Premier Risk Management

Integrity of Science Review in Current Mask Science

CONDUCTED ON:

Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE

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1. EXECUTIVE SUMMARY

Background

By this time, the World Health Organization (WHO) declared COVID-19 a worldwide pandemic, the virus causing SARS-CoV-2 was already spreading throughout the United States (U.S.). In response many in the public understandably assumed that “mask” use was an obvious response for protection from infection. But public health officials at the National Institute of Health (NIH) Director Anthony Fauci and then U.S. Surgeon General Jerome Adams and Center for Disease Control (CDC) Director Robert Redfield affirmed the long-standing science that masks are not considered respiratory protection and should not be considered for universal use in the public or a community.

Then on April 3, 2020, the before mentioned public health officials reversed their position by recommending universal mask use claiming new scientific evidence. This new evidence reportedly supports mask wearing in all aspects of public human interaction, plus many private, personal interactions. Masks, it was now claimed, would provide protection for the wearer, and would reduce infectious material from being spread in a community. Therefore, masks were prescribed for all.

This new claim surprised many in the exposure science field. Exposure science is an applied science that anticipates, recognizes, evaluates, controls, and confirms protection from hazards that may result in injury, illness, or affect the well-being of people. Members in the exposure science sector often serve as instructors to the health care industry on topics of exposure prevention methodologies such as ventilation, air filtration, ergonomics, proper personal protective equipment (PPE) use (such as masks), and respiratory protection.

These new claims for broad employment of masks surprised specialists in the exposure science sector because no such evidence had ever been previously discovered and these new claims had no existing published studies to support this new doctrine. Studies supporting these claims began to be posed in May of 2020, though without scrutiny from exposure scientists. It was as though an alloy had been proposed for all new bridge construction, though never used for such purpose, and without first consulting any experts in metallurgy.

Standards

This report reviews new mask science referenced by the before mentioned and current public health officials in their mask recommendations. We examine other criteria for assessing such research and we then apply those standards to this research to determine if it is being properly described and it possesses the same level of integrity with the extensive system of review that is typical in protective efforts before they are implemented in society. We further compare the efforts of the current study to identify, explore and answer the relevant questions of the new public policies of this universal public masking.

Significant Highlights

The study “Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE” was primarily authored by Amy Mueller and Loretta Fernandez, et. al., highlights those surgical masks removed 53% to 75% of particles and cloth masks ranged in particle removal efficiency from 28% to 91% when worn as designed. This is the study that begot the claim that a face mask will provide protection.

The research team evaded long standing scientific protocols to determine if a facepiece provides protection. Also, the research was conducted with equipment that was out of calibration and the research team omitted that fact in their published study. As such, by not adhering to established science and manipulating procedures, the claims made through the study “Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE”, should only be considered opinion based and not fact-based research.

2. UNIVERSAL PUBLIC MASKING

The point of the science at the CDC is to support the idea that everybody wearing masks is the correct policy. The premise for the presentation of published scientific papers on the CDC's website, is to support its recommendation of universal public masking in the form of cloth or homemade face masks. The studies displayed therein are the basis of government and private sector policy and guidelines regarding COVID-19 response strategies. Universal public masking is the keystone foundation point from which all supporting science should be built upon. As such, the first basic question must be asked; What happens in Universal Public Masking?

Answering that question reveals the components, obstacles, items, behaviors, and time frames that make up the whole equation of what is taking place in the real world setting of "universal public masking." We may not have a full scope understanding of every element of universal public masking, but we know at some point in the equation there are potentially infectious droplets that travel from our mouth to a barrier (mask). We also know at a minimum; universal public masking calls for extended amounts of time wearing a mask. We know that it involves children, infants, and adults, with differing physiologies and varying health conditions and work circumstances. It is primarily self-managed in a public society with varying biases and behaviors. A critically low level of contamination training and habits compared to professional mask wearers in healthcare and bio-lab environments.

In addition, unlike professionals who work in contamination protected environments with professionally manufactured and tested PPE, the public is encouraged to construct its own respiratory protection using generalized processes, and nonspecific material to try to achieve protection levels as near as possible to the professional grade tools. We rely on science to identify and explore all the inter-working components to provide us the net result of its function. This report seeks to examine how current science is fulfilling its role on this issue.

3. REVIEW METHODOLOGY

As a risk management firm, it is critical to know whether these claims of new science are true or not, so that we can render proper guidance to our clientele. To ensure there is consistency with long standing exposure sciences we are using known regulations, science, and procedures that have been used for several decades to protect personnel in the workplace. To ensure there's consistent understanding of our evaluation methodology the following baseline criteria shall be adhered to:

A. A review of the regulation 29 CFR § 1910.132 (Personal Protective Equipment). To ensure these legal requirements are met in the new mask studies.

B. A review of the regulation 29 CFR § 1910.134 (Respiratory Protection). To ensure these legal requirements are met in the new mask studies that deem a mask as a form of respiratory protection.

C. A review of studies in accordance with the Hierarchy of Controls to determine if there's contamination in the research with other higher level of controls in research that encompasses occupied environments in the research.

D. A comparison to the Hierarchy of Evidence to determine if the level of new research is comparative to long standing exposure sciences. Typically, research that is a Level two (2) or higher that shows attainment will be deployed for public use.

E. An examination of misuse of equipment, the inability to access data behind a "pay wall", limitation of the study statements from researchers, and other items that could spoil the claimed findings of the studies.

F. An assessment of how well the methodology and conclusions of the study related to and satisfied the components of universal public masking.

4. LEGAL REQUIREMENTS

As part of this evaluation, we have considered U.S. legal requirements. In particular, the Occupational, Safety, and Health Administration (OSHA) provides long-standing, science-based rules for safety equipment design and use. Namely, 29 CFR § 1910.132 (Personal Protective Equipment), 1910.134 (Respiratory Protection) serve as key references for this report.

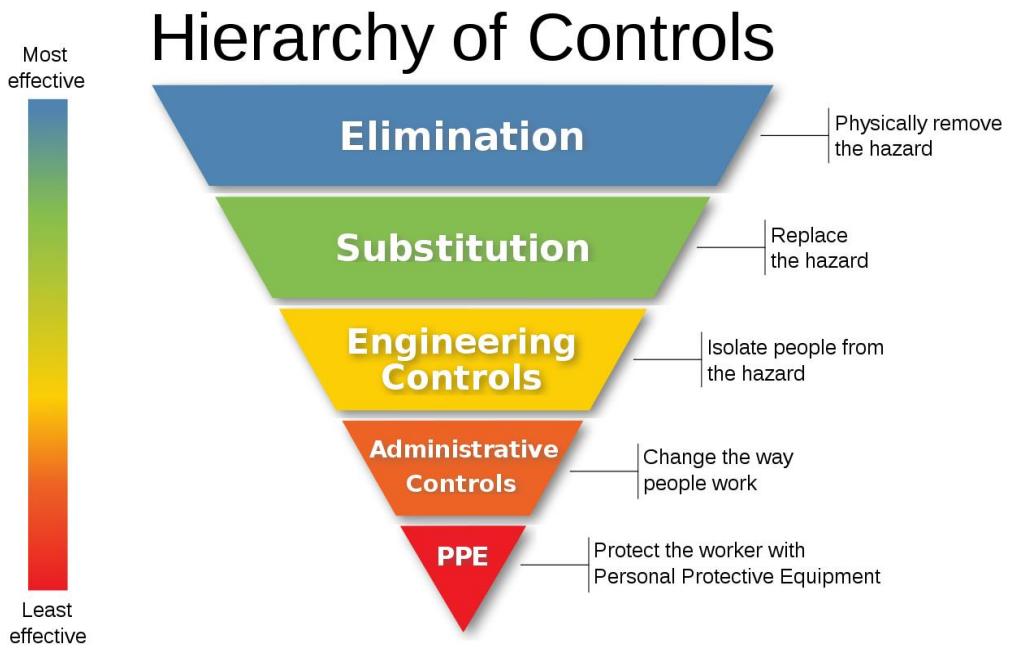
With that context, the focus of this report is an evaluation of the CDC's advice as outlined in their web pages "Considerations for Wearing Masks" and "Scientific Brief-Community Use of Cloth Masks". These pages are found on the CDC's website.

5. HIEARCHY OF CONTROLS

For any given exposure problem there exists a spectrum of mitigating options ranging from a solution that is "most effective" to one that might still be a solution, but it is likely to be least reliable and thus "less effective".

The National Institute for Occupational Safety and Health (NIOSH) has published exactly such a continuum, which is called the "Hierarchy of Controls" (NIOSH is the United States federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness).

The Hierarchy of Controls is a system used to implement effective controls within an organization, workplace, or community to identify the most effective ways to mitigate hazards. Within the inverted pyramid below the more effective controls are on the large, top side of the pyramid, whereas the least effective controls are on the bottom. Following this hierarchy normally leads to the implementation of inherently safer systems, where the risk of illness or injury has been substantially reduced.



Here is a brief description of each level of effectiveness – from most effective to least effective – within the Hierarchy of Controls model.

Elimination

Elimination is a hazard control strategy based on completely removing a material or process causing a hazard. Elimination is the most effective of the five members of the hierarchy of controls in protecting personnel, and where possible should be implemented before all other control methods.

Removing the use of a hazardous chemical is an example of elimination. Some substances are difficult or impossible to eliminate because they have unique properties necessary to the process, but it may be possible to instead substitute less hazardous versions of the substance. Elimination also applies to equipment as well. For example, noisy equipment can be removed from a room used for other purposes, or an unnecessary blade can be removed from a machine.

Substitution

Substitution is a hazard control strategy in which a material or process is replaced with another that is less hazardous. Substitution is the second most effective of the five (5) members of the hierarchy of hazard controls in protecting people, after elimination.

A common substitution is to replace a toxic chemical with a less toxic one. Some examples include replacing the solvent benzene, a carcinogen, with toluene; switching from organic solvents to water-based detergents; and replacing paints containing lead with those containing non-leaded pigments.

Engineering Controls

Engineering controls is the third of five (5) members of the hierarchy of controls, which orders control strategies by their feasibility and effectiveness. These are strategies designed to protect workers from hazardous conditions by placing a barrier between the person and the hazard or by removing a hazardous substance through air ventilation. Some examples of engineering controls are Heating, Ventilation, and Air Condition (HVAC) systems, area specific air ventilation systems, Ultraviolet (UV) air sanitation systems, specifically designed workspaces, machine guards, and physical barriers.

Administrative Controls

Administrative controls are the efforts to change the behavior of personnel to act safer. Within organizations, this is typically done through training, policies, procedures, and disciplinary action. Generally, administrative controls are cheaper to begin, but they may become more expensive over time as higher failure rates and the need for constant training or re-certification eclipse the initial investments of the three (3) more desirable hazard controls in the hierarchy.

PPE

The purpose of personal protective equipment (PPE) is to reduce human exposure to hazards when engineering controls and administrative controls are not feasible or effective to reduce these risks to acceptable levels. PPE is needed when there are hazards present. PPE has the serious limitation that it does not eliminate the hazard at the source and may result in personnel being exposed to the hazard if the equipment fails.

Examples of PPE use is protective clothing, helmets, eye and hand protection, or other garments or equipment designed to protect the wearer's body from injury or infection. The hazards addressed by protective equipment include physical, electrical, heat, chemicals, biohazards, and airborne particulate matter.

6. MASKS vs RESPIRATORS

Protecting oneself and others from a virus contamination has been a confusing matter for the public and for public health officials. In part, that confusion may stem from confusion about masks and respirators, especially N95 respirators.

In fact, many people now believe that an N95 respirator and a surgical mask belong in the same category. They do not! They are different tools for different jobs. Worse, that dangerous misunderstanding has been exacerbated by many of the mask studies conflate these vastly different forms of PPE in their research. Such errors horribly undermine any “scientific” results.

Briefly, here is the difference between masks and respirators, and why it matters:

Surgical masks are designed to keep rooms sterile, prevent germs from the mouth and nose of a wearer from contaminating the surrounding area, and is fluid resistant to splash and spatter of blood and other infectious material. Surgical masks are not designed to filter out viruses (which are smaller than germs) and are not designed for respiratory protection or long-term use since their constructive material will degrade with exposure to heat and moisture and there is a possibility for contamination.

The N95 is, in fact, not merely a mask but is a respirator. The N95 respirator is made of a fine mesh of synthetic polymer fibers, specifically a nonwoven polypropylene fabric. It is produced by melt blowing and forms the inner filtration layer that filters out hazardous particles. The following table explains what the letters and numbers mean in the respirator’s name. For example, an N95 respirator is non-oil resistant with 95% filter efficiency.

Filter Efficiency	**N (Non-Oil Environments)**	**R (Oil Resistant)**	**P (Oil Proof)**
95%	95	95	95
99%	99	99	99
99.97%	100	100	100

Respirators are designed to protect the wearer which is why the filter efficiency is so high. The air breathed out is not filtered and should be considered one-way protection. To properly use a respirator a medical evaluation and a “Fit Test” is required to ensure it is safe for the wearer to use a respirator and that there is a size match to the wearer’s face (29 CFR § 1910.134 App A). This is a critically important and is the only scientific methodology to determine a “Fit Factor”. The Fit Test enables the wearer to achieve maximum protection for which the respirator was designed.

It is also important to know that most N95s will degrade after two (2) to four (4) hours of use. The more heat and moisture the N95 respirator are exposed the faster the degradation. Especially harmful to the N95 respirator is the wearer’s heat and moisture which comes from the wearer’s breath in the form of Carbon Dioxide and droplets. Plus, additional moisture exposure will come from sweating or perspiration.

It is critical in examining masks to differentiate the abilities of respirators and masks. Then match the proper tool to the task. This is assuming that any sort of PPE is a safe last resort option. Please see CDC and NIOSH publication in Appendix G.

7. HIEARCHY OF EVIDENCE

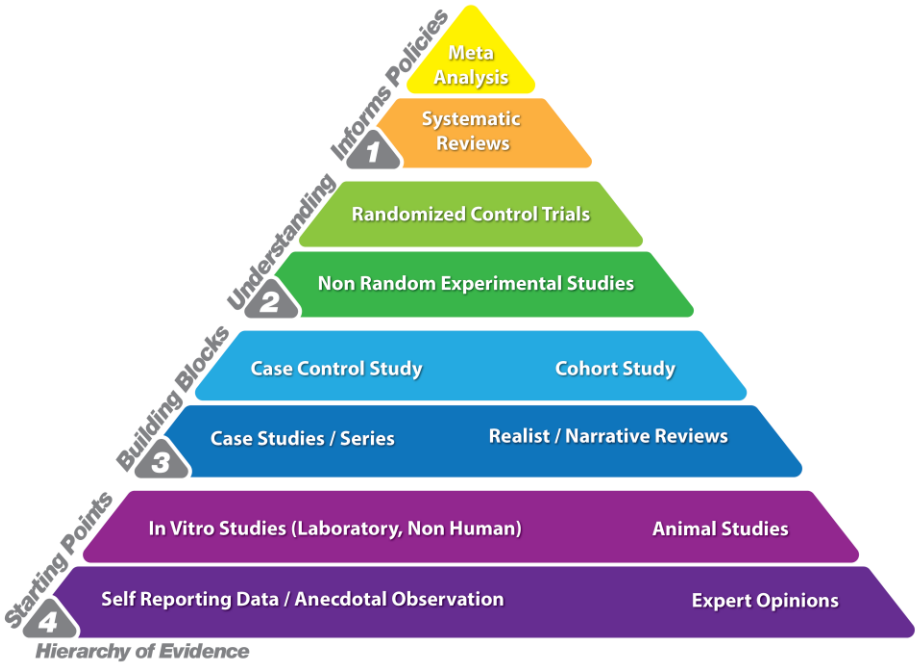
According to the NIH, several hierarchies of evidence have been developed to enable different research methods to be ranked according to the validity of their findings. However, most have focused on evaluation of the effectiveness of researched interventions. The development of such a hierarchy is for ranking of evidence. The aims of this hierarchy are twofold.

First, it is to provide a means by which the evidence from a range of methodologically different types of research can be graded. Second, it is to provide a logical framework that can be used during the development of systematic review protocols to help determine the study designs which can contribute valid evidence when the evaluation extends beyond effectiveness.

Since the Hierarchy of Evidence is not as specific as the Hierarchy of Controls, this version of the Hierarchy of Evidence was chosen as a simple means to demonstrate what category of scientific evidence each study falls under.

The proposed hierarchy was developed based on a review of literature, investigation of existing hierarchies and examination of the strengths and limitations of different research methods. It closely follows the typically accepted order of evidence-based hierarchies. The proposed hierarchy of evidence focuses on three (3) dimensions of the evaluation: effectiveness, appropriateness, and feasibility. Research that can contribute valid evidence to each is suggested with its levels. To address the varying strengths of different research designs, four (4) fundamental grades of value are inferred to align with each noted section: four (4) Poor, three (3) Fair, two (2) Good, and one (1) Excellent. This hierarchy proposes that there is a logical path from four (4) through one (1) to achieve the best science possible.

“Starting Points” progresses to “Building Blocks” which moves us into “Understanding” and finally evolving to a quality that “Informs Policies”. To support policies and scientific protocols, such a standard is built upon considerable rigor and direction inclusive of preceding data from many complimentary studies.



Level 1: Meta-Analysis

Meta-analysis is a research process used to systematically synthesize or merge the findings of single, independent studies, using statistical methods to calculate an overall or ‘absolute’ effect. Meta-analysis does not simply pool data from smaller studies to achieve a larger sample size. Analysts use well recognized, systematic methods to account for differences in sample size, variability in study approach and findings. Results can be duplicated by others.

Level 1: Systematic Reviews

A review of the evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research, and to extract and analyze data from the studies that are included in the review. The methods used must be reproducible and transparent.

Level 2: Randomized Control Trials

A study design that randomly assigns participants into an experimental group or a control group. As the study is conducted, the only expected difference between the control and experimental groups in a randomized controlled trial (RCT) is the outcome variable being studied. RCTs are quantitative,

comparative, controlled experiments in which investigators study two or more interventions in a series of individuals who receive them in random order.

Level 2: Non-Randomized Experimental Studies

These are studies that aim to evaluate interventions but that do not use randomization. Like randomized trials, these experiments aim to demonstrate causality between an intervention and an outcome. Non-randomized studies can use both preintervention and postintervention measurements as well as nonrandomly selected control groups.

Level 3: Case Control Study

A case-control study is usually a retrospective study that looks back in time to find the relative risk between a specific exposure and an outcome. A control group of people who do not have the disease or who did not experience the event is used for comparison. The goal is figure out the relationship between risk factors and disease or outcome and estimate the odds of an individual getting a disease or experiencing an event.

Level 3: Cohort Studies

Cohort studies can be retrospective or prospective. Retrospective cohort studies are NOT the same as case-control studies. In retrospective cohort studies, the exposure and outcomes have already happened. They are usually conducted on data that already exists (from prospective studies) and the exposures are defined before looking at the existing outcome data to see whether exposure to a risk factor is associated with a statistically significant difference in the outcome development rate.

Prospective cohort studies are more common. People are recruited into cohort studies regardless of their exposure or outcome status. This is one of their important strengths. People are often recruited because of their geographical area or occupation, and researchers can then measure and analyze a range of exposures and outcomes.

The study then follows these participants for a defined period to assess the proportion that develop the outcome/disease of interest. Cohort studies are good for assessing prognosis, risk factors and harm. The outcome measure in cohort studies is usually a risk ratio / relative risk.

Level 3: Case Studies / Series

A report based on a single patient or subject; sometimes collected into a short series of similar cases. Case Series or Reports that are an uncontrolled, observational, or descriptive study design involving an intervention and outcome with a detailed profile of the people and systems in play. Although limited in making causal inferences about the relationship between risk factors and an outcome of interest, they are helpful in developing a hypothesis that can be tested using an analytic study design.

Level 3: Realist / Narrative Reviews

A Realist Review provides an explanatory analysis aimed at discerning what works for whom, in what circumstances, in what respects and how. This is not a systemized data synthesis approach and may include many types of evidence, or varying quality. Narrative Reviews aim to identify several studies that describe a problem of interest. Narrative reviews have no predetermined research question or specified search strategy, only a topic of interest. They are not systematic and follow no specified protocol or level of scientific vigor that systematic reviews do; however narrative reviews are better suited to addressing a topic in wider ways.

Level 4: In Vitro Studies (Laboratory, Non-Human)

In vitro methods used in a laboratory can often include things like studying bacterial, animal, or human cells in culture. Although this can provide a controlled environment for an experiment, it occurs outside of a living organism and results must be considered carefully. The key components of In Vitro experiments are a controlled environment, adjustable variables, and no human involvement in the mechanics of an experiment.

Level 4: Animal Studies

It is important to realize that animal models are indeed just models. They often cannot fully represent or copy the human condition. But the animal model will often provide relevant information where the genetics and molecular pathways are similar. One should also realize that the alternatives in the form of cell cultures or more complex alternatives such as organoids or organs on a chip are also just models. They also have their limitations and the questions that one can answer with them are often more limited.

Level 4: Expert Opinion

The opinions of experts are based not only on their personal clinical experiences, but also on their accumulated knowledge from a wide range of sources. These include the expert's personal assessment of the validity of published reports, new knowledge learned at meetings and symposia, awareness of unpublished studies with "negative" results, and knowledge of the (often unreported) practice styles of colleagues in their field of expertise.

Level 4: Self-Reporting Data / Anecdotal Observations

Information collected from survey or self-reporting is highly subject to a number of biases, some of which effect recall accuracy, understanding, interpretation of expectations, and effect of circumstances. For example, answering yes to a question which triggers consequences they would rather avoid. Anecdotal observation may be the initial testing or sampling of an idea or process. It could be considered the first impression, or what seems apparent at the onset.

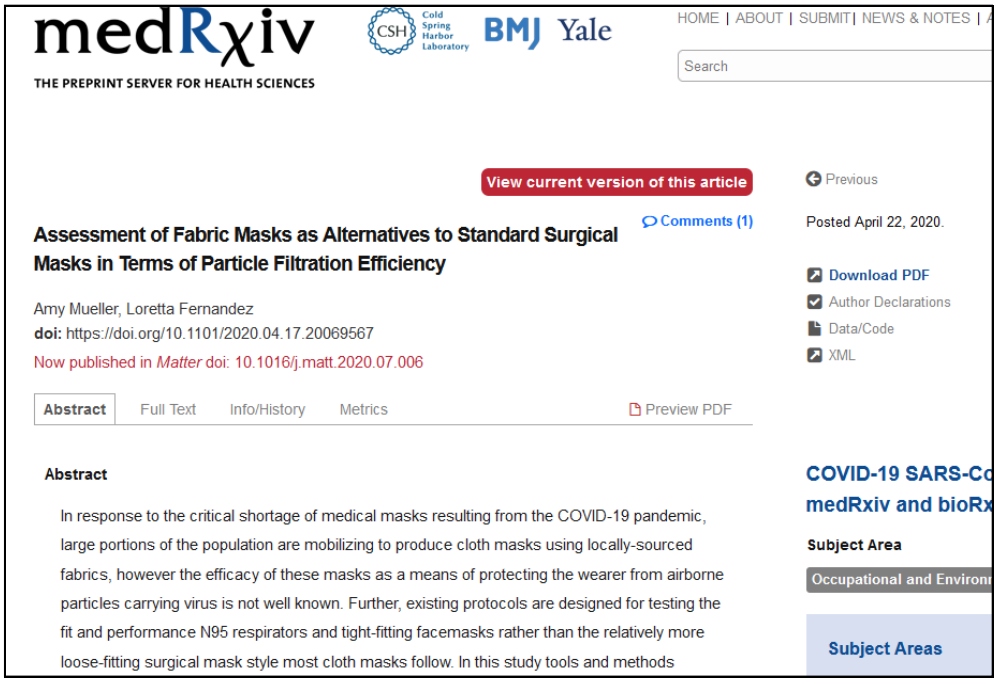
8. REVIEW FINDINGS

Finding #1: The Portacounts were not calibrated before the study (preprint published on MedRxiv April 22, 2020). The researchers did daily calculations as their version of calibration quality control. However, this introduces human subjectivity to the quality of the research and reduces the quality of the study. In addition, this fact was omitted from the published study. Evidence is found in Appendix A.

> ***Calibration***. Two PortaCount Plus instruments were used to report particle counts in air sampled from inside the mask (Mask PortaCount) and ambient air just outside the mask (Reference PortaCount) (Figure 1). Because these instruments were not recently calibrated, nor last calibrated at the same time, an inter-calibration was conducted to allow calibration adjustments on collected data. Each sampling day, calibration data (a minimum of three one-minute time series, n=180) were collected by recording readings simultaneously on both instruments while sample tubes were side-by-side (within 3 cm), open to the air (no mask), and a minimum of 1m from any person and 2m from the particle generator (as recommended by the manufacturer). The Mask PortaCount consistently reported higher particle counts; however, correlation coefficient between the readings from the two instruments was consistently above 0.9. Therefore day-specific linear regressions were used to normalize particle counts from the Reference PortaCount to equivalent particle counts from the Mask PortaCount.

Finding #2: The research team changed the original preprint title of this study. A significant difference in the original preprint and the preprint utilized by the research team (which became the official study name) was that the initial admission of the Portacounts being out of calibration was removed and no further indication of this limitation was mentioned in the official preprint and published study. Evidence is found in Appendices A, B, and C.

Original Preprint from April 22, 2020



Utilized Preprint from May 18, 2020

Finding #3: The study was striving to discover other mask options for the public to use to supplement the need for an N95 respirator. As such 29 CFR § 1910.134 App A clearly defines a long proven scientific method to make this determination. The study did mention this regulatory standard but instead misused the Portacounts by setting them to the particulate "count" setting instead of the "fit test" setting. They did not follow this long-standing scientific process. Evidence is found in Appendices C, D, and E.

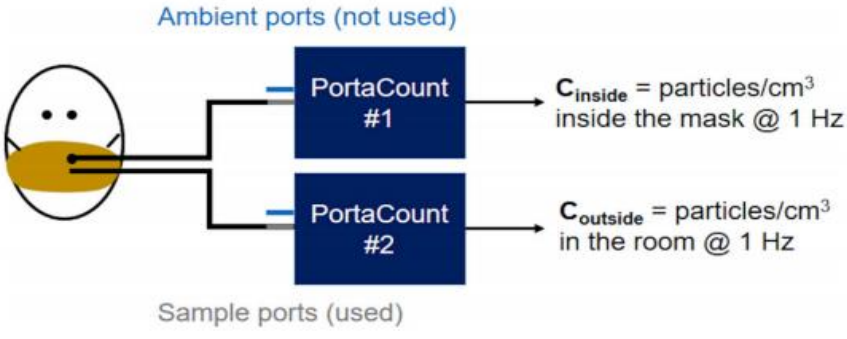


Figure 1. Schematic Diagram of Testing Setup
Test setup has two PortaCount systems running in parallel; 1/8" diameter tubing of identical length connects (top) the mask port to one instrument sampling port and (bottom) a tube inlet located just outside the mask to the second instrument sampling port. Both instruments are run in "Count" mode whereby concentrations are reported once per second (1 Hz). The dual-instrument configuration is required because each instrument has only one internal measurement cell, for which the input is swapped between the sampling and ambient inputs during standard fit testing. Photograph of PortaCounts used, including ports and tubing, is provided in Figure S1.

Finding #4: To determine a fit factor the respiratory protective device is required to be tested against real world scenarios of body movement (29 CFR § 1910.134 App A "Section 14. Test Exercises"). This study decided that because of social distancing practices this was not necessary, and they had their single test subject not move her head, not breathe out of her mouth, and to only breathe from her nose. It is assumed that the researchers presumed that people in public would not move their heads and talk while wearing a mask. Evidence is found in Appendices C, D, and E.

an initial set of commercial and homemade masks, although results from ongoing tests are being updated regularly at a public web portal as additional prototype masks are evaluated (see Supplemental Information). Given the limited time and current social distancing precautions, all tests were conducted while masks were being worn by the same subject, breathing normally, through the nose, with the mouth closed, while holding the head at a steady position. Data reported by van der Sande et al.[11] provide confidence that limitation of motions and positions does not significantly limit the conclusions that can be drawn from the resulting data, and results from a single test subject are used here primarily to validate the protocol itself.

Finding #5: The masks had to be manipulated and a nylon layer was used to obtain a performance suitable to justify mask use. 29 CFR § 1910.132(c) Design. "All personal protective equipment shall be of safe design and construction for the work to be performed". Evidence is found in Appendices C and F.

Finding #6: The research team used several types of masks and used different methods to achieve high levels of filter efficiency. However, each mask with a protocol for proper use to achieve high filter efficiency was not produced. There was no documented method to deliver to the public to properly fulfill the opportunity for the mask to provide protection in real world settings. 29 CFR § 1910.132(c) Design. "All personal protective equipment shall be of safe design and construction for the work to be performed". The researchers did make mention of this regulatory standard but did not properly apply its requirement. Evidence is found in Appendices C and F.

Finding #7: A risk analysis was not conducted to validate the introduction to new masks and using properly designed masks outside of their scope of design. 29 CFR § 1910.132(c) Design. “All personal protective equipment shall be of safe design and construction for the work to be performed”. 29 CFR § 1910.132(f)(1)(iv) Each such employee shall be trained to know “The limitations of the PPE”. Evidence is found in Appendices C and F.

Finding #8: The study used 1 test subject and not another sized person to determine results that would represent small, medium, large mask wearers - 29 CFR § 1910.134(f)(2). Evidence is found in Appendices C, D, and E.

Finding #9: As stated in the title of this study, the researchers were attempting to find an alternative to masks for the public to use for PPE. As such they made no mention of the need for people to have a medical evaluation before using respiratory devices that can achieve a high level of filter efficiency. 29 CFR § 1910.134(e) Medical evaluation. “Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee's ability to use a respirator”. The researchers did make mention of this regulatory standard but did not properly apply its requirement. Evidence is found in Appendices C and D.

Finding #10: The fact that the equipment was not calibrated, the researchers mentioned but did not follow 29 CFR § 1910.134 App A and 29 CFR § 1910.132(c) and manipulated the methodology of their research, his study falls to the level four (4) “Expert Opinion” in the Hierarchy of Evidence. This is due to the appearance of deliberate missteps to achieve a desired outcome of results instead of factual scientific data. See section 7.0 “Hierarchy of Evidence”.

9. IN-STUDY LIMITATIONS REPORTED

No limitations acknowledged by authors.

10. DISCUSSION

The “Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE” study has been used in the media and other publications to make the false claim that face masks provide protection (see Appendix E). This must be rescinded and corrected for the public to make appropriate decisions for their reasoning in mask use.

The methodology used to achieve filtration efficiency relied solely on one adult test subject, who breathed only through the nose with her mouth shut for the duration of each timed session. This renders void any correlation or application of its conclusions to the real world. Clearly then, it cannot continue its current role as support of societal policies that effect the functioning world.

In addition, the study made mention of 29 CFR § 1910.134 but made no effort to apply the requirements in the regulation. The research team did not provide a safe alternative for the public to use a mask as PPE by not applying the before mentioned safety regulation and no protocol for properly using the mask to obtain a high efficiency fit.

More critically the researchers omitted the fact that their Portacounts were not calibrated in the published report of this study. This team lacked critical integrity to provide valid data for the public to use to protect from COVID-19 virus contamination. Because of these facts to their defective research, it leaves the appearance that the researchers intentionally set out to achieve a preferred result which would align with unqualified opinions of the medical science community. This is the lowest form of research in the Hierarchy of Evidence and in no way carries the capability of being used in a real-world setting.

Finally, the overall response to the pandemic would have better served the public by teaching the Hierarchy of Controls and help invest in those forms of controls such as improving HVAC systems (Engineering Control) and keep businesses open. Teaching this base form of exposure prevention efforts would have enabled the public with the proper way of prioritizing their efforts of protection.

11. CONCLUSION

This study has been used by members in the medical industry to stipulate that a face mask (not a respirator) can achieve a "fit factor" and protects the wearer. This research included a review of the published paper of the research along with the original report that had some important information that was omitted from the final paper.

Not only was this study unnecessary because we already have the science and methods to determine if a face covering can be qualified as a respiratory protective piece, but this study significantly lowered the bar of standards the exposure science industry has long adhered to.

This study encourages an uninformed, untrained public to engage in indiscriminate PPE construction and use, to attempt in achieving what is believe greater protection for themselves or their children, by means of any process or materials their imagination conjures.

This study did not follow OSHA regulations to determine protection, proper use, or if their new guidelines for mask use were even safe. This is an example of evidence from the lowest form research in the hierarchy of evidence and should be removed from all reputable sources for scientific guidance.

Finally, the CDC and publications must retract the claim that face masks protect the wearer. This study was that claim's foundation and the fact that this mask study is voided, that claim of masks protecting the wearer too must be annulled and communicated to the public. This is due to the large amount of media attention this invalid research received (see Appendix H).

Sincerely,

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12. ACKNOWLEDGEMENTS

Funding for this report was provided by Premier Risk Management (PRM). Mr. David Howard (founder of PRM) played an intricate role in supporting this effort to investigate the new mask recommendations from the CDC. Mr. Doran Peck was the data and research analyst on this project. Special thanks for his volunteered time to accumulate and review information needed to prepare this report.

Appendix A
(Pre-Published Study Report)

Assessment of Fabric Masks as Alternatives to Standard Surgical Masks in Terms of Particle Filtration Efficiency

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Abstract

In response to the critical shortage of medical masks resulting from the COVID-19 pandemic, large portions of the population are mobilizing to produce cloth masks using locally-sourced fabrics, however the efficacy of these masks as a means of protecting the wearer from airborne particles carrying virus is not well known. Further, existing protocols are designed for testing the fit and performance N95 respirators and tight-fitting facemasks rather than the relatively more loose-fitting surgical mask style most cloth masks follow. In this study tools and methods typically used to assess tight-fitting facemasks were modified to assess the efficacy of community-produced fabric and commercially-produced surgical masks in terms of protecting the wearer from airborne particles that may be carrying virus. Two TSI PortaCount (model 8028) instruments were operated concurrently to collect particle counts (particles/cm^3) in size range 0.02 to >1 µm from ambient air and air just inside the breathing zone of the mask (1 measurement per second, evaluation period of 1 minute per test). Percent particle removal was determined for ten home-made, fabric masks of different designs, with and without filter layers, as well as three commercially-produced surgical-type masks. N95 masks were used to validate the method, and a 3M model 1826 surgical mask was used as a baseline for comparison of other masks of this style. Home-made masks worn as designed always had lower particle removal rates than the 3M masks, achieving between 38% and 96% of this baseline. As has been previously observed by Cooper et al. (1983), adding a layer of nylon stocking over the masks minimized the flow of air around the edges of the masks and improved particle filtration efficiency for all masks, including all commercial products tested. Use of a nylon stocking overlayer brought the particle filtration efficiency for five of the ten fabric masks above the 3M surgical mask baseline. This rapid testing method (<2 hours per mask design) provides a holistic evaluation of mask particle removal efficacy (material, design, and fit), and use of this method for testing a wider range of mask materials and designs will provide the public and health care providers with information needed to optimize health protection given resources at hand.

1. Introduction

In response to the critical shortage of medical masks resulting from the COVID-19 pandemic, large portions of the population are mobilizing to produce cloth masks using locally-sourced fabrics. While the general population is being advised to wear masks to protect others from virus that may be spread from the wearer, the efficacy of these masks as a means of protecting the wearer from airborne particles carrying virus is also a concern, particularly as medical masks grow scarce. This issue may become more critical if it becomes necessary for medical care workers to use similar alternative personal protective equipment.

The effectiveness of cloth masks to protect wearers from airborne particles, when studied previously, has been shown to be a function of both materials and fit. Anticipating the need to produce face coverings from readily-available materials, several studies used standard methods for materials testing to compare the filtration efficiency of materials such as cotton t-shirts, sweatshirts, handkerchiefs, and towels with the filtration efficiency of facepiece respirators (N95 masks) and surgical masks (Cooper et al. 1983a; OSHA 1998; van der Sande et al. 2008; Rengasamy et al. 2010; ASTM 2017b; a; 2019a; b). While none of these materials produced filtration efficiency close to respirators such as N95s, cotton cloth facemasks were found to provide about half the protection of standard surgical masks against airborne particles (van der Sande et al. 2008), while an elastic layer (e.g., nylon stocking) placed over the mask material was found to improve filtration efficiency of loose-fitting masks by minimizing air flow around the cloth layers (Cooper

et al. 1983b).

Standard methods to test the fit and performance of respirators and masks designed to form a seal against the face, such as N95 masks and respirators used by firefighters, employ instruments that can concurrently count particles in air inside and outside of the masks while the subject moves his/her head through a series of positions (OSHA 1998). Several instruments have been specifically designed to perform fit tests of respirators and tight-sealing facemasks (e.g., TSI PortaCount). These tools and methods have been modified in the past to collect particle filtration data for loose-fitting, surgical type masks (van der Sande et al. 2008), revealing that head motions and positions do not significantly affect the performance of loose-fitting masks in terms of filtering out nano-sized particles. This suggests that a simplified mask testing protocol for loose-fitting masks can provide a representative measure of particle filtration efficacy, something critically needed given the highly varied results and protocol shortcomings noted in prior studies (Brosseau and Sietsema, 2020).

The purpose of this work was to develop a standardized method to compare the efficacy of sewn fabric facemasks (produced using a variety of patterns and materials) to standard surgical masks in terms of protecting the wearer from airborne particulates of the size range expected to carry viruses. By collecting data on the counts of particles (0.02 to >1 μm) from both sides of the mask while it is being worn, both the material and the fit of the masks are tested simultaneously, and a simplified protocol enables testing of a novel mask design within <2 hours. These tests provide a rapid screening tool to test a variety of mask designs produced from readily-available materials. By conducting separate tests for masks worn loosely (as designed) and for the masks held close to the face using a layer of nylon stocking (as recommended by (Cooper et al. 1983b)), this work also allows for separate evaluation of the combined effect of mask fit and materials on overall filtration efficiency versus the efficiency of the materials alone.

This manuscript reports data collected from an initial set of commercial and homemade masks, however results will be updated regularly as data from additional prototype masks are collected.

2. Materials and Methods

Masks. To date, tests have been run on three commercially-produced, medical-type facemasks (masks with elastic ear loops and in-sewn wires to adjust fit to the bridge of the nose), and ten sewn, multi-ply cotton fabric facemasks of various designs (Table 1). Masks were sourced from community volunteers currently producing masks for essential personnel working in human services; when possible multiple masks of each type were tested. Several of the fabric masks included filter layers such as cotton batting, Halyard H600 (sterilization wrap), and sections of HEPA vacuum bags. In addition, several sewn masks included hydrophobic interfacing layers (Pellon). Some masks included wires to fit the masks across the bridge of the nose (Table 1: 3M, Staple, Charcoal, and Sewn Fabric Masks B and C); some did not (Table 1: Sewn Fabric Masks A and D – J). Three N95 masks (3M model 1860) were also tested to confirm that >95% particle removal could be measured using the modified protocol.

Particles. All tests were run in a 65 m^3 rectangular room after at least 15 minutes of operating a TSI Particle Generator Model 8026 (TSI Incorporated, Shoreview, MN, USA). This tool is typically used in conjunction with TSI PortaCount instruments to ensure high enough particle counts and size distributions to meet OSHA standards. Particles were generated from a dilute (2%) solution of sodium chloride (NaCl) and were expected to have a nominal size of 0.04 μm with a geometric standard deviation of 2.2 based on instrument specifications.

Particle counters. Particles in ambient air and air inside of the masks were simultaneously counted using two PortaCount Plus Model 8028 instruments running in count mode. The PortaCount Plus instruments use condensation particle counters (CPCs), which nucleate alcohol droplets from the smaller sampled particles. The larger alcohol droplets can then be counted using a light scatter detector (consisting of pumps to control flow rate, a laser, focusing elements, and a photodetector). Each PortaCount samples at a flow rate of 1.67 cm^3/s and reports the number of particles per cubic centimeter, P, of air sampled each second as

$$P = \frac{N}{(1\ s)\ 1.67\ cm^3/_s} \quad (1)$$

where *N* is the number of particles counted by the CPC. Data on the particle size distribution for particulates measured by the PortaCounts are not available, however, ~90% of the particles detected were produced by the TSI Particle Generator as described above.

Mask fit testing is usually conducted using a single instrument in fit test mode, which sequentially tests air inside and outside the mask. Here in order to collect and display continuous data for ambient air and inside mask air at high frequency during minute-long tests, two PortaCount instruments were used. Two tubes of equal length sample air just inside and outside of each mask. Air inside the mask was sampled through a tight-fitting grommet inserted into each mask and positioned at the philtrum of the upper lip. Ambient air was sampled from a position ~3 cm from the grommet on the outside of the mask. All tests were conducted while masks were being worn by the same subject, breathing normally, through the nose, with the mouth closed, while holding the head at a steady position. Tests using multiple subjects, motions, and positions were not feasible given the limited time and social distancing precautions, however prior research results (van der Sande et al. 2008) provide confidence that limitation of motions and positions does not significantly limit the conclusions that can be drawn from the resulting data.

Table 1. Information on commercially fabricated and sewn fabric masks used in this work.

Sample	Description	Number of masks tested
3M	3M 1826 surgical mask. 3-ply nonwoven material with nose wire and ear loops.	3
Staples	Medical/Dental masks purchased from Staples Online. No product number available. Specification sheet indicates 3-ply polypropylene. Includes a nose wire and ear loops.	3
Charcoal	Charcoal filter mask with no brand/producer information available. 3-ply nonwoven material with 1-ply charcoal/polymer nonwoven filter and nose wire and ear loops.	3
Sewn Fabric Mask A	2-ply cotton pocket with replaceable organic cotton batting filter. 21 cm ×10 cm rectangular pocket without pleats and with elastic ear loops.	1
Sewn Fabric Mask B	2-ply cotton with organic cotton batting with nose wire and elastic ear loops. Constructed from approx. 21 cm × 13 cm rectangle (finished size) gathered to 9 cm on short edge.	1
Sewn Fabric Mask C	2-ply cotton with nose wire and elastic ear loops. Constructed from approx. 21 cm × 13 cm rectangle (finished size) gathered to 9 cm on short edge.	1
Sewn Fabric Mask D	2-ply cotton with Pellon interfacing with elastic ear loops. Constructed from 25 cm × 20 cm rectangular layers, pleated at the short edges to 8 cm, with 22 cm elastic ear loops sewn through the pleated edge.	4
Sewn Fabric Mask E	2-ply cotton with elastic ear loops. Finished size 20 cm × 16 cm rectangle gathered to 10 cm on short edge.	3
Sewn Fabric Mask F	2-layer cotton with vacuum cleaner bag section as filter insert with elastic ear loops. Made using the Gather Here Fabric Face Mask pattern (https://drive.google.com/file/d/1zpagdPA89kHFfV2YZzfejyDIN95mTvG8/view)	1
Sewn Fabric Mask G	2-layer cotton with Halyard H600 filter insert with elastic ear loops. Made using the Gather Here Fabric Face Mask pattern (https://drive.google.com/file/d/1zpagdPA89kHFfV2YZzfejyDIN95mTvG8/view)	1
Sewn Fabric Mask H	2-layer cotton pocket without insert with elastic ear loops. Made using the Gather Here Fabric Face Mask pattern (https://drive.google.com/file/d/1zpagdPA89kHFfV2YZzfejyDIN95mTvG8/view)	1
Sewn Fabric Mask I	2-ply cotton pocket without filter and with elastic ear loops. Finished size 17 cm × 16 cm gathered to 7 cm on short edge.	1
Sewn Fabric Mask J	Cotton and 2-ply cotton muslin pocket without filter and with elastic ear loops. Finished size 21 cm × 16 cm pleated to 7 cm along short edge.	1

Calibration. Two PortaCount Plus instruments were used to report particle counts in air sampled from inside the mask (Mask PortaCount) and ambient air just outside the mask (Reference PortaCount) (Figure 1). Because these instruments were not recently calibrated, nor last calibrated at the same time, an inter-calibration was conducted to allow calibration adjustments on collected data. Each sampling day, calibration data (a minimum of three one-minute time series, n=180) were collected by recording readings simultaneously on both instruments while sample tubes were side-by-side (within 3 cm), open to the air (no mask), and a minimum of 1m from any person and 2m from the particle generator (as recommended by the manufacturer). The Mask PortaCount consistently reported higher particle counts; however, correlation coefficient between the readings from the two instruments was consistently above 0.9. Therefore day-specific linear regressions were used to normalize particle counts from the Reference PortaCount to equivalent particle counts from the Mask PortaCount.

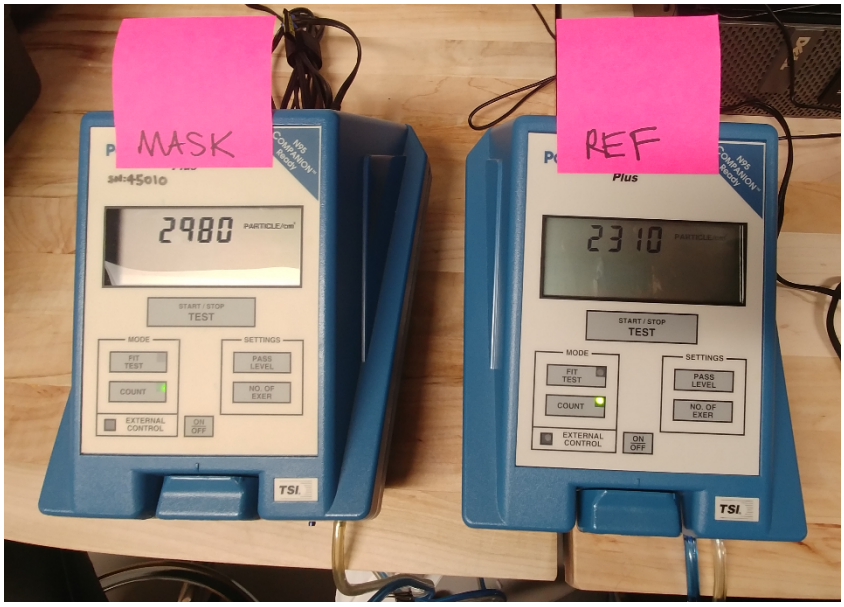

Figure 1. Testing set up included two TSI PortaCount Plus Model 8028 instruments sampling concurrently in Count Mode. The PortaCount labeled "Mask" was used to sample air inside the masks, while the PortaCount labeled "Ref" was used to sample air just outside the mask.

Data collection and processing. Each mask test consisted of three one-minute runs while wearing the mask as designed (Figure 2(a)). To simulate a face-hugging fit like that used for N95 masks, each mask was also tested for one minute while pressing the material to the face around the breathing zone (across the bridge of nose, cheeks, and around the chin) using two hands. In addition, a more practical method of holding the mask material against the face was tested by adding section of nylon stocking over the entire mask area following recommendations from Copper et al. (1983a) (Figure 2(b)). The N95 was not tested using either of these additional methods as this is already a tight-fitting mask. Tests were run on at least three replicate sample masks whenever possible, however for many masks only one sample was available.

Particle concentration data from inside and outside the mask was logged each second for the one minute tests using video capture and subsequently transcribed to a database. Particle removal at each time step was then calculated as follows:

$$\%particle\ removal = \frac{P_{outside} - P_{inside}}{P_{outside}} \times 100 \qquad (2)$$

where $P_{outside}$ is the corrected reading from the Reference PortaCount (as described above). The average and standard deviation for particle removal over each one-minute test were then computed. Changes in particle removal due to alternative test configurations (i.e., pressing around the breathing zone, addition of nylon stocking layer) were also computed to compare "as designed" fit performance with "optimized" fit. Finally performance metrics for all masks were calculated in reference to the 3M brand 1826 Standard Ear Loop Masks.

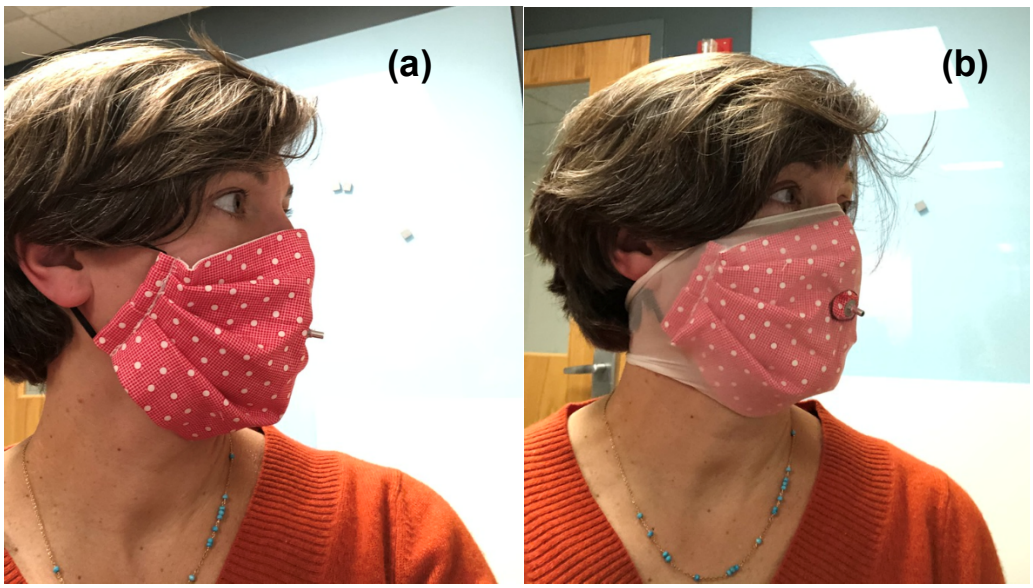

Figure 2. Facemask (Mask D) worn as designed **(a)** and with a nylon stocking layer **(b)** with tightly-sealed grommet positioned at the philtrum of the upper lip. The grommet is used to sample air from inside the mask during testing.

3. Results and Discussion

The percent removal of particles ranging from 0.02 μm to >1 μm for each mask was computed from data collected each second over one minute runs (example for one run for one mask provided in Figure 3). Particles generated through breathing can be observed as oscillations in the "inside mask" data both for tested surgical-style masks (Figure 3) and in tests of the N95 masks (Figure 4).

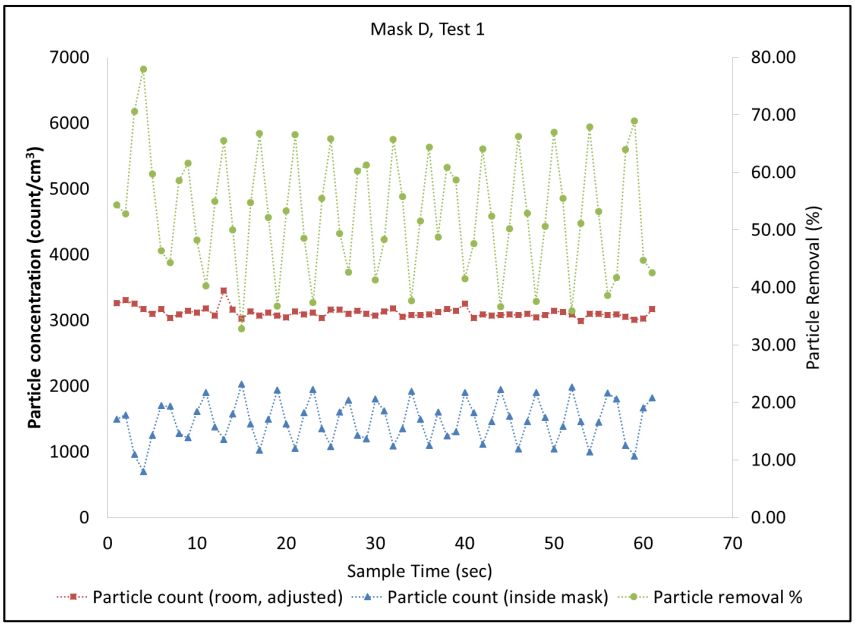

Figure 3. Particle concentrations in room (red squares) and inside mask (blue triangles) with removal percentage (green circles) vs. time for the first one-minute test of Mask D (worn as designed).

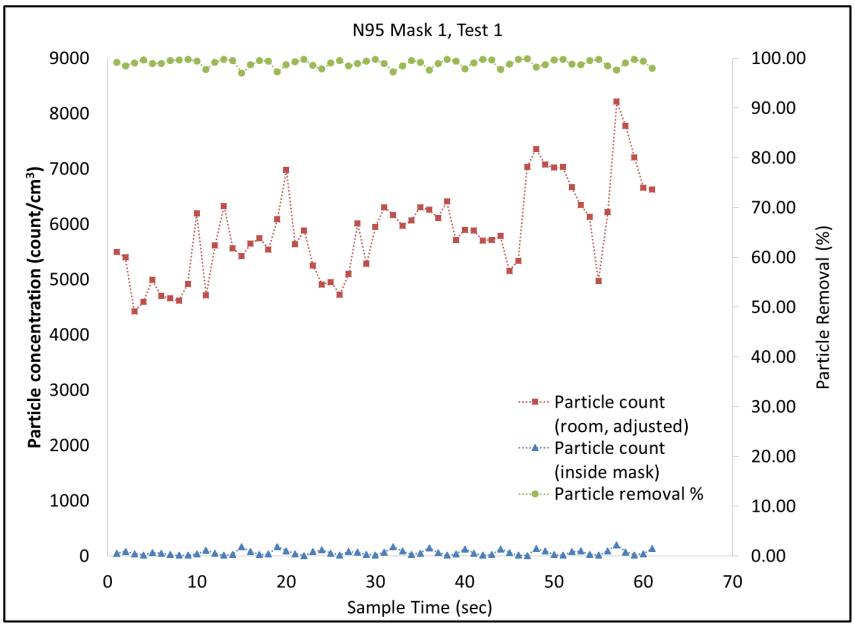

Figure 4. Particle concentrations in room (red squares) and inside mask (blue triangles) with removal percentage (green circles) vs. time for the first one-minute test of an N95 mask. Particles inside the mask appear to increase while the wearer exhales.

Average particle removal efficiency (as % removal) and standard deviation over the one-minute tests were computed for each mask with and without a nylon stocking layer (Figure 5). As expected, the removal efficiency for the tight-fitting N95 mask is greater than 99%. The standard medical-type masks (3M brand), when worn over the chin and with an adjusted nose wire, had a mean removal efficiency of 75%. With the exception of the Charcoal Air Pollution facemask and Sewn Mask J, which came close to this removal efficiency, all other masks achieved removal efficiencies of less than 60% when worn as loose-fitting masks.

The addition of a nylon stocking overlayer improved the removal efficiency for all loose-fitting masks, including commercial medical-type masks, providing similar or better results to the “N95-like” fit imitated using the wearer’s hands. The stocking layer also reduced the variability with time as indicated by a decrease in the time-based standard deviation. Both of these metrics indicate improved protection for the wearer from particle inhalation.

Using the 3M masks worn as designed as a baseline, the addition of the stocking layer improves the particle removal efficiency of several of the masks to match or exceed this baseline (Figure 6). The masks that achieved this level of filtration using the stocking layer each included a filter layer in addition to two layers of cotton fabric. These filters included organic cotton batting, both lightweight and heavier interfacing (Pellon), a section of vacuum cleaner bag, and loosely-woven cotton muslin. However, on closer inspection, the vacuum cleaner bag included a health warning indicating that it contained carcinogens and teratogens, so these types of filters would not be suitable for facemasks. Interestingly, a single layer of Halyard H600 surgical wrapping as a filter insert in Mask G did not result in particle removal efficiency matching a standard medical facemask even when fit was controlled using a stocking layer.

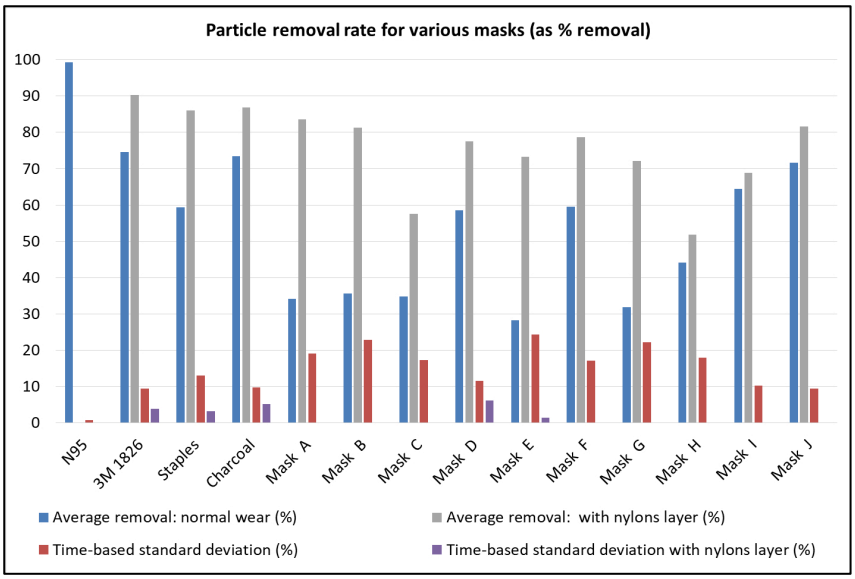

Figure 5. Average particle removal efficiency and time-based standard deviation for each mask type, with (gray bar) and without (blue bar) nylon stocking layer to form a tight seal with face.

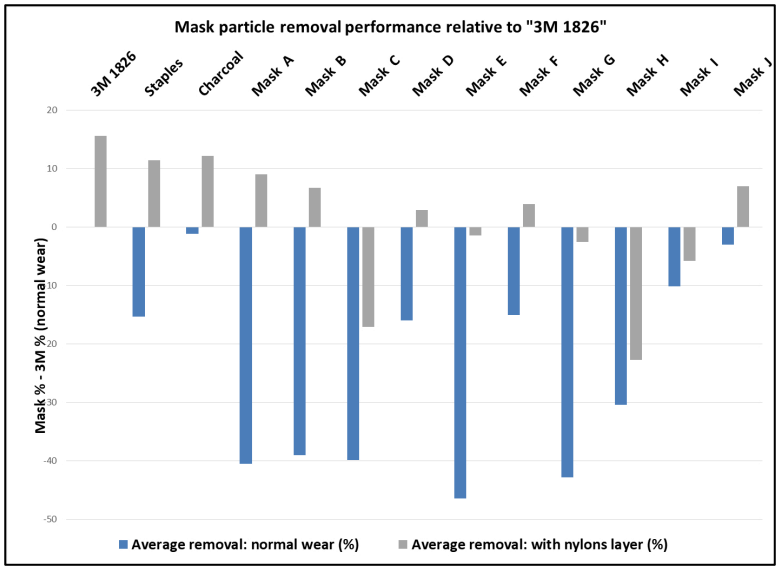

Figure 6. Mask particle removal performance relative to 3M 1826 worn as designed, with (gray bar) and without (blue bar) nylon stocking layer to form a tight seal with face.

4. Conclusions and Future Work

A rapid testing protocol is presented for evaluation of loose-fitting type masks to provide information to individuals on particle removal efficacy of masks made with different types of fabrics and with different designs/fits. The protocol collects high-resolution particle count data inside and immediately outside of masks to report both mean and time-based standard deviation of particle removal efficiency. The protocol is validated on N95 masks, and a commercial (3M brand) medical-type mask is used as a baseline for evaluation of alternative mask particle removal efficiencies. The 3M brand mask worn as designed had a mean removal efficiency of 75%; with the exception of the Charcoal Air Pollution facemask and Sewn Mask J, which came close to this removal efficiency, all other masks achieved removal efficiencies of less than 60% (range of 30-60%) when worn as loose-fitting masks. The addition of a nylon stocking overlayer improved the removal efficiency for all loose-fitting masks, including commercial medical-type masks, by 15 to 50 percentage points and also decreased the time-based standard deviation (indicating more consistent particle removal); this provides a recommendation for mask efficacy improvement that can

easily be implemented by individual mask wearers. When compared to commercial baseline masks, the addition of the stocking layer improved particle removal efficiency of many masks to match or exceed the baseline; the masks that achieved this level of filtration using the stocking layer each included a filter layer (organic cotton batting, Pellon, or loosely-woven cotton muslin) in addition to two layers of cotton fabric. This rapid testing method (<2 hours per mask design) provides a holistic evaluation of mask particle removal efficacy (material, design, and fit).

The forward-looking intent is to use this method for testing a wider range of mask materials and designs to provide the public and health care providers with information needed to optimize health protection given resources at hand. We are currently integrating an additional instrument into the testing protocol that will enable us to explicitly characterize particle size during tests as well as developing a website through which to provide the public with access to (anonymized) results for all masks evaluated. We strongly welcome feedback on additional ways to improve the value of collected data.

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Matter, Volume *3*

Supplemental Information

Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE

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SUPPLEMENTAL INFORMATION

Table SI1. Mask details, mean filtration efficiency ($\overline{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiency over one minute runs (s_t).

		worn as designed			worn with overlayer		
Sample	Description	$\overline{x}$	s_r	s_t	$\overline{x}$	s_r	s_t
N95-1		99.2%	0.4%	0.8%	-	-	-
N95-2	Makrite model 9500-N95	90.6%	5.9%	4.6%	95.2%	0.9%	4.7%
S-1	3M surgical mask model 1826	74.6%	4.1%	9.5%	90.3%	1.5%	3.9%
S-2	Keystone surgical mask model FM-EL-BLUE	59.3%	3.3%	13.0%	86.0%	3.2%	2.7%
S-3	Hong Da Wei Cai surgical mask labeled for medical use	53.4%	4.4%	12.6%	90.0%	6.0%	5.6%
O-1	surgical style 4 layer mask with black "charcoal" layer (no brand information available)	73.4%	4.1%	9.7%	86.8%	0.4%	5.2%
CS-1	cloth surgical-style mask with earloops and wired nose bridge, layers (3): two cotton quilting fabric and one Pellon interfacing fabric	58.6%	5.0%	11.6%	77.5%	6.2%	0.8%
CS-2	fabric surgical style mask with earloops, no wire at bridge of nose, layers: two cotton plain weave	28.2%	5.9%	24.3%	73.2%	1.4%	1.2%
CS-3	fabric surgical style mask with ties, wired nose bridge, layers (6): two Smartfab nonwoven fabric, two disposable baby wipe (dry), one massage table non-woven fabric cover, one meltblown filter (BFE85)	85.0%	1.3%	5.4%	81.3%	3.4%	7.9%
CS-4	fabric surgical style mask with ties, wired nose bridge, layers (2): two cotton duck	72.9%	8.8%	7.1%	78.5%	12.3%	6.7%
CS-5	fabric surgical style mask with ties, no wire at bridge of nose, layers (2): two layers of cotton twill (sold by Reformation clothing company at thereformation.com)	56.0%	3.9%	13.1%	66.9%	1.7%	10.2%

Table SI1 (cont.). Mask details, mean filtration efficiency ($\overline{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiency over one minute runs (s_t).

		worn as designed			worn with overlayer		
Sample	Description	$\overline{x}$	s_r	s_t	$\overline{x}$	s_r	s_t
CS-6	fabric surgical style mask with earloops, no wire at bridge of nose, layers (2): woven nylon	47.1%	2.3%	12.2%	56.8%	5.9%	8.7%
CC-1	commercially produced nuisance dust mask modified with cloth liner, layers (4): two Smartfab nonwoven fabric , one disposable baby wipe (dry), one meltblown filter (BFE84)	85.9%	6.3%	4.7%	89.3%	1.5%	3.8%
CC-2	commercially produced nuisance dust mask	60.3%	3.2%	10.4%	61.1%	2.8%	9.4%
CC-3	fabric cone-shaped mask with elastic head band and wired nose bridge, layers (6): two cotton muslin fabric, two disposable baby wipe (dry), one massage table cover non-woven fabric, one meltblown filter (BFE85)	86.2%	1.0%	5.5%	88.5%	0.9%	3.8%
CC-4	fabric cone-shaped mask with elastic head band, layers (6): two Smartfab nonwoven fabric, two disposable baby wipe (dry), one massage table non-woven fabric cover, one meltblown filter (BFE85)	89.1%	1.7%	3.4%	91.7%	2.8%	4.3%
CC-5	fabric cone-shaped mask with elastic head band, wired nose bridge, PM2.5 filter insert, layers (4, including pocket): three cotton muslin, one massage table non-woven fabric cover	80.2%	2.5%	7.1%	84.3%	2.5%	5.9%

Table SI1 (cont.). Mask details, mean filtration efficiency ($\overline{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiency over one minute runs (s_t).

		worn as designed			worn with overlayer		
Sample	Description	$\overline{x}$	s_r	s_t	$\overline{x}$	s_r	s_t
CC-6	fabric cone-shaped mask with elastic head band, layers (5): two Smartfab nonwoven fabric, one massage table non-woven fabric cover, two meltblown filter (BFE85)	90.7%	0.8%	3.1%	91.5%	1.1%	3.1%
CC-7	fabric cone-shaped mask with elastic head band, wired nose bridge, layers (4): two Smartfab nonwoven, one massage table non-woven fabric cover, two meltblown filter (BFE85)	85.3%	2.2%	4.6%	87.2%	0.9%	4.4%
CC-8	fabric cone-shaped mask with two sets of ties, wired nose bridge, layers (3): two cotton fabric, one non-woven polypropylene (recycled grocery bag)	82.6%	1.2%	5.7%	81.3%	2.4%	8.5%
CD-1	duck-bill shaped mask with elastic head band, wired nose bridge, layers (6): 4 cotton fabric, 2 Pellon interfacing	64.2%	11.0%	9.5%	80.2%	1.8%	6.3%
N only	woven nylon stocking	7.0%	2.5%	18.0%	-	-	-

* n=4 replicates for mask CS-1, all other masks n=3 replicates

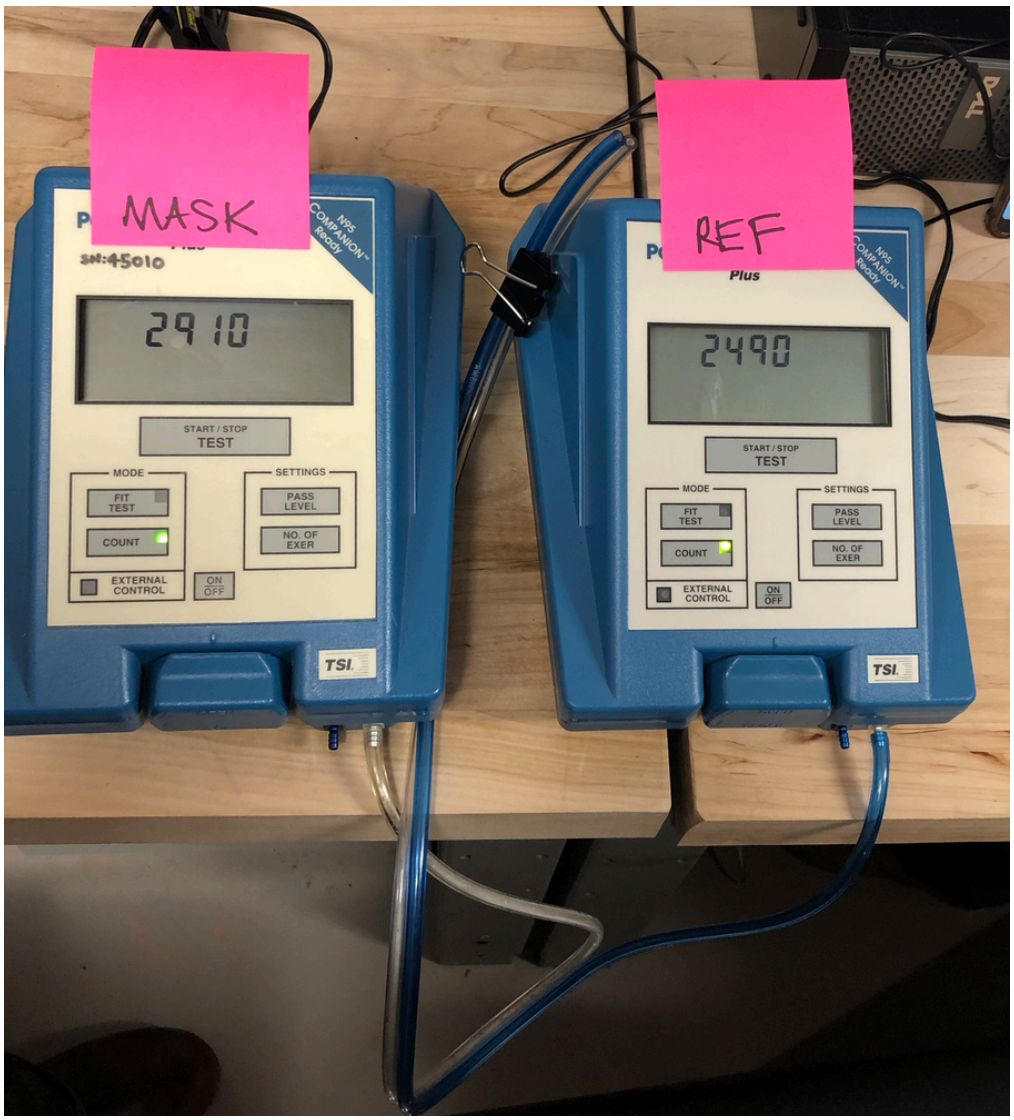

Figure S1. Two TSI PortaCount model 8028 used in this work. Sample tubes are of equal length and are connected to right-hand ports labeled “sample”. Instruments were operated in count mode with “Mask”-labeled instrument sampling air from inside the mask and “Ref”-labeled instrument sampling ambient air just outside of the mask.

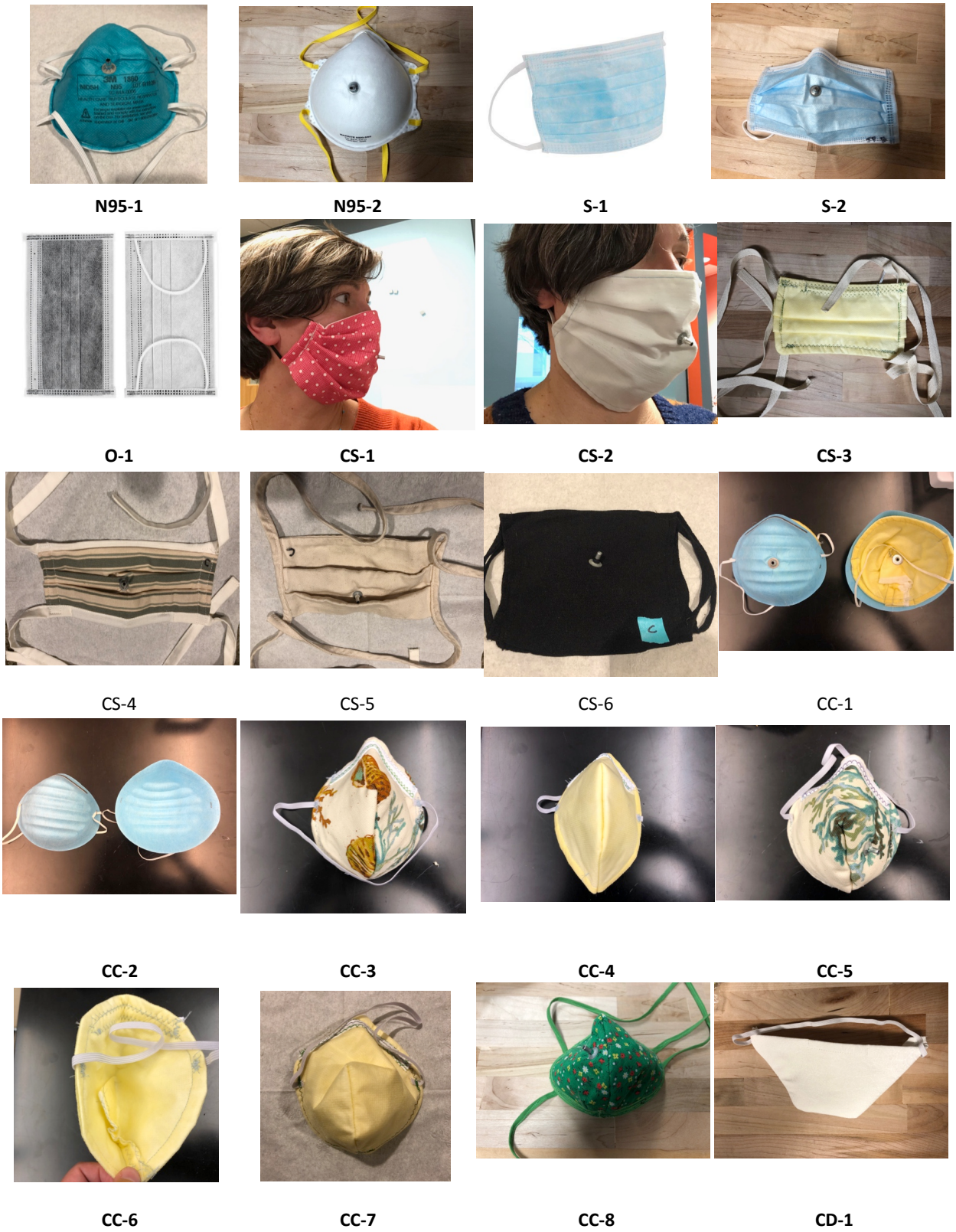

Figure S2. Gallery of mask images. Masks ordered by sample ID. Descriptions included in Table S1.

Additional and updated results are available through a web portal at masktestingatNU.com.

Appendix B
(Utilized Pre-Print Study Report)

Quantitative Method for Comparative Assessment of Particle Filtration Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE

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Conceptualization, L. A. F. and A. V. M; Methodology, , L. A. F. and A. V. M; Formal Analysis, A. V. M. and C. B.; Investigation, L. A. F., A. V. M., M. J. E., J. M. O., and C. B., Writing – Original Draft, L. A. F. and A. V. M.; Writing – Review & Editing, A. V. M., C. B., and L. A. F.

Summary

In response to the COVID-19 pandemic, cloth masks are being used to control the spread of virus, but the efficacy of these loose-fitting masks is not well known. Here, tools and methods typically used to assess tight-fitting respirators were modified to quantify the efficacy of community- and commercially-produced fabric masks as PPE. Two particle counters concurrently sample ambient air and air inside the masks; mask performance is evaluated by mean particle removal efficiency and statistical variability when worn as designed and with a nylon overlayer, to independently assess fit and material. Worn as designed both commercial surgical masks and cloth masks had widely varying effectiveness (53-75% and 28-90% filtration efficiency, respectively). Most surgical-style masks improved with the nylon overlayer, indicating poor fit. This rapid testing method uses widely available hardware, requires only a few calculations from collected data, and provides both a holistic and aspect-wise evaluation of mask performance.

1. Introduction

In response to the critical shortage of medical masks resulting from the COVID-19 pandemic, large portions of the population are mobilizing to produce cloth masks using locally-sourced fabrics. While the general population is being advised to wear masks to protect others from virus that may be spread from the wearer, the efficacy of these masks as a means of protecting the wearer from airborne particles carrying virus is also a concern, particularly as medical masks grow scarce. This issue may become more critical if it becomes necessary for medical care workers to use similar alternative personal protective equipment,[1] but is already important for individuals who may be caring for a household member who is ill or who may be in a high-risk category for complications.[2]

The effectiveness of masks to protect wearers from airborne particles is known to be a function of both materials and fit. Standard methods to test the performance of respirators and masks designed to form a seal against the face, such as N95 respirators, assume that appropriate high-filtration materials have been used in the construction of the masks and therefore employ instruments that test the fit by comparing the concentration of particles in air inside and outside of the mask while the subject moves his/her head through a series of positions.[3] Several instruments have been specifically designed to perform these tests (e.g., the TSI PortaCount), simplifying the testing process for users by reporting a single metric of "fit" (i.e., Fit Factor = ratio of time-averaged particle concentration outside and inside mask). In contrast, standard methods for surgical masks focus exclusively on testing the materials and do not provide for a measurement of the mask as constructed or as worn.[4-7]

Anticipating the need to produce face coverings from readily-available materials, several studies have used these standard methods for materials testing to compare the filtration efficiency of materials such as cotton t-shirts, sweatshirts, handkerchiefs, and towels with the filtration efficiency of materials used to manufacture facepiece respirators (N95 masks) and surgical masks.[8-10] Further, tools developed for N95-type masks have been applied directly to evaluate particle filtration for loose-fitting, surgical type masks.[11]

Generally, these studies have found that no commonly-available materials produce filtration efficiency close to respirators such as N95s, with cotton cloth facemasks providing about half the protection (i.e., "Fit Factor" decrease by a factor of 2) of standard surgical masks against airborne particles.[11] Notably, these previous studies are unable to pinpoint the problems with loose-fitting masks (i.e., separate out a poor fit from poor materials used in the construction), though in other work an elastic layer (e.g., nylon stocking) placed over the mask when worn has been found to improve filtration efficiency of loose-fitting masks by minimizing air flow around the cloth layers.[12]

Importantly, it has been shown that head motions and positions do not significantly affect the performance of loose-fitting masks in terms of filtering out nano-sized particles,[11] suggesting that a simplified mask testing protocol (compared to the multi-step fit test used for respirators) may be sufficient for characterizing particle filtration efficacy of loose-fitting masks. Given the highly varied results and protocol shortcomings noted for prior studies,[13] development of a rapid and quantitative method for evaluating potential PPE options would be of great value to the general public at this time.

The purpose of this work was to develop a standardized method to quantitatively assess the efficacy of sewn fabric facemasks and standard surgical masks in terms of protecting the wearer from airborne particulates of the size range potentially associated with viral transmission (<300 nm). This leverages instrumentation designed for respirator fit testing, which is widely available nationally at health care centers, fire departments, etc., but provides two key adjustments that improve the data quality for loose-fitting mask testing. First, two instruments are used to simultaneously record high resolution (1 Hz) particle concentration measurements in the room and behind the mask, enabling the method to be used in cases where particle concentration may vary on the timescale of tests, in comparison to standard fit testing which assumes consistent particle concentrations in the room over ~minutes and therefore sequentially samples the ambient and in-mask air. Data recorded during experiments described below show variability of particle concentrations by up to a factor of 2 over <1 minute, supporting the need for this dual-instrument configuration if used more broadly, especially outside of specialized testing rooms. Second, by conducting separate tests for masks worn loosely (as designed) and for the masks held close

to the face using a layer of nylon stocking (as recommended by Cooper et al.[12]), the method enables independent evaluation of the mask fit and mask materials as they contribute to overall filtration efficiency.

The proposed protocol enables testing of an individual mask design (n=3 masks for statistical analysis) within ~30 minutes for systems with digital data collection, providing a rapid screening tool to test a variety of mask designs produced from readily-available materials. This method can be easily replicated in health care centers, fire stations, and other facilities nationally, to vet specific masks in near-real time. To validate the methodology, this manuscript reports data collected from an initial set of commercial and homemade masks, however results from ongoing tests are being updated regularly at a public web portal as additional prototype masks are evaluated. Given the limited time and current social distancing precautions, all tests were conducted while masks were being worn by the same subject, breathing normally, through the nose, with the mouth closed, while holding the head at a steady position. Data reported by van der Sande et al.[11] provide confidence that limitation of motions and positions does not significantly limit the conclusions that can be drawn from the resulting data, and results from a single test subject are used here primarily to validate the protocol itself.

2. Results and Discussion

The percent removal of particles (of size range characterized below, D<300 nm) for each mask was computed from data collected each second over one minute tests; examples of the high resolution data collected for each test are provided in Figure 1 for a well-fitted N95 mask (N95-1) and a surgical-style cloth mask (CS-1). The breathing pattern of the wearer can be observed as oscillations in the “inside mask” data, and the issue of variability in ambient particle concentrations over a 1-minute test is clearly visible in the top panel.

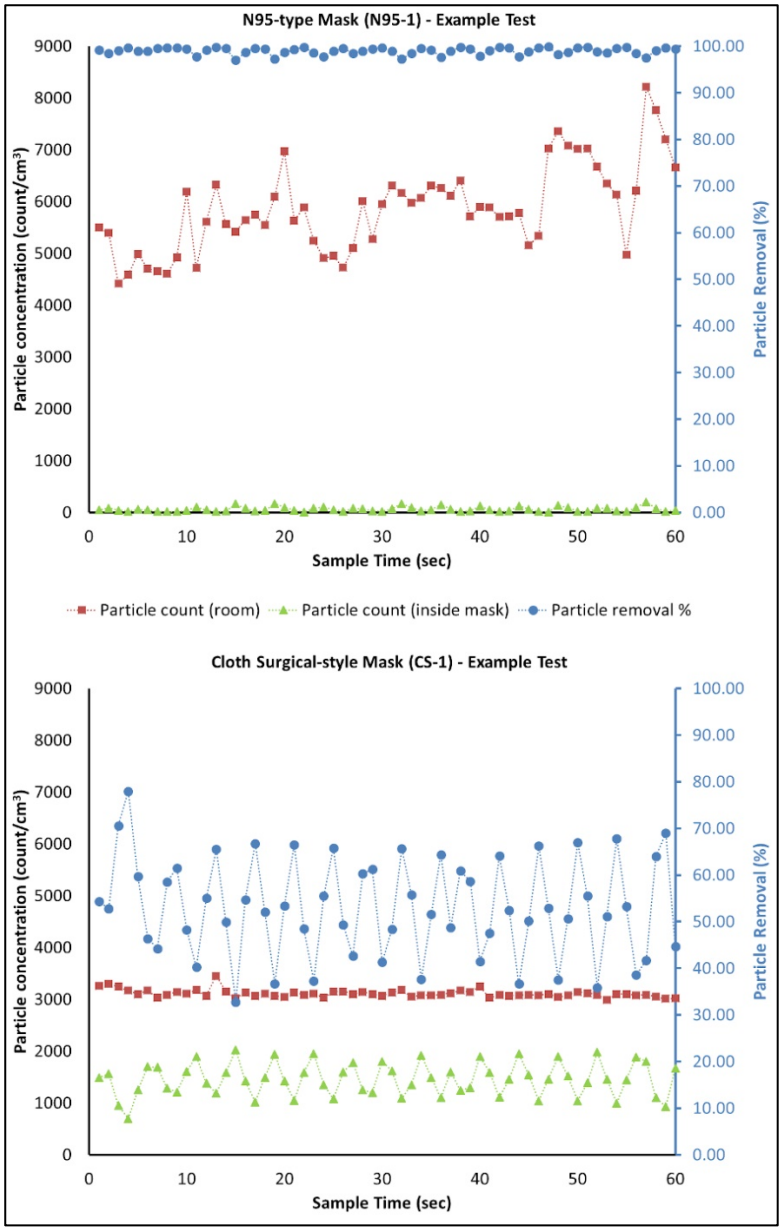

Figure 1: Particle concentrations in the room (red squares) and inside the mask (green triangles) with calculated removal percentage (blue circles) vs. time for a single one-minute test of a well-fitted N95 mask (N95-1, top) and an example cloth surgical-style mask (CS-1, bottom). Time-based variability in filtration efficiency corresponds to the breathing patterns of the mask wearer (inhales vs. exhales). As expected, the N95 mask has high and consistent filtration efficiency ($\bar{x}$=99.0 %, s_t=0.75 % for this single test). The cloth surgical-style mask has both lower filtration efficiency and higher variability ($\bar{x}$=53.0 %, s_t=10.5 % for this single test).

From these data, one can extract both mean removal efficiency and a measure of time-based variation ($\bar{\mathbf{x}}$ and s_t, as defined below), which each provide information on mask performance. It is observed that $\bar{\mathbf{x}}$ and s_t are inversely correlated (Figure 2), wherein an improved fit generally leads to both higher mean particle

removal efficiency and lower time-based standard deviation (consistency in particle removal), independent of the materials being used.

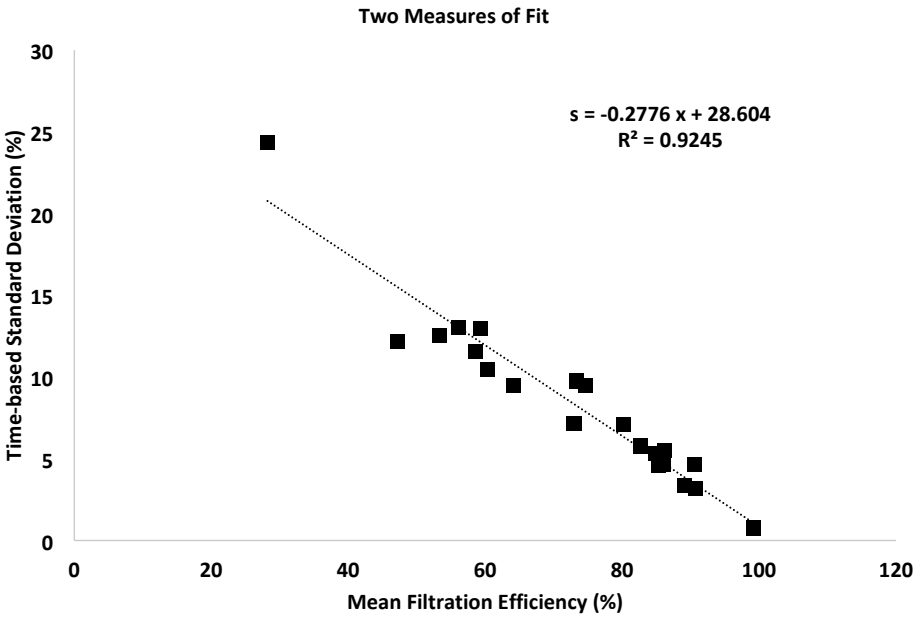

Figure 2: Improving mask performance through better fit and filtration materials leads both to increased mean particle removal efficiency and decreased variation in filtration over time; data shown for masks worn as designed.

Data collected with the subject wearing the nylon overlayer alone had $\bar{x}$=7.0% ± 2.5% (standard deviation calculated from n=3 replicates) with s_t=18%; it is concluded therefore that the overlayer itself does not provide significant filtration capacity and in the following discussion it is considered primarily to improve the snugness of fit of the underlying mask.

The method is first evaluated through analysis of available commercial masks (Figure 3), including N95 respirators, surgical masks marketed for medical use, and other (in this case, a surgical-style mask with a charcoal-embedded layer marketed for persons with allergies or wearing while exercising in areas with high levels of air pollution). Blue bars show mean particle filtration for masks worn as designed, while gray bars provide a proxy for best possible fit by adding the nylon overlayer. Differences between blue and gray bars provide a measure of the looseness of the fit (extent of leakage of air around the mask in normal wear) while gray bars provide a measure of filtration capacity of the mask material.

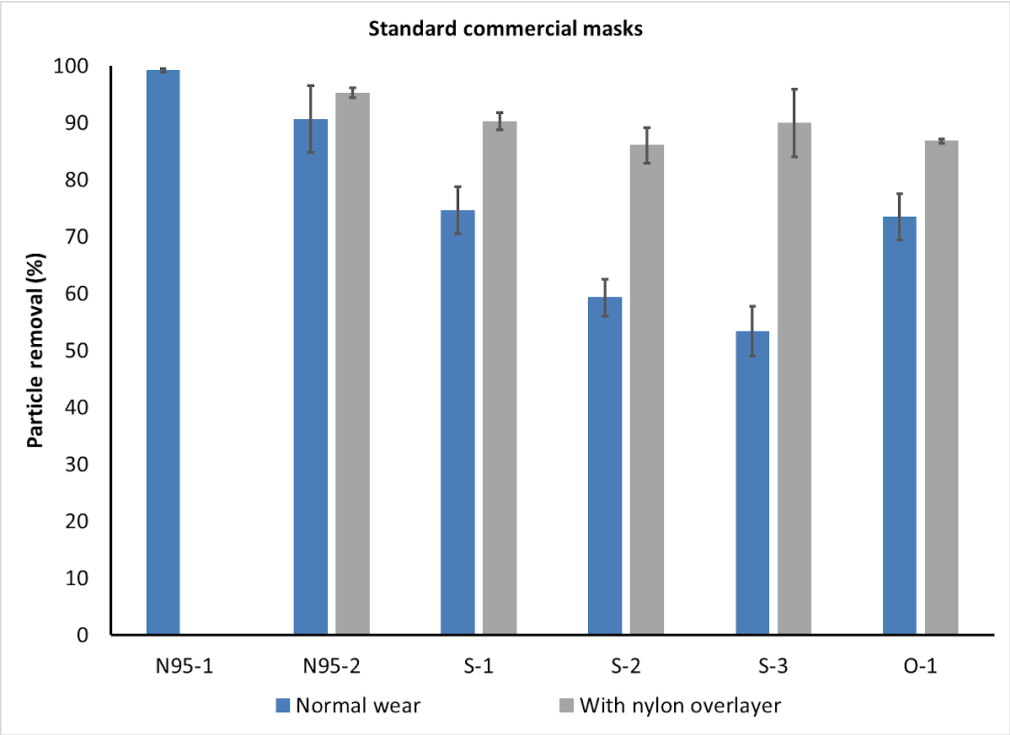

Figure 3: Particle filtration efficiency of standard commercial masks of 3 types: N95 (N95-n), surgical style marketed for medical use (S-n), and Other (O-1, a charcoal filter mask). Data collected with a nylon overlayer holding the mask in place represent a proxy for best-possible fit, i.e., gray bars provide a measure of the filtration capacity of the materials. N95-1 was well-fitted to the mask wearer and shows the expected >99% filtration, while N95-2 was less well fitted, as seen by the difference between the blue and gray bars. While the fit of the three surgical masks (S-1 to S-3) is quite different (blue bars), the materials are comparable (gray bars). Error bars show standard deviation between replicates (n=3 masks for each type tested).

As expected, the mean removal efficiency for the well-fitted N95 mask (N95-1) is greater than 99% with very low variability between replicates (s=0.36%) and low time-based standard deviation (s_t=0.78%, see Figure 2 data point with highest filtration efficiency). This corresponds to a Fit Factor ($C_{outside}/C_{inside}$) of 126, which is above the minimum passable standard of 100,[14] however presentation of results as mean and variability provides more information on the range of particle filtration efficiencies experienced by the user. The poorly-fitted N95 mask (N95-2) has a lower mean removal efficiency ($\bar{x}$=90.6%), higher variability between replicates (s=5.9%), and higher time-based standard deviation (s_t=4.6%). This corresponds to a fit factor of 10.6, which is below the minimum passable standard.

In comparison, the standard medical-type masks (S-1 to S-3), when worn over the chin and with an

adjusted nose wire, had a mean removal efficiency of only 50 to 75% when worn as designed. In comparison, when tightly fitted to the face using a nylon overlayer these masks achieve from 86 to 90% mean removal efficiency, indicating that (1) the material can actually provide much better filtration than is achieved in normal wear and (2) differences between brands are primarily in the quality of fit rather than the quality of material used. Interestingly, in this case the carbon filter mask (O-1) performs approximately as well as the best performing surgical mask despite a significant difference in the design specifications and materials used.

The same measurements and metrics were then used to test fifteen different cloth masks being made or marketed to the public at this time (April-May 2020). Results (Figure 4) are presented as absolute particle removal efficiency (top panel) and in comparison with the top performing surgical mask (S-1) (bottom panel). While these masks represent a small subset of available masks and materials, several useful preliminary observations can be made.

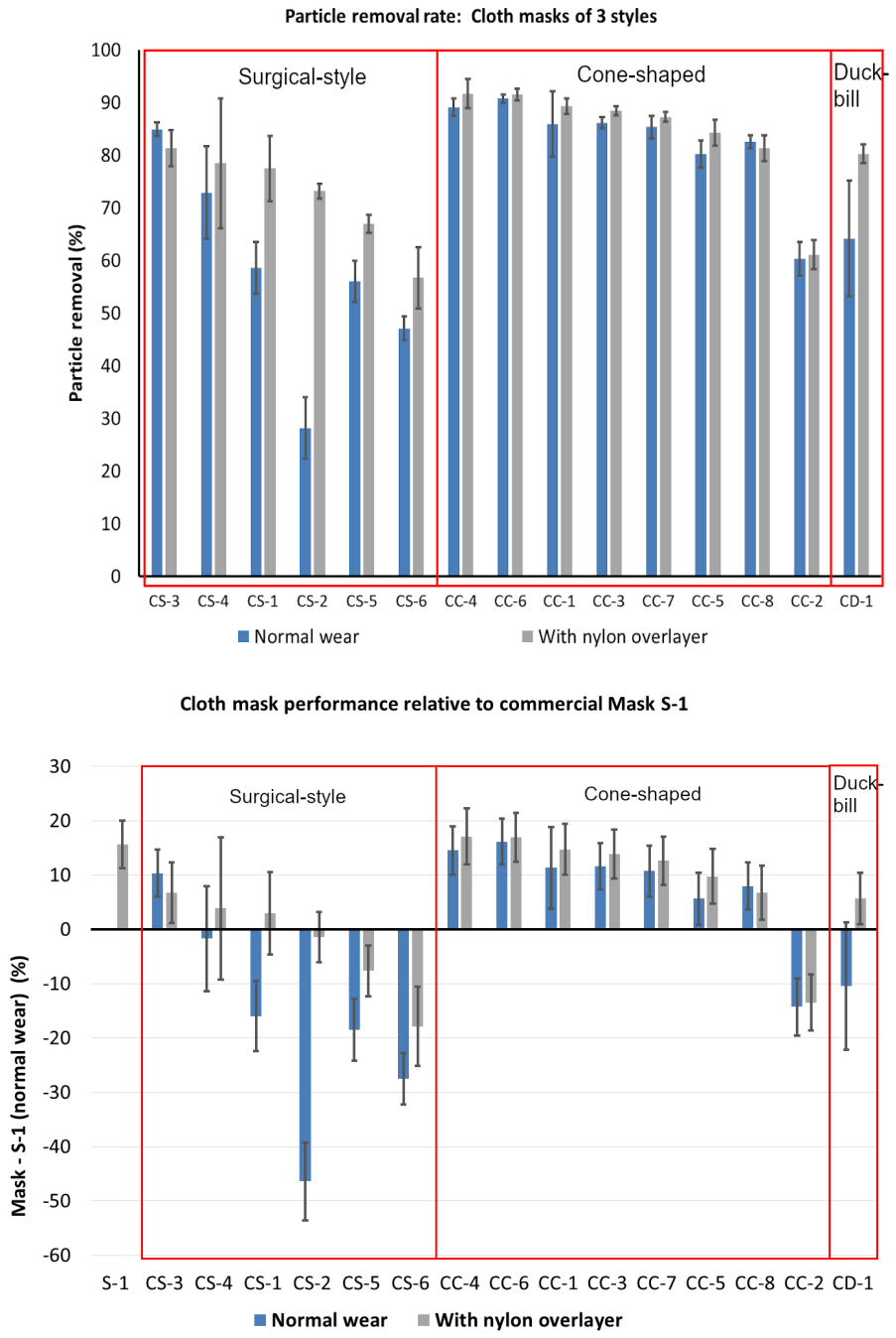

Figure 4: Performance of a range of cloth masks being made by the community and by commercial vendors presented as absolute performance (top panel) and in comparison to S-1, the top performing surgical mask (bottom panel). Preliminary data show the difference between performance of masks using different form factors, e.g., cone-shaped masks appear to have a better and more consistent fit to the face. Notably multiple cloth masks perform as well as or better than surgical masks when worn as designed, and some provide equivalent filtration to surgical masks snugged to the face. However, there is wide variability in filtration provided by cloth masks, due both to fit (difference between blue and gray bars) and materials (gray bars).

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First, quality of cloth masks is highly variable, both in fit (difference between blue and gray bars) and material filtration capacity (gray bars); therefore the public would greatly benefit from a quantitative method for evaluating masks they may be considering for health protective reasons. Second, it appears that different masks shapes may provide a more consistent fit even when hand-made using standard patterns; e.g., in these data the cone masks appear generally to fit better than the surgical-style masks (as evaluated by difference between blue and gray bars, where addition of the nylon layer generally improved performance for surgical-style masks but not for cone-shaped masks). Exceptions to improvement when adding the nylon overlayer were rare and due to material stiffness where the mask could not completely conform to the wearer's face and therefore the nylon layer led to bunching (creation of new air leakage pathways). The nylon layer also reduced the variability with time as indicated by a decrease in the time-based standard deviation. Both of these metrics indicate improved protection for the wearer from particle inhalation.

When using mask S-1 worn as designed as a baseline, several of the cloth masks match or exceed this performance (Figure *4*, bottom panel). The masks that achieved this level of filtration without the stocking overlayer were cone shaped and included a layer of meltblown filter fabric, similar to interfacing layers being added to many homemade masks, and specified as BFE85, between fabric cover layers. Additional filter layers including water-repellent non-woven cloth marketed as disposable massage table covering and dry disposable baby wipes, improved the filtration efficiency only moderately in the cone shaped masks. Surgical-style masks that achieved the best filtration efficiency with the addition of a nylon overlayer included a filter layer (organic cotton batting, Pellon, or loosely-woven cotton muslin) between two layers of cotton fabric. These data are not included here due to limited number of replicates, but are available on a web portal (SI).

3. Conclusion

A rapid testing protocol is presented for evaluation of loose-fitting type masks to provide quantitative, intercomparable data for particle removal efficacy of masks made with different types of fabrics and with different designs/fits, independently providing an assessment of the quality of the mask fit and the

material used. The protocol collects high-resolution particle count data inside and immediately outside of masks to report both mean and time-based standard deviation of particle removal efficiency, while wearing the mask as-designed and under a nylon layer that snugs the mask to the face. The protocol is validated on a well-fitted N95 mask, and a commercial surgical-type mask is used as a reference baseline for evaluation of alternative mask particle removal efficiencies. Commercial surgical masks marketed for medical use had mean particle removal efficiencies from 50-75% when worn as designed but up to 90% when snugged to the face under a nylon layer. Cloth masks tested had widely varying mean particle removal efficiencies (<30% to near 90%), with some cloth masks achieving similar filtration efficiencies as commercial surgical masks. However, in general, surgical-style cloth masks had poor fit (i.e., performance was greatly enhanced with the nylon overlayer) compared to cone-shaped masks, and masks with good material filtration performance tended to have a filter layer (e.g., meltblown BFE85 filter layer) in addition to two layers of cotton or non-woven fabric.

This rapid testing method (~30 minutes per mask design including replicates for statistical validity) provides a holistic evaluation of mask particle removal efficacy (material, design, and fit) while enabling independent evaluation of these characteristics. This method uses instrumentation that is typically available in many health centers and fire stations, as well as other facilities, and compensates for assumptions made in fit-testing programs so that it can be easily replicated for on-site testing of specific masks across many communities.

4. Experimental Procedures

Particle counters*.* Particles in ambient air and air inside of the mask breathing zone were counted using two PortaCount Plus Model 8028 instruments running in count mode. The PortaCount Plus instrument uses a condensation particle counter to determine particles per cm^3 in air sampled at a flow rate of 1.67 cm^3/s and reports one value (in particles/cm^3) each second.[15] The instrument counts particles ranging in size from 0.02 to >1 μm, however data on the size distribution of counted particulates is not reported; size distribution of the particles used to challenge the masks was therefore measured independently, as reported in the following section.

Mask fit testing is usually conducted using a single instrument in fit test mode, which sequentially tests air inside and outside the mask and therefore depends on an assumption of consistent particle concentration in the room. As this assumption was frequently violated in our test setup even in cases where particle generation was used (which may therefore commonly be the case in other facilities), here two PortaCount instruments were used in count mode to simultaneously collect and display continuous data for ambient air and inside mask air at high frequency (1 Hz) during minute-long tests.

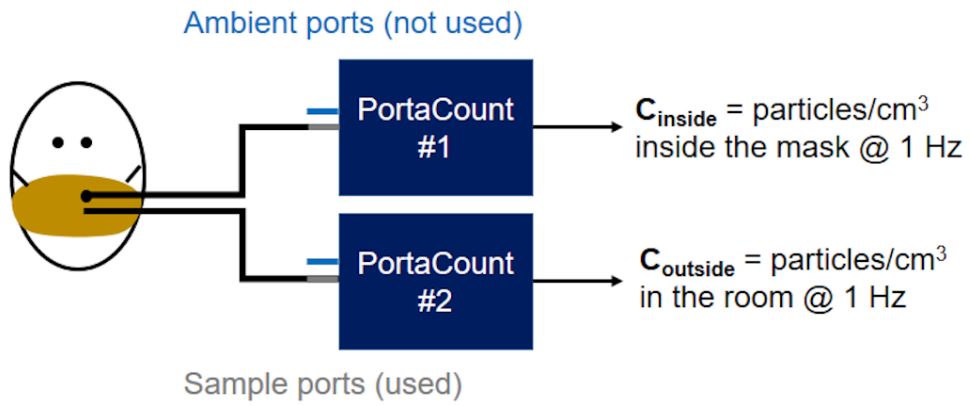

Figure 5: Test setup has two PortaCount systems running in parallel; 1/8" diameter tubing of identical length connects (top) the mask port to one instrument sampling port and (bottom) a tube inlet located just outside the mask to the second instrument sampling port. Both instruments are run in "Count" mode where concentrations are reported once per second (1 Hz). The dual-instrument configuration is required because each instrument has only one internal measurement cell, for which the input is swapped between the sampling and ambient inputs during standard fit testing. Photograph of PortaCounts used, including ports and tubing available in SI (Figure S1).

Two 1/8" ID tubes (sold with the PortaCount Instrument) trimmed to equal length (approximately 100 cm) sampled air just inside and outside of the mask. Air inside the mask was sampled through a tight-fitting grommet inserted into each mask using a TSI Fit Test Probe Kit (model 8025-N95) and positioned at the philtrum of the upper lip per standard mask testing guidance appropriate to the shape of each mask. Ambient air was sampled from a position ~3 cm from the grommet on the outside of the mask.

Particle Generation and Characterization. All tests were run in a 65 m^3 rectangular room after at least 15 minutes of operating a TSI Particle Generator Model 8026 (TSI Incorporated, Shoreview, MN, USA).

This tool is typically used in conjunction with TSI PortaCount instruments to ensure sufficiently high particle counts and appropriate size distributions to meet OSHA standards. Particles were generated from a dilute (2%) solution of sodium chloride (NaCl), reported to have a nominal size of 40 nm with a geometric standard deviation of 2.2 based on instrument specifications.[16] To verify that the particles challenging the masks was comprised primarily of these generated particles, the particle size distribution in the room was characterized by running three 5-minute tests approximately hourly on several testing days (n=21 in replicates of 3) using the TSI Engine Exhaust Particle Sizer Spectrometer (EEPS) Model 3090 (for particles in the range 5.6 to 560 nm, with 32 channels acquired at 10 Hz) and the TSI Optical Particle Size Spectrometer (OPS) Model 3330 (for particles in the range 0.3 to 10 μm, with 16 channels acquired at 1 Hz). The size distribution of particle number concentration was consistent at all times and days sampled, which supported the averaging of collected data. The histogram of average normalized particle frequency revealed a bimodal distribution of particle sizes, shown in Figure 6. Confidence intervals (CI) for the count median diameter (CMD) and the geometric standard deviation (GSD) were calculated from Student's t-test statistics, with p=0.05 and M=20 degrees of freedom. The first peak likely represents particles that are not filtered by building HVAC systems, as the distribution parameters (CMD=9.53 ± 2.19 nm, GSD=1.23 ± 0.13; average ± 95% CI) are consistent with background air measurements reported by the authors in other rooms and buildings on campus.[17] Features of the second peak (CMD = 37.30 ± 15.40 nm, GSD = 1.79 ± 0.44) are in agreement with specifications reported for the TSI Particle Generator manual. Overall, 97.01 ± 0.02% (average ± 1•s) of particles are in the standard range used to challenge masks (<300 nm), so the reported particle filtration efficiencies can be directly compared to numbers reported to comply with OSHA standards.

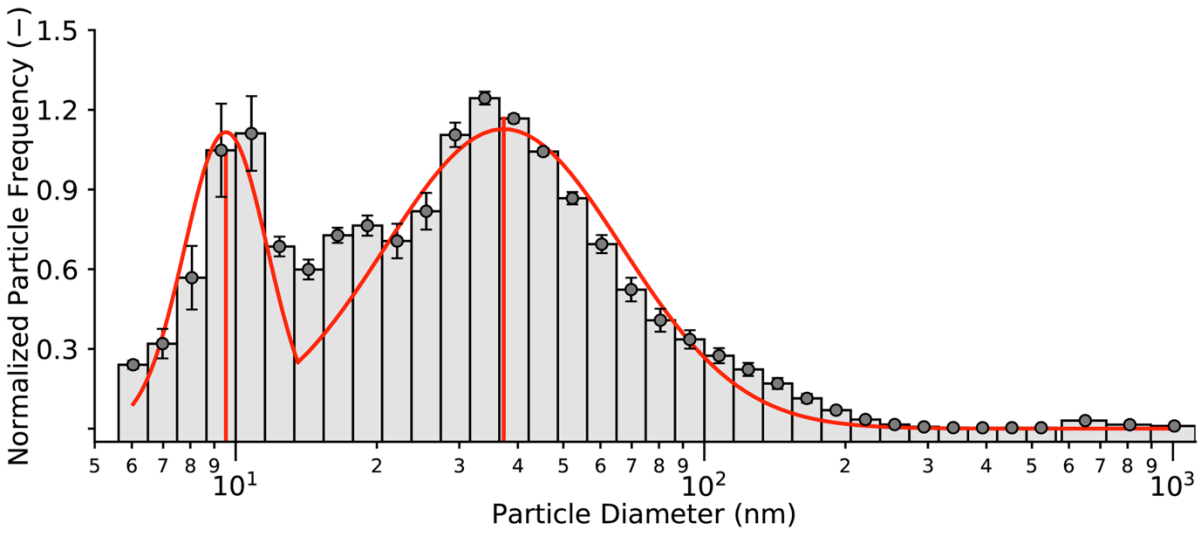

Figure 6: Average histograms of normalized particle frequency as a function of size, with superimposed bimodal lognormal distribution. Count median diameter (CMD ± 95% CI) is 9.53 ± 2.19nm for the first peak and 37.30 ± 15.40nm for the second peak. Geometric standard deviation (GSD ± 95% CI) is 1.23 ± 0.13 for the first peak and 1.79 ± 0.44 for the second peak. Particles generated by the TSI Particle Generator account for the larger peak, while particles in lab air account for the smaller peak.

Calibration. An inter-calibration was conducted between the two PortaCount modules to account for any drift or changes in calibrations due to, e.g., wick saturation. Each sampling day, calibration data (a minimum of three one-minute time series, n=180) were collected by recording readings simultaneously on both instruments while sample tubes were side-by-side (within 3 cm), open to the air (no mask), and a minimum of 1m from any person and 2m from the particle generator (as recommended by the manufacturer). Correlation coefficients between the readings from the two instruments were consistently above 0.9, and day-specific linear regressions were used to normalize particle counts from the Reference PortaCount to equivalent particle counts from the Mask PortaCount before calculating particle removal efficiencies.

Data collection and processing. Each mask test consisted of three one-minute runs while wearing the mask as designed (Figure 7 (a)). In addition, the mask material was held against the face by adding a section of nylon stocking over the entire mask area following recommendations from Copper et al.[9] (Figure 7 (b)) to simulate best possible fit and provide information on material filtration, and a single one-minute test was recorded in this configuration. All masks except the well-fitted N95 were tested in this

second configuration. Results are reported only for masks for which at least three replicate sample masks were available (data for masks with n<3 are being provided through our web portal).

Particle concentration data from inside and outside the mask was logged each second for the one minute tests using video capture and subsequently transcribed to a database (noting that newer PortaCount models can log count data through a software interface to simplify data collection). Particle removal at each time step was calculated as follows:

$$\%\ particle\ removal = PPR = \frac{C_{outside} - C_{inside}}{C_{outside}} \times 100 \quad (1)$$

where $C_{outside}$ is the corrected reading from the Reference PortaCount (as described above) and C_{inside} is the reading in the breathing zone of the mask.

Average particle removal efficiency ($\bar{\mathbf{x}}$, reported as % removal), standard deviation between masks (generally n=3, $\boldsymbol{s}$ reported as %), and mean standard deviation over the one-minute tests ($\boldsymbol{s}_t$, reported as %) were computed for each mask with and without a nylon stocking layer. These summary statistics can be used to calculate Fit Factor for the masks, if desired, using Eqn. 2:

$$Fit\ Factor = \frac{C_{outside}}{C_{inside}} = \frac{1}{1 - PPR/100} \quad (2)$$

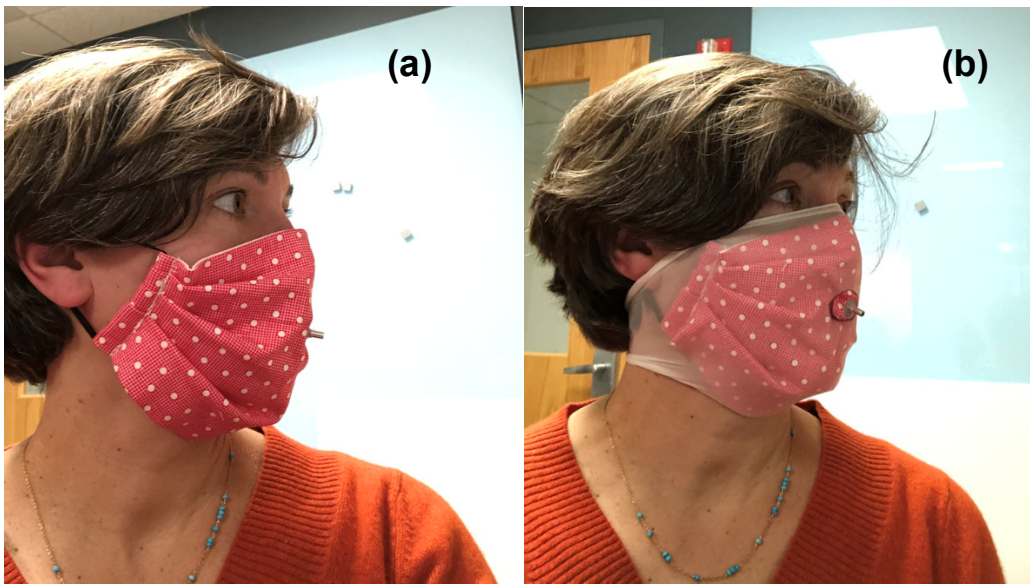

Figure 7: Facemask (Mask CS-1) worn as designed **(a)** and with a nylon stocking layer **(b)** with tightly-sealed grommet positioned at the philtrum of the upper lip. The grommet is used to sample air from inside the mask during testing. Note: this mask could have been worn inside-out to ensure the folds faced down. However, for the purposes of this test precautions against particle collection in folds were not considered necessary.

Masks. Masks tested are given labels according to the mask type and then an individualized sample number. Commercial masks are divided into N95-type (N95-1, N95-2, etc.), surgical-style (S-1, etc.), and other (O-1, etc.). Cloth masks are given a pre-pended "C" identifier and divided into surgical-style (CS-1, etc.), cone-shaped (CC-1, etc.), and duck-bill shaped (CD-1, etc.) (Figure S2). Results are reported for a range of commercially-produced, medical-type facemasks (masks with elastic ear loops and in-sewn wires to adjust fit to the bridge of the nose), and fifteen sewn fabric facemasks of various designs that were sourced from community volunteers producing masks for essential personnel as well as online vendors that have started to market masks of this type since March 2020 (Table S1). Several of the fabric masks included filter layers such as non-woven polypropylene fabric, meltblown textiles, and disposable baby wipes. In addition, several sewn masks included hydrophobic layers including interfacing (Pellon) and non-woven fabric marketed as disposable massage table covering. Some masks included wires to fit the masks across the bridge of the nose. A set of well-fitted (N95-1) and poorly fitted (N95-2) masks were tested to validate the protocol.

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SUPPLEMENTAL INFORMATION

Table SI1. Mask details, mean filtration efficiency ($\bar{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiencency over one minute runs (s_t).

Sample	Description	Mask worn as designed			Mask worn with nylon overlayer		
		$\bar{x}$	s_r	s_t	$\bar{x}$	s_r	s_t
N95-1	3M N95 model 1860	99.2%	0.4%	0.8%	-	-	-
N95-2	Makrite model 9500-N95	90.6%	5.9%	4.6%	95.2%	0.9%	4.7%
S-1	3M surgical mask model 1826	74.6%	4.1%	9.5%	90.3%	1.5%	3.9%
S-2	Keystone surgical mask model FM-EL-BLUE	59.3%	3.3%	13.0%	86.0%	3.2%	2.7%
S-3	Hong Da Wei Cai surgical mask labele for medical use	53.4%	4.4%	12.6%	90.0%	6.0%	5.6%
O-1	surgical style 4 layer mask with black "charcoal" layer (no brand information available)	73.4%	4.1%	9.7%	86.8%	0.4%	5.2%
CS-1	cloth surgical-style mask with earloops and wired nose bridge, layers (3): two cotton quilting fabric and one Pellon interfacing	58.6%	5.0%	11.6%	77.5%	6.2%	0.8%
CS-2	fabric surgical style mask with earloops, no wire at bridge of nose, layers: two cotton plainweave	28.2%	5.9%	24.3%	73.2%	1.4%	1.2%
CS-3	fabric surgical style mask with ties, wired nose bridge, layers (6): two Smartfab nonwoven fabric, two disposable baby wipe (dry), one massage table non-woven fabric cover, one meltblown filter (BFE85)	85.0%	1.3%	5.4%	81.3%	3.4%	7.9%
CS-4	fabric surgical style mask with ties, wired nose bridge, layers (2): two cotton duck	72.9%	8.8%	7.1%	78.5%	12.3%	6.7%
CS-5	nose, layers (2): two layers of cotton twill (sold by Reformation clothing company at thereformation.com)	56.0%	3.9%	13.1%	66.9%	1.7%	10.2%
CS-6	fabric surgical style mask with earloops, no wire at bridge of nose, layers (2): woven nylon	47.1%	2.3%	12.2%	56.8%	5.9%	8.7%
CC-1	commercially produce nuisance dust mask with cloth liner, layers (4): two Smartfab nonwoven fabric , one disposable baby wipe (dry), one meltblown filter (BFE84)	85.9%	6.3%	4.7%	89.3%	1.5%	3.8%
CC-2	comercially produced nuisance dust mask	60.3%	3.2%	10.4%	61.1%	2.8%	9.4%
CC-3	fabric cone-shaped mask with elastic head band and wired nose bridge, layers (6): two cotton muslin fabric, two disposable baby wipe (dry), one massage tablecover non-woven fabric, one meltblown filter (BFE85)	86.2%	1.0%	5.5%	88.5%	0.9%	3.8%
CC-4	fabric cone-shaped mask with elastic head band, layers (6): two Smartfab nonwoven fabric, two disposable baby wipe (dry), one massage table non-woven fabric cover, one meltblown filter (BFE85)	89.1%	1.7%	3.4%	91.7%	2.8%	4.3%
CC-5	fabric cone-shaped mask with elastic head band, wired nose bridge, PM2.5 filter insert, layers (4,including pocket): three cotton muslin, one masage table non-woven fabric cover	80.2%	2.5%	7.1%	84.3%	2.5%	5.9%
CC-6	fabric cone-shaped mask with elastic head band, layers (5): two Smartfab nonwoven fabric, one massage table non-woven fabric cover, two meltblown filter (BFE85)	90.7%	0.8%	3.1%	91.5%	1.1%	3.1%
CC-7	fabric con-shaped mask with elastic head band, wired nose bridge, layers (4): two Smartfab nonwoven, one massage table non-woven fabric cover, two meltblown filter (BFE85)	85.3%	2.2%	4.6%	87.2%	0.9%	4.4%
CC-8	fabric cone-shaped mask with two sets of ties, wired nose bridge, layers (3): two cotton fabric, one non-woven polypropylene (recycled grocery bag)	82.6%	1.2%	5.7%	81.3%	2.4%	8.5%
CD-1	duck-bill shaped mask with elastic head band, wired nose bridge, layers (6): 4 cotton fabric, 2 Pellon interfacing	64.2%	11.0%	9.5%	80.2%	1.8%	6.3%
N only	woven nylon stocking	7.0%	2.5%	18.0%	-	-	-

* n=4 replicates for mask CS-1, all other masks n=3 replicates

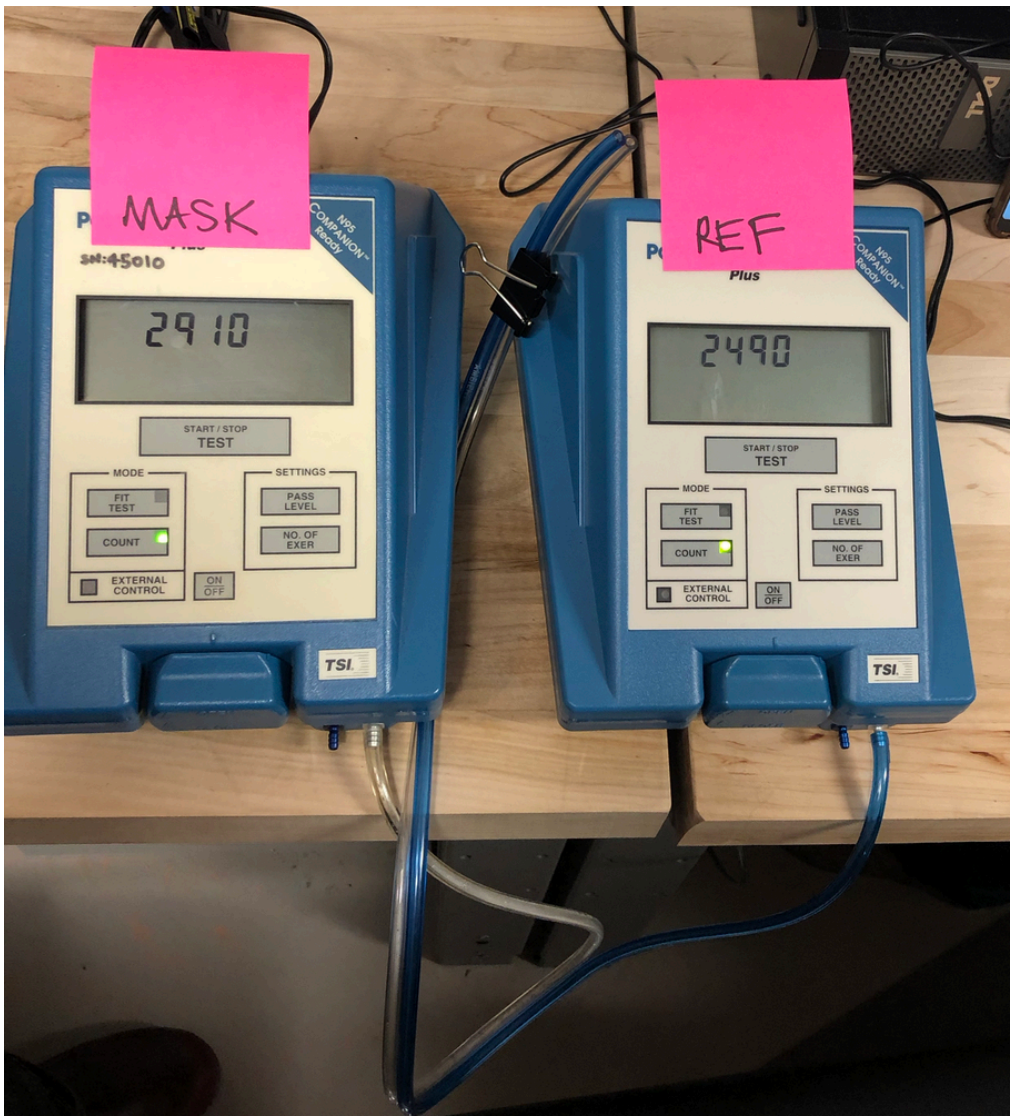


Figure S1. Two TSI PortaCount model 8028 used in this work. Sample tubes are of equal length and are connected to right-hand ports labeled “sample”. Instruments were operated in count mode with “Mask”-labeled instrument sampling air from inside the mask and “Ref”-labeled instrument sampling ambient air just outside of the mask.

Figure S2. Gallery of mask images. Masks ordered by sample ID. Descriptions included in Table S1.

Additional and updated results are available through a web portal at masktestingatNU.com.

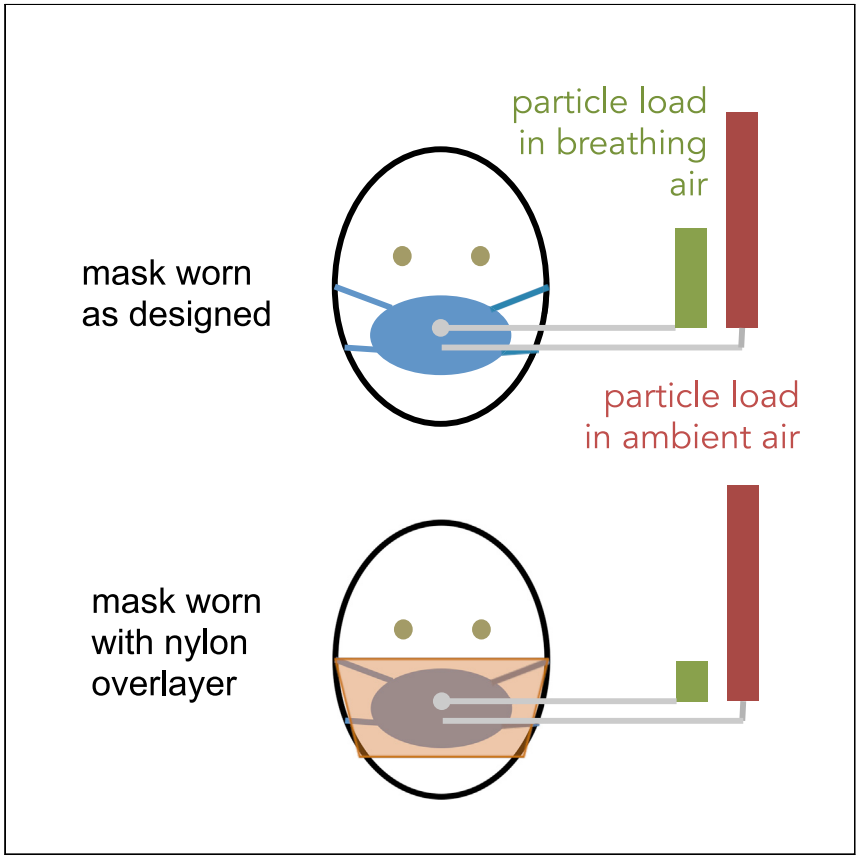
Appendix C
(Published Study Report)

Matter

CellPress

Article

Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE



Cloth masks are being used to control the spread of SARS-Cov-2 virus, but the efficacy of these masks is not well known. Here, tools and methods typically used to assess tight-fitting respirators were modified to quantify the efficacy of fabric masks at removing small aerosol particles (<300 nm) from breathing air. Both commercial surgical masks and cloth masks had widely varying effectiveness (53%–75% and 28%–91% particle removal, respectively). Surgical-style mask efficacy generally improved with addition of an elastic nylon overlayer.

6 **Development**
Practical, real world, technological considerations and constraints

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HIGHLIGHTS

Surgical masks removed 53%–75% of particles <300 nm from air when worn as designed

Cloth masks ranged in particle removal efficiency from 28% to 91% when worn as designed

A nylon overlayer improved particle removal efficiency of many masks by minimizing gaps

Mueller et al., Matter 3, 950–962
September 2, 2020
https://doi.org/10.1016/j.matt.2020.07.006

CellPress

Matter

Article

Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE

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SUMMARY

In response to the COVID-19 pandemic, cloth masks are being used to control the spread of virus, but the efficacy of these loose-fitting masks is not well known. Here, tools and methods typically used to assess tight-fitting respirators were modified to quantify the efficacy of community-produced and commercially produced fabric masks as personal protective equipment. Two particle counters concurrently sample ambient air and air inside the masks; mask performance is evaluated by mean particle removal efficiency and statistical variability when worn as designed and with a nylon overlayer, to independently assess fit and material. Worn as designed, both commercial surgical masks and cloth masks had widely varying effectiveness (53%–75% and 28%–91% particle removal efficiency, respectively). Most surgical-style masks improved with the nylon overlayer, indicating poor fit. This rapid testing method uses widely available hardware, requires only a few calculations from collected data, and provides both a holistic and aspect-wise evaluation of mask performance.

INTRODUCTION

In response to the critical shortage of medical masks resulting from the COVID-19 pandemic, large portions of the population are mobilizing to produce cloth masks using locally sourced fabrics. While the general population is being advised to wear masks to protect others from virus that may be spread from the wearer, the efficacy of these masks as a means of protecting the wearer from airborne particles carrying virus is also a concern, particularly as medical masks grow scarce. This issue may become more critical if it becomes necessary for medical care workers to use similar alternative personal protective equipment (PPE),[1] but is already important for individuals who may be caring for a household member who is ill or who may be in a high-risk category for complications.[2]

The effectiveness of masks to protect wearers from airborne particles is known to be a function of both materials and fit. Standard methods to test the performance of respirators and masks designed to form a seal against the face, such as N95 respirators, assume that appropriate high-filtration materials have been used in the construction of the masks and therefore employ instruments that test the fit by comparing the concentration of particles in air inside and outside of the mask while the subject moves his/her head through a series of positions.[3] Several instruments have been specifically designed to perform these tests (e.g., the TSI PortaCount), simplifying the testing process for users by reporting a single metric of "fit" (i.e., Fit Factor = ratio of time-averaged particle concentration outside and inside mask). In contrast,

Progress and Potential Statement

This work was initiated in response to the need to understand the potential personal protective benefits of commercially produced and homemade masks for use during the COVID-19 pandemic. Understanding that the specialized equipment required to measure filtration efficiency of mask materials for the most penetrating particle size (usually around 300 nm) is not widely available and that the protection provided by any mask is dependent on the mask fit at well as materials, we sought to develop a method for rapidly assessing new mask designs using readily available instrumentation. The methods described in this work may be used to help home in on materials, construction techniques, and designs that are most effective at removing small (<300 nm) non-oil aerosol particles from air breathed through a mask. If applied broadly to a large set of masks, best practices for constructing, cleaning, and wearing masks with the goal of protecting public health may be found.

standard methods for surgical masks focus exclusively on testing the materials and do not provide for a measurement of the mask as constructed or as worn.[4–7]

Anticipating the need to produce face coverings from readily available materials, several studies have used these standard methods for materials testing to compare the particle removal efficiency of materials such as cotton T-shirts, sweatshirts, handkerchiefs, and towels with the particle removal efficiency of materials used to manufacture facepiece respirators (N95 masks) and surgical masks.[8–10] Furthermore, tools developed for N95-type masks have been applied directly to evaluate particle filtration for loose-fitting, surgical-type masks.[11] Generally, these studies have found that no commonly available materials produce particle removal efficiency close to respirators such as N95s, with cotton cloth facemasks providing about half the protection (i.e., Fit Factor decrease by a factor of 2) of standard surgical masks against airborne particles.[11] Notably, these previous studies were unable to pinpoint the problems with loose-fitting masks (i.e., separate out a poor fit from poor materials used in the construction), although in other work an elastic layer (e.g., nylon stocking) placed over the mask when worn has been found to improve particle removal efficiency of loose-fitting masks by minimizing air flow around the cloth layers.[12]

Importantly, it has been shown that head motions and positions do not significantly affect the performance of loose-fitting masks in terms of filtering out nanosized particles,[11] suggesting that a simplified mask-testing protocol (compared with the multi-step fit test used for respirators) may be sufficient for characterizing particle removal efficacy of loose-fitting masks. Given the highly varied results and protocol shortcomings noted for prior studies,[13] development of a rapid and quantitative method for evaluating potential PPE options would be of great value to the general public at this time.

The purpose of this work was to develop a standardized method to quantitatively assess the efficacy of sewn fabric facemasks and standard surgical masks in terms of protecting the wearer from airborne particulates of the size range associated with aerosolized SARS-CoV-2 virus (<10 μm), hypothesized to be important in transmission from asymptomatic or pre-symptomatic carriers.[14] This leverages widely available instrumentation designed for respirator fit testing, but provides two key adjustments that improve the data quality for loose-fitting mask testing. First, two instruments are used to simultaneously record high-resolution (1 Hz) particle concentration measurements in the room and behind the mask, enabling the method to be used in cases where particle concentration may vary on the timescale of tests, in comparison with standard fit testing, which requires large differences in particle concentrations in the room and behind the mask (approximately two orders of magnitude) but are not affected by smaller variations in ambient particle concentration (Figure 1). Data recorded during experiments described below show variability of particle concentrations by up to a factor of 2 over <1 min, supporting the need for this dual-instrument configuration if used outside of specialized testing rooms. Second, by conducting separate tests for masks worn loosely (as designed) and for the masks held close to the face using a layer of nylon stocking (as recommended by Cooper et al.[12]) (Figure 2), the method enables independent evaluation of the mask fit and mask materials as they contribute to overall particle removal efficiency.

The proposed protocol enables testing of an individual mask design (n = 3 masks for statistical analysis) within ~30 min for systems with digital data collection, providing a rapid screening tool to test a variety of mask designs produced from readily available materials. To validate the methodology, we report here the data collected from

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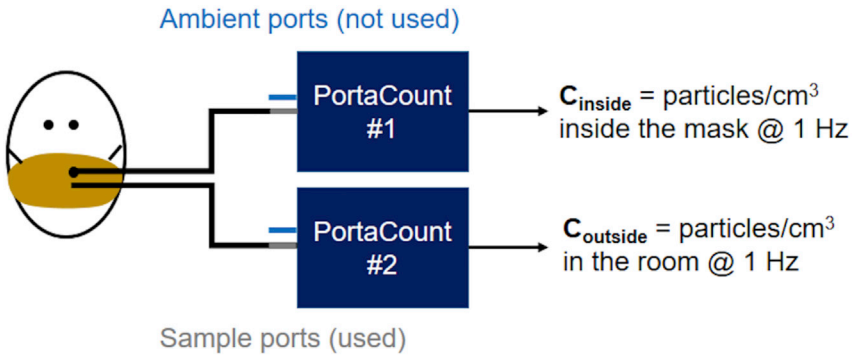

Figure 1. Schematic Diagram of Testing Setup

Test setup has two PortaCount systems running in parallel; 1/8″ diameter tubing of identical length connects (top) the mask port to one instrument sampling port and (bottom) a tube inlet located just outside the mask to the second instrument sampling port. Both instruments are run in "Count" mode whereby concentrations are reported once per second (1 Hz). The dual-instrument configuration is required because each instrument has only one internal measurement cell, for which the input is swapped between the sampling and ambient inputs during standard fit testing. Photograph of PortaCounts used, including ports and tubing, is provided in Figure S1.

an initial set of commercial and homemade masks, although results from ongoing tests are being updated regularly at a public web portal as additional prototype masks are evaluated (see Supplemental Information). Given the limited time and current social distancing precautions, all tests were conducted while masks were being worn by the same subject, breathing normally, through the nose, with the mouth closed, while holding the head at a steady position. Data reported by van der Sande et al.[11] provide confidence that limitation of motions and positions does not significantly limit the conclusions that can be drawn from the resulting data, and results from a single test subject are used here primarily to validate the protocol itself.

RESULTS AND DISCUSSION

The percent removal of particles (of size range characterized below, Dp < 300 nm) (Figure 3) for each mask was computed from data collected each second over 1-min tests; examples of the high-resolution data collected for each test are provided in Figure 4 for a well-fitted N95 mask (N95-1) and a surgical-style cloth mask (CS-1). The breathing pattern of the wearer can be observed as oscillations in the "inside mask" data. The particle count while wearing the N95 respirator is likely dipping during inhalation as air is filtered through the mask and rising as particles are exhaled (<100 p/cc, based on three replicate mask tests). The sawtooth pattern for the loose-fitting mask, however, is likely peaking on the inhale as particle-laden air is pulled around the mask and dipping on the exhale as lower particle air from the lungs blends with air inside the mask. The issue of variability in ambient particle concentrations over a 1-min test is clearly visible in the top of Figure 4.

From these data, one can extract both mean removal efficiency and a measure of time-based variation ($\bar{x}$ and s_t, as defined below), which each provide information on mask performance. It is observed that $\bar{x}$ and s_t are inversely correlated (Figure 5), whereby an improved fit generally leads to both higher mean particle removal efficiency and lower time-based standard deviation (consistency in particle removal), independent of the materials being used.

Data collected with the subject wearing the nylon overlayer alone had $\bar{x}$ = 7.0% ± 2.5% (standard deviation calculated from n = 3 replicates) with s_t = 18%; it is

Figure 2. Example of Facemask and Nylon Overlayer Used in Tests
Facemask (Mask CS-1) worn as designed (A) and with a nylon overlayer (B) with tightly sealed grommet positioned at the philtrum of the upper lip. The grommet is used to sample air from inside the mask during testing. Note that: this mask could have been worn inside-out to ensure the folds faced down. However, for the purposes of this test, precautions against particle collection in folds were not considered necessary.

concluded, therefore, that the overlayer itself does not provide significant particle removal, and in the following discussion it is considered primarily to improve the snugness of fit of the underlying mask. In addition, aerosol neutralizers and dryers are not used with the TSI PortaCount and its accompanying particle generator. Thus, masks with charged fibers may yield greater particle removal using this method than would be observed using methods and instruments that test only uncharged, dry particles.

The method is first evaluated through analysis of available commercial masks (Figure 6), including N95 respirators, surgical masks marketed for medical use, and others (in this case, a surgical-style mask with a charcoal-embedded layer marketed for persons with allergies or wearing while exercising in areas with high levels of air pollution). Blue bars in Figure 6 show mean particle removal percentage for masks worn as designed, while gray bars provide a proxy for best possible fit by adding the nylon overlayer. Differences between blue and gray bars provide a measure of the looseness of the fit (extent of leakage of air around the mask in normal wear) while gray bars provide a measure of particle removal capacity of the mask material.

As expected, the mean removal efficiency for the well-fitted N95 mask (N95-1) is greater than 99%, with very low variability between replicates (s = 0.36%) and low time-based standard deviation (s_t = 0.78%, see Figure 5 data point with highest particle removal efficiency). This corresponds to a Fit Factor ($C_{outside}/C_{inside}$) of 126, which is above the minimum passable standard of 100;[15] however presentation of results as mean and variability provides more information on the range of particle removal efficiencies experienced by the user. The poorly fitted N95 mask (N95-2) has a lower mean removal efficiency ($\bar{x}$=90.6%), higher variability between replicates (s = 5.9%), and higher time-based standard deviation (s_t = 4.6%). This corresponds to a fit factor of 10.6, which is below the minimum passable standard.

In comparison, the standard medical-type masks (S-1 to S-3), when worn over the chin and with an adjusted nose wire, had a mean removal efficiency of only

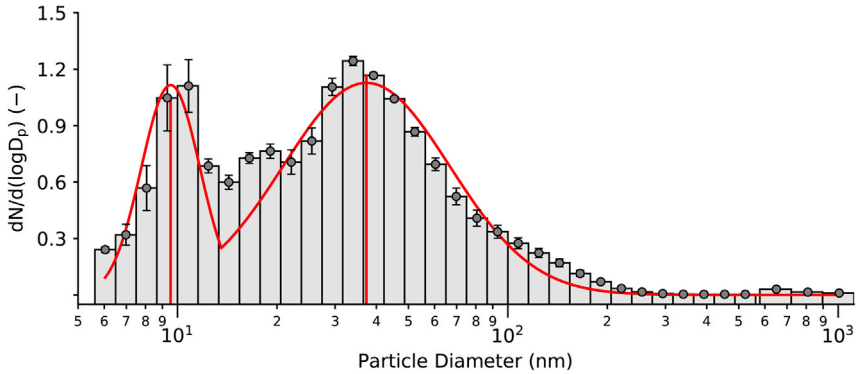

Figure 3. Particle Size Distribution in Ambient Air

Average histograms of normalized particle frequency as a function of size, with superimposed bimodal lognormal distribution. Count median diameter (CMD ± 95% CI) is 9.53 ± 2.19 nm for the first peak and 37.30 ± 15.40 nm for the second peak. Geometric standard deviation (GSD ± 95% CI) is 1.23 ± 0.13 for the first peak and 1.79 ± 0.44 for the second peak. Particles generated by the TSI Particle Generator account for the larger peak, while particles in lab air account for the smaller peak.

50%–75% when worn as designed. In comparison, when tightly fitted to the face using a nylon overlayer, these masks achieve from 86% to 90% mean removal efficiency, indicating that (1) the material can actually provide much better filtration than is achieved in normal wear and (2) differences between brands are primarily in the quality of fit rather than the quality of material used. Interestingly, in this case the carbon filter mask (O-1) performs approximately as well as the best-performing surgical mask despite a significant difference in the design specifications and materials used.

The same measurements and metrics were then used to test 15 different cloth masks made by or being marketed to the public at this time (April to May 2020). Results (Figure 7) are presented as absolute particle removal efficiency (top) and in comparison with the top-performing surgical mask (S-1) (bottom), which the cloth masks are expected to replace outside of medical settings. While these masks represent a small subset of available masks and materials, several useful preliminary observations can be made.

First, the quality of cloth masks is highly variable, both in fit (difference between blue and gray bars) and material particle removal capacity (gray bars); therefore, the public would greatly benefit from a quantitative method for evaluating masks they may be considering for health-protective reasons. Second, it appears that different mask shapes may provide a more consistent fit even when hand-made using standard patterns; for example, in these data the cone masks appear generally to fit better than the surgical-style masks (as evaluated by difference between blue and gray bars in Figure 7, where addition of the nylon layer generally improved performance for surgical-style masks but not for cone-shaped masks). Exceptions to improvement when adding the nylon overlayer were rare and due to material stiffness whereby the mask could not completely conform to the wearer's face and therefore the nylon layer led to bunching (creation of new air-leakage pathways). The nylon layer also reduced the variability with time, as indicated by a decrease in the time-based standard deviation. Both of these metrics indicate improved protection for the wearer from particle inhalation.

When using mask S-1 worn as designed as a baseline, several of the cloth masks match or exceed this performance (Figure 7, bottom). The masks that achieved

Figure 4. Examples of High-Resolution Data Collected Using PortaCount

Particle concentrations in the room (red squares) and inside the mask (green triangles) with calculated removal percentage (blue circles) versus time for a single 1-min test of a well-fitted N95 mask (N95-1, top) and an example cloth surgical-style mask (CS-1, bottom). Time-based variability in particle removal efficiency corresponds to the breathing patterns of the mask wearer (inhales versus exhales). As expected, the N95 mask has high and consistent particle removal efficiency ($\bar{x}$=99.0%, s_t = 0.75% for this single test). The cloth surgical-style mask has both lower particle removal efficiency and higher variability ($\bar{x}$=53.0%, s_t = 10.5% for this single test).

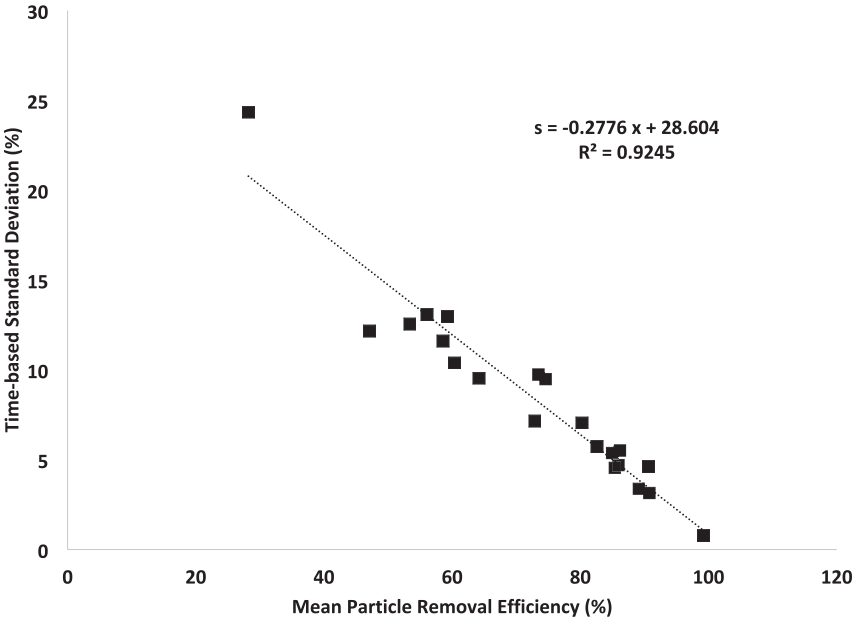

Figure 5. Linear Correlation between Mean Particle Removal Efficiency and Standard Deviation of the Measurement

Improving mask performance through better fit and filtration materials leads both to increased mean particle removal efficiency and decreased variation in filtration over time; data shown for masks worn as designed.

this level of filtration without the nylon overlayer were cone shaped and included a layer of meltblown filter fabric, similar to interfacing fabric being added to many homemade masks, and specified as BFE85, between fabric cover layers. Additional filter layers, including water-repellent non-woven cloth marketed as disposable massage table covering and dry disposable baby wipes, improved the particle removal efficiency only moderately in the cone-shaped masks. Surgical-style masks that achieved the best particle removal efficiency with the addition of a nylon overlayer included a filter layer (organic cotton batting, interfacing fabric, or loosely woven cotton muslin) between two layers of cotton fabric. These data are not included here due to the limited number of replicates but are available on a web portal (Supplemental Information).

Conclusion

A rapid testing protocol is presented for evaluation of loose-fitting type masks to provide quantitative, intercomparable data for particle removal efficacy of masks made with different types of fabrics and with different designs/fits, independently providing an assessment of the quality of the mask fit and the material used. The protocol collects high-resolution particle-count data inside and immediately outside of masks to report both mean and time-based standard deviation of particle removal efficiency while wearing the mask as designed and under a nylon layer that snugs the mask to the face. The protocol is validated on a well-fitted N95 mask, and a commercial surgical-type mask is used as a reference baseline for evaluation of alternative mask particle removal efficiencies. Commercial surgical masks marketed for medical use had mean particle removal efficiencies from 53% to 75% when worn as designed but up to 90% when snugged to the face under a nylon layer. Cloth masks tested had widely varying mean particle removal efficiencies (<30% to 91%), with some cloth masks achieving particle removal efficiencies similar to those of commercial surgical masks. However, in general, surgical-style cloth masks had poor fit (i.e., performance

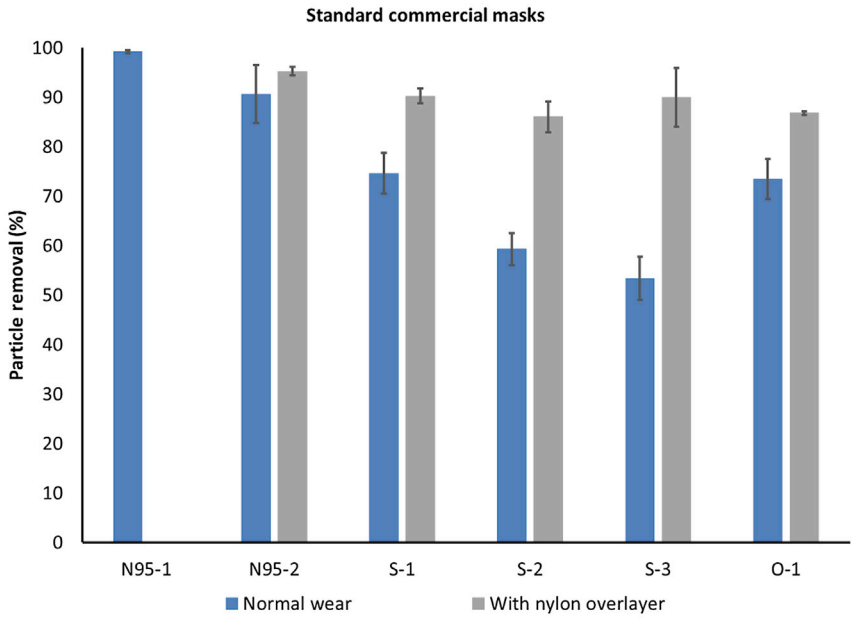

Figure 6. Performance of Commercially Available Masks and Respirators

Particle removal efficiency of standard commercial masks of three types: N95 (N95-n), surgical style marketed for medical use (S-n), and other (O-1, a charcoal filter mask). Data collected with a nylon overlayer holding the mask in place represent a proxy for best possible fit, i.e., gray bars provide a measure of the particle removal capacity of the materials. N95-1 was well fitted to the mask wearer and shows the expected >99% filtration, while N95-2 was less well fitted, as seen by the difference between the blue and gray bars. While the fit of the three surgical masks (S-1 to S-3) is quite different (blue bars), the materials are comparable (gray bars). Error bars show standard deviation between replicates (n = 3 masks for each type tested).

was greatly enhanced with the nylon overlayer) compared with cone-shaped masks, and masks with higher particle removal efficiency tended to have a filter layer (e.g., meltblown BFE85 filter layer) in addition to two layers of cotton or non-woven fabric. This rapid testing method (~30 min per mask design including replicates for statistical validity) provides a holistic evaluation of mask particle removal efficacy (material, design, and fit) while enabling independent evaluation of these characteristics.

EXPERIMENTAL PROCEDURES

Resource Availability

Lead Contact

Loretta Fernandez, l.fernandez@northeastern.edu.

Materials Availability

This study did not generate new or unique reagents.

Data and Code Availability

All experimental data are available upon reasonable request to the Lead Contact author.

Particle Counters

Particles in ambient air and air inside of the mask breathing zone were counted using two PortaCount Plus Model 8028 instruments running in count mode. The PortaCount Plus instrument uses a condensation particle counter to determine particles per cm^3 in air sampled at a flow rate of 1.67 cm^3/s and reports one value (in

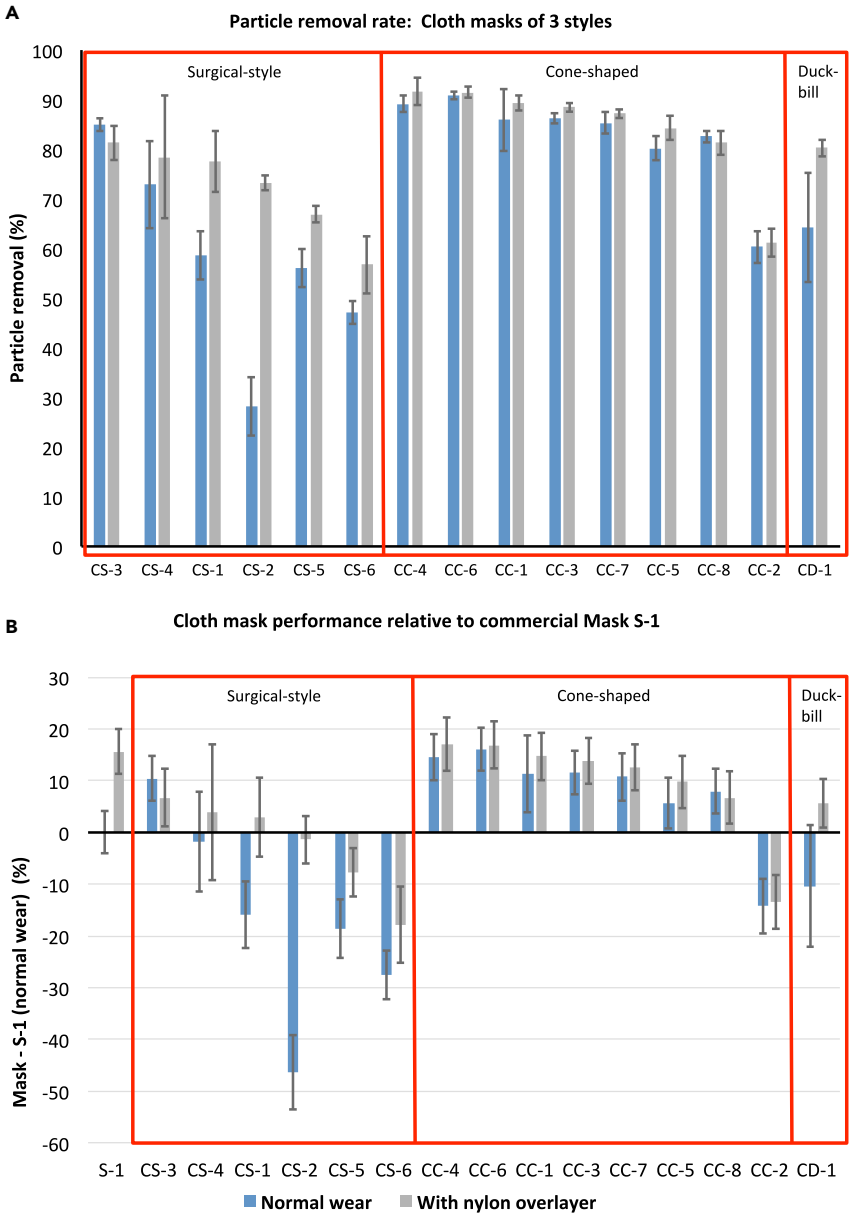

Figure 7. Performance of Cloth Masks and How They Compare with a Standard Surgical Mask

Performance of a range of cloth masks being made by the community and by commercial vendors presented as absolute performance (A) and in comparison with S-1, the top-performing surgical mask (B). Preliminary data show the difference between performance of masks using different form factors, e.g., cone-shaped masks appear to have a better and more consistent fit to the face. Notably, multiple cloth masks perform as well as or better than surgical masks when worn as designed, and some provide particle removal equivalent to that of surgical masks snugged to the face. However, there is wide variability in particle removal provided by cloth masks, due to both fit (difference between blue and gray bars) and materials (gray bars). Error bars show SD between replicates (n = 3 masks for each type tested).

particles/cm^3) each second.[16] The instrument counts particles ranging in size from 0.02 to >1 μm; however, data on the size distribution of counted particulates is not reported. Size distribution of the particles used to challenge the masks was therefore measured independently, as reported in the following section.

Mask fit testing is usually conducted using a single instrument in fit test mode, which sequentially tests air inside and outside the mask and therefore depends on an assumption of consistent particle concentration in the room. As this assumption was frequently violated in our test setup even in cases where particle generation was used, two PortaCount instruments were used in count mode to simultaneously collect and display continuous data for ambient air and inside mask air at high frequency (1 Hz) during minute-long tests.

Two tubes of 1/8″ inner diameter (sold with the PortaCount Instrument) and trimmed to equal length (approximately 100 cm) sampled air just inside and outside of the mask. Air inside the mask was sampled through a tight-fitting grommet inserted into each mask using a TSI Fit Test Probe Kit (model 8025-N95) and positioned at the philtrum of the upper lip per standard mask-testing guidance appropriate to the shape of each mask. Ambient air was sampled from a position ~3 cm from the grommet on the outside of the mask.

Particle Generation and Characterization

All tests were run in a 65-m^3 rectangular room after at least 15 min of operating a TSI Particle Generator Model 8026 (TSI, Shoreview, MN, USA). This tool is typically used in conjunction with TSI PortaCount instruments to ensure sufficiently high particle counts and appropriate size distributions to meet Occupational Safety and Health Administration (OSHA) standards. Particles were generated from a dilute (2%) solution of sodium chloride (NaCl), reported to have a nominal size of 40 nm with a geometric standard deviation of 2.2 based on instrument specifications.[17] To verify that the particles challenging the masks were composed primarily of these generated particles, the particle size distribution in the room was characterized by running three 5-min tests approximately hourly on several testing days (n = 21 in replicates of three) using the TSI Engine Exhaust Particle Sizer Spectrometer Model 3090 (for particles in the range 5.6–560 nm, with 32 channels acquired at 10 Hz) and the TSI Optical Particle Size Spectrometer Model 3330 (for particles in the range 0.3–10 μm, with 16 channels acquired at 1 Hz). The size distribution of particle number concentration was consistent at all times and days sampled, which supported the averaging of collected data. The histogram of average normalized particle frequency revealed a bimodal distribution of particle sizes, shown in Figure 3. Confidence intervals (CI) for the count median diameter (CMD) and the geometric standard deviation (GSD) were calculated from Student's t test statistics, with p = 0.05 and M = 20 degrees of freedom. The first peak likely represents particles that are not filtered by building HVAC (heating/ventilation/air-conditioning) systems, as the distribution parameters (CMD = 9.53 ± 2.19 nm, GSD = 1.23 ± 0.13; average ± 95% CI) are consistent with background air measurements reported by the authors in other rooms and buildings on campus.[18] Features of the second peak (CMD = 37.30 ± 15.40 nm, GSD = 1.79 ± 0.44) are in agreement with specifications reported for the TSI Particle Generator manual. Overall, 97.01% ± 0.02% (average ± 1●s) of particles are in the standard range used to challenge masks (<300 nm), so the reported particle removal efficiencies can be directly compared with numbers reported to comply with OSHA standards.

Calibration

An inter-calibration was conducted between the two PortaCount modules to account for any drift or changes in calibrations due to, e.g., wick saturation. Each sampling day, calibration data (a minimum of three 1-min time series, n = 180) were collected by recording readings simultaneously on both instruments while sample tubes were side by side (within 3 cm), open to the air (no mask), and a minimum of 1 m from any person and 2 m from the particle generator (as recommended by the manufacturer). Correlation coefficients between the readings from the two instruments were consistently above 0.9,

and day-specific linear regressions were used to normalize particle counts from the Reference PortaCount to equivalent particle counts from the Mask PortaCount before calculating particle removal efficiencies.

Data Collection and Processing

Each mask test consisted of three 1-min runs while wearing the mask as designed (Figure 2A). In addition, the mask material was held against the face by adding a section of nylon stocking over the entire mask area following recommendations from Cooper et al.[9] (Figure 2B) to simulate best possible fit and provide information on material filtration, and a single 1-min test was recorded in this configuration. All masks except the well-fitted N95 were tested in this second configuration. Results are reported only for masks for which at least three replicate sample masks were available (data for masks with n < 3 are being provided through our web portal; see Supplemental Information).

Particle concentration data from inside and outside the mask was logged each second for the 1-min tests using video capture and subsequently transcribed to a database (noting that newer PortaCount models can log count data through a software interface to simplify data collection). Particle removal at each time step was calculated as follows:

$$\%\ \text{particle removal} = \text{PPR} = \frac{C_{\text{outside}} - C_{\text{inside}}}{C_{\text{outside}}} \times 100, \qquad \text{(Equation 1)}$$

where C_{outside} is the corrected reading from the Reference PortaCount (as described above) and C_{inside} is the reading in the breathing zone of the mask.

Average particle removal efficiency ($\bar{x}$, reported as percent removal), standard deviation between masks (generally n = 3, s reported as percentage), and mean standard deviation over the 1-min tests (s_t, reported as percentage) were computed for each mask with and without a nylon overlayer. These summary statistics can be used to calculate Fit Factor for the masks, if desired, using Equation 2:

$$\text{Fit Factor} = \frac{C_{\text{outside}}}{C_{\text{inside}}} = \frac{1}{1 - \text{PPR}/100}. \qquad \text{(Equation 2)}$$

Masks

Masks tested are given labels according to the mask type and then an individualized sample number. Commercial masks are divided into N95 type (N95-1, N95-2, and so forth), surgical-style (S-1 and so forth), and other (O-1 and so forth) masks. Cloth masks are given a pre-pended "C" identifier and divided into surgical-style (CS-1 and so forth), cone-shaped (CC-1 and so forth), and duck-bill-shaped (CD-1 and so forth) masks (Figure S2). Results are reported for a range of commercially produced, medical-type facemasks (masks with elastic ear loops and in-sewn wires to adjust fit to the bridge of the nose), and 15 sewn fabric facemasks of various designs that were sourced from community volunteers producing masks for essential personnel as well as online vendors that have started to market masks of this type since March 2020 (Table S1). Several of the fabric masks included filter layers such as non-woven polypropylene fabric, meltblown textiles, and disposable baby wipes. In addition, several sewn masks included hydrophobic layers including interfacing (Pellon) and non-woven fabric marketed as disposable massage table covering. Some masks included wires to fit the masks across the bridge of the nose. A set of well-fitted (N95-1) and poorly fitted (N95-2) masks were tested to validate the protocol.

SUPPLEMENTAL INFORMATION

Supplemental Information can be found online at https://doi.org/10.1016/j.matt.2020.07.006.

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AUTHOR CONTRIBUTIONS

Conceptualization, L.A.F. and A.V.M.; Methodology, L.A.F., A.V.M., C.B., and J.M.O.; Formal Analysis, A.V.M. and C.B.; Investigation, L.A.F., A.V.M., M.J.E., J.M.O., and C.B., Writing – Original Draft, L.A.F., A.V.M., and C.B.; Writing – Review & Editing, A.V.M., C.B., and L.A.F.

DECLARATION OF INTERESTS

The authors declare no competing interests.

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Matter, Volume *3*

Supplemental Information

Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE

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SUPPLEMENTAL INFORMATION

Table SI1. Mask details, mean filtration efficiency ($\overline{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiency over one minute runs (s_t).

		worn as designed			worn with overlayer		
Sample	Description	$\overline{x}$	s_r	s_t	$\overline{x}$	s_r	s_t
N95-1		99.2%	0.4%	0.8%	-	-	-
N95-2	Makrite model 9500-N95	90.6%	5.9%	4.6%	95.2%	0.9%	4.7%
S-1	3M surgical mask model 1826	74.6%	4.1%	9.5%	90.3%	1.5%	3.9%
S-2	Keystone surgical mask model FM-EL-BLUE	59.3%	3.3%	13.0%	86.0%	3.2%	2.7%
S-3	Hong Da Wei Cai surgical mask labeled for medical use	53.4%	4.4%	12.6%	90.0%	6.0%	5.6%
O-1	surgical style 4 layer mask with black "charcoal" layer (no brand information available)	73.4%	4.1%	9.7%	86.8%	0.4%	5.2%
CS-1	cloth surgical-style mask with earloops and wired nose bridge, layers (3): two cotton quilting fabric and one Pellon interfacing fabric	58.6%	5.0%	11.6%	77.5%	6.2%	0.8%
CS-2	fabric surgical style mask with earloops, no wire at bridge of nose, layers: two cotton plain weave	28.2%	5.9%	24.3%	73.2%	1.4%	1.2%
CS-3	fabric surgical style mask with ties, wired nose bridge, layers (6): two Smartfab nonwoven fabric, two disposable baby wipe (dry), one massage table non-woven fabric cover, one meltblown filter (BFE85)	85.0%	1.3%	5.4%	81.3%	3.4%	7.9%
CS-4	fabric surgical style mask with ties, wired nose bridge, layers (2): two cotton duck	72.9%	8.8%	7.1%	78.5%	12.3%	6.7%
CS-5	fabric surgical style mask with ties, no wire at bridge of nose, layers (2): two layers of cotton twill (sold by Reformation clothing company at thereformation.com)	56.0%	3.9%	13.1%	66.9%	1.7%	10.2%

Table SI1 (cont.). Mask details, mean filtration efficiency ($\overline{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiency over one minute runs (s_t).

		worn as designed			worn with overlayer		
Sample	Description	$\overline{x}$	s_r	s_t	$\overline{x}$	s_r	s_t
CS-6	fabric surgical style mask with earloops, no wire at bridge of nose, layers (2): woven nylon	47.1%	2.3%	12.2%	56.8%	5.9%	8.7%
CC-1	commercially produced nuisance dust mask modified with cloth liner, layers (4): two Smartfab nonwoven fabric , one disposable baby wipe (dry), one meltblown filter (BFE84)	85.9%	6.3%	4.7%	89.3%	1.5%	3.8%
CC-2	commercially produced nuisance dust mask	60.3%	3.2%	10.4%	61.1%	2.8%	9.4%
CC-3	fabric cone-shaped mask with elastic head band and wired nose bridge, layers (6): two cotton muslin fabric, two disposable baby wipe (dry), one massage table cover non-woven fabric, one meltblown filter (BFE85)	86.2%	1.0%	5.5%	88.5%	0.9%	3.8%
CC-4	fabric cone-shaped mask with elastic head band, layers (6): two Smartfab nonwoven fabric, two disposable baby wipe (dry), one massage table non-woven fabric cover, one meltblown filter (BFE85)	89.1%	1.7%	3.4%	91.7%	2.8%	4.3%
CC-5	fabric cone-shaped mask with elastic head band, wired nose bridge, PM2.5 filter insert, layers (4, including pocket): three cotton muslin, one massage table non-woven fabric cover	80.2%	2.5%	7.1%	84.3%	2.5%	5.9%

Table SI1 (cont.). Mask details, mean filtration efficiency ($\overline{x}$), standard deviation of mean filtration efficiency between replicates* (s_r), and standard deviation of filtration efficiency over one minute runs (s_t).

		worn as designed			worn with overlayer		
Sample	Description	$\overline{x}$	s_r	s_t	$\overline{x}$	s_r	s_t
CC-6	fabric cone-shaped mask with elastic head band, layers (5): two Smartfab nonwoven fabric, one massage table non-woven fabric cover, two meltblown filter (BFE85)	90.7%	0.8%	3.1%	91.5%	1.1%	3.1%
CC-7	fabric cone-shaped mask with elastic head band, wired nose bridge, layers (4): two Smartfab nonwoven, one massage table non-woven fabric cover, two meltblown filter (BFE85)	85.3%	2.2%	4.6%	87.2%	0.9%	4.4%
CC-8	fabric cone-shaped mask with two sets of ties, wired nose bridge, layers (3): two cotton fabric, one non-woven polypropylene (recycled grocery bag)	82.6%	1.2%	5.7%	81.3%	2.4%	8.5%
CD-1	duck-bill shaped mask with elastic head band, wired nose bridge, layers (6): 4 cotton fabric, 2 Pellon interfacing	64.2%	11.0%	9.5%	80.2%	1.8%	6.3%
N only	woven nylon stocking	7.0%	2.5%	18.0%	-	-	-

* n=4 replicates for mask CS-1, all other masks n=3 replicates

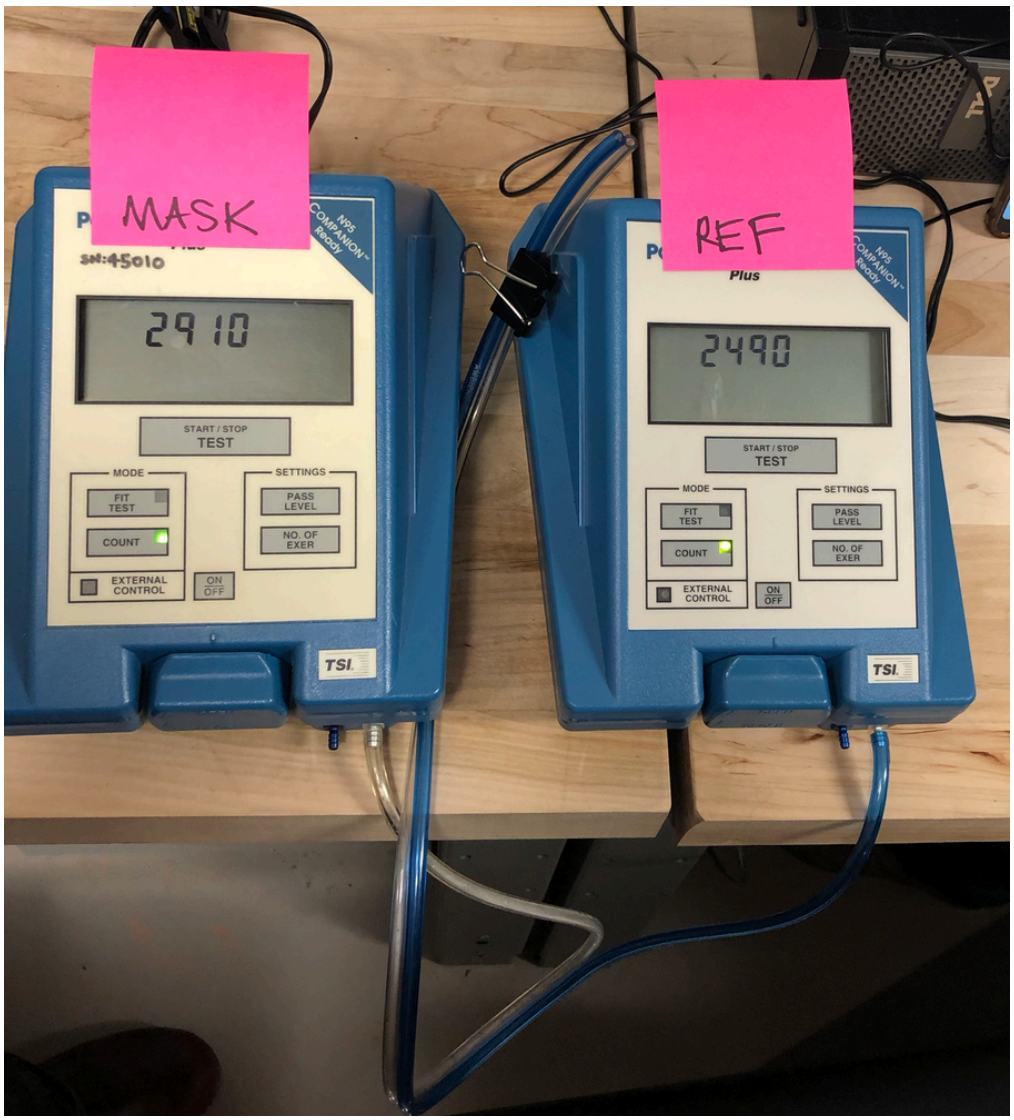

Figure S1. Two TSI PortaCount model 8028 used in this work. Sample tubes are of equal length and are connected to right-hand ports labeled “sample”. Instruments were operated in count mode with “Mask”-labeled instrument sampling air from inside the mask and “Ref”-labeled instrument sampling ambient air just outside of the mask.

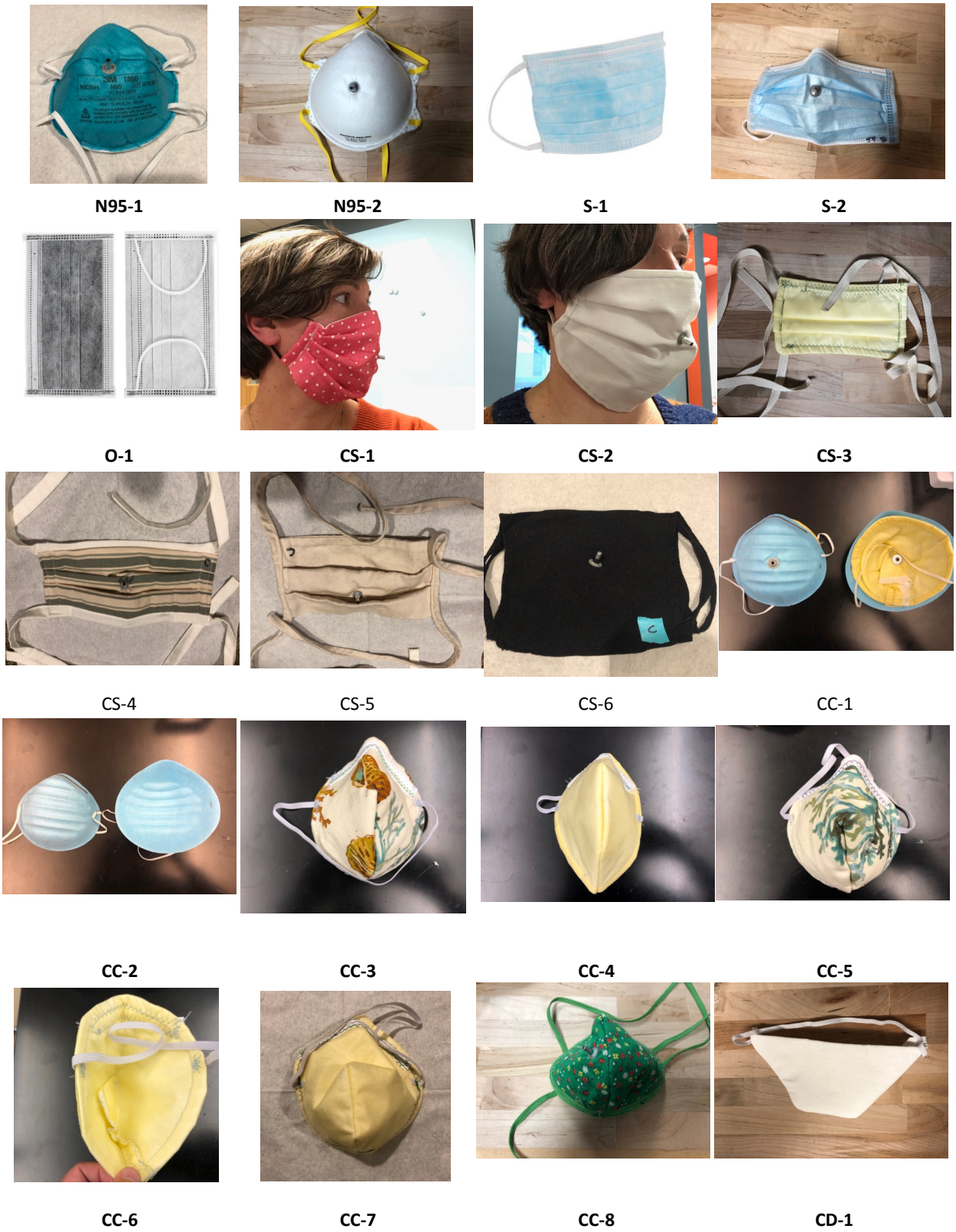

Figure S2. Gallery of mask images. Masks ordered by sample ID. Descriptions included in Table S1.

Additional and updated results are available through a web portal at masktestingatNU.com.

Appendix D
(29 CFR § 1910.134 Respiratory Protection)

- **Part Number:** 1910
- **Part Title:** Occupational Safety and Health Standards
- **Subpart:** I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.134
- **Title:** Respiratory Protection.
- **Appendix:** A , B-1 , B-2 , C , D
- **GPO Source:** e-CFR

This section applies to General Industry (part 1910), Shipyards (part 1915), Marine Terminals (part 1917), Longshoring (part 1918), and Construction (part 1926).

1910.134(a)

Permissible practice.

1910.134(a)(1)

In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section.

1910.134(a)(2)

A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in paragraph (c) of this section. The program shall cover each employee required by this section to use a respirator.

1910.134(b)

Definitions. The following definitions are important terms used in the respiratory protection standard in this section.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

Assigned protection factor (APF) means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Canister or cartridge means a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Emergency situation means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of an airborne contaminant.

Employee exposure means exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.

End-of-service-life indicator (ESLI) means a system that warns the respirator user of the approach of the end of adequate respiratory protection, for example, that the sorbent is approaching saturation or is no longer effective.

Escape-only respirator means a respirator intended to be used only for emergency exit.

Filter or air purifying element means a component used in respirators to remove solid or liquid aerosols from the inspired air.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual. (See also Qualitative fit test QLFT and Quantitative fit test QNFT.)

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High efficiency particulate air (HEPA) filter means a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Immediately dangerous to life or health (IDLH) means an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Interior structural firefighting means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage. (See 29 CFR 1910.155)

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Maximum use concentration (MUC) means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance. The MUC can be determined mathematically by multiplying the assigned protection factor specified for a respirator by the required OSHA permissible exposure limit, short-term exposure limit, or ceiling limit. When no OSHA exposure limit is available for a hazardous substance, an employer must determine an MUC on the basis of relevant available information and informed professional judgment.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Oxygen deficient atmosphere means an atmosphere with an oxygen content below 19.5% by volume.

Physician or other licensed health care professional (PLHCP) means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide, or be delegated the responsibility to provide, some or all of the health care services required by paragraph (e) of this section.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the

respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Respiratory inlet covering means that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood, suit, or a mouthpiece respirator with nose clamp.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Service life means the period of time that a respirator, filter or sorbent, or other respiratory equipment provides adequate protection to the wearer.

Supplied-air respirator (SAR) or airline respirator means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

This section means this respiratory protection standard.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

User seal check means an action conducted by the respirator user to determine if the respirator is properly seated to the face.

1910.134(c)

Respiratory protection program. This paragraph requires the employer to develop and implement a written respiratory protection program with required worksite-specific procedures and elements for required respirator use. The program must be administered by a suitably trained program administrator. In addition, certain program elements may be required for voluntary use to prevent potential hazards associated with the use of the respirator. The Small Entity Compliance Guide contains criteria for the selection of a program administrator and a sample program that meets the requirements of this paragraph. Copies of the Small Entity Compliance Guide will be available on or about April 8, 1998 from the Occupational Safety and Health Administration's Office of Publications, Room N 3101, 200 Constitution Avenue, NW, Washington, DC, 20210 (202-219-4667).

1910.134(c)(1)

In any workplace where respirators are necessary to protect the health of the employee or whenever respirators are required by the employer, the employer shall establish and implement a written respiratory protection program with worksite-specific procedures. The program shall be updated as necessary to reflect those changes in workplace conditions that affect respirator use. The employer shall include in the program the following provisions of this section, as applicable:

1910.134(c)(1)(i)

Procedures for selecting respirators for use in the workplace;

1910.134(c)(1)(ii)

Medical evaluations of employees required to use respirators;

1910.134(c)(1)(iii)

Fit testing procedures for tight-fitting respirators;

1910.134(c)(1)(iv)

Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;

1910.134(c)(1)(v)

Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators;

1910.134(c)(1)(vi)

Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators;

1910.134(c)(1)(vii)

Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations;

1910.134(c)(1)(viii)

Training of employees in the proper use of respirators, including putting on and removing them, any limitations on their use, and their maintenance; and

1910.134(c)(1)(ix)

Procedures for regularly evaluating the effectiveness of the program.

1910.134(c)(2)

Where respirator use is not required:

1910.134(c)(2)(i)

An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard. If the employer determines that any voluntary respirator use is permissible, the employer shall provide the respirator users with the information contained in Appendix D to this section ("Information for Employees Using Respirators When Not Required Under the Standard"); and

1910.134(c)(2)(ii)

In addition, the employer must establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored, and maintained so that its use does not present a health hazard to the user. Exception: Employers are not required to include in a written respiratory protection program those employees whose only use of respirators involves the voluntary use of filtering facepieces (dust masks).

1910.134(c)(3)

The employer shall designate a program administrator who is qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness.

1910.134(c)(4)

The employer shall provide respirators, training, and medical evaluations at no cost to the employee.

1910.134(d)

Selection of respirators. This paragraph requires the employer to evaluate respiratory hazard(s) in the workplace, identify relevant workplace and user factors, and base respirator selection on these factors. The paragraph also specifies appropriately protective respirators for use in IDLH atmospheres, and limits the selection and use of air-purifying respirators.

1910.134(d)(1)

General requirements.

1910.134(d)(1)(i)

The employer shall select and provide an appropriate respirator based on the respiratory hazard(s) to which the worker is exposed and workplace and user factors that affect respirator performance and reliability.

1910.134(d)(1)(ii)

The employer shall select a NIOSH-certified respirator. The respirator shall be used in compliance with the conditions of its certification.

1910.134(d)(1)(iii)

The employer shall identify and evaluate the respiratory hazard(s) in the workplace; this evaluation shall include a reasonable estimate of employee exposures to respiratory hazard(s) and an identification of the contaminant's chemical state and physical form. Where the employer cannot identify or reasonably estimate the employee exposure, the employer shall consider the atmosphere to be IDLH.

1910.134(d)(1)(iv)

The employer shall select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

1910.134(d)(2)

Respirators for IDLH atmospheres.

1910.134(d)(2)(i)

The employer shall provide the following respirators for employee use in IDLH atmospheres:

1910.134(d)(2)(i)(A)

A full facepiece pressure demand SCBA certified by NIOSH for a minimum service life of thirty minutes, or

1910.134(d)(2)(i)(B)

A combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.

1910.134(d)(2)(ii)

Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

1910.134(d)(2)(iii)

All oxygen-deficient atmospheres shall be considered IDLH. Exception: If the employer demonstrates that, under all foreseeable conditions, the oxygen concentration can be maintained within the ranges specified in Table II of this section (i.e., for the altitudes set out in the table), then any atmosphere-supplying respirator may be used.

1910.134(d)(3)

Respirators for atmospheres that are not IDLH.

1910.134(d)(3)(i)

The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations.

1910.134(d)(3)(i)(A)

Assigned Protection Factors (APFs) Employers must use the assigned protection factors listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection. When using a combination respirator (e.g., airline respirators with an air-purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.

Table 1. -- Assigned Protection Factors[5]

Type of respirator[1], [2]	Quarter mask	Half mask	Full facepiece	Helmet/ hood	Loose-fitting facepiece
1. Air-Purifying Respirator	5	[3]10	50	.....	.....
2. Powered Air-Purifying Respirator (PAPR)	.....	50	1,000	[4]25/1,000	25
3. Supplied-Air Respirator (SAR) or Airline Respirator					
• Demand mode	.....	10	50	.....	.....
• Continuous flow mode	.....	50	1,000	[4]25/1,000	25
• Pressure-demand or other positive-pressure mode	.....	50	1,000	.....	.....
4. Self-Contained Breathing Apparatus (SCBA)					
• Demand mode	.....	10	50	50	.....
• Pressure-demand or other positive-pressure mode (e.g., open/closed circuit)	.....	.....	10,000	10,000	.....

Notes:

[1]Employers may select respirators assigned for use in higher workplace concentrations of a hazardous substance for use at lower concentrations of that substance, or when required respirator use is independent of concentration.

[2]The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[3]This APF category includes filtering facepieces, and half masks with elastomeric facepieces.

[4]The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a WPF or SWPF study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

[5]These APFs do not apply to respirators used solely for escape. For escape respirators used in association with specific substances covered by 29 CFR 1910 subpart Z, employers must refer to the appropriate substance-specific standards in that subpart. Escape respirators for other IDLH atmospheres are specified by 29 CFR 1910.134 (d)(2)(ii).

1910.134(d)(3)(i)(B)

Maximum Use Concentration (MUC)

1910.134(d)(3)(i)(B)(1)

The employer must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the MUC.

1910.134(d)(3)(i)(B)(2)

Employers must not apply MUCs to conditions that are immediately dangerous to life or health (IDLH); instead, they must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.

1910.134(d)(3)(i)(B)(3)

When the calculated MUC exceeds the IDLH level for a hazardous substance, or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.

1910.134(d)(3)(ii)

The respirator selected shall be appropriate for the chemical state and physical form of the contaminant.

1910.134(d)(3)(iii)

For protection against gases and vapors, the employer shall provide:

1910.134(d)(3)(iii)(A)

An atmosphere-supplying respirator, or

1910.134(d)(3)(iii)(B)

An air-purifying respirator, provided that:

1910.134(d)(3)(iii)(B)(1)

The respirator is equipped with an end-of-service-life indicator (ESLI) certified by NIOSH for the contaminant; or

1910.134(d)(3)(iii)(B)(2)

If there is no ESLI appropriate for conditions in the employer's workplace, the employer implements a change schedule for canisters and cartridges that is based on objective information or data that will ensure that canisters and cartridges are changed before the end of their service life. The employer shall describe in the respirator program the information and data relied upon and the basis for the canister and cartridge change schedule and the basis for reliance on the data.

1910.134(d)(3)(iv)

For protection against particulates, the employer shall provide:

1910.134(d)(3)(iv)(A)

An atmosphere-supplying respirator; or

1910.134(d)(3)(iv)(B)

An air-purifying respirator equipped with a filter certified by NIOSH under 30 CFR part 11 as a high efficiency particulate air (HEPA) filter, or an air-purifying respirator equipped with a filter certified for particulates by NIOSH under 42 CFR part 84; or

1910.134(d)(3)(iv)(C)

For contaminants consisting primarily of particles with mass median aerodynamic diameters (MMAD) of at least 2 micrometers, an air-purifying respirator equipped with any filter certified for particulates by NIOSH.

TABLE I. -- ASSIGNED PROTECTION FACTORS
[RESERVED]

TABLE II

Altitude (ft.)	Oxygen deficient Atmospheres (% 0_2) for which the employer atmosphere-may rely on supplying respirators
Less than 3,001	16.0-19.5
3,001-4,000	16.4-19.5
4,001-5,000	17.1-19.5
5,001-6,000	17.8-19.5
6,001-7,000	18.5-19.5
7,001-8,000[1]	19.3-19.5.

[1]Above 8,000 feet the exception does not apply. Oxygen-enriched breathing air must be supplied above 14,000 feet.

1910.134(e)

Medical evaluation. Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee. Accordingly, this paragraph specifies the minimum requirements for medical evaluation that employers must implement to determine the employee's ability to use a respirator.

1910.134(e)(1)

General. The employer shall provide a medical evaluation to determine the employee's ability to use a respirator, before the employee is fit tested or required to use the respirator in the workplace. The employer may discontinue an employee's medical evaluations when the employee is no longer required to use a respirator.

1910.134(e)(2)

Medical evaluation procedures.

1910.134(e)(2)(i)

The employer shall identify a physician or other licensed health care professional (PLHCP) to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire.

1910.134(e)(2)(ii)

The medical evaluation shall obtain the information requested by the questionnaire in Sections 1 and 2, Part A of Appendix C of this section.

1910.134(e)(3)

Follow-up medical examination.

1910.134(e)(3)(i)

The employer shall ensure that a follow-up medical examination is provided for an employee who gives a positive response to any question among questions 1 through 8 in Section 2, Part A of Appendix C or whose initial medical examination demonstrates the need for a follow-up medical examination.

1910.134(e)(3)(ii)

The follow-up medical examination shall include any medical tests, consultations, or diagnostic procedures that the PLHCP deems necessary to make a final determination.

1910.134(e)(4)

Administration of the medical questionnaire and examinations.

1910.134(e)(4)(i)

The medical questionnaire and examinations shall be administered confidentially during the employee's normal working hours or at a time and place convenient to the employee. The medical questionnaire shall be administered in a manner that ensures that the employee understands its content.

1910.134(e)(4)(ii)

The employer shall provide the employee with an opportunity to discuss the questionnaire and examination results with the PLHCP.

1910.134(e)(5)

Supplemental information for the PLHCP.

1910.134(e)(5)(i)

The following information must be provided to the PLHCP before the PLHCP makes a recommendation concerning an employee's ability to use a respirator:

1910.134(e)(5)(i)(A)

(A) The type and weight of the respirator to be used by the employee;

1910.134(e)(5)(i)(B)

The duration and frequency of respirator use (including use for rescue and escape);

1910.134(e)(5)(i)(C)

The expected physical work effort;

1910.134(e)(5)(i)(D)

Additional protective clothing and equipment to be worn; and

1910.134(e)(5)(i)(E)

Temperature and humidity extremes that may be encountered.

1910.134(e)(5)(ii)

Any supplemental information provided previously to the PLHCP regarding an employee need not be provided for a subsequent medical evaluation if the information and the PLHCP remain the same.

1910.134(e)(5)(iii)

The employer shall provide the PLHCP with a copy of the written respiratory protection program and a copy of this section.

Note to Paragraph (e)(5)(iii): When the employer replaces a PLHCP, the employer must ensure that the new PLHCP obtains this information, either by providing the documents directly to the PLHCP or having the documents transferred from the former PLHCP to the new PLHCP. However, OSHA does not expect employers to have employees medically reevaluated solely because a new PLHCP has been selected.

1910.134(e)(6)

Medical determination. In determining the employee's ability to use a respirator, the employer shall:

1910.134(e)(6)(i)

Obtain a written recommendation regarding the employee's ability to use the respirator from the PLHCP. The recommendation shall provide only the following information:

1910.134(e)(6)(i)(A)

Any limitations on respirator use related to the medical condition of the employee, or relating to the workplace conditions in which the respirator will be used, including whether or not the employee is medically able to use the respirator;

1910.134(e)(6)(i)(B)

The need, if any, for follow-up medical evaluations; and

1910.134(e)(6)(i)(C)

A statement that the PLHCP has provided the employee with a copy of the PLHCP's written recommendation.

1910.134(e)(6)(ii)

If the respirator is a negative pressure respirator and the PLHCP finds a medical condition that may place the employee's health at increased risk if the respirator is used, the employer shall provide a PAPR if the PLHCP's medical evaluation finds that the employee can use such a respirator; if a subsequent medical evaluation finds that the employee is medically able to use a negative pressure respirator, then the employer is no longer required to provide a PAPR.

1910.134(e)(7)

Additional medical evaluations. At a minimum, the employer shall provide additional medical evaluations that comply with the requirements of this section if:

1910.134(e)(7)(i)

An employee reports medical signs or symptoms that are related to ability to use a respirator;

1910.134(e)(7)(ii)

A PLHCP, supervisor, or the respirator program administrator informs the employer that an employee needs to be reevaluated;

1910.134(e)(7)(iii)

Information from the respiratory protection program, including observations made during fit testing and program evaluation, indicates a need for employee reevaluation; or

1910.134(e)(7)(iv)

A change occurs in workplace conditions (e.g., physical work effort, protective clothing, temperature) that may result in a substantial increase in the physiological burden placed on an employee.

1910.134(f)

Fit testing. This paragraph requires that, before an employee may be required to use any respirator with a negative or positive pressure tight-fitting facepiece, the employee must be fit tested with the same make, model, style, and size of respirator that will be used. This paragraph specifies the kinds of fit tests allowed, the procedures for conducting them, and how the results of the fit tests must be used.

1910.134(f)(1)

The employer shall ensure that employees using a tight-fitting facepiece respirator pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as stated in this paragraph.

1910.134(f)(2)

The employer shall ensure that an employee using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or make) is used, and at least annually thereafter.

1910.134(f)(3)

The employer shall conduct an additional fit test whenever the employee reports, or the employer, PLHCP, supervisor, or program administrator makes visual observations of, changes in the employee's physical condition that could affect respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.

1910.134(f)(4)

If after passing a QLFT or QNFT, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.

1910.134(f)(5)

The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol. The OSHA-accepted QLFT and QNFT protocols and procedures are contained in Appendix A of this section.

1910.134(f)(6)

QLFT may only be used to fit test negative pressure air-purifying respirators that must achieve a fit factor of 100 or less.

1910.134(f)(7)

If the fit factor, as determined through an OSHA-accepted QNFT protocol, is equal to or greater than 100 for tight-fitting half facepieces, or equal to or greater than 500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.

1910.134(f)(8)

Fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators shall be accomplished by performing quantitative or qualitative fit testing in the negative pressure mode, regardless of the mode of operation (negative or positive pressure) that is used for respiratory protection.

1910.134(f)(8)(i)

Qualitative fit testing of these respirators shall be accomplished by temporarily converting the respirator user's actual facepiece into a negative pressure respirator with appropriate filters, or by using an identical negative pressure air-purifying respirator facepiece with the same sealing surfaces as a surrogate for the atmosphere-supplying or powered air-purifying respirator facepiece.

1910.134(f)(8)(ii)

Quantitative fit testing of these respirators shall be accomplished by modifying the facepiece to allow sampling inside the facepiece in the breathing zone of the user, midway between the nose and mouth. This requirement shall be accomplished by installing a permanent sampling probe onto a surrogate facepiece, or by using a sampling adapter designed to temporarily provide a means of sampling air from inside the facepiece.

1910.134(f)(8)(iii)

Any modifications to the respirator facepiece for fit testing shall be completely removed, and the facepiece restored to NIOSH-approved configuration, before that facepiece can be used in the workplace.

1910.134(g)

Use of respirators. This paragraph requires employers to establish and implement procedures for the proper use of respirators. These requirements include prohibiting conditions that may result in facepiece seal leakage, preventing employees from removing respirators in hazardous environments, taking actions to ensure continued effective respirator operation throughout the work shift, and establishing procedures for the use of respirators in IDLH atmospheres or in interior structural firefighting situations.

1910.134(g)(1)

Facepiece seal protection.

1910.134(g)(1)(i)

The employer shall not permit respirators with tight-fitting facepieces to be worn by employees who have:

1910.134(g)(1)(i)(A)

Facial hair that comes between the sealing surface of the facepiece and the face or that interferes with valve function; or

1910.134(g)(1)(i)(B)

Any condition that interferes with the face-to-facepiece seal or valve function.

1910.134(g)(1)(ii)

If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user.

1910.134(g)(1)(iii)

For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section.

1910.134(g)(2)

Continuing respirator effectiveness.

1910.134(g)(2)(i)

Appropriate surveillance shall be maintained of work area conditions and degree of employee exposure or stress. When there is a change in work area conditions or degree of employee exposure or stress that may affect respirator effectiveness, the employer shall reevaluate the continued effectiveness of the respirator.

1910.134(g)(2)(ii)

The employer shall ensure that employees leave the respirator use area:

1910.134(g)(2)(ii)(A)

To wash their faces and respirator facepieces as necessary to prevent eye or skin irritation associated with respirator use; or

1910.134(g)(2)(ii)(B)

If they detect vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece; or

1910.134(g)(2)(ii)(C)

To replace the respirator or the filter, cartridge, or canister elements.

1910.134(g)(2)(iii)

If the employee detects vapor or gas breakthrough, changes in breathing resistance, or leakage of the facepiece, the employer must replace or repair the respirator before allowing the employee to return to the work area.

1910.134(g)(3)

Procedures for IDLH atmospheres. For all IDLH atmospheres, the employer shall ensure that:

1910.134(g)(3)(i)

One employee or, when needed, more than one employee is located outside the IDLH atmosphere;

1910.134(g)(3)(ii)

Visual, voice, or signal line communication is maintained between the employee(s) in the IDLH atmosphere and the employee(s) located outside the IDLH atmosphere;

1910.134(g)(3)(iii)

The employee(s) located outside the IDLH atmosphere are trained and equipped to provide effective emergency rescue;

1910.134(g)(3)(iv)

The employer or designee is notified before the employee(s) located outside the IDLH atmosphere enter the IDLH atmosphere to provide emergency rescue;

1910.134(g)(3)(v)

The employer or designee authorized to do so by the employer, once notified, provides necessary assistance appropriate to the situation;

1910.134(g)(3)(vi)

Employee(s) located outside the IDLH atmospheres are equipped with:

1910.134(g)(3)(vi)(A)

Pressure demand or other positive pressure SCBAs, or a pressure demand or other positive pressure supplied-air respirator with auxiliary SCBA; and either

1910.134(g)(3)(vi)(B)

Appropriate retrieval equipment for removing the employee(s) who enter(s) these hazardous atmospheres where retrieval equipment would contribute to the rescue of the employee(s) and would not increase the overall risk resulting from entry; or

1910.134(g)(3)(vi)(C)

Equivalent means for rescue where retrieval equipment is not required under paragraph (g)(3)(vi)(B).

1910.134(g)(4)

Procedures for interior structural firefighting. In addition to the requirements set forth under paragraph (g)(3), in interior structural fires, the employer shall ensure that:

1910.134(g)(4)(i)

At least two employees enter the IDLH atmosphere and remain in visual or voice contact with one another at all times;

1910.134(g)(4)(ii)

At least two employees are located outside the IDLH atmosphere; and

1910.134(g)(4)(iii)

All employees engaged in interior structural firefighting use SCBAs.

Note 1 to paragraph (g): One of the two individuals located outside the IDLH atmosphere may be assigned to an additional role, such as incident commander in charge of the emergency or safety officer, so long as this individual is able to perform assistance or rescue activities without jeopardizing the safety or health of any firefighter working at the incident.

Note 2 to paragraph (g): Nothing in this section is meant to preclude firefighters from performing emergency rescue activities before an entire team has assembled.

1910.134(h)

Maintenance and care of respirators. This paragraph requires the employer to provide for the cleaning and disinfecting, storage, inspection, and repair of respirators used by employees.

1910.134(h)(1)

Cleaning and disinfecting. The employer shall provide each respirator user with a respirator that is clean, sanitary, and in good working order. The employer shall ensure that respirators are cleaned and disinfected using the procedures in Appendix B-2 of this section, or procedures recommended by the respirator manufacturer, provided that such procedures are of equivalent effectiveness. The respirators shall be cleaned and disinfected at the following intervals:

1910.134(h)(1)(i)

Respirators issued for the exclusive use of an employee shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition;

1910.134(h)(1)(ii)

Respirators issued to more than one employee shall be cleaned and disinfected before being worn by different individuals;

1910.134(h)(1)(iii)

Respirators maintained for emergency use shall be cleaned and disinfected after each use; and

1910.134(h)(1)(iv)

Respirators used in fit testing and training shall be cleaned and disinfected after each use.

1910.134(h)(2)

Storage. The employer shall ensure that respirators are stored as follows:

1910.134(h)(2)(i)

All respirators shall be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and they shall be packed or stored to prevent deformation of the facepiece and exhalation valve.

1910.134(h)(2)(ii)

In addition to the requirements of paragraph (h)(2)(i) of this section, emergency respirators shall be:

1910.134(h)(2)(ii)(A)

Kept accessible to the work area;

1910.134(h)(2)(ii)(B)

Stored in compartments or in covers that are clearly marked as containing emergency respirators; and

1910.134(h)(2)(ii)(C)

Stored in accordance with any applicable manufacturer instructions.

1910.134(h)(3)

Inspection.

1910.134(h)(3)(i)

The employer shall ensure that respirators are inspected as follows:

1910.134(h)(3)(i)(A)

All respirators used in routine situations shall be inspected before each use and during cleaning;

1910.134(h)(3)(i)(B)

All respirators maintained for use in emergency situations shall be inspected at least monthly and in accordance with the manufacturer's recommendations, and shall be checked for proper function before and after each use; and

1910.134(h)(3)(i)(C)

Emergency escape-only respirators shall be inspected before being carried into the workplace for use.

1910.134(h)(3)(ii)

The employer shall ensure that respirator inspections include the following:

1910.134(h)(3)(ii)(A)

A check of respirator function, tightness of connections, and the condition of the various parts including, but not limited to, the facepiece, head straps, valves, connecting tube, and cartridges, canisters or filters; and

1910.134(h)(3)(ii)(B)

A check of elastomeric parts for pliability and signs of deterioration.

1910.134(h)(3)(iii)

In addition to the requirements of paragraphs (h)(3)(i) and (ii) of this section, self-contained breathing apparatus shall be inspected monthly. Air and oxygen cylinders shall be maintained in a fully charged state and shall be recharged when the pressure falls to 90% of the manufacturer's recommended pressure level. The employer shall determine that the regulator and warning devices function properly.

1910.134(h)(3)(iv)

For respirators maintained for emergency use, the employer shall:

1910.134(h)(3)(iv)(A)

Certify the respirator by documenting the date the inspection was performed, the name (or signature) of the person who made the inspection, the findings, required remedial action, and a serial number or other means of identifying the inspected respirator; and

1910.134(h)(3)(iv)(B)

Provide this information on a tag or label that is attached to the storage compartment for the respirator, is kept with the respirator, or is included in inspection reports stored as paper or electronic files. This information shall be maintained until replaced following a subsequent certification.

1910.134(h)(4)

Repairs. The employer shall ensure that respirators that fail an inspection or are otherwise found to be defective are removed from service, and are discarded or repaired or adjusted in accordance with the following procedures:

1910.134(h)(4)(i)

Repairs or adjustments to respirators are to be made only by persons appropriately trained to perform such operations and shall use only the respirator manufacturer's NIOSH-approved parts designed for the respirator;

1910.134(h)(4)(ii)

Repairs shall be made according to the manufacturer's recommendations and specifications for the type and extent of repairs to be performed; and

1910.134(h)(4)(iii)

Reducing and admission valves, regulators, and alarms shall be adjusted or repaired only by the manufacturer or a technician trained by the manufacturer.

1910.134(i)

Breathing air quality and use. This paragraph requires the employer to provide employees using atmosphere-supplying respirators (supplied-air and SCBA) with breathing gases of high purity.

1910.134(i)(1)

The employer shall ensure that compressed air, compressed oxygen, liquid air, and liquid oxygen used for respiration accords with the following specifications:

1910.134(i)(1)(i)

Compressed and liquid oxygen shall meet the United States Pharmacopoeia requirements for medical or breathing oxygen; and

1910.134(i)(1)(ii)

Compressed breathing air shall meet at least the requirements for Grade D breathing air described in ANSI/Compressed Gas Association Commodity Specification for Air, G-7.1-1989, to include:

1910.134(i)(1)(ii)(A)

Oxygen content (v/v) of 19.5-23.5%;

1910.134(i)(1)(ii)(B)

Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

1910.134(i)(1)(ii)(C)

Carbon monoxide (CO) content of 10 ppm or less;

1910.134(i)(1)(ii)(D)

Carbon dioxide content of 1,000 ppm or less; and

1910.134(i)(1)(ii)(E)

Lack of noticeable odor.

1910.134(i)(2)

The employer shall ensure that compressed oxygen is not used in atmosphere-supplying respirators that have previously used compressed air.

1910.134(i)(3)

The employer shall ensure that oxygen concentrations greater than 23.5% are used only in equipment designed for oxygen service or distribution.

1910.134(i)(4)

The employer shall ensure that cylinders used to supply breathing air to respirators meet the following requirements:

1910.134(i)(4)(i)

Cylinders are tested and maintained as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR part 180);

1910.134(i)(4)(ii)

Cylinders of purchased breathing air have a certificate of analysis from the supplier that the breathing air meets the requirements for Grade D breathing air; and

1910.134(i)(4)(iii)

The moisture content in the cylinder does not exceed a dew point of -50 deg.F (-45.6 deg.C) at 1 atmosphere pressure.

1910.134(i)(5)

The employer shall ensure that compressors used to supply breathing air to respirators are constructed and situated so as to:

1910.134(i)(5)(i)

Prevent entry of contaminated air into the air-supply system;

1910.134(i)(5)(ii)

Minimize moisture content so that the dew point at 1 atmosphere pressure is 10 degrees F (5.56 deg.C) below the ambient temperature;

1910.134(i)(5)(iii)

Have suitable in-line air-purifying sorbent beds and filters to further ensure breathing air quality. Sorbent beds and filters shall be maintained and replaced or refurbished periodically following the manufacturer's instructions.

1910.134(i)(5)(iv)

Have a tag containing the most recent change date and the signature of the person authorized by the employer to perform the change. The tag shall be maintained at the compressor.

1910.134(i)(6)

For compressors that are not oil-lubricated, the employer shall ensure that carbon monoxide levels in the breathing air do not exceed 10 ppm.

1910.134(i)(7)

For oil-lubricated compressors, the employer shall use a high-temperature or carbon monoxide alarm, or both, to monitor carbon monoxide levels. If only high-temperature alarms are used, the air supply shall be monitored at intervals sufficient to prevent carbon monoxide in the breathing air from exceeding 10 ppm.

1910.134(i)(8)

The employer shall ensure that breathing air couplings are incompatible with outlets for nonrespirable worksite air or other gas systems. No asphyxiating substance shall be introduced into breathing air lines.

1910.134(i)(9)

The employer shall use only the respirator manufacturer's NIOSH-approved breathing-gas containers,marked and maintained in accordance with the Quality Assurance provisions of the NIOSH approval for the SCBA as issued in accordance with the NIOSH respirator-certification standard at 42 CFR part 84.

1910.134(j)

Identification of filters, cartridges, and canisters. The employer shall ensure that all filters, cartridges and canisters used in the workplace are labeled and color coded with the NIOSH approval label and that the label is not removed and remains legible.

1910.134(k)

Training and information. This paragraph requires the employer to provide effective training to employees who are required to use respirators. The training must be comprehensive, understandable, and recur annually, and more often if necessary. This paragraph also requires the employer to provide the basic information on respirators in Appendix D of this section to employees who wear respirators when not required by this section or by the employer to do so.

1910.134(k)(1)

The employer shall ensure that each employee can demonstrate knowledge of at least the following:

1910.134(k)(1)(i)

Why the respirator is necessary and how improper fit, usage, or maintenance can compromise the protective effect of the respirator;

1910.134(k)(1)(ii)

What the limitations and capabilities of the respirator are;

1910.134(k)(1)(iii)

How to use the respirator effectively in emergency situations, including situations in which the respirator malfunctions;

1910.134(k)(1)(iv)

How to inspect, put on and remove, use, and check the seals of the respirator;

1910.134(k)(1)(v)

What the procedures are for maintenance and storage of the respirator;

1910.134(k)(1)(vi)

How to recognize medical signs and symptoms that may limit or prevent the effective use of respirators; and

1910.134(k)(1)(vii)

The general requirements of this section.

1910.134(k)(2)

The training shall be conducted in a manner that is understandable to the employee.

1910.134(k)(3)

The employer shall provide the training prior to requiring the employee to use a respirator in the workplace.

1910.134(k)(4)

An employer who is able to demonstrate that a new employee has received training within the last 12 months that addresses the elements specified in paragraph (k)(1)(i) through (vii) is not required to repeat such training provided that, as required by paragraph (k)(1), the employee can demonstrate knowledge of those element(s). Previous training not repeated initially by the employer must be provided no later than 12 months from the date of the previous training.

1910.134(k)(5)

Retraining shall be administered annually, and when the following situations occur:

1910.134(k)(5)(i)

Changes in the workplace or the type of respirator render previous training obsolete;

1910.134(k)(5)(ii)

Inadequacies in the employee's knowledge or use of the respirator indicate that the employee has not retained the requisite understanding or skill; or

1910.134(k)(5)(iii)

Any other situation arises in which retraining appears necessary to ensure safe respirator use.

1910.134(k)(6)

The basic advisory information on respirators, as presented in Appendix D of this section, shall be provided by the employer in any written or oral format, to employees who wear respirators when such use is not required by this section or by the employer.

1910.134(l)

Program evaluation. This section requires the employer to conduct evaluations of the workplace to ensure that the written respiratory protection program is being properly implemented, and to consult employees to ensure that they are using the respirators properly.

1910.134(l)(1)

The employer shall conduct evaluations of the workplace as necessary to ensure that the provisions of the current written program are being effectively implemented and that it continues to be effective.

1910.134(l)(2)

The employer shall regularly consult employees required to use respirators to assess the employees' views on program effectiveness and to identify any problems. Any problems that are identified during this assessment shall be corrected. Factors to be assessed include, but are not limited to:

1910.134(l)(2)(i)

Respirator fit (including the ability to use the respirator without interfering with effective workplace performance);

1910.134(l)(2)(ii)

Appropriate respirator selection for the hazards to which the employee is exposed;

1910.134(l)(2)(iii)

Proper respirator use under the workplace conditions the employee encounters; and

1910.134(l)(2)(iv)

Proper respirator maintenance.

1910.134(m)

Recordkeeping. This section requires the employer to establish and retain written information regarding medical evaluations, fit testing, and the respirator program. This information will facilitate employee involvement in the respirator program, assist the employer in auditing the adequacy of the program, and provide a record for compliance determinations by OSHA.

1910.134(m)(1)

Medical evaluation. Records of medical evaluations required by this section must be retained and made available in accordance with 29 CFR 1910.1020.

1910.134(m)(2)

Fit testing.

1910.134(m)(2)(i)

The employer shall establish a record of the qualitative and quantitative fit tests administered to an employee including:

1910.134(m)(2)(i)(A)

The name or identification of the employee tested;

1910.134(m)(2)(i)(B)

Type of fit test performed;

1910.134(m)(2)(i)(C)

Specific make, model, style, and size of respirator tested;

1910.134(m)(2)(i)(D)

Date of test; and

1910.134(m)(2)(i)(E)

The pass/fail results for QLFTs or the fit factor and strip chart recording or other recording of the test results for QNFTs.

1910.134(m)(2)(ii)

Fit test records shall be retained for respirator users until the next fit test is administered.

1910.134(m)(3)

A written copy of the current respirator program shall be retained by the employer.

1910.134(m)(4)

Written materials required to be retained under this paragraph shall be made available upon request to affected employees and to the Assistant Secretary or designee for examination and copying.

1910.134(n)

Effective date. Paragraphs (d)(3)(i)(A) and (d)(3)(i)(B) of this section become effective November 22, 2006.

1910.134(o)

Appendices. Compliance with Appendix A, Appendix B-1, Appendix B-2, Appendix C, and Appendix D to this section are mandatory.

[63 FR 1152, Jan. 8, 1998; 63 FR 20098, April 23, 1998; 71 FR 16672, April 3, 2006; 71 FR 50187, August 24, 2006; 73 FR 75584, Dec. 12, 2008; 76 FR 33606, June 8, 2011]

Next Standard (1910.134 App A)

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Appendix E
(29 CFR § 1910.134 App A)

By Standard Number / 1910.134 App A - Fit Testing Procedures (Mandatory).

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Subpart:** 1910 Subpart I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.134 App A
- **Title:** Fit Testing Procedures (Mandatory).
- **GPO Source:** e-CFR

Appendix A to §1910.134—Fit Testing Procedures (Mandatory)

Part I. OSHA-Accepted Fit Test Protocols

A. Fit Testing Procedures—General Requirements

The employer shall conduct fit testing using the following procedures. The requirements in this appendix apply to all OSHA-accepted fit test methods, both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item A.6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose

(b) Room for eye protection

(c) Room to talk

(d) Position of mask on face and cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in appendix B-1 of this section or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in appendix B-1. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.

14. Test Exercises.

(a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the two modified ambient aerosol CNC quantitative fit testing protocols, the CNP quantitative fit testing protocol, and the CNP REDON quantitative fit testing protocol. For the modified ambient aerosol CNC quantitative fit testing protocols, employers shall ensure that the test subjects (*i.e.*, employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for full-facepiece and half-mask elastomeric respirators, or the exercise procedure specified in Part I.C.5(b) for filtering facepiece respirators. Employers shall ensure that the test subjects (i.e., employees) perform the exercise procedure specified in Part I.C.6(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.7(b) of this appendix for the CNP REDON quantitative fit testing protocol. For the remaining fit testing methods, employers shall ensure that the test exercises are performed in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for QLFT)

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

(8) Normal breathing. Same as exercise (1).

(b) Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 °C (77 °F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(7) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): “The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.”

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the

IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾ -inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a sweet taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.

Note to paragraph 3(a): If the test subject eats or drinks something sweet before the screening test, he/she may be unable to taste the weak saccharin solution.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in 3. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he/she tastes the sweet taste of saccharin.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

(12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening.

The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾ inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes

actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex Solution Aerosol Fit Test Procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure as that described in 4. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.

(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses a person's response to the irritating chemicals released in the “smoke” produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.

(a) General Requirements and Precautions

(1) The respirator to be tested shall be equipped with high efficiency particulate air (HEPA) or P100 series filter(s).

(2) Only stannic chloride smoke tubes shall be used for this protocol.

(3) No form of test enclosure or hood for the test subject shall be used.

(4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.

(5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.

(b) Sensitivity Screening Check

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

(1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his/her eyes closed while the test is performed.

(3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he/she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he/she can detect it.

(c) Irritant Smoke Fit Test Procedure

(1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).

(2) The test subject shall be instructed to keep his/her eyes closed.

(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the facepiece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.

(4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.

(5) The exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.

(6) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.

(7) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he/she still reacts to the smoke. Failure to evoke a response shall void the fit test.

(8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QNFT equipment is kept clean, and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

(a) Apparatus.

(1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols shall be used for quantitative fit testing.

(2) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the test agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the test agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high efficiency particulate air (HEPA) or P100 series filter supplied by the same manufacturer.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, test agent and test agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(7) The test setup shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the test atmosphere shall maintain the concentration of test agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

(b) Procedural Requirements.

(1) When performing the initial user seal check using a positive or negative pressure check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these pressure checks.

(2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirators that passed the positive and/or negative pressure test and reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable test agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the test agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable test agent concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over-tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use. The respirator shall not be adjusted once the fit test exercises begin.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(8) Calculation of fit factors.

(i) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(ii) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(iii) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(A) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(B) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(C) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(D) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

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Where ff1, ff2, ff3, etc. are the fit factors for exercises 1, 2, 3, etc.

(9) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(10) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (PortaCount®) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The primary CNC instrument manufacturer, TSI Incorporated, also provides probe attachments (TSI mask sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator (elastomeric or filtering facepiece), and a minimum fit factor pass level of at least 500 is required for a full-facepiece elastomeric respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) PortaCount® Fit Test Requirements. (1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

(2) Instruct the person to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already have been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the person wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the PortaCount® and proceed with the test.

(6) The test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(7) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(b) PortaCount® Test Instrument.

(1) The PortaCount® will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) Since the pass or fail criterion of the PortaCount® is user programmable, the test operator shall ensure that the pass or fail criterion meet the requirements for minimum respirator performance in this Appendix.

(3) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style, and size of respirator used; and date tested.

4. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A-1 of this appendix.

Table A-1-- Modified Ambient Aerosal CNC Quantitative Fit Testing Protocol for Full Facepiece and Half-Mask Elastomeric Respirators

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2].	A 20 second ambient sample, followed by a 30 second mask sample.
Jogging-in-Place	The test subject shall jog in place comfortably for 30 seconds	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample.

Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

5. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for filtering facepiece respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A–2 of this appendix

TABLE A–2— MODIFIED AMBIENT AEROSAL CNC QUANTITATIVE FIT TESTING PROTOCOL FOR FILTERING FACEPIECE RESPIRATORS

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2].	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

6. Controlled negative pressure (CNP) quantitative fit testing protocol.

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator. The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Occupational Health Dynamics of Birmingham, Alabama also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his/her breath, after which an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) CNP Fit Test Requirements.

(1) The instrument shall have a non-adjustable test pressure of 15.0 mm water pressure.

(2) The CNP system defaults selected for test pressure shall be set at −15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

Note: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.)

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

(7) The QNFT protocol shall be followed according to section I. C. 1. of this appendix with an exception for the CNP test exercises.

(b) CNP Test Exercises.

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) Moving head up and down. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject shall hold his or her head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject shall hold his or her head full down and hold his or her breath for 10 seconds during test measurement.

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) Grimace. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) Bending Over. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) Normal Breathing. The test subject shall remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement. After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) CNP Test Instrument.

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails to hold his or her breath during the test. The test subject then may be refitted and retested.

(2) A record of the test shall be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style and size of respirator used; and date tested.

7. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of part I.C.6 of this appendix (``Controlled negative pressure (CNP) quantitative fit testing protocol,'') as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of part I.C.6 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration described in Table A-3 of this appendix.

Table A-3—CNP REDON Quantitative Fit Testing Protocol

Exercises[1]	Exercise procedure	Measurement procedure

Facing Forward	Stand and breathe normally, without talking, for 30 seconds	Face forward, while holding breath for 10 seconds.
Bending Over	Bend at the waist, as if going to touch his or her toes, for 30 seconds	Face parallel to the floor, while holding breath for 10 seconds
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting	Face forward, while holding breath for 10 seconds
REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask	Face forward, while holding breath for 10 seconds.
REDON 2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again	Face forward, while holding breath for 10 seconds.

[1]Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{\left[1/FF_1 + 1/FF_2 + \ldots\ 1/FF_N\right]}$$

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Where:

N = The number of exercises;

FF1 = The fit factor for the first exercise;

FF2 = The fit factor for the second exercise; and

FFN = The fit factor for the nth exercise.

Part II. New Fit Test Protocols

A. Any person may submit to OSHA an application for approval of a new fit test protocol. If the application meets the following criteria, OSHA will initiate a rulemaking proceeding under section 6(b)(7) of the OSH Act to determine whether to list the new protocol as an approved protocol in this appendix A.

B. The application must include a detailed description of the proposed new fit test protocol. This application must be supported by either:

1. A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory has tested the protocol and had found it to be accurate and reliable; or

2. An article that has been published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how test data support the protocol's accuracy and reliability.

C. If OSHA determines that additional information is required before the Agency commences a rulemaking proceeding under this section, OSHA will so notify the applicant and afford the applicant the opportunity to submit the supplemental information. Initiation of a rulemaking proceeding will be deferred until OSHA has received and evaluated the supplemental information.

[63 FR 20098, April 23, 1998; 69 FR 46993, August 4, 2004]

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Appendix F
(29 CFR § 1910.132 PPE)

By Standard Number / 1910.132 - General requirements.

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Subpart:** 1910 Subpart I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.132
- **Title:** General requirements.
- **GPO Source:** e-CFR

1910.132(a)

Application. Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.

1910.132(b)

Employee-owned equipment. Where employees provide their own protective equipment, the employer shall be responsible to assure its adequacy, including proper maintenance, and sanitation of such equipment.

1910.132(c)

Design. All personal protective equipment shall be of safe design and construction for the work to be performed.

1910.132(d)

Hazard assessment and equipment selection.

1910.132(d)(1)

The employer shall assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE). If such hazards are present, or likely to be present, the employer shall:

1910.132(d)(1)(i)

Select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment;

1910.132(d)(1)(ii)

Communicate selection decisions to each affected employee; and,

1910.132(d)(1)(iii)

Select PPE that properly fits each affected employee.

Note: Non-mandatory appendix B contains an example of procedures that would comply with the requirement for a hazard assessment.

1910.132(d)(2)

The employer shall verify that the required workplace hazard assessment has been performed through a written certification that identifies the workplace evaluated; the person certifying that the evaluation has been performed; the date(s) of the hazard assessment; and, which identifies the document as a certification of hazard assessment.

1910.132(e)

Defective and damaged equipment. Defective or damaged personal protective equipment shall not be used.

1910.132(f)

Training.

1910.132(f)(1)

The employer shall provide training to each employee who is required by this section to use PPE. Each such employee shall be trained to know at least the following:

1910.132(f)(1)(i)

When PPE is necessary;

1910.132(f)(1)(ii)

What PPE is necessary;

1910.132(f)(1)(iii)

How to properly don, doff, adjust, and wear PPE;

1910.132(f)(1)(iv)

The limitations of the PPE; and,

1910.132(f)(1)(v)

The proper care, maintenance, useful life and disposal of the PPE.

1910.132(f)(2)

Each affected employee shall demonstrate an understanding of the training specified in paragraph (f)(1) of this section, and the ability to use PPE properly, before being allowed to perform work requiring the use of PPE.

1910.132(f)(3)

When the employer has reason to believe that any affected employee who has already been trained does not have the understanding and skill required by paragraph (f)(2) of this section, the employer shall retrain each such employee. Circumstances where retraining is required include, but are not limited to, situations where:

1910.132(f)(3)(i)

Changes in the workplace render previous training obsolete; or

1910.132(f)(3)(ii)

Changes in the types of PPE to be used render previous training obsolete; or

1910.132(f)(3)(iii)

Inadequacies in an affected employee's knowledge or use of assigned PPE indicate that the employee has not retained the requisite understanding or skill.

1910.132(g)

Paragraphs (d) and (f) of this section apply only to §§ 1910.133, 1910.135, 1910.136, 1910.138, and 1910.140. Paragraphs (d) and (f) of this section do not apply to §§ 1910.134 and 1910.137.

1910.132(h)

Payment for protective equipment.

1910.132(h)(1)

Except as provided by paragraphs (h)(2) through (h)(6) of this section, the protective equipment, including personal protective equipment (PPE), used to comply with this part, shall be provided by the employer at no cost to employees.

1910.132(h)(2)

The employer is not required to pay for non-specialty safety-toe protective footwear (including steel-toe shoes or steel-toe boots) and non-specialty prescription safety eyewear, provided that the employer permits such items to be worn off the job-site.

1910.132(h)(3)

When the employer provides metatarsal guards and allows the employee, at his or her request, to use shoes or boots with built-in metatarsal protection, the employer is not required to reimburse the employee for the shoes or boots.

1910.132(h)(4)

The employer is not required to pay for:

1910.132(h)(4)(i)

The logging boots required by 29 CFR 1910.266(d)(1)(v);

1910.132(h)(4)(ii)

Everyday clothing, such as long-sleeve shirts, long pants, street shoes, and normal work boots; or

1910.132(h)(4)(iii)

Ordinary clothing, skin creams, or other items, used solely for protection from weather, such as winter coats, jackets, gloves, parkas, rubber boots, hats, raincoats, ordinary sunglasses, and sunscreen.

1910.132(h)(5)

The employer must pay for replacement PPE, except when the employee has lost or intentionally damaged the PPE.

1910.132(h)(6)

Where an employee provides adequate protective equipment he or she owns pursuant to paragraph (b) of this section, the employer may allow the employee to use it and is not required to reimburse the employee for that equipment. The employer shall not require an employee to provide or pay for his or her own PPE, unless the PPE is excepted by paragraphs (h)(2) through (h)(5) of this section.

1910.132(h)(7)

This paragraph (h) shall become effective on February 13, 2008. Employers must implement the PPE payment requirements no later than May 15, 2008.

Note to §1910.132(h): When the provisions of another OSHA standard specify whether or not the employer must pay for specific equipment, the payment provisions of that standard shall prevail.

[39 FR 23502, June 27, 1974, as amended at 59 FR 16334, April 6, 1994; 59 FR 33910, July 1, 1994; 59 FR 34580, July 6, 1994; 72 FR 64428, Nov. 15, 2007; 76 FR 33606, June 8, 2011; 81 FR 82999, Nov. 18, 2016]

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Appendix G

(Masks vs Respirators “Understanding the Difference”)

Understanding the Difference

Surgical Mask

N95 Respirator

	Surgical Mask	N95 Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (**FDA**)	Evaluated, tested, and approved by **NIOSH** as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (**only non-oil aerosols**).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Appendix H
(Media Uses for this Study)

Centers for Disease Control and Prevention

COVID-19

Guidance for Wearing Masks

Help Slow the Spread of COVID-19

Updated Apr. 19, 2021 Print

What you need to know

- When you wear a mask, you protect others as well as yourself. Masks work best when everyone wears one.
- A mask is NOT a substitute for social distancing. Masks should still be worn in addition to staying at least 6 feet apart, especially when indoors around people who don't live in your household.
- Masks should completely cover the nose **and** mouth and fit snugly against the sides of face without gaps.
- Masks should be worn any time you are traveling on a plane, bus, train, or other form of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations.
- People age 2 and older should wear masks in public settings and when around people who don't live in their household.
- Wear a mask inside your home if someone you live with is sick with symptoms of COVID-19 or has tested positive for COVID-19.
- Wash your hands with soap and water for at least 20 seconds or use hand sanitizer with at least 60% alcohol after touching or removing your mask.
- Masks may not be necessary when you are outside by yourself away from others, or with people who live in your household. However, some areas may have mask mandates while out in public, so please check the rules in your local area (such as in your city, county, or state). Additionally, check whether any federal mask mandates apply to where you will be going.
- CDC continues to study the effectiveness of different types of masks and update our recommendations as new scientific evidence becomes available. The most recent scientific brief is available here: Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2 | CDC
- CDC recently conducted a study in a laboratory that tested the performance of different mask combinations.
- There are several easy methods to improve the performance of your mask. Visit CDC's Improve the Fit and Filtration of Your Mask to Reduce the Spread of COVID-19 webpage to learn more.

Evidence for Effectiveness of Masks

Your mask helps protect those around you

COVID-19 spreads mainly from person to person through respiratory droplets. Respiratory droplets travel into the air when you cough, sneeze, talk, shout, or sing. These droplets can then land in the mouths or noses of people who are near you or they may breathe these droplets in.

Masks are a simple barrier to help prevent your respiratory droplets from reaching others. Studies show that masks reduce the spray of droplets when worn over the nose and mouth.

You should wear a mask, even if you do not feel sick. This is because several studies have found that people with COVID-19 who never develop symptoms (asymptomatic) and those who are not yet showing symptoms (pre-symptomatic) can still spread the virus to other people. Wearing a mask helps protect those around you, in case you are infected but not showing symptoms.

It is especially important to wear a mask when you are indoors with people you do not live with and when you are unable to stay at least 6 feet apart since COVID-19 spreads mainly among people who are in close contact with one another.

Your mask offers some protection to you

A cloth mask also offers some protection to you too. How well it protects you from breathing in the virus likely depends on the fabrics used and how your mask is made (such as the type of fabric, the number of layers of fabric, and how well the mask fits). CDC is currently studying these factors.

Who should or should not wear a mask

Masks should be worn:

- By people 2 years of age and older
- Any time you are in a public setting
- Any time you are traveling on a plane, bus, train, or other form of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations
- When you are around people who do not live with you, including inside your home or inside someone else's home
- Inside your home if someone you live with is sick with symptoms of COVID-19 or has tested positive for COVID-19

CDC recognizes there are specific instances when wearing a mask may not be feasible. In these instances, consider adaptations and alternatives.

The following categories of people are exempt from the requirement to wear a mask:

- A child under the age of 2 years;
- A person with a disability who cannot wear a mask, or cannot safely wear a mask, for reasons related to the disability;
- A person for whom wearing a mask would create a risk to workplace health, safety, or job duty as determined by the workplace risk assessment .

Types of masks

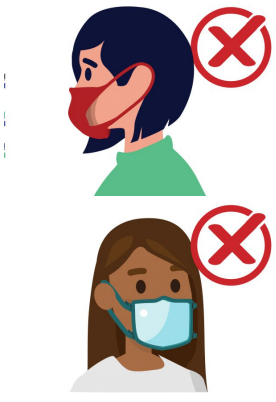
Some masks work better than others to help slow the spread of the virus that causes COVID-19. Note: N95 respirators approved by CDC's National Institute for Occupational Safety and Health (NIOSH) should be prioritized for healthcare personnel.

Recommended

Medical procedure masks (sometimes referred to as surgical masks or disposable face masks)

Masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face)

Not Recommended



Masks that do not fit properly (large gaps, too loose or too tight)

Masks made from materials that are hard to breathe through (such as plastic or leather)

Masks made with breathable fabric (such as cotton)

Masks made with tightly woven fabric (i.e., fabrics that do not let light pass through when held up to a light source)

Masks with two or three layers

Masks with inner filter pockets

Masks made from fabric that is loosely woven or knitted, such as fabrics that let light pass through

Masks with one layer

Masks with exhalation valves or vents

Wearing a scarf/ski mask

Cloth masks

More effective fabrics for cloth masks are

- Tightly woven fabrics, such as cotton and cotton blends
- Breathable
- Two or three fabric layers

Less effective fabrics for cloth masks are

- Loosely woven fabrics, such as loose knit fabrics
- Single layer

CDC is currently studying the effectiveness of various cloth mask materials. Refer to our Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2 | CDC for more information.

Medical procedure masks (sometimes referred to as Surgical Masks or Disposable Face Masks)

Medical procedure masks are single-use masks that are not made of cloth and are not designed to be washed or laundered. They are sold online and through large retail stores. These are not the same as other medical masks.

You may prefer using medical procedure masks in situations where your mask is likely to get wet or dirty. As with cloth masks, make sure your medical procedure mask fits close to your face without large side gaps and completely covers your nose and mouth. Bring extra medical procedure masks with you in case you need to change out a dirty or wet mask.

Masks with exhalation valves or vents

CDC **does not recommend** using masks with exhalation valves or vents. The hole in the material may allow your respiratory droplets to escape and reach others. Research on the effectiveness of these types of masks is ongoing.

NIOSH-approved N95 respirators

N95 respirators are critical supplies that should be prioritized for healthcare workers and other medical first responders to prevent supply shortages.

Clear masks or cloth masks with a clear plastic panel

Clear masks or cloth masks with a clear plastic panel are an alternative type of mask for people who interact with

- People who are deaf or hard of hearing
- Young children or students learning to read
- Students learning a new language
- People with disabilities
- People who need to see the proper shape of the mouth for making appropriate vowel sounds (for example, when singing)

If you use this type of mask, make sure

- You can breathe easily
- Excess moisture does not collect on the inside of the mask
- You remove the mask before sleeping, since the plastic part could form a seal around your mouth and nose and make it hard to breathe

The FDA recently approved a transparent [186 KB, 3 Pages] medical mask. These transparent medical masks should be reserved for use by healthcare workers and patients who require them.

There are several easy methods to improve the performance of your mask. Visit CDC's Improve the Fit and Filtration of Your Mask to Reduce the Spread of COVID-19 webpage to learn more. You can also learn more by reading about a CDC study conducted in a laboratory that tested the performance of different mask combinations.

Other Types of Face Protection

CDC does not recommend using face shields or goggles as a substitute for masks. Goggles or other eye protection may be used in addition to a mask. Do NOT put a plastic face shield (or a mask) on newborns or infants.

Face shields and goggles are primarily used to protect the eyes of the person wearing it. Goggles do not cover the nose and mouth. Face shields are not as effective at protecting you or the people around you from respiratory droplets. Face shields have large gaps below and alongside the face, where your respiratory droplets may escape and reach others around you and will not protect you from respiratory droplets from others. However, wearing a mask may not be feasible in every situation for some people.

Face shields and goggles

For example, people who interact with those who are deaf or hearing impaired may find that a face shield is better than a mask when communicating. If you must wear a face shield instead of a mask:

- Choose a face shield that wraps around the sides of your face and extends below your chin or a hooded face shield. This is based on the limited available data that suggest these types of face shields are better at preventing spray of respiratory droplets.
- Wash your hands after removing the face shield. Avoid touching your eyes, nose, and mouth when removing it.
- Clean and disinfect reusable face shields according to the manufacturer's instructions or by following CDC face shield cleaning instructions. If you use a disposable face shield, wear it once and throw it away according to the manufacturer's instructions.

Mask adaptations and alternatives

CDC recognizes that wearing masks may not be possible in every situation or for some people. Those who cannot wear a mask are urged to prioritize virtual engagement when possible. For in-person activities, we have provided a few examples of what you can do to make wearing a mask more feasible and how to reduce the spread of COVID-19 if you cannot wear a mask.

Situations where wearing a mask may not be possible

- Make sure to maintain physical distance from others when you cannot wear a mask.

Dining

- CDC recommends wearing a mask while dining in a restaurant, particularly indoors and when speaking with restaurant workers and servers, except when actively eating or drinking. The risk of COVID-19 spread increases in a restaurant or bar setting as interactions within 6 feet of others increase. Masks may reduce the risk of COVID-19 spread when worn in any of these risk scenarios.

Water activities

- Do not wear a mask when doing activities that may get your mask wet, like swimming at the beach or pool. A wet mask can make it difficult to breathe and may not work as well when wet.

High intensity activities

- Masks should always be used in public settings, but if you are unable to wear a mask because of difficulty breathing during high intensity activities, choose a location with greater ventilation and air exchange (for instance, outdoors versus indoors) and where you can keep at least 6 feet of distance from others during the activity. If such a location is not available, opt for low-intensity activities such as walking or yoga that allow for mask wearing.
- If you are able to wear a mask, remove your mask if it gets moist from sweat and replace it with a clean mask.
- Opt for an activity that does not require using mouth guards or helmets. Wearing a mask with these types of protective equipment is not safe if it makes it hard to breathe.
- Supervise children who are wearing a mask while playing sports.

Certain groups of people who may find it difficult to wear a mask

Some children 2 years and older, and people of any age with certain disabilities

Appropriate and consistent use of masks may be challenging for some children and for people of any age with certain disabilities, including people who have high sensitivity to materials on their faces, difficulty understanding why wearing a mask is protective (such as those with an intellectual disability), or those who have problems controlling their behavior.

When determining if children and people with certain disabilities should wear a mask, assess their ability to:

- Use a mask correctly
- Avoid frequent touching of the mask and their face
- Limit sucking, drooling, or having excess saliva on the mask
- Remove the mask without assistance

Those caring for children and people with certain disabilities who may need assistance with wearing masks should

- Ask their healthcare provider for advice about the person you are caring for wearing a mask. If they are unable to wear a mask, ask their healthcare provider about alternative ways of reducing transmission risk
- Ensure proper mask size and fit
- Remove their mask before sleeping, napping, when they may fall asleep (such as in a car seat or stroller), and in situations when continual supervision is not possible
- Consider prioritizing wearing a mask in public settings and when around people who don't live in your household, particularly when indoors. Masks may not be necessary when you and the person you are caring for are outside and away from others, or with other people who live in the same household. However, some localities may have mask mandates while out in public and these mandates should always be followed.

Masks should **not** be worn by:

- Child under 2 years of age
- A person with a disability who cannot wear a mask, or cannot safely wear a mask, for reasons related to the disability
- A person for whom wearing a mask would create a risk to workplace health, safety, or job duty as determined by the workplace risk assessment

People who are deaf or hard of hearing, and those who will interact with people who are hearing impaired

If you interact with people who rely on reading lips, you may have difficulty communicating while wearing a mask.

- Consider wearing a clear mask or a cloth mask with a clear panel
- If you are not able to get a clear mask, consider using written communication, closed captioning, or decreasing background noise to make communication possible while wearing a mask that blocks lips

People with certain underlying medical conditions

Most people with underlying medical conditions can and should wear masks.

- If you have respiratory conditions and are concerned about wearing a mask safely, discuss with your healthcare provider the benefits and potential risks of wearing a mask.
- If you have asthma, you can wear a mask. Discuss with your healthcare provider if you have any concerns about wearing a mask.

Outdoor workers

If you work in a setting where masks could increase the risk of heat-related illness or cause safety concerns (for example, straps getting caught in machinery):

- Discuss with an occupational safety and health professional what mask would be suitable.
- Prioritize wearing masks indoors and when in close contact with other people, like during group travel or shift meetings. Some localities may require wearing masks in public while outdoors, and these requirements should be followed.
- In cold weather, wear masks under winter gear such as scarves and ski masks. If masks become wet from breathing or snow, replace them with dry ones. Keep one or more backups for this purpose.

What to do if you find wearing a mask uncomfortable?

- It may help to practice wearing a mask at home for short periods to get used to the feeling and try different styles and fabrics recommended above.
- Try relaxation techniques such as breathing in and out deeply or listening to soothing music while wearing a face mask, which can help to keep you calm.

Mask use and carbon dioxide

Wearing a mask does not raise the carbon dioxide (CO_2) level in the air you breathe

A cloth mask does not provide an airtight fit across the face. The CO_2 completely escapes into the air through the cloth mask when you breathe out or talk. CO_2 molecules are small enough to easily pass through any cloth mask material. In contrast, the respiratory droplets that carry the virus that causes COVID-19 are much larger than CO_2, so they cannot pass **as easily** through a properly designed and properly worn cloth mask.

Cold Weather

- In cold weather, masks may become wet from breathing, snow, or other precipitation. Change a mask when it becomes wet. A wet mask is harder to breathe through, is less efficient at preventing your respiratory droplets from reaching others, and allows for more respiratory droplets to escape around the edges of the mask. It is especially important to have one or more replacement masks during cold weather. If your reusable mask becomes wet, put it in a sealed plastic bag until you can wash it.
- Scarves and other headwear such as ski masks and balaclavas used for warmth are usually made of loosely knit fabrics that are not suitable for use as masks to prevent COVID-19 transmission. They can be worn over a mask.
- If you wear glasses, find a mask that fits closely over your nose or has a nose wire to help reduce fogging. Consider using an antifogging spray that is made for eyeglasses.

People with beards

Certain types of facial hair, like beards, can make mask fitting difficult. People with beards can

- Shave their beards.
- Trim their beards close to the face.
- Use a mask fitter or brace.
- Wear one disposable mask underneath a cloth mask that has multiple layers of fabric. The second mask should push the edges of the inner mask snugly against the face and beard.

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Last Updated Apr. 19, 2021

Mask Testing at Northeastern University

Preliminary Findings

Based on preliminary studies (submitted for peer review but not yet published; pending suggestions for improvement from our peers):

- We have developed a rapid testing protocol for loose-fitting type masks that provides information on particle removal efficacy and an interpretation of the results that independently assesses the quality of the mask fit and of the mask material. This takes less than 2 hours to test a new mask design (n=3 masks tested, n=3 tests per mask).
- The protocol was validated on N95 masks; for the well-fitted mask we record >99% particle removal efficiency, and for the poorly-fitted mask the mean removal efficiency is just about 90%.
- We have tested three different brands of commercial surgical masks. Worn as designed these had mean removal efficiency ranging from 50% to 75%, however all of them had close to 90% particle removal efficiency when a nylon layer was added. This indicates that the weakness of these masks is primarily a poor fit rather than a poor filter material.
- Fabric masks have highly variable results, from less than 30% to nearly 90% particle removal efficiencies when worn as designed. The table below provides detailed data for each mask tested, including average

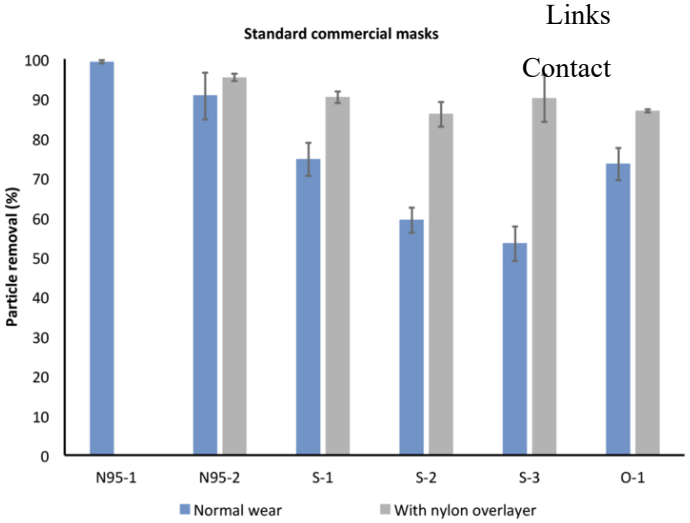


Figure 1. Particle filtration efficiency of standard commercial masks of 3 types: N95 (N95-n), surgical style marketed for medical use (S-n), and Other (O-1, a charcoal filter mask). Data collected with a nylon overlayer holding the mask in place represent a proxy for best-possible fit, i.e., gray bars provide a measure of the filtration capacity of the materials. N95-1 was well-fitted to the mask wearer and shows the expected >99% filtration, while N95-2 was less well fitted, as seen by the difference between the blue and gray bars. While the fit of the three surgical masks (S-1 to S-3) is quite different (blue bars), the materials are comparable (gray bars). Error bars show standard deviation between replicates (n=3 masks for each type tested).

(mean) particle removal efficiency and whether or not improvement was seen by adding a nylon layer. Some were as effective as commercial medical masks.

- The addition of a nylon stocking overlayer improved the removal efficiency for nearly all of the surgical-style loose-fitting masks but few of the cone-shaped masks. This may indicate that cone-shaped masks have fewer air-leakage pathways, although our tests were run using only a single mask-wearer, so this result could vary from face-to-face.
- The masks that achieved the highest levels of filtration when using the nylon stocking layer (the indicative test for material quality) each included a filter layer (organic cotton batting, Pellon, or loosely-woven cotton muslin) in addition to two layers of cotton fabric.

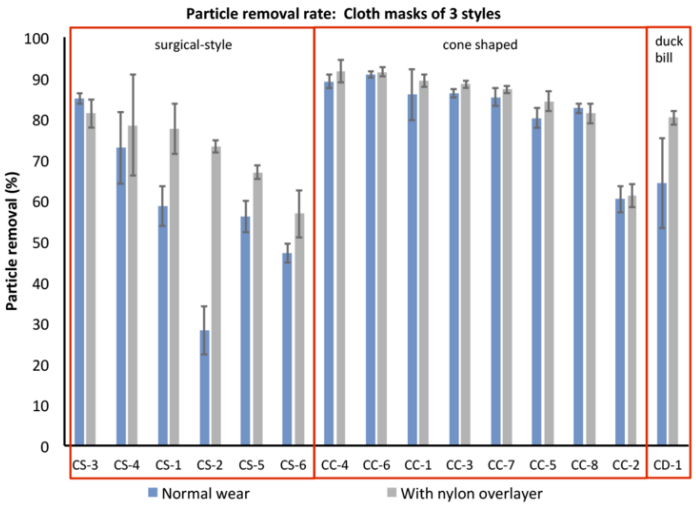


Figure 2. Performance of a range of cloth masks being made by the community and by commercial vendors. Preliminary data show the difference between performance of masks using different form factors, e.g., cone-shaped masks appear to have a better and more consistent fit to the face. Notably multiple cloth masks perform as well as or better than surgical masks when worn as designed, and some provide equivalent filtration to surgical masks snugged to the face. However, there is wide variability in filtration provided by cloth masks, due both to fit (difference between blue and gray bars) and materials (gray bars).

Detailed results

Results for commercial masks tested

Results for cloth masks tested

Results for mask “fixes” tested

Publications

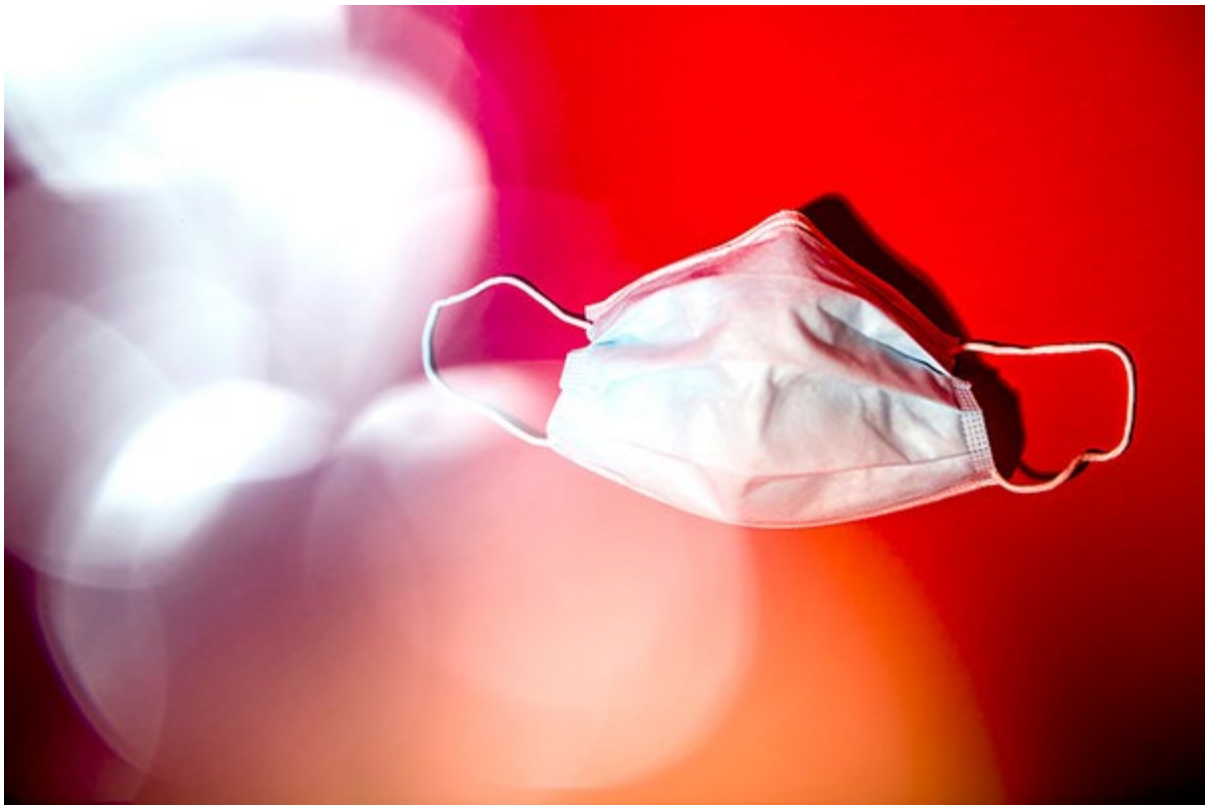
A manuscript describing the method in detail is available at *Matter* at Cell Press:

https://www.cell.com/matter/fulltext/S2590-2385(20)30364-7

Mueller AV, Eden, MJ, Oakes, JM, Bellini, C, Fernandez, LA. 2020. Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE. *Matter*, DOI: 10.1016/j.matt.2020.07.006.

Making Sure Masks Are Effective

April 21, 2020



CEE/MES Assistant Professors Loretta Fernandez and Amy Mueller are examining the layering of materials and how the masks are worn to determine which are the most effective in blocking the COVID-19 virus.

Pantyhose? Toilet paper? Coffee filters? Which materials make the best masks?

Main Photo: Questions about how to make homemade face masks that will seal your nose from the novel coronavirus abound. Loretta Fernandez, an assistant professor of civil and environmental engineering, is starting to get some answers. Photo by Matthew Modoono/Northeastern University

It's not news that health officials want everybody to wear a face mask in public as a measure to slow the spread of COVID-19.

The novel coronavirus is an extremely small particle that hitches a ride with droplets of saliva and mucus expelled through breathing, speaking, sneezing, coughing, and laughing. That's why using simple fabrics to cover the mouth and nose of an infected person reduces the spread of the virus as it *leaves* their body.

But the extent to which masks prevent the virus from *entering* another person's body through the airway varies. And, amidst the bombardment of online tutorials on face masks, questions abound about how to make them at home, and what materials to use.

Arguably, the one question to rule them all is how well those masks—made with t-shirts, pillowcases, coffee filters, toilet paper—will perform in sealing your nose from the coronavirus.

Even for masks that might not filter out everything, a tight fit against the face significantly lowers the chances of viral droplets making it to the airway, says Loretta Fernandez, an assistant professor of civil and environmental engineering at Northeastern.

That's why any sort of filtering and interfacing that people can use in their masks could be highly protective. The idea is to create an efficient series of layers with bends within the fabric that make it harder for the virus to have a straight shot at a person's nose. Every bend of that path provides more chances for the viral particles to stick to the fibers, instead of a person's throat.

"By including a filter layer—coffee filters, toilet paper, any sort of thing in there that is safe to breathe—you're just making the air have to follow a more circuitous route to get to your nose," Fernandez says. "Putting a layer of nylon over improves that."

Fernandez, who tested 10 different types of homemade masks made with different materials, used nylon stocking layers to make for a tighter fit. The optimized fit improved the performance of all face masks—homemade or not. Photos courtesy Loretta Fernandez

Fernandez's research focuses on pollutants in the environment, including harmful microscopic particles, and how they end up in the air we breathe, the water we drink, and the food we eat.

After the COVID-19 pandemic forced researchers to consider how their work could be repurposed to help with research to slow the spread of the novel coronavirus, Fernandez had a hunch. She started considering the tiny pollutants she studies and the laboratory instruments she uses.

"One of them is a particulate matter counter," she says about a machine that can analyze the concentrations of hazardous particles suspended in the air.

But particles of SARS-CoV-2, the virus that causes COVID-19, aren't easy to count. They are as small as they are hard to catch, with a diameter several times smaller than bacterial cells. That *is* tiny—too tiny to be blocked by most materials in a mask without making it hard to breathe through, and too small to be detected by Fernandez's instruments.

Still, she knew her expertise in sampling complex and microscopic particles could help. She just needed the right machine to do it.

At Northeastern, the Office of Environmental Health and Safety had started looking into university inventories, and found an old instrument that Fernandez could repurpose to count particles the size of the new coronavirus. Pfizer, the multinational biopharmaceutical

corporation, also donated an instrument that served as the perfect complement to that machine.

Then, Fernandez enlisted Amy Mueller, an assistant professor of civil and environmental engineering at Northeastern, along with people and businesses in the Boston area who donated their masks.

“What’s really been the most remarkable thing is how quickly these connections formed, and how willing everyone is to share what they know, to share their equipment, and to do whatever they can to contribute,” Fernandez says.

Fernandez herself donned 10 different types of homemade masks, generated non-hazardous particles of a similar size to those that carry the novel coronavirus, and counted the amount of particles that the masks filtered.

But the instruments Fernandez and Mueller were using had not been devised to count viruses. Their software normally produces rigorous pass-or-fail assessments on *whether* a mask will protect firefighters from inhaling dangerous smokes and fumes.

And more than a yes-or-no answer, the goal was to determine *how* efficiently those masks performed, Fernandez says.

As the machines measured particles passing through the masks, they flashed values taken at every second. Fernandez and Mueller recorded those readings on video. The process required a group effort that also involved engineering students, who watched each video and paused at every second to record the data.

The preliminary results, available online, show that the most important factor to determining whether a mask will protect a person is not the material used, but how well it fits on the wearer’s face.

The tests included N95 respirators, the masks designed specifically to protect healthcare professionals who treat patients with infectious diseases, as a standard to test the efficiency of other homemade and commercial masks made with different layers of fabric, interfacing, and filters.

Commercial surgical masks performed better, filtering out about 75 percent of particles released from a particle generator located about two meters away. Homemade masks, which fit loosely over the face, generally filtered out less than 60 percent of the particles.

To improve the fit, Fernandez and Mueller wore cutouts of nylon pantyhose over the

masks. That improved the effectiveness of all masks considerably, by as much as 50 percent. The idea of the nylon layer, which presses the masks closer to the face and keeps the air from circuiting around the filters, came from the past.

The early 1980s, to be specific.

John M. Price, who directs Northeastern's Office of Environmental Health and Safety, conducted research in 1983 on methods to make homemade masks to protect people from the radioactive fallout following the Three Mile Island nuclear accident.

"We were in the laboratory trying to recreate the seal that one would get with the N95 masks by just pressing the material around the breathing zone, and Jack said, 'you know, in the 80s, we just used pantyhose,'" Fernandez says. "The next day, we came into the lab, cut a little section to fit over the masks, and used that as a more reproducible way to hold the material to our faces."

Fernandez says she hopes other researchers use data from her tests to study more materials and conclude which work best.

The key part, she says, is to use the results and help people at home produce the best masks they can make with whichever materials they have—as well as helping businesses put their manufacturing muscle to work.

"That information can be shared, and these masks can be put into production locally, using the best materials we can identify," Fernandez says. "I'll be sharing the information directly back with all the people who shared their masks with me, and hopefully that can help them toward crowdsourcing a better design."

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by Roberto Molar Candanosa, News @ Northeastern

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Masking during the COVID-19 pandemic

Topics Biological Agents Contaminants and Hazards COVID-19 Infectious Diseases

[Updated: Oct 21, 2020]

Introduction

Extensive debate over when, where, and what types of masks should be worn, and by whom, has persisted during the COVID-19 pandemic with questions arising over the efficacy of different types of face covering in different settings. Since the beginning of the pandemic, agencies such as the World Health Organization (WHO)[1] have updated their guidance on the use of non-medical masks in community settings, recommending mask wearing where there is a high level of community spread of the virus and in crowded locations where it is difficult to maintain physical distancing. The Public Health Agency of Canada (PHAC) similarly updated recommendations for wearing of non-medical masks or face covering in settings such as crowded shopping areas, public transportation, and other settings where it is difficult to maintain physical distancing. PHAC has provided additional advice on wearing and making of non-medical masks.[2]

The purpose of this document is to outline the most commonly used types of masks, their effectiveness in providing protection against pathogenic hazards based on a rapid review of the literature, and to list key considerations for the safe use. Given the changes to guidance from public health agencies and emergence of newly published literature, this document has been updated from the previous version published in April 2020 to reflect these changes and address additional questions arising about the use of masks to reduce transmission of SARS-CoV-2.

Types of masks

There are now a wide variety of masks used for medical and non-medical purposes. In simple terms these can be grouped as medical masks, which include **respirators** (commonly referred to as N95, or filtering facepieces [FFP] masks) **and surgical masks**, and non-medical masks including homemade **cloth masks and other face covering not intended for healthcare settings**. Differences between these are summarized in **Table 1.**

	Respirator	Surgical or procedure mask	Non-medical cloth mask

			
Types	N95, 99, 100 (US, Canada), FFP2 or FFP3 (EU). Various styles including cup, flat-fold and duckbill. May also include an exhalation valve.	Typically a 3-layer laminate structure that can include a combination of non-woven air-laid paper and polypropylene.[3]	Wide variability in fabric, number of layers and design with 2-layer cotton being a common design.
Use	For use in environments where exposure to aerosols is likely. Protect against most particles (e.g., N95 block 95% of particles and provide some splash and spray protection). Medical grade N95s are tested for resistance to fluids including blood, but commercial grade are not.	For use in routine care to reduce inward and outward transfer of respiratory droplets. Filter particles > 20 µm diameter and some finer droplet nuclei.[4] Block blood and infectious materials from contact with oral, nasal and skin area. Effective against splash and sprays.	For use by the public in non-healthcare settings as source control to reduce respiratory emissions from the wearer and to reduce exposure to respiratory emissions of others.[3,5]
Approval	U.S. National Institute for Occupational Safety and Health (NIOSH) for N95 or similar and EU standards for FFP equivalents.[6] The Government of Canada lists other approved alternatives to N95s.	FDA with grading based on the level of resistance to splashing (e.g., ASTM 1 – venous pressure; ASTM 2 – arterial pressure; ASTM 3 – high velocity splash).	Not approved for use in any healthcare setting; not tested to any standard of effectiveness. **Note:** Many procedure-type masks found in retail outlets may not be assessed to any approval standards, and would also be considered non-medical masks.
Advantages	Medical grade respirators can be effective against aerosol penetration. Can be reused and disinfected with precautions.	Some protection against contact transmission, are disposable and inexpensive. Fit testing is not required.	Inexpensive and can be made from household materials. Can act as a reminder to not touch face.[5] Can be reused and laundered.[7]
Disadvantages	Filtration efficiency for aerosols is only effective if properly fit tested.	Less effective against smaller particles (e.g., 0.4-1.3 µm), looser fit than N95 respirators,	Variable performance for respiratory protection and breathability depending on the

	Some users may experience some reduction in comfort/breathability. Expensive and may be in short supply.	and therefore more penetration via leaks.[8] Not recommended for reuse or disinfection for use in healthcare environments.	material and design.[9] They do not replace other protective measures (e.g., hand hygiene and distancing).[5,10]

Evaluating the effectiveness of masks

Masks are worn by individuals either to provide a barrier to the inhalation of particles (**protection of the wearer**), or to act as source control to prevent the exhalation or release of particles due to coughing, sneezing or other respiratory activities (**protection of others**). Many studies have assessed the performance of mask types for both purposes. For example:

- Studies that assess **protection of the wearer.**[5,9-22]
  - **Penetration studies** to measure the movement of particles from the external environment through mask material into the breathing zone of the wearer.
  - **Protective effect studies** that compare clinical outcomes for mask wearers. Examples include those assessing the reduced incidence of clinical respiratory illness (CRI), influenza-like illness (ILI) or laboratory-confirmed viral infection among healthcare workers (HCWs) wearing masks versus no masks.
- Studies that assess **protection of others** from an infected individual. [9,12,14,21,23-30]
  - **Penetration studies** such as coughing tests that measure the movement of particles through a mask to the external environment.
  - **Secondary attack rate (SAR) studies** to evaluate the effect of mask wearing by an infected individual to prevent transmission to others in close contact (e.g. household members)

Respirators (e.g., N95, KN95, FFP2):

Respirators approved to performance standards in different countries such as N95 (USA), KN95 (China), P2 (Australia/New Zealand), FFP2 (Europe) and others provide a superior level of filtration and fit for protection against particles including aerosols compared to surgical and non-medical masks.[6,13,21] Respirators approved by agencies such as NIOSH, are guaranteed to perform to a minimal level of particle penetration (e.g., 95% blockage or better for N95 respirators). Respirators have also been found to be effective in reducing release of respiratory particles from the wearer.[31] In protective effect studies, respirators are found to provide a greater level of protection as compared to surgical masks, with incidence of CRI found to be lower in N95 wearers compared to surgical mask wearers.[16,17,19,22] A protective effect has also been observed in the COVID-19 pandemic. A retrospective study of a group of 493 HCWs in Wuhan, China, found that none of those wearing N95 respirators (278) working in a high-risk environment and observing regular hand hygiene were infected with SARS-CoV-2 compared to 10 of 213 staff working in a much lower-risk environment and not wearing masks and only washing hands occasionally.[22] The protective effect of respirators for HCWs exposed to SARS-CoV-2 during an aerosol generating procedure has also been observed.[32]

Surgical/procedure masks

Surgical masks are found to provide a higher level of protection to the wearer compared to most cloth masks.[5,9,10,13,21,33,34] In penetration studies for protection of the wearer, surgical masks have been found to block about 60% of particles but may allow penetration by virus particles in high concentration environments.[13,18] Penetration studies for protection of others find that surgical masks block the release of some large droplets but are less effective at blocking the release of infectious aerosols from exhaled breath and coughs.[9,14,23,28]

The protective effect of surgical masks has been demonstrated in healthcare studies. A retrospective study of SARS-CoV-2 infection among HCW in a US hospital before and after the implementation of universal masking with surgical masks for HCWs and patients found that masking was associated with a lower rate of infection.[20,35] A systematic review by Bartoszko et al. (2020) found that surgical masks offered a similar level of protection against respiratory viruses as N95 respirators in non-aerosol-

generating healthcare settings.[36] In a case report from China, 41 HCWs were exposed to aerosol-generating procedures for a patient who subsequently tested positive for SARS-CoV-2. None of the HCWs, of whom 85% wore surgical masks and 15% wore respirators, tested positive for SARS-CoV-2.[32] Secondary attack rate (SAR) studies in healthcare settings have found that the use of surgical masks by visitors and HCW has been shown to reduce the incidence of respiratory viral infections among patients.[29]

In non-healthcare settings, several studies in France, Germany, Hong Kong, China and Australia have assessed the effectiveness of wearing surgical masks in the home by patients with influenza or ILI to reduce secondary transmission to other members of the household. Some of these studies have found a lower SAR, but did not show statistically significant reductions[12,24,27] including one study that assessed the protective effect of both surgical masks and N95 equivalent masks.[15] The greatest reductions in SAR have been observed in studies where mask wearing was implemented early after the onset of symptoms in the sick patient, or where mask wearing was combined with other measures such as hand hygiene.[11,25,30]

Cloth masks or face coverings

The range of styles, materials, and design of cloth masks vary significantly as does performance. Studies assessing the protective effect of cloth masks in healthcare settings find that the incidence of CRI, ILI and viral infections was higher among cloth mask wearers compared to surgical mask wearers.[16,19] Cloth masks are not recommended for healthcare, or high-risk settings, but may be effective in community settings where there is a high level of adherence to mask wearing.[37]

Penetration studies of cloth masks for protection of the wearer find that performance is affected by the fit and the type of material used. Loose-fitting cloth masks (e.g., handkerchiefs) provide only minimal protection from inhalation and release of particles.[5,13,33] Particle removal efficiency has been found to vary from 28-90%, with most removing less than 60% when worn as loose-fitting masks.[9,38,39] Penetration studies measuring release of droplets or aerosols from wearers find that cloth masks can block the release of some large droplets but are generally less effective at blocking the release of infectious aerosols, particularly loose-fitting designs and porous fabrics.[9,28,33] Adding multiple layers of the same material provides only limited additional protection, but can reduce breathability.[9,13] Hao et al. (2020) found that fabrics with very low filtration efficiency (e.g., a wool scarf and a cotton bandana) provided minimal filtration efficiency even when tested as four layers. The most effective multi-layer designs use layers of different materials, such as absorbent layers and water repellent outer barrier layers (e.g., synthetic materials such as polypropylene and polyester).[40] Fabrics that allow for electrostatic interaction such as polyester and silk can provide superior removal compared to cotton but breathability of fabrics can be a trade-off for filterability.

Face shields

There may be situations where face shields are considered for specific uses. Face shields allow for visibility of facial movements and expression, which may be beneficial for the hearing impaired. For HCWs or those caring for an infected person, the use of goggles or a face shield may be considered as complementary PPE (i.e., with a surgical mask) to prevent additional exposures due to splash and spray and some intake of particles that could occur due to loose-fitting masks.

There has been limited study of the effectiveness of face shields for reducing transmission of infectious respiratory diseases. There is some evidence that face shields may provide some additional protection when used as complementary PPE with masks. The use of an integral visor with a surgical mask has been found to reduce leakage into the breathing zone around the nose.[18] Face shields can extend the usability of respirators or masks by reducing the potential for surface deposition or accidental contact with mask surfaces.[1] There is some evidence that infection with SARS-CoV-2 via the eyes is possible and face shields may provide additional protection of the wearer by preventing self-inoculation due to touching of the face or eyes.[41-45] A study using a coughing patient simulator and a breathing worker simulator found that face shields reduced surface contamination of a respirator by up to 97% for larger aerosols and 76% for smaller aerosols (median 8.5 and 3.5 µm diameter respectively). The same study found that the face shield provided a high reduction in initial inhalation exposure (96%) for larger aerosols, and a moderate reduction in exposure (68%) for smaller aerosols. After 1-30 minutes after the cough, the face shield only reduced aerosol inhalation by 23% as aerosols dispersed throughout the room and were able to flow around the sides of the shield.[46]

The use of face shields as source control has not been widely assessed. [45] Ronen et al. (2020) demonstrated that using a face shield over a cough simulator blocked the release of droplets from the source and exposure to a nearby manikin.[47] While face shields block forward protection of droplets, they allow for leakage from seams and joints, and upward, downward, sideways and

backward leakage jets, so may provide limited protection to others.[48]

Systematic reviews

There have been several systematic reviews of the effectiveness of face masks to reduce the spread of respiratory viruses.[49-58] The key findings of these reviews vary, linked to the scope and inclusion criteria of the reviews. Two reviews indicate insufficient evidence, or no significant reduction in transmission of influenza or ILI with the use of face masks. These studies are limited to randomized control trials (RCT) and influenza or ILI.[54,58] Other reviews indicate a range in the degree of protective effect depending on variables such as the setting (healthcare versus community), mask type (respirator, surgical mask or cloth mask), the mask wearer (infected versus susceptible), the range of respiratory viruses considered (influenza, ILI, H1N1, coronaviruses, SARS-CoV-2) and whether mask wearing is combined with another protective measure such as hand hygiene. The key findings of a selection of systematic reviews are summarized in Table 2.

[1] Public Health Ontario. Recommended steps for donning and doffing of PPE: https://www.publichealthontario.ca/-/media/documents/rpap-recommeded-ppe-steps.pdf?la=en

Table 2 Key findings of systematic reviews evaluating the effectiveness of mask wearing for prevention of respiratory illness.

Reference	Key Findings
Jefferson et al. (2020,) [54] *Pre-print*	Insufficient evidence was identified for reduction in ILI or influenza in community or healthcare settings due to mask wearing based on analysis of 14 RCTs.
Xiao et al. (2020) [58] *Pre-print*	No significant reduction in influenza transmission was found to be associated with the use of face masks. Most studies were observed to be underpowered due to a small sample size, and some studies reported variable adherence to mask wearing.
Jefferson et al. (2011) [53]	Mask wearing reduced respiratory illness in healthcare and community settings, with N95s providing superior protection over surgical masks.
Wei et al. (2020) [57] *Pre-print*	Mask wearing reduced the transmission of ILI in the community, with the effect greater where masks were worn by both sick and healthy individuals.
Chu et al. (2020) [51]	Mask wearing provided a protective effect against coronaviruses based on observational studies for MERS, SARS and COVID-19. Eye protection (e.g., visor, face shield, goggles) was associated with a lower risk of infection in both healthcare and community settings.
Liang et al. (2020) [55]	Mask wearing provided a significant protective effect when worn by HCW and non-HCW in non-household settings in a review of studies including influenza, SARS, H1N1 and COVID-19.
Gupta et al. (2020) [52] *Pre-print*	The effectiveness of mask wearing to prevent respiratory viruses on a community scale was found to be greater when used early and where there was a greater degree of

	adherence to mask wearing.
Brainard et al. (2020) [49] *Pre-print*	Mask wearing was found to be slightly protective against respiratory infection in a community setting and modestly protective for closer contacts such as households when both infected and susceptible wear a mask based on a review of RCT and observational studies.
Chou et el. (2020) [50]	Mask wearing was found to be associated with a decreased risk of SARS and MERS infection. In healthcare settings N95 and surgical masks had a similar level of risk of ILI, but N95 may be associated with decreased risk of SARS compared to surgical masks. Better adherence to mask wearing was associated with a decreased risk of infection for SARS and MERS.
MacIntyre and Chughtai (2020) [56]	Mask wearing may provide a protective effect, which is enhanced when combined with other measures such as hand hygiene based on a review of RCTs. Continuous wearing of respirators by HCW was found to be protective, but intermittent use was not, and medical and cloth masks had less effect.

On balance, most systematic reviews on the protective effect of masks against respiratory illness transmission indicate some benefit from mask wearing. The evidence of a protective effect appears to be stronger in observational studies as compared to RCTs, which may be based upon the paucity of RCTs for mask use in community settings, and the small sample size used in some studies.[49]

Modelling studies

Modelling studies use data from various sources to estimate the effects of interventions on different health outcomes. There have been several studies that have estimated the effect that mask wearing has had on reducing the spread of COVID-19 in different geographical locations by comparing progression of the pandemic before and after mask-wearing mandates were introduced.[59-62] Leffler et al. (2020) found that average mortality due to COVID-19 was lower in the majority of countries with early adoption of mask wearing in the community compared to countries without early adoption of mask wearing.[63] Studies have estimated that universal mask-wearing mandates reduced cases or the growth rate of COVID-19 in locations such as San Francisco,[61] a selection of US states,[60,64,65] the City of Jena and other cities with high population density in Germany,[66] and Morocco. [67] Other models estimate that mask use can suppress transmission of COVID-19, but the effectiveness may be more significant where there is widespread adherence, interactions between masks wearers and non-mask wearers are minimized, and other complementary public health measures such as hand hygiene and distancing are widely used.[68,69] Modelling results from a survey of over 8000 Chinese adults found that mask wearing provided the most protective effect from COVID-19 infection among four non-pharmaceutical interventions (NPIs - hand hygiene, respiratory etiquette, social distancing and mask wearing), and the effect was increased where additional NPIs were used.[62] Emerging research is considering the effect of mask wearing on severity of infection, including the rate of asymptomatic infection. Further research is needed to understand the relationship between mask wearing, infectious dose, and severity of disease.[70,71]

Considerations for mask use

Mask fit

Where respirators are used as PPE, a **fit test**, and user **seal check** are essential for ensuring effectiveness of N95 type respirators. Fit tests are used to confirm that a specific make, model and size of respirator provides adequate respiratory protection

to the user by providing a tight seal between the facepiece and the face that prevents leakage into or out of the respirator facepiece (**Box 1**). If the respirator does not pass a fit test, another make, model or size is tested until a suitable respirator is found. The wearer can then use the same make, model, and size of respirator, repeating the test once per year to confirm that fit is maintained, or reconfirming fit if physical changes to the face have occurred, such as weight loss or injury. If the user changes the make, model or size of respirator, a new fit test is required.

Box 1: How is a fit test done?

A fit test can include either a **qualitative** or **quantitative** test and usually takes about 15 to 20 minutes to complete, during which time the wearer may perform various movements (e.g., turning head side to side or moving the head up or down). If the wearer normally uses a respirator in combination with other PPE, such as goggles or a face shield, these should also be worn during the test. The wearer should also perform a seal check before starting the fit test.

- **Qualitative** fit testing assesses whether the mask wearer can detect the taste or smell of a substance introduced into a chamber placed over the mask wearer. Common substances used in qualitative fit tests include isoamyl acetate (banana smell), saccharin (sweet taste), Bitrex™ (bitter taste) or irritant smoke, which causes coughing.
- **Quantitative** fit testing uses instrumentation with a fit testing adaptor and probe that is attached to the face piece. The instrumentation can measure generated aerosol, ambient aerosol, or controlled negative pressure and will compare the conditions inside and outside the respirator to determine a fit factor.

A demonstration of fit testing by the US Occupational Safety and Health Administration can be viewed here: https://www.osha.gov/video/respiratory_protection/fittesting.html

A user seal check is different from a fit test and should be performed every time a respirator is put on. Advice on user seal checks is provided by the Canadian Centre for Occupational Health and Safety (CCOHS)[1] and can differ depending on the type of respirator. In general, the wearer identifies a good seal on inhalation by checking that there is slight collapse in the respirator and checks for leakage on exhalation by feeling around the edges or surface of the facepiece. Factors that can influence a poor fit or seal can include damage or deformation of the mask, and the presence of obstructions to fit such as facial hair.[72]

For other types of mask, a good fit that aligns to the contours of the face can reduce seepage of air around the edges of the mask. A tight but comfortable fit with effective coverage of the nose and mouth that does not restrict breathability can reduce the frequency that a user touches a mask for readjustment. Masks with conical or tetrahedral shapes that fit closely with face contours perform better than loose-fitting masks.[10] Where face shields are used as complementary to masks, they should be easy to don and doff, fit snugly with reduced areas for leakage, providing full face coverage around the face and below the chin.[73]

[1] CCOHS https://www.ccohs.ca/oshanswers/prevention/ppe/wearing.html?=undefined&wbdisable=true

Exhalation valves in masks

Exhalation valves improve breathability of respirators while maintaining the protective effect for the wearer but may provide less

protection of others from the wearer. Many health authorities, including the US CDC , advise against the use of valved respirators as source control, particularly in sterile environments due to the potential for release of an unfiltered exhalation jet from the wearer.[74] This has been demonstrated in a visualization study of the exhalation jet from a valved respirator, which indicated significantly more leakage of aerosols compared to an un-valved respirator.[75]

There is limited evidence available to assess whether the use of valved masks in community settings increases transmission risks compared to other non-medical face coverings.[76] A quantitative study by Fischer et al. (2020) found that a valved N95 respirator released more particles over time compared to an un-valved N95 and a surgical mask but performed similarly or better than some cloth masks.[33] A study comparing emission of aerosol-size particles during breathing, talking and coughing found that in comparison to a surgical mask and an un-valved KN95 respirator, a valved N95 mask demonstrated similar performance, and all were better than homemade paper and cloth masks for blocking aerosol transmission, albeit the valved mask was tested on a smaller number of study participants.[31]

Length of use

The longer a mask is used, the greater the risk for infectious particles to become deposited on the surface.[77] Surgical masks or respirators (e.g., N95) that become wet, damaged, torn, visibly dirty, or contaminated following close contact with an infected person will not provide adequate protection. A study of mask use by HCWs found that very low infection was observed for masks used ≤ 6 hours, however a greater virus positivity was found beyond 6 hours of use, and for HCWs who examined more than 25 patients.[77] The potential presence of viruses on the outer surface suggests a need for caution during doffing practices by avoiding contact with the mask surface (**Box 2**), and preventing the resuspension of deposited aerosols.[78] Frequent donning and doffing of the same mask can increase the risk of surface contamination on both the inside and the outside of masks and continuous use of respirators may reduce the potential for contamination as compared to frequent donning and doffing of the same mask.[79]

Early in the pandemic, concern was raised that adoption of universal masking in the community could reduce adherence to other public health measures such as distancing and handwashing. Doung-ngern et al. (2020) found that mask wearers in Thailand were more likely to observe distancing and handwashing measures compared to non-mask wearers, but were also more likely to have physical contact, and long duration of contact (e.g., > 60 minutes) compared to non-mask wearers.[80] Communication on mask wearing by public health authorities should emphasize the importance of continued adherence to other protective behaviours, along with mask-wearing. Masks should not be used by those who are symptomatic or may have been exposed to COVID-19, to avoid quarantine requirements.

Box 2: Tips for safe mask doffing

1. Assume that the surface of a mask or respirator is contaminated and take care not to touch the surface when removing the mask.
2. Remove the loops around the ear, or for ties or straps that go around the back of the head, untie or remove the bottom ties first followed by the top ties, without touching mask surface. Pull the mask away from the face.
3. For disposable masks, hold by the straps or ties and place directly in a garbage bin with a lid.
4. For reusable masks that may be disinfected (respirators) or laundered (cloth masks), hold the ties and place into a suitable receptacle such as a sealable bin or disposable plastic bag until the mask can be placed in the laundry or disinfection chamber.
5. Wash hands with soap and water or sanitize after discarding the mask.

Decontamination and reuse of masks

Masks can become contaminated by the user and the external environment. For cloth masks, laundering in a hot wash and

thoroughly drying is recommended by PHAC, but any damage, deterioration or reduced fit will reduce the already limited protective function of cloth masks. In general, surgical masks are considered disposable and not recommended for decontamination and reuse. Laundering or disinfection processes can potentially damage the protective layers of the surgical masks, reducing their effectiveness.

Several decontamination methods have been considered for the purpose of providing additional supplies of respirators when there is high demand. The key criteria for effective decontamination methods are stated as: the ability to remove the viral threat, maintaining the integrity of mask elements, and being harmless to the user.[3,81,82] Decontamination methods include autoclaving; microwave steam sterilization; washing in soap and water; dry heat treatment; treatment with isopropyl alcohol, bleach, hydrogen peroxide vapour, gamma irradiation; ozone decontamination; UV germicidal irradiation (UVGI) and ethylene oxide treatment.[81-85] Promising results have been observed for hydrogen peroxide vapour and UVGI; however, any reuse of decontaminated respirators should include steps to inspect respirators for deterioration and damage and to include user seal testing prior to re-use.[34,81,82,84]

Expired, counterfeit and recalled masks

Surgical masks and respirators that have been certified by organizations such as NIOSH or the FDA have an expiry date, after which they are no longer considered to be certified. In times of high demand, expired masks may be considered for use following a visual inspection for any damage or degradation of the mask components, including the straps. For expired N95 respirators, the ability to form an effective face seal should also be confirmed by a fit test and user seal check.[86]

Health Canada has issued recalls for several mask and respirator products including some surgical masks and KN95 and N95 respirators. Reasons for recalls include improper or misleading packaging such as labelling as “N95” respirators without NIOSH certification, or testing by Health Canada indicating that the product does not meet the specification stated. These recalls are intended to remove products that may not provide consistent and adequate respiratory protection. Further advice from Health Canada on fraudulent and unauthorized N95 respirators is provided here. The US CDC also keeps up-to-date lists of counterfeit respirators or devices that misrepresent NIOSH-approval.

Mask use for children

The WHO has published advice on the use of masks for children.[87] The evidence on the benefits or harms of children wearing masks to limit transmission of SARS-CoV-2 is limited, although evidence from other respiratory diseases suggests mask wearing may be more effective for older children (e.g., nine years and above) than younger children. This may be due to multiple factors, such as the mechanisms of disease transmission, and the acceptability of mask wearing and level of compliance among children of different ages. The WHO recommends that masks are not worn by children aged up to five years for source control, but where a lower cut-off age is used, adult supervision is recommended. For older children up to 11 years, a risk-based approach to decision making is recommended based on the level of community transmission, socio-cultural factors, impacts on learning and development, and the settings and scenarios in which mask wearing may be more appropriate. Older children 12 and above are recommended to follow guidance on masks for adults. The WHO also recommends that children with cognitive or respiratory impairments should not be required to wear masks, and alternatives for children with developmental disorders and disabilities should be considered.

Mask use for persons with cognitive difficulties or physical disabilities

There are some people who may not be able to wear masks such as persons with cognitive difficulties or physical disabilities who are unable to safely don or doff a mask without help. For persons who are unable to wear a mask safely, those providing care and support should be aware of appropriate infection prevention and control measures and take precautions to minimize risk of transmission to the person under care, and to others.[88]

Persons with hearing impairments may find communication with others difficult where their communication partners are wearing masks. Mask wearing may also provide discomfort to those with breathing difficulties. Where safe to do so, wearing of alternative face coverings such as face shields or clear masks may be considered, recognizing the limitations of these alternatives and importance of other measures such as physical distancing and hand hygiene.[88,89]

Conclusions

Masks vary widely in their design and construction and the level of protection against respiratory viruses that they can provide to the wearer and to others as source control. The use of medical masks including approved respirators (e.g., N95 and similar) and surgical masks can reduce the transmission of respiratory infection in healthcare settings. The use of non-medical masks by the public may also reduce the risk of transmission of respiratory infection, especially when used by both infected and susceptible persons, but masking does not eliminate the risk of transmission.

Key messages

- Systematic reviews and modelling studies have indicated that mask wearing has reduced the number of cases and growth rate of COVID-19 infections where there was early uptake, widespread adherence, and where used in combination with other non-pharmaceutical interventions such as hand hygiene and physical distancing.
- Users of medical masks and respirators should be aware of appropriate fit testing (where necessary) and safe donning and doffing procedures.
- Counterfeit and recalled products may provide inadequate respiratory protection, so users should consult trusted government sources prior to procuring products.
- Cloth masks vary widely in their ability to reduce exposure to infectious droplets and aerosols and as source control for protection of others. The most effective masks are those that provide a good fit around the nose, sides, and chin, and are made of materials that provide a high level of particle filtration, while maintaining breathability.
- Exhalation valves can reduce the effectiveness of masks as source control.
- Face shields should be considered as complementary to wearing of masks, but not as an alternative, except in circumstances where mask wearing is not possible.
- Special consideration should be given to children, persons with cognitive difficulties or physical disabilities when considering appropriate mask use.

The information provided in this document is based on current understanding and interpretation of the effectiveness of mask wearing. As new evidence and new interpretations evolve, this document will be updated.

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STORIES OF LIFE IN A CHANGING WORLD

THE CORONAVIRUS CRISIS

Adding A Nylon Stocking Layer Could Boost Protection From Cloth Masks, Study Finds

April 22, 2020 · 1:34 PM ET

MARIA GODOY

Researcher Loretta Fernandez of Northeastern University wears a homemade face mask without and with an extra outer layer made from nylon stockings (right). The added nylon outer layer significantly boosted masks' ability to filter out small particles, her research found.

Loretta Fernandez

During World War II, nylon stockings disappeared from store shelves as the valuable synthetic material was diverted to make critical wartime supplies such as parachutes, flak jackets and aircraft fuel tanks. Now, new research suggests that nylon stockings could once again play a critical role in a national battle — this time by making homemade cloth masks significantly more protective.

Researchers at Northeastern University have found that adding an outer layer made from nylon stockings to a homemade face covering can boost its ability to filter out small particles in the air by creating a tighter seal between the mask and the wearer's face. In some cases, that extra nylon layer helped homemade cloth masks match or exceed the filtering capability of medical-grade surgical masks.

"It really improved the performance of all of the masks, and it brought several of them up and over the baseline mask we were using, which was a 3M surgical-type mask," says Loretta Fernandez, an assistant professor of civil and environmental engineering at Northeastern University and one of the scientists who conducted the research.

YouTube

Even the 3M surgical mask performed better with stockings in their study: Testing

showed that it went from blocking out 75% of small particles to 90% with the addition of a pantyhose overlayer. By comparison, an N95 respirator, which is designed to create a tight seal around the face, blocks out at least 95% of small particles when worn properly.

"Adding a layer that keeps the mask tight to the face is going to improve the function of any of these masks," Fernandez explains, "because how well they protect us is not only a matter of what material we're using to do the filtering but also how well [the mask] seals to the face, so that we're trying to avoid air making it around the mask into our breathing zone." The pantyhose layer, she says, helps creates a tighter seal around the face to reduce how much air leaks around loose edges — similar to the seal on an N95 respirator.

The findings come at a time when the Centers for Disease Control and Prevention is recommending that Americans wear cloth face coverings in public to help reduce the transmission of the coronavirus, but without offering much guidance on the best practices for making such coverings.

GOATS AND SODA

Coronavirus FAQs: Is A Homemade Mask Effective? And What's The Best Way To Wear One?

The research has not yet been peer-reviewed, but it was posted Wednesday on the scientific preprint site medRxiv and on the university's website in the interest of sharing information quickly in the midst of a pandemic. Scientists who reviewed the study at NPR's request praised it as vitally needed work.

"I think it's really a very important study," says Ben Cowling, a professor of infectious disease epidemiology at the University of Hong Kong who has studied the efficacy of face masks. "We need better information on what kind of homemade masks, what kind of fabric masks, are the best and how we can improve or upgrade basic masks to make them better."

The CDC guidelines on cloth face coverings are intended to protect other people *from* the wearer, since evidence shows that people can spread the coronavirus

before they're even showing symptoms of infection. However, the new research shows that with the added nylon layer, homemade masks may also offer lots more benefit *for* the wearer.

"Cloth masks," Cowling says, "most likely provide some protection, maybe not as good as surgical masks" — which are constructed with nonwoven fabrics made from plastics. "But if we can upgrade [cloth masks] with nylon wrapping around the outside or some other special components, then perhaps we can get a cloth mask which is just as good or even better than a surgical mask."

"It's a good design feature that they've come up with," says Raina MacIntyre, a biosecurity researcher at the University of New South Wales in Australia and the author of one of the few studies comparing the effectiveness of cloth face coverings with surgical masks. The current shortage of medical-grade masks, she notes, is spurring a new wave of research into creating more effective homemade masks. "There's some really good solutions out there, some really promising ideas. And this looks like one of them."

As part of the research, Fernandez and her colleagues solicited homemade masks from volunteers who were making them to donate to Boston-area hospitals. To test the various masks' filtration capabilities, they used an instrument called a PortaCount — which is normally used to fit-test the filtering capabilities of medical-grade masks like N95 respirators — to measure the ability to block out particles ranging from 20 nanometers to 1,000 nanometers. (The coronavirus that causes COVID-19 is approximately 60 to 140 nanometers in diameter — far too small to be visible to the human eye.)

The device measured the number of particles immediately outside and inside each mask while someone was wearing it. A surgical mask was also tested as a baseline measurement; it blocked out 75% of the particles on average, which is in line with other testing that has suggested that surgical masks filter out between 60% and 80% of small particles in a lab setting.

Then, the researchers added to the masks a nylon stocking overlayer made by cutting a ring of material, about 8 to 10 inches top to bottom, from one leg on a

pair of pantyhose. "I would recommend perhaps a queen-sized [pair of pantyhose] just to make breathing easier," Fernandez says. The wearer puts the ring over their head like a headband, then pulls it down on top of the cloth mask, creating a tight fit to the face. This forces particles that might have otherwise gone around the loose edges of the mask and been inhaled to instead go through the mask, which can filter them out, Fernandez explains.

When worn alone, the homemade masks' abilities to filter varied widely, with some blocking fewer than 30% of particles. But adding the pantyhose layer boosted all the masks' performance by anywhere from 15% to 50%, the study found. Tights should also work, as long as they offer a snug fit, says Fernandez, who plans to include tights in future testing.

Fernandez says the idea to try stockings came from a colleague at Northeastern who had previously studied how to make effective homemade masks in the early 1980s, in the wake of the 1979 Three Mile Island nuclear accident in Pennsylvania. "And what they found in the '80s was that if you just put a section of pantyhose over your face and stuffed anything in there, that would do a pretty good job of keeping the fallout particles out," she says.

The homemade cloth masks that performed best in the testing with the nylon layer were all made of a tightly woven cotton, the kind used for quilting, and they all contained a filter of some kind — either organic cotton batting or what's known as interfacing, a lightweight, gauzy textile used to stiffen fabrics, such as shirt collars.

MacIntyre notes that more research needs to be done, such as how many washings the delicate nylon hosiery can withstand before it loses effectiveness. But in principle, she says, it makes sense that people who are donning homemade masks start snipping away at pantyhose and adding it as an extra layer now. Cowling agrees that it "could be an important aspect of everybody wearing face masks."

As research into homemade masks grows, "we'd like to see recommendations from the CDC or elsewhere in the world, from other public health authorities, on

what are the best ways to do it," he says.

That said, Cowling stresses that masks alone won't be enough to manage the transmission of the coronavirus as the world begins to contemplate how to emerge from lockdowns. But in combination with other strategies, such as enhanced testing, contact tracing for confirmed cases and continued social distancing measures, masks could help keep transmission of the virus at a low level.

So what should I use to make my homemade mask?

While getting a pair of nylons is pretty easy (for now), questions remain in the public's mind about the best material for a homemade mask. Here are some tips from mask researchers:

Use a thick-weave cotton: In general, thicker, high-grade cotton masks tend to do a better job of filtering out small particles, says Dr. Scott Segal, a professor and chair of anesthesiology at Wake Forest School of Medicine who has been putting various cloth masks to the test since March. His rule of thumb: Hold up the fabric to a bright light or to the sun. If "you can see the light outlining the individual fibers in the fabric, it's probably not a good filter. And if you can't, it's probably going to filter better." Thin T-shirt material didn't do a great job in his testing, though "probably anything is better than nothing," he says. Thicker, heavier-weight T-shirts would probably be better filters, he adds.

Layer your fabric: Cloth masks made from multiple layers seem to do a better job than single-layer ones, says Yang Wang, an assistant professor of environmental engineering at Missouri University of Science and Technology who studies how fine particles like aerosols are transmitted and has been testing how various household items hold up as mask materials. A single-layer mask made from a 400-thread-count pillowcase had a filtration efficiency of around 10%, but if you bumped it up to four layers of cloth, the efficiency went up to around 20%. "It's not ideal, but by using more layers, you can bump up the filtration efficiency," Wang says — just make sure not to use so many layers that you can't

breathe.

Editor's note: The original photo on this story has been replaced to show the researcher wearing a mask without a grommet, which was only inserted in the mask for testing. Face masks should be worn with the pleats opening downward, not upward, as in the previous image.

face masks | covid-19 | coronavirus

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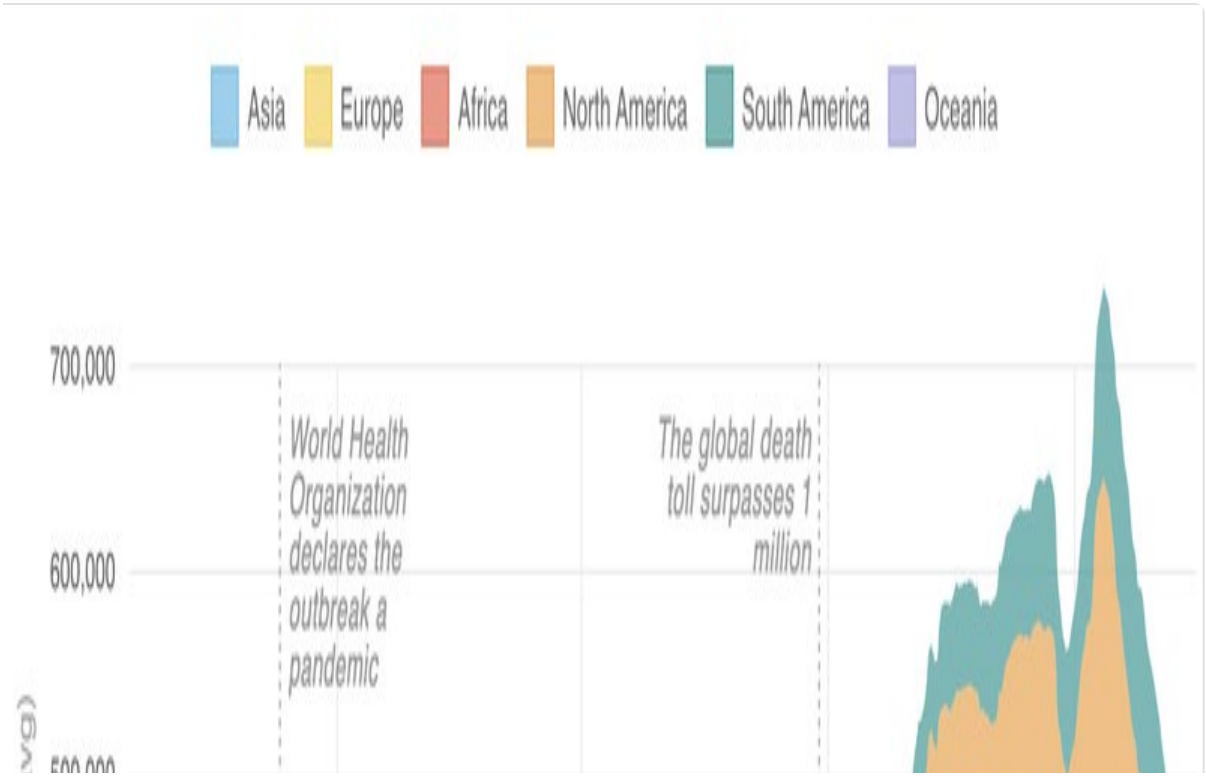

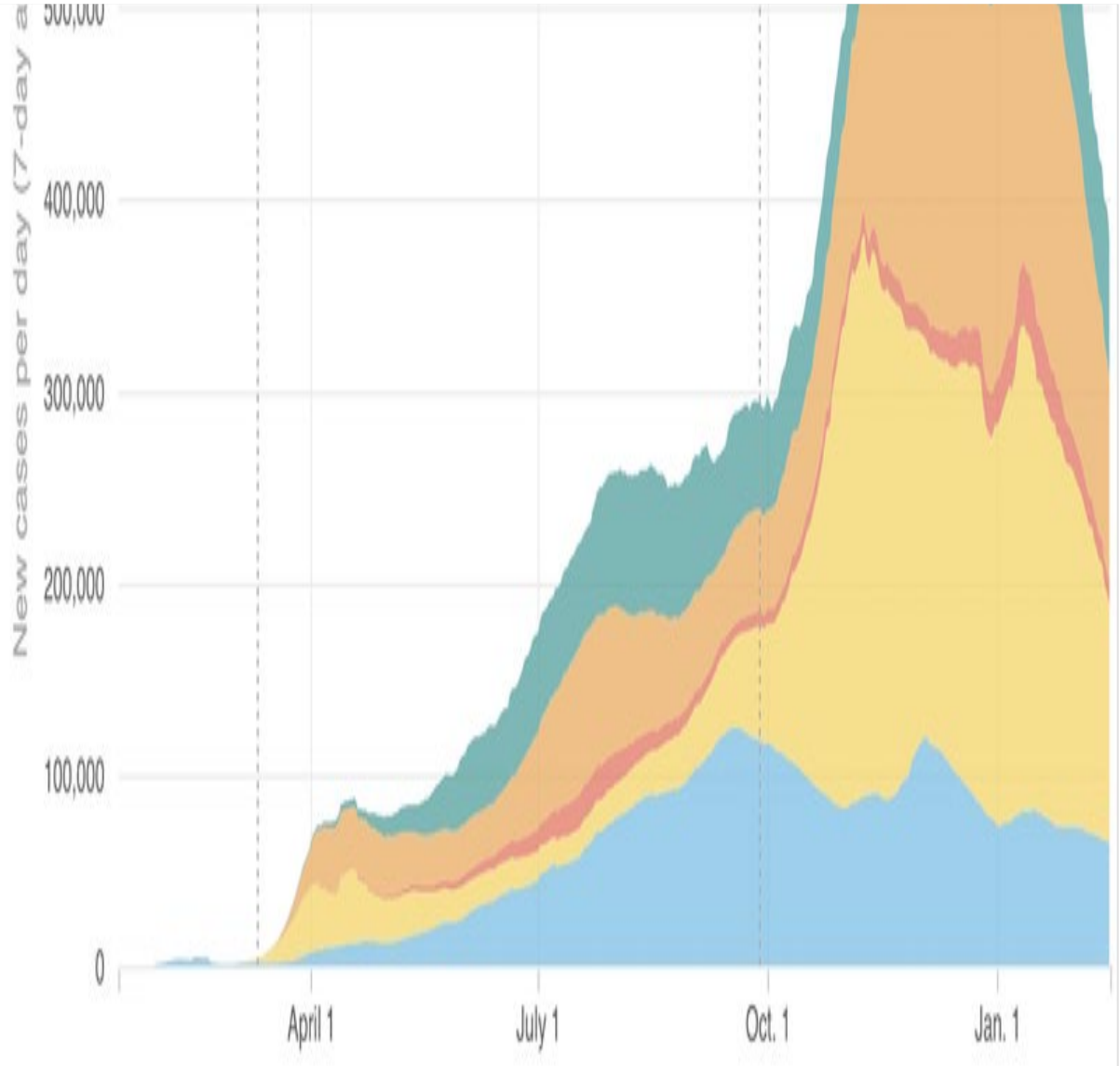

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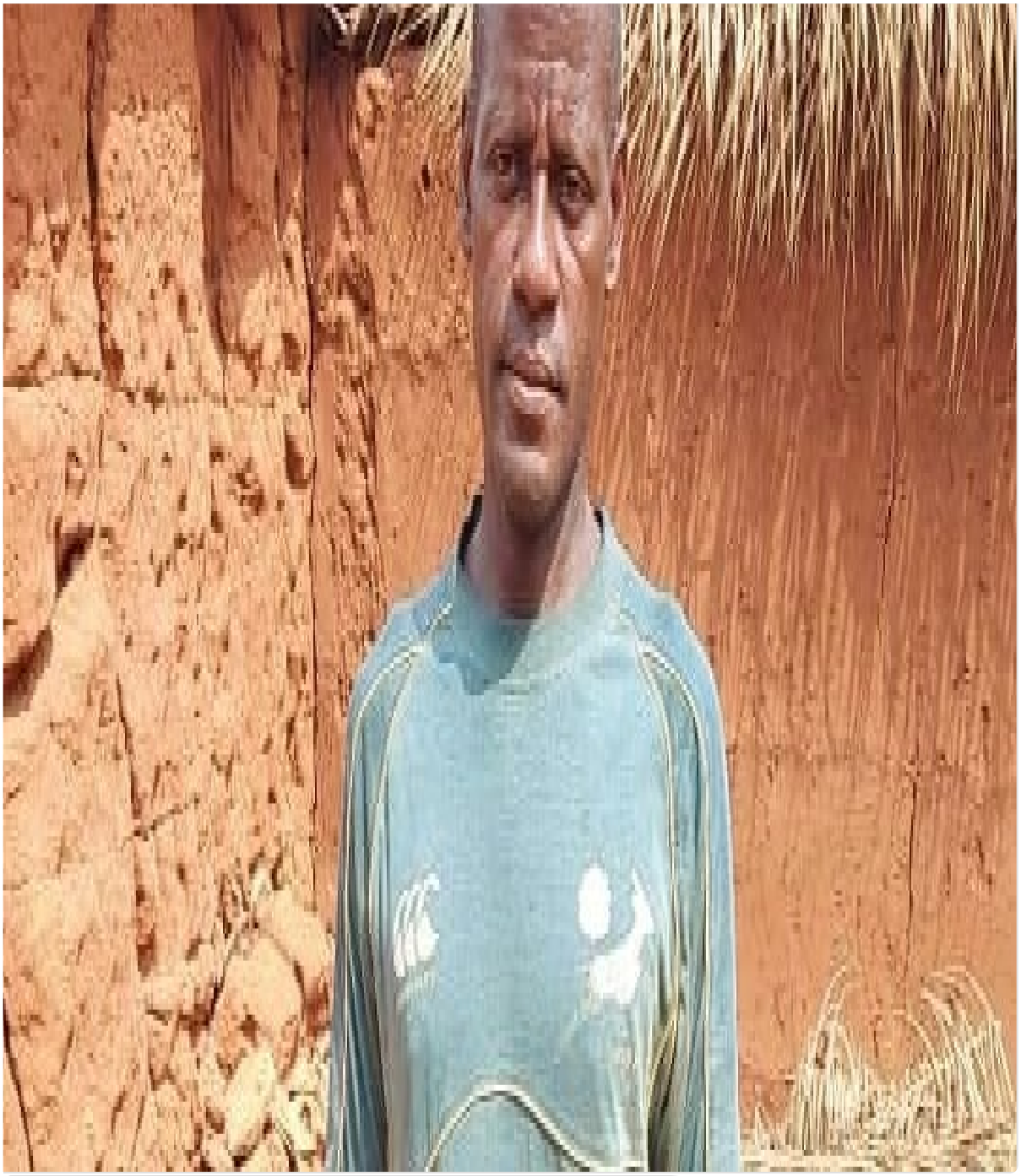

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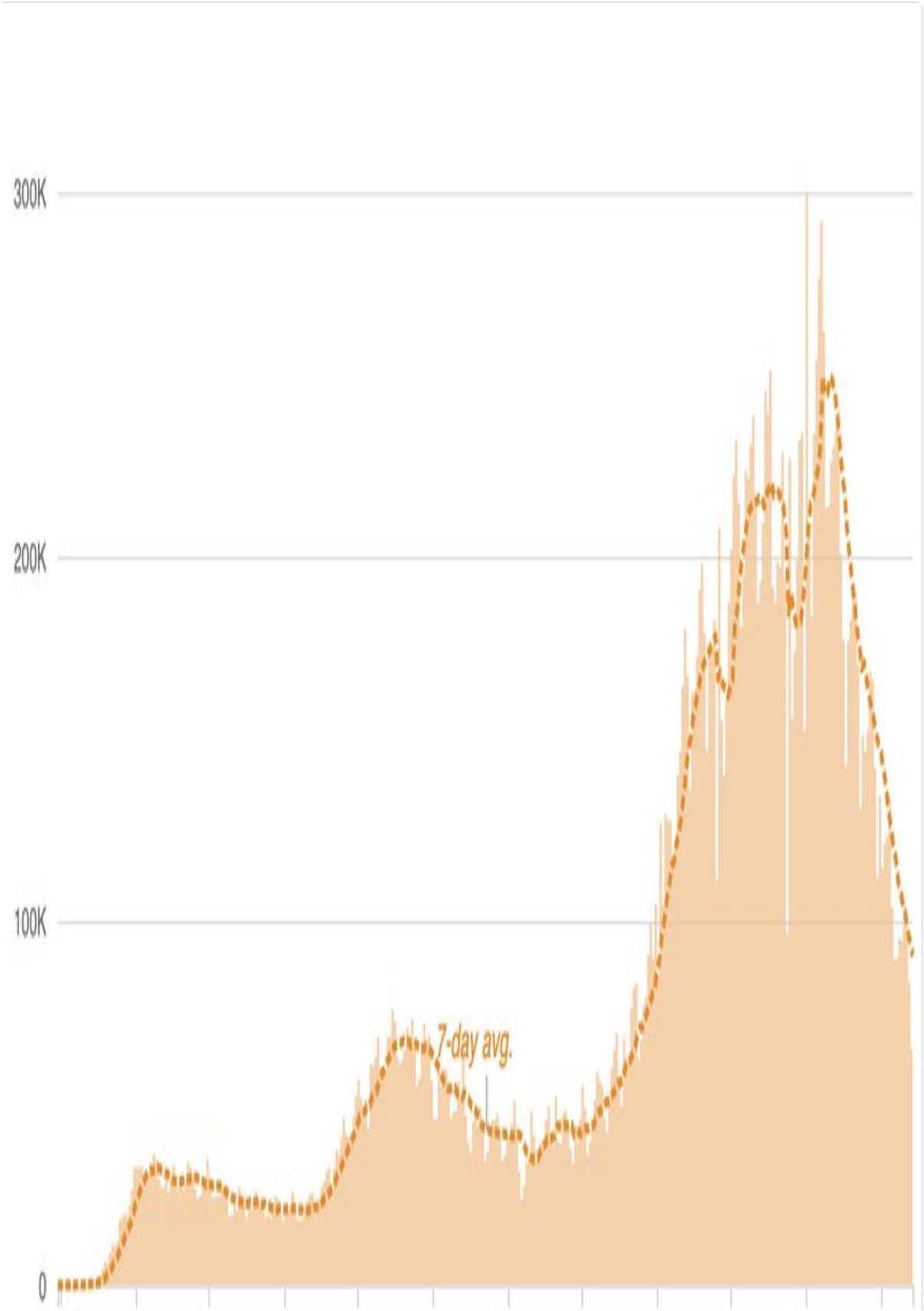

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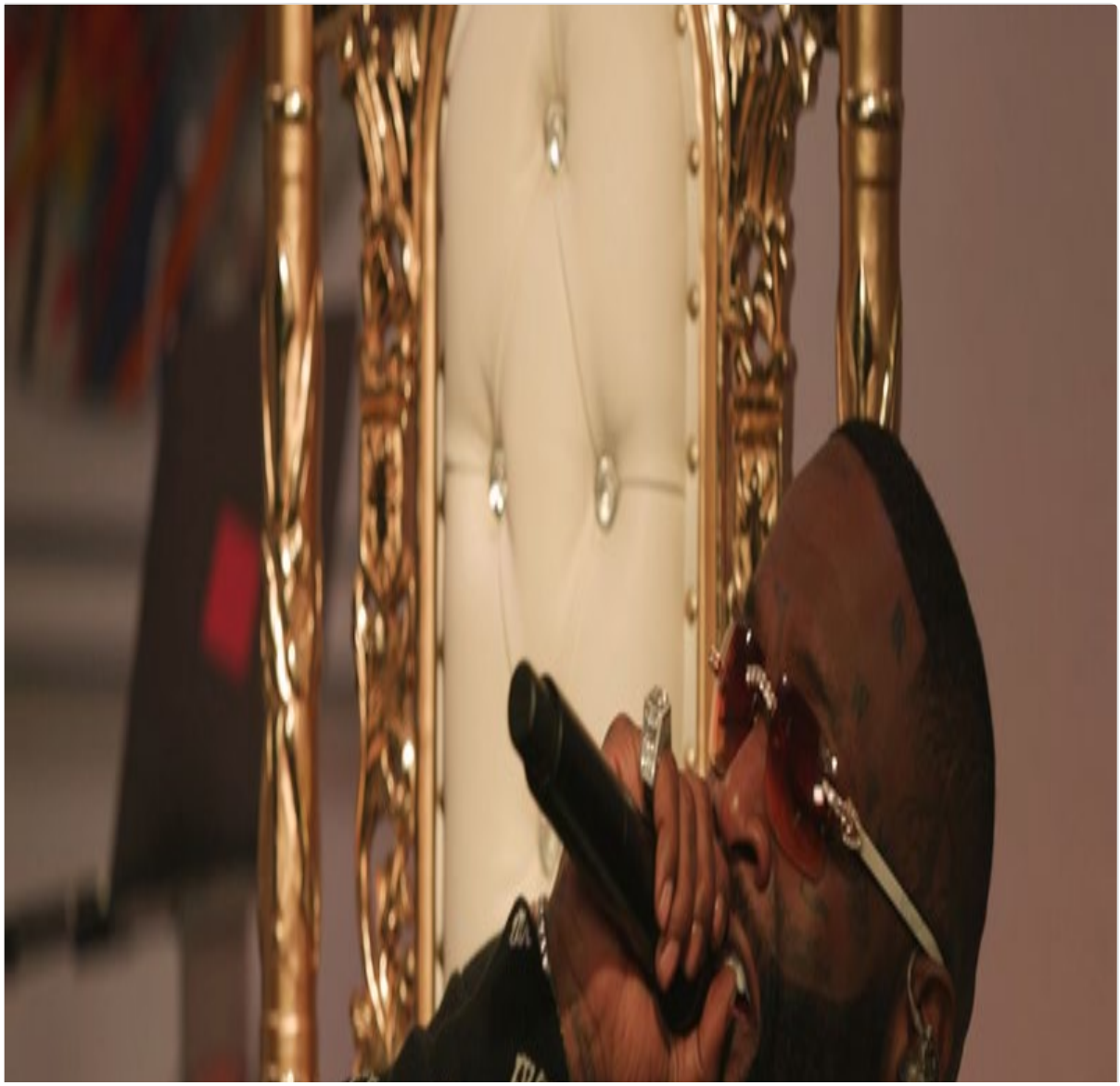

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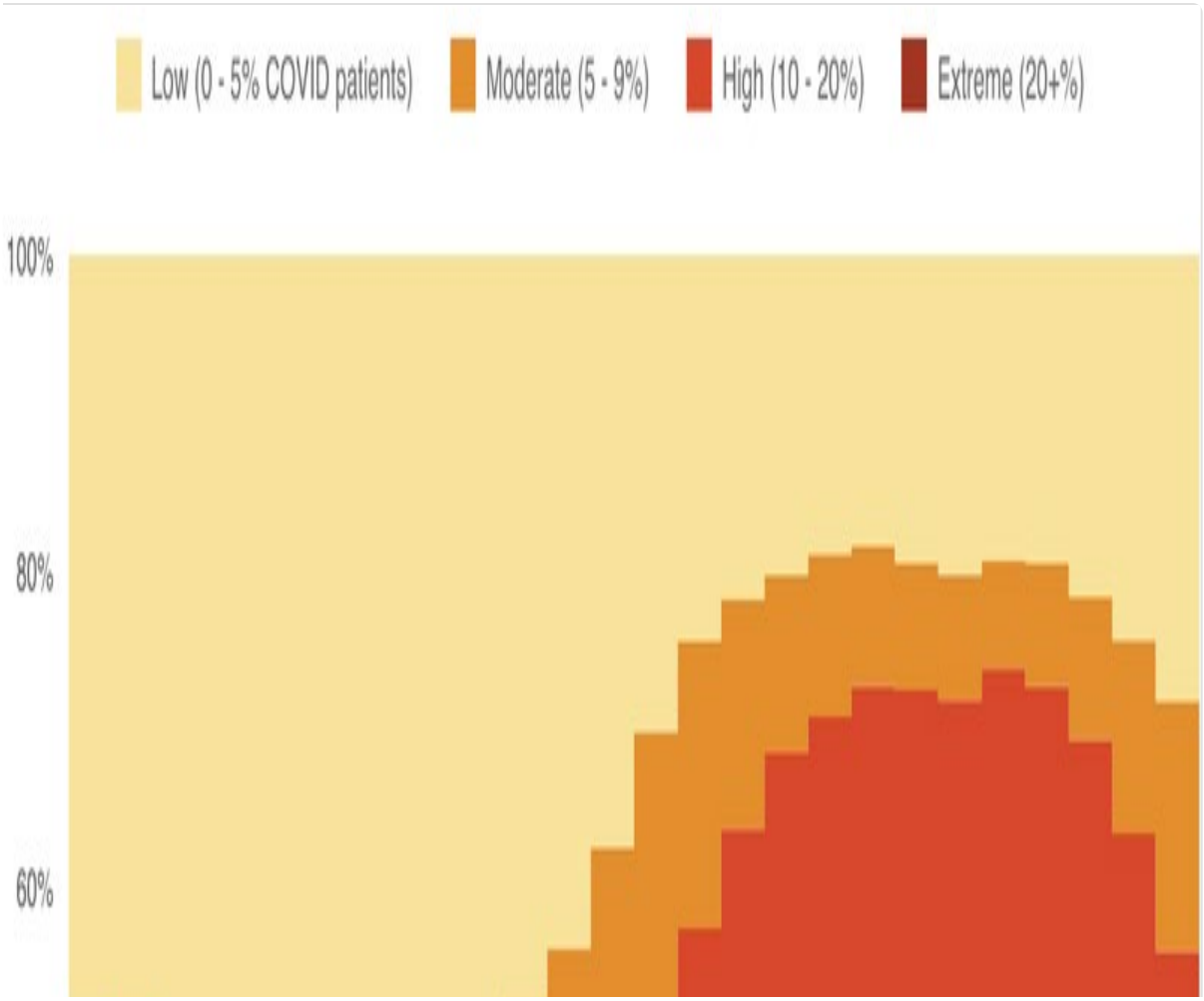

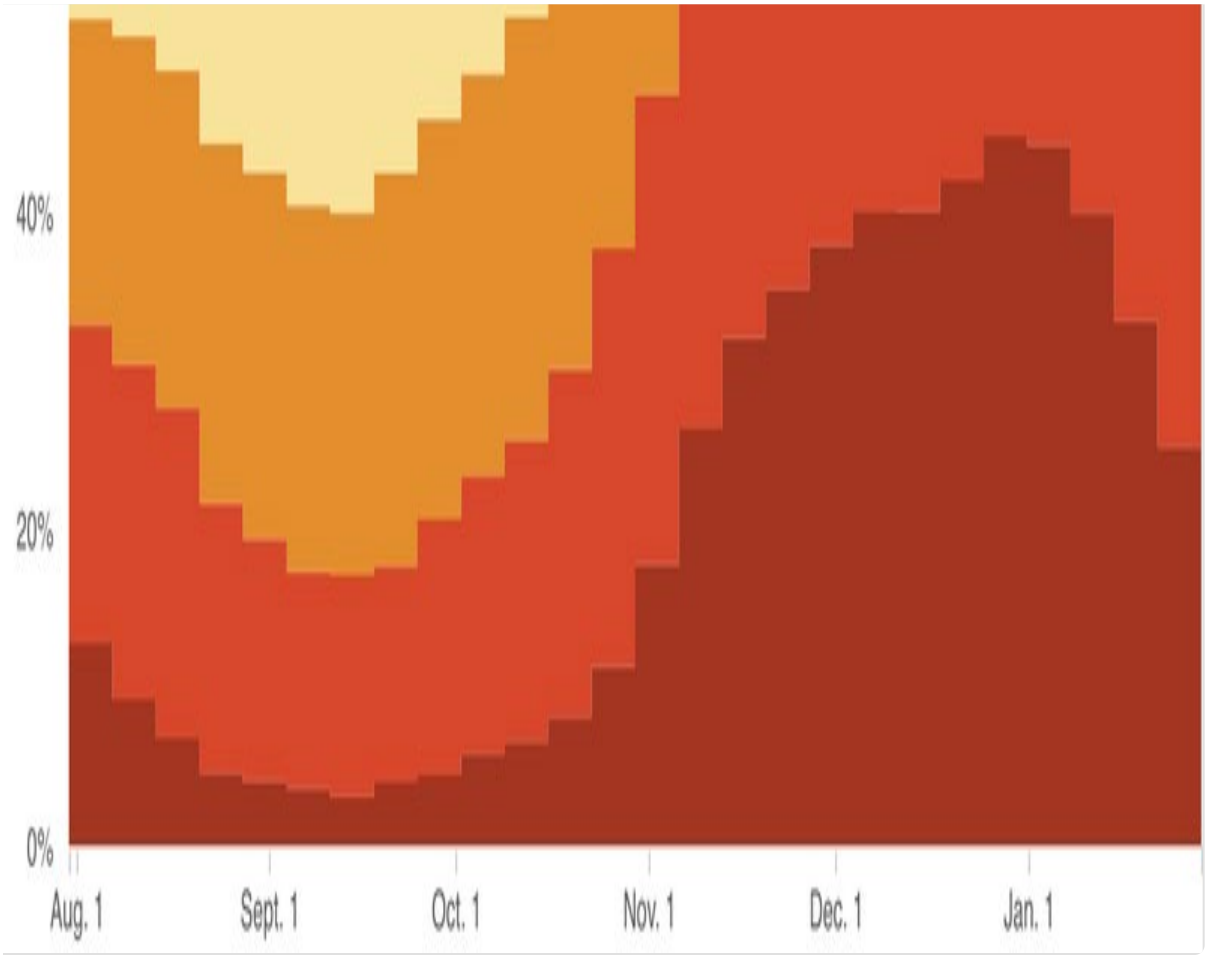

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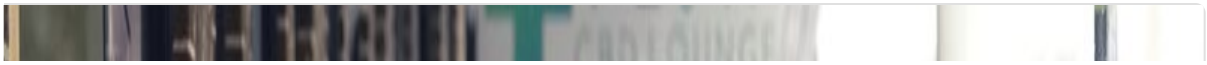

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Reinventing Cloth Masks in the Face of Pandemics

Stephen Salter

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Abstract

Because asymptomatic carriers of COVID-19 produce respiratory droplets that can remain suspended in air for several hours, social distancing may not be a reliable physical barrier to transmission. During the COVID-19 pandemic, however, some governments were reluctant to mandate public mask use out of concern this would worsen shortages of respirators for healthcare workers. Cloth masks with a filtering effectiveness of 70–90% can be made from widely available materials, and are a better option than respirators for the public. Countries could rapidly implement Effective Fiber Mask Programs (EFMPs) to use local resources to mass produce effective and affordable cloth masks, and to engage the public in their correct use. EFMPs could be a cost-effective measure to ease isolation while limiting new infections during pandemics. EFMPs could also protect healthcare workers by increasing the supply of respirators for their use, reducing their risk of acquiring the illness from their communities, and by reducing the number of patients they must treat.

1 INTRODUCTION

This article was written during the COVID-19 pandemic, but its analysis can apply to pandemics in

general. Novel human viruses have been reported at the rate of one to two per year, a trend epidemiologists expect will continue (Woolhouse et al., **2008**). Several interrelated issues emerged during the COVID-19 epidemic. First, healthcare facilities experienced shortages of respirators because of a limited capacity to manufacture the electrospun filter materials used in their manufacture (Wu, Huang, Zhang, He, & Ming, **2020**). Second, social distancing and isolation were used as physical barriers to reduce transmission, but social distancing is not always practical, and isolation brings significant economic and social costs. Authorities faced the challenging question of how to end lockdowns without triggering successive waves of infections (Lawton, **2020**). Third, guidance from health authorities regarding the use of masks in public varied widely. Some countries mandated the public use of masks while others asked people not to wear masks out of concern that doing so would reduce the supply of masks for healthcare workers (Javid, Weekes, & Matheson, **2020**). What if countries used local resources to produce effective masks for the public? How could these masks be made, and how effective would they need to be? Addressing these questions requires insights from epidemiology, virology, biochemistry, physics, mathematics, environmental science, material sciences, building engineering, psychology, and public policy. This article draws on current research in these fields to propose the development and public use of more effective cloth face masks during pandemics. The article does not provide medical advice but offers information to professionals who advise governments on public policy.

2 TRANSMISSION OF COVID-19

2.1 Asymptomatic Transmission and Respiratory Droplets

COVID-19 can be transmitted to susceptible individuals by asymptomatic individuals, who are less likely to sneeze or cough (Asadi, Bouvier, Wexler, & Ristenpart, **2020**). He et al. (**2020**) estimated that "*44% (95% confidence interval, 25–69%) of secondary cases were infected during the index cases' presymptomatic stage*." Lauer et al. (**2020**) reported a median incubation period for COVID-19 of five days.

Coughing and sneezing produce the largest respiratory droplets at 10 μm and up to 1,000 μm respectively. Breathing and speaking produce the smallest, in the ranges of 0.8–1 μm and 3.5–5.5 μm respectively (Asadi et al., **2019**; Han, Weng, & Huang, **2013**; Morawska et al., **2009**). Leung, Lam, and Cheng (**2020**) reported "*Viral RNA was identified from respiratory droplets and aerosols for all three viruses, including 30, 26, and 28% of respiratory droplets and 40, 35, and 56% of aerosols collected while not wearing a face mask, from coronavirus, influenza virus, and rhinovirus-infected participants, respectively*." Interestingly, Milton, Fabian, Cowling, Grantham, and McDevitt (**2013**) found the number of virus copies in the exhaled breath of influenza patients was 8.8 times higher in particles smaller than 5 μm than in larger particles. Stadnytskyi, Bax, Bax, and Anfinrud (**2020**) reported that "*At an average viral load of 7×10^6 per milliliter, we estimate that one minute of loud speaking generates at least 1,000 virion-containing droplet nuclei that remain airborne for more than eight minutes*."

2.2 Respiratory Droplets and Aerosols

The size of droplets and particles is a continuum, but there are important differences between aerosols and larger droplets or particles. In physics the upper limit of the size of an aerosol is 100 μm (Baron, Kulkarni, & Willeke, 2011; Hinds, 1999; Thomas, Charvet, Bardin-Monnier, & Appert-Collin, 2017). Aerosols behave differently from larger droplets and particles in significant ways:

1. Under normal conditions, the high surface-to-volume ratio of liquid aerosols causes them to evaporate rapidly.

2. Smaller aerosols are affected more strongly by air currents than by gravity (Baron et al., **2011**).

3. While larger particles and larger aerosols tend to be deposited in the upper respiratory tract, smaller aerosols (<2.5 μm) can be deposited in the lungs (Roy & Milton, **2004**).

Because respiratory droplets contain salts, proteins, and carbohydrates, their droplet nuclei are hygroscopic and do not become completely dehydrated (O'Shaughnessy et al., **2020**; Vejerano & Marr, **2018**). Droplets containing salt evaporate more slowly than pure water droplets, but at isotonic concentrations this difference is negligible (Qu, Escobar, Li, Rao, & Xu, **2020**). Except under conditions of high relative humidity (RH), most of the water they contain evaporates to leave droplet nuclei that are 60–70% smaller than the original droplet. These residual droplet nuclei are also aerosols, having even greater mobility than the original droplets.

Some descriptions of small droplet behavior in the literature, however, are incomplete. For example, one source refers to particles larger than 10 μm as “large particles” that fall to the ground in a few seconds (Public Health Agency of Canada, **2017**). Based on the relationships provided by Holterman (**2003**) and the characteristics of saliva described by Liu, Wei, Li, and Ooi (**2016**), however, it can be calculated that at 20 °C and 50% RH, 10 μm droplets of saliva evaporate to 3.5 μm residual droplet nuclei in under a second, which would then require more than an hour to settle in still air. Under real life conditions, these droplet nuclei are more likely to travel with air currents than to reach the ground directly. Although some medical scientists and physicists may discuss the upper size limit of aerosols differently, these differences are unimportant to the question of how respiratory droplets from asymptomatic individuals behave. These droplets are smaller than 10 μm, and their behavior is well understood.

To illustrate how the behavior of droplets and aerosols differs by size, the time for a droplet to settle through a vertical distance of 1.5 m to the ground in still air, and the time to form a droplet nucleus through evaporation were calculated for a temperature of 20 °C and RH of 50% and the results are shown in Table **I**. The calculations are based on the relationships provided by Holterman (**2003**) and the characteristics of saliva described by Liu et al. (**2016**). The calculations ignore the initial speed of droplets, and assume they are spherical and electrically neutral. The

initial concentrations of salts and solids in the respiratory droplet were assumed to be 0.9% and 1.8% respectively, after Liu et al. (**2016**).

Table I. The Fate of Respiratory Droplets by Size at 20°C and 50% Relative Humidity

Original size	Estimated final size	Fate of droplets at 20 °C and 50% relative humidity
1 mm	350 μm	Sneezing produces droplets of this size. These droplets are not aerosols but are comparable in size to raindrops and would settle in 0.4 seconds.
100 μm	35 μm	A 100 μm droplet will settle in six seconds.
10 μm	3.5 μm	Coughing produces droplets of this size, which evaporate in 0.2 seconds to 3.5 μm droplet nuclei. The nuclei would theoretically require one hour to settle in still air, but in practice are entrained in air currents.
5 μm	1.8 μm	Speaking produces droplets of this size, which evaporate in 0.1 seconds to 1.8 μm droplet nuclei. The nuclei would theoretically require four hours to settle in still air, but in practice are entrained in air currents.
0.8 μm	0.3 μm	Breathing produces droplets of this size, which evaporate in a few milliseconds to 0.3 μm droplet nuclei (comparable in size to smoke particles). The nuclei would theoretically require 20 hours to settle in still air, but in practice are entrained in air currents.

Under ambient conditions of 20 °C and RH of 50%, droplets initially smaller than approximately 80 μm form smaller droplet nuclei before they can fall 1.5 m to the floor or ground. Similar results have been found for droplets containing salt (Ferron & Soderholm, **1990**; Yang & Marr, **2011**) and for sputum droplets expelled by a cough.

The evaporation of respiratory droplets is one reason that loose-fitting masks reduce the risk of infection for others more than for the wearer: the concentration and diameter of respiration droplets are at a maximum as they are expelled (Redrow, Mao, Celik, Posada, & Feng, **2011**). It is therefore easier to reduce respiration droplets at their source than to filter out their smaller and more diffuse residual droplet nuclei later. This outcome matches experience with pollution control, where it is more efficient and cost-effective to reduce contaminants at the source than to remove them from the environment later.

2.3 Limitations of Social Distancing

After respiratory droplets leave the body their temperature decreases and their concentration of salt ions increases through evaporation; both affect the viability of the virus (Lin & Marr, **2019**). Van

Doremalen et al. (**2020**) measured the viability of SARS-CoV-2 and SARS-CoV-1 in aerosols smaller than 5 μm produced in a laboratory and found the half-life of each virus was approximately one hour. Their study measured viability by end point titration rather than detection of RNA. Other researchers found that SARS-CoV-1 was transmitted among individuals in aerosol form (Booth et al., **2005**; Morawska & Cao, **2020**; Yu, Wong, Chiu, Lee, & Li, **2005**).

During the COVID-19 pandemic, social distancing of 2 m was recommended. Here, distance is used as a proxy for time: the time for larger droplets to reach the ground or floor in the spaces among individuals, the time for smaller droplet nuclei to disperse in air currents, and the time for virus particles in droplet nuclei to become inactive. The challenge is that ambient conditions vary so widely that time cannot reliably be represented by a fixed distance.

Aerosol droplet nuclei produced by individuals disperse in air, so their concentration decreases with distance. In most buildings, however, ventilation systems remove air contaminants relatively slowly. For example, if a building ventilation system achieves six air changes per hour, then (assuming air in a room moves vertically, so the calculated velocity is independent of floor area) the resulting average air velocity would be 4 mm per second. In contrast, a light outdoor breeze of 6 km/h moves 400 times faster. Higher air change rates in buildings can remove contaminants more quickly, but can also move aerosols more rapidly toward others (Ghia et al., **2012**; Liu et al., **2020**). Issues of ventilation rates, indoor air quality, and sick building syndrome have been extensively researched (Fisk, Mirer, & Mendell, **2009**; Jaakkola & Miettinen, **1995**). Interestingly, a study of COVID-19 outbreaks in China in January and February 2020 found only one of 318 outbreaks could be traced to an outdoor contact: the balance occurred indoors (Qian et al., **2020**).

The shortcomings of social distancing have been researched by Anderson, Turnham, Griffin, and Clarke (2020); Asadi et al. (2020); Bahl et al. (2020); Drossinos and Stilianakis (2020); Feng, Marchal, Sperry, and Yi (2020); and Setti et al. (2020) among others. Guzman (2020) concluded "***A SARS-CoV-2 carrier person talking, sneezing, or coughing at distance of 2 m can still provide a pathogenic bioaerosol load with submicron particles that remain viable in air for up to three hours for exposure of healthy persons near and far from the source in a stagnant environment***." Professionals who advise governments on public policy could therefore consider:

1. Medical science shows asymptomatic individuals produce respiratory droplets from speaking and breathing smaller than 5 μm that contain virus particles.

2. Physics shows droplets of this size rapidly evaporate to smaller droplet nuclei, that remain suspended in air for several hours. The original droplets and residual droplet nuclei are both aerosols.

3. Medical science shows the SARS-CoV-2 virus survives in aerosol droplet nuclei for several hours, which is significantly longer than the time required for droplet nuclei produced by an infected individual to reach a susceptible one.

4. Physics shows that indoors, air currents move droplet nuclei more slowly toward others, but also disperse them more slowly. Outdoors, air currents can disperse droplet nuclei more quickly, but can also move them more rapidly toward others.

Together, medical science and physics strongly suggest social distancing is not a reliable barrier to transmission of COVID-19. The question of whether an illness can spread through aerosols is less important if effective masks are used as barriers to transmission, because they can reduce emissions of respiratory droplets to air and consequently contamination of surfaces and fomites, and can also reduce inhalation of aerosols.

3 MASKS AS BARRIERS

Estimating the risk of transmission between two individuals would be highly complex, because of the large number of variables involved. Such mechanistic modeling is unnecessary because the goal is not to determine if a given individual will become ill, but to estimate how the risk of transmission may be reduced in a population. Tian et al. (**2020**) developed a model to show how general mask use can reduce transmission of infection, and hence R_0. They developed a "*semiquantitative model to show that mask-wearing reduces* β_{eff} *and hence* R_0 *by a factor* $(1 - E \cdot P)^2$ *where* E *is the efficacy of trapping viral particles inside the mask, and* P *the percentage of mask-wearing population*" (Tian et al., **2020**). Based on Tian et al. (**2020**) the relationship between the rate of transmission between two individuals, the effectiveness of masks, and the percentage of people who wear them in public can be expressed as:

Equation 1. Mask Effectiveness and Mask Use

$$\beta_{mask} = \beta(1 - E_i \cdot P)(1 - E_0 \cdot P) \quad (1)$$

where:

β is the rate of transmission of infection from an infected person to a susceptible person in the case where neither person wears a mask,

β_{mask} is the rate of transmission of infection from an infected person to a susceptible person in the case where a percentage of people wear masks,

P is the percentage of people who wear masks in public,

E_i is the % reduction in the risk of transmission from others to the wearer by masks

E_0 is the % reduction in the risk of transmission to others from the wearer by masks.

Equation 1 is based on the assumption that the mask of person "A" reduces transmission from "A"

to the shared space between them, and the mask of person "B" reduces transmission from the shared space to "B." Because the two masks act in series, their effect on transmission is compounded. Even if each mask is only 50% effective, the two masks together would reduce the risk of transmission by 75%. The reduction in transmission is simply:

Equation 2. Reduction in Transmission

$$\text{Reduction in Transmission} = 1 - \frac{\text{mask}}{} \tag{2}$$

Equations 1 and 2 can be combined to find the required "incoming effectiveness" of masks:

Equation 3. Mask Effectiveness as a Function of Mask Use

$$1 - \frac{1 - \frac{\text{mask}}{}}{(1 - \cdot)} \tag{3}$$

where:

P is the percentage of people who wear masks in public,

E_i is the % reduction in the risk of transmission from others to the wearer by masks

E_0 is the % reduction in the risk of transmission to others from the wearer by masks.

The required combinations of P, Ei, and $E0$ to reduce transmission by 50% are shown in Fig. 1.

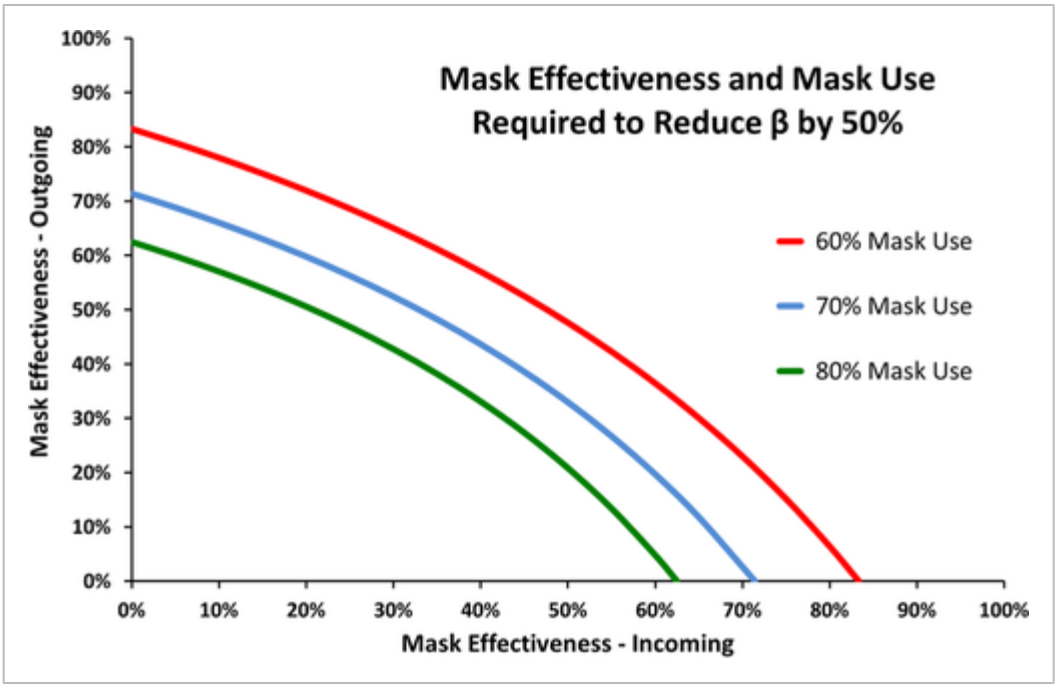

Fig 1

Open in figure viewer | **PowerPoint**

Impact of mask effectiveness and mask use on β

In this high-level model it does not matter whether transmission is reduced by masks that reduce the risk of infection to the wearer (but not to others), or masks that reduce the risk of infection to others (but not to the wearer). The model also shows even imperfect masks can reduce the risk of transmission. Similarly, Kai, Goldstein, Morgunov, Nangalia, and Rotkirch (**2020**) concluded if 80% of people wear masks in public, and if masks have an effectiveness of 70%, then daily case growth rates could be significantly reduced.

In this model the relationship between the filtering effectiveness of masks and the risk of transmission is linear, which may be inaccurate. If a minimum infectious dose is required for an airborne pathogen to cause illness, then models could account for the potential of masks to reduce exposure to a level below this dose. Further, a higher initial dose may cause more severe illness (Paulo, Correia-Neves, Domingos, Murta, & Pedrosa, **2010**). Research has shown that the severity of illness caused by the influenza A virus depends on whether infection began in the nose or in the lower respiratory tract (Nikitin, Petrova, Trifonova, & Karpova, **2014**; Tellier, **2006**). If this proves true for COVID-19, then research could determine if a second benefit of public mask could be less severe illnesses.

The model also shows a small improvement in mask use can strongly affect outcomes because the effect on β is proportional to the square of P. Further, R_0 is proportional to β, so reducing β will cause an exponential reduction in cases over time. This effect is discussed by Abaluck et al. (**2020**) who found "*If masks reduce the transmission rate of the virus by only 10%, epidemiological models*

suggest that hundreds of thousands of deaths could be prevented globally, creating trillions of dollars in economic value. According to one commonly used epidemiological model, a 10% reduction in transmission probabilities would generate $3,000–6,000 in value per capita from reduced mortality risk in the United States alone."

4 TYPES OF MASK

When reading studies of the performance of masks, it is helpful to note:

1. In some studies masks are sealed to a machine or mannequin for testing. The results show the filtering efficiency of the mask's materials, but not the effectiveness of the mask as worn (Davidson et al., **2013**). Other studies use quantitative fit tests of masks worn by people, which better indicate their effectiveness.

2. Studies may report the effectiveness of masks as filter penetration, filtering efficiency, or fit factor. In this article, results are presented as filtering efficiency.

3. Results do not always include breathing rate ($L \cdot min^{-1} \cdot cm^{-2}$) and differential pressure. These are important aspects of performance because filtering efficiency and breathability change with air velocity.

4. Particles used for testing can be monodisperse or polydisperse and may not be charge-neutralized. Further, particle counting equipment may not report results for different particle sizes. This is important since filtering efficiency varies with particle size.

4.1 N95 and FFP Respirators

N95 and FFP respirators are made with highly efficient electret filter materials, and with a means of forming a close fit and seal with the wearer's face. These masks were originally designed to protect industrial workers and are certified to filter more than 95% of particles 0.3 μm in diameter. N95 respirators are unsuitable for public use during pandemics because they are needed by healthcare and industrial workers, and because their effectiveness cannot be assured without individual fit testing and training (U.S. FDA, **2020**).

4.2 Surgical Masks

Surgical masks (also called procedure masks or medical masks) are designed to resist penetration by fluids under pressure, and to reduce emissions of droplets from the wearer. A confusion regarding certified surgical masks is that while they are made with materials having a high filtration efficiency, their effectiveness in actual use is lower. The reason is that the filtration efficiency of surgical mask material is measured by devices that do not allow air to bypass the material, but in use surgical masks cannot provide a tight fit. The incoming filtering effectiveness of surgical masks has been measured as 53–74% (Mueller, Eden, Oakes, Bellini, & Fernandez, **2020**), 20–80% (Bałazy et al., **2005**), 16–80% (Bałazy et al., **2006**), and 10–86% (Oberg & Brosseau, **2008**). The U.S. FDA

(**2020**) states: "*While a surgical mask may be effective in blocking splashes and large-particle droplets, a face mask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes, or certain medical procedures. Surgical masks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the face mask and your face*." 3M (**2020**), the Milton et al. (**2013**), U.S. CDC (**2020**), and Oberg and Brosseau (**2008**) give similar descriptions of surgical masks. Surgical masks are unsuitable for public use during pandemics because they are needed by healthcare workers for their intended purpose.

4.3 Cloth Masks

Cloth masks have been made with a wide variety of designs and materials. Some disadvantages of cloth masks include:

1. Their filtering effectiveness varies widely.
2. Education is required to ensure they are properly used.
3. Less area of a cloth mask is available for filtration than in a respirator.
4. Breathing resistance in some cloth masks is high.
5. They require more time and effort to make than disposable masks.
6. They are not normally certified to ensure they meet minimum requirements.
7. To date, highly effective cloth masks have not been widely available.

Some advantages of cloth masks include:

1. Cloth masks can be made with widely available materials and low-tech methods (Konda et al., **2020**; Mueller et al., **2020**).
2. Resources needed to make cloth masks do not compete with those needed to make respirators.
3. Making cloth masks can employ people who might otherwise be unemployed during pandemics.
4. Making cloth masks indirectly increases availability of respirators for healthcare workers, by providing the public with an alternative.
5. Cloth masks can be designed to provide a better fit than pleated disposable masks (Mueller et al., **2020**).

6. Cloth masks do not require fit testing and can be made for different shapes and sizes of faces, including the faces of children.

7. Cloth masks can be disinfected in an autoclave, or laundered since the lipid membrane of the SARS-CoV-2 virus is disrupted by surfactants (Welch et al., **2020**).

8. New cloth masks have no expiry date and can be stored in preparation for future pandemics, and against air pollution from wildfires and fossil fuel combustion.

9. The cost per hour of use of cloth masks is lower than that of disposable masks. (These costs are discussed in Section **7.3**.)

Cloth masks have strengths and weaknesses: how can they be improved?

5 IMPROVING CLOTH MASKS

Hand-sewn cloth masks are often made with tightly woven fabrics, in the hope they will screen droplets and particles. However, this screening or sieving effect cannot block small droplets and particles. Air filters actually remove small particles in four ways, which are summarized in Fig. **2** (Kowalski, Bahnfleth, & Whittam, **1999**; Lee & Liu, **1982**).

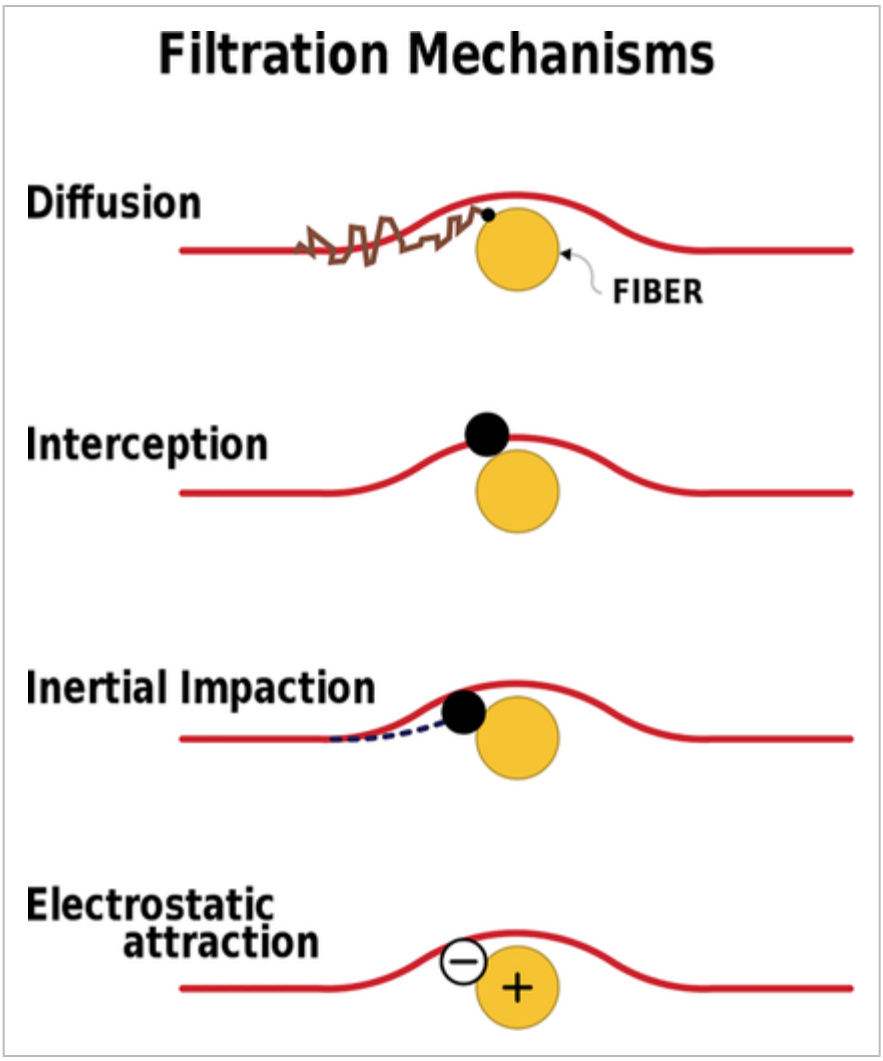

Fig 2

Open in figure viewer | **PowerPoint**

Filtration mechanisms

Diffusion. Collisions between particles and gas molecules cause Brownian motion, which randomly moves particles out of the path of the air stream and toward filter fibers.

Interception. Particles adhere to fibers when the path of the air stream is within approximately one radius of the fiber.

Inertial Impaction. Because of their inertia, particles are unable to follow the air stream around fibers, and instead adhere to them.

Electrostatic Attraction. Surface charges on the fiber cause electrostatic fields, which attract particles to the fiber.

Woven fabrics are not ideal air filters. As Fig. 3 shows, the spaces between threads are larger than the spaces between fibers in threads: most air flows through these spaces. Further, individual fibers in a thread lie parallel to each other, so less than 5% of their surface area is exposed to air moving through the fabric.

Fig 3

Open in figure viewer | **PowerPoint**

Woven fabric

Photo credit: Edal Anton Lefterov / CC-BY-SA-3.0

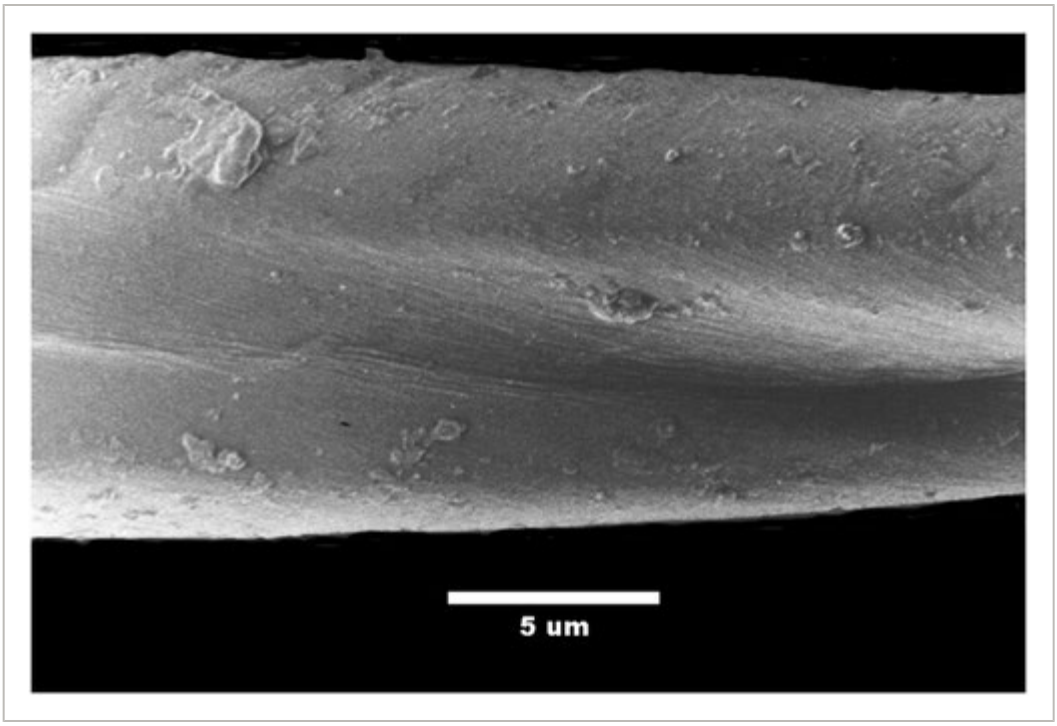

Fig 4

Open in figure viewer | **PowerPoint**

Cotton fiber

Photo Credit: CSIRO / CC-BY-SA-3.0

Fig 5

Open in figure viewer | **PowerPoint**

Cotton batting mask interior

Because smaller particles are adsorbed onto the surfaces of fibers in a filter, increasing the surface area of fibers exposed to moving air improves filtering efficiency. In nonwoven fabrics the area of fibers exposed to moving air is larger than in woven fabrics, which is one reason they are used in N95 respirators (Lam et al., **2019**). Cotton batting is a common three-dimensional nonwoven material. Cotton fibers are typically 15 μm wide and 7 μm thick, and 95% of the surface area of fibers in cotton batting is exposed to air moving through the material. If a cloth mask with a filter area of 120 cm^2 incorporates cotton batting with a basis weight of 200 $g.m^{-2}$, the fibers would have a total surface area of approximately 6,000 cm^2.

The surface of cotton fibers is physically irregular, as Fig. **4** shows, and is also chemically heterogeneous. During processing, cotton fibers twist arbitrarily in a left-handed or right-handed direction, causing approximately five convolutions per millimeter. Cotton fibers are 90% cellulose, and their surfaces include pectins, proteins, minerals, and waxes. Each beta glucose monomer in cellulose has several hydroxyl groups, which cause hydrogen bonding among cellulose molecules in cotton fibers. Surface hydroxyl groups in cotton may attract and hold small particles though dipole-induced-dipole forces. Cotton batting also gives particles more time to interact with and adhere to fibers. For example, a surgical mask is typically 0.4 mm thick (Leonas & Jones, **2003**). For a given mask area and breathing rate, a particle would spend twelve times longer moving through 5 mm cotton batting than it would moving through a surgical mask. Konda et al. (**2020**) reported that a traditional cotton quilt (5 mm of blended cotton batting sandwiched between cotton fabric) had a filtering efficiency of 96% for particles smaller than 0.3 μm.

5.1 Cotton Batting Masks

To evaluate the effectiveness of cotton batting as a filter, cloth masks were made from the following materials:

- Outer and inner fabrics: 100% cotton, 120 threads per inch
- Inner filter: 100% cotton batting (2.5 mm thick and 150 $g.m^{-2}$ or 3.5 mm thick and 200 $g.m^{-2}$)
- Nose wire: 20 gauge stainless steel
- Ties: hockey skate laces

The wholesale value of these materials was US$1.50. The area of fabric in each mask was 120 cm^2, although the area through which air can flow was reduced by contact of the mask with the face. Fig. **5** shows the inner cotton batting layer of the mask, and Fig. **6** shows how the mask wraps around the face to give closer contact than a pleated mask design.

Fig 6

Open in figure viewer | **PowerPoint**

Cotton batting face mask

5.2 Test Results

In May and June of 2020, 17 cotton batting masks underwent 35 tests. The tests were carried out by three independent people using commercial quantitative fit testing equipment and quantitative fit testing methods. The three tests reported filtering effectiveness of 90.2% (95% CI 88.4–92%), 77.3% (95% CI 75.1–79.4%), and 76.5% (95% CI 72.3–80.6%). Some limitations of the tests are that particle size was not known in all cases, particles were not charge-neutralized, filtering effectiveness was not measured for a range of particle sizes, and pressure drop was not measured. The thickness of cotton batting used in the tested masks varied from 3.5 mm to 7 mm, but the results did not show a correlation between thickness and effectiveness. Although the tests showed the fit of the mask and variability among masks needs improvement, they also showed that cloth masks made by novices can reduce the amount of small particles inhaled by the wearer. Test methodologies and detailed results are described in the Supporting Information.

6 ARGUMENTS FOR AND AGAINST THE GENERAL USE OF MASKS

During the COVID-19 pandemic, guidance from officials regarding public use of masks varied

widely. Some of the arguments for and against cloth masks and general mask use are discussed here.

6.1 General Use of Masks Will Deprive Healthcare Workers of Personal Protective Equipment

This dilemma can be avoided if effective cloth masks are available to the public during pandemics.

6.2 Wearing a Mask Makes People Careless

Objective evidence to support this concern does not appear to be available (Cheng, Lam, & Leung, **2020**). If the public must wear masks they must be educated about their correct use, and about the ongoing need for other measures.

6.3 There is No Scientific Evidence Masks Reduce the Risk of Transmission

Epidemiological studies to determine whether general mask use reduces transmission of diseases like COVID-19 have examined areas where masks are commonly used. A weakness of these studies is that they do not report data regarding the filtering effectiveness of masks against outgoing respiratory droplets and incoming droplet nuclei, nor how effectively masks were used. Despite the limitations of epidemiological studies of general mask use, research by Abaluck et al. (**2020**); Cheng et al. (**2020**); Eikenberry et al. (**2020**); Esposito, Principi, Leung, and Migliori (**2020**); and Howard et al. (**2020**) have concluded that general mask use is helpful.

6.4 Cloth Masks Can Become Contaminated

All masks can become contaminated, and in pandemics, some people reuse disposable masks (Leung et al., **2020**). During pandemics, people must be educated to use masks safely. The government of France, for example, has recommended that cloth masks be worn for no longer than four hours (AFNOR, **2020**).

6.5 Cloth Masks Are Ineffective

The term "cloth mask" is ambiguous since it refers to materials rather than effectiveness. For example, one study of 1,607 hospital healthcare workers in Vietnam compared the rates of infection among two groups with a control group (MacIntyre et al., **2015**). One group in the study wore cloth masks, and a second group was issued with two disposable medical masks per shift. The study found that "***The rates of all infection outcomes were highest in the cloth mask arm***." The study also measured the filtering effectiveness of the cloth masks and medical masks that were used, and reported that "***Penetration of cloth masks by particles was almost 97% and medical masks 44%***." In other words, the study showed that healthcare workers wearing cloth masks with a filtering efficiency of 3% became infected more often than those who wore masks with a filtering efficiency of 56%. The issue found by the study was not that "cloth masks" per se are ineffective,

but that cloth masks with a filtering efficiency of 3% are ineffective.

7 AN EFFECTIVE FIBER MASK PROGRAM

If cloth masks are to be useful during pandemics, they must be produced as part of an integrated program. the proposed elements of an effective fiber mask program (EFMP) are shown in Fig. 7.

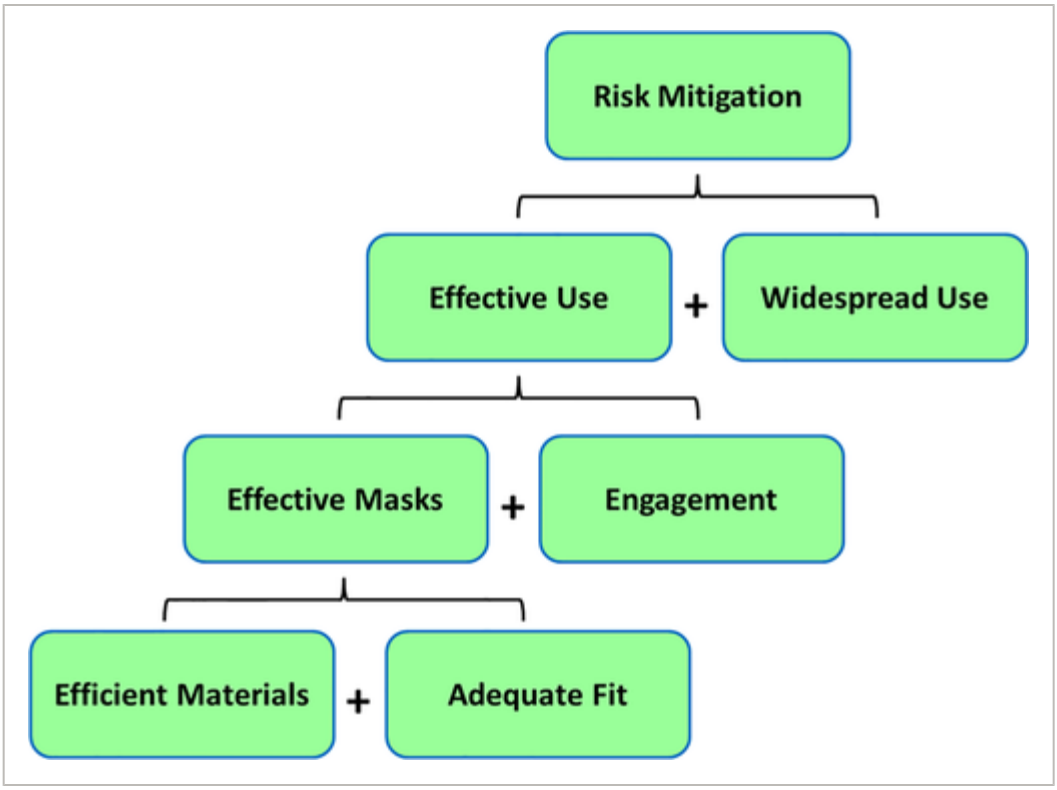

Fig 7

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Elements of an effective fiber mask program

7.1 Effective Masks

Masks proven to reduce both incoming droplet nuclei and outgoing droplets could be called EFM. For example, the minimum requirements for an "EFM90" mask could include 90% filtering effectiveness against incoming and outgoing particles, breathability, and durability of at least 30 laundering cycles. Approved masks could be labeled. To avoid solving one problem while creating others, the EFM Program could mandate that manufacturers:

- Use commonly available materials and local manufacturing resources to reduce dependence on long supply chains across borders, which are subject to logistical challenges and political forces during pandemics.
- Ensure workers in their supply chain are treated ethically, by contractually requiring compliance with the Conventions of the *International Labor Organization Declaration on Fundamental*

Principles and Rights at Work.

- Minimize lifecycle environmental impacts of materials and production.
- Require consumers to return masks that have reached their end of life for safe recycling.

7.2 Engagement

To ensure effective masks are used effectively, the public must be educated to understand how infections are transmitted, how masks help reduce transmission, how to use and care for masks, and why other measures such as hand hygiene are important.

7.3 Widespread Use

EFMs must be produced locally at reasonable cost. If EFMs cost US$6, at 30 uses of four hours each the cost per hour of use would be US$0.05. The economic benefits of general mask usage during the COVID-19 pandemic were evaluated by Abaluck et al. (**2020**), who concluded: "*...the benefits of each additional cloth mask worn by the public are conservatively in the $3,000–6,000 range due to their impact in slowing the spread of the virus*." This cost-benefit ratio suggests governments should consider subsidizing the cost of masks for the public.

7.4 Continuous Improvement

Manufacturers can use quality assurance techniques to reduce the variability of cloth masks. Manufacturers can also use production methods not available to individuals and can undertake research and development work. For example:

- A thin layer of medical-grade silicone could be applied around a mask's edges to improve contact with the skin and reduce leakage.
- A hybrid design could be based on the elastomeric half-mask but designed to accept replaceable and reusable fiber filters.
- Fiber masks could include a hemispherical polymer sieve to hold materials away from the face. This would increase the area of material involved in filtering, which improves breathability and filtering effectiveness.
- Much harvested cotton is wasted because fibers are lower than desirable (Dashtbani & Afra, 2015). Could this material be used in cotton batting masks?
- Natural fibers can be functionalized to increase their surface energy and fibrillated to increase roughness and surface area. Would doing so improve their efficiency as nonwoven filters?
- Cotton used in air filters can be treated with antimicrobial agents to reduce the activity of microorganisms in bioaerosols (Ali, Pan, Tilly, Zia, & Wu, 2018; de Freitas Rosa, Aguiar, & Bernardo, 2017. Could treated fibers be safely used in face masks?

7.5 Cloth Mask Production in France

In early 2020 France used isolation to slow the transmission of COVID-19. As part of its program for ending confinement, on May 11, 2020, France mandated mask use on public transport, in high schools, and in some other public spaces (République Français **2020a**, **2020b**; Santé Publique France, **2020**). France gave the public information about transmission of COVID-19, the intended purpose of masks, and instructions for properly using cloth masks. In March 2020 France announced new categories of nonmedical cloth masks: "Masque alternatif à Usage Non Sanitaire Catégorie 1" (UNS-1) for people who work with the public, and UNS-2 for people who work together, for example in an office. "AFNOR Spec S76-001—Barrier Masks" defines performance requirements, and UNS-1 and UNS-2 masks must have filtering efficiencies for 3 μm particles over 90% and 70%, respectively (AFNOR, **2020**). Manufacturers submitted masks for testing by the French Direction Générale de L'armement. By June 16 2020, over 800 masks had been tested, and the average reported filtering efficiencies for 3 μm particles were 96% for UNS-1 masks and 82% for UNS-2 masks (Government of France, **2020**). In June 2020, UNS-1 masks were available in France at US$3.

One unanticipated outcome of the French program was that the public continued to buy disposable masks, which resulted in unsold stocks of cloth masks (Willsher, **2020**). This outcome can be avoided if EFMPs mandate that the public use only approved fiber masks.

8 CONCLUSIONS

Medical research and physics show social distancing is not a reliable barrier to aerosol respiratory droplets and their residual droplet nuclei. The question of whether COVID-19 is transmitted by aerosols as well as by droplets is less important if masks are used by the public, because masks reduce transmission of droplets from infected individuals to air and to surfaces, and also reduce inhalation of droplet nuclei by susceptible individuals. During the COVID-19 pandemic, however, some governments expressed concern that mandating general mask use would reduce the supply of respirators for healthcare workers. This is an unnecessary dilemma, as we have shown that effective fiber masks can be made by novices.

Individual countries or regions could implement EFMPs to encourage local manufacturers to use locally available resources to mass produce "EFMs" that meet high standards for filtering effectiveness, breathability, and durability. EFMPs could protect healthcare workers by safeguarding their supplies of respirators, reducing their risk of acquiring COVID-19 from their communities, and by reducing the number of patients they must treat. In the interval between the onset of a pandemic and its resolution, an EFMP could help societies find a viable balance between supporting the economy, protecting vulnerable groups, and reducing illness. Public policy must often be made despite a degree of uncertainty, especially when societies face novel challenges (Greenhalgh, Schmid, Czypionka, Bassler, & Gruer, **2020**). In the case of general mask use, available information suggests that EFMPs can improve the capacity of societies to face

pandemics.

9 SUGGESTIONS FOR FURTHER WORK

(1) Cloth masks could become "mobile air samplers." Volunteers willing to share their location data could send their masks at the end of each day for testing to identify virus RNA. Dynamic maps to show the movement of a virus through communities could be created from the location data and RNA test data. The relationship between positive mask RNA tests and negative COVID-19 tests of wearers could also indicate the protective effectiveness of masks in actual use.
(2) If a minimum infectious dose is required for a pathogen to cause illness, research could evaluate the ability of effective masks to reduce exposure below this threshold. Further, if higher initial doses cause more severe illness, research could determine if another benefit of effective masks could be less severe illnesses.
(3) Epidemiological studies have tried to determine if general mask use reduces transmission of droplet-borne or airborne illnesses. Future studies should characterize the actual effectiveness of masks in use as a key variable.
(4) Van Doremalen et al. (2020) found the SARS-CoV-2 virus lives longer on plastic than on cardboard. Research is needed to measure the viability of viruses on synthetic and natural fibers.
(5) It will be helpful to research some psychological aspects of wearing masks in public. For example:
    a Are people more likely to voluntarily wear a mask if they believe it can not only reduce the risk that they will infect others, but also the risk that others will infect them?
    b What are the pros and cons of mandating mask use? Do mandates help by removing social judgements regarding mask use? Alternatively, could enough people be persuaded to voluntarily wear masks that mandates become unnecessary?
    c While masks interfere with nonverbal communication and can somewhat muffle speech, effective masks may allow people who would otherwise be isolated to interact with others. Could effective masks support mental health during pandemics?
    d The COVID-19 pandemic left many people feeling helpless and depressed. Could wearing a mask give people a sense of empowerment in the face of pandemics?

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Supporting Information

REFERENCES

PHYSICS

Science offers recipes for homemade coronavirus masks

With a snug fit, some might filter almost as well as medical gear, studies suggest

Many people wear homemade masks to limit the spread of the novel coronavirus. How well those masks work depends on what they're made of, and how well they fit.

TI-JA/E+/GETTY IMAGES

By **Kathiann Kowalski**

May 14, 2020 at 6:30 am

More and more people are wearing homemade masks at supermarkets, hardware stores, workplaces and more. The goal is to slow the spread of the virus that causes COVID-19. Now two new studies provide data on which fabrics to use. Also important, they show: a snug fit.

To see why, it helps to understand how the virus travels through air. People infected with COVID-19 breathe out some of the virus particles in very small droplets of spit, snot or water vapor. Without something to stop them, the larger droplets will fall within a few feet. That's one reason why physical distancing between people matters. But the tiniest droplets, called aerosols, can remain aloft for a few hours before falling onto surfaces. That's also a reason for frequent handwashing, cleaning of surfaces and other sanitizing steps.

Explainer: What is a coronavirus?

Masks can help to limit the spread of aerosols. But medical-grade masks are in short supply. Hospitals and health practices need them most. Among the public, therefore, many people have begun making masks at home. It's been unclear, however, which materials might work best.

Aerosols can range from about 6 micrometers (or microns) down to 10 nanometers across, notes Supratik Guha. In comparison, the materials scientist explains, "a human hair is about 7,500 microns." (A micron is one millionth of a meter; a nanometer is one billionth of a meter.) Guha works at Argonne National Laboratory in Lemont, Ill., and at the nearby University of Chicago.

To see which fabrics worked best in blocking out aerosols, Guha and his colleagues performed tests. They set up a chamber to create aerosols of salt in the size range of the droplets that can carry the COVID-19 virus. A fan blew these aerosols toward tubes. A piece of fabric — sometimes layers of one or more types of fabric — covered the near end of each tube. The team then measured what share of the aerosols made it through the fabrics.

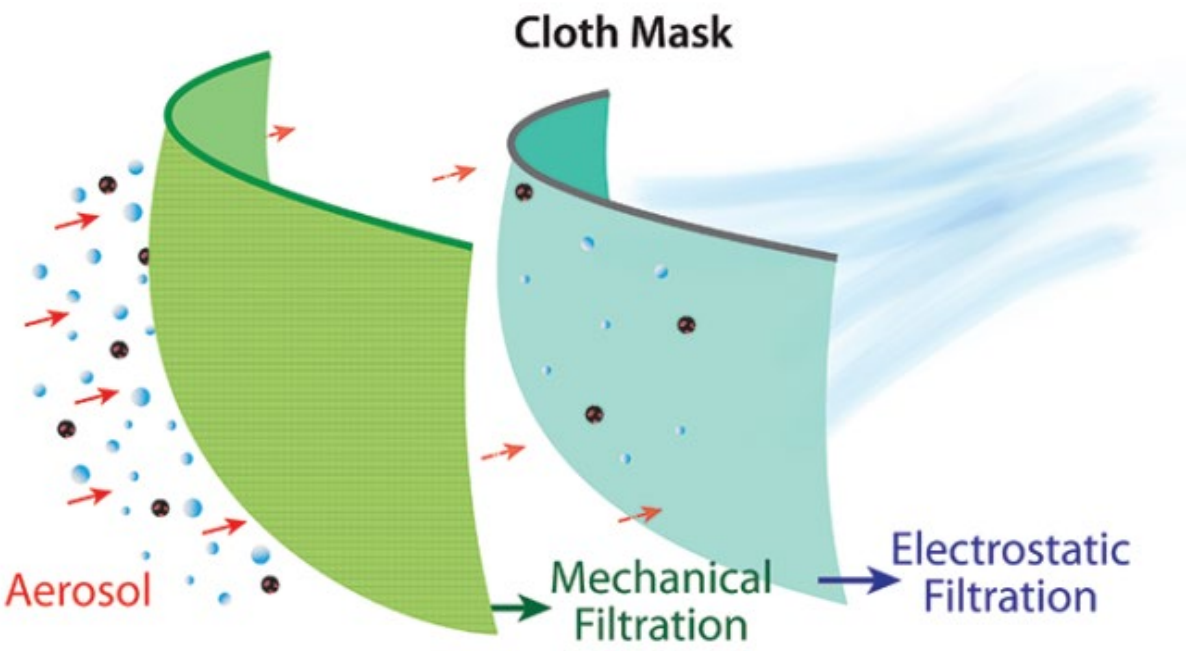
See all our coverage of the new coronovirus outbreak

Overall, a combination of fabrics worked best. And not just any fabrics. The top performers paired 600-thread-count cotton (meaning 600 threads were woven to make up each square inch of fabric) with two layers of either silk or chiffon. On average, each type stopped at least 90 percent of the particles.

What does this mean if you make your own mask? "Use tighter fabrics with tighter weaves," Guha says. A tighter weave has smaller holes for particles to sneak through. "Try to use combinations of materials," he adds, "They filter the particles in different ways."

For example, tightly woven cotton works as a mechanical filter. Like a sieve, it keeps airborne bits that are too big from going through the holes between its threads. Chiffon or silk can work a second way, too. The structure of the molecules that make up those fabrics lets them attract electrons or give them up, Guha explains. That lets them attract charged aerosols. This electrostatic property lets the threads and aerosols bind to each other.

But don't stress out if you don't have exactly the right type of high-count cotton, silk or chiffon. A sample from a cotton quilt with batting also worked very well in the tests as did four layers of silk. The important lesson, Guha found, is that "there are simple materials available that work very well." (And as the author of this story shows, making a mask out of them isn't too challenging.)



This drawing illustrates the two ways that some fabrics can filter out small aerosols, including those carrying viruses. Mechanical blockage by fabrics such as tightly woven cotton keeps big particles from moving through. The electrostatic control of silk and chiffon fibers can then trap certain charged aerosols for extra filtration.

A. KONDA *ET AL/ACS NANO* 2020

Fit matters

But even the best fabric will not perform well, Guha says, if the mask doesn't fit well. The goal is to limit leaks.

Any air that can leak through the sides, top or bottom of masks can carry virus-laden aerosols. To test the importance of such leaks, Guha's team drilled tiny holes at the side of the fabric mounts. These created gaps of maybe 1 percent of the fabrics' filtering area. Yet that small amount cut the filtering efficiency by at least 50 percent!

"What we did was not rocket science," Guha notes. None of what his team learned, he says, "was really surprising. But we wanted good, solid data." In other words, the team had a hypothesis. But until it was tested, the researchers couldn't know for sure how well it might hold up.

The team reported its findings April 24 in *ACS Nano*.

The team's work is an "excellent study that adds more to our understanding of cloth masks," says Raina MacIntyre. She heads research on biosecurity at the University of New South Wales in Sydney, Australia. "The results confirm firstly that fit is important," she says. "Even an N95 mask has vastly reduced efficiency if it does not fit." (Medical workers wear N95 masks in high-risk situations).

Environmental scientist Loretta Fernandez used a nylon stocking to get a snug fit for filtration tests that she and colleague Amy Mueller have conducted.

A. MUELLER AND L. FERNANDEZ, 2020

Loretta Fernandez and Amy Mueller are environmental scientists at Northeastern University in Boston, Mass. They don't usually study masks. But talk about masks during the current pandemic left them curious. So they used science to compare 10 types of homemade fabric masks to an N95 mask and to somewhat less protective surgical masks. Quips Fernandez, "We really just felt like we were working on a science fair project."

They, too, set up a particle generator to churn out particles of salt. But instead of testing the masks on a solid stand, one of the researchers wore each mask. Separate counters measured the concentration of particles outside a mask and inside it. The sewn masks filtered out anywhere from around 30 percent to 70 percent of the particles.

Then the team tested the role of a snug fit on a mask's performance. To do that, they used part of a ladies' stocking.

They cut across the leg of the stocking, creating a tube of stretchy nylon mesh. Then the researchers slid the tube over the head until it covered the mask being worn. This greatly improved the filtration of each mask.

A cotton mask with a cotton batting filter, for example, initially filtered out roughly 33 percent of the salt particles. After being held snugly in place with the nylon sleeve, it now kept more than 80 percent from moving through the mask. Fernandez and Mueller's findings appear on the medRxiv website. (Their study has not yet been peer reviewed.)

Other filtration issues

Water resistance is also key, MacIntyre says, yet neither of the new studies addresses it. Moisture from exhaled breaths or sweat on the inside will make a mask uncomfortable. A bigger issue: "Masks that get soggy or allow liquid through will not protect well," she notes, "no matter how well they filter [dry] air."

Some people insert filters made of various materials into homemade masks. Consider the safety of breathing in any particles from those filters, Fernandez advises. The fact that something is safe for one type of use — such as a fabric softener sheet or a vacuum cleaner bag — doesn't always mean it's safe to breathe through.

Also key: You need to be able to breathe easily through a mask. A fabric like silk can be "very breathable," Guha notes. It can be thin but still have a tight weave. And while some groups at high risk might try a stocking to get a tight fit, Fernandez says she just wears a mask on its own when she goes out. Otherwise, it can feel too tight and hot.

After all, she points out, a mask won't protect you or others unless you wear it.

The Centers for Disease Control and Prevention has begun recommending that people wear cloth face masks to cut down the spread of COVID-19. The American Chemical Society sent out a reporter to speak with experts about why — and how well homemade masks might help.

Power Words

More About Power Words

aerosol: A group of tiny particles suspended in air or gas. Aerosols can be natural, such as fog or gas from volcanic eruptions, or artificial, such as smoke from burning fossil fuels.

Argonne National Laboratory: A federal laboratory owned by the U.S. Department of Energy, outside of Chicago, Ill. It was formally created on July 1, 1946. Today, its roughly 1,400 scientists and engineers (and 1,000 students) conduct research across a broad range of fields, from biology and physics to materials science, energy development and climate studies.

average: (in science) A term for the arithmetic mean, which is the sum of a group of numbers that is then divided by the size of the group.

batting: (in textiles) A lofty material, usually nonwoven, such as the filling between quilt layers.

colleague: Someone who works with another; a co-worker or team member.

concentration: (in chemistry) A measurement of how much of one substance has been dissolved into another.

COVID-19: A name given the coronavirus that caused a massive outbreak of potentially lethal disease, beginning in December 2019. Symptoms included pneumonia, fever, headaches and trouble breathing.

electron: A negatively charged particle, usually found orbiting the outer regions of an atom; also, the carrier of electricity within solids.

electrostatic: Referring to a condition that exists around an area that has an imbalance of electrons compared to its surroundings. A positive electrostatic charge exists when one surface has fewer electrons than the surrounding area. A negative electrostatic field occurs when there are excess electrons.

fabric: Any flexible material that is woven, knitted or can be fused into a sheet by heat.

filter: (in chemistry and environmental science) A device or system that allows some materials to pass through but not others, based on their size or some other feature. (in physics) A screen, plate or layer of a substance that absorbs light or other radiation or selectively prevents the transmission of some of its components.

filtration: The process of using a fabric, screen or some other type of material — known as filters — to prevent something from moving through. Drapes can limit the filtration of sunlight into a room. A wire mesh can filter large particles from water or the air. Sand or soils can provide filtration to keep some waterborne chemicals or germs from reaching groundwater.

hypothesis: (v. hypothesize) A proposed explanation for a phenomenon. In science, a hypothesis is an idea that must be rigorously tested before it is accepted or rejected.

materials scientist: A researcher who studies how the atomic and molecular structure of a material is related to its overall properties. Materials scientists can design new materials or analyze existing ones. Their analyses of a material's overall properties (such as density, strength and melting point) can help engineers and other researchers select materials that are best suited to a new application.

matter: Something that occupies space and has mass. Anything on Earth with matter will have a property described as "weight."

mechanical: Having to do with the devices that move, including tools, engines and other machines (even, potentially, living machines); or something caused by the physical movement of another thing.

micrometer: (sometimes called a micron) One thousandth of a millimeter, or one millionth of a meter. It's also equivalent to a few one-hundred-thousandths of an inch.

moisture: Small amounts of water present in the air, as vapor. It can also be present as a liquid, such as water droplets condensed on the inside of a window, or dampness present in clothing or soil.

molecule: An electrically neutral group of atoms that represents the smallest possible amount of a chemical compound. Molecules can be made of single types of atoms or of different types. For example, the oxygen in the air is made of two oxygen atoms (O_2), but water is made of two hydrogen atoms and one oxygen atom (H_2O).

nano: A prefix indicating a billionth. In the metric system of measurements, it's often used as an abbreviation to refer to objects that are a billionth of a meter long or in diameter.

New South Wales: One of the Eastern states that make up Australia. Home to some 8 million people, it's the oldest, largest and most urban of those states. Located in the east-central and southeastern part of the nation, most of its residents live in or near the state capital of Sydney.

nylon: A silky material that is made from long, manufactured molecules called polymers. These are long chains of atoms linked together.

pandemic: An epidemic that affects a large proportion of the population across a country or the world.

particle: A minute amount of something.

peer review: (in science) A process in which scientists in a field carefully read and critique the work of their peers before it is published in a scientific journal. Peer review helps to prevent sloppy science and bad mistakes from being published.

physical: (adj.) A term for things that exist in the real world, as opposed to in memories or the imagination. It can also refer to properties of materials that are due to their size and non-chemical interactions (such as when one block slams with force into another).

range: The full extent or distribution of something. For instance, a plant or animal's range is the area over which it naturally exists.

resistance: (in physics) Something that keeps a physical material (such as a block of wood, flow of water or air) from moving freely, usually because it provides friction to impede its motion.

risk: The chance or mathematical likelihood that some bad thing might happen. For instance, exposure to radiation poses a risk of cancer. Or the hazard — or peril — itself. (For instance: *Among cancer risks that the people faced were radiation and drinking water tainted with arsenic*.)

salt: A compound made by combining an acid with a base (in a reaction that also creates water). The ocean contains many

different salts — collectively called “sea salt.” Common table salt is a made of sodium and chlorine.

solid: Firm and stable in shape; not liquid or gaseous.

stress: (in biology) A factor — such as unusual temperatures, movements, moisture or pollution — that affects the health of a species or ecosystem. (in psychology) A mental, physical, emotional or behavioral reaction to an event or circumstance (stressor) that disturbs a person or animal’s usual state of being or places increased demands on a person or animal; psychological stress can be either positive or negative. (in physics) Pressure or tension exerted on a material object.

virus: Tiny infectious particles consisting of RNA or DNA surrounded by protein. Viruses can reproduce only by injecting their genetic material into the cells of living creatures. Although scientists frequently refer to viruses as live or dead, in fact no virus is truly alive. It doesn’t eat like animals do, or make its own food the way plants do. It must hijack the cellular machinery of a living cell in order to survive.

CITATIONS

Journal: A. Konda et al. Aerosol filtration efficiency of common fabrics used in respiratory cloth masks. *ACS Nano*. April 24, 2020. doi: 10.1021/acsnano.0c03252.

Preprint: A. Mueller and L. Fernandez. Assessment of fabric masks as alternatives to standard surgical masks in terms of particle filtration efficiency. *medRxiv*. April 2020. doi: 10.1101/2020.04.17.20069567.

About Kathiann Kowalski

Kathiann Kowalski reports on all sorts of cutting-edge science. Previously, she practiced law with a large firm. Kathi enjoys hiking, sewing and reading. She also enjoys travel, especially family adventures and beach trips.

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NEWS

We had questions about Tennessee's free cloth masks, so Knox News had them tested

Vincent Gabrielle Knoxville News Sentinel

Published 10:36 a.m. ET May 18, 2020 | Updated 8:42 a.m. ET May 19, 2020

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Why 975 doses of COVID-19 vaccine may have been accidentally discarded in Knox County

Dr. Martha Buchanan explains why the Knox County Health Department can't account for 975 doses of COVID-19 vaccines.
Angela M. Gosnell, Knoxville News Sentinel

Tennessee took a lot of flak for the free masks it began distributing this month, with critics saying the sock-like material the masks are made of wouldn't be effective at stopping the spread of coronavirus.

Social media critics were bashing the masks on sight alone, though, so Knox News decided to put them to the test. We enlisted Northeastern University engineering professor Amy Mueller – she's running a cloth mask testing project.

The masks made by sock manufacturer Renfro Corp., it turns out, can be as effective as surgical masks in some cases.

Cloth mask manufactured by Renfro distributed free at the Knox County Health Department. *Saul Young/News Sentinel*

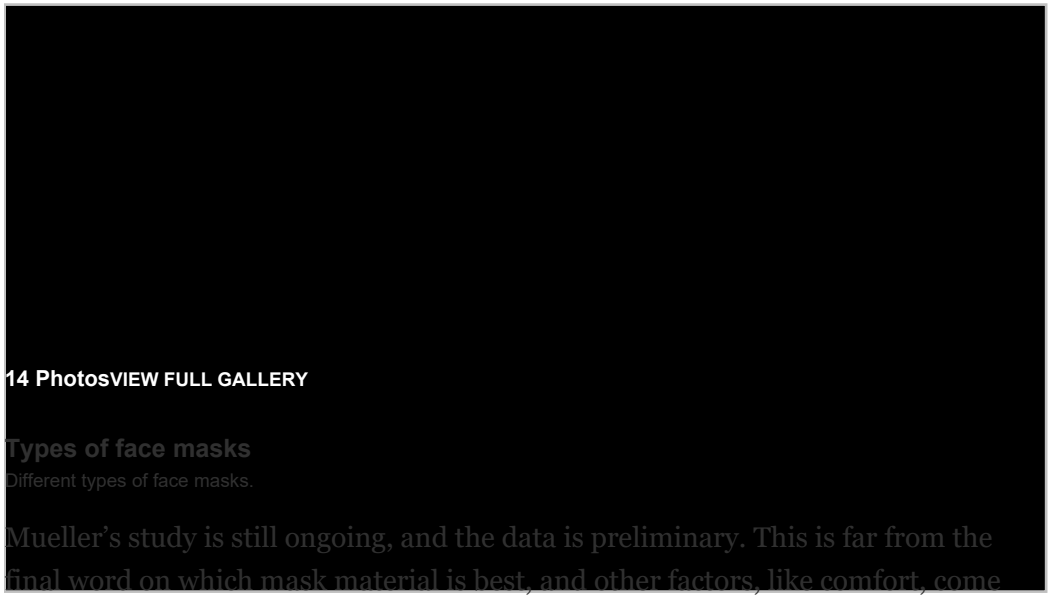
Mueller's study examines how well cloth masks filter out airborne particles and compares them to surgical masks and N95 respirators. According to Mueller's study, Tennessee's masks can effectively filter 57-63% of small, airborne particles, putting them in the same neighborhood as surgical masks, which tested at 53-75% effective. N95s masks were able to filter out 99% of test particles.

Other cloth masks varied widely in filtration effectiveness. They ranged from 47-90% effective. Tennessee's masks sit squarely in the middle of a big pack.

Mueller's team also tested whether tightening cloth masks would improve filtration. This is done by layering nylon stocking over the masks like a neck gaiter. Tennessee's masks did not improve when tightened which suggests they might have a good flexible fit. In comparison, surgical masks improved to 86-90% filtration when tightened with nylons.

A researcher demonstrates how they layer nylon over masks to increase fit. The nylons are worn like a neck gaiter over a cloth mask to pin them in place. *Loretta Fernandez, Northeastern University*

“Given that we saw this has a relatively good fit to the face, I would expect that filtration number for small particles at least to be in the same ballpark for inhalation or exhalation," wrote Dr. Amy Mueller in an email to Knox News, "However the exact efficiency as personal health protective equipment should be measured by a materials testing lab to confirm this.”



Mueller’s study is still ongoing, and the data is preliminary. This is far from the final word on which mask material is best, and other factors, like comfort, come into play. The masks distributed by the state are light and breathable and easily washed.

The tests were also conducted on new, out-of-the-package masks. Whether this material holds up after repeated use is still unknown (although in any case it’s best to wash your mask after use).

The state intends to purchase 5 million of the masks from Renfro. The North Carolina-based international sock distributor has a Cleveland, Tennessee, manufacturing and distribution plant.

Social distancing and minimizing exposure are still necessary even if everyone was wearing these masks or equivalent ones.

The science behind whether masks prevent the spread of COVID-19 is still unclear. Standards for how effectively cloth masks should catch droplets from the wearer's mouth have not been developed.

The Centers for Disease Control and Prevention recommends the public wear cloth masks to help prevent asymptomatic transmission in areas where social distancing might not be possible, like a grocery store aisle. This also reduces stress on the medical supply chain. It’s a precautionary measure.

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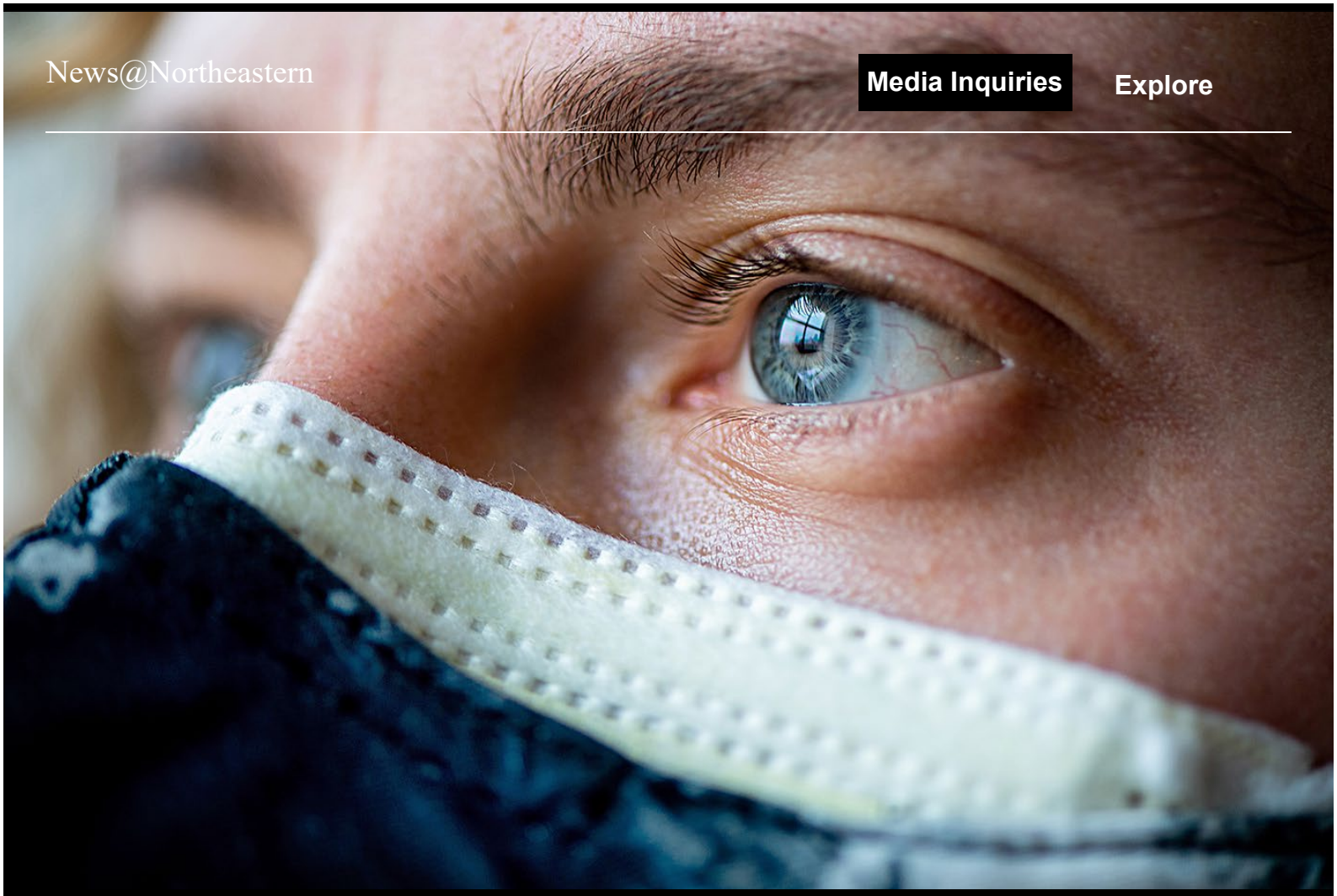


2 MASKS ARE BETTER THAN 1 TO PROTECT AGAINST NEW COVID-19 VARIANTS

Photo Matthew Modoono/Northeastern University

by Emily Arntsen - contributor January 29, 2021

As a **new, more contagious variant of the coronavirus** sweeps across the globe, so has a resurgence of interest in masks—which ones are safest, and how can people maximize protection with the resources they already have?

The **verdict is in**: Two masks are better than one.

Layering surgical masks under cloth masks can decrease the amount of viral particles that reach the nose and mouth compared to using either mask alone, according to **new research published in *Cell Press***. The surgical mask serves as the main filter, while the cloth mask improves the fit and adds a layer of filtration.

Left to right: Loretta Fernandez, assistant professor of civil and environmental engineering and Amy Mueller, assistant professor of civil and environmental engineering. Photos by Matthew Modoono/Northeastern University

But there are some caveats, says **Amy Mueller**, an assistant professor at Northeastern who conducted research with associate professor **Loretta Fernandez** this spring to **test which fabrics and styles** blocked the most air particles from reaching the mask wearer's face.

"Effectiveness is always a balance of these two factors: filtration efficiency and fit," she says. In other words, doubling up on masks will only increase protection so long as the masks are still fitted snugly to the face.

"If you double up masks, same as if you add more fabric layers to a mask, you will increase the pressure needed to pull and push air through the fabrics," she says. "This means you could end up pulling and pushing air around the edges of the mask if the fit is not sufficiently tight."

In their research, Mueller and Fernandez found that **adding a tight nylon layer on top of a mask** increased the percent of particles blocked from the nose and mouth—but not because the nylon was adding extra filtration. "It was just making the mask tighter," Fernandez says.

"If we started with a mask that was removing 50 percent of particles, adding a nylon layer to make the

mask fit more securely to the face brought that same mask up to 75 percent of particles removed," Fernandez said.

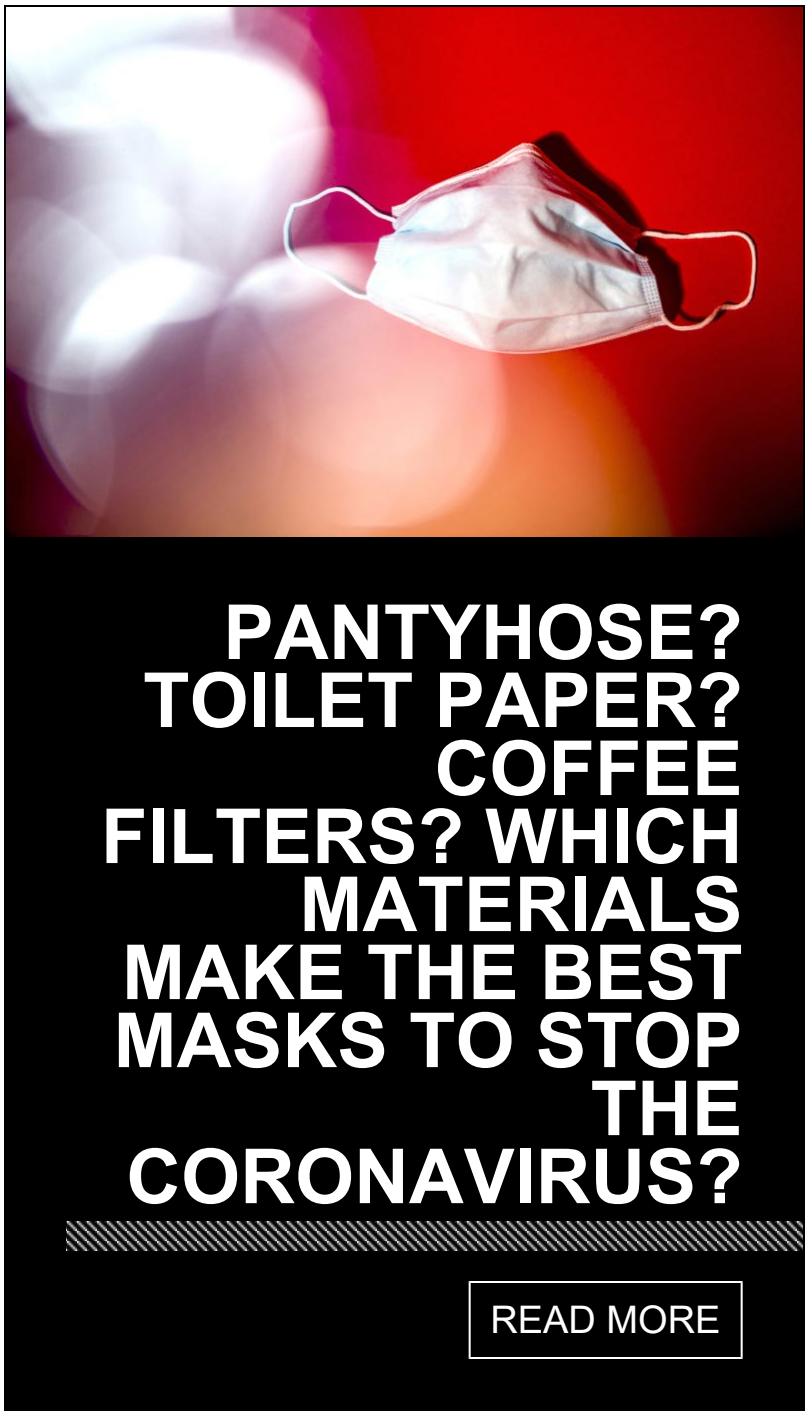
It seems a little counterintuitive that masks should be breathable, since the point of a mask is to stop the exchange of viral particles between people's sneezes, coughs, spit, *breath.* But if air can't penetrate through the mask, unfiltered air will enter and escape around the edges, defeating the purpose of the mask in the first place.

"If you're huffing and puffing and you can feel air coming across your cheeks and the bridge of your nose, the air you're breathing in and out isn't being filtered. It's just going around the mask," Fernandez says.

While a snug fit should be top priority in a mask, the type of material is also an important consideration—some fabrics are "stickier" than others when it comes to trapping the viral particles, Fernandez explains.

First of all, the viral particles are hardly ever floating around on their own, she says. "They're usually stuck to a dust particle or something like that."

When those particles interact with the fibers of the mask, one of three things can happen: The particle can slowly and eventually drift toward the fibers and get stuck, the particle can "run into" the fibers directly and fuse with them, or the particle can actually be drawn to the fibers through an electric charge.



"An electrostatic force attracts the particle to the fiber. That's how N95 masks work," she says. "Any material that can carry a charge, anything that can make your hair stand on end, will work better than materials that don't carry a charge."

For example, masks made of wool, which tends to have a positive electrical charge, will perform better than masks made of cotton, which tends to have a neutral electrical charge, Fernandez says.

Being able to trap the virus in fabric fibers is great. But what should people do once the particles are stuck after a day's use?

"People should definitely be changing their masks if they wear them for a long time," Fernandez says. "Eventually they become drenched with exhalation. And if you keep breathing through that soggy mask, you're going to be expelling water droplets through the fabric, and that's the exact thing we're trying to prevent."

As for washing and replacing masks, the Centers for Disease Control and Prevention recommends **washing cloth masks at least once per day** and throwing away disposable masks after one use.

***For media inquiries**, please contact Marirose Sartoretto at m.sartoretto@northeastern.edu or 617-373-5718.*

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