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Personal Protective Equipment (PPE)
Summary

Cloth masks are ineffective at preventing person-to-person transmission of viral respiratory disease. The United States must have stockpiles and production capacity of N95 filtering facepiece or similar respirators to ensure adequate supplies for the public and workers during future surges and pandemics.

Aerosols, Not Droplets

Early in the pandemic, the CDC stated that Covid spread person-to-person by droplets from coughs and sneezes propelled into the nose or mouth of someone nearby, although they admitted the possibility of inhalation as well. Droplets are large (> 5 µm) and fall to the ground within seconds or a few minutes. Aerosols are smaller, remain suspended in air for many minutes or hours, and are easily dispersed throughout a room. Despite numerous studies and substantial expert consensus, the CDC waited until late October 2020 —11 months into the pandemic —before finally acknowledging the possibility of airborne spread of SARS-CoV-2.33,34,35,36,37

Route of transmission has important implications for the efficacy of masks or respirators as a means of minimizing person-to-person spread of Covid. Only certified respirators can fulfill the three criteria of effective masks or respirators: high filter efficiency, low breathing resistance, and the potential for minimal leakage around the facepiece.

A simple comparison based on the CDC definition of close contact (less than 6 feet away from an infected person for a cumulative total of 15 min or more over a 24-hour period) shows that cloth and medical masks provide only minutes of additional protection. Only with a respirator will this time extend beyond an hour.40

In January 2022, two years into the pandemic, the CDC finally recommended that the public use high quality N95 filtering facepiece respirators (FFRs) or something similar but did not withdraw its advice about wearing cloth masks. Unfortunately, there are many important deficiencies — in study design and data analysis — that diminish the usefulness of most of the mask studies conducted during the pandemic, which may have led to delays in government action.41

N95 FFRs were in short supply throughout 2020 because most were manufactured offshore, and stockpiled respirators were inadequate to healthcare needs. Retooling by legacy manufacturers, entry of new manufacturers, use of different designs, and around-

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the-clock NIOSH testing eventually resolved the supply chain issues by early 2021.

In situations where interventions like ventilation fail to eliminate person-to-person transmission, respiratory protection can play an important role. In addition to protecting the wearer, a well-fitting respirator can prevent outward emission of infectious virus from the wearer. This is important for a virus that easily transmits pre- and asymptotically. Respirators cannot be the only intervention, however, because people must wear them correctly and continuously during all contacts (including at home), which is difficult to achieve. Respirators are the last line of defense and should be combined with source and pathway interventions like ventilation.

**The Fixes Needed**

When Covid transmission rates are high or suddenly surge, respiratory protection indoors will be necessary in many situations. Workers in higher-risk settings need access to reusable respirators, and all workers should have access to N95 FFRs. The public should have access to inexpensive or free N95 FFRs or similar respirators, and the government should prioritize distribution to low-income, minority, and rural communities that may have increased difficulties acquiring them and have been especially hard-hit by the pandemic. There should be a robust domestic respirator manufacturing industry to ensure sufficient supply for healthcare and other high-risk settings, with capacity to ramp up production during respiratory emergencies such as another pandemic or surge. In addition, there needs to be a testing and certification process for respirators for the public, including children. The federal government needs to ensure there are sufficient respirator supplies for workers and the public in the Strategic National Stockpile and should establish a national registry of approved respirators for the public. These recommendations are all supported by the National Academies’ 2022 Consensus Study Report.42

The January 25, 2022 discussion draft of the bipartisan PREVENT Pandemics Act recognizes these needs.43 Among other items, it authorizes the HHS Secretary to contract with private companies to enhance PPE surge capacity and supply chain flexibility, provides the FDA with additional enforcement authority to crack down on counterfeit PPE and other fake medical devices, and establishes a pilot program to fund states’ development of their own stockpiles.

**Aerosol Transmission**

The default assumption must be that transmission for all respiratory viruses occurs through small particle aerosol inhalation. Assuming droplet transmission as the default puts too many people at risk and does not reflect current knowledge of transmission by inhalation of human-generated aerosols.

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Public Areas
The federal government (CDC or another agency) should develop a public communication program to inform communities when transmission is elevated and individuals should wear well-fitting N95 FFRs or similar respirators when spending time in indoor locations with other people during shopping, entertainment, worship, dining, or similar activities.

The supply chain of respirator manufacturing must be considered a national and economic security priority.

Supply and Supply Chain Issues
The national stockpile should be replenished with elastomeric and powered air purifying respirators for healthcare workers, which must be deployed immediately as future surges or pandemics occur. A regular inspection and replacement process must be initiated to ensure the integrity of stockpiled respirators.

The national stockpile should also have adequate supplies of N95 FFRs for all essential workers as well as the public, to be deployed as needed during future surges or pandemics. FFRs must be regularly inspected and replaced well ahead of expiration, with regular deployment to states and FEMA for use during wildfire, flooding and similar emergencies.

The supply chain of respirator manufacturing must be considered a national and economic security priority. Where necessary, domestic manufacturing capacity for respirators must be assured. Enough respirators must be available to the public and easily purchased online and in department stores.

The Department of Health and Human Services or an appropriate federal agency must be directed to conduct a thorough assessment of domestic respirator manufacturing supply and needs for the immediate and long-term future.

Regulatory Oversight
The CDC/NIOSH National Personal Protective Technology Laboratory (NPPTL) has all of the necessary expertise for managing the oversight and approval of respirators in workplaces. Its mandate should be expanded to include the oversight and approval of respirators worn by the public, and additional resources should be provided to meet these new responsibilities. NPPTL should be provided the level of funding needed to ensure the ongoing development of up-to-date standards and testing methods for respirators and other PPE relevant to preventing transmission of viral respiratory pathogens.

Workplaces
A science-driven, objective, systematic, risk-based framework for selecting respirators for infectious respiratory pathogens is needed and should be incorporated into OSHA standards and guidance. Risk must be defined in terms of the nature of exposure, which should take into consideration a host of factors. These include: the number of contacts, length of exposure, nature of human respiratory activities (talking, singing and shouting generate more particles than silent breathing), ventilation quantity and quality, and room size. Distance from the infection source should not be considered an important feature of exposure nor a method for preventing transmission. Small infectious respiratory particles spread easily throughout an indoor space especially where ventilation is sub-optimal. While risk for serious health outcomes may be related to sex, age, co-morbidities and other demographic factors, these should not be the primary variables for determining workplace risk.

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Demography should only be used to adjust the level of risk after first determining the likelihood and degree of exposure. The level of respiratory protection must be matched with the level of risk. Respirators with higher assigned protection factors must be used for higher exposure jobs, workplaces, and work activities. Employers must be required to deploy source and pathway controls like ventilation before implementing respiratory protection since respirators cannot be the only method for preventing person-to-person infection from an aerosol-transmissible infectious respiratory disease.

Healthcare workers with direct patient care responsibilities should top the priority list for personal protective equipment. They must be provided reusable respirators such as elastomeric half-mask respirators for the remainder of the pandemic. These respirators must be fit-tested and workers trained as part of a comprehensive respiratory protection program complying with OSHA’s respiratory protection standard. Where the risks are elevated, workers should be provided more protective powered air purifying or similar respirators.

Next on the priority list are people who work in non-healthcare high-risk settings like emergency services, meat packing, poultry, food processing, corrections, grocers, and warehousing. These are followed by workers in moderate-risk settings such as restaurants, retail, and transportation. Both sets of workers should be provided respirators by employers and fit-tested in the context of comprehensive respiratory programs.

Workers in lower-risk jobs in which interactions with co-workers or the public are few and brief should be encouraged and permitted to wear N95 FFRs, preferably provided and paid for by their employer.

OSHA should update its Workplace Covid Guidelines to outline these updated requirements and recommendations for respirator use.

The CDC should update and strengthen the Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (Covid) Pandemic to require respiratory protection for all healthcare workers exposed to SARS-CoV-2 on the job, rather than only healthcare workers involved with the care of or who have direct contact with patients with confirmed or suspected Covid infection.

Most of the focus has been on filtering facepiece style respirators. Innovative designs of elastomeric respirators are available, many without exhalation valves. These should be made available to more workers and required in healthcare settings. NIOSH and OSHA should undertake the research and regulatory changes needed to encourage the development and deployment of reusable respirators for both source control and personal protection.

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PPE Strategic Goals

1. The CDC NIOSH National Personal Protective Technology Laboratory (NPPTL) should define, assess, and approve performance standards for respirators for public use.
   
   a. Fund NPPTL to expand its scope of operations as the primary assessor and approver of respirators for public use.
   b. Direct NPPTL to develop and implement a ratings and certification process for evaluating public-use respirators.
   c. Direct NPPTL to develop specifications and performance tests that evaluate respirators for outward and inward leakage.
   d. Direct NPPTL to develop specifications and performance tests that evaluate respirators for use by children.
   e. Direct NPPTL to develop and implement comfort assessments that will encourage use of respirators by the public.
   f. Launch a CDC-led public education program on how to select, fit, and use a N95 FFR or similar respirator, and provide ongoing guidance on recommended respirator use in indoor settings.
   g. Direct the FDA to recognize all NPPTL standards, testing, and approval processes for public-use respirators without requiring further testing or approval.
   h. Utilize the Defense Production Act to ramp up production if necessary.
   i. Direct NPPTL to develop simple, standardized respirator designs that can be quickly manufactured when supplies are low or supply chains are disrupted.
   j. Restock the Strategic National Stockpile with reusable and disposable respirators for distribution to employers and the public during future surges and re-evaluate and replace supply on a regular cadence.
   k. Establish and fund a national free or low-cost distribution program that prioritizes equitable respirator distribution, with a focus on low-income and minority Americans.
   l. Require, support, and incentivize hospitals and other healthcare facilities to stockpile reusable respirators for use in surge situations.

2. An appropriate federal agency should use regulatory and financial incentives to increase onshore production and equitable distribution of N95 FFRs or similar respirators.
   
   a. Use advanced purchasing agreements to incentivize long-term domestic production of affordable respirators and smooth demand.
   b. Promote respirator production at geographically dispersed domestic facilities to protect against supply chain disruptions and increase access.
   c. Diversify sources of respirator production to include SME respirator manufacturers, which can bolster product innovation and supply.
   d. Direct OSHA to update regulations to apply the respiratory protection standard to all moderate- and high-risk work environments.
   e. Require or recommend all employers to provide workers in healthcare, long-term care, correctional facilities, homeless shelters, and other settings with direct patient care or customer, co-worker, or visitor contacts with fit-tested, reusable N95-equivalent or more protective respirators.