

September 21, 2023

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
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Dear Dr. Cohen:

We are writing to acknowledge and follow-up on CDC's response to the July 20, 2023, letter from 900 public health and medical experts regarding updates to CDC's *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*. We again urge CDC to involve key experts and all stakeholders in the development process, and call upon CDC to follow past practice and hold public meetings on the Isolation Precaution Guideline as was done for the update of Guidelines on Tuberculosis in Health-Care Facilities in the 1990's.

In our earlier letter we expressed deep concerns that the draft guidelines being developed by a workgroup of the Healthcare Infection Control Advisory Committee (HICPAC) fail to protect health care personnel and patients exposed to infectious aerosols and the process for the developing the guidelines failed to include key stakeholders and was closed to the public and non-transparent. We outlined specific weaknesses in the draft guidelines, put forth recommendations for making the process more inclusive and more transparent and requested that any vote on the draft guidelines by HICPAC be delayed until these deficiencies were corrected.

We appreciate that CDC delayed the HICPAC vote on adoption of the recommended guidelines from the August meeting until the November meeting. But CDC's response failed to address any of the substantive concerns outlined in the experts' letter, including the serious problems with the scientific evidence review that concluded that surgical masks were as effective as NIOSH-approved N95 respirators in protecting against transmission of infectious aerosols.

Moreover, CDC has indicated that it has no plans to open-up the process to seek the input and involvement of other experts in key disciplines (e.g., industrial hygiene, respiratory protection, and ventilation), healthcare workers and unions and patient representatives in the development of the draft guidelines. Rather, CDC intends to rely on HICPAC – a committee that is composed almost exclusively of infection control professionals from hospitals and other medical organizations to develop the recommendations. Other stakeholders and the public will be allowed to provide written comments **after** HICPAC votes on recommended guidelines, with the barest minimum of input during their development.

At the most recent HICPAC meeting on August 22, 2023, only 45 minutes were allowed for 14 members of the public to present oral comments to the committee, out of the many more who wanted to speak. CDC limited written comments to one page.¹ All who spoke expressed deep concerns about the failure of the proposed draft guidelines presented in June 2023 to protect healthcare workers and patients. Many relayed their personal experiences of being infected because of the lack of protections in

¹ 88 Fed. Reg. 45426 (July 17, 2023). <https://www.govinfo.gov/content/pkg/FR-2023-07-17/pdf/2023-15038.pdf>

healthcare settings. Others shared that due to being at increased risk, they or family members were not seeking necessary medical care afraid that they would become infected and seriously ill.²

Unfortunately, there is no indication that HICPAC or CDC are taking the concerns that so many have raised into account. During the August 22, 2023, meeting, there was no acknowledgement of or response to any of the issues and serious concerns raised by the public at the previous HICPAC meeting in June, in the experts' letter or other earlier written comments.

We have no confidence that the HICPAC process will produce recommended guidelines that are responsive to these concerns and provide strong protections; and instead, will simply reflect the views of the healthcare industry.

We urge you to take a different course that provides for broad meaningful participation and input on the development of the Isolation Precautions Guidelines.

Specifically, we ask CDC, itself, not HICPAC, to convene public meetings that involve all key experts, healthcare workers, patients, other stakeholders, members of the public and other agencies to seek input on the scientific evidence on transmission and risk, recommended infection control measures and real-world experiences in healthcare settings.

This was the exact approach followed by CDC in the 1990's in response to another infectious disease of broad concern—tuberculosis— when it updated the Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities.

In October 1992, CDC convened a two-day public meeting to bring together a broad range of experts and stakeholders to seek input on updating the tuberculosis guidelines:

"Announcement of Meeting on Tuberculosis Prevention in Health-Care Facilities

CDC will sponsor a meeting, "Issues in Preventing Tuberculosis Transmission in Health-Care Facilities," October 22-23, 1992, in Atlanta. The goal of the meeting is to review and assess the need to revise CDC guidelines for reducing the risk for tuberculosis (TB) transmission in health-care settings (1).

The meeting will bring together experts in TB prevention and control, nosocomial infection prevention, biosafety, and occupational safety and health, as well as representatives of labor, medical, hospital, and administration organizations. Topics will include patient management; TB isolation precautions; engineering controls, such as ventilation and ultraviolet irradiation; health-care worker TB screening; and personal respiratory protection, including discussion of recent recommendations by CDC's National Institute for Occupational Safety and Health (2).³

The input from this and another public meeting were utilized in developing the draft CDC TB guidelines which were then published in the Federal register for public comment, reviewed by the CDC in crafting the final recommended 1994 guidelines.

² <https://www.youtube.com/watch?v=OqjC26DGr38>. Public comments start at 1:41 of video. We urge you to listen.

³Announcement of Meeting on Tuberculosis Prevention in Health-Care Facilities, MMWR 41(38);716-717
<https://www.cdc.gov/mmwr/preview/mmwrhtml/00017681.htm>

“Public meetings were held in October 1992 and January 1993 to discuss revision of the 1990 TB Guidelines (2). CDC received considerable input on various aspects of infection control, including health-care worker (HCW) education; administrative controls (e.g., having protocols for the early identification and management of patients who have TB); the need for more specific recommendations regarding ventilation; and clarification on the use of respiratory protection in health-care settings. On the basis of these events and the input received, on October 12, 1993, CDC published in the Federal Register the Draft Guidelines For Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition (3). During and after the 90-day comment period following publication of this draft, CDC's TB Infection-Control Guidelines Work Group received and reviewed more than 2,500 comments.”⁴

To provide full public access and involvement, we ask that public meetings on the Isolation Precautions Guidelines be conducted online and allow for sufficient time for questions and discussion.

We also request that CDC establish a public docket on the Isolation Precaution Guidelines on *regulations.gov* and post the presentations, written comments (of any length), summaries, minutes, and proceedings from these public meetings and HICPAC meetings along with any scientific reviews and evidence presented or discussed at these meetings.

We appreciate your consideration of these recommended actions to open-up the process to seek and gain broad input on draft Guidelines on Isolation Precautions that will protect healthcare workers and patients from infections in healthcare settings, and we stand ready to assist CDC in this critical undertaking.

Sincerely,

The undersigned public health experts, health care workers, and public supporters.

**Organizations are listed for identification purposes only.*

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⁴Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994. MMWR 43(RR13);1-132 <https://wonder.cdc.gov/wonder/prevguid/m0035909/m0035909.asp>

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