Background for Joint Consensus Statement: Public Health Experts Urge CDC's Advisory Committee to Follow the Science and Protect Health Care Workers and Patients[1]

The U.S. Centers for Disease Control and Prevention (CDC) has tasked its advisory committee on health care infection control practices (HICPAC) to update isolation precautions guidance for health care settings, last updated in 2007.

HICPAC established a workgroup to draft guidance updates. Like HICPAC, the Isolation Precautions Workgroup (IP Workgroup) membership has expertise in infection prevention management, but has lacked essential perspectives in aerosol science, industrial hygiene, respiratory protection, ventilation engineering, other disciplines, and representatives of frontline health care workers and patients. In a January 2024 blog post, the CDC made a commitment to expand the scope of technical expertise on both HICPAC and the IP Workgroup. Recently, individuals with expertise in some of these disciplines (e.g. respiratory protection) have been added, but key disciplines and perspectives, including of health care workers, unions, and patients, are still missing.

The IP Workgroup presented its draft to HICPAC in November 2023. The draft proposals are extremely problematic, ignore important scientific updates on aerosol transmission of infectious diseases and respiratory protection, omit recommendations on important protections such as ventilation, and would weaken existing protections. HICPAC voted unanimously to send the draft to CDC for review.

In December 2023, nearly a thousand public health experts expressed significant concerns with HICPAC's draft and urged the CDC Director to reject HICPAC's draft.

In response, on January 23, 2024, the CDC returned draft guidance updates to HICPAC for

Figure 1: Questions posed to HICPAC by CDC.

1. Should there be a category of Transmission-based Precautions that includes masks (instead of NIOSH Approved® N95® [or higher-level] respirators) for pathogens that spread by the air? Should N95 respirators be recommended for all pathogens that spread by the air?
2. Can the workgroup clarify the criteria that would be used to determine which transmission by air category applies for a pathogen? For the category of Special Air Precautions, can you clarify if this category includes only new or emerging pathogens or if this category might also include other pathogens that are more established? Can you also clarify what constitutes a severe illness?
3. Is the current guideline language sufficient to allow for voluntary use of a NIOSH Approved N95 (or higher-level) respirator? Should the document include a recommendation about healthcare organizations allowing voluntary use?
4. Should there be a recommendation for use of source control in healthcare settings that is broader than current draft recommendations? Should source control be recommended at all times in healthcare facilities?

CDC Safe Healthcare Blog, January 23, 2024.

[1] This Joint Consensus Statement was prepared by a joint work group of the American Public Health Association-Occupational Health Section (APHA-OHS) and American Industrial Hygiene Association (AIHA). It was prepared and endorsed prior to the publication of the new WHO publication: *Global technical consultation report on proposed terminology for pathogens that transmit through the air.* Geneva: World Health Organization; 2024. License: CC BY-NC-SA 3.0 IGO.

further work on specific concerns in response to advocacy by public health experts and the public (see Figure 1). In its communication to HICPAC, the CDC asked the committee to address core issues around the categories of transmission-based precautions, the use of respiratory protection vs masks, and source control recommendations.

Public health experts urge HICPAC and its IP Workgroup to significantly strengthen its draft guidance updates in response to CDC's questions and to follow the science and protect health care workers and patients in the following ways:

1. When Responding to Questions 1-4, HICPAC Should Recognize That Employers and Health Care Facilities Are Responsible for Planning and Implementing Infection Prevention Programs.

Approach that HICPAC should take:

- Reorient the guidance to recognize that employers and health care facilities, not individual health care workers, hold the responsibility for infection prevention in health care facilities.
- Recognize that an integrated program, which addresses engineering and work practice controls (e.g., ventilation and isolation of potentially infectious individuals) in addition to personal protective equipment (PPE) according to the hierarchy of controls, is necessary to prevent transmission of infectious diseases to health care workers and patients.
- Include the importance of preparedness to ensure effective infection prevention programs. If policies, procedures, and resources are not assembled ahead of time, they will be unavailable when needed to protect health care workers and patients.

Supporting scientific evidence & rationale:

At the November 2023 meeting, HICPAC members stated that the proposed guidelines were aimed at what frontline staff can do to prevent transmission of infectious diseases, not at health care facility management. This was provided as a reason for why the proposed guidance does not include recommendations around measures like ventilation. This is a deviation from the 2007 Isolation Precautions guidance, which serves as a reference for both management and frontline staff.[2] It is also an incomplete and inappropriate approach to infection prevention and occupational safety and health—the employer is the one who has responsibility and authority for the work environment, including the physical conditions, procurement and stocking of resources such as PPE, and creation and implementation of policies and protocols such as patient screening and placement procedures. HICPAC's draft should serve as a reference for frontline staff but should aim recommendations at health care facility management.

While the draft discusses the hierarchy of controls, HICPAC's proposal is almost exclusively focused on PPE and excludes other measures that are essential to effective infection prevention programs, including ventilation, patient screening and isolation, and staffing. CDC's 2007 Isolation Precautions guidance addresses multiple measures that have been left out of HICPAC's proposals,

[2] CDC, "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings," July 2023, https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf (Accessed March 20, 2024).

including nurse staffing levels, management support and employer resources, training, and surveillance. This must be remedied to ensure protection of health care workers and patients—PPE is just one element of protection and cannot be relied upon as an exclusive measure of protection. Engineering and work practice controls, such as ventilation, staffing, and patient screening and isolation, are essential to effective management of infectious diseases in health care settings.[3]

Additionally, HICPAC's draft fails to address the importance of preparedness for infection prevention and management of infectious disease outbreaks. The impact on health care workers and patients when health care facilities fail to prepare was seen clearly when the Covid-19 pandemic began. Many health care facilities had no plans in place for how to screen or isolate a high number of patients with an infectious respiratory disease, how to expand or convert and staff spaces for isolation, and did not have ample PPE stock on hand. As a result, health care workers and patients experienced preventable Covid-19 infections in high numbers.[4,5,6] HICPAC's draft must take into account the essential role that preparation plays for the ability of health care facilities to respond to future infectious disease outbreaks and pandemics.

2. When Responding to Questions 1-4, HICPAC Should Recognize the Scientific Research on Aerosol Transmission.

Approach that HICPAC should take:

- Recognize that distance is only one of many factors that influence infectious disease transmission. Multiple factors, such as time, dose, phase of infection, size and viability of particles shed by infected individuals, environmental factors, etc., contribute to transmission.
- Recognize that aerosols emitted by infected individuals can travel long distances and remain viable aloft in the air for long periods of time. Focusing only on short-range transmission means that many situations where health care workers and patients are exposed will be missed.
- Recognize that prevention of aerosol transmission requires the use of multiple measures at the same time in order to minimize the travel of infectious aerosols through the air via engineering controls, work practice controls (e.g., ventilation and isolation of potentially infectious individuals), and PPE.
- Engage the expertise of aerosol scientists, industrial hygienists, other experts, patients, and frontline health care workers and unions in the IP Workgroup.

Supporting scientific evidence & rationale:

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[3] CDC NIOSH, "Hospital Respiratory Protection Program Toolkit," April 2022, https://www.cdc.gov/niosh/docs/2015-117/default.html (Accessed March 25, 2024).
[4] Billock, R.M., A.L. Steege, et al., "COVID-19 Mortality by Usual Occupation and Industry: 46 States and New York City, United States, 2020," CDC National Vital Statistics Reports, October 28, 2022, 71(6).
[5] Gebreegziabher, E., D. Bui, et al., "Temporal assessment of disparities in California COVID-19 mortality by industry: a population-based retrospective cohort study," Annals of Epidemiology, 2023, 87: 51-9.
[6] Hawkins, D., L. Davis, and D. Kriebel, "COVID-19 deaths by occupation, Massachusetts, March 1–July 31, 2020," Am J Ind Med, 2021, 64(4): 238-44.

HICPAC has failed to adequately incorporate updated science on aerosol transmission in their proposed precautions for pathogens that transmit through the air. HICPAC proposes to update terminology on infectious disease transmission modes to replace droplet/airborne transmission with one new category, "transmission through the air." For pathogens that transmit through the air, HICPAC proposes three levels of precautions and distinguishes between those categories based on whether the pathogens "spread efficiently across long distances and over extended times" (Extended Air Precautions), "over long distances" (Special Air Precautions), and "short distances" (Routine Air Precautions) (pg 15). HICPAC's proposed draft is exclusively focused on distance as the determining factor in transmission, which ignores extensive scientific research on aerosol transmission of infectious diseases.

Updated research on aerosol transmission of infectious diseases indicates that respiratory aerosols are emitted in a wide range of sizes, many of which can contain infectious pathogens. These aerosols can travel through and remain suspended in the air for long distances and long times, depending on multiple factors including particle characteristics, environmental temperature and humidity, etc. In indoor spaces, ventilation rates, air flow directions, and filtration levels impact where infectious aerosols travel and how quickly they can accumulate. These factors all contribute to the risk of exposure to health care workers and patients.

HICPAC's draft, because of its focus on distance and failure to incorporate updated aerosol science, is overly focused on PPE. Specifically, HICPAC's draft fails to include recommendations on ventilation, which is a significant omission. Ventilation is an essential measure to mitigate infectious disease transmission and exposure in health care settings. Recommendations should follow the hierarchy of controls and must include engineering and work practice controls in addition to PPE.

Fundamentally, members of HICPAC and its IP Workgroup need to understand aerosol transmission. There are multiple reviews that provide a comprehensive and digestible overview of the scientific research, including:

- Drossinos, Y. and N.I. Stilianakis, "What aerosol physics tells us about airborne pathogen transmission," Aerosol Science and Technology, 2020, 54(6): 639-43.
- Fernstrom, A. and M. Goldblatt, "Aerobiology and Its Role in the Transmission of Infectious Diseases," Journal of Pathogens, 2013, Article ID 493960.
- Jones, R.M. and L.M. Brosseau, "Aerosol transmission of infectious disease," J Occup Environ Med, 2015; 57(5): 501-8.
- Klompas, M., D.K. Milton, et al., "Current Insights Into Respiratory Virus Transmission and Potential Implications for Infection Control Programs : A Narrative Review," Ann Intern med, 2021, 174(12): 1710-18.
- Randall, K., E.T. Ewing, et al., "How did we get here: what are droplets and aerosols and how far do they go? A historical perspective on the transmission of respiratory infectious diseases," Interface Focus, 2021, 11(6): 20210049.
- Tellier, R., "Aerosol transmission of influenza A virus: a review of new studies," Journal of the Royal Society Interface, 2009, 6(6): S783-90.
- Tellier, R., Y. Li, et al., "Recognition of aerosol transmission of infectious agents: a commentary," BMC Infectious Diseases, 2019; 19 (101).

- World Health Organization, "Indoor airborne risk assessment in the context of SARS-CoV-2: description of airborne transmission mechanism and method to develop a new standardized model for risk assessment," 2024. https://iris.who.int/bitstream/handle/10665/376346/9789240090576-eng.pdf (Accessed April 1, 2024)

3. When Responding to Questions 1 and 2, HICPAC Should Establish More Robust, Explicit Criteria for Deciding Which Protective Measures are Used for Which Pathogens.

Approach that HICPAC should take:

- Create a science-based, explicit framework to determine which protective measures are used for different pathogens, including airborne infection isolation rooms (AIIR), respiratory protection and other PPE, in addition to other measures.
- Frameworks used to determine protective measures for different pathogens must include an exposure assessment to determine when, where, how, and at what level employees may be exposed.
- Frameworks used to determine protective measures for different pathogens must also consider factors that can make an individual health care worker or a member of their household more vulnerable to infection, severe disease, or death such as immunocompromise status, treatments, or medications.
- Frameworks used to assess the risks from exposure must consider the full range of impacts from infection, including the long-term impacts (like Long Covid and long-term impacts of influenza) in determining the level of protection that is needed. It is not appropriate to limit the assessment of risks and impacts to hospitalizations and deaths, or to assume that the availability of vaccines and treatments is sufficient to protect people from infection and serious outcomes.
- Engage the expertise of ventilation engineers, industrial hygienists, biosafety experts, other experts, patients, and frontline health care workers and unions in the IP Workgroup.

Supporting evidence & rationale:

HICPAC has not adequately explained how the committee plans to assign precautions to each pathogen. The proposed guidelines establish three categories of precautions for pathogens that transmit through the air: Extended Air Precautions recommend use of an AIIR and respirators, Special Air Precautions recommend use of respirators but not an AIIR, and Routine Air Precautions recommend use of a mask and no AIIR (pg 15). In its proposal, HICPAC provides no clear rationale for how it plans to assign pathogens to these categories of precautions, such as what data it plans to analyze or what criteria it plans to use. HICPAC's proposal includes only vague reference to some general factors, such as transmission over long vs short distances, transmission over extended times, severity of illness, degree of immunity, and presence of effective treatments.

HICPAC must establish a clear, science-based framework for assigning precautions to different pathogens. This framework must be explicit about the criteria to be utilized, how the criteria will be

applied, and the method for gathering and analyzing data on each criterion. The goal of the framework must be to protect health care workers, patients, and other individuals present in health care facilities from exposure to infectious diseases. Where data is lacking, the precautionary principle should be followed. HICPAC's framework for assigning precautions to different pathogens should also include the following:

- Exposure assessments, which are essential to preventing transmission to health care workers and patients. An exposure assessment must first determine when, where, and how workers and patients are exposed to infectious diseases. Then, the risk of transmission from those exposures must be evaluated. Mitigation measures must then be based upon such exposure assessments. When exposures are not identified effectively, transmission can occur to patients and health care workers.
    - Input and expertise from frontline health care workers and their unions is essential to conducting thorough and accurate exposure assessments.
    - HICPAC and its IP Workgroup must include recommendations for exposure assessments and create clear criteria for use in these assessments.
    - Real-time measurement of the concentration of infectious aerosols may not be practical in most health care settings, so exposure assessments must rely on evaluating the effectiveness of control measures such as ventilation systems and the time and activities to be performed in the area.
- The need to protect health care workers and patients who may be more vulnerable to infection upon exposure or more vulnerable to severe disease upon infection, such as due to age, immunocompromise status, treatment or medication, or other factors, when establishing frameworks to evaluate exposures and risks. Employers are not always in a position to know individual workers' or patients' risk factors, so all individuals should be protected. Additionally, some heath care workers and patients may have close contact with individuals outside the healthcare setting who are vulnerable to severe disease if infected by the worker or patient.
- Consistent application of precautions to different pathogens. In the IP Workgroup's June 2023 proposals to HICPAC,[7] there were significant inconsistencies in the criteria that HICPAC reported using to assign precautions to different pathogens that transmit through the air. For example, the IP Workgroup assigned TB, measles, and varicella to Extended Air Precautions (AIIR, respirator) but SARS-CoV-2 and influenza to Special Air Precautions (in the "pandemic-phase", respirator, no AIIR) or Routine Air Precautions (in the "seasonal phase", no AIIR, mask). There is clear evidence that TB, measles, varicella, SARS-CoV-1, SARS-CoV-2/Covid-19, and influenza can transmit through the air beyond a small room.[8,9]

[7] Routine Air Precautions: seasonal coronavirus, seasonal influenza
Novel Air Precautions (renamed Special Air Precautions in November draft): MERS, SARS-CoV-1, pandemic-phase respiratory viruses (e.g., influenza, SARS-CoV-2)
Extended Air Precautions: Tuberculosis, measles, varicella
CDC, Isolation Precautions Guideline Workgroup, HICPAC update June 8, 2023
https://www.cdc.gov/hicpac/pdf/2023-June-IPWG-508.pdf (Accessed March 20, 2024).
[8] Wang, C.C., K.A. Prather, et al., "Airborne transmission of respiratory viruses," Science, 2021, 373(6558).
[9] Riley, R.L., "AIRBORNE PULMONARY TUBERCULOSIS," Bacteriological Reviews, 1961, 24(3): 243-8.

All six pathogens can cause severe disease.[10] There are also vaccines and/or treatments available for five of the six pathogens,[11] with the exception of SARS-CoV-1 and a novel emerging pathogen where there is unlikely to be a vaccine or treatment available, at least initially. So why are these six pathogens placed into different categories of precautions? HICPAC offers no explanation. Establishment of an explicit, science-based framework is important to ensure consistent application of precautions to different pathogens.

- Specifically, the ongoing health threat posed by SARS-CoV-2/Covid-19 must not be downplayed and must be addressed by HICPAC. Since the start of 2024 there have been approximately 1000-2000 deaths per week due to SARS-CoV-2.[12] Long-COVID remains a serious health problem. About 7 percent of the U.S. population is currently experiencing Long Covid, 78 percent of whom report activity limitations, and 25% of whom report that Long-COVID seriously limits their ability to carry out day-to-day activities.[13] Recent research has demonstrated that the long-term effects of influenza and other infections are also significant.[14] Further, immune protection against SARS-CoV-2 is known to wane over time,[15] whether from previous infection, vaccination, or both, and newly emergent strains have often developed

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[10] CDC, "Tuberculosis: Signs & Symptoms," February 14, 2023, https://www.cdc.gov/tb/topic/basics/signsandsymptoms.htm (Accessed March 27, 2024).
CDC, "Measles Symptoms and Complications," Nov 5, 2020, https://www.cdc.gov/measles/symptoms/index.html (Accessed March 27, 2024).
CDC, "About Chickenpox," October 21, 2022, https://www.cdc.gov/chickenpox/about/index.html (Accessed March 27, 2024).
World Health Organization, "Severe Acute Respiratory Syndrome (SARS)," https://www.who.int/health-topics/severe-acute-respiratory-syndrome#tab=tab_1 (Accessed March 27, 2024).
CDC, "About COVID-19," July 10, 2023 https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19.html (Accessed March 27, 2024).
CDC, "Key Facts About Influenza (Flu)," March 22, 2024, https://www.cdc.gov/flu/about/keyfacts.htm (Accessed March 27, 2024).
[11] CDC, "Treatment for Latent TB Infection and TB Disease," March 22, 2023, https://www.cdc.gov/tb/topic/treatment/default.htm (Accessed March 27, 2024).
CDC, "Vaccine for Measles," November 5, 2020, https://www.cdc.gov/measles/vaccination.html (Accessed March 27, 2024).
CDC, "Chickenpox/Varicella Vaccination," November 22, 2016, https://www.cdc.gov/vaccines/vpd/varicella/index.html (Accessed March 27, 2024).
CDC, "Vaccines for COVID-19," July 13, 2023, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html (Accessed March 27, 2024).
CDC, "Key Facts About Seasonal Flu Vaccine," March 22, 2024, https://www.cdc.gov/flu/prevent/keyfacts.htm (Accessed March 27, 2024).
[12] CDC, COVID Data Tracker: Trends in United States COVID-19 Hospitalizations, Deaths, Emergency Department (ED) Visits, and Test Positivity by Geographic Area (Weekly deaths), March 9, 2024, https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00 (Accessed March 19, 2024).
[13] CDC National Center for Health Statistics, "Long COVID Household Pulse Survey" March 4, 2024, https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm (Accessed March 19, 2024).
[14] Xie, Y., Choi, T., & Al-Aly, Z. (2024). Long-term outcomes following hospital admission for COVID-19 versus seasonal influenza: a cohort study. The Lancet. Infectious diseases, 24(3), 239–255. https://doi.org/10.1016/S1473-3099(23)00684-9
[15] COVID-19 Forecasting Team, "Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis," The Lancet, 2023, 401(10379): 833-42.

the ability to escape existing immunity.[16] There should be no difference in precautions between "pandemic" and "seasonal" phase for the same pathogen, as is proposed in HICPAC's draft guidance. The pathogen transmits in the same manner regardless of the terms used to describe the virus.

4. When Responding to Questions 1 and 3, HICPAC Should Strengthen Respiratory Protection Recommendations and Recognize That NIOSH-Approved Respiratory Protection, Not Surgical/Medical Masks, Must Be Used to Protect Health Care Workers from Aerosol Hazards.

In the healthcare environment, engineering and work practice controls are essential to limit exposures to infectious diseases to health care workers and patients. However, where sick patients are the source of the hazard, there are situations where health care workers are necessarily close to the patient where engineering and work practice controls are not sufficient to mitigate exposure, even inside AIIRs. In these situations, appropriate PPE selection is critical.

Approach that HICPAC should take:

- Based on scientific evidence, redo CDC's evidence review regarding the effectiveness of N95 respirators vs surgical/medical masks in protecting health care workers from respiratory illness in conjunction with subject matter experts from CDC's National Institute for Occupational Safety and Health (NIOSH). This evidence must take into account whether respirators were used effectively in the studies (by direct investigator observation), whether filtering facepiece respirators were initially fit-tested, whether users were part of a comprehensive respirator program, and whether respirators were redonned after use.
- Review and utilize the extensive evidence from laboratory studies and non-health care workplaces regarding the effectiveness of N95 filtering facepiece and other respirators to protect against inhalation exposure.
- Follow and clearly state OSHA's requirement that NIOSH-approved respirators be provided when employees are exposed to inhalation hazards, including infectious aerosols, when engineering and other controls do not sufficiently protect against the exposure. This necessitates changing HICPAC's proposed Routine Air Precautions category, which calls for surgical/medical masks rather than respirators and would leave health care workers unprotected, including those who are at higher risk for more serious outcomes due to underlying conditions, age, immune status, etc.
- Explicitly recognize that N95 filtering facepiece respirators offer the minimum level of respiratory protection against inhalation hazards and that other respirators, such as powered air-purifying and elastomeric respirators, offer higher levels of and more reliable protection, and do not experience the same supply chain challenges because they can be safely cleaned and reused without compromising their effectiveness. The guidelines should discuss and provide examples of higher-risk procedures and situations where higher levels

[16] World Health Organization, "Tracking SARS-CoV-2 variants," February 16, 2024, https://www.who.int/activities/tracking-SARS-CoV-2-variants (Accessed March 27, 2024).

of respiratory protection are warranted. The guidelines should not try to redefine surgical masks as acceptable inhalation protection.

- Include recommendations for use of engineering and work practice controls, such as ventilation and patient screening and isolation. When engineering and work practice controls are used effectively, fewer health care workers and patients are exposed, and the number of people who require respirators to prevent exposure is limited.
- Clearly recognize that NIOSH-approved respirators must be used within the context of an Occupational Safety and Health Administration (OSHA)-compliant comprehensive respiratory protection program, including ensuring sufficient supplies and fit testing. Such programs are critical to provide health care workers with a reliable level of respiratory protection and are the legal standard in occupational health for respiratory PPE used to control inhalation hazards.
- Ensure that all health care workers have the right to access and use appropriate respirators, even if the employer has determined that respirators are not required ("voluntary use"), and are included in the full respirator program, including fit testing.
- Engage the expertise of respiratory protection experts, industrial hygienists, other experts, patients, and frontline health care workers and unions in the IP Workgroup.

Supporting scientific evidence & rationale:

In developing draft guidance, HICPAC requested an evidence review from the CDC regarding the effectiveness of N95 respirators vs. surgical masks in protecting health care workers from respiratory illness. The review was problematic and biased and concluded there was no difference between N95s and surgical masks. It overemphasized the findings of some randomized controlled trials (RCTs) while omitting other applicable data and studies. Issues with the CDC/HICPAC's evidence review include:

- Included studies did not examine whether N95 respirators were worn for all exposures (or whether exposures occurred while N95s were not worn by workers), which means they are missing important data about the effectiveness of N95 respirators. Specifically, CDC/HICPAC left out an important RCT conducted by Dr. Raina MacIntyre with no explanation.[17] This RCT found clearly that continuous N95 respirator use (use during all exposures) significantly reduced the risk of respiratory virus transmission to health care personnel, while intermittent N95 use (only during some exposures) and surgical mask use did not.
- Included studies failed to observe whether health care personnel were actually wearing respirators and using them correctly. While the CDC states that it is focused on "real world evidence" in evaluating N95 respirators and surgical masks, the included studies failed to assess whether respirators were used in the context of an OSHA-compliant respiratory protection program, including whether respirators were fit-tested or whether users donned them correctly. OSHA's Respiratory Protection Program Standard requires employers to implement a comprehensive plan to ensure that respirators provide reliable protection to workers and are used safely, which includes exposure assessments, medical evaluation, fit testing, and training. Research has documented the importance of these elements—for

[17] MacIntyre, C.R., A.A. Chughtai, et al., "The efficacy of medical masks and respirators against respiratory infection in healthcare workers," Influenza Other Respir Viruses, 2017, 11(6): 511-17.

example, training on doffing and conducting user seal checks can lead to better respirator fit.[18,19,20,21] Studies have found that particle penetration of N95 respirators is significantly more likely to occur via the faceseal than the filter,[22] thus fit testing and following appropriate donning procedures are essential for respirators to provide protection.[23,24,25]

- Included studies failed to evaluate practices involving N95 use, including whether N95s were repeatedly redonned or reused. Nearly half of the studies included in CDC's evidence review were conducted early in the Covid-19 pandemic (2020-21) when practices to reuse N95 filtering facepiece respirators designed for single use were common. Redonning or reusing N95 respirators has been shown to lead to fit test failure, even after just one re-donning, which undermines protection.[26,27]
- Included studies conducted early in the Covid-19 pandemic also did not account for the fact that there were also significant issues with counterfeit N95 respirators that were not certified by NIOSH and that did not provide adequate respiratory protection.
- Studies included in the CDC's review did not include a control group (i.e., subjects wearing no mask or respirator), which undermines the ability of those studies to draw accurate conclusions about the impact of N95 respirators.
- 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. For example, the National Academies of Science, Engineering, and Medicine (NASEM) has published multiple reviews of the effectiveness of respiratory protection to protect workers

[18] Or, P., J. Chung, et al., "Does Training in Performing a Fit Check Enhance N95 Respirator Efficacy?," AAOHN, 2012, 60(12): 511-15.
[19] Rembialkowsi, B., M. Sietsema, and L. Brosseau, "Impact of time and assisted donning on respirator fit," JOEH, 2017, 14(9): 669-73.
[20] Kim, H., J. Lee, et al., "Comparison of fit factors among healthcare providers working in the Emergency Department Center before and after training with three types of N95 and higher filter respirators," Medicine, 98(6): e14250.
[21] Chen, H., E.R. Pennington, et al., "Improvement in Fitted Filtration Efficiency of N95 Respirators With Escalating Instruction of the Wearer," AJPM Focus, 2022, 1(1): 100014.
[22] Grinshpun, S.A., H. Haruta, et al., "Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: two pathways for particle penetration," J Occup Environ Hyg, 2009, 6(10): 593-603.
[23] Goko, C., E. Forster, et al., "Effectiveness of fit testing versus fit checking for healthcare workers respiratory protective equipment: A systematic review," International Journal of Nursing Sciences, 2023, 10(4): 568-78.
[24] Reponen, T., S. Lee, et al., "Effect of Fit Testing on the Protection Offered by N95 Filtering Facepiece Respirators Against Fine Particles in a Laboratory Setting," Annals of Work Exposures and Health, 2011, 55(3): 264-71.
[25] Viscusi, D.J., M.S. Bergman, et al., "Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit," JOEH, 2012, 9(6): 408-16.
[26] Wang, R.C., N.F. Degesys, et al., "Incidence of Fit Test Failure During N95 Respirator Reuse and Extended Use," JAMA Network Open, 2024, 7(1): e2353631.
[27] Jung, J., J. Kim, et al., "Fit-failure rate associated with simulated reuse and extended use of N95 respirators assessed by a quantitative fit test," Infection Control & Hospital Epidemiology, 2021, 42(11): 1313-17.

from harmful aerosols, including for health care personnel from infectious aerosols.[28,29,30] There is nothing different or special about the behavior of hazardous aerosols encountered in health care settings. Respirators will collect infectious aerosols and protect the wearer in the same manner in all workplaces. CDC's own NIOSH has a respirator certification system that is based on sound science and research and which includes an independent quality assurance program (National Personal Protective Technology Laboratory/NPPTL).

HICPAC's draft is focused on N95 filtering facepiece respirators and fails to fully recognize the importance of elastomeric respirators and powered air-purifying respirators (PAPRs). N95 filtering facepiece respirators are the minimum level of respiratory protection certified by NIOSH. Research has found that the protection of N95 filtering facepiece respirators is highly dependent on achieving a tight face seal and that the face seal can be disrupted during periods of heavy work activity, such as performing CPR.[31,32] In contrast, elastomeric respirators and PAPRs can provide higher levels of filtration and more reliable protection during periods of heavy work activity.[33,34] HICPAC's draft should more clearly recommend the use of elastomeric respirators and PAPRs to protect health care workers, especially in situations where there is a higher risk of transmission (such as when multiple infectious patients are cohorted together).

The draft presented by the IP Workgroup to HICPAC at the November 2023 meeting initially had references to OSHA's Respiratory Protection Program Standard, but many of those references were removed by HICPAC during discussions prior to the committee vote. OSHA has had standards

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[28] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Giammaria C, Yost O, Nicholson A, editors. "Current Issues in the Assessment of Respiratory Protective Devices for Occupational and Non-Occupational Uses: Proceedings of a Workshop." Washington (DC): National Academies Press (US); 2020 Dec 22, Available at https://www.ncbi.nlm.nih.gov/books/NBK567467/.

[29] 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.

[30] Institute of Medicine (US) Committee on Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A Catharyn T. Liverman, Tracy A. Harris, M.E. Bonnie Rogers, Kenneth I. Shine , editors. "Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report," Washington (DC): National Academies Press (US); 2009. Available at https://nap.nationalacademies.org/catalog/12748/respiratory-protection-for-healthcare-workers-in-the-workplace-against-novel-h1n1-influenza-a.

[31] Suen, L.K.P., L. Yang, et al., "Reliability of N95 respirators for respiratory protection before, during, and after nursing procedures," American Journal of Infection Control, 2017, 45(9): 974-8.

[32] Hwang, S.Y., H. Yoon, et al., "N95 filtering facepiece respirators do not reliably afford respiratory protection during chest compression: A simulation study," American Journal of Emergency Medicine, 2020, 38(1): 12-17.

[33] Park, S.H., S.Y. Hwang, et al., "Are loose-fitting powered air-purifying respirators safe during chest compression? A simulation study," American Journal of Emergency Medicine, 2021, 44: 235-40.

[34] Barros, A.J., C.D. Sifri, et al., "Effectiveness of Elastomeric Half-Mask Respirators vs N95 Filtering Facepiece Respirators During Simulated Resuscitation: A Nonrandomized Controlled Trial," JAMA Network Open, 2021, 4(3): e211564.

regulating the use of respirators in place since 1972.[35] Currently, OSHA's Respiratory Protection Program Standard, 29 CFR 1910.134, requires employers to control occupational diseases caused by breathing air contaminated with a hazard with engineering controls as far as feasible and to implement respirators when engineering controls are infeasible or insufficient. Where respirators are necessary to protect the health of the employee and where employers require employees to utilize respirators, employers must create a respiratory protection program, including procedures for selecting respirators, medical evaluations, fit-testing procedures, and training of employees. These programmatic elements are essential to ensuring that respirators provide the necessary protection for employees and can be used safely.

HICPAC should ensure that all health care workers have the right to access and use respirators ("voluntary use") and that employers include those workers in the full respirator program, including fit testing. Employers must conduct exposure assessments to determine where PPE is required to protect workers. In situations where workers deem their employer's exposure assessment to be inadequate or inaccurate and that respiratory protection is warranted to reduce or prevent exposure, those workers should have the right to access and utilize effective respiratory protection. Respirators provide effective protection only when utilized in the context of a respirator program compliant with OSHA's Respiratory Protection Program Standard, which requires training, medical surveillance, and fit testing.

5. When Responding to Question 4, HICPAC Should Strengthen Source Control Recommendations.

Approach that HICPAC should take:

- Expand the definition of source control to include more measures that limit the release of infectious aerosols into shared airspace, including procedures to screen people entering the facility and ensure prompt isolation of potentially infectious persons, improving ventilation in both patient care and non-patient care areas (e.g., lobbies, waiting rooms, hallways, and elevators), and utilizing and expanding the use of AIIRs—in addition to wearing masks and observing cough/respiratory etiquette.
- Place infectious patients with aerosol-transmissible diseases in AIIRs. If a healthcare facility has an insufficient number of AIIRs, or no AIIRs, to house infectious patients, and cannot transfer these patients to another healthcare facility, HICPAC should include specific recommendations for how facilities can expand or convert spaces to reduce aerosol transmission.
- Expand the use of AIIRs, including ensuring that for novel and emerging pathogens always start with isolation in an AIIR plus respiratory protection for health care workers entering the room (i.e., emerging pathogens should be classified under Extended Air Precautions, not Special Air Precautions).
- HICPAC's recommendations, instead of limiting the use of AIIRs, should include recommendations for health care facilities to create plans that can be implemented quickly

[35] CDC, NIOSH, National Personal Protective Technology Laboratory, "100 Years of Respiratory Protection History," July 31, 2019, https://www.cdc.gov/niosh/npptl/Respiratory-Protection-history.html (Accessed March 20, 2024).

to expand the number of spaces that can be used as AIIRs when needed (e.g., during an outbreak or surge in cases of respiratory infections).

- Include recommendations to enhance and test the effectiveness of ventilation and filtration in all areas of the facility, including both patient care and non-patient care areas. CDC should incorporate expertise from ventilation experts in NIOSH and from the American Society for Heating and Air-Conditioning Engineers (ASHRAE).
- Where cohorting is necessary due to a lack of available isolation facilities, address how cohorting can be effectively accomplished without increasing risk of exposure to health care workers or patients. HICPAC should include recommendations for enhancing protections for health care workers in areas where infectious patients are cohorted due to the higher exposure conditions.
- Expand the use of masks for source control as a preventive measure, not just in response to high rates of transmission already occurring.
- Engage the expertise of aerosol scientists, industrial hygienists, ventilation engineers, respiratory protection experts, patients, and frontline health care workers and unions in the IP Workgroup.

Supporting scientific evidence & rationale:

HICPAC's draft limits the discussion of source control to the use of masks by patients (both symptomatic and asymptomatic), but this definition should be expanded to include multiple other measures that can be effective in limiting emission of infectious aerosols from infected patients or health care workers. In the hierarchy of controls, eliminating the hazard is a primary goal—source control measures can help achieve that goal.

Specifically, HICPAC should expand recommendations on patient screening and placement to better utilize ventilation systems and isolation protocols to eliminate the hazard from other areas in the health care facility. Facilities should establish procedures to quickly identify potentially infectious persons and provide for prompt isolation. This may necessitate expanding areas used for isolation.[36]

Use of AIIRs is particularly important for source control. AIIRs are rooms with specially designed ventilation systems to provide a high rate of air flow, operating under negative pressure to limit the transport of infectious aerosols outside the room, and exhausting contaminated room air outside or via a HEPA filter. AIIRs play an essential role in limiting the potential for exposure of other patients and health care workers and HICPAC should expand their use, not limit it. If a healthcare facility has an insufficient number of AIIRs, or no AIIRs, to house infectious patients, and cannot transfer these patients to another healthcare facility, HICPAC should specify that the facility make efforts, if feasible, to: (i) use an in-room HEPA filtration unit (or multiple units depending on the room volume and the rate of airflow moved by a unit) to increase the effective rate of disinfecting room air by physically removing infectious aerosol, and (ii) promote a room negative pressure by directly exhausting air from the HEPA filtration unit via a duct to outside the building (for example, through a window that is sealed around the opening for the duct).

[36] California Department of Health Care Access and Information, Office of Statewide Hospital Planning and Development, "Design Guide for Planning and Preparing for Disasters," March 1, 2024.

HICPAC's draft proposes to weaken existing practice when it comes to the use of AIIRs to isolate patients with novel pathogens. This must be changed in updated drafts. When a novel pathogen begins to cause an outbreak, there is little information available about its transmission modes. Under the precautionary principle and in order to protect patients and health care workers, treatment of novel pathogens must always start with isolation in an AIIR—the highest level of protection—plus respirators and other PPE for health care workers entering the room. Instead of limiting the use of AIIRs, HICPAC's draft should include recommendations for health care facilities to create plans that can be implemented quickly to expand the number of spaces that can be used as AIIRs when needed (e.g., during an outbreak or surge in cases of respiratory infections).

Ventilation is an essential protective measure in all areas of the facility, including both patient care and non-patient care areas such as lobbies, hallways, elevators, and breakrooms. Ventilation and filtration are essential elements of source control because they can remove infectious aerosols from the air or decrease the concentration of pathogens through dilution, limiting the possibility of transmission to other individuals.[37] However, ventilation must be assessed so that it is not moving contaminated air into less contaminated areas. CDC should incorporate expertise from ventilation experts in NIOSH and from ASHRAE when updating draft guidance and reference consensus standard ASHRAE 170-2021 as providing minimum guidelines on ventilation.

HICPAC's draft does not adequately address situations where there may be a higher risk of transmission, such as when multiple patients with an infectious disease are cohorted in the same room or area. In these situations, facilities need to have a plan in place for how they will enhance protections for health care workers to limit the risk.

HICPAC's draft includes the use of masks for source control, including by both symptomatic and asymptomatic individuals. However, HICPAC's draft limits the recommendations for use of masks for source control to "periods of higher levels of community respiratory virus transmission." Evidence regarding the effectiveness of the use of masks for source control is positive.[38,39,40] Instead of waiting until cases are already high, HICPAC's draft should recommend the use of masks in a proactive fashion to help prevent transmission, before outbreaks occur. Medical or surgical facemasks are typically used for source control, though N95 filtering facepiece respirators can also be utilized and more effectively limit respiratory emissions from infectious sources.[41]

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[37] World Health Organization, "Indoor airborne risk assessment in the context of SARS-CoV-2: description of airborne transmission mechanism and method to develop a new standardized model for risk assessment," 2024. https://iris.who.int/bitstream/handle/10665/376346/9789240090576-eng.pdf (Accessed April 1, 2024)

[38] MacIntyre, C.R., A.A. Chughtai, "A rapid systematic review of the efficacy of face masks and respirators against coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick patients," Int J Nursing Studies, 2020, 108: 103629.

[39] Lindsley, W.G., D.H. Beezhold, et al., "Efficacy of universal masking for source control and personal protection from simulated cough and exhaled aerosols in a room," J Occup Environ Hyg, 2021, 18(8): 409-22.

[40] Andrejko, K.L., J.M. Pry, et al., "Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection — California, February–December 2021," MMWR, Feb 11, 2022, 71(6): 212-16.

[41] Milton, D., J. Lai, and C.K. Kristen, et al., "Evidence That N95 Respirators Should Become the Standard for Source Control of SARSCoV-2 and Other Respiratory Pathogens," Am J Respr Crit Care Med, 2023, 207:A3811.

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