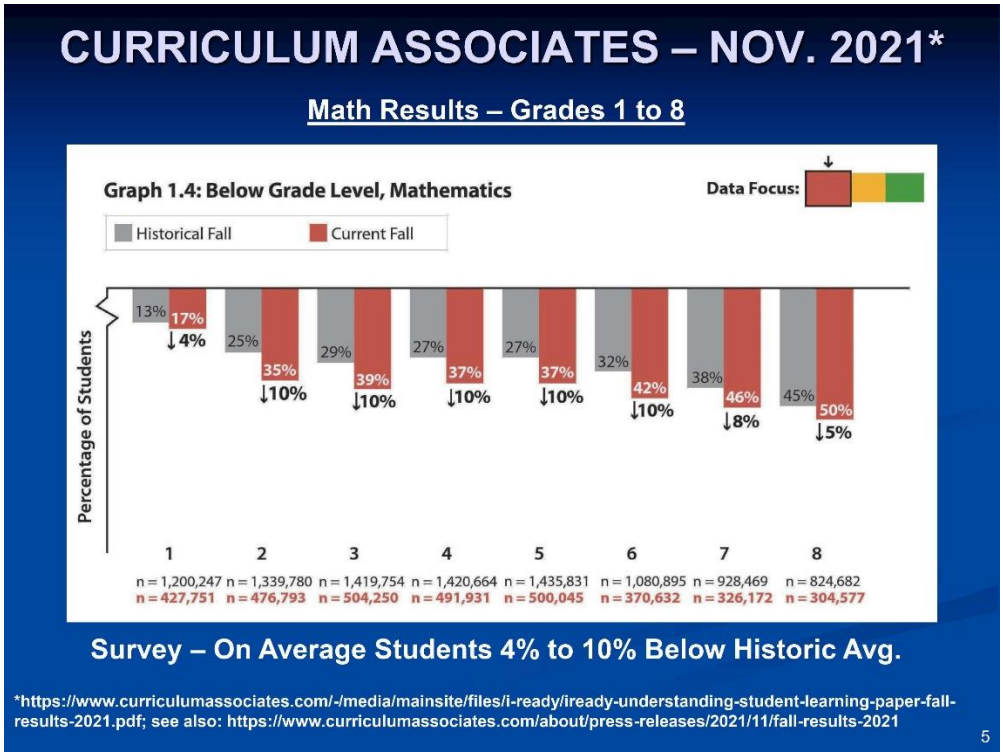


Figure 11: Curriculum Associates – Math Deficits in 2021 vs. Prior Years

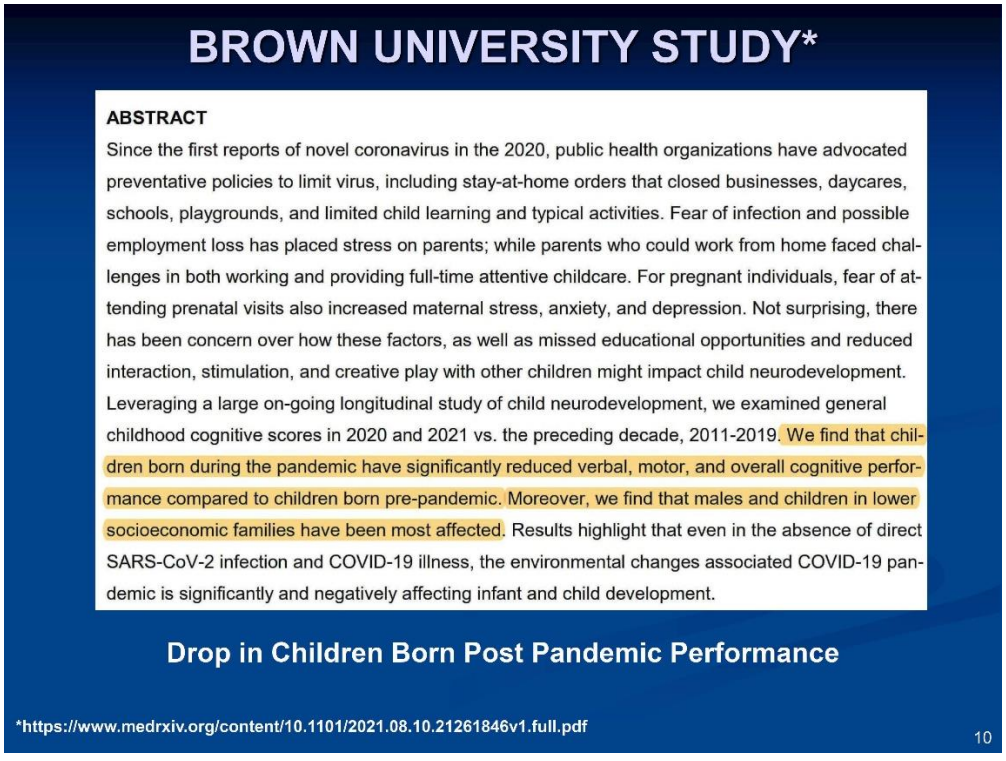


Figure 12: Brown University – Cognitive Deficits

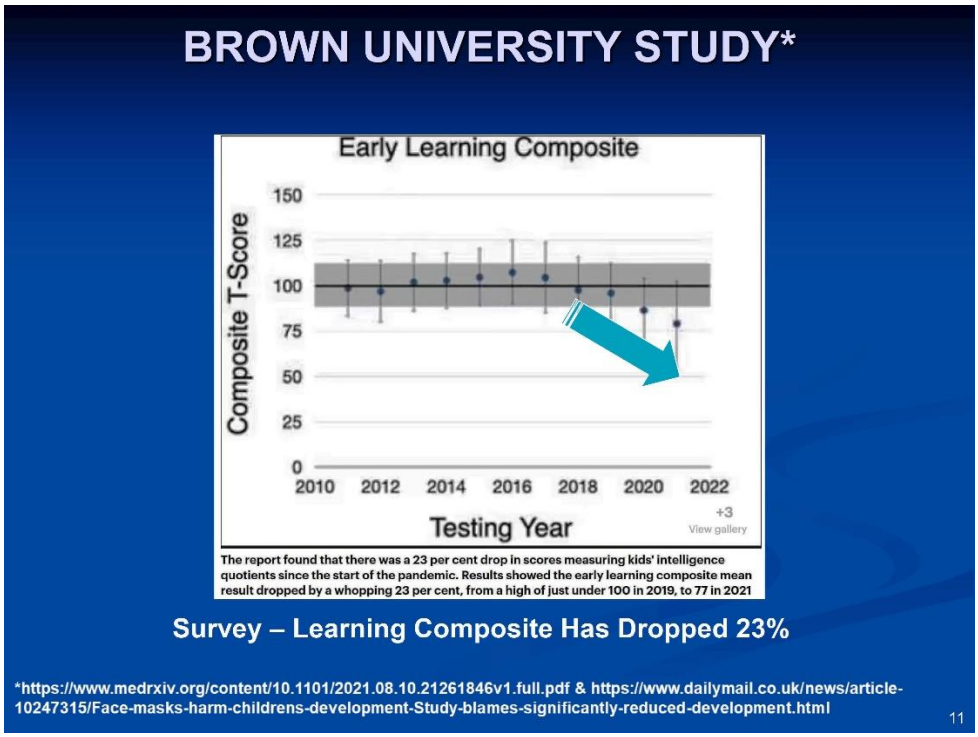


Figure 13: Brown University Study – Learning Loss of 23% for Children Born Since Pandemic

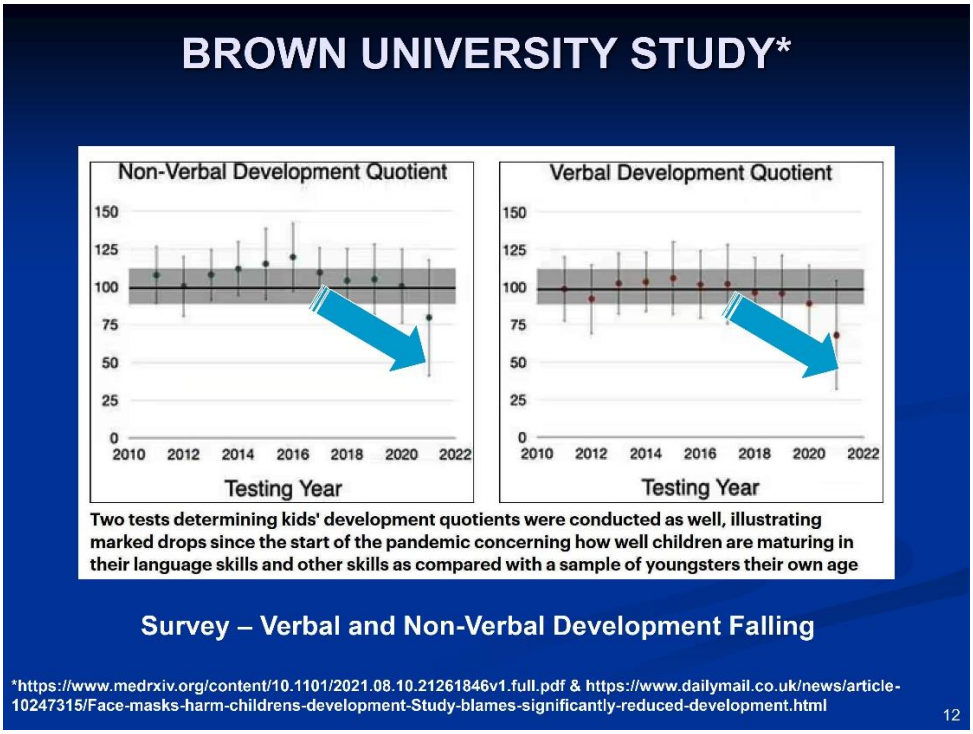


Figure 14: Brown University Study – Non-Verbal and Verbal Development Losses

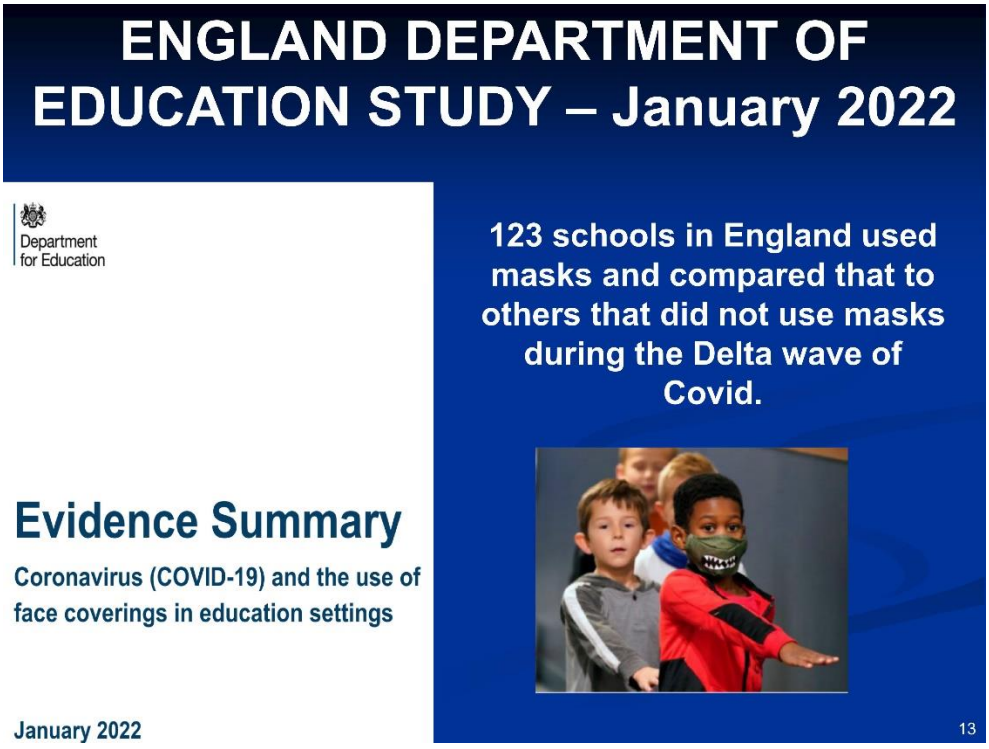


Figure 15: England Department of Education

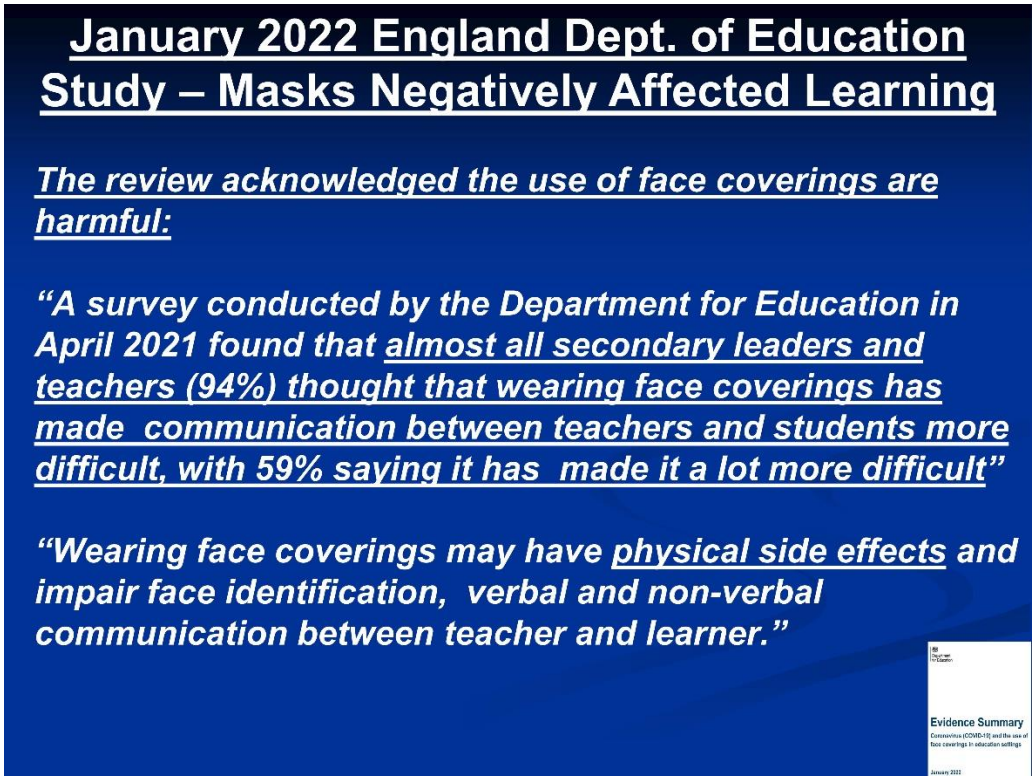


Figure 16: England Department of Education – Loss of Communication and Physical Effects

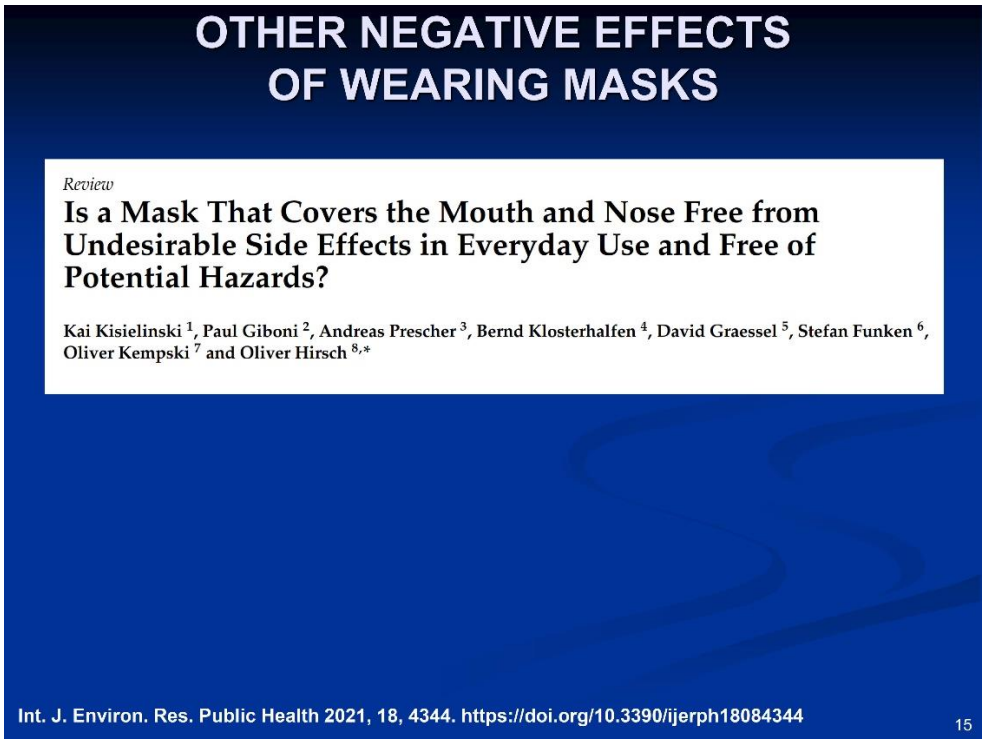


Figure 17: Kisielinski et al. – Mask Meta Study – Reviewed 1,226 Studies

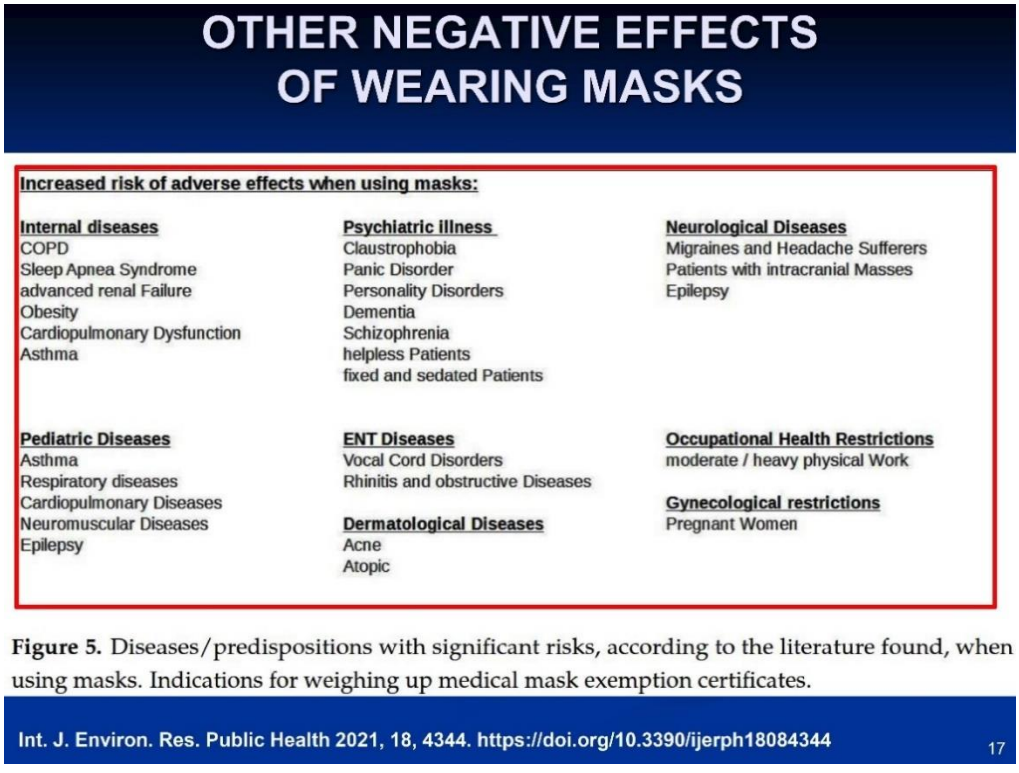


Figure 18: Kisielinski et al., – Areas of Quantitated Adverse Effects on Children and Adults

Clearly, the CDC has not conducted a net risk assessment and should have, and must do so to avoid continuing harms to children.

Even more disturbing, in their innocent looking, new Guidance for Children (Learn the Signs, Act Early) the CDC has in part, extended the timeframes for children to achieve learning outcomes (https://www.cdc.gov/ncbddd/actearly/milestones/index.html). Regarding these changes – Figure 19, CDC refers the reader to an American Academy of Pediatrics (AAP) webpage (https://publications.aap.org/pediatrics/article-abstract/doi/10.1542/peds.2021-052138/184748/Evidence-Informed-Milestones-for-Developmental?redirectedFrom=fulltext):

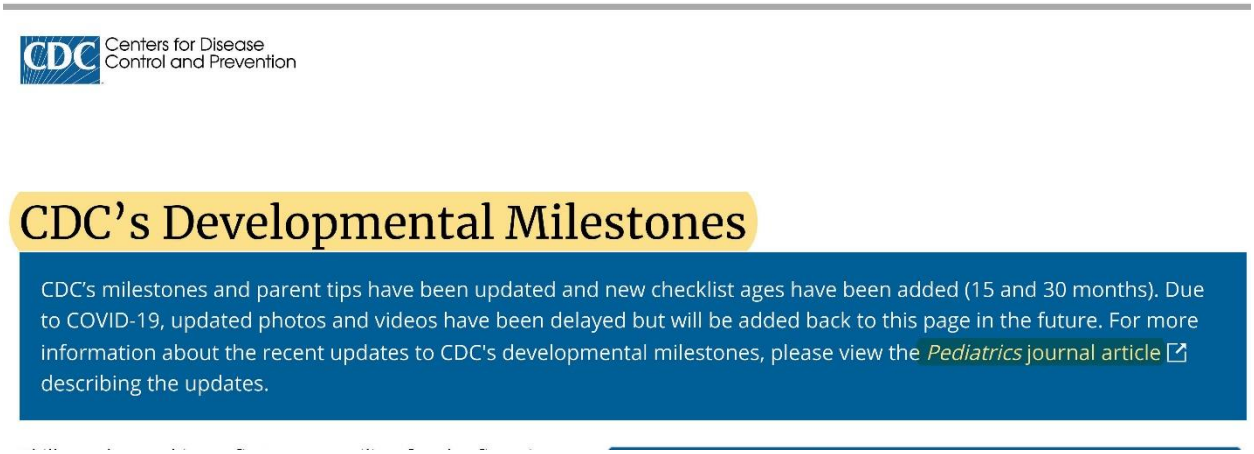


Figure 19: CDC Learn the Signs, Act Early New Webpage – Reference to AAP

The headlines for the reference paper are reproduced as Figure 20:

Figure 20: CDC Referenced AAP Paper by Zubler (CDC) et al. Dated February 8, 2022

Zubler et al., write in part:

"*The Centers for Disease Control and Prevention's (CDC) Learn the Signs. Act Early. program, funded the American Academy of Pediatrics (AAP) to convene an expert working group to revise its developmental surveillance checklists*. The goals of the group were to identify evidence-informed milestones to include in CDC checklists, clarify when most children can be expected to reach a milestone (to discourage a wait-and-see approach), and support clinical judgment regarding screening between recommended ages. Subject matter experts identified by the AAP established 11 criteria for CDC milestone checklists, including using milestones most children (≥75%) would be expected to achieve by specific health supervision visit ages and those that are easily observed in natural settings. A database of normative data for individual milestones, common screening and evaluation tools, and published clinical opinion was created to inform revisions. ***Application of the criteria established by the AAP working group and adding milestones for the 15- and 30-month health supervision visits resulted in a 26.4% reduction and 40.9% replacement of previous CDC milestones***. ***One third of the retained milestones were transferred to different ages; 67.7% of those transferred were moved to older ages.*** *Approximately 80% of the final milestones had normative data from ≥1 sources*. Social-emotional and cognitive milestones had the least normative data. These criteria and revised checklists can be used to support developmental surveillance, clinical judgment regarding additional developmental screening, and research in developmental surveillance processes. Gaps in developmental data were identified particularly for social-emotional and cognitive milestones.

Thus, at least 22.3% [67.7% of 33%] of the CDC child developmental milestones in place for ~18 years, were moved from a younger age to an older age in February 2022.

One must conclude the CDC, rather than acknowledging the harms being done to children's development by their COVID policies, including masking, is simply moving the goalposts for what constitutes normal child development rather than admitting and moving away from failed policies.

Statements under "Respirators" and "Selecting Masks":

- 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*.
- ***Masks and respirators should not be worn by children younger than 2 years.***
- Choose a size that fits over the child's nose and under the chin but does not impair vision. ***Follow the user instructions for the mask or respirator.*** *These instructions may show how to make sure the product fits properly.*

This language may be the most misleading and egregious given that the links CDC provides to manufacturers' instruction state that their N95s are not for use with children – the CDC has to know this.

The links to manufacturers' instructions from the January 28, 2022 mask and January 25, 2022 How to Use Your N95 Respirator are shown in Figures 21 and 22 respectively:

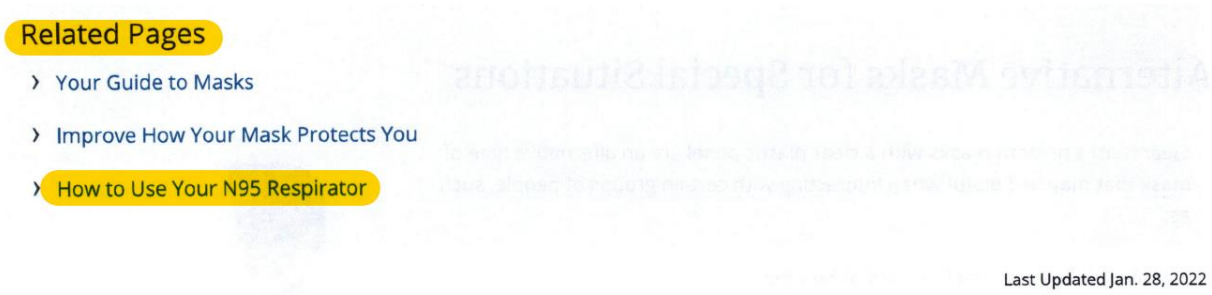


Figure 21: CDC January 28, 2022 Link – Bottom of Page and CDC January 25, 2022 Link to Manufacturers' Guidance and Warnings

The "How to Use Your N95 Respirator" is at the bottom of the CDC January 28, 2022 webpage.

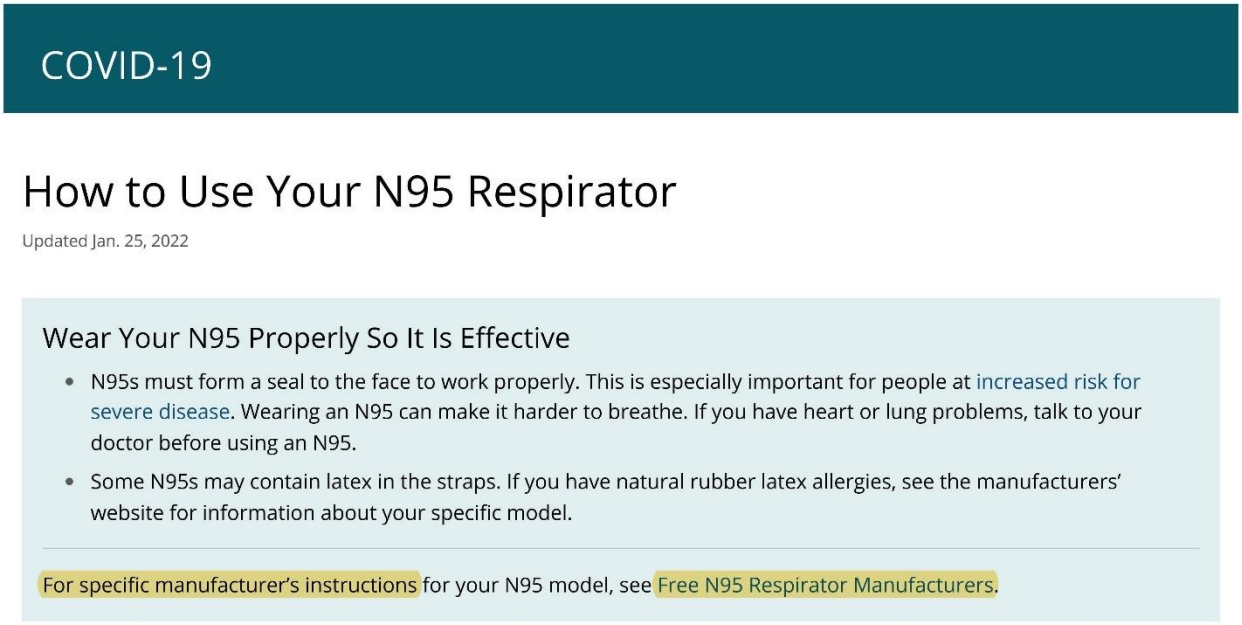


Figure 22: CDC January 15, 2022 Link to How to Use Your N-95 Respirator – Link to Manufacturers

The link in turn takes one to the following page (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/free-n95-manufacturers.html) (Figure 23):

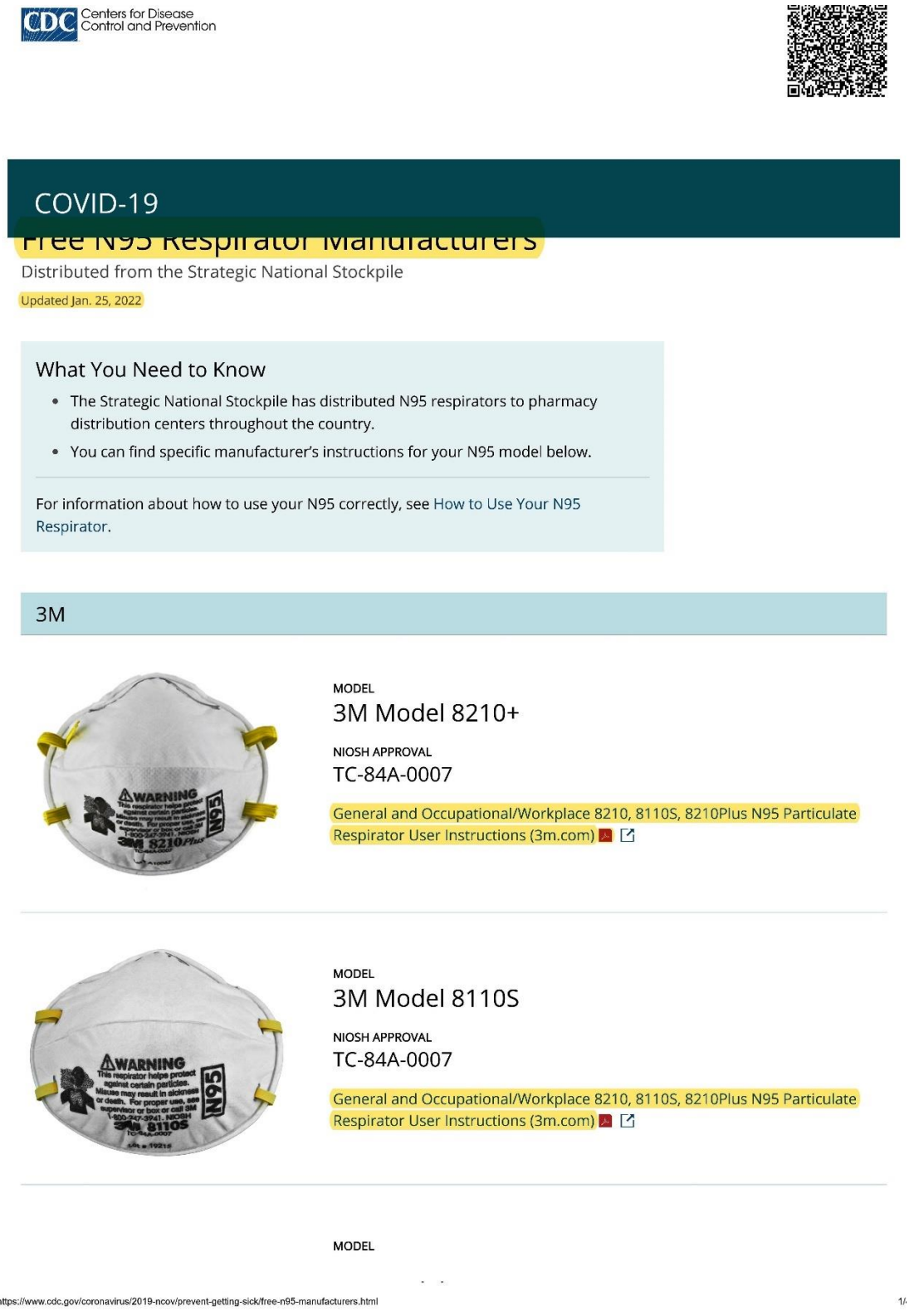


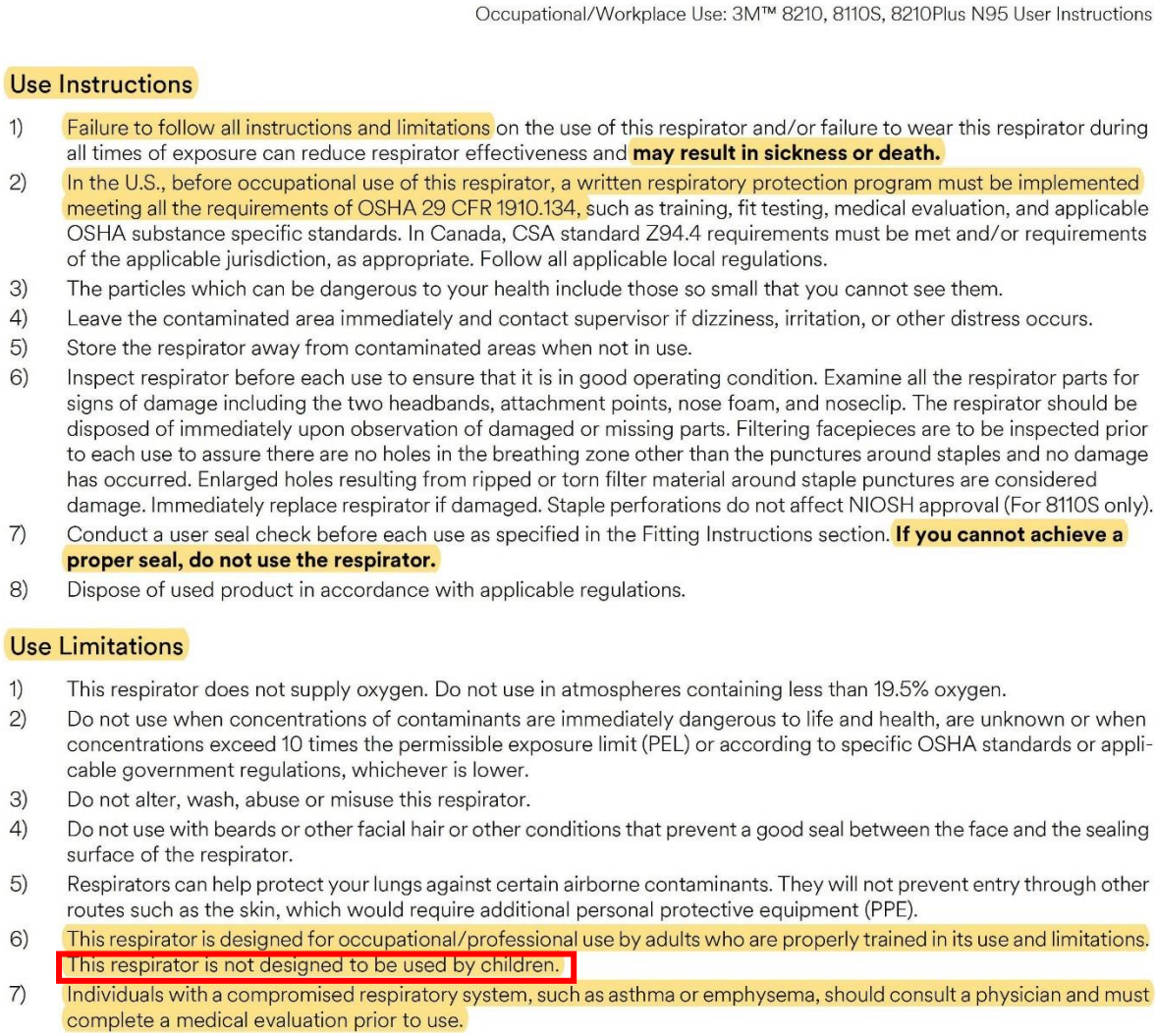
Figure 23: CDC January 15, 2022 Link to How to Use Your N-95 Respirator – Link to Manufacturers – pg. 1

From this webpage, four manufacturers are listed representing 12 respirators:

- 3M (6 models)
- Drager (1 model)
- Honeywell (2 models)
- Moldex (3 models).

For each model, the link can be clicked to get directly to the manufacturers' instructions for each respirator. For 3M and Moldex, major suppliers, only one set of instructions is used for each of their individually listed respirators. In other words, the same instructions were provided for each of the manufacturers' listed products.

Both 3M and Moldex explicitly state that their masks are not to be use by children (Figure 24).



Occupational/Workplace Use: 3M™ 8210, 8110S, 8210Plus N95 User Instructions

Use Instructions

1) Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and **may result in sickness or death.**
2) In the U.S., before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134, such as training, fit testing, medical evaluation, and applicable OSHA substance specific standards. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Follow all applicable local regulations.
3) The particles which can be dangerous to your health include those so small that you cannot see them.
4) Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
5) Store the respirator away from contaminated areas when not in use.
6) Inspect respirator before each use to ensure that it is in good operating condition. Examine all the respirator parts for signs of damage including the two headbands, attachment points, nose foam, and noseclip. The respirator should be disposed of immediately upon observation of damaged or missing parts. Filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. Immediately replace respirator if damaged. Staple perforations do not affect NIOSH approval (For 8110S only).
7) Conduct a user seal check before each use as specified in the Fitting Instructions section. **If you cannot achieve a proper seal, do not use the respirator.**
8) Dispose of used product in accordance with applicable regulations.

Use Limitations

1) This respirator does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen.
2) Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown or when concentrations exceed 10 times the permissible exposure limit (PEL) or according to specific OSHA standards or applicable government regulations, whichever is lower.
3) Do not alter, wash, abuse or misuse this respirator.
4) Do not use with beards or other facial hair or other conditions that prevent a good seal between the face and the sealing surface of the respirator.
5) Respirators can help protect your lungs against certain airborne contaminants. They will not prevent entry through other routes such as the skin, which would require additional personal protective equipment (PPE).
6) This respirator is designed for occupational/professional use by adults who are properly trained in its use and limitations. This respirator is not designed to be used by children.
7) Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician and must complete a medical evaluation prior to use.

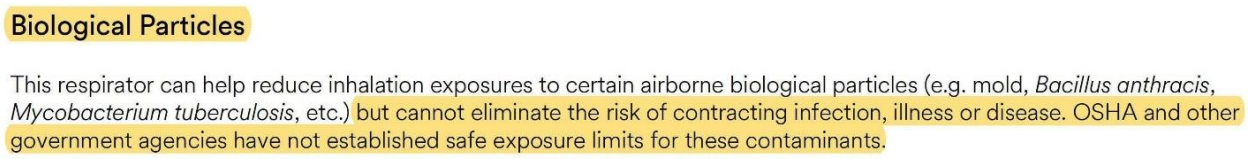
Figure 24: 3M Instructions for CDC Listed 3M N95 Respirators – Not Designed to be Used by Children

Note the following observations from Figure 24:

- ***This respirator is not designed to be used by children***!
- The respirator is only intended to be used for occupational or professional adults properly trained (e.g., under the RPS).
- Failure to follow instructions may result in sickness or death.
- A written respiratory protection plan, under the requirements of 29 CFR 1910.134 (RPS) must be in place prior to use of this respirator.

The Moldex instructions are essentially the same.

Moreover, 3M warns it is not protective against infectious diseases (Figure 25):



Biological Particles

This respirator can help reduce inhalation exposures to certain airborne biological particles (e.g. mold, *Bacillus anthracis*, *Mycobacterium tuberculosis*, etc.) but cannot eliminate the risk of contracting infection, illness or disease. OSHA and other government agencies have not established safe exposure limits for these contaminants.

5

Figure 25: 3M Instructions for CDC Listed 3M N95 Respirators – Not Protective Against Infection, Illness, or Disease

Note that anthrax and TB are much larger particles than virus particles like the COVID-19 virus.

In light of this discussion, the CDC should immediately correct their webpage stating explicitly that respirators, according to manufacturers' instructions, "Are not designed to be used by Children" and that anyone using a respirator must be doing so under a written respiratory protection plan that follows the OSHA RPS.

Issue #3: The CDC continues to ignore the fact that COVID-19 is primarily spread by aerosols (not droplets) making mask use mostly ineffective:

The CDC continues to make the misleading argument that masks stop COVID droplets. This is misleading because while masks do stop some droplets (> 50 to 10 micron), the vast majority of COVID particles are smaller aerosols (≤ 5 microns) – see Figure 26:

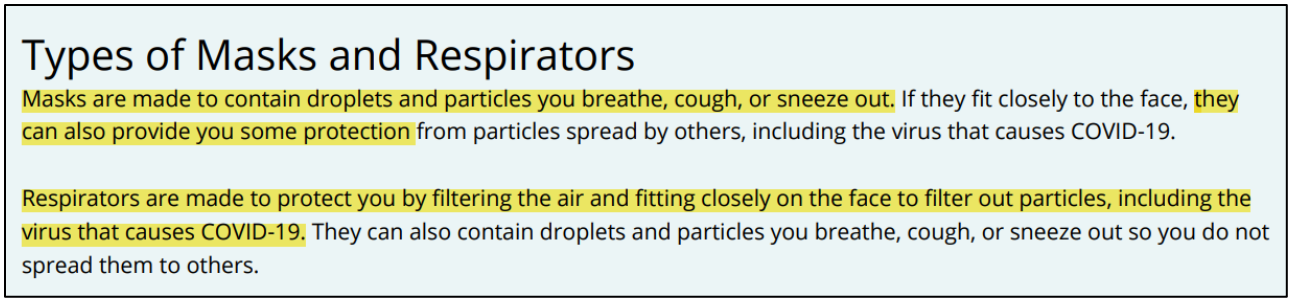


Figure 26: CDC – Misleading Guidance on Masks and Droplets

We are not the only ones who have written you regarding this issue. On February 15, 2021, the following scientists wrote a lengthy memo to you regarding your misleading language in this area and asked you to correct it:

- Rick Bright, PhD, Former Director of BARDA, Dept of Health and Human Services
- Lisa M. Brosseau, ScD, CIH, University of Minnesota CIDRAP
- Lynn R. Goldman, MD, MS, MPH, George Washington University
- Céline Gounder, MD, ScM, NYU Grossman School of Medicine & Bellevue Hospital Center
- Jose Jimenez, PhD, University of Colorado at Boulder
- Yoshihiro Kawaoka, DVM, PhD, University of Wisconsin-Madison and University of Tokyo
- Linsey Marr, PhD, Virginia Tech
- David Michaels, PhD, MPH, George Washington University
- Donald K. Milton, MD, DrPH, University of Maryland
- Michael Osterholm, PhD, MPH, University of Minnesota CIDRAP
- Kimberly Prather, PhD, University of California San Diego
- Robert T. Schooley, MD, University of California San Diego
- Peg Seminario, MS, AFL-CIO (retired)

They wrote in part:

> "To address and limit transmission via inhalation exposure and prevent COVID infections and deaths, we urge the Biden administration to take the following immediate actions:
>
> - Update and strengthen CDC guidelines to fully address transmission via inhalation exposure to *small inhalable particles* from infectious sources at close, mid and longer range. Updated guidelines should be informed by a risk assessment model that focuses on source and pathway (ventilation) controls first, followed by respiratory protection…

- *Issue an OSHA emergency standard on COVID-19 that recognizes the importance of aerosol inhalation, includes requirements to assess risks of exposure, and requires implementation of control measures following a hierarchy of controls*…

Edwards et al. (https://www.pnas.org/content/118/8/e2021830118) demonstrated that that the vast majority of COVID particles emitted during illness are aerosols not droplets (see Figure 27):

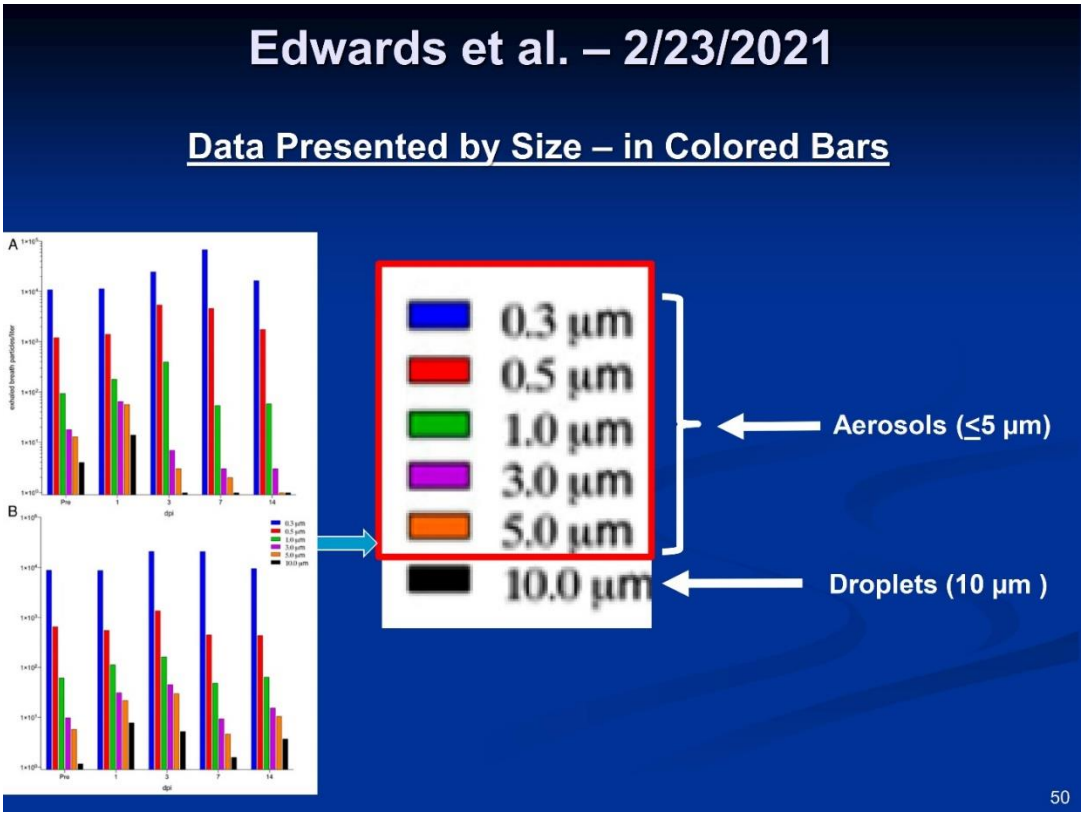


Figure 27: Edwards et al., 2021 – Particle Size Emissions by Size and Time

Edwards et al. concluded their paper with the following statements:

- Our finding that *the proportion of small respiratory droplets (i.e., aerosols) were the majority of particles exhaled in all subjects*.
- There may be an elevated risk of the airborne transmission of SARS CoV 2 by way of the very small droplets (aerosols) that transmit through conventional masks and *traverse distances far exceeding the conventional social distance of 2 m (~7').*
- Exhaled aerosol numbers appear to be not only an indicator of disease progression, *but a marker of disease risk in non-infected individuals.*

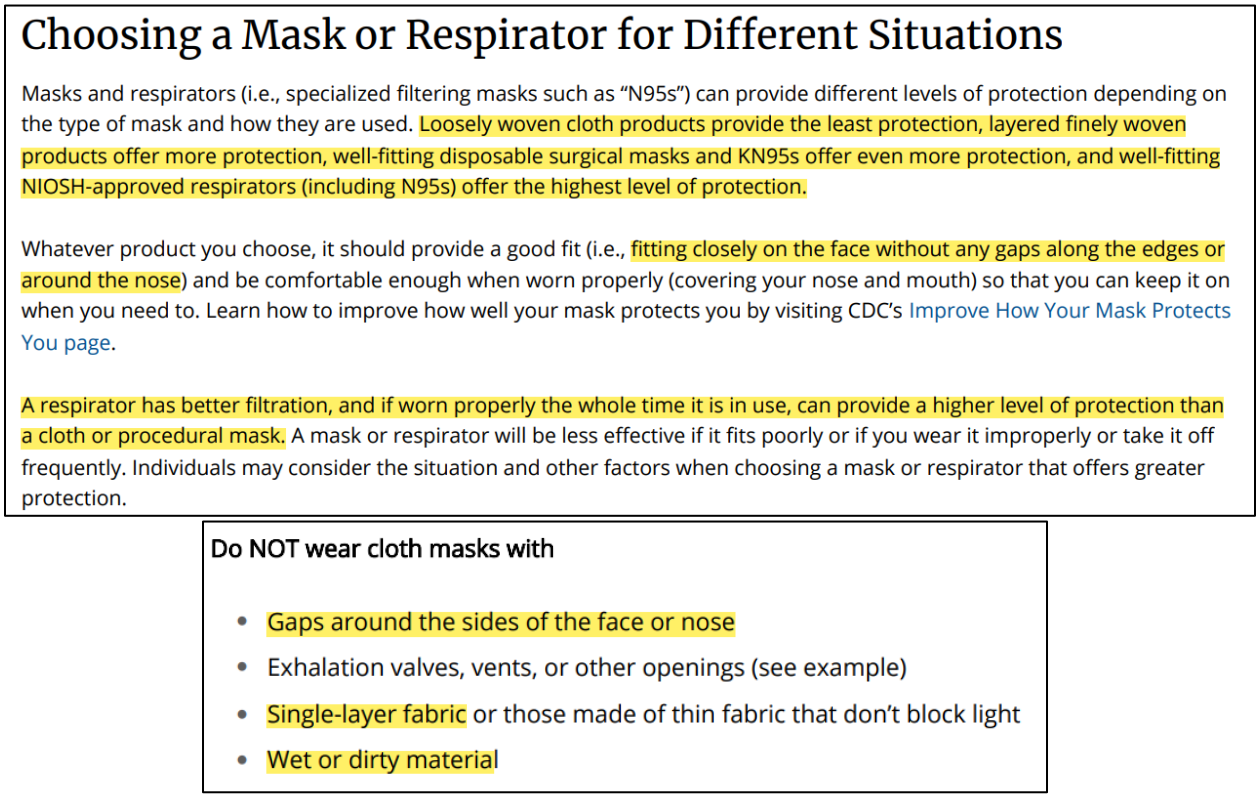
While the mask may contain droplets, they only do so for a period. As the masks are exposed to heat and moisture they suffer from degradation within a few hours.

We ask that the CDC immediately suspend misleading statements in all their public information that masks stop droplets when the vast majority of particles are smaller aerosols that stay suspended for days to weeks (vs. minutes for droplets), readily pass through gaps around the masks, and can reach deep into the lungs (see for example Fennelly, Kevin, P., 2020, Particle sizes of infectious aerosols: implications for infection control, Lancet Respir Med 2020; 8: 914–24).

Issue #4: CDC's position for masks used by the general public lacks proper scientific justification and creates potential harm based on a false sense of security:

Statements that a mask can provide protection are false and mislead the public into a false sense of security. Industrial Hygiene solutions seek a more than 90% relative risk reduction, and this publication continues to focus on the lowest form of non-protection that does not meet the least desirable mode of protection (PPE) in the Hierarchy of Controls with PPE. The September 9, 2020 guidance from AIHA illustrated this concept of the need for a super reduction in relative risk, not a minor one (https://aiha-assets.sfo2.digitaloceanspaces.com/AIHA/resources/Guidance-Documents/Reducing-the-Risk-of-COVID-19-using-Engineering-Controls-Guidance-Document.pdf - pg. 4).

Moreover, the CDC continues to provide guidance that gaps in masks can be eliminated; in the real world that never happens (Figure 28):



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.

Figure 28: CDC Guidance Suggesting Gaps in Masks Can be Eliminated

The CDC statement that masks should not be worn if gaps cannot be eliminated is meaningless because this cannot occur; only properly selected and fitted respirators can accomplish this.

Masks cannot ever obtain a perfect fit to the face and efficiencies of masks when worn in real world scenarios (day-long usage). When the mask has more than a 3% gap, it offers effectively zero protection (Figure 29):

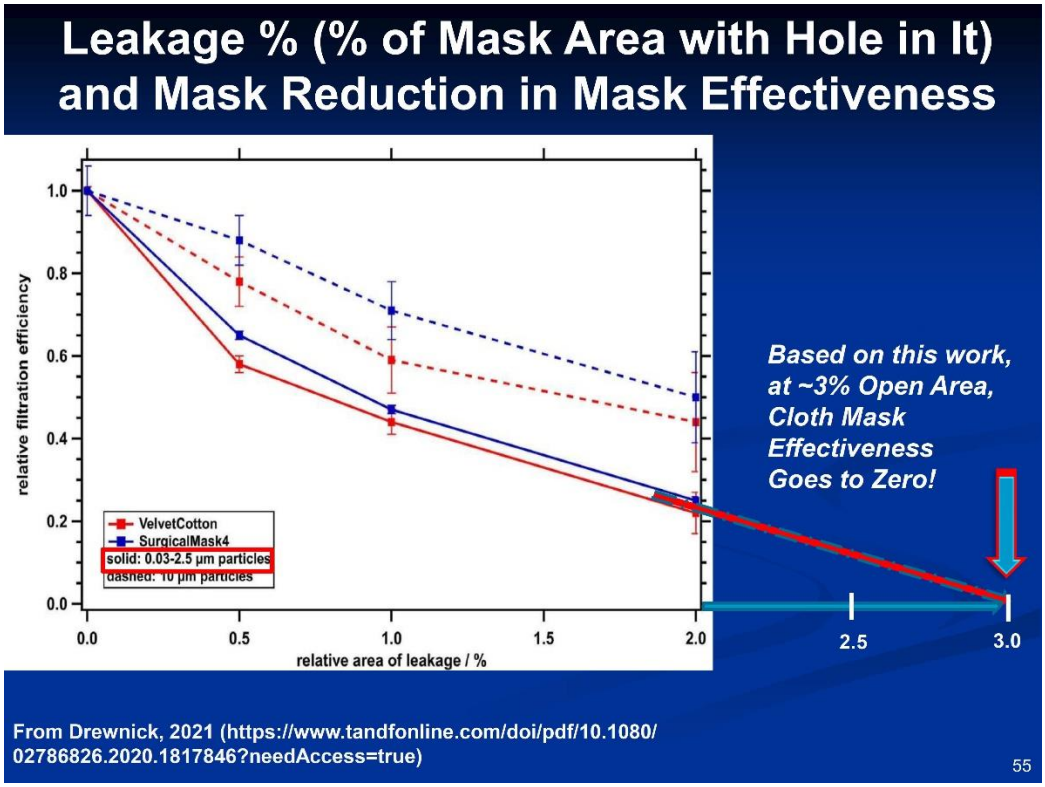


Figure 29: Loss of Mask Effectiveness in the Real World

Thus, the core issue with masks, and even respirators, is the seal – small gap areas effectively render these devices ineffective.

The American Society for Testing and Materials (ASTM) Standard Specification for Barrier Face Coverings F3502-21 Note 2 states, “There are currently no established methods for measuring outward leakage from a barrier face covering, medical mask, or respirator. Nothing in this standard addressed or implied a quantitative assessment of outward leakage and no claims can be made about the degree to which a barrier face covering reduces emission of human-generated particles.”

As well as, importantly, Note 5, “There are currently no specific accepted techniques that are available to measure outward leakage from a barrier face covering or other products. Thus, no claims may be made with respect to the degree of source control offered by the barrier face covering based on the leakage assessment.”

Every breath increases atmospheric viral load, or the amount of viral matter held aloft in an enclosed space. In instances when it does not take very much of an airborne pathogen for vulnerable individuals to get sick, a contagious individual should not wear a mask or respirator that creates a concentrated plume of aerosols, thinking they are protecting others from their respiratory emissions.

Explosive force-generating events, such as coughs and sneezes, increase the pressure behind exhaled matter. Masks can exacerbate the spread of airborne pathogens by creating focused plumes of fine particulates, in turn increasing emission trajectory, with the added concern of aerosolization of droplets through the mask membrane.

Finally, what is now most concerning, is that public entities are taking CDC guidance and making respirators available for free (Figure 30):

Figure 30: "Free" Open Contaminated N95s Being Given Away to the Public at Grocery Stores

These entities, based on CDC guidance, likely and/or unknowingly, do not address the requirements of the Respiratory Protection Standard and causing additional harm to the public by such a lack of understanding. Inevitably, this practice will result in harm and liability to their employees and customers for improper distribution and storage of respirators under the RPS.

Conclusion:

The CDC has built a series of recommendations for masking that are inconsistent with the technical and medical literature. The policy and procedural recommendations exaggerate the benefits, while ignoring the limitations and harms, especially for children and the general population. In addition, the CDC has taken a policy position of "it might work" and "it can't hurt" and use selective and weak observational data in the place of actual controlled scientific study to justify inappropriate recommendations for masks and face coverings.

Recently, the CDC has deployed a respiratory protection policy (i.e., masks to N95s) that dismisses the key principles in any Safety and Health program regarding the use of respirators – namely the Respiratory Protection Program. There is no mention of potential risks if the respirator is not properly used or fitted correctly. Moreover, it is clear that respirators are not intended for use with children. In our profession, if PPE and respiratory protection guidance was to ever be delivered without risk identification, fit testing, and training, we would be liable for putting personnel in a high-risk scenario, which is what the CDC is doing with their policy.

We would ask the CDC to accept these basic industrial hygiene facts that we have presented, update their public guidance accordingly regarding the issue of droplets vs. aerosols, stop confusing the public regarding the effectiveness of masks, and stop implying respirators are acceptable for children, and to be given generally to the public. In addition, it is clear the CDC knows, or should know, that gaps between the face and mask are a major problem for real mask effectiveness and could never have met our industry's requirement of 90% relative risk reduction.

The CDC is doing enormous damage to science and scientists by allowing politics to dictate public health policy rather than actual science. Increasingly, and for good reason as we have illustrated, the public does not trust the CDC and its science; this must change.

We recognize that it is easy to judge from afar and know that you and your team are under tremendous stress during this period. Our desire is to see the CDC and our country succeed in these efforts. As such, instead of just being critical, we want to offer our time to your organization to find solutions together. We would be willing to collaborate in the creation of a competent plan that will be based on the Hierarchy of Controls and will be tailored to various work and living environments. We will also help develop data points we can use to monitor and measure this program to enable proper adjustments as needed.

We look forward to your responses to our concerns as we continue to work to protect the public.

Sincerely:

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