

World Health Network

September 26, 2023

Subject: Response to Letter dated August 18, 2023 Addressing Our Urgent Concerns and Recommendations Regarding HICPAC Draft Guidelines

From: Infection Prevention Team, World Health Network

To: Daniel Jernigan, MD, MPH Director, National Center for Emerging and Zoonotic Infectious Diseases, CDC

and

Members of the Healthcare Infection Control Practices Advisory Committee (HICPAC)

Dear Dr. Jernigan,

Thank you for replying to our letter sent on August 7th, 2023. We have carefully reviewed your letter dated August 18, 2023 in response to our concerns about the draft recommendations discussed at the June 8-9, 2023, HICPAC meeting. First, we appreciate you taking the time to write such an informative letter. However, while we appreciate your engagement, we must express our disappointment at the lack of direct responses to several critical issues we raised:

Aerosol Transmission: Your response letter does not begin to adequately address aerosol transmission of SARs-CoV-2 and our concern that the draft recommendations both do not fully recognize the science on aerosolized pathogens and inadequately address the risks of aerosol transmission.

The distinction between aerosol and droplet spread is not just academic because the "air" category is overly simplistic and conflates risk from aerosol and droplets. This leads to recommendations for insufficient respiratory protection and has real-world implications for the safety of healthcare workers and patients. Finally, the "air" and "touch"

categorization does not properly reflect the complexities of transmission dynamics as expertly delineated in the article by Lisa M Brosseau et al¹ excerpted below:

Droplet transmission occurs when someone coughs or sneezes into the eyes, nose, or mouth of someone nearby. This might happen when a healthcare provider is in close contact with a symptomatic person and perhaps when parents are caring for sick children, but otherwise this is a fairly unlikely event.

People continuously release many particles in a wide range of sizes but most of them are relatively small (around 1 micrometer), when they're breathing, talking, singing—and coughing or sneezing. The smaller particles remain suspended in air for long periods—minutes to hours—and can accumulate over time and easily disperse throughout an indoor space. Numerically, breathing and talking contribute much more than coughing or sneezing to the amount of virus in the air because they occur continuously or very frequently.

SARS-CoV-2 is capable of remaining viable in air for some hours. We know that people with COVID-19 are most infectious just before and as symptoms are developing, so transmission is possible before anyone knows they're infected. Some 30% or more of infected people never develop symptoms but are still infectious.

All of these facts explain why aerosol inhalation is much more likely than droplet transmission. They also explain why infection can occur both near and far from an infected source."

Trisha Greenhalgh, Jose L Jimenez, Kimberly A Prather, Zeynep Tufekci, David Fisman, and Robert Schooley document ten scientific reasons in support of airborne transmission in their Lancet commentary. They dispute the flawed medical dogma that "since respiratory droplets are larger than aerosols, they must contain more viruses." They point out that" …in diseases where pathogen concentrations have been quantified by particle size, smaller aerosols showed higher concentrations than droplets when both were measured…There is consistent strong evidence that SARs-CoV-2 spreads by airborne

¹ Brosseau M, MacIntyre CR, Ulrich A, Osterholm, M. Wear a respirator, not a cloth or surgical mask, to protect against respiratory diseases. CIDRAP Online February 23, 2023.

transmission. Although other routes can contribute, we believe that the airborne route is likely to be dominant."²

Until HICPAC and the CDC recognizes aerosol transmission and aerosol inhalation as the predominant route of transmission for SARS-CoV-2 the infection control standards promulgated will be substandard and will result in inadequate respiratory protection for healthcare workers and patients.

Respiratory Protection and Source Control Measures: Our concern that the draft guidelines fail to ensure adequate respiratory protection against infectious aerosols by determining that surgical masks are as effective as respirators was not adequately addressed in your letter.

You indicate that the CDC performed a systematic search of peer-reviewed research and data evaluated using systematic methods. However, this scientific review was flawed and incomplete. The over reliance on randomized clinical trials has interfered with the development of these draft guidelines. Respiratory protection has been validated over decades with NIOSH and CSA (Canada) standards that specify protection from viruses and bacteria. Other types of research such as observational, lab and modeling studies have been ignored.

The draft guidelines included a review of 13 studies, concluding that the "evidence suggests no difference between N95s and surgical masks." This conclusion was reached even though these cited studies were at risk of confounding by variables, wide confidence intervals, and recall bias which should have prevented HICPAC from drawing firm conclusions. Reviewed studies did not look at full-time wear and did not observe whether health care personnel were wearing the respirators and using them correctly.

This scientific review has thus resulted in a recommendation that contradicts a large body of scientific evidence. It is not only contrary to established scientific consensus but also poses a direct threat to the safety of healthcare professionals. The evidence is clear: respirators offer superior protection against infectious aerosols. The National Institute for Occupational Safety and Health (NIOSH) has addressed the superior protection provided by a properly sized and fit tested respirator as have numerous academic publications. Your stance on this matter appears to be in direct contradiction to NIOSH recommendations. Furthermore, the findings differ from the CDC's 2022 study, which

²Greenhalgh T, Jimenez JL, Prather KA, Tufekci Z, Fisman D, Schooley R. Ten scientific reasons in support of airborne transmission of SARS-CoV-2. The Lancet. 2021;0(0). doi: https://doi.org/10.1016/S0140-6736(21)00869-2

indicated that N95 masks reduce the likelihood of a positive coronavirus test by 83%, in contrast to 66% for surgical masks and 56% for cloth masks.³

The HICPAC mask review also neglects the role of asymptomatic transmission which makes it likely that without adequate respiratory protection, healthcare workers will infect patients. Asymptomatic transmission makes it impossible for health care workers to accurately assess their own risk, which the draft guidelines state is the responsibility of the healthcare worker. Moreover, the draft guidelines fail to account for patient healthcare-acquired infections, and adverse outcomes. Strikingly, vulnerable patients are not even mentioned.

Comprehensive Source Control Measures: The omission of core control measures for infectious aerosols which was emphasized in our letter was not even addressed in your response. There is a large body of evidence on the effectiveness and importance of ventilation, UV disinfection, HEPA filtration, and NIOSH-approved respirators for controlling worker and patient exposure to infectious aerosols that has been ignored. The airborne infection isolation room proposal is significantly limited.

The absence of guidance on all these measures, especially in the context of the well-documented aerosol transmission of SARS-CoV-2, is a glaring oversight.

Composition of the Committee: While we understand that the HICPAC members are experts in the field of infection prevention and control and that nursing members are specifically mentioned, your response failed to address the absence of experts in aerosol transmission, a concern that we raised in our letter.

HICPAC is charged with providing to the CDC guidance in relation to preventing transmission of infectious agents in healthcare settings. Providing such guidance is one of its key functions. The Federal Advisory Committee Act (FACA), furthermore, requires that the committee be fairly balanced in terms of the points of view related to its functions.

There is a significant body of expert opinion that strongly supports the view that a consequential mode of transmission for Covid-19 is via aerosols. This widespread point of view is thus directly related to a key function of the committee, and as such, a significant number of voting committee members should be experts in aerosol transmission.

³ Andrejko, K. L., Pry, J. M., Myers, J. F., Fukui, N., DeGuzman, J. L., Openshaw, J., ... & California COVID-19 Case-Control Study Team. (2022). Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection — California, February–December 2021. *MMWR Weekly*, 71(6), 212–216. Retrieved on February 4, 2022, from MMWR Early Release.

HIPCAC, however, fails to have a significant number of voting members who are experts in such areas as aerosol science, ventilation engineering, industrial hygiene, UV and HEPA filtration experts, respiratory protection and occupational health and safety.

Regarding the inadequate inclusion of patient advocates and union representatives of healthcare workers, Paul Conway, President of the American Association of Kidney Patients, liaison to HICPAC, stated in comments at the June 8-9 meeting of HICPAC:

"I do think that the process here should be re-examined by CDC to make certain that public comment precedes the vote because, as an immunosuppressant kidney patient, and for the American Association of Kidney Patient members who have been listening today, it is nonsensical to change the standards for protection for immunosuppressed patients, whether they are organ transplant recipients or others, without having a clear insight into the mortality data and the risk that we've just gone through for three years. And we have an ongoing and serious concern about the lack of clear communications that are coming out of federal agencies, and unfortunately, I don't like to say this publicly, including the CDC. I have a role today as a liaison, but the representative voice of patients and caregivers needs to be incorporated throughout the process. Not on the day of the meeting"

manifesting the inadequacy of the process that we are pointing to.

Lack of Committee Transparency: While your letter emphasizes your compliance with FACA in meeting the requirements for transparency, working group meetings regarding guidance updates are closed and not open to the public. HICPAC committee votes have been held before public comment and meeting presentations have not been publicly posted and updates from the working group to HIPCAC are not publicly posted and meeting summaries are posted months after the fact.

Our call for broader stakeholder input was not adequately addressed. The public may make short comments during each HICPAC meeting, but there is no other mechanism for the committee or its working groups to garner input from frontline healthcare workers or the unions that represent them, experts who should be consulted, or patients who will be impacted by an updated Guidance.

In light of the concerns and issues raised, we outline the following immediate actions that we believe are essential for the betterment of healthcare guidelines and the safety of all involved:

- 1. **Acknowledge Aerosol Transmission**: Recognize and address aerosol transmission as the primary route of SARS-CoV-2 transmission in your guidelines.
- 2. **Reassess Respiratory Protection**: Undertake a thorough re-evaluation of the draft guidelines concerning respiratory protection, ensuring that the guidelines reflect the superior protection offered by respirators over surgical masks.
- 3. **Incorporate Comprehensive Control Measures**: Integrate guidance on essential control measures for infectious aerosols, including but not limited to ventilation, UV disinfection, HEPA filtration, and the utilization of NIOSH-approved respirators.
- 4. **Revise Committee Composition**: Ensure the HICPAC committee includes experts in aerosol transmission, patient advocates, and union representatives of healthcare workers to provide a comprehensive perspective.
- 5. **Enhance Committee Transparency**: Adopt measures to increase transparency, such as opening working group meetings to the public, promptly posting meeting presentations and summaries, and facilitating broader stakeholder input.
- 6. **Broaden Stakeholder Engagement**: Establish mechanisms to actively seek and incorporate input from frontline healthcare workers, their representative unions, relevant experts, and the patients who will be directly impacted by the guidelines.
- 7. **Provide a Comprehensive Response**: We expect a detailed, point-by-point response to each concern raised in our communications, demonstrating a genuine commitment to addressing these critical issues.

In conclusion, we urge the US Department of Health and Human Services to take these actions seriously and promptly. The health and safety of healthcare workers, patients, and the broader community are at stake. We anticipate your timely response and are hopeful for collaboration in a constructive approach using the lessons learned from the recent pandemic to further improving and refining the guidelines.

Sincerely,

Infection Prevention Team, World Health Network

CC:

The Honorable Xavier Becerra, Secretary U.S. Department of Health and Human Services

Mandy K. Cohen, MD. MPH, Director Centers for Disease Control and Prevention

Arati Prabhakar, Ph.D., Director

White House Office of Science and Technology Policy (OSTP) Assistant to the President for Science and Technology

The Honorable Neera Tanden Assistant to the President and Domestic Policy Advisor