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The National Voice for Direct-Care RNs

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October 18, 2024

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

Dear Dr. Cohen:
On behalf of our nearly 225,000 members, National Nurses United (NNU), the largest labor union and professional association for registered nurses (RNs) in the United States, monitors policy developments that may impact our members and their patients. Over the past two years, we have expressed grave concerns regarding both the process and content of the Centers for Disease Control's (CDC) updates to foundational infection control guidance for health care settings, the *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, and how proposed updates from CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) would impact the health and safety of nurses and our patients.[1]

While we commend the CDC for making improvements to this process in response to our concerns—including improved transparency in posting meeting materials and recordings, the addition of NNU Health and Safety staff to the Isolation Precautions Guideline Workgroup, and the addition of NNU-state affiliate New York State Nurses Association (NYSNA) Health and Safety staff to HICPAC—we are writing again today to express additional concerns regarding HICPAC's process and proposals from the CDC's Division of Healthcare Quality Promotion (DHQP).

HICPAC continues to undermine public engagement and avoid transparency in its process to update infection prevention guidance for health care settings, despite recent improvements and legal requirements.
We are concerned that HICPAC is not operating fully in compliance with requirements for Federal Advisory Committees. Title 41 CFR § 102-3.150 states that, for federal advisory committees, "(a) A notice in the Federal Register must be published at least 15 calendar days prior to an advisory committee meeting," and that notice must include, among other things, "(6) Instructions for submitting written comments, and oral comments if permitted." When HICPAC published the notice regarding its meeting held on August 22, 2024, it only included instructions for how the public could submit oral public comment; there was no information on how to submit written comments.[2] HICPAC also only included

[1] National Nurses United, "Updates on the CDC Advisory Committee's efforts to weaken infection control guidance for health care," last updated August 28, 2024, https://www.nationalnursesunited.org/cdc-and-hicpac (Accessed October 10, 2024).
[2] Meeting of the Healthcare Infection Control Practices Advisory Committee, 89 Fed. Reg. 63,432 (August 5, 2024)

oral public comment in the notice for the November 14-15, 2024 meeting.[3] Notices for previous meetings included instructions on how to submit both oral and written comments.[4] It is not clear why HICPAC deviated from its requirements and past practice.

Public engagement is key to HICPAC's process.
Federal advisory committees provide important insights and advice to government agencies on policies and, in HICPAC's case, do extensive work to evaluate evidence and formulate drafts that often become or form the basis for official CDC policy. HICPAC has just 14 chartered positions—currently only 11 of which are filled.[5,6] The guidance that HICPAC writes has broad-reaching impacts as it is incorporated into laws and regulations and consulted by health care facilities around the world. The small number of individuals who sit on HICPAC must be able to hear from the public in order to understand the different perspectives, experiences, challenges, and successes that are necessary to crafting infection prevention guidance that is well-rounded, science-based, and implementable.

Both written and oral comments are essential to effective public engagement.
In order for HICPAC members to effectively hear from the public, both written and oral comments are essential. Oral comments ensure that HICPAC members hear from the public while they are deliberating and voting on proposals. When changes are made or proposed during the meeting, it is essential for the public to have a mechanism to provide their insights and responses to HICPAC's discussions *before* HICPAC votes. It was a key improvement in HICPAC's process to rearrange the typical agenda order to ensure that voting occurred only after public comment, not before.[7]

But oral comments alone are insufficient. Limited slots are available for oral comments at each meeting. Additionally, many individuals who work, especially direct care health care workers who have essential insights for HICPAC members to consider, may not be able to take time off to join HICPAC meetings live to provide oral comments. Thus, providing an opportunity to submit written comments—both before and following the meeting—is an essential mechanism for effectively engaging the public.

By failing to solicit written comments regarding its August 2024 meeting, HICPAC decreased transparency and undermined the ability of the public to engage.
It is not only important for HICPAC members to hear from the public, it is also important for the public to be able to view comments submitted to HICPAC. This provides an important level of transparency regarding the context in which HICPAC is assessing

[3] Meeting of the Healthcare Infection Control Practices Advisory Committee, 89 Fed. Reg. 83,688 (October 17, 2024)

[4] For example, see the notice for HICPAC's November 2023 meeting (88 Fed. Reg. 69,931), which invited written public comments between November 1 and 6, 2023 in writing via email to hicpac@cdc.gov.

[5] Centers for Disease Control and Prevention, "HICPAC Charter," updated April 15, 2024, available at https://www.cdc.gov/hicpac/php/about/charter.html (Accessed October 14, 2024).

[6] Centers for Disease Control and Prevention, "HICPAC Roster," updated August 12, 2024, available at https://www.cdc.gov/hicpac/php/roster/index.html (Accessed October 14, 2024).

[7] Prior to the August 2023 meeting, HICPAC's meeting agendas held votes prior to public comment, which was the last item on the agenda. Centers for Disease Control and Prevention, "Previous Meeting Materials," October 4, 2024, https://www.cdc.gov/hicpac/php/meeting-materials/index.html (Accessed October 15, 2024).

science, making decisions, and crafting recommendations. Up to this point, the only mechanism for comments submitted to HICPAC to be made publicly available has been in meeting summaries, which are often posted weeks to months after the meeting date. In failing to include a solicitation for written comments in the August and November 2024 meeting notices, HICPAC has introduced a lack of clarity on whether written comments submitted to HICPAC in the period surrounding the meeting will be included in meeting minutes.

Other CDC advisory committees, like the Advisory Committee on Immunization Practices (ACIP), the Advisory Committee to the Director, and the Board of Scientific Counselors for the CDC's National Institute for Occupational Safety and Health, create a public docket on regulations.gov for each of their meetings.[8,9,10,11] These dockets provide ready access to all public comments submitted regarding the advisory committee's meeting. This is an important level of transparency for these committee proceedings. It is unclear why HICPAC—also an advisory committee to the CDC—is allowed to function so differently from other federal advisory committees at the same agency.

CDC should ensure that solicitation of both written and oral comments is included in the meeting notice for future meetings, including by updating the notice for the upcoming meeting in November, as is required. NNU also encourages CDC to create a public docket for written public comments, similar to other CDC advisory committees to better ensure transparency in this process.

NNU has significant concerns about the draft Recommendations Categorization Scheme presented by DHQP at HICPAC's August 2024 public meeting.

At the August 2024 HICPAC meeting, CDC staff presented an update to the committee on a new draft scheme for categorizing recommendations from HICPAC and DHQP.[12] Since the 1990s, DHQP has used a system to rank recommendations based on the strength of supporting evidence. In the 2010s, DHQP started using the Grading of Recommendations, Assessment, Development, and Evaluations, or GRADE, framework for evaluating evidence to formulate recommendations. The GRADE framework was proposed in the early 2000's

[8] The CDC received 620 public comments regarding the April 2023 Advisory Committee on Immunization Practices (ACIP) meeting. Centers for Disease Control and Prevention, Docket No. CDC-2023-0028 (April 17, 2023), Advisory Committee on Immunization Practices, https://www.regulations.gov/document/CDC-2023-0028-0001.

[9] The CDC received 3,140 comments regarding the February 2024 meeting of the Advisory Committee on Immunization Practices. Centers for Disease Control and Prevention, Docket No. CDC-2024-0001, Advisory Committee on Immunization Practices, https://www.regulations.gov/document/CDC-2024-0001-0001.

[10] The CDC received seven public comments regarding the November 2023 meeting of the Advisory Committee to the Director. Centers for Disease Control and Prevention, Docket No. CDC-2023-0082 (Oct 1, 2023), Advisory Committee to the Director, https://www.regulations.gov/document/CDC-2023-0082-0001.

[11] The CDC received ten public comments regarding the August 2022 meeting of the Advisory Committee to the Director. Centers for Disease Control and Prevention, Docket No. CDC-2022-0083, Advisory Committee to the Director, https://www.regulations.gov/document/CDC-2022-0083-0001.

[12] Stone, E., "Draft Update to the Division of Healthcare Quality Promotion (DHQP) Recommendation Categorization Framework." HICPAC Virtual Meeting, August 22, 2024, available at https://www.cdc.gov/hicpac/media/pdfs/DHQP-RecommendationFramework-HICPAC-August-2024-508.pdf (Accessed October 14, 2024).

to attempt to standardize methods for formulating recommendations based on evidence for health care, specifically focused on clinical interventions and treatments for patients.[13] Since 2017, the Division has established practices related to the types of language used for each category of recommendation (i.e., a recommendation that has strong supporting evidence would include language like "should" vs. a conditional recommendation that has lower quality supporting evidence would use language like "consider").

DHQP is proposing to add a "Good Practice Statement" category to the currently used recommendation ranking scheme. Good Practice Statements are generally considered routine or accepted practice and are not supported by GRADEd evidence. Under this proposal, expert experience and opinion would be sufficient to include such a recommendation to guidance. NNU has multiple concerns with DHQP's proposals.

NNU is concerned that DHQP's draft Recommendations Categories Scheme neglects scientific evidence that is important to shaping robust, science-based public and occupational health guidance.

While the GRADE method's general principles around transparency and standardizing evaluation of evidence align with occupational and public health, GRADE overprioritizes certain types of evidence and deprioritizes others. GRADE directs users to evaluate the strength of evidence using rankings (high, moderate, low, or very low quality). Randomized control trials (RCTs) start as high-quality evidence while observational studies start as low-quality evidence.[14] Rankings can move up or down depending on additional considerations that impact confidence in the study's results (e.g., risks of bias, variability, magnitude of effect, etc.). Recommendations based on that evidence are then rated as either strong (conditional) or weak (discretionary). When it comes to occupational and public health interventions, multiple study methodologies—not just RCTs—can provide valid, reliable results to support recommendations for action. In fact, RCTs are often not feasible and can even be unethical in occupational health (one would not knowingly expose workers to a hazard with no known controls just to create a control group for a study).

Researchers have documented challenges with utilizing RCT study designs to evaluate the complex interventions that are frequently utilized in occupational and public health. For example, Schelvis, Oude Hengel, et al. provided an analysis of challenges with using RCTs to evaluate occupational health interventions, which often involve multiple components, providers, locations, conditions, and outcomes that can be interdependent and thus difficult to standardize (a requirement for RCTs).[15] They go on to provide considerations for multiple alternative study methodologies that are feasible and can provide "sufficiently strong evidence to guide decisions on implementation of interventions in the workplace." This has implications for the use of the GRADE system—which is narrow in the types of epidemiologic evidence it considers—in occupational and public health. A survey of more

[13] GRADE working group, "What is GRADE?" https://www.gradeworkinggroup.org/ (Accessed October 14, 2024).

[14] BMJ, "What is "quality of evidence" and why is it important to clinicians?," 2008, 336: 995.

[15] Schelvis, R.M.C., K.M. Oude Hengel, et al., "Evaluation of occupational health interventions using a randomized controlled trial: challenges and alternative research designs," Scand J Work Environ Health, 2015, 41(5): 491-503.

than two dozen researchers who had utilized GRADE to formulate public health guidance found that the majority reported challenges in implementing the system.[16] The authors noted that, "evidence-based public health guidance… needs to draw on sources of evidence beyond the traditional hierarchy of epidemiological study designs."[17] Public health is, by definition, multidisciplinary and multi-sectoral and is "never context-free," meaning that information about the context in which interventions are implemented, even in RCTs, is necessary to evaluate reliability of the results. In public health, broader sources of evidence are relied on than in clinical settings and can help strengthen the overall confidence in outcomes, but the GRADE system does not account for these factors.

Additionally, the GRADE system deprioritizes evidence that is important for evaluating occupational and public health interventions. One study evaluated systematic reviews that utilized the GRADE method to evaluate either simple or complex interventions.[18] They found that outcomes of complex interventions were much more likely to be categorized as "very low" quality than for simple interventions (37.5 percent of primary benefit outcomes vs. 9.1 percent, respectively). None of the complex intervention reviews were given a "high" GRADE ranking compared to 18.2 percent of simple intervention primary benefit outcomes. The authors note the consequences of these issues: "The main concern associated with the use of the GRADE approach in complex interventions is therefore the risk of dismissing a vast amount of evidence that may alternatively signal important information on generalizable intervention effects."[19] The use of the GRADE system in occupational and public health leaves policymakers with an often unnecessarily limited evidence base from which to formulate recommendations.

NNU is concerned that DHQP's draft Recommendations Categories Scheme could lead to ineffective and even harmful guidance if DHQP continues to consult only a narrow group of experts in infection prevention management.

Expert experience and opinion are necessary to evaluate evidence and formulate recommendations. The GRADE Handbook recognizes that judgment plays a significant role in how evidence is graded— GRADE is not an objective system.[20] It matters who the experts are and that there is appropriate diversity in perspectives to allow for a wholesome evaluation of the evidence to shape and support recommendations. But DHQP has a long track record of relying on very limited types of expertise when formulating guidance, generally excluding other experts with essential insights. This results in unprotective guidance that fails to appropriately protect workers and patients.

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[16] Rehfuess, E.A. and E.A. Akl, "Current experience with applying the GRADE approach to public health interventions: an empirical study," BMC Public Health, 2013, 13:9.

[17] *Ibid.*

[18] Movsisyan, A., G.J. Melendez-Torres, and Paul Montgomery, "Outcomes in systematic reviews of complex interventions never reached ''high'' GRADE ratings when compared with those of simple interventions," J Clinical Epidemiol, 2016, 78: 22-33.

[19] *Ibid.*

[20] Schünemann, H., J. Brożek, et al. (ed.), "GRADE Handbook," updated October 2013, https://gdt.gradepro.org/app/handbook/handbook.html#h.fzuoa9x107cu (Accessed October 15, 2024).

Indeed, several experts have recognized these issues. A review article published by the GRADE Public Health Group, which was established to explore issues related to the use of GRADE in public health, recognizes several common challenges in applying GRADE to public health guidance, including the need to incorporate diverse perspectives in how evidence is reviewed and recommendations are formed to ensure the guidelines have intended impacts.[21]

NNU is concerned that DHQP's proposals to expand the GRADE system to include expert opinion to support Good Practice Statements could have negative impacts on health care worker and patient health and safety. For example, see HICPAC's process to update the 2007 Isolation Precautions guidance document.[22] For many years, there has been very little diversity in the perspectives represented on HICPAC and its associated workgroups; infection prevention managers have and continue to predominate the committee.[23] Until earlier this year, there was no industrial hygiene, aerosol science, respiratory protection, direct care health care workers, patient advocates, or unions, or other expertise important to establishing protective, implementable guidance. Additionally, many of the organizations represented by liaisons to HICPAC represent health care management, such as the American Hospital Association, the America Healthcare Association, the Joint Commission, America's Essential Hospitals, and the American Nurses Association. Only a small proportion represent patients. No liaisons represent direct care health care workers—an omission that should be remedied by adding labor unions representing health care workers to the organizational liaisons roster.

As a result of this narrow set of perspectives, when the Isolation Precautions Guideline (IPG) Workgroup evaluated evidence on a fundamental question—how effective respirators vs. medical masks are in protecting health care workers from respiratory viruses—a limited subset of the available evidence was reviewed and the IPG Workgroup incorrectly concluded that respirators are no more protective than medical masks. This conclusion then shaped guidance updates that were proposed to and approved by HICPAC in November 2023.[24] These proposals limited the use of respirators to only certain pathogens (e.g., measles, varicella, tuberculosis, and novel pathogens) and recommended the use of medical masks for other respiratory pathogens that spread through the air (e.g., seasonal influenza and coronaviruses). Medical masks do not effectively filter infectious aerosols out of the air being breathed in by the wearer and thus do not provide respiratory

[21] Boon, M.H., H. Thomson, et al., "Challenges in applying the GRADE approach in public health guidelines and systematic reviews: a concept article from the GRADE Public Health Group," J Clinical Epidemiology, 2021, 135: 42-53.

[22] National Nurses United, "Updates on the CDC Advisory Committee's efforts to weaken infection control guidance for health care," updated August 28, 2024, https://www.nationalnursesunited.org/cdc-and-hicpac (Accessed October 15, 2024).

[23] Centers for Disease Control and Prevention, "Archived HICPAC Rosters," https://archive.cdc.gov/www_cdc_gov/hicpac/roster_1715951477.html (Accessed October 15, 2024).

[24] Centers for Disease Control and Prevention, "Previous Meeting Materials: November 2-3, 2023," https://www.cdc.gov/hicpac/php/meeting-materials/index.html (Accessed October 15, 2024).

protection.[25] On the other hand, N95 filtering facepiece respirators and other types of respirators are certified to provide a certain level of filtration to the wearer when used as directed by the manufacturer and in the context of a respiratory protection program compliant with the Occupational Safety and Health Administration (OSHA).[26]

This means that HICPAC's November 2023 proposals would have led to health care worker and patient exposures and infections. If occupational health, industrial hygiene, respiratory protection, aerosol science, direct care health care worker, and union expertise had been involved in the process from the beginning, more evidence could have been evaluated, which clearly shows that respirators are more protective and are necessary to prevent transmission in health care facilities.

NNU commends the CDC for adding NYSNA Health and Safety staff to HICPAC earlier this year and NNU Health and Safety staff to the IPG Workgroup, but the reality is that both the HICPAC and the IPG Workgroup are still dominated by infection prevention managers. NNU urges the CDC that additional work is needed to expand the perspectives represented on HICPAC and its IPG Workgroup, including by adding direct care health care workers, patients, their families, unions, and experts in other fields such as respiratory protection, aerosol science, occupational health, and industrial hygiene. Well-balanced perspectives are essential to crafting robust, science-based, implementable infection prevention guidance for health care settings.

In Conclusion

Infectious diseases increasingly pose a threat to health care workers and patients. Health care-associated infections occur at high rates—the CDC estimates that one in 31 hospital patients has at least one health care-associated infection on any given day.[27] There is no systemic tracking of work-related infections among health care workers, but the best available data indicate that health care workers experience a significant burden of infections. Earlier this year, NNU surveyed a national sample of RNs and found that about 65 percent have sustained at least one infection at work, such as the common cold, influenza, Covid-19, methicillin-resistant *Staphylococcus aureus*, norovirus, and tuberculosis.[28] Scientists predict that the risk of another pandemic is high and could double over the coming decades.[29]

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[25] The CDC has noted this multiple times on its website. For example, see the answer to the question "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?" Infection Control Guidance: SARS-CoV-2, June 24, 2024, https://www.cdc.gov/covid/hcp/infection-control/index.html (Accessed October 15, 2024).

[26] 29 CFR §1910.134

[27] Centers for Disease Control and Prevention, "HAIs: Reports and Data," May 7, 2024, https://www.cdc.gov/healthcare-associated-infections/php/data/index.html (Accessed October 15, 2024).

[28] National Nurses United, "NNU Infectious Diseases Survey final results (March-April 2024)," https://www.nationalnursesunited.org/nnu-infectious-diseases-survey-final-results-march-april-2024 (Accessed October 15, 2024).

[29] Marani, M., G.G. Katul, et al., "Intensity and frequency of extreme novel epidemics," PNAS, August 23, 2021, 118(35): e2105482118.

It is clear that the status quo in infection prevention is not sufficient and more work is needed to better prevent the transmission of pathogens within our health care settings. In order to meet these needs, CDC, including DHQP, must continue to take material steps to improve the diversity of expertise engaged in formulating guidance, including by ensuring that both written and oral comments are solicited in the November 2024 HICPAC meeting notice, creating a public docket for written comments regarding HICPAC meetings, adding labor unions representing health care workers to the HICPAC organizational liaisons roster, and continuing to expand the perspectives represented on HICPAC and its IPG Workgroup to ensure a well-balanced, diverse membership that includes direct care health care workers, patients, their families, unions, and experts in fields in addition to infection prevention, including respiratory protection, aerosol science, occupational health, and industrial hygiene.

NNU's members, as bedside RNs, have extensive scientific training and regularly utilize data to formulate assessments, implement interventions, and evaluate the effectiveness of those interventions. Through providing hands on care to patients in health care facilities across the nation, RNs play an essential role in implementing infection prevention plans and thus have important expertise to share. NNU stands ready to assist the CDC in formulating science-based, implementable guidance that protects health care workers, patients, and their families from infectious diseases.

If you have any questions or wish to meet regarding these matters, please contact Eleanor Godfrey, NNU's Health and Safety Division Director, at egodfrey@nationalnursesunited.org.

Sincerely,

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President, National Nurses United