

July 20, 2023

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329

Re: CDC/HICPAC's Plan to Weaken Guidance for Health Care Respiratory Protection and Infection Control

Dear Dr. Cohen:

We write to you as experts in occupational safety and health, medicine, epidemiology, industrial hygiene, ventilation, aerosol science, and public health, joined by members of the public, to congratulate you on your appointment as Director of the Centers for Disease Control and Prevention (CDC) and to bring to your attention current efforts of CDC that will weaken protection of health care personnel from infectious aerosols in health care settings.

The Healthcare Infection Control Practices Advisory Committee (HICPAC) to the CDC has initiated work to revise the CDC's *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, last updated in 2007. This foundational guidance directs infection control practices for a wide range of pathogens in health care settings in the United States and influences guidelines and practices around the world.

HICPAC has established a work group charged with reviewing the current Isolation Precautions guidance and making initial recommendations to HICPAC for consideration. The updates are intended to reflect the current scientific evidence and make existing guidance more "user friendly." HICPAC is expected to formally vote to recommend these proposals to CDC during its upcoming August 2023 meeting.

We are deeply concerned, based on work group presentations at the June 2023 HICPAC meeting, that the revised CDC/HICPAC guidelines will severely weaken protections for health care personnel exposed to infectious aerosols, including SARS-CoV-2. The draft recommendations fail to reflect what has been confirmed about aerosol transmission by inhalation during the COVID-19 pandemic. The draft recommendations do not adequately provide for the proper control measures – isolation, ventilation, and NIOSH-approved respirators – to protect against transmission of infectious aerosols. They are weaker than existing CDC infection control guidelines. The draft recommendations, if adopted, will put health care personnel and patients at serious risk of harm from exposure to infectious aerosols.

Outlined below, and in greater detail in the attached background document, are specific deficiencies and problems with the review and draft recommendations:

What's Wrong With CDC/HICPAC's Draft Proposed Guidelines and Recommendations?

1. The draft proposal has been developed without input from many important stakeholders, including frontline personnel and unions, patient safety advocates, and other experts and scientists.
2. CDC/HICPAC's process is non-transparent and essentially closed to public access or engagement. HICPAC meeting presentations and documents used to make recommendations to the CDC are not posted publicly, in contrast to other CDC advisory committees. Given the broad public interest in CDC's guidance to protect health care personnel, patients, and the public from infectious diseases, it is particularly concerning that CDC/HICPAC's process is so closed.
3. There are significant errors in the new draft recommended categories of "air" and "touch" as modes of transmission for health care-related infections. While CDC/HICPAC proposes the new category of "air" transmission, they continue to recommend use of surgical/medical masks, which do not provide respiratory protection against infectious aerosols. Thus, CDC/HICPAC proposals update terminology but not personal protective equipment (PPE) recommendations and ultimately move backwards in protections for health care personnel.
4. CDC/HICPAC's proposed flexible approach to implementing precautions is likely to cause harm to health care personnel. A protective approach should include assessments that evaluate the level of exposure, select appropriate control measures and PPE for each job, task, and location, and result in a written exposure control plan using the hierarchy of controls.
5. CDC/HICPAC inexplicably fails to acknowledge the importance and function of core control measures for infectious aerosols. The large body of evidence on the effectiveness of respirators and the importance of ventilation for controlling worker exposure to infectious aerosols have not been considered, and the proposed use of airborne infection isolation rooms (AIIRs) is significantly limited. Source control (limiting outward emission of infectious aerosols) is not adequately considered in the context of personal protection from inhalation.

What CDC and HICPAC Must Do Immediately

We urge CDC, HICPAC, and the work group to take the following immediate actions to correct their review and decision-making processes and recommendations:

1. **Seek input on proposed changes during the development of the draft guidelines from the public and all key stakeholders, including:**
 - a. Health care personnel and their representatives
 - b. Industrial hygienists, occupational health nurses, and safety professionals
 - c. Engineers, including those with expertise in ventilation design and operation
 - d. Research scientists, including those with expertise in aerosols and respiratory protection
 - e. Experts in respiratory protection, including scientists from NIOSH's National Personal Protective Technology Laboratory (NPPTL) and the Occupational Safety and Health Administration (OSHA).
2. **Make the process for updating the guidelines fully open and transparent:**
 - a. Open work group meetings to the public.

- b. Post work group reports, all presentations to the workgroup and committee, and transcripts/recordings of the HICPAC meetings on the CDC/HICPAC website in a timely fashion.
- c. As the recommendations are being developed and *before* finalization and voting by HICPAC, create a public docket on the development of the guidelines that includes this information, the draft guidelines, all scientific evidence used in the development of the guidelines and all written comments from the public. HICPAC is chartered under the Federal Advisory Committee Act (FACA) and should operate with openness and full transparency.

3. Improve the CDC’s and HICPAC’s understanding and assessment of key scientific evidence by seeking input from scientific researchers and key stakeholders, including health care personnel and their unions, and by making those written reviews publicly available:

- a. Fully recognize aerosol/inhalation transmission of SARS-CoV-2 and other infectious aerosols and describe in detail the proposed “air” transmission category.
- b. Ensure that updated guidance includes the use of multiple control measures that have been shown to effectively prevent transmission of infectious aerosols, including ventilation, isolation, respiratory protection, and other PPE.
- c. Maintain and strengthen respiratory protection and other PPE as critical methods for preventing health care personnel inhalation of infectious aerosols.

4. Maintain an approach in any updated infection control guidance that is clear and explicit on the precautions that are needed in situations where infectious pathogens are or may be present in health care settings.

Do not use an approach that recommends only minimal protections for health care personnel and allows health care employers undefined broad discretion in creating and implementing their infection control and prevention plans. Such an approach was adopted by the CDC during the COVID-19 pandemic and enabled health care employers to provide inadequate protection based on cost considerations, instead of basing protections for health care personnel and patients on exposure assessments.

The COVID-19 pandemic has taken a massive toll on health care personnel – millions have been infected, thousands have died and tens of thousands are suffering the disabling impacts of Long Covid. Under your leadership, we urge CDC and HICPAC to change course and develop updated guidelines and recommendations, in consultation with key stakeholders, based on the full body of the scientific evidence and experience confirmed during the COVID-19 pandemic that will fully protect health care personnel against infectious aerosols.

We appreciate your attention to this pressing matter and look forward to working with you and CDC to protect the health of workers and the public.

Sincerely,

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Attachment: Background: CDC/HICPAC's Draft Isolation Precautions Guidelines Weaken Protections for Health Care Personnel

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Background

CDC/HICPAC's Draft Isolation Precautions Guidelines Weaken Protections for Health Care Personnel

The [Healthcare Infection Control Practices Advisory Committee](#) (HICPAC) is a federal advisory committee appointed to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) on infection control practices in healthcare settings. The committee is comprised primarily of infectious disease doctors and infection control professionals from hospitals and large university-based medical centers. In 2021, HICPAC initiated work to revise the CDC's *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, last updated in 2007. This foundational guidance directs infection control practices for a wide range of pathogens in health care settings in the United States and influences guidelines and practices around the world.

HICPAC has established a work group charged with reviewing the current Isolation Precautions guidance and making initial recommendations to HICPAC for consideration. The work group includes some HICPAC members, HICPAC liaisons, and outside infectious disease doctors and infection control professionals. The updates are intended to reflect the current scientific evidence and make existing guidance more "user friendly." HICPAC is expected to formally vote to recommend these proposals to CDC during its upcoming August 2023 meeting.

Work group presentations at the June 2023 HICPAC meeting indicate that proposed updates are weaker than existing CDC infection control guidelines. The draft review fails to reflect what we have learned about aerosol transmission during the COVID-19 pandemic. The draft recommendations do not provide for the proper control measures – including isolation, ventilation, and National Institute of Occupational Safety and Health (NIOSH)-approved respirators—to protect against transmission of infectious aerosols. The proposed recommendations for updated CDC/HICPAC guidelines will severely weaken protections for health care personnel exposed to infectious aerosols.

Key Deficiencies and Problems with the CDC/HICPAC Review and Draft Recommendations.

- 1. CDC/HICPAC's review and drafting process has so far failed to include the expertise of important stakeholders, including:**
 - Frontline health care personnel and unions
 - Patient safety advocates
 - Occupational safety and health professionals, including industrial hygienists, safety professionals, and occupational health nurses,
 - Engineers, including those with expertise in ventilation design and operation
 - Research scientists, including those with expertise in aerosols and respiratory protection
 - Representatives from the NIOSH National Personal Protective Technology Laboratory (NPPTL) and the Occupational Safety and Health Administration (OSHA).

As a result of knowledge gained during the COVID-19 pandemic, it is now more widely recognized that many pathogens, including SARS-CoV-2 are transmitted by infectious aerosols, and that ventilation,

isolation practices, and respiratory protection are necessary control measures to limit exposure and transmission. Aerosol scientists, industrial hygienists, ventilation engineers, and respiratory protection experts are professionals with valuable expertise on transmission and control of infectious aerosols who should be fully included in the revision of the guidelines.

But there is currently no mechanism for HICPAC members to garner input from these experts or health care personnel, their unions, patients, and community members regarding the updates to guidance before they are finalized. Input from these groups is essential to creating effective guidance because they have insights regarding content, implementation, and language that will be key to the guidance being effectively adopted after publication. The Liaisons to CDC/HICPAC, some of whom are members of the work group, primarily represent health care associations and health care employers.

2. CDC/HICPAC’s process is non-transparent and essentially closed to public access or engagement.

- There has been no opportunity for input to the work group other than a few minutes for public comment at full HICPAC meetings. Work group meetings are closed to the public.
- No information/presentations from the work group or full HICPAC committee meetings are posted on the CDC website or made publicly available through a docket on regulations.gov.
- Meeting minutes are posted to the CDC’s website often after a long delay and meeting recordings are not posted at all. This is in stark contrast to the practices of other CDC Federal Advisory Committee Act (FACA) committees such as the CDC’s [Advisory Committee on Immunization Practices](#) (ACIP) which provides detailed information on the committee’s meetings and activities, including copies of all meeting presentations and videos of committee meetings on the CDC website.

3. There are significant errors in the newly recommended categories of “air” and “touch” as the sole modes of transmission for health care-related infections.

CDC/HICPAC proposes two new categories of transmission—through the air and by touch—to replace the existing contact/droplet/airborne terminology used in the current guidelines. However, CDC/HICPAC has failed to consider the overriding scientific and epidemiologic evidence in support of transmission of pathogens by inhalation of human-generated infectious aerosols in shared spaces, irrespective of distance from the source, including COVID-19.

- The proposals represent a change in terminology, but there are no corresponding changes in recommended protections or personal protective equipment (PPE) practice. The draft recommendations merge and eliminate the current droplet and airborne categories to create one new category, “air.” However, draft proposals indicate that HICPAC/CDC remains focused on short (i.e., droplet transmission) vs. long distance transmission (i.e., airborne transmission) and fails to acknowledge research on respiratory emissions and aerosol dynamics.
- The proposed definition of “air” transmission focuses solely on distance, fails to recognize inhalation as a key route of pathogen entry into the human body and ignores the basic premise that exposure (and thus dose) is a function of particle concentration in the air and time spent in contact with (inhaling) that concentration.

- Many pathogens are transmitted from one person to another by the inhalation of infectious aerosols generated when the infected source person breathes, talks, sings, coughs, sneezes, vomits, or other aerosolizing events occur.
- Most of these particles are relatively small (near 1 micron) and can remain suspended in air for long periods of time (many minutes to hours). With time these particles will disperse throughout an indoor space and may be transported by air currents far from a source. Particle concentrations may be highest near the source but will eventually increase throughout a shared space if ventilation is not adequate, putting everyone in that space at risk of inhaling an infectious dose.
- An infectious dose can result from a short time inhaling a high concentration of particles (as during an aerosol generating procedure) or from a long time inhaling a low concentration of particles (as occurs when entering or remaining in a space with infectious aerosols from one or more sources).
- The National Academies of Science, Engineering, and Medicine’s (NASEM) 2020 [workshop on Airborne Transmission of SARS-CoV-2](#) provides a good overview of this science with references.
- CDC/HICPAC fails to adequately understand and incorporate scientific evidence on aerosol transmission and what has been learned about transmission of pathogens via inhalation of infectious aerosols during the past nearly two decades, including the SARS-CoV-2 pandemic. There is clear evidence of infectious aerosol transmission by inhalation for many pathogens, including influenza, RSV, rhinovirus, norovirus, and meningococcal disease.ⁱ
- CDC/HICPAC’s update of transmission modes for infectious diseases contradicts the 2021 CDC Science Brief regarding the transmission of SARS-CoV-2.ⁱⁱ

4. CDC/HICPAC’s proposed “flexible” approach to implementing precautions is likely to cause harm to health care personnel. A protective approach should include assessments that evaluate the level of exposure, select appropriate control measures and PPE for each job, task, and location, and result in a written exposure control plan using the hierarchy of control measures.

Instead of clear and explicit recommendations for precautions that are needed when dealing with specific pathogens, discussions at past meetings have indicated that HICPAC and CDC want the updated guidance to provide a minimal “basement” upon which individual health care employers should build their infection control programs based on individual risk assessments regarding patient population, staff, and facilities. The issues with this approach include:

- The draft “basement” recommendations presented by the work group are inadequate levels of protection.
- Health care personnel with underlying conditions can be at high risk of severe infection, and we can’t assume that health care personnel are generally healthy and leave it up to employers to decide the level of protection needed.
- Distinguishing between pandemic-phase and seasonal categorization for recommendations for the same pathogen has no basis in scientific research or practice since transmission modes are the same in either circumstance. Currently, the CDC/HICPAC draft proposes

selecting an N95 respirator only for “pandemic-phase” viruses that are known to spread via infectious aerosols (such as influenza and coronaviruses) and a surgical mask for the same viruses in the “seasonal phase.”

- Staffing considerations should not be used to determine the level of occupational protections provided to health care personnel.
- This type of crisis-standards approach was adopted by the CDC during the COVID-19 pandemic and enabled health care employers to provide inadequate protection based on cost considerations, instead of basing protections for health care personnel and patients on exposure assessments, leading to an untold number of infections among health care personnel and patients.

Surgical masks cannot be recommended to protect health care personnel against inhalation of infectious aerosols, but CDC/HICPAC draft proposals continue to recommend surgical masks for protection of health care personnel from infectious aerosols.

- CDC has already explicitly recognized that surgical masks do not protect against inhalation of aerosols and that respirators are necessary to protect health care personnel exposed to suspected/confirmed COVID patients.ⁱⁱⁱ
- The exposure level (concentration of pathogens in the air) plays a key role in determining the correct type of respiratory protection. Higher exposure levels require higher levels of protection. A half-facepiece respirator (such as an N95 filtering facepiece respirator) offers the minimum level of protection against inhalation exposure, decreasing the inhaled particle concentration by 10 times. For higher exposure levels, such as when performing aerosol-generating procedures, or longer exposure times, a respirator with a higher protection level (e.g., powered air purifying respirator or PAPR) is recommended. Although we lack exposure limits for most infectious organisms, a qualitative risk assessment (such as control banding) can be used to determine the most appropriate level of respiratory protection for any given task, job or exposure scenario. CDC/HICPAC’s proposals provide no consideration for these issues.

5. CDC/HICPAC inexplicably fails to acknowledge the importance and function of core control measures for infectious aerosols. The vast body of evidence on the effectiveness of respirators and the importance of ventilation for controlling worker exposure to infectious aerosols has not been considered, and the proposed use of airborne infection isolation rooms (AIIRs) is significantly limited. Source control (limiting outward emission of infectious aerosols) is not adequately considered in the context of personal protection from inhalation.

CDC/HICPAC’s proposed recommendations fail to follow the well-established [hierarchy of controls](#) for limiting exposures to hazardous agents. The hierarchy prioritizes control measures that eliminate the hazard at its source, followed by engineering controls, including ventilation. PPE is at the bottom of the hierarchy to be used when other feasible controls are not sufficient to protect workers against exposure, such as when health care personnel are in the near field.

For pathogens that can be transmitted by infectious aerosols, the primary interventions that should be used in health care settings include:

- Isolation and source control
- Ventilation
- Respiratory protection and other PPE

CDC has long recognized the need for these control measures for pathogens that can be spread by infectious aerosols. The existing 2007 CDC *Guidelines for Isolation Precautions* recommend these precautions.^{iv} Similarly, these control measures have been recommended by CDC since March 2020 in its guidelines for Infection Control and Prevention for Healthcare Personnel for COVID-19 and in earlier infection control guidelines for SARS, H1N1, and MERS.^{v,vi,vii,viii}

A. *CDC/HICPAC Proposals Inadequately Address Isolation and Source Control*

Plans to isolate infectious and potentially infectious patients and implement source control are essential to controlling transmission of infectious diseases in health care facilities, but it is unclear how CDC/HICPAC is going to effectively address these measures in updated guidance. Updating recommendations on source control is essential, as many pathogens that can be spread via infectious aerosols are capable of eliciting infection without symptoms, resulting in asymptomatic or pre-symptomatic transmission to others in a shared space. Effective source control includes multiple measures, such as patient placement, including in AIIRs, and masking policies, as well as procedures for exposure monitoring, post-exposure quarantine and paid sick leave policies that enable infected staff to stay home without penalty.

- CDC/HICPAC is proposing to limit the use of airborne infection isolation rooms (AIIRs) in updated guidance. Specifically, CDC/HICPAC proposes to no longer use AIIRs for novel pathogens. AIIRs are the most effective engineering control to achieve isolation of patients with confirmed or suspected aerosol-transmitted diseases. AIIRs have negative pressure relative to other parts of the health care facility and room air is exhausted directly outdoors or through HEPA filters. AIIRs can be used to prevent the spread of infectious aerosols from patients with an aerosol-transmitted infection or with a novel pathogen whose transmission modes are unknown and limit the need for health care personnel to use respiratory protection when they are not in the AIIR.
- Where AIIRs are not available, establishing designated isolation units and cohorting patients with the same infectious disease are additional isolation measures that can be used. The lack of isolation measures likely contributed to widespread COVID-19 outbreaks in congregate settings such as nursing homes and prisons.^{ix} It is not clear how, if at all, CDC/HICPAC will address these issues in updated guidance.
- Screening and surveillance for infectious diseases is important to identify patients with infections or who are potentially infected. It is not clear how, if at all, CDC/HICPAC will address these issues in updated guidance.

Presentations and discussions at HICPAC meetings indicate that work group and committee members and CDC staff consider source control measures, such as surgical masks and barrier face coverings, as equivalent to respiratory protection, which they are not, and desire and may be planning to incorporate Workplace Performance and Workplace Performance Plus masks (ASTM F3502-21) into updated infection control guidance for health care settings.

- Workplace Performance and Performance Plus masks are new categories designated by NIOSH that must conform to the criteria in the ASTM F3502-21 consensus standard,^x which was primarily crafted to help the public evaluate face masks available for purchase during initial COVID-19 surges. NIOSH is [clear](#) that these new mask categories are NOT respiratory protection and has not certified, approved or recommended their use in place of NIOSH-approved respirators in health care settings.
- Facemasks (surgical, procedure, medical and similar masks) and barrier face coverings (such as those described in ASTM F3502) provide some measure of source control but do not protect the wearer from inhalation of infectious aerosols. Only respirators, such as those certified by NIOSH, are capable of providing such protection. To provide the intended level of protection, respirators must be worn in the context of a respiratory protection program (RPP), which includes respirator selection guided by an assessment of exposure and risk, medical clearance, fit testing, training, maintenance, and storage, as required by OSHA’s Respiratory Protection Program Standard (29 CFR §1910.134).
- Surgical and certain medical masks are intended as protection from splashes and sprays only, not against the inhalation of infectious aerosols.
- If CDC/HICPAC do adopt Workplace Performance/Performance Plus masks into health care settings, then they will be ignoring clear recommendations from experts. In 2022, NASEM concluded that: “Based on its review of the literature on the performance of respiratory protective devices, the committee believes the filtration and fit characteristics of face coverings and masks currently do not adequately protect workers facing inhalation hazards. **Therefore, in the context of workplace exposures to inhalation hazards, recommendations regarding the use of face coverings (including barrier face coverings) and masks should be avoided, and employers should be advised to institute an RPP and provide employees with respirators as described by OSHA’s Respiratory Protection Standard (1910.134).**” (emphasis added). The report formally recommended that agencies that develop guidelines, such as CDC, recommend only NIOSH-approved respirators in their guidance for protecting workers facing inhalation hazards.^{xi}

B. CDC/HICPAC Proposals Inadequately Address Ventilation

Ventilation is an important core intervention in all occupied spaces, and the current CDC Isolation Protection Guidelines include specific recommendations for ventilation to control airborne pathogens. But the work group has not reported what its plans are, if any, to address ventilation in updated guidance.

- Dilution or general ventilation from a building heating and ventilation system can reduce particle concentrations by providing an adequate volume of air and filtration to mix, dilute and remove particles.
- Local exhaust ventilation can be very effective at removing particles from stationary sources (e.g., patients) and usually requires less air and energy than dilution ventilation.
- Directional airflow (i.e., negative pressure) can limit spread of infectious aerosols to other areas, such as hallways, other patient rooms, and nurses’ stations.
- Portable air cleaners equipped with high efficiency filters can provide both dilution and local exhaust ventilation, if properly sized for the space.

- Ultraviolet germicidal irradiation may be effective in some types of spaces but requires careful design to ensure particles experience an adequate residence or contact time.

C. CDC/HICPAC Proposals Fail to Appropriately Recommend Respiratory Protection and Other PPE

NIOSH-approved respirators are recommended by NIOSH and required by OSHA’s Respiratory Protection Standard (29 CFR 1910.134) to protect employees from exposure to inhalation hazards, including infectious aerosols. CDC has recognized that aerosol transmission is a major route of exposure for SARS-CoV-2 and several other infectious pathogens. But the draft proposals fail to recommend the use of respiratory protection for health care personnel exposed to some infectious aerosols under some exposure conditions and fail to include recommendations for more protective respirators for higher risk situations.

The current draft proposes three categories of Transmission-Based Precautions to Prevent Transmission by Air: Routine Air Precautions, Novel Air Precautions and Extended Air Precautions and recommends control measures for each category.

- Routine Air Precautions are recommended for seasonal agents such as seasonal coronaviruses, seasonal influenza, and other agents not in pandemic-phase or specifically listed under Extended Air Precautions. Medical/Surgical masks, not NIOSH-approved respirators, are recommended for these agents, even those spread via inhalation of infectious aerosols, regardless of exposure conditions.
- Novel Air Precautions are designated for pandemic-phase respiratory viruses (such as influenza, SARS-CoV-2) and specific viruses like MERS and SARS-CoV-1; N95 respirators are recommended for this category.
- Extended Air Precautions, which include the use of N95 respirators and AIIRs, are recommended for tuberculosis, measles and varicella.

Under these draft recommendations, surgical masks, not NIOSH-approved respirators, would be the default for health care personnel caring for all patients with seasonal viruses, including those with suspected or confirmed SARS-CoV-2, once the virus is deemed a “seasonal respiratory virus” and is no longer considered a “novel pathogen.” This would severely weaken protections provided under current CDC guidelines. As noted earlier, there is no scientific basis for distinguishing between pandemic-phase and seasonal categorization for recommendations for control of infectious aerosols for the same pathogen since transmission modes are the same in either circumstance.

CDC/HICPAC has failed to include any discussion of or recommendations for the utilization of more protective respirators such as Elastomeric Half-Mask Respirators (EHMRs) and Powered Air Purifying Respirators (PAPRs), despite evidence and experience demonstrating the effectiveness of these devices in protecting health care personnel from infectious aerosols.^{xiii} As noted above, there is also no discussion of selecting respirators with higher associated protection factors when health care personnel are at higher risk, such as when performing procedures known to generate higher aerosols in higher concentrations.

CDC/HICPAC conducted an evidence review of the effectiveness of N95 respirators vs. surgical masks in developing their draft recommendations. The review prioritized the findings of randomized controlled

trials (RCTs) to conclude no difference between N95s and surgical masks, omitting other applicable data and studies. Issues with the CDC/HICPAC's evidence review include:

- CDC/HICPAC left out an important RCT conducted by Dr. Raina MacIntyre with no explanation.^{xiii} This RCT found clearly that continuous N95 respirator use significantly reduced the risk of respiratory virus transmission to health care personnel, while intermittent N95 use and surgical masks did not.
- CDC/HICPAC cherry picked data from RCTs that were included in their review. For example, in the Loeb 2009 study,^{xiv} the CDC only included the endpoint of lab-confirmed viral respiratory infections and failed to take into account that the study found that N95 use protected health care personnel from influenza-like illness.
- Studies they did include have significant flaws. Reviewed studies did not look at full-time wear and didn't observe whether health care personnel were actually wearing the respirators and using them correctly, including whether N95s were repeatedly redonned (which undermines protection) and whether the respirators were fit-tested. Studies did not include a control group (i.e., subjects wearing no mask or respirator).
- CDC/HICPAC failed to look at evidence from laboratory studies and studies in non-health care workplaces that evaluate the effectiveness of N95s to protect against inhalation exposure. There is nothing different or special about the hazardous aerosols encountered in health care settings. Respirators will collect infectious aerosols and protect the wearer in the same manner in all workplaces. For example:
 - CDC's own NIOSH has a respirator certification system that is based on sound science and research ([National Personal Protective Technology Laboratory/NPPTL](#)).
 - NASEM has published multiple reviews of the effectiveness of respiratory protection to protect workers from harmful aerosols, including for health care personnel from infectious aerosols.^{xv,xvi,xvii}

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ⁱ For example, see Table 1 in Wang, CC, KA Prather, et al., "Airborne transmission of respiratory viruses," *Science*, Aug 27, 2021, <https://www.science.org/doi/10.1126/science.abd9149>.

ⁱⁱ In May 2021, CDC finally recognized that aerosol transmission of SARS-CoV-2 was a major route of exposure to the virus, issuing a scientific brief that found: "The principal mode by which people are infected with SARS-CoV-2 (the virus that causes COVID-19) is through exposure to respiratory fluids carrying infectious virus. Exposure occurs in three principal ways: (1) inhalation of very fine respiratory droplets and aerosol particles, (2) deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays, and (3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them."

See: <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html>.

ⁱⁱⁱ CDC, Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic, Why does CDC continue to recommend respiratory protection with a NIOSH-approved particulate respirator with N95 filters or higher for care of patients with known or

suspected COVID-19?, May 8, 2023, Available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html#Infection-Control-FAQ>.

^{iv} See Sections v.D.1, V.d.2.a.i and V.D4.a.i. of the guidelines at <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>.

^v <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

^{vi} <https://www.cdc.gov/sars/guidance/i-infection/downloads/i-infection-full.pdf>

^{vii} https://www.cdc.gov/h1n1flu/guidelines_infection_control.htm

^{viii} <https://www.cdc.gov/coronavirus/mers/infection-prevention-control.html>

^{ix} Chin, ET, T Ryckman, et al., “COVID-19 in the California State Prison System: an Observational Study of Decarceration, Ongoing Risks, and Risk Factors,” *J General Internal Med*, 2021, 36: 3096-3102, <https://doi.org/10.1007/s11606-021-07022-x>.

^x The ASTM F3502-21 consensus standard has two primary metrics that masks must meet: they must be designed to cover the wearer’s nose and mouth and to fit snugly and they must meet minimum filtration levels (50 percent or 80 percent) and leakage testing on a limited population sample. For more info: <https://www.cdc.gov/niosh/topics/emres/pandemic/default.html>. Notably, there are no fit-testing requirements or recommendations.

^{xi} Recommendation 6-5 in National Academies of Sciences, Engineering, and Medicine. 2022. Frameworks for Protecting Workers and the Public from Inhalation Hazards. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26372>.

^{xii} National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Use of Elastomeric Respirators in Health Care Catharyn T. Liverman, Olivia C. Yost, Bonnie M. E. Rogers, Linda Hawes Clever , editors. “Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use.” Washington (DC): National Academies Press (US); 2018 Dec 6, Available at <https://nap.nationalacademies.org/catalog/25275/reusable-elastomeric-respirators-in-health-care-considerations-for-routine-and>.

^{xiii} MacIntyre, CR, AA Chughtai, et al., “The efficacy of medical masks and respirators against respiratory infection in healthcare workers,” *Influenza and Other Respiratory Viruses*, 2017, 11: 511-17.

^{xiv} Loeb, M., N. Dafoe, et al., “Surgical mask vs N95 respirator for preventing influenza among health care workers: a randomized trial,” *JAMA*, 2009, 302(17): 1865-71, <https://doi.org/10.1001/jama.2009.1466>.

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