

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion**



Healthcare Infection Control Practices Advisory Committee

June 8-9, 2023

Atlanta, Georgia

Record of the Proceedings

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Attendees

HICPAC Members

Elaine Dekker, RN
Mohamad Fakih, MD, MPH
Judy Guzman-Cottrill, DO
Colleen Kraft, MD, MSc
Jennie H. Kwon, DO, MSCl
Michael Lin, MD, MPH
Erica Shenoy, MD, PhD
JoAnne Reifsnyder, PHD, MBA, MSN
David Jay Weber, MD MPH
Sharon Wright, MD, MPH

Ex Officio Members

Jasmine Dhindsa, MD, Centers for Medicare & Medicaid Services (CMS)
David Henderson, MD, National Institutes of Health (NIH)
Jimi Risse, RN, Indian Health Service (IHS)
Leyi Lin, MD, Agency for Healthcare Research and Quality (AHRQ)
LCDR Scott Steffen, PhD, CQIA, CQI, Food and Drug Administration (FDA)

Liaison Representatives

Lilian Abbo, MD, MBA, Infectious Disease Society of America (IDSA)
Nicole Anselme, PhD, MBA, MSM, American Nurses Association (ANA)
Hilary Babcock, MD, MPH, Society for Healthcare Epidemiology of America (SHEA)
Kristina Bryant, MD, American Society of Nephrology (ASN)
Natalie Bruce, MScN, BScN, Public Health Agency of Canada (PHAC)
Maureen Carew, MD MSc FRCPC, Public Health Agency of Canada (PHAC)
Paul Conway, American Association of Kidney Patients (AAKP)
Eve Cuny, MS, Organization for Safety, Asepsis and Prevention (OSAP)
Karen DeKay, MSN, RN, CNOR, CIC, Association of periOperative Registered Nurses (AORN)
Jasmine Dhindsa, MD, Centers for Medicare & Medicaid Services (CMS)
Hana E. Hinkle, PhD, MPH, National Rural Health Association (NRHA)
Lisa McGiffert, Patient Safety Action Network (PSAN)
Riza Mauricio, PhD, RN, CPNP-PC/AC, FCCM, CCRN, Society of Critical Care Medicine (SCCM)
Karen Ravin, MD, Pediatric Infectious Diseases Society (PIDS)
Mark Russi, MD, MPH, American College of Occupational and Environmental Medicine (ACOEM)
Robert Sawyer, MD, Surgical Site Infection Society (SIS)
Benjamin Schwartz, MD, National Association of County and City Health Officials (NACCHO)
Sarah Smathers, MPH, CIC, FAPIC, Association for Professionals in Infection Control and Epidemiology (APIC)
Stephanie Taylor, University of Michigan, Society of Hospital Medicine (SHM)
Tiffany Wiksten, BSN, APN, DNP, The Joint Commission (TJC)

CDC Representatives

Michael Bell, MD
Sydnee Byrd, MPA
Beth Golshir, MPH
Alexander J. Kallen, MD, MPH
Aaron Kofman, MD
David Kuhar, MD
Michele Neuburger, DDS, MPH
Erin Stone, MPH
Laura Wells, MA

Members of the Public

Yaneer Bar-Yam, PhD, Professor & President, New England Complex Systems Institute, Co-Founder, World Health Network

Lisa Brosseau, ScD, CIH, Center for Infectious Disease, Research, and Policy, University of Michigan

Kathleen Fagan, MD, MPH, Occupational and Environmental Medicine

Mary Kathryn (MK) Fletcher, MSPH, Safety & Health Specialist, AFL-CIO

Greta Fox, MS, Nurse Practitioner, Founding Member, World Health Network (WHN)

Deborah Gold, Retired Annuitant, Cal/OSHA

Barry Hunt, President, Canadian Association of PPE Manufacturers; President & CEO, Prescientx; Vice Chair, Coalition for Healthcare-Acquired Infection Reduction (CHAIR)

Jester Jersey, Vaccine Advocate

Lara Zeina Jirmanus, MD, PhD, Speaking on Behalf of Massachusetts Coalition for Health Equity

Dheerendra Kommala, MD, Chief Medical Officer, Emergency Care Research Institute (ECRI)

Kevin Kavanagh, Health Watch USAsm

Barbara Materna, Retired Chief, Occupational Health Branch, California Department of Public Health

Roy McAllister, United Food and Commercial Workers (UFCW)

Mary E. Miller, NP, Retired Occupational Health Nurse Practitioner, Representing the Occupational Health and Safety Section of the American Public Health Association

Nathanael Nerode, Representing Himself & Partner

Mark Nicas, PhD, MPH, CIH, Emeritus, Adjunct Professor, University of California, Berkeley

Shimi Sharief MD, MPH, Physician/Public Health Practitioner

Darius Sivin, PhD, Industrial Hygienist, United Auto Workers (UAW)

Kaitlin Sundling, MD, PhD

Jane Thomason, MSPH, BA, National Nurses United

Rita Valenti, RN (retired), Concerned Community Advocate and Volunteer, People's CDC

Stephanie Wallace, PhD, MS, Cambridge Communications & Training Institute (CCTI)

Andrew Wang, PhD, Federally Qualified Healthcare Center (FQHC)

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Kerri Wizner, MPH, CPH, Occupational Epidemiologist, Representing the Occupational Health and Safety Section of the American Public Health Association

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Healthcare Infection Control Practices Advisory Committee (HICPAC)

June 8-9, 2023
Atlanta, Georgia

Minutes of the Meeting

The United States (US) Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) convened a hybrid meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC) on June 8-9, 2023.

Thursday: June 8, 2023

Call to Order / Roll Call / Announcements

**Sydnee Byrd, MPA, Program Analyst
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention**

**Michael Bell, MD
HICPAC Designated Federal Officer (DFO)**

Ms. Byrd called to order the June 8-9, 2023 HICPAC meeting at 9:03 AM Eastern Time (ET), welcomed everyone, and called the roll. Quorum was established and maintained throughout the meeting. HICPAC members disclosed the following conflicts of interest (COIs):

- Dr. Judy Guzman-Cottrill is a consultant for Oregon Health Authority's Healthcare-Associated Infections (HAI) Program.
- Dr. Colleen Kraft is a scientific advisor for Seres Therapeutics and a consultant for Rebiotix Inc.
- Dr. Michael Lin receives research support in the form of contributed products from OpGen, LLC and Sage Products, which is now a part of Stryker Corporation. He previously received an investigator-initiated grant from CareFusion Foundation, which is now part of BD.
- Dr. Kristina Bryant receives research support from Gilead and Pfizer.

Ms. Byrd indicated that public comment was scheduled following the presentations. She explained public comments would be limited to 3 minutes each, and that commenters should state their names and organization for the record before speaking. She reminded everyone that the public comment period is not a question and answer (Q&A) session.

Dr. Bell expressed gratitude to those in attendance in-person and via Zoom, noting that HICPAC is in a transition phase of a fully remote experience of the last 2 years to its first partially in-person meeting. It is still not possible to open meetings for in-person attendance of all public participants. While only members, liaisons, and *ex officios* were present in the room, over the course of time, it is anticipated that HICPAC eventually will be open in-person to all participants. He thanked everyone for their participation in the interim. He expressed excitement about welcoming new members to this meeting and lamented the less happy issue of saying farewell to those whose time with HICPAC was coming to an end. He emphasized that the end is never really the end with a capital "E." HICPAC tends to have long and enduring relationships and looks forward to that being the case. He welcomed several new members, *ex officio* members, and liaison members and bid farewell to members whose term was ending:

New Members

- Dr. Jennie Kwon: Associate Professor of Medicine, Medical Director of Infection Prevention and Control, and Senior Epidemiologist in the Division of Infectious Diseases at Washington University. Her focus is on antimicrobial resistance and related epidemiology.
- Dr. Erica Shenoy: Chief of Infection Control, Mass General Brigham; Associate Chief, Infection Control Unit, Massachusetts General Hospital; and Associate Professor, Harvard Medical School. Her focus is on clinical, operational, and economic impact of infection control strategies related to a variety of pathogens. She has an additional focus on mathematical modeling, electronic health record (EHR) use, applied machine learning (ML), among others.
- Dr. David Weber: Charles Addison and Elizabeth Ann Sanders Distinguished Professor of Medicine, Pediatrics and Epidemiology in the University of North Carolina (UNC) School of Medicine and UNC Gillings School of Global Public Health; Associate Chief Medical Officer, UNC Medical Center; Medical Director, Department of Infection Prevention at UNC Medical Center.

New Ex Officio Members

- Dr. Jasmine Dhindsa (CMS): Internal Medicine and Infectious Disease Physician; Director of Infection Control in a large hospital; and has worked in the past for the Defense Health Agency (DHA) and the Washington State Medicaid System. She is currently representing CMS as the Chief Medical Officer for the New York Region.

New Liaison Members

- Dr. Lilian Abbo (IDSA): Associate Chief Medical Officer for Infectious Diseases Jackson Health System; and Professor of Clinical Infectious Diseases University of Miami Miller School of Medicine and the Miami Transplant Institute (MTI).
- Jimi Rissi, RN, CIC (IHS): Nurse and Infection Prevention and Control Coordinator for the Office of Quality at the IHS. She is a registered enrolled member of the Oglala Lakota Tribe. She has a focus on rural health settings, including Medical Surgical Units (Med/Surg) and Emergency Departments (EDs) in multiple small jurisdictions.

Farewells

- Elaine Dekker, RN, CIC who has been with HICPAC since 2018. She has served admirably from California at the Priscilla Chan and Mark Zuckerberg San Francisco General Hospital & Trauma Center (ZSFG) where she serves as the Infection Prevention & Control Program Manager. HICPAC has had the tremendous benefit of her practical experience and extensive understanding of how to get people to do the right thing even when it is really hard. HICPAC looks forward to having her continued expertise on the Isolation Guideline Working Group.
- Dr. JoAnne Reifsnyder, Executive Vice President of Clinical Operations at Genesis HealthCare, who has been a stellar member of HICPAC who brought a perspective of long-term care and the management of health systems and health system interactions. Dr. Bell first met Dr. Reifsnyder at a meeting where he listened to her speak and recognized that she had a special perspective that could benefit HICPAC.
- Dr. Mohamad Fakih, Vice President of Quality and Clinical Integration at Ascension, who has been an exceptional HICPAC member who has provided frontline practical health systems experience and asked some of the most helpful, insightful, and challenging questions through his years with the committee. He will continue to work with HICPAC into the future.

Division of Healthcare Quality Promotion (DHQP) Update

Michael Bell, MD HICPAC Designated Federal Officer

Dr. Bell provided a brief DHQP update. There have been tremendous activities over the course of the past few years. The extent of growth and reach that has been accomplished over the past few years and the amount of work that has been done in terms of growing the ability to collect data has been incredible. First, the National Healthcare Safety Network (NHSN) surveillance system was expanded to encompass nursing homes and skilled nursing facilities (SNFs) in a way that was unprecedented. While DHQP thought there had been a large growth spurt from 300 to 5000 facilities, they are now at 38,000 facilities. That took an incredible amount effort for which Dr. Bell thanked DHQP's in-house team and their partners in health systems and healthcare facilities. This growth experience is anticipated to yield tremendous value over the coming decades, so they are focused on and planning for continuation of this effort despite current challenging times. Second and although not directly related to HICPAC and infection control, the vaccine safety monitoring program has been an incredible area of growth and a very important asset in everything that CDC does. Vaccines are certainly important tools from the infection prevention perspective, and it is important to ensure that all vaccines are safe. Third, another incredible activity has been the insane and complex efforts that went into creating and then adjusting COVID-19 guidance from week-to-week and month-to-month to accommodate changing understanding, patterns, risk factors, and capabilities. These efforts are ongoing and even the winding down of the public health emergency has included a great deal of work on that front. Fourth, Alexander J. Kallen, MD, MPH will be taking over as the HICPAC DFO this year.

In the background, there is always a tremendous amount of work. The Guidelines Evidence Review Team has worked on not only COVID-related guidance, but also risk factors for severe disease and helping other parts of the agency. The Epidemiology, Research, and Innovations Branch has been involved in a lot of modeling and assessing some of the data streams

available to them. There also are the Modeling Infectious Diseases in Healthcare Network (MInD-Healthcare) group, massive outreach to state health departments, and leveraging of investments that have been made throughout the decades with state health departments and state health laboratories. That network has allowed healthcare-associated infection (HAI) and healthcare-associated COVID efforts to extend into communities and toward the frontlines in ways that would not be possible otherwise. Dr. Bell emphasized that while there were many other facets to share, but he would stop here in the interest of time.

Isolation Precautions Guideline Workgroup Update

General Overview of Framework & Proposed Sections A, B, and C

Sharon Wright, MD, MPH

Michael Lin, MD, MPH

Co-Chairs, Isolation Precautions Guideline WG

Dr. Wright reminded everyone that the findings and conclusions being shared during this session were draft, had not been formally disseminated by the CDC, and should not be construed to represent any agency determination or policy. She reviewed the agenda for this session, which included a general overview regarding the process by which the Isolation Precautions Guideline Workgroup (WG) has been developing this work; key concept updates to the proposed guidance concepts for Sections A, B, and C; and the renaming of isolation precautions transmission categories. Additionally, an Evidence Review was presented by Erin Stone on behalf of the CDC Office of Guidelines and Evidence Review Team, and there was an open discussion period.

Starting with the overview, Dr. Wright reported that the WG goal over the last 2 years has been to create an update to the 2007 Isolation Precautions Guideline in order to: 1) create a more concise guideline that is suitable for use on mobile devices; 2) provide an updated scientific foundation for how pathogens spread in the healthcare setting; and 3) recommend new categories of transmission-based precautions intended to be applicable to all healthcare settings instead of having separate guidance for different settings, for example for nursing homes.

In terms of the development process that was used, the 2007 Isolation Precautions Guideline was reviewed for its current content and compared to other existing CDC documents, with a focus on narrowing the scope of the new guideline and appropriately dispersing other important information to documents that already exist, such as the Core Practices, other existing CDC guidelines (e.g., Environmental Infection Control documents), and new guidelines or white papers in the future, as appropriate. The 2007 Guideline structure contains the following sections:

Part I: Scientific Data

Part II: Fundamental Elements

Part III: Precautions

Part IV: Recommendations

Appendix A

The outline structure of the 2024 Guideline will include the following:

Part 1: Scientific Data, Fundamental Elements, Precautions, Recommendations (*the focus of this session*)

Part 2: Appendix A (*the focus of future HICPAC meetings*)

The first 4 components of the 2007 Guideline constitute 45 pages, which the WG hopes to reduce to 10 to 15 pages in Part 1 of the new 2024 Guideline. The new Part 1 will define the new transmission framework and evidence base and focus on modes of transmission of infection and prevention. The 2024 Guideline outline details are depicted in the following table:

2024 Label	2024 Title
Part 1	Section A Overview of Transmission of Pathogens in Healthcare Settings
	Section B Fundamental Elements Needed to Prevent Transmission of Infectious Agents in Healthcare Settings
	Hand Hygiene
	Personal Protective Equipment (PPE) for Healthcare Personnel
	Section C Precautions to Prevent Transmission of Infectious Agents
	Standard Precautions
	Transmissionbased Precautions
Part 2	Type and Duration of Precautions Recommended for Selected Infections and Conditions

Dr. Wright began with a summary of Section A, Overview of Transmission of Pathogens in Healthcare Settings. Transmission is a process by which a pathogen can leave an infected or colonized individual or reservoir and arrive at the body site of an affected at-risk individual and cause infection. Whether transmission occurs is determined by the pathogen, environmental factors, and host factors at the time of the event. Pathogen factors are largely biologically intrinsic, including viability during transit. Environmental and host factors may vary over time and by location and include air conditions (e.g., temperature, humidity, ventilation) and surface conditions (e.g., material, porosity). Host factors include non-immune defenses (e.g., intact skin) and immunity (e.g., prior infection, vaccination).

Not all infections are uniform in severity or consequence. On the basis of the health impact an infection has on an individual in the community, some pathogens are recognized as requiring intensive efforts to prevent morbidity and mortality, while others do not rise to that level. Less intensive effort might be indicated when outcomes are not usually severe, the population has a high degree of immunity, and effective therapeutics and vaccines are available. The boundaries describing these categories require risk assessment over time by public health leaders, healthcare epidemiologists, and society at large and can vary depending upon the setting and the exposed population.

Transmission can occur by air and by touch. Pathogens generally spread via a major pathway, though minor pathways may contribute to spread. Pathogen transmission epidemiology is informed by observing patterns of infection transmission. Pathogens can transmit via air over short distances through direct splash or spray of the pathogen onto a part of the body, or variably across ranges of distance and time via suspended infectious particles. Historically, the infection prevention community has categorized transmission of respiratory pathogens as “droplet” or “airborne.” While these epidemiologic terms reflect observed patterns of short versus long distance transmission respectively, the terms do not explicitly describe a continuum of respiratory pathogen transmission through the air. All pathogens that spread via the air

preferentially transmit over short distances due to greater concentrations of infectious particles in the air near an infectious person. However, each pathogen has a signature pattern of observed transmission that extends variably across short-to-long distances and over time, reflecting unique characteristics of pathogen durability while suspended in the air or the required dose for causing an infection in a susceptible host.

Transmission via touch occurs through physical contact with the pathogen. Transmission in healthcare settings can occur via intact skin; via non-intact skin, including percutaneous routes such as needlestick injury; or via contact with mucous membranes of the face and gastrointestinal tract. Transmission by touch can involve intermediary reservoirs such as people, surfaces, or equipment that facilitate spread.

Recommendations for transmission-based precautions utilize multiple layers of intervention (e.g., hierarchy of engineering and administrative controls, and personal protective equipment (PPE)) that can exist in healthcare settings to reduce transmission risk.

Dr. Lin reviewed Section B, Fundamental Elements Needed to Prevent Transmission of Infectious Agents in Healthcare Settings. In terms of concepts related to masks and respirators as described in section B, PPE worn over the nose and mouth has 3 primary functions, which are to block direct splashes to the mucous membranes of the nose and mouth; contain exhaled respiratory secretions (e.g., source control); and provide filtration of inhaled air. Different devices have different abilities to perform these functions. Factors influencing selection include, but are not limited to, pathogen-associated morbidity and mortality from infection; amount of aerosols of infectious respiratory particles anticipated to be present; lack of effective treatment or vaccine; and the transmissibility of the pathogen.

This section discusses the importance of fit for masks and respirators. Well-fitted masks fit closely against the face, especially along the edges of the mask, to minimize the ability of air to bypass the material of the mask (e.g., medical/surgical mask that fits well alone or with knotted ear loops or mask fitters, facemasks conforming to ASTM F3502-21). For respirators, “fit” concerns the importance of limiting the amount of inhaled air coming from leaks around the respirator since that air is unfiltered. Examples of respirators include disposable filtering face pieces [such as N95 respirators], elastomeric respirators, and powered air purifying respirators [PAPRs].

In terms of source control, individuals breathing, speaking, or coughing generate aerosols of respiratory secretions that can contain infectious organisms. A mask or respirator reduces the amount of secretions released into the environment by the wearer, reducing exposure of people in a shared space to respiratory pathogens. The 2007 Guideline focused on symptomatic source patients only. The updated guidance includes patients, healthcare personnel (HCP), and visitors who may be infectious and not yet symptomatic. The updated guidance also recommends consideration of use of source control during periods of high local prevalence of acute respiratory viral infections for all individuals entering a healthcare facility or a part of the facility where patients at risk for more severe outcomes are housed.

Eye protection should be considered when caring for patients who might not be able to effectively contain their coughs wearing a mask (e.g., children) and to reduce the risk of inadvertent self-inoculation (e.g., providing a barrier to prevent the wearer from rubbing their face with a soiled hand). Selection of a device or combination of devices for eye and face protection depends upon the extent and nature of coverage needed.

Regarding gowns and gloves, the function of gowns and gloves remains unchanged from the 2007 Isolation Precautions Guideline; however, the indications for use of gowns and gloves in skilled nursing facilities (SNF) have evolved since the 2007 guideline and will be discussed in Section C.

Dr. Lin then described Section C, Precautions to Prevent Transmission of Infectious Agents. This section contains Standard Precautions as a foundational aspect of infection prevention. Components of Standard Precautions, which are further described in CDC's Core Practices, include the following:

- Hand hygiene
- Environmental cleaning and disinfection
- Injection and medication safety
- Risk assessment with use of appropriate personal protective equipment (e.g., gloves, gowns, facemasks) based on activities being performed
- Minimizing potential exposures (e.g., wearing a mask when respiratory symptoms are present)
- Reprocessing reusable medical equipment between each patient or when soiled

There are several key points with regard to Standard Precautions. Standard Precautions have multi-directional benefits, including protecting HCP from acquiring infections from patients and preventing HCP or the healthcare environment from transmitting pathogens to patients. Performing a risk assessment is central to Standard Precautions. HCP assess their risk of exposure to potentially infectious materials for each activity being performed and implement practices and PPE to prevent possible exposure. HCP might not anticipate all potential opportunities for exposure. Facilities may choose to systematically apply elements of Standard Precautions to situations likely to present a risk of pathogen transmission (e.g., PPE ensembles for specific procedures or encounters).

The remainder of this presentation focused on transmission-based precautions, which are used when the routes of transmission are not completely interrupted using Standard Precautions alone. Transmission-based precautions employ multiple types of precautions for pathogens that have multiple routes of transmission (e.g., disseminated varicella zoster infection). Transmission-based precautions are a foundational component of patient and HCP safety when applied promptly and early, including empiric application. Transmission-based precautions may change as the understanding of transmission and immunity to infection evolve over time, and they take advantage of multiple layers of interventions (e.g., PPE, rooming, ventilation, disinfection) to reduce the risk of transmission. To update the transmission-based precautions guidelines, the Isolations Precautions WG asked the CDC Office of Guidelines and Evidence Review (OGER) Team led by Erin Stone to perform targeted evidence reviews for 3 key questions.

Evidence Review

Erin Stone, MPH, MS, MA
Public Health Analyst
Office of Guidelines and Evidence Review
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Ms. Stone thanked the Isolations Precautions Guideline WG for the opportunity to present and for their input on the draft evidence reviews conducted at the request of HICPAC in their process of updating the general categories of transmission-based precautions. These reviews are not intended to inform pathogen-specific implementation of transmission-based precaution categories. The reviews were developed and executed to answer the following 3 questions:

1. For healthcare personnel caring for patients with respiratory infections, what is the effectiveness of medical/surgical masks compared with N95 respirators in preventing infections?
2. For healthcare personnel caring for patients with respiratory infections, what is the effectiveness of adding eye protection, compared to no eye protection, in preventing infection?
3. What is the effectiveness of *risk-based* application of gown/gloves, or gloves alone, in preventing transmission of pathogens?

OGER followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) protocols in the systematic methods used to answer the questions. The internal validity of individual studies was assessed using scales developed by DHQP. The results of studies were then aggregated by outcome and evaluated across the domains of strength, direction, consistency, directness, and overall confidence. The results of these evaluations are represented by icons in the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach. The evidence snapshot tables summarize the overall confidence in the evidence and the icons within them represent strong concerns (red circle), moderate concerns (yellow triangle), or no concerns (green circle) with the overall evidence for each outcome of interest.

Beginning with the evidence for Question 1 pertaining to N95 respirators compared to medical/surgical masks for preventing infection in healthcare personnel, the outcomes found in the evidence were all laboratory-confirmed pandemic and seasonal viral respiratory infections (VRIs). These were analyzed and stratified by the following sub-groups:

- a) Pandemic laboratory-confirmed VRIs (SARS-CoV-2, SARS-CoV-1, H1N1 influenza)
- b) Seasonal laboratory-confirmed VRIs (adenoviruses; human metapneumovirus; coronavirus 229E/NL63; parainfluenza viruses 1, 2 and 3; influenza viruses A and B; respiratory syncytial virus A and B; rhinovirus A/B; coronavirus OC43/HKU1)

For all laboratory-confirmed VRIs, 13 studies were retrieved from the literature, and the quantitative results for the outcomes of importance were meta-analyzed, and stratified by pandemic and seasonal outcomes. For the outcome of all VRI, the meta-analysis suggests no difference among HCP wearing N95 respirators and those wearing surgical masks. There were strong concerns with the strength of this evidence. There is serious confounding, among all studies. Confounding means that there are factors that could offer alternate explanations for the results we see, and for these studies confounding factors can include patient masking, eye protection use, co-worker and community exposures, and the context of the task in which the HCP wore the mask. Further, over half of these studies were retrospective in nature, which raised the concern of recall bias, or memory, affecting the results. Many of these studies did not report on compliance or did not report compliance that was measured objectively with either mask type, further, mask and respirator fit was not assessed in a majority of the pandemic

studies. When examining the precision of results across the body of evidence, of the 10 studies that reported confidence intervals, 8 were wide which further reduces our confidence in these findings. In terms of directionality across these studies, there was high heterogeneity in the directionality of results. When taken as a whole, this could result in no difference in the estimate of effect. All of the studies were conducted in the populations and settings of interest. When all of these concerns are taken as a whole, there are concerns with the overall confidence in the evidence because it may change with new publications.

When sub-analyzed according to pandemic or seasonal, the results were similar. The data suggests no difference in the outcome of lab-confirmed seasonal VRI or the outcome of lab-confirmed pandemic VRI among healthcare personnel when comparing N95 respirators and surgical masks. The strongest data, consisting of 4 randomized control trials (RCT) reporting the outcome of seasonal VRI among healthcare personnel were subject to similar concerns with confounding as noted in the main analysis. All 4 studies reported wide confidence intervals and inconsistencies, which led to the assessment of moderate confidence in the results.

For the outcome of pandemic laboratory confirmed VRI, the data similarly suggests no difference in these outcomes among HCP wearing N95 respirators or surgical masks, however this data are subject to similar confounding concerns as noted previously. These data come from cohort studies and retrospective case control studies. The retrospective data brings additional concerns for recall bias in over half of the studies. Importantly, this meta-analysis has high heterogeneity (seen in the I^2 score of 87%). Heterogeneity this high means we have very low confidence in the results of this meta-analysis. There are similar strong concerns for precision in this analysis. However, since the peak of the included pandemics (SARS CoV-1 and SARS CoV2) have passed, we have moderate confidence that these results will not change.

Any differences in adverse events (AEs) between N95 respirators and masks, were assessed across a series of physical, and psychological and emotional, and job performance-related outcomes. The data suggest no difference in vital signs between masks and N95 respirators. Specifically for SpO₂ and heart rate. The directionality was inconclusive for pCO₂. Difficulty breathing, headaches, and dizziness were more frequently reported among N95 respirator users than surgical mask users. The data suggest there was no difference in nausea, but there was a very small number of studies reporting this outcome, and these had small denominators.

There was quite a bit of data for skin issues, with 14 studies reporting these outcomes. The data suggests no difference in dermatitis and itching between masks and N95 respirators; however, outcomes such as pressure injuries, skin damage, and acne were reported more frequently among N95 respirators. OGER did not expect that the publication of new data would change the results for the majority of these skin outcomes.

For psychological adverse events, the evidence suggests that fatigue is more frequent in N95 respirator users than in surgical mask users. It is important to keep in mind that data were collected for many of these studies in the context of the pandemic, so fatigue could be highly confounded by hours worked, duration of PPE use, and number PPE items worn. Difficulty talking and work interference were reported more frequently among N95 respirator users than in surgical mask users. Finally, results for difficulty concentrating were inconsistent across studies and, therefore, inconclusive.

Moving to the second question regarding the addition of eye protection (e.g., goggles, glasses, face shields) compared to no protection, the primary outcome was laboratory-confirmed pandemic VRIs. Therefore, VRIs included:

- a) Laboratory-confirmed SARS-CoV-1
- b) Laboratory-confirmed SARS-CoV-2

The overall evidence from 11 studies suggested protection from the addition of eye protection. OGER assessed that there were strong concerns for confounding in this data as they had with the series of studies for masks. There were strong concerns for strength and precision in this dataset, so the overall confidence in this evidence base was low. Splitting the 11 studies into laboratory-confirmed SARS-CoV-1 and laboratory-confirmed SARS-CoV-2, there was still a suggestion of benefit. However, the confidence intervals did not cross the null because there were only 3 studies for SARS-CoV-1. There was stronger confidence in the SARS CoV-1 evidence because it is unlikely SARS-CoV-1 will occur again in the same manner, despite the likelihood of new pandemics.

Data still may be published for SARS-CoV-2 and eye protection, which lowers confidence overall findings won't change with the publication of new data. Most of the heterogeneity in the primary meta-analysis came from the SARS-CoV-2 studies. For all SARS-CoV-2 -related eye protection and masking meta-analyses the I^2 was very high. AEs were aggregated into job performance-related, physical, and psychological and emotional AE outcomes. A total of 13 studies were identified for job performance-related AEs. The addition of eye protection was found to result in an increase in fogging and decreased visibility. For physical adverse events, across 14 studies, the addition of eye protection was associated with an increase in headaches and skin reactions with a duration of use longer than 4 hours. Finally, for psychological and emotional adverse events, the evidence was inconclusive on any association between these outcomes and the addition of eye protection.

Specific to Question 3, in the phrase “risk-based use of gowns and gloves”, “risk-based” can mean patient risks (e.g., target certain patient-level factors other than Multidrug-resistant organism (MDRO) status, such as presence of wound or device) or task risk (e.g., tasks involving direct patient contact versus indirect/no patient contact). The outcomes retrieved in the data included:

- a) Pathogen colonization acquisition (*Staphylococcus aureus*)
- b) HCP self-contamination of gown/glove: a surrogate marker (Methicillin-resistant *Staphylococcus aureus*, resistant gram-negative bacteria)

Only one study reported on *Staphylococcus aureus* (*S. aureus*) colonization acquisition by patients. While this study showed a reduction, it is important to highlight the limitations which include that there were only 221 patients and this was a pilot study. Because of its size and the fact that there is only one study, OGER expressed strong concerns about the strength, precision, consistency, and confidence in the overall evidence. This will likely change with publication of additional evidence examining the targeted use of gowns and gloves. It is important to note that this study also implemented targeted gown and glove use as a part of a multi-component implementation strategy including education and human factors engineering (HFE) interventions such as where to locate the gowns and gloves to encourage their use.

For indirect outcomes, two studies were identified that examined the association between routine care activities and the contamination of gowns and gloves. These 2 studies reported on Methicillin-resistant *S. aureus* (MRSA) contamination of HCP PPE. It is important to note that there are 4 studies total in this section of data. However, these 4 studies at their core are 2 studies that report outcomes for two different bacteria: MRSA and Resistant Gram-negative Bacteria (RGNB). For example, the data for Pineles 2017 (MRSA) and Blanco 2018 (RGNB) were collected at the same time. While the data for Roughmann 2016 (MRSA) and Blanco 2017 (RGNB) were also collected at the same time. There were multiple tasks, or activities, assessed for PPE contamination in each study. The outcome of MRSA contamination of gowns and gloves, was associated with dressing and providing hygiene to a resident, which could include brushing teeth or combing hair. For the outcome of RGNB contamination of gowns and gloves, there was no consistency in which activities were associated across both studies. Each of these studies examines contamination for different HCP patient care activities, and there were about 15 activities included across the four studies. There are strong concerns with the strength of this evidence because all of these studies are at risk of confounding by delivery of concurrent healthcare, HCP training, patient characteristics, and the location of contamination on the gowns. Of the total studies, 4 studies did not report power calculations and it was unclear whether they were adequately powered to detect a result. There were strong concerns with precision because some of these studies also did not report confidence intervals, and when they were reported, the confidence intervals were wide. The combination of these assessments resulted in an overall lower confidence in the evidence for these outcomes.

Transmission-Based Precautions

Sharon Wright, MD, MPH

Michael Lin, MD, MPH

Co-Chairs, Isolation Precautions Guideline WG

Dr. Wright began the transmission-based precautions discussion by reviewing the draft framework of the Transmission-Based Precautions to Prevent Transmission by Air.

She explained that the first category, Routine Air Precautions, is focused on reducing transmission of common, often endemic respiratory pathogens that spread predominantly over short distances based on observed patterns of transmission, and for which individuals and their communities are likely to have some degree of immunity. Example pathogens include seasonal coronavirus and seasonal influenza.¹ For this precaution category, a medical/surgical face mask is required, and eye protection is recommended per Standard Precautions. Specialized air handling is not routinely recommended.

The second category, Novel Air Precautions, would be used for providing care to patients with new or emerging respiratory pathogens that are not anticipated to spread efficiently over long distances and in which infection generally leads to more than mild illness and immunity, vaccination, and effective therapy are not available. Example pathogens include Middle East Respiratory Syndrome (MERS), SARS caused by SARS-CoV-1, pandemic respiratory viruses (e.g., influenza, COVID-19 caused by SARS-CoV-2). A NIOSH-approved®, fit-tested N95®

¹ Note: The inclusion of example pathogens in the Table is to provide context and is not meant to imply the type of Transmission-based Precautions that will be recommended for the specific pathogen.

respirator or higher level of respiratory protection is required.² Eye protection is recommended as routine. Specialized air handling is not routinely recommended.

The third category, Extended Air Precautions, currently called Airborne Precautions, would be used when providing care to patients with pathogens that are observed to spread efficiently across long distances and remain infectious for extended times such that room air needs to be prevented from moving to parts of the facility where individuals are not appropriately protected (e.g., a hallway). Examples for this category include tuberculosis (TB), measles, and varicella. The protection required would continue to be a NIOSH-approved, fit-tested N95 respirator or higher level of protection. Eye protection would be used per Standard Precautions. Specialized air handling is required.

Dr. Lin reviewed the draft framework for the Transmission-Based Precautions to Prevent Transmission by Touch for Healthcare Facilities (*Except Skilled Nursing Facilities*), highlighting that Standard Precautions applied to all situations regardless of the transmission-based precautions used. He explained that the single option that is the prevailing guidance for non-skilled nursing facilities is Contact Precautions. PPE involves gown/glove for all activities, applies to any room entry, and dedicated medical equipment is recommended. Single occupancy is preferred, and if not available, consideration should be given to cohorting patients with the same pathogen (e.g., Norovirus, *C. difficile*, *C. auris*, scabies).

In terms of the draft framework for the Transmission-Based Precautions to Prevent Transmission by Touch for Skilled Nursing Facilities, Dr. Lin indicated that there were 2 options beyond Standard Precautions. The first is Contact Precautions, which involves gown/glove for all activities and applies to any room entry. Dedicated medical equipment is recommended. Single occupancy is preferred, but if not available, cohorting is recommended. Sample pathogens include Norovirus, *C. difficile*, and scabies. Contact Precautions also can be applied for MDROs during outbreaks, but the key point is that Contact Precautions are intended to be time-limited. The second row describes what would be considered to be a new transmission-based precaution category compared to the 2007 guideline. This is known as Enhanced Barrier Precautions and involves gown/glove use during high contact patient care activities, such as dressing, bathing, or toileting of residents. This may be indicated when Contact Precautions do not otherwise apply for residents with infection or colonization with an MDRO and residents with wounds or indwelling medical devices, regardless of MDRO colonization status. Dedicated medical equipment is not required. Equipment should be cleaned and disinfected between residents per Standard Precautions. Single occupancy is not required. Example pathogens include MDROs targeted by CDC (e.g., CRE, CRPA, CRAB, *C. auris*). In distinction from the Contract Precautions that are time-limited, Enhanced Barrier Precautions are meant to be more resident-centric and are intended to be for longer periods of time and sometimes indefinitely. Enhanced Barrier Precautions are currently endorsed by the CDC on the PPE for Nursing Homes Webpage but are not currently in the Isolations Precautions Guidelines, so that would be a new addition.

In terms of next steps, the goal is to have a Precautions Guideline for HICPAC to review and vote on during the next HICPAC meeting in August 2023.

Discussion Points

² N95 and NIOSH Approved are certification marks of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

For this discussion, HICPAC members, ex officios, and liaison representatives raised the following questions, observations, and suggestions/recommendations:

A HICPAC member noted that it is not clear in some cases whether cohorting is permitted. For example, for the organism of endemic coronaviruses, no cohorting would be allowed because this would be Standard Precautions under the current guideline.

Dr. Wright responded that this is still a draft, and the workgroup has not made a final decision, but the workgroup has discussed no cohorting unless the facility does not have enough space and the residents have the same organism.

A HICPAC member noted that “medical/surgical masks” are listed in several places, but perhaps “fluid-resistant” should be listed under some of the features to denote the difference between a surgical mask which is fluid-resistant and a medical mask which is not.

The Public Health Agency of Canada (PHAC) suggested providing further clarification on the eye protection listed. Goggles and face shields are mentioned, but certain types of protective glasses are not listed and perhaps should be included.

A HICPAC *ex officio* inquired about N95 respirators still being recommended for the pandemic phase of respiratory viruses even though there was not evidence to show that an N95 respirator is better than a surgical mask.

Dr. Wright responded that the data continues to evolve, especially for SARS-CoV-2, so an N95 respirator or higher level of protection is indicated for novel pathogens. Once more information is learned about a novel pathogen, it could move into either the routine air or extended air category.

Regarding a comment from an *ex officio* that “Indwelling devices” are not clearly described in the Enhanced Barrier Precautions table, Dr. Lin indicated that these are already described on the CDC website under Frequently Asked Questions that define qualifying devices. This generally includes devices that enter the body or body cavity. It does not include implanted devices such as pacemakers.

In terms of Contact Precautions on the Transmission-Based Precautions to Prevent Transmission by Touch table (Slide 41), a HICPAC liaison recognized that the example pathogens list was not exhaustive but wondered whether some respiratory viruses also could go into Contact Precautions. For instance, MDROs are not called out under Example Pathogens.

Dr. Lin responded this is a very brief list of examples and is not exhaustive. It is intended to include MDROs and certain respiratory viruses that require contact precautions.³

A HICPAC liaison pointed out that dialysis facilities are unique. While Contact Precautions is meant to apply to all healthcare facilities except SNF, there are some challenges with Contact Precautions in dialysis facilities. Perhaps consideration could be given to providing additional guidance about how to implement in unique facilities like dialysis centers.

³ Note: inclusion of example pathogens in the Table is to provide context and is not meant to imply the type of Transmission-based Precautions that will be recommended for the specific pathogen

Dr. Lin pointed out that many facilities have particular needs. This is intended to be high-level guidance, but there will be forthcoming guidance specific to special areas of care. Dr. Bell added that this is a very high-level framing document. If they try to address the implementation specifics for every type of healthcare facility, this will be a 1000-page document. They are intentionally trying to keep this as lean and usable as possible, using secondary documents that focus on specific implementation or practical issues.

Despite spending a fair amount of time with the literature about masks and respirators, a HICPAC *ex officio* found it striking that so little is still known about them. Anyone reviewing these studies likely would recommend either rejecting the papers or sending them back to the authors to determine whether they could do more about precision, especially with regard to use compliance, which Ms. Stone mentioned. Perhaps CDC could capitalize on the current unique situation in which facilities are going to be more or less conservative in terms of learning more about whether masks are beneficial or not.

Dr. Bell noted that this is a topic for a week-long conference. It is not that nothing is known. Some knowledge is well-established, such as “fit” making a difference between an effective filter and a useless filter. It also is well-established that source control has a much greater effect than PPE use in many situations and that indoor air quality is underutilized. He cautioned everyone about the red stop signs in the evidence review signifying lack of strength of studies. Strong data is inherently described as a large RCT, resulting in downgrading of everything that is not an RCT. That is somewhat artificial. Having said that, there are important questions about gaps that are getting much toward human factors (e.g., how well people adhere to recommendations, whether they do it correctly, how to observe that in a systematic way and measure it, et cetera). There are many opportunities for not only CDC, but also CDC’s colleagues at NIH, SHEA, APIC, and others to take advantage of the moment to examine the human behavior/human interface elements.

The HICPAC *ex officio* acknowledged that the laboratory studies to which Dr. Bell referred are compelling in terms of mask efficacy and the differences in the types of masks versus respirators. There are no studies in which everyone is wearing a mask compared to no one wearing a mask. In those studies, as many as 60% of the people who are supposed to wear a mask are not and 35% of those who are not supposed to be wearing a mask wear them. This is very difficult to tease out in the large clinical trial. With so many smart people looking at this around the table, they should be able to come up with something to answer these very important questions. A lot of what is known comes from laboratory studies, which are compelling. However, the clinical trials do not really support the laboratory studies data for all the reasons that were pointed out during the presentations.

A HICPAC liaison inquired as to whether any consideration was given to special patient populations, such as pediatric patients, who may require more hands-on care (e.g., diapering, holding, cuddling, walking around with them) than the typical adult patient. She asked if there is an opportunity to provide additional guidance for these special populations.

Dr. Lin noted that this sounded like Enhanced Barrier Precautions. The WG did consider that concept for non-SNFs such as hospitals. They did not find enough evidence to recommend Enhanced Barrier Precautions for non-SNFs. Enhanced Barrier Precautions for SNFs states, “May be considered for other congregate settings in healthcare facilities.” That does include acute care hospitals. The WG was thinking about psychiatric wards, for example, so there is latitude in the application of Enhanced Barrier Precautions.

A HICPAC liaison inquired as to whether attention was paid to mortality rates, such as reported in the United States Renal Data System (USRDS) data. For example, AAKP is the largest kidney patient organization in the US. During COVID-19, the dialysis population statistically had the highest impacted populations in terms of mortality. For the draft Transmission-Based Precautions to Prevent Transmission by Air, the Routine Air Precautions has medical/surgical masks—not N95 respirators for seasonal influenza and seasonal coronavirus. For kidney patients, especially immunosuppressed transplant patients, it was not clear what practical precaution would be recommended for HCP who are interacting with these patients—surgical masks or N95 respirators?

Dr. Wright responded that the specific recommendations for specific populations would be focused on more in Part 2 (currently called Appendix A) by organism if there are specific recommendations that would change by organism or for specific populations. She reminded everyone that what was presented represented the standard for the category of precautions and facilities may choose to do more based on a local risk assessment.

The HICPAC liaison emphasized that a minimal standard in regard to certain populations is not good enough and strongly encouraged the WG to think about this in terms of public messaging and the practical implications for patients.

In terms of development of the draft, the HICPAC liaison inquired as to whether partners or stakeholder organizations were involved.

Dr. Bell responded that it was the intent of this session and discussion to obtain feedback from HICPAC members, *ex officios*, and liaison representatives about the draft updates.

The HICPAC liaison also noted the importance of considering the impact of these updates on purchases made for the National Stockpile. This was an issue in 2020 in terms of the aging of masks and whether the elastic had deteriorated. Consideration should be given to the potential longer-term implications for national policy.

Dr. Bell said he thought the National Stockpile question was out of scope for this particular conversation but that he would be happy to engage offline about this. There are multiple factors that inform other agencies' decisions about their stockpile that CDC does not control. While others may look at this guideline, they are not bound by what CDC recommends.

An Isolation Precautions WG and HICPAC liaison commented that the WG did engage in some conversation about the release of this updated guidance being an opportunity to refresh and remind people about what Standard Precautions really is, the importance of it, and how/when to use it. She also commented that the WG has discussed how to be thoughtful about when a novel pathogen might transition to one of the other transmission categories once more information is available about how it transmits, how to treat it, and if immunity has increased due to exposure and the availability of a vaccine.

Regarding the Contact Precautions guidance and situations where the update says “any room entry,” the Isolation Precautions WG member and HICPAC liaison asked the larger HICPAC membership to provide additional feedback about whether it is better to continue saying “any room entry” or whether it would be better to say something like “for any contact with the patient, their surroundings, or their environment” and then let facilities decide based on their own setting and room design.

A HICPAC member said she had the same question because it does box facilities into using full PPE when crossing the threshold of the room. There are some advantages to that because often someone will enter a patient room and not realize that they are going to engage in contact with the patient or environment. HCP often take care of patients in actual rooms and it really is about the contact.

Dr. Lin noted that there probably was room in the text to call out different situations because the table, by definition, has to be a little more fleshed out. This is an ongoing discussion with the WG.

Regarding Enhanced Barrier Precautions in nursing homes, an Isolation Precautions WG member and HICPAC member observed that the information presented during this session said that Enhanced Barrier Precautions “may be indicated.” The current CDC FAQs that are posted use the term “recommended” in multiple places. While it was not their role during this session to critique or parse the FAQs, there appears to be a discrepancy between the guideline update versus the FAQs. Given the lack of adequate evidence and the burden of implementation to make a stronger recommendation, the language “may be indicated” or “may be considered” seems prudent.

Dr. Lin indicated that there is an ongoing discussion about the language around Enhanced Barrier Precautions. The guidance on the CDC web page may use the word “recommended” but in essence, nursing homes and the regulatory agencies that oversee nursing homes consider it to be more or less mandatory when a recommendation is made on the web page. In his state, Illinois, Enhanced Barrier Precautions is a de facto mandatory approach to MDRO control. The approach does have evidence in terms of very limited studies that use surrogate markers and the Enhanced Barrier Precautions study involved the pilot study that showed promising evidence. When HICPAC was in 2020 when the white paper was published, the words “consideration of Enhanced Barrier Precautions to control MDROs through risk-based application” were used. The WG needs to continue to discuss whether the language should be “may be indicated” or “should be indicated” or something stronger. Right now, they selected the word “may,” but that is an ongoing discussion.

A HICPAC member suggested that while it may be in the footnotes or background section, it is important to make a clear statement that a mask is still needed under a face shield. While this did not appear to be identified in the review, face shields alone are not adequately protective for aerosol spray. He noted that the word “pathogen” was used for cohorting and suggested that perhaps there could be further discussion about the level at which this needs to occur. Some viral infections have a higher mortality. For example, one MDRO pseudomonas may not be the same as another MDRO pseudomonas.

Dr. Lin pointed out that single occupancy and cohorting depend upon the outbreak response phase in which one is trying to control the organism. In an outbreak situation, most public health entities would recommend cohorting (microphones in room cutting in and out).

A HICPAC member wondered whether the term “Standard Precautions” should still be used. This update offers an opportunity to consider a better term. This is a chance to rebrand and reeducate the whole workforce and potentially to consider changing that term to something else that would give them an opportunity to teach something that they have been trying to teach for decades. A new term would spotlight what is important.

Dr. Bell asked PHAC to comment on Standard Precautions and the different language they are considering.

PHAC said that working with colleagues in the US, they translated “Standard Precautions” very quickly. The term they are using currently is “Routine Practice.” They are behind HICPAC/CDC in reviewing their routine practice and additional precautions. It is always hard to make a change for something that has absolutely been the cornerstone of the messaging. While she did not have an alternative suggestion, she agreed that the term “Standard Precautions” could be misleading or confusing. With a caveat of complete bias, the term “Routine Practice” seemed to settle with her and others. PHAC was very impressed with the amazing work HICPAC has done, particularly with the literature review.

Dr. Bell called on a HICPAC member to share her insight about the terminology. She indicated that she has been teaching Standard Precautions for quite some time. She views the term “Standard Precautions” as being the standard of care in that it is what they want people to be doing all of the time. She emphasized that as HICPAC updates the transmission-based guidelines and these guidelines, that is their moment to reeducate everybody. The WG members discussed creating some educational support materials to accompany the updates. She truly believes that is where their efforts are best placed once the guideline is developed and completed. This is extremely important for infection preventionists to use as they work to educate and teach how to implement risk-based application of Standard Precautions and then transmission-based when there is a diagnosis or a suspect organism or pathogen of concern. Education of the workforce is absolutely essential.

Other HICPAC members agreed with the importance of the education component. People have been focused on the epidemiologic terms of “airborne” and “droplets” for so long within the media and healthcare setting, it will be absolutely critical to reeducate on the continuum rather than the “droplet” versus “airborne” concept. Perhaps visuals can be used to educate the public as to what they are referring to and condense this very large document to smaller sections.

A HICPAC liaison pointed out that perhaps the thinking should be reframed to consider the footprint that is being left in the environment with all of the gloves, gowns, et cetera that are being required. It is important to understand whether there is truly the evidence—that this is actually preventing the transmission of these organisms when the focus of the conversation needs to be on hand hygiene, cleaning and disinfection of the environment, and cleaning and disinfection of shared equipment. A lot of gloves and gowns are being recommended just for entering a room when sometimes the providers are not touching anything. The efforts may be diluted sometimes with such recommendations. This is affecting the way HCPs are caring for their patients and it is not clear that it is having the intended outcomes they think it is. Dr. Lin acknowledged that the WG did not explicitly factor in environmental impact related to these guidelines but recognized that in general it is an important concept.

Dr. Lin and Dr. Wright will take this feedback to the WG for further consideration as they work to develop a guideline draft.

Proposed Update of Isolation Precautions Appendix A for Selected High-Consequence Pathogens

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Dr. Kofman presented an issue that was raised as an opportunity for refinement and proposed update of Appendix A Isolation Precautions Guideline pertaining to Selected High-Consequence Pathogens. During this session, Dr. Kofman provided a rationale for the proposed update; review of viral hemorrhagic fevers (VHF) and patient placement recommendations (Appendix A); review of isolation precaution considerations for select high-consequence viral pathogens including, Marburg viral infection, Crimean Congo Hemorrhagic Fever (CCHF), Lassa Fever, South American Hemorrhagic Fevers (SAHF), Andes viral infection, and Nipah virus infection with a goal to inform a recommendation update for Appendix A of the 2007 Isolation precaution Guideline.

In terms of the rationale for the update, CDC has received a number of recent inquiries in the last year alone regarding non-Ebola special pathogens. There were 2 Marburg outbreaks in 2023 in Equatorial Guinea, Tanzania in 2023. At the outset of those outbreaks, questions were immediately raised regarding whether the current Ebola guidance is the same for Marburg. In addition, 2 patients in the US in 2023 had Nipah virus infection on the differential. While there was thought to be a relatively low likelihood of risk of Nipah virus, a question arose as to what the isolation precaution recommendations are for Nipah virus. Lassa Fever and CCHF are also often in the differential for ill returning travelers from endemic regions. In 2018, the US had an imported Andes virus case, which is a type of hantavirus that is known to be transmissible from person-to-person. Thankfully, there were no secondary cases even though it was identified somewhat later in the course of the patient's illness. These cases illustrate the possibility that such diseases can make their way to the US and that there is a need to revisit the literature and update the recommendations for healthcare infection control precautions prior to any imported cases or outbreaks.

In the current VHF PPE and patient placement recommendations, Appendix A—Viral Hemorrhagic Fevers encompasses VHFs due to Lassa, Ebola, Marburg, and Crimean-Congo fever viruses. The precautions include Droplet + Contact + Standard. The explanatory section essentially references the Ebola Virus Disease for Healthcare Workers section [2014], with an exclamation point in a yellow triangle signifying that there is an update and including a hyperlink to the Ebola for Clinicians update.⁴ The Ebola Clinician Update differs somewhat from the fourth column in the current Appendix A table, which reads as follows:

Single-patient room preferred. Emphasize:

1. use of sharps safety devices and safe work practices;
2. hand hygiene;
3. barrier protection against blood and body fluids upon entry into room (single gloves and fluid-resistant or impermeable gown, face/eye protection with masks, goggles or face shields); and
4. appropriate waste handling.

Use N95 or higher respirators when performing aerosol-generating procedures. Largest viral load in final stages of illness when hemorrhage may occur; additional PPE, including double gloves, leg and shoe coverings may be used, especially in resource-limited settings where options for cleaning and laundry are limited. Notify public health officials immediately if Ebola is suspected [212, 314, 740, 772]. Also see [Table 3C](#) for Ebola as a bioterrorism agent.

With that in mind, CDC wants to clarify what is indicated for each of these pathogens. The Ebola-specific guidance in the hyperlink and the current recommendations both have fairly extensive web pages. Dr. Kofman explained that the goal of this session was to highlight the

⁴ <https://www.cdc.gov/vhf/ebola/clinicians/index.html>

key recommendations for each pathogen. He also provided a summary of the 2 categories of recommendations for patients with suspected Ebola Virus Disease which are unchanged from that provided in the web pages. One category is for those who have suspected Ebola Virus Disease (EVD) who are otherwise stable and colloquially referred to as “dry” patients and, the other category is for those who are suspected or confirmed to have EVD and who are colloquially referred to as “wet” patients as follows:

Recommended PPE and Patient Placement for Patients with suspected EVD (stable or “dry” patients)

While evaluating and managing people under investigation (PUIs) who are clinically stable and do not have bleeding, vomiting, or diarrhea, healthcare providers should at a minimum wear:

- Fluid-resistant gown that extends to at least mid-calf or single-use (disposable) fluid-resistant coveralls without integrated hood
- Full face shield
- Facemask
- Gloves with extended cuffs. Two pairs of gloves should be worn. At a minimum, outer gloves should have extended cuffs.

Patient Placement:

- Single patient room with closed door
- Airborne infection isolation room (AIIR) for Aerosol-Generating Procedures (AGP)

Recommended PPE for unstable/“wet” patients with suspected EVD or confirmed patients with EVD

While evaluating and managing PUIs who are clinically unstable and/or have bleeding, vomiting, or diarrhea, healthcare providers should at a minimum wear:

- Impermeable gown or coverall
- PAPR or N95 respirator
- Examination gloves with extended gloves. Two pairs of gloves should be worn.
- Boot covers (or shoe covers in combination with coverall with integrated socks)
- Apron
- Full face shield

Patient Placement:

- Single patient room with closed door
- AIIR for AGPs

The proposed Appendix A update would include updates for the following pathogens:

- VHF_s
 - Marburg
 - CCHF
 - Lassa
 - South American Arenaviruses (Junin, Machupo, Chapare, Guanarito, Sabia)
- Andes Virus (a species of hantavirus)
- Nipah Virus

A review of virus-specific information informed the decision-making on the recommended precautions. Dr. Kofman reviewed the Infection Prevention Control (IPC) considerations for the selected high-consequence pathogens beginning with Marburg, which is a clinical illness that is very similar to EVD in that it is a febrile illness that has some initial influenza-like prodromal symptoms (e.g., fever, chills, headache, myalgia, sore throat, nausea, vomiting) that may progress to severe illness with multi-organ failure, massive hemorrhage, and death. Mortality is variable depending upon the outbreak, but ranges from 23% to 90%. Unlike for Ebola, no vaccine or approved treatments are available. While remdesivir has been used as treatment, its efficacy remains unclear. The modes of person-to-person transmission of Marburg are similar to EVD in terms of the literature and experience with outbreaks, which is essentially contact with body fluids—particularly blood. Marburg virus has been isolated from blood, urine, throat, liver biopsy (autopsy), and eye (anterior chamber). There have been episodes of occupationally-acquired transmission in healthcare in the setting of insufficient or no PPE (skin contact with body fluids), sharps injuries, and mucous membrane exposures. The proposed PPE and patient placement are “Same as currently recommended for patients with EVD.”

Moving on to CCHF, this is a virus that is found in a broad swath of the globe from Russia and Central Asia through the Middle East, Mediterranean and into many parts of Africa. Clinical illness includes fever, headache, back/joint pain, stomach pain, nausea, vomiting, and jaundice with progression to severe illness including severe bruising, nosebleeds, and uncontrolled bleeding at injection sites. CCHF has been well-described in many outbreaks. The mortality rate is somewhat lower overall than Marburg or Ebola at 3% to 30%. No vaccine or approved treatments are available. As with Marburg and Ebola, contact with body fluids is the predominant mode of transmission from person-to-person. Transmission also has been found in association with improper sterilization of medical equipment, percutaneous inoculation from needles, and possible droplet/aerosol transmission according to an older study from the Soviet Union. PCR has been detected in blood, nasal swab, saliva, urine, stool, and vaginal fluid. Viral isolation has been reported from patients and cadavers. Episodes of occupationally-acquired transmission in healthcare have been reported in the literature due to percutaneous and cutaneous transmission and possible droplet/aerosol transmission. Proposed PPE and patient placement are again stated to be the “Same as currently recommended for patients with EVD .”

In terms of Lassa, this is a rodent-borne virus that is endemic to parts of West Africa. This virus is typically milder on average in terms of its presentation with more of an influenza-like illness (ILI). A minority of cases can develop severe illness, which can include hemorrhage, respiratory distress, vomiting, hearing loss, tremors, encephalitis, and multi-organ failure. The mortality rate among hospitalized patients in endemic settings is known to be 15% to 20%. The overall mortality rate is 1%. Ribavirin is sometimes used as a treatment in endemic settings, but the efficacy remains somewhat unclear. No vaccine is available. The modes of person-to-person transmission have been attributed to prolonged contact in settings of unknown exposure. Respiratory droplet or aerosol spread was implicated in earlier outbreaks closer to the time of the virus’s discovery when the source was unknown. Positive viral cultures have been found in blood, urine, saliva and semen. Occupationally-acquired transmission of Lassa in healthcare settings has been well-described. It also has been noted not to always transmit in healthcare—even in the absence of sufficient PPE. However, it has been noted to spread quite well in other outbreak settings with insufficient PPE. Nevertheless, there is sufficient available evidence to suggest that it can lead to severe illness and it is transmissible by body fluids in the healthcare setting. Again, the proposed PPE and patient placement are “Same as currently recommended for patients with EVD .”

Regarding the group of viruses known as SAHFs or Arenaviruses, the update focuses on the 5 most common in the group: Junin (Argentine HF), Machupo (Bolivian HF), Chapare (Chapare HF), Guanarito (Venezuelan HF), and Sabia (Brazilian HF). In terms of clinical illness, all have ILI; Junin has an absence of respiratory symptoms; Machupo may develop neurologic/hemorrhagic manifestations; Chapare may develop acute respiratory distress syndrome (ARDS)/multiorgan dysfunction; Guanarito has respiratory symptoms and may develop neurological/hemorrhagic manifestations; and Sabia may develop multiorgan dysfunction. The mortality rate can be quite high: Junin (15%-30%, 1% with treatment), Machupo (25%), Chapare (60%), Guanarito (33%), Sabia (50%). Only Junin has a vaccine, but it is not available in the US. There are no proven treatments for any of these diseases. In terms of modes of transmission, person-to-person transmission has been surmised for Junin in large-scale outbreaks. Person-to-person transmission was demonstrated for Machupo in 1971. Transmission is unclear for Guanarito for which there has been only 1 case of secondary transmission identified. Chapare has been transmitted by contact with body fluids. Mode of transmission has not been established for Sabia. In terms of body fluids, Junin has been reported from oral swabs, urine, breastmilk, and sexual transmission. Machupo has been reported from a blood/throat swab/post-mortem liver/spleen (viral culture). Chapare was reported in a 2019 outbreak in blood, urine, conjunctival, and semen, as well as nasopharyngeal and oropharyngeal swabs (positive PCR, and viral isolation from culture). Presence of virus in body fluids has not been established for Guanarito or Sabia. No episodes of occupationally-acquired transmission in healthcare have been identified for Junin or Guanarito, but have been reported in Machupo, Chapare, and Sabia, the latter of which had transmission via 2 laboratory exposures. Collectively, this group of viruses has high mortality and convincing evidence of person-to-person transmission. The proposed PPE and patient placement are again "Same as currently recommended for patients with EVD."

In terms of Andes, this is a type of hantavirus that is transmissible from person to person, and it has a somewhat different clinical picture than all of the others discussed thus far. Clinical illness includes ILI with fever, chills, and headaches followed by cough and shortness of breath. This can lead to acute respiratory distress syndrome (ARDS), respiratory failure, coagulopathy, and multiorgan dysfunction. The mortality rate is about 30%, and no vaccines or treatments are available. Person-to-person transmission is well-documented, particularly among those with close contact and prolonged contact to case-patients. Endemic settings include Argentina and Chile. It has been found by PCR in most body fluids, including breastmilk, blood, serum, peripheral blood mononuclear cells (PBMCs), urine, and respiratory samples. There have been implications of episodes of occupationally-acquired transmission in healthcare, but no transmissions have been reported in terms of incomplete PPE. The proposed PPE and placement recommendations differ for Andes, given that spread is thought to be mostly on the droplet or aerosol-based. Given that this is not particularly well-established, the proposed PPE includes a gown; single pair of gloves; respirator out of an abundance of caution given the high mortality rate and uncertainty around the transmission dynamics of respiratory spread; and eye protection. The recommendation for patient placement is AIIR.

Nipah virus (NiV) is found in parts of Southeast Asia, specifically Malaysia and Bangladesh and is somewhat clinically different from some of the other viruses described in this session. Clinical illness includes a non-specific prodromal phase (fever, headache, myalgia, dizziness), respiratory symptoms, and vomiting. Neurological symptoms appear within 1 week and can include coma, hyporeflexia, areflexia, segmental myoclonus, and seizures. Survivors also may experience relapse or late-onset encephalitis. The clinical picture can sometimes be complicated and not always fully acute. The mortality rate for Nipah is quite high at 40% to 75%

and there are no vaccines or treatments. A considerable amount of work has been done on the modes of person-to-person transmission, which are reported to be through contact with body fluids, particularly respiratory secretions; and prolonged exposure Nipah virus (NiV) patients, those with respiratory symptoms, and older patients who are thought to have a higher viral load. While there is some uncertainty in the literature regarding whether there is truly a difference in the infectiousness of the NiV_B (Bangladesh) and NiV_M (Malaysia), this is unlikely to affect the recommendation. NiV has been found in a number of body fluids, including respiratory samples with positive NiV RNA on PCR and viral culture positivity from throat and nasal swabs and urine (NiV_M). Episodes of occupationally-acquired transmission in healthcare have been identified. The proposed PPE recommendation for clinically stable patients without vomiting (suspect Nipah) includes gown, single pair of gloves, respirator, and eye protection. If clinically unstable (suspect Nipah) or confirmed Nipah, the PPE recommendation is the same as is currently recommended for a confirmed EVD patient. Regardless of symptoms, the recommendation for patient placement would be AIIR. Dr. Kofman shared an image⁵ of a corridor outside of a CT room to illustrate transmission in a recent outbreak. The patient was waiting for hours in the corridor to get into the CT scanner room. Numerous HCP who were traversing the hallway and did not otherwise have contact with the patient were infected while walking through. Camera footage was reviewed retrospectively to help determine who walked through.

Discussion Points

HICPAC supported the inclusion of “Same as currently recommended for patients with EVD ” because it makes the recommendation very clear, which helps with patient placement and training teams.

Instead of pointing to Ebola, HICPAC suggested that perhaps referring to it as “Viral Hemorrhagic Fever Guidance” instead of “Ebola Guidance” so that it applies only to those listed in this presentation would be helpful. There could be confusion if one is reading about Lassa and everything refers to what is currently called “Ebola Guidance.”

Dr. Kofman indicated that they would be happy to brainstorm this suggestion. The plan is also to state on the Ebola webpage what other viruses that guidance applies to, so if not in the title, at least there would be a clear message. The tricky part of using “Viral Hemorrhagic Fever Guidance” is that it is still not all of them.

HICPAC suggested that it could be addressed by using “Clinically Significant Viral Hemorrhagic Fevers Guidance” or some sort of subset that describes it. This is likely to occur with Nipah eventually as well.

SHEA was struck by the carving out of the specific viruses, but inquired as to whether the Nipah and Andes PPE match the clinically stable Ebola PPE or if the difference was just a single pair of gloves. It appeared that Andes and clinically stable Nipah were the same just in the PPE part, not AIIR. These are so close, it was suggested that perhaps they all could be combined somehow or create 3 categories of VHF rather than “Same as Ebola” for each one: Stable Without Respirator, Stable With Respirator, and Unstable with respirator on all of the others and putting each one of these into one of these categories.

Dr. Kofman clarified that there was no other category for Andes, so it is all-inclusive because it does not have another “wet” beyond respirator. The guidance in Argentina and Chile typically is

⁵ Arunkumar et al JID 2019

facemask with a respirator. The feeling was to opt for a respiratory based on the high mortality and some uncertainty about the precise nature of transmission. The main difference between these and unstable Ebola is 2 pairs of gloves versus 1 pair, apron, boots, and AIIR. He clarified that by “Same as currently recommended for patients with EVD” they meant “wet” and “dry” because those have a “stable” and “unstable” component. That would be clarified bi-directionally.

A HICPAC member did not think Nipah should be like Andes. They wanted to put Andes into a hantavirus category, because it just has the respiratory viral hemorrhagic fever category rather than “other.” The scheme of naming proposed by SHEA is agreeable, though Nipah has a wet and dry phase.

HICPAC asked whether an Ebola patient who has survived, is convalescing, but is not yet out of isolation would remain in the higher level or would be moved to “dry.”

At least thinking through the other hemorrhagic fevers for which “Same as Ebola” is being recommended, Dr. Kofman pointed out that enough of them act sufficiently similar in that regard that it would seem to make sense for most but Andes and Nipah may be different. With Andes, it would be just one category. For Nipah, there is not a lot of evidence to guide the decision, particularly for survivors who are dry but have a relapse later.

Given that the evidence is not sufficiently clear to make that kind of off-the-cuff decision, the preference would be not do that right now and perhaps to re-address this when the WG works on Appendix A in the near future.

Dr. Bell clarified that this arose because of the recent outbreaks and DHQP’s viral hemorrhagic fever epidemiology colleagues coming to them asking whether they could coalesce these viruses or if they would be updated separately. The answer was to do something practical and focused with what exists. It is a response to the agency need and is not meant to avoid the process with the Appendix A update.. As the WG addresses Appendix A, there will be an opportunity to add that kind of thoughtfulness in terms of what people are being asked to do.

A HICPAC member noted that the approach to the “dry” patient for Ebola or for other viral hemorrhagic viruses is important because it must be practical for any hospital or emergency department (ED) to be able to implement. Hospitals that are potentially putting a patient who has Ebola or something like that on the differential feel very uncomfortable with even starting the “dry” phase PPE and they may stop caring for the patient. It is known that most of these patients do not have VHF, but have something more common. It was striking that a single pair of gloves was recommended for Nipah and Andes. Perhaps there would be an opportunity to readjust the “dry” PPE for Ebola patients to make it more pragmatic. Perhaps clarification could be provided about the single pair of standard gloves being allowable. Because there is so much reference to Ebola, it is unclear what kind of gloves to use.

Dr. Kofman appreciated the sentiment and emphasized that the goal was to try to help address these. Part of the rationale for these recommended updates was to make everyone feel more comfortable with what they are doing and why they are doing it, particularly because of the 2 Nipah cases.

A HICPAC member offered a counter argument that there has not been sufficient study of high reliability PPE. Many groups are working on it, including North Carolina. There is a practical aspect of what can be done in a clinical setting in terms of a suspected and not confirmed

Nipah, as well as the aspect of not wanting anyone to ever get this from an occupational setting. Consideration also must be given to what staff are being asked to do in a high-risk function, particularly in the context of hospitals that already are experiencing high staff turnover.

Dr. Bell pointed out that there is a lot of mortality data that reflects care in extremely resource-limited locations, which do not translate to what is seen in the US. By the same token, a lot of what is practiced in those locations where the data come from are not nearly as involved or contact prone as the type of intensive care provided now in this country. He pointed out that whether it is gloves or anything else, thought must be given to mapping what the US expects its staff to be doing for these patients, even if it does not necessarily match some of the field evidence that has been published. In terms of PPE reliability, it is one thing to have a team of constantly trained, extremely confident individuals who are engaged in this type of activity all of the time versus having a wide array of staff engaging in a care process who do not have that degree of experience. There are easy parallels here in terms of surgical procedures by which a different approach might be taken if a world expert is using robotic surgery versus having a lot of junior staff coming in for a routine procedure. The move away from having dozens of “recipes” for isolation practices and simplification into a handful or two at the most for Appendix A would be prudent, especially for daily use by a wide array of people. Considerable medical care is shifting into LTCFs and nursing homes, so it seems that getting everyone able to do the right thing intuitively is going to be very helpful.

HICPAC noted that because everything is tied to Ebola, it will affect all of these other diseases should there be changes in Ebola recommendations in the future.

Dr. Bell pointed out that while they were referring to something labeled “Ebola” because it exists and is recognized and the recommendations hinge on a legacy document, ultimately there is a desire to move toward a quasi-syndromic or categorical approach to severe “messy” pathogens.

HICPAC observed that for Nipah and Andes, the specific type of gloves was not stated. This may cause confusion. A well-fitted standard cuff and properly fitted gown will result in proper skin coverage to the HCP. The extended cuff would provide extra security. HICPAC also recognized the need to be flexible in terms of resources.

Dr. Bell pointed out that while flexibility is fine, they need to be concrete when they talk about these issues in terms of how people actually become infected from these viruses. For instance, is the gap between the glove and gown really how people get infected so they need to be sealed up, or is the sealing up driven by fear and anxiety related to a gap between the glove and the gown? The reasoning must be clear. In 2014, people were putting duct tape around their necks because they did not want anything exposed, but causing themselves skin injuries. That was clearly not the goal and was not adding to their safety. It is important to have clarity in what they write so that there is not confusion among HCP.

The phrase “with the exception of” means “not including.” Perhaps it would be better to use “with the addition of” a respirator and “only a single pair of gloves” because the word “exception” is confusing.

A suggestion was made that perhaps the Nipah and Andes recommendations could be tabled in order to have more time to clarify the language.

Dr. Bell did not think it was necessary to vote on each of these at this point. If they could clump some of them together that would be helpful, and perhaps a WG could hammer out some options with Dr. Kofman and company.

Votes: Special Pathogens

Vote: Proposed Update for Marburg

Proposal:

- Change recommended PPE and placement for Marburg to be the same as recommended for Ebola

If change is accepted:

- Appendix A will be updated to refer to Ebola guidance
- Ebola guidance will also be updated to include other pathogens to which it applies in addition to Ebola

HICPAC voted unanimously to approve the language as proposed above for the Marburg update. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Vote: Proposed Update for CCHF

Proposal:

- Change recommended PPE and placement for CCHF to be same as recommended for Ebola

If change is accepted:

- Appendix A will be updated to refer to Ebola guidance
- Ebola guidance will also be updated to include other pathogens to which it applies in addition to Ebola

HICPAC voted unanimously to approve the language as proposed above for the CCHF update. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Vote: Proposed Update for Lassa Fever

Proposal:

- Change recommended PPE and placement for Lassa to be same as recommended for Ebola

If change is accepted:

- Appendix A will be updated to refer to Ebola guidance
- Ebola guidance will also be updated to include other pathogens to which it applies in addition to Ebola

HICPAC voted unanimously to approve the language as proposed above for the Lassa update. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Vote: Proposed Update for SAHFs

Proposal:

- Change recommended PPE and placement for South American Hemorrhagic Fevers to be same as recommended for Ebola

If change is accepted:

- Appendix A will be updated to refer to Ebola guidance
- Ebola guidance will also be updated to include other pathogens to which it applies in addition to Ebola

HICPAC voted unanimously to approve the language as proposed above for the SAHFs update.

Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

HICPAC agreed to form a mini WG to delve further into the following proposed updates for Andes and Nipah to address the issues raised during the discussion.

Vote: Proposed Update for Andes virus

Proposal:

- Same as Suspect Ebola “dry” precautions with the exception of: respirator, single pair of gloves and patient placement in AIIR

If change is accepted:

- Andes would be added to Appendix A as proposed

Vote: Proposed Update for Nipah virus

Proposal:

- If clinically stable without vomiting (suspect Nipah): same as Suspect Ebola “dry” precautions with exception of single pair of gloves, respirator, and patient placement in AIIR
- If clinically unstable or confirmed Nipah: same as confirmed Ebola “wet”) precautions and patient placement in AIIR

If change is accepted:

- Nipah would be added to Appendix A as above

Healthcare Personnel Guideline Workgroup Update

Colleen Kraft, MD

Chair, HCP Workgroup

Dr. Kraft provided an update on the *Guideline for Infection Control in Healthcare Personnel*, 1998. She noted that the findings and conclusions being presented during this session were draft, had not been formally disseminated by CDC, and should not be construed to represent any agency determination or policy. As a reminder, the original guideline was published in 1998. The Healthcare Personnel Guideline Workgroup’s (HCP WG’s) charge was to focus on pathogen-specific issues for Infection Control in Healthcare Personnel. Where information is out of date, the WG will make updates using evidence-based methods where evidence is available.

Regarding the status report, **Section 1: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services** was published in October 2019.⁶ The WG is now working its way through the pathogen sections to try to get them reviewed, approved, and posted. In terms of **Section 2: Epidemiology and Control of Selected Infections Transmitted Among HCP and Patients**, Diphtheria, Group A *Streptococcus*, Meningococcal Disease, and Pertussis were published in November 2021, and Rabies was published in November 2022.⁷

Regarding the current status report, Measles, Mumps, Rubella, and Varicella are completing clearance and then will be posted to the *Federal Register*. The Pregnant HCP section is posted to the *Federal Register* for public comment until June 26, 2023. Cytomegalovirus (CMV), Parvovirus B19, and Conjunctivitis draft recommendations would be presented and voted upon during this meeting and, pending approval, would go into clearance. *S. aureus* is on hold pending a literature review. “On Deck” are Scabies/Pediculosis, Hepatitis A, Bloodborne Pathogens (Hepatitis B, Hepatitis C, HIV), Herpes, Tuberculosis (TB), Gastroenteritis (GI).

For Section 2, the WG has proposed updated draft recommendations for the CMV, Parvovirus B19, and Conjunctivitis sections. The narrative sections to support these draft recommendations are in progress. CDC subject matter experts (SMEs) have provided some initial input on the draft narrative. Dr. Kraft reviewed the 1998 guidelines and draft updated recommendations for each of these sections.

1998 Cytomegalovirus Recommendations

- Do not restrict personnel from work who contract CMV-related illnesses. **Category IB**
- Ensure that pregnant personnel are aware of the risks associated with CMV infection and infection control procedures to prevent transmission when working with high-risk patient groups. **Category IA**
- Do not routinely use workplace reassignment as a method to reduce CMV exposures among seronegative pregnant personnel. **Category IA**

Cytomegalovirus Draft Updated Recommendations

1. Work restrictions are not necessary for healthcare personnel who have an exposure to cytomegalovirus.
2. Work restrictions are not necessary for healthcare personnel with active cytomegalovirus infection.

For recommendations about healthcare personnel who are pregnant or intending to become pregnant and exposure to cytomegalovirus, please see the **Pregnant HCP** section.

1998 Parvovirus B19 Recommendations

- Ensure that pregnant personnel are aware of the risks associated with parvovirus infection and of infection control procedures to prevent transmission when working with high-risk patient groups. **Category IB**
- Do not routinely exclude pregnant personnel from caring for patients with B19. **Category IB**

Parvovirus B19 Draft Recommendations

1. For asymptomatic healthcare personnel who have an exposure to parvovirus B19, they may continue to work, including providing direct care to patients at increased risk for

⁶ <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/infrastructure.html>

⁷ <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/selected-infections/index.html>

complications from parvovirus B19 infection, if they wear a source control device (e.g., facemask) for 14 days after their last exposure.

2. For symptomatic healthcare personnel who have had an exposure to parvovirus B19 within the previous 14 days and have signs or symptoms of the prodrome of parvovirus B19 infection (e.g., fever, cough):
 - They should be evaluated by Occupational Health and Safety (OHS).
 - If they are suspected or known to have acute parvovirus B19 infection, they should be restricted from work for 5 days from the onset of their symptoms and until they have been fever-free for at least 24 hours, whichever is longer.
 - If fever is not resolved or other prodromal symptoms are not improving after 5 days, they should be reevaluated by OHS.
 - Upon return to work, if respiratory symptoms have not completely resolved, they should continue to wear a source control device (e.g., facemask) until resolution of their respiratory symptoms.

For recommendations about healthcare personnel who are pregnant or intending to become pregnant, please see the **Pregnant HCP** section.

1998 Conjunctivitis Recommendation

- Restrict personnel with epidemic keratoconjunctivitis or purulent conjunctivitis caused by other microorganisms from patient care and the patient's environment for the duration of symptoms. If symptoms persist longer than 5 to 7 days, refer personnel to an ophthalmologist for evaluation of continued infectiousness. **Category IB**

A debate in the literature about work restriction duration for conjunctivitis led to the decision to conduct a literature review to assess 14 days versus duration of symptoms for epidemic keratoconjunctivitis. Given that 14 days differs from the 1998 recommendation, the WG wanted to confirm that there would be no harm from recommending duration of symptoms. The Key Question for the literature review was developed by SMEs to address the appropriate duration of work restriction for adults with conjunctivitis working in healthcare settings. The resultant Key Question was vetted and approved by HICPAC. The Key Question for the literature review was, "For adults with conjunctivitis working in healthcare settings, does work restrictions for duration of symptoms, compared with work restrictions for 14 days, prevent transmission of conjunctivitis in healthcare settings?"

In terms of the study selection process, 849 potentially relevant studies were identified in literature searches of which 2 were excluded as duplicates. Of the remaining 847 studies, 847 titles/abstracts were screened and 782 studies were excluded as not being relevant to the key question. A full-text article review was then performed for 65 studies. Of these, 56 studies were excluded. Of these, 27 were not relevant to the key question; 14 were not primary research, systematic reviews, or meta-analyses; 6 were not in English; 4 included no HCPs; 3 included overlapping populations; and 2 did not have full-text articles available. This left a total of 9 studies available for the review. Regarding the results, 1 observational and 8 descriptive outbreak studies implemented work restrictions as 1 of multiple sequential or concurrent infection control measures. Duration of work restrictions varied from duration of symptoms to 10 days or 14-15 days. All methods helped to end outbreaks, but 10 to 14-15 days of work restrictions were lengthened when HCP still had active conjunctivitis. HCP may be able to return to work earlier or may need to be restricted longer than 14 days, showing that there is great variability in this syndrome. Cost savings were inconclusive, and staffing shortages were not addressed. In one outlier report, transmission ended after implementing screening and

furloughing of asymptomatic HCP because both methods would have failed. Therefore, the evidence is insufficient to warrant a change in the recommendation.

Conjunctivitis DRAFT Recommendations

1. For healthcare personnel with purulent conjunctivitis, including epidemic keratoconjunctivitis, exclude from work for the duration of their symptoms.

Discussion Points

CMV Section

No comments or questions.

Parvovirus B19 Section

HICPAC inquired as to whether the recommendation will define just the populations at risk for infections, given that part of the recommendation pertains to whom asymptomatic HCP are able to care for.

Dr. Kraft thought the WG was not defining populations at risk because, sometimes, all of the populations at risk are not known. Instead, all patients are treated as the population at risk. HCP who are symptomatic should not be at work.

Dr. Kuhar added that for populations at risk, part of the reason for not making this specific just for those who are at risk for severe disease was because they did not feel like they could ensure that HCP would not interact with people at risk for complications.

Dr. Babcock added that this is in the narrative of the document rather than the recommendation itself.

HICPAC suggested using the language “fever-free in the absence of an anti-pyretic for 24 hours” to clarify that this does not refer to someone who is fever-free because they took Tylenol® for instance.

Dr. Kraft responded that perhaps there is a more global way to make a statement about “fever-free” rather than stating this in each individual recommendation.

Conjunctivitis Section

No comments or questions.

Vote: Parvovirus B19 Draft Recommendations

1. For asymptomatic healthcare personnel who have an exposure to parvovirus B19, they may continue to work, including providing direct care to patients at increased risk for complications from parvovirus B19 infection, if they wear a source control device (e.g., facemask) for 14 days after their last exposure.
2. For symptomatic healthcare personnel who have had an exposure to parvovirus B19 within the previous 14 days and have signs or symptoms of the prodrome of parvovirus B19 infection (e.g., fever, cough):
 - They should be evaluated by OHS.
 - If they are suspected or known to have acute parvovirus B19 infection, they should be restricted from work for 5 days from the onset of their symptoms and until they have been fever-free for at least 24 hours, whichever is longer.

- If fever is not resolved or other prodromal symptoms are not improving after 5 days, they should be reevaluated by OHS.
- Upon return to work, if respiratory symptoms have not completely resolved, they should continue to wear a source control device (e.g., facemask) until resolution of their respiratory symptoms.

For recommendations about healthcare personnel who are pregnant or intending to become pregnant, please see the **Pregnant HCP** section.

HICPAC voted unanimously to approve the language as proposed above for the Parvovirus B19 Draft Recommendations. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Cytomegalovirus Draft Updated Recommendations

1. Work restrictions are not necessary for healthcare personnel who have an exposure to cytomegalovirus.
2. Work restrictions are not necessary for healthcare personnel with active cytomegalovirus infection.

For recommendations about healthcare personnel who are pregnant or intending to become pregnant and exposure to cytomegalovirus, please see the **Pregnant HCP** section.

HICPAC voted unanimously to approve the language as proposed above for the Cytomegalovirus Draft Updated Recommendations. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Conjunctivitis DRAFT Recommendations

1. For healthcare personnel with purulent conjunctivitis, including epidemic keratoconjunctivitis, exclude from work for the duration of their symptoms.

HICPAC voted unanimously to approve the language as proposed above for the Conjunctivitis DRAFT Recommendations. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Proposed Update to Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007), 'Protective Environment' Recommendation

David Kuhar, MD
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Kuhar provided background and rationale for the ad hoc topic of a proposed update to one Protective Environment recommendation in the *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)*. As a reminder, the 2007 Isolation Precautions guideline is being updated by the HICPAC Isolation Precautions Guideline WG. As everyone heard earlier in the day, the WG is working on other parts of the guideline and has not yet gotten to the Appendix. In May 2023, the end of the COVID-19 Public Health Emergency (PHE) prompted medical centers to update policies for the use of source control devices (i.e., masking). Concerns were expressed about one recommendation in Section VI. Protective Environment and Appendix A, Table 5:

2007 VI. Protective Environment

VI.F. Use of Standard and Transmission-Based Precautions in a Protective Environment

VI.F.3. Barrier precautions (e.g., masks, gowns, gloves) are not required for healthcare personnel in the absence of suspected or confirmed infection in the patient or if they are not indicated according to Standard Precautions. **Category II**

This recommendation is reiterated in slightly different words in Appendix A, Table 5, which summarizes actions for protective environments and is highlighted in gray in the following existing table.

2007 Isolation Guidelines, Appendix A, Table 5

II. Standard and Expanded Precautions

- Hand hygiene observed before and after patient contact
- Gown, gloves, mask NOT required for HCWs or visitors for routine entry into the room
- Use of gown, gloves, mask by HCWs and visitors according to Standard Precautions as indicated for suspected or proven infections for which Transmission-Based Precautions are recommended

The concern was that this recommendation was being interpreted by some as indicating that masking for source control in a protective environment is simply not appropriate and that this was being used to apply to periods of increased respiratory virus transmission in the area. Beyond that, it was being used to say that if masking in a protective environment where the most vulnerable are located is not needed, then perhaps masking is not needed in other areas either. With that in mind, the proposed option for addressing this was as follows:

Proposed Update to the Recommendation and Appendix A, Table 5

Delete the following recommendation and Appendix A statement, pending further section review by the WG:

- Recommendation VI.F.3.: "Barrier precautions, (e.g., masks, gowns, gloves) are not required for healthcare personnel in the absence of suspected or confirmed infection in the patient or if they are not indicated according to Standard Precautions."
- Appendix A, Table 5: "Gown, gloves, mask NOT required for HCWs or visitors for routine entry into the room."

Doing this would remove recommendations on when not to wear PPE in the protective environment but would not affect when PPE is recommended in a protective environment. However, it is important to think through what the unintended consequences might be from deleting this recommendation.

Discussion Points

HICPAC noted that one of the unintended consequences is that because the protective environment is about risk of fungal infection, when it was originally written, it was likely to ensure that PPE does not keep getting added to these interactions. There are known downsides to adding PPE, and people tend to use gloves as a substitute for hand hygiene or other reasons. Hence, one of the unintended consequences of deleting this would be that people are confusing the rationale for what a protective environment actually is—protection from fungal infection for which this PPE is not indicated except for Transmission-Based Precautions. Separate from that is the issue of Source Control, which would live in other policies at a hospital or other facilities. There is an important role for the guideline to state that extra PPE is not indicated for the reason that someone is in a protective environment.

HICPAC requested further clarification on the intent of the protective environment in terms of the types of pathogens to help frame the conversation. There was discussion about multiple pathogens that might affect immunocompromised hosts and host factors, making them susceptible to infections.

Dr. Bell pointed out that there seemed to be some conflation between the environment itself as built, designed, and maintained, which was about avoiding the delivery of air loaded with fungal spores. It is the same thing that is done when there is a construction site nearby, only more. From a healthcare delivery perspective, there is reason to believe that somebody who requires that specialized environment might be at risk for a worse outcome or more complicated course if they are infected. Source control in that context seems to be not so much about the fungal issue, but more about the respiratory pathogen issue. That said, he expressed interest in hearing more about what was said about avoiding piling on too much PPE. That is a practical reality, but it is 2023, and source control remains an issue.

ASN suggested that it might be helpful to be clear with people about whether the recommendation pertains to source control or something else. Practically in healthcare systems, there are groups who want to put their patients in protective isolation or reverse isolation, though it is not clear what that means because it varies. “Wear source control when respiratory viruses are circulating” would send a clear message. Practically though, that would be year-round.

SHEA agreed that there are some potential unintended consequences in terms of people sometimes thinking that patients who are at high risk for fungal infections might be put in a protective environment based on that. Sometimes people think that someone who is immunocompromised and is very sick should be put in a protective environment, even if they do not know exactly what that means. There is a tendency to think that the patient will be safer if the HCP wears gowns and gloves into the room, even though this may not necessarily be true. Perhaps what they were trying to say was that these precautions are not required in the absence of suspected or confirmed infection in the patient, or if they are not indicated according to Standard Precautions, or if not being worn for source control. Perhaps rather than just taking these sections out, they could state what they are actually trying to say, which is, “If you need a mask for source control, that is not what we are talking about here.”

HICPAC noted that the current Appendix A does essentially make the statement about the gowns and gloves not being required. Right after that, it states, “Use of gowns, gloves, masks

for HCWs and visitors according to Standard Precautions and as indicated for suspected or proven infections for which Transmission-Based Precautions are recommended.”

SHEA suggested stating “as indicated for a suspected infection or as needed for source control.”

Dr. Bell said he was reading the last bullet as in the patient to protect the HCP as opposed to the reverse, which he thought was the concern.

Dr. Kuhar suggested that one way to fix the second highlighted bullet would be to make it more similar to the recommendation. The intent here is definitely not to provide new recommendations about when to implement source control, but rather to leave it as an option. The concern about this was that it was forbidding.

Dr. Bell recapped that based on the comments, there is a sufficient lack of clarity in the way the recommendation and appendix are currently worded, which is causing some problems, and that HICPAC might want to make some amendments for clarification. It did not seem like entire removal was needed.

Suggested language for the highlighted bullet: Add a comma at the end of the sentence and the language “with the exception of the use of masks for source control when indicated.” That way, it would not be saying this is needed across the board.

Dr. Kuhar noted that this recommendation leaves open Transmission-Based Precautions and Standard Precautions as a reason for using PPE. The idea is to ensure that source control, if the facility wants to use this at various times during the year, is also allowed. The intent is “Do No Harm.”

AAKP observed that one thing that has been learned over the past 3 years from the patient community is that clarity matters. Perhaps they could think in terms of what is the objective the recommendation is trying to achieve, and then think of it in terms of a patient-back statement. While this is targeted to medical professionals, inevitably, the customer is the one who is most impacted. The plainest language possible would be most helpful. Patients have been at the tail end of miscommunication across many federal agencies and across many healthcare administrators and systems. HCP who are not familiar with how to deal with an organ transplant patient or dialysis patients are making a subjective judgment about whether they do or do not have to do something. The patient has to self-advocate.

The group took a break to spend time incorporating the input provided during the discussion in order to develop revised language for the vote.

Vote: Amended Update on Protective Environment

Proposed Option: To improve clarity, modify the recommendation and combine the highlighted second bullet and the third bullet in the existing appendix into a single second bullet that restates updated Recommendation VI.F.3.

1. **Existing Recommendation VI.F.3.:** Barrier precautions (e.g., masks, gowns, gloves) are not required for healthcare personnel in the absence of suspected or confirmed infection in the patient or if they are not indicated according to Standard Precautions.

Proposed Update: Barrier precautions (e.g., masks, gowns, gloves) are not required for healthcare personnel in the absence of suspected or confirmed infection unless indicated according to Standard Precautions or if recommended for source control (e.g., mask) for any individuals entering the protective environment room.

2. **Existing Appendix A, Table 5:** Gown, gloves, mask NOT required for HCWs or visitors for routine entry into the room.

Proposed Update: Barrier precautions (e.g., masks, gowns, gloves) are not required for healthcare personnel in the absence of suspected or confirmed infection unless indicated according to Standard Precautions or if recommended for source control (e.g., mask) for any individual entering the protective environment room.

HICPAC voted unanimously to approve the language as proposed above for the updates to Recommendation VI.F.3. and Appendix A, Table 5. Disposition of the vote was as follows:

- 8 Approved: Dekker, Guzman-Cottrill, Kraft, Kwon, Reifsnnyder, Shenoy, Weber, Wright
- 0 Opposed
- 0 Abstained

Federal Entity Comment

No federal entity comments were provided on June 8, 2023.

Public Comment

Andrew Wang, PhD
Federally Qualified Healthcare Center

Thank you so much for having me. I am very grateful that I could be here. My name is Andrew Wang. Just want to express my sincerest appreciation for all of you here today, especially the physicians working in infectious diseases and working in public health. I know it has been a very exhausting last 4 years. Nonetheless, we need to consider and remember that COVID-19 remains a pandemic here in the United States and across the country. Just providing a little background, I have no financial disclosures today. I have a PhD of Public Health from Northwestern University and a Master's of Public Health from Columbia University as well. I previously worked in Occupational Medicine protecting healthcare workers for a large academic institution in Philadelphia. Currently, I work in a Federally Qualified Healthcare Center (FQHC) serving over 70,000 to 80,000 individuals living in the West side of Chicago. The majority of those are Black, African American, Hispanic, Latino, and Latinx. I would like to express my sincere appreciation for this chance to comment on this current proposal. Thank you, Dr. Lin, for your time today to let me speak today. I just wanted to express that the COVID pandemic has not ended, that healthcare workers need to be protected, and patients need to be protected. COVID-19 is an airborne disease. It is transmitted through aerosols and that is why N95s are more superior than surgical masks. When I previously worked in Occupational Medicine, we strongly recommended and urged our healthcare workers to don N95 masks whenever they care for patients who have an aerosol situation. Therefore, this is why N95s are necessary. N95s are not that expensive. They are not a huge burden for healthcare systems as I previously had to handle and manage the financial situation for my healthcare system. Second, the CDC HICPAC should include more expertise from aerosol scientists. Infectious disease scientists and

physicians are really important, but we need to include aerosol scientists and occupational hygienists to be a part of this discussion. We have already seen today that this review that was demonstrated in the slide deck regarding masks is not a full GRADE review. I have done systematic reviews before and this review does not prove or demonstrate that N95 masks are not effective. Compare this to the example of parachutes. If people jump out of planes with parachutes, then it is effective. If some parachutes don't work, we don't necessarily take away parachutes. We add another layer of parachutes. We provide a second back-up parachute for those who jump out of planes. My last comment here is that patients who are admitted for procedures need to be tested for COVID-19. The prevalence continues to remain high across the country and wastewater remains high as well. Patients should be tested for COVID-19. If they are tested positive, they should be kept in isolation and placed in negative pressure rooms. So, I just want to say thank you so much for your time today. Continue to be transparent. Allow the public to be part of this conversation. Thank you so much.

Jane Thomason
Certified Industrial Hygienist
National Nurses United

My name is Jane Thomason. I am a Certified Industrial Hygienist with National Nurses United (NNU), which is the largest union and professional association of registered nurses in the US. NNU stands with more than 2 dozen other organizations to urge HICPAC and the CDC to ensure that the following elements are upheld in any updates to the 2007 *Guideline for Isolation Precautions*:⁸

1. Fully recognize aerosol transmission of SARS-CoV-2 and other respiratory pathogens. HICPAC and the CDC should ensure that updated guidance includes the use of multiple control measures that have been shown to effectively prevent transmission of respiratory pathogens, including SARS-CoV-2 and others, including:
 - Ventilation to remove aerosolized viral particles and other pathogens, including the use of negative pressure isolation and other engineering controls.
 - Respiratory and eye protection for healthcare workers (HCW) providing care to patients with suspected or confirmed respiratory infections.
 - Safe staffing, which is essential to effective infection control and prevention. Updated CDC/HICPAC guidance must recognize this and must not make allowances for healthcare employers to circumvent measures necessary to protect worker and patient health due to staffing concerns.

2. CDC and HICPAC should maintain and strengthen respiratory protection and other protections for HCWs caring for patients with suspected or confirmed respiratory infections:
 - N95 respirators represent the minimum level of respiratory protection available and are essential to protecting HCWs from respiratory infections.
 - HICPAC and CDC should clearly and explicitly incorporate elastomeric and powered air-purifying respirators (PAPRs) into any updated guidance on health care infection control.

⁸ <https://www.cdc.gov/infectioncontrol/pdf/guidelines/Isolation-guidelines-H.pdf>

- PAPRs and elastomeric respirators can provide a higher level and more reliable protection than N95s, be more comfortable to wear, and more cost-effective for employers to implement.
3. The CDC must be clear and explicit on the precautions that are needed in situations where infectious pathogens are or may be present in health care settings. Don't adopt a crisis standards approach.
 4. CDC and HICPAC should engage with stakeholders, including direct care health care workers, their unions, patients, and community members to provide them with the ability to review and provide essential input into guidance updates.

We are concerned about the lack of transparency in your process to update the CDC's guidance document. Changes to this guidance will impact HCWs, patients, and communities in every state, but you have no clear mechanism to garner input from those HCWs, their unions, or patients and community members before the updates are finalized. For example, you voted before hearing public comments in this meeting today. Other organizations in support of these points have or are planning to comment for themselves and also include the International Union (UAW), Occupational Health and Safety (OHS) Section of the American Public Health Association (APHA), National Council for Occupational Safety and Health (National COSH), National Federation of Federal Employees (NFFE), National Union of Healthcare Workers (NUHW), United Food & Commercial Workers Union (USDW) Local 222, Civil Service Employees Association (CSEA) Local 1000 American Federation of State, County & Municipal Employees (AFSCME), Pandemic Equity Initiative, Long COVID Justice, and others. Thank you.

Irma L. Westmoreland, RN
Vice President
National Nurses United

My name is Irma Westmoreland. I am a Registered Nurse and Vice President for NNU, the largest labor union and professional association for Registered Nurses in the US. As you update the isolation precautions guidance, it is important for you to incorporate input from direct care nurses and members of my union. I strongly urge HICPAC and the CDC to maintain strong and clear guidance on the precautions necessary to protect HCWs and our patients from infectious diseases and to refrain from flexibility that ignores science. Healthcare employers say they need flexibility to respond to the healthcare staffing crisis, but our experience as direct care nurses during the COVID pandemic have underlined the dangers of too much flexibility in infection control. Early in the pandemic, many of our employers removed protections for nurses and other HCWs caring for COVID patients. Nurses saw our employers restrict our access to N95 respirators and then give us simple surgical masks, even when we were caring for known COVID patients. They implemented dangerous, unproven decontamination practices—even while having a supply of new N95s in storage. Nurses confronted our employers about these unsafe practices, while our employers responded by saying they were following CDC guidance. CDC's crisis and contingency standards for COVID allowed our employers to race to the lowest level of protection, even when they could and should have done better. This led to many nurses becoming infected with COVID. By NNU's count based on publicly available data, at least 5700 HCW have died from COVID, including at least 499 Registered Nurses, which is most likely severely undercounted. NNU's most recent nationwide survey found that many nurses are experiencing long COVID, which can disrupt our ability to work. It is because of these unsafe conditions created by employers that nurses are now leaving the bedside in high numbers. Nurses are no longer able or willing to risk their or their patients' safety. The flexibility that our

employers have enjoyed during the pandemic is significantly contributing to the staffing crisis. If HICPAC incorporates a similar approach into the isolation precautions guidance, it will have disastrous impacts on patients and nurse safety and will only worsen the staffing crisis. Strong protections from infectious diseases are essential to retaining nurses at the bedside. Please ensure updated guidance is clear and explicit on necessary precautions to protect us and our patients. Thank you.

Kaitlin Sundling, MD, PhD
Physician Scientists, Pathologist, and Assistant Professor
Madison, Wisconsin

I am Kaitlin Sundling, an MD/PhD, Physician Scientists, Pathologist, and Assistant Professor in Madison, Wisconsin. I'm a volunteer with the People's CDC. I have not been able to safely work in a hospital environment due to the loss of universal masking in non-patient care areas over a year ago. Now patient care masking has also been dropped. I have multiple high-risk and immunocompromised family members and they are not able to access care. Members of our community, including high-risk and disabled folks find that they must beg their healthcare providers to mask and even then, they're moving through crowded waiting areas and other shared spaces with no masking in order to get their necessary care. Airborne is airborne. There is no physical basis for variable distances of airborne transmission for different pathogens. COVID is airborne and can be transmitted by patients and healthcare workers who are asymptomatic. Healthcare facilities must require universal masking, ideally with N95 or better respirators for everyone in these settings. The proposal for 3 different levels of air precautions is inappropriate and dangerous. It is shocking to suggest that we need more studies to know whether N95 respirators are effective against an airborne pathogen. The science of N95 respirators is well-established based on physical properties, engineered filter materials, and our scientific understanding of how airborne transmission works—not clinical trials. N95 respirators have a great advantage in providing both respiratory protection to the wearer, as well as providing excellent source control. Fit testing should be provided to all workers in healthcare settings. We do not need to put patients and workers at risk in order to gather more data. In many healthcare settings, we've been doing universal masking for 3 years and we just need to continue doing it. This is something that should have been part of basic infection control prior to the pandemic. Now that we understand we can reduce the risk of transmission of infectious diseases within healthcare settings through this measure, we need to add it to our arsenal. We need to add routine universal masking to our routine standard precautions. Now is the time to provide education for all healthcare workers so that everyone knows why and how to protect themselves from COVID and other airborne pathogens. Many healthcare workers do not understand how to protect themselves or that repeated COVID infection poses increased risks of organ system damage and long COVID. We must not allow crisis standards to become the new lower routine standards of care that put patients and workers at risk. We at the People's CDC, as healthcare workers, patients, and others who are dedicated to improving public health, need your help. We need the CDC's HICPAC committee to help us implement universal masking and other protections to build safer healthcare for all of us. Thank you.

Kevin Kavanagh, MD
Health Watch USAsm

Thank you. Kevin Kavanagh. Health Watch USAsm We'd like to compliment the CDC on addressing aerosol spread of respiratory pathogens. However, we have some concerns regarding the proposed recommendations. Aerosolized particles have a continuum in science as they can be both solids and liquids. Smaller particles arrive deeper in the respiratory track

and are more likely to contain culturable viral particles. The National Academy of Sciences have found that aerosolization can occur with particle sciences up to 100 microns. The recent Cochrane Review on masking focused attention on the quality of randomized controlled trials regarding mask effectiveness. Trials comparing the effectiveness of masks were plagued with poor compliance and intermittent usage. Masking trials cannot ethically be optimally designed and should not be used to undermine decades of occupational research. We have a number of concerns with the interim guidance for healthcare staff and patient safety during the COVID-19 pandemic. Cloth masks and surgical masks should not be advocated for the prevention of spread of respiratory pathogens. These are sub-optimal for healthcare personnel and sub-optimal for use in the community. Current recommendations regarding limiting the number of persons in waiting rooms are vague and non-specific. Visitors of patients with COVID-19 should not be allowed into other areas of a facility and need to wear full PPE plus N95 masks. COVID-19 patients must have, not ideally have, a dedicated bathroom. They should also have a separately ventilated room which utilizes portable HEPA filters plus upper room UVC lighting. COVID-19 nursing home patients must be placed in single rooms or cohorted. They should not remain in current locations if this exposes other residents. Healthcare-associated SARS-CoV-2 is an unreliable metric to determine when to use respirators since the definition of “hospital onset” is flawed and will rarely be met. Facilities cannot use the levels of community transmission for guidance since the data is no longer collected. We recommend expanding surveillance and leveraging EMR to identify cases. Facility-wide masking should be universally used in all hospitals and healthcare settings at all times. COVID-19 is endemic at an unacceptable level. Plus, immunocompromised individuals frequent these settings. Even exposure of one susceptible individual is unacceptable. N95 masks or a comparable mask must be used by all. ASHRAE is proposing equivalent air exchanges of 60 liters per second per person in healthcare waiting areas and 90 in healthcare patient rooms. The CDC needs to provide clear and specific recommendations for air ventilation, filtration, and UVC utilization. Thank you.

Deborah Gold
Certified Industrial Hygienist
Retired Annuitant, Cal/OSHA

My name is Deborah Gold. I'm a Certified Industrial Hygienist and I'm working for Cal/OSHA as a Retired Annuitant (RA). Thank you for the opportunity to provide comments. I also refer to the May 31st letter from Cal-OSHA Deputy Chief, Eric Berg, for further elaboration. It will be helpful to update and revise the 2007 guidelines to learn from the almost 2 decades of research and experience regarding the behavior of infectious aerosols and occupational exposures to illnesses, including the 2009 H1N1 Avian Influenza, occupational Ebola, and COVID-19 and to make clear and protective recommendations. We agree that the distinction between droplet and airborne transmission of the 2007 guidelines often leaves out the inhalation route of infectious aerosols in the near or medium fields. California's experience with COVID-19 for example in prisons, nursing homes, and hospitals demonstrates that many aerosols can be disseminated through shared air spaces over various distances. The revised guideline should address appropriate and feasible isolation, including airborne infection isolation rooms, donning and doffing procedures for PPE, and sufficient and directional ventilation. The Evidence Review Team yesterday released slides listing the studies upon which it has relied in determining that surgical masks and N95 respirators provide equivalent protection from most respiratory illness. Both the conclusion and the evidence cited are problematic. I have not yet had a chance to review all of the cited studies, but I am aware that at least one of these studies that found no difference for laboratory-confirmed infection did find differences in other outcomes. The Loeb 2009 study found statistically significant higher incidence of febrile illness in the surgical mask

group and a difference of $p = 0.06$ of influenza-like illness. Also, several studies that are cited did not include assessment of effective respirator use, including observation of whether respirators were worn consistently, whether respirator users were trained and fit tested, and whether the effectiveness of the filtering face piece respirators was reduced due to re-donning. Some studies, such as those by Raina MacIntyre, did find greater protection with the use of respirators. Limiting the outcome to laboratory-confirmed infections biases the conclusions to the null as do most of the factors mentioned by the workgroup. Finally, the finding of “no difference” lacks scientific plausibility because research by the National Institute for Occupational Safety and Health (NIOSH) and other experts provide strong evidence that respirators, when used effectively, provide greater protection against the inhalation of aerosols. It also doesn't make sense to recommend respirators for a disease when it's classified as a pandemic and then drop it to masks when it's no longer considered a pandemic. The Evidence Review Team should consult with NIOSH MPPTL on Respiratory Protection. OSHA requires that in the workplace, respiratory protection be approved by NIOSH. Strong public health recommendations are essential to public health planning. At all levels, government and private organizations were unprepared for a pathogen that was as transmissible and virulent as SARS-CoV-2. HICPAC/CDC needs to broaden this process and include healthcare worker unions, safety and health agencies, professionals, and scientists. Thank you.

Jester Jersey
Vaccine Advocate

My name is Jester Jersey. Good afternoon HICPAC. Thank you. I wanted to mention that I have no pharmaceutical conflicts to disclose. Thank you for allowing me to address the committee. I am a vaccine advocate and I have worked with the Fraternal Service Organization, Kiwanis International, as well as UNICEF on Project Eliminate, a tetanus vaccine campaign to significantly reduce the global incidence of tetanus from 2010 to 2020. I currently volunteer with Vaccinate Your Family (VYF) and Voices for Vaccine, 2 great organizations that promote vaccine safety, support vaccine quality, and support the well-being of all Americans from vaccine-preventable diseases. Today, I want to speak about my efficacy efforts. Immunizations are important. Last month, I addressed the FDA to support the new Pfizer vaccine, ABRYSVO, and suggested strategies to limit the spread of RSV and other vaccine-preventable diseases. However, just as important are preventive measures for health personnel like is being discussed today like gloves, masking, and other strategies. After continuing recovery from the COVID pandemic, more investment is needed towards prevention. You never know when an event arises that requires preventive measures to be taken. An example of this are the Canadian wildfires affecting air quality in many US cities, like New York City. Masking has now returned to the national radar. However, unlike smoke from fires, contagious pathogens circulate silently and visibly. We don't always have the luxury of national news coverage informing prompt preventative response. At this time, we have an opportunity to lessen the burden of RSV on the health field. However, recent low vaccination rates for the flu and COVID boosters are concerning as we prepare for this year's colder season. I think there is room for improvement for all of us engaged in preventive work. I have 2 suggestions to make to the Healthcare Infection Control Practices Advisory Committee that you can pass on to your colleagues at the CDC, HHS, and other health leaders in President Joe Biden's Administration. First, public prevention implementation is hard but can be easier by working with trusted messengers such as community-based organizations (CBOs) that have vaccine advocacy experience as Surgeon General Murthy has suggested for COVID. Second, continue to ensure accessibility of vaccines like Section 317 of the Public Health Service Act (PHSA) does. This ensures vaccines are available for providers to give to those who need them and to help Americans catch-up on missed routine vaccinations. Together, these 2 suggestions can prevent strains on the national

health system, including health personnel and save lives in the process. Thank you for your time and consideration and for the work that you do to protect healthcare personnel who, in turn, are helping protect all Americans. Thank you.

**Shimi Sharief MD, MPH
Physician and Public Health Practitioner**

My name is Shimi Sharief. I am a Physician and Public Health Practitioner commenting in reference to the presentation by the IP Workgroup today. I do appreciate the discussion around protective environment and considerations for source control. I'm speaking in partnership with NNU, National Nurses United, regarding the need for infection prevention of SARS-CoV-2 and other infectious agents with known aerosol transmission in healthcare settings to keep patients and healthcare providers safe from infection. Personally, I left my urgent care practice in early 2020 at the height of the COVID-19 pandemic where I practiced part-time due to the unavailability and inconsistency of PPE recommendations and application in my particular setting in January 2020. The situation improved dramatically over the pandemic enough for me to return to clinical practice in 2021 to 2022. The revision of transmission guidance to "by air" and "by touch" modalities is an improvement from the previously faulty dichotomy of exclusively droplet or airborne, which we grappled with as I worked at state governmental public health for 18 months at the height of the pandemic. SARS-CoV-2, unlike other pathogens, continues to have high rates of airborne spread in disease and symptomatic transmission. The studies on masking presented today comparing N95 to surgical masks in healthcare settings have been rife with confounding and lack of consistency and use, enforcement, and community exposures at the time that the studies were conducted. The use of N95 respirators argues for the effectiveness of N95 over surgical masks by definition for prevention of aerosolized infection. The American Society for Testing and Materials (ASTM) guidelines for face masks moreover was designed for a lower level of protection to the wearer and for source control, especially with the models available in healthcare settings, which do not guarantee a closed fit against the wearer's face. We are also at a time of COVID-19 where vaccines are not uniformly effective for infection or for long-term disability for most, let alone for immunocompromised people and the availability of effective treatment and vaccines, experiencing a huge gap with the loss of monoclonal antibodies EVUSHELD and outpatient remdesivir treatment. NNU reflects the needs of healthcare workers, including myself, in asking for the following, which includes to fully recognize aerosol transmission of SARS-Co-V 2 and other respiratory pathogens and the need for multiple infection control measures, including ventilation and PPE. The loss of several pandemic-era data gathering tools, such as pre-symptomatic and asymptomatic testing in healthcare also means that we should assume periods of moderate to high transmission in healthcare settings at all times, given the unique circumstances of combining infected patients with vulnerable patients in the same settings. Consider a maximum approach to PPE instead of a crisis care guidance and baseline required for healthcare employers to implement. We need to maintain and strengthen respiratory protection and other protections for healthcare workers, including the use of elastomeric and powered air purified respirators into recommendations, which can be more comfortable for extended periods of wear and also address concerns around skin breakdown, fatigue, breathing difficulty, and others. Thank you so much.

**Kathleen Fagan, MD, MPH
Board-Certified Physician
Occupational and Environmental Medicine**

Thank you for the opportunity to speak today. My name is Dr. Kathleen Fagan. I am a physician, board-certified in occupational and environmental medicine. I'm also Board President of the

Association of Occupational and Environmental Clinics (AOEC), a network of some 50 clinics across the US and Canada whose chief goal is to present work in environmentally-related injuries and illnesses. Many thousands of healthcare workers are treated in our member clinics. We rely on CDC's *2007 Isolation Precautions* as the authoritative source on infection control to protect healthcare workers. We are greatly appreciative of your committee's efforts to update this guidance. The COVID pandemic has highlighted the vulnerability of healthcare workers. The Bureau of Labor Statistics reported that in 2020, the healthcare and social service industry was the only industry to experience an increase in work-related injuries and illnesses—a whopping 40% increase from the year before. 288,000 illness cases with days away from work were due to viral illnesses, primarily COVID. The CDC estimated that 1496 US healthcare workers died of COVID as of October 21. Other estimates are even higher at 3600 deaths. We have failed healthcare workers. We know how to prevent exposure to airborne infectious diseases. Ventilation, effective PPE, and administrative controls, including sick leave and safe staffing, should have prevented these illnesses and deaths. N95 Filtering Facepiece Respirators (FFRs), elastomeric respirators, and PAPRs should be a requirement for healthcare workers with airborne infectious disease exposure. All respirators should be fit tested per the Occupational Safety And Health Administration's (OSHA's) *Respiratory Protection Standard*.⁹ Studies show that the use of disinfection of elastomerics and PAPRs is feasible in healthcare settings. During your process, we strongly encourage you to obtain input from researchers; from healthcare workers; and from occupational health professions, organizations, and agencies, including NIOSH, OSHA, and the American Conference of Governmental Industrial Hygienists (ACGIH). Healthcare workers' exposure to aerosol transmission of COVID and other airborne infectious diseases is only likely to increase. As others have already said, our approach to protecting healthcare workers should be proactive and precautionary rather than reactive and crisis-driven. We owe it to our healthcare workers who are on the frontlines caring for all of us. Thank you.

Yaneer Bar-Yam, PhD
Professor & President, New England Complex Systems Institute
Co-Founder, World Health Network

My name is Yaneer Bar-Yam. I am Professor and President of the New England Complex Systems Institute (NECSI) and a Co-Founder of the World Health Network (WHN). I have 6 statements to make:

1. The evidence review of N95 respirators compared with surgical masks cited today is incorrect because it is based upon incorrect mathematical assumptions. Even though this study admits limitations, the mathematical expressions used to evaluate uncertain intervals is incorrect, both in their means (the results are biased toward null results) and in their range (resulting in smaller ranges than is consistent for this data). Again, while the limitations of the RCTs are often acknowledged, the mathematics of those studies and of the meta-analyses are not corrected to account for those limitations. Thus, the study conclusions are based upon the wrong analysis. The evidence review also chose studies that are subject to those errors, omitting many scientific studies whose results indicate that N95s are much better than surgical masks. We have previously published one relevant study on mask study assumptions with a title starting "Unmasking the mask studies . . ." ¹⁰ and will submit a second study shortly, which we can provide to the panel.

⁹ <https://www.osha.gov/respiratory-protection/standards>

¹⁰ <https://arxiv.org/abs/2102.04882>

2. While invalid, the dismissal of the increased effectiveness of N95s by these studies does not apply to elastomeric masks or PAPRs, just as for many other measures, scientifically validated causal transmission mechanisms demonstrate their effectiveness. Thus, higher levels of protection from transmission are available and can and should be used in practice and adopted in policies.
3. Where are the studies measuring the impact of provider N95 respirators on patients? Absent. Also, the adverse effects? Current UK reports say over one-quarter of infected patients were infected in the healthcare setting. Their deaths rates are also much higher.
4. The Isolation Precaution Guideline Workgroup materials do not directly mention asymptomatic transmission and should.
5. It should be a given that protecting individuals who are vulnerable to consequences of COVID infection should be a top priority in healthcare settings whose responsibility is making people well—not sick.
6. Everyone is vulnerable to organ damage from COVID. This includes, but is not limited to, non-COVID symptoms. This should be mentioned. Indeed, it should be emphasized in your statements and referred to in your policy recommendations.

Thank you.

Barbara Materna
Certified Industrial Hygienist
Retired Chief, Occupational Health Branch, California Department of Public Health

I'm Barbara Materna, a Certified Industrial Hygienist. I'm retired from the position as Chief of the Occupational Health Branch (OHB) in the California Department of Public Health (CDPH), so my comments are not official comments from CDPH. First, I fully support updating the transmission-based precautions guidance. The current guidance's distinction between droplet and airborne transmission of respiratory pathogens must be replaced with a new framework supported by the substantial science and experience accumulated since 2007. Second, the workgroup's process must be made more transparent to the public, with prompt online posting of meeting minutes and presentations. Early input is needed from the best experts in aerosol science, respiratory protection, and occupational health and all important stakeholders including healthcare worker unions; NIOSH, in particular its National Personal Protective Technology Laboratory (NPPTL); federal OSHA; and state OSHA plans. Third, the workgroup's categorization scheme for airborne pathogens must be re-evaluated and replaced with a more justifiable approach. I would like more clarity on the basis for assigning pathogens to the 3 categories, but I don't see how the proposal reflects the evidence for aerosol transport within indoor spaces over medium distances beyond 6 feet. I'm very concerned that medical or surgical masks are the recommended protection for Category 1 pathogens, with seasonal influenza and coronavirus listed as examples. This approach acknowledges these viruses are transmitted by air but would not effectively prevent worker exposure. Surgical masks are simply not designed to seal to the face and prevent inhalation exposure, nor are they certified for this purpose. Also, the proposal does not address higher risk aerosol-generating procedures. Fourth, it is essential to maintain effective OSHA-compliant respiratory protection programs in healthcare workplaces. Updated guidance should not allow for a watered-down approach to respiratory protection, such as relying on surgical masks or respirators that lack NIOSH certification. Fifth, we must improve emergency preparedness in our healthcare systems. The

COVID pandemic highlighted the need to assume inhalation transmission of emerging viral pathogens and protect healthcare workers accordingly with multiple control measures. Finally, we need to maintain worker protections for SARS-CoV-2. Long COVID poses an ongoing risk and healthcare workers are already in short supply. Nothing less than a fit tested N95 or better respirator is adequate protection. Thank you for your attention.

Nathanael Nerode
Representing Himself & Partner

This is Nathanael Nerode. I am affiliated with several organizations, but not speaking on behalf of any of them. In December of 2021, my partner who is immunocompromised, went to a doctor's office for a routine gynecological exam and was infected with COVID by doctors wearing loose surgical masks. After recovering from this, in March she went to another office for the same problem and was infected with COVID again by doctors wearing loose surgical masks. This is because surgical masks are not sufficient for prevention of aerosol transmission. It is essential that N95 or better respirators be used at all times. The standard precautions currently listed are insufficient and must be updated to require them under all circumstances. In both of the situations where my partner got infected, there were no suspected cases in the office. It makes no sense to go, "Well, there are no suspected cases, so we won't wash our hands." It makes no sense to go, "There are no suspected cases, so we won't take aerosol precautions." I have to add that the evidence review was not fit-for-purpose. In addition to the comments made by previous people, this omits the highest quality studies, which are available at the Addenbrooke's Air Disinfection Study (AAirDS). You should read them. It includes studies by Loeb 2022. Loeb 2022 has been debunked multiple times and I have emailed the Debunking Studio. In addition, Loeb failed to disclose a conflict of interest. Loeb was personally responsible from preventing Canadian nurses from getting access to N95 masks, which may well have injured and killed them. He did not disclose this conflict of interest. This makes all of his work suspect. In addition, many of the studies listed there, including Loeb 2022, contained protocols that assumed that the droplet dynamic, which is now discredited and known to be false. So, I would like to thank you again for recognizing the nature of aerosol transmission as understood by physicists and aerosol scientists—the scientific consensus, but I would like to say that you need to understand the implications of that and provide aerosol precautions as part of standard precautions for all healthcare facilities. Until then, we will continue to have the extremely high healthcare-acquired infection rate which we currently have. About a third of the cases of COVID in hospitals in Britain have been caught in hospitals for the last 12 months and it is similar in the US. Please update the *Standard Precautions*. Thank you.

Mark Nicas, PhD, MPH, CIH
Emeritus, Adjunct Professor
University of California, Berkeley

Good afternoon. My name is Mark Nicas. I am an Emeritus, Adjunct Professor in the School of Public Health at the University of California, Berkeley. I have brief comments on several related topics. First, the particle sizes in an aerosol emitted from the respiratory tract range from <1 micron to >1000 microns. Large particles may not travel far, but particles 5 microns and smaller easily disperse throughout room air and will travel outside the room if negative pressure isolation is not maintained. Fewer secondary infections at a distance from, rather than close to, an infectious person would not involve the ability of particles to travel in air. Rather, the difference would likely involve issues of infectious dose and a decreasing concentration in the air as the infectious particles move away from the source. Second, for any respiratory tract infection transmissible by inhalation, which includes seasonal influenza, such patients should be

housed in negative pressure rooms. This is especially important for pandemic-type pathogens causing high morbidity and mortality, like COVID-19 virus. Third, healthcare workers who attend patients with a respiratory tract infection transmissible by inhalation need to be provided, at a minimum, with N95 FFRs. For pandemic-type pathogens causing high morbidity and mortality, a PAPR with high efficiency filters is preferred. Surgical masks and medical masks are not sufficient, nor are barrier face coverings. Fourth, some HICPAC members believe a surgical mask is just as protective as an N95 filtering facepiece and they cite studies purporting to show no difference. When establishing disease causation by a chemical, I'm sure everyone ascribes to the Bradford Hill criterion of the biological plausibility of causation. The analogous criterion here is physical plausibility—that is, by a lot of laboratory testing, it is well-established that surgical masks permit more filter penetration and more facial leakage than do N95s. Therefore, how can a surgical mask perform just as well as an N95 in preventing an infection transmitted by inhaling infectious particles? That result is physically implausible and indicates one or more errors in how the study was conducted. The errors likely include accurately determining exposure potential and compliance with using the N95 respirator. Here is my experience as part of the study that evaluated adherence to CDC *TB Control Guidelines* in 3 hospitals. We evaluated compliance with respirator use by sitting down the hallway from TB patient rooms and directly observing the staff as they entered the rooms. Failure to wear a respirator as required was not uncommon. I doubt that self-administrated questionnaires would have indicated the same degree of non-compliance. Thank you.

Mary Kathryn (MK) Fletcher, MSPH
Safety & Health Specialist
AFL-CIO

Thank you so much. I'm MK Fletcher. I'm a Safety & Health Specialist for the AFL-CIO. We are a federation of 60 unions. We represent more than 12.5 million working people, including millions of healthcare workers, those who work in healthcare settings, and those who have been and will be patients. We are happy that the guidelines are being updated, as we have learned so much more about how to control infectious diseases since 2007 and from the world's experience with airborne COVID-19. We know that in order to protect workers and control the spread in healthcare facilities, adequate ventilation and quality respirators must be used. There are numerous lab studies that show the effectiveness of respiratory protection to protect airborne pathogens over surgical masks. The evidence review needs to be expanded to include these laboratory studies so that it is presenting the full body of evidence on respirators, masks, and other PPE. Also, the guidelines must be grounded in transmission and exposure control. There is a lot of infection expertise around the table, but this must include exposure control expertise, including aerosol scientists, ventilation experts, respiratory protection experts, and industrial hygienists. Industrial hygienists are those who understand workplaces and have combined hazard and control information into worker protections. It is unclear how these experts have been involved or if they've been involved. This is how to make sure that those impacted by this guidance, healthcare workers and patients, are properly protected from exposure to infectious agents. The impact of this guidance and the change that is made here is significant. We've watched the horror in hospitals with COVID and now things have somewhat improved with COVID, but from the limited data we currently have, it is still circulating and causing at least 30 fatalities among nursing home workers last month and many more hospital-acquired infections. We must apply the lessons learned to all pathogens. We wish we had been here earlier in the process, but the process is not as transparent as it should be. Within just today, I heard the group discuss how to word things with clarity for all healthcare workers and the public. Yet, the language has not been reviewed by those individuals or those who have expertise in that type of communication to ensure clarity. We hope to work with you all to ensure that this

guidance is strong and protects everyone in healthcare settings. If there are other ways to participate, we would love to know, to be involved, and to help ensure that all areas of expertise are at the table. Thank you so much.

Lara Zeina Jirmanus, MD, PhD
Family Medicine Specialist, Cambridge Health Alliance
Faculty, Harvard Medical School
FXB Center for Health and Human Rights, Harvard T.H. Chan School of Public Health
Member, People's CDC
Speaking on Behalf of Massachusetts Coalition for Health Equity

Hello and thank you so much for the opportunity. My name is Lara Jirmanus. I am a practicing primary care physician who has spent my career working with under-served populations and communities of color. I today testify on behalf of the Massachusetts Coalition for Health Equity (MCHE), an organization of over 400 medical providers, disabled patients, and community advocates in Massachusetts. I am also on faculty at the Harvard Medical School and also affiliated with the François-Xavier Bagnoud (FXB) Center for Health and Human Rights at the Harvard T.H. Chan School of Public Health. I have no conflicts of interest to disclose, and I do not speak on behalf my academic institution. I am grateful that the CDC is discussing the issue of airborne transmission and I agree with all of the critiques that have been put forth here today. I am also concerned that large hospitals may have a conflict of interest in the implementation of infection control measures because of the cost of masks, universal screening, testing, and other issues. I'm deeply concerned with the lack of input in this process and that the public comment portion of the agenda has occurred after many of the votes have occurred. I should also note that I am a member of the People's CDC and we remain committed to working together with CDC to ensure an equitable and comprehensive response to end the COVID-19 pandemic, because it unfortunately has not ended. We need input from occupational health experts, industrial hygienists, and aerosol scientists whose expertise would be very helpful in this area. We need more input from impacted communities, workers, unions, disabled and immunocompromised patients, and health workers. This process was essentially kept secret and even so, you can see the broad range of people from experience as well as geographies and professions that took time from their schedules to unanimously call for increased protection today for healthcare workers and patients in healthcare facilities using N95 respirators, PAPRs, and other respirators. I'm also concerned by undue influence from large hospitals, some of whose administrators sit on these committees. With hospitals in an unprecedented budget crisis and losing money cancelling procedures due to COVID-19 infections being detected in patients, along with the fact that liability waivers are no longer in effect, so patients who are infected with COVID-19 may now more easily seek legal recourse if and when they are infected with COVID-19 during medical care, means that hospitals may be advocating against COVID-19 infection control measures because it benefits them financially. This is a potential conflict of interest which should be investigated. I would argue that employees of large hospitals should not sit on this committee. I am lastly troubled by the suggestion that we have reached a point of population immunity where we do not have to try and prevent COVID. I urge you to implement a more broad process for public comment and maximize aerosol protections, including the use of N95 respirators and universal screening testing in healthcare facilities to prevent COVID infections. Thank you.

Rita Valenti, RN (retired)
Retired Bedside & Triage Nurse
Former Georgia State Legislator
Concerned Community Advocate

Volunteer, People's CDC

My name is Rita Valenti. I live in Clarkston, Georgia. I am a retired Registered Nurse from a large hospital in Atlanta. I'm a former Georgia State Legislator and I'm here today because of my decades as a bedside and triage nurse, a concerned and deeply involved community advocate, and as a volunteer with the People's CDC. I want to thank you for organizing this hearing and listening to our testimonies specifically regarding the transmission of SARS-CoV-2. I have a few brief points to make. One, COVID is airborne and can be transmitted by patients and healthcare workers who are asymptomatic. Healthcare facilities must require universal masking of well-fitting masks for everyone in the facility, with N95 as the baseline. It is true on the masking question that while a surgical mask may be effective in blocking splashes and large particle droplets, it does not filter or block very small particles in the air that may be transmitted by coughs, sneezes, and talking. Surgical masks do not provide a complete protection from germs or viruses and other contaminants because of the loose fit between the surface of the mask and your face. Instead of recommending surgical masks as a baseline, HICPAC should recommend the use of N95s along with better implementation of N95 protocols. N95 masking should be required for healthcare workers. CDC and HICPAC should consider the inclusion of expertise of aerosol scientists and occupational hygienists in reviewing studies before making recommendations and prior to voting on those recommendations. It is also important to recognize that the optimal way to prevent transmission of microorganisms such as viruses is to use a combination of interventions from across the hierarchy of controls—not just PPE alone. Patients being admitted for outpatient procedures or inpatient admissions must be tested for COVID-19. Hospitals should continue to report all COVID-19 positive tests to the CDC as well as percentage of positivity. Patients who test positive for COVID-19 should be admitted into isolation and placed in negative pressure rooms. Basement level standards of a crisis standards approach that leaves determinations of protocols for respiratory transmission of pathogens up to employers is unacceptable and can undermine both the health and safety of patients and healthcare workers, and by extension, the community. Though the CDC does not have regulatory powers, strong universal recommendations from the CDC are needed. More transparency and ease of accessing deliberations of HICPAC and CDC would help to re-establish badly needed trust with communities that are unequally impacted and concerned communities, as well as healthcare workers. Thank you for your time today.

Roy McAllister, Director Occupational Safety & Health Office United Food and Commercial Workers

Good afternoon. My name is Roy McAllister. I am the Director of the Occupational Safety & Health (OSH) Office of the United Food and Commercial Workers (UFCW). CDC and HICPAC should engage with stakeholders more effectively, including direct care healthcare workers, their unions, patients, and community members to provide them with the ability to review and provide essential input into guidance updates. The United Food and Commercial Workers represents 1.3 million members of various industries from healthcare, food processing, meat packing, retail food and non-food, chemical, and facilities. Our membership is as diverse as the industries we represent. Because of our demographics, we are important stakeholders in maintaining the health and safety interest of our members and the community at large. Part of our diverse union membership includes tens of thousands of healthcare workers. The COVID-19 pandemic brought forth the importance of ensuring the safety of our healthcare workers and illustrated distressful conditions in which they work, and how vulnerable they are for the risk of being exposed to the everyday hazards of infectious diseases. CDC and HICPAC have, through their practices, processes, and organizational composition, excluded UFCW healthcare workers from

having the ability to review and provide valuable, essential, and direct impact on the guidelines under which they are governed. Those practices are ineffective and counterproductive to engaging the unions, the communities, and the frontline healthcare workers in the development of updates that will keep everyone safe. The lack of transparency has further eroded the foundation of enabling the stakeholders to have an opportunity to be proactive instead of reactive in matters of health and safety as it relates to keeping everyone safe. To rectify those issues, there needs to be representation from the unions who represent healthcare workers, especially the UFCW, on the committees on which HICPAC and CDC serve. The committee should also provide a liaison between the healthcare community and HICPAC and CDC. This would give them a better understanding of what is needed to make sure the processes and procedures that are in place will protect healthcare workers when they are confronted with the next public health crisis. Thank you for your time and thank you for the opportunity to speak today.

**Darius Sivin, PhD
Industrial Hygienist
United Auto Workers**

I'm Dr. Darius Sivin, an Industrial Hygienist with the United Auto Workers (UAW). Although we don't have a major healthcare presence, we do represent about 5000 workers in the healthcare sector. We would like to very much associate ourselves with many of the concerns expressed today. Particularly, it took far too long to recognize that SARS-CoV-2 was transmitted by the airborne route and it took far too long to get the proper recommendations for ventilation and personal protective equipment, such as N95 respirators or even elastomeric respirators in place. We are terribly concerned that the way this body is going today is a major step backwards and does not provide adequate protection for healthcare workers from an airborne-transmitted disease. We would like to see, as many other people, we do believe that the science supports N95s and other NIOSH-approved respirators over surgical masks and ventilation for the purpose of capturing pathogenic aerosols. We are terribly concerned that this body is not going in the correct direction, and we would like to see the recommendations strengthened. Thank you very much for the opportunity to present these comments.

**Barry Hunt
President, Canadian Association of PPE Manufacturers
President & CEO, Prescient^x
Vice Chair, Coalition for Healthcare-Acquired Infection Reduction (CHAIR)**

I'm Barry Hunt and I'm coming to you from Canada today. I've been involved with healthcare for about 40 years, with the CSA National Standards for Healthcare for about 30 years, and with ISO International Standards for Health for about 20 years now. I'm the President of the Canadian Association of PPE Manufacturers (CAPPEM). I'm the CEO of a private company, Prescient^x, that develops engineered infection prevention, including reusable respirators and specialized materials like nanofiber and plant-based filtration materials for respirators. I'm involved with the Coalition for Healthcare-Acquired Infection Reduction (CHAIR), with the Canadian Healthcare Engineering Society (CHES), with Infection Prevention and Control Canada (IPAC), Society for Healthcare Epidemiology of America (SHEA), Association for Professionals in Infection Control and Epidemiology (APIC), and a dozen other organizations. I'm really heartened to see that there is almost universal support from the public comments for universal use of N95s, so that's great. I'm glad to see that novel air precautions recommends N95s and your extended air precautions. I don't like the fact that we have routine air precautions only recommending medical and surgical face masks. They are half measures, and half

measures will never work. I think we've seen that. Eventually, we have to transition away from surgical masks to a minimum N95. I'm currently involved with a CSA National Standard update for the selection, care, and use of respirators, and we're really wrestling with the fact that our current standard currently says if you follow our control mandate, a minimum N95 is required for SARS2. However, that is not universally happening in healthcare. So, it needs to be re-written in a format where people will clearly see that that would be required. One of the problems though—one of the reasons people don't want to wear N95s is they're uncomfortable, they're too hard to breath through, they're too hot, et cetera, et cetera. That is a fundamental problem. If we look at how we got to respirators, they came from the mining industry initially and they were designed to prevent rock dust—not bioaerosols. We have 2 layers of filtration material in each respirator when 1 layer would do. We could make every respirator used for healthcare twice as easy to breathe through by using a single layer. It's exactly the same construction that we have for medical masks, but of course, medical masks aren't sealed. So, I'm firmly in favor of using comfortable, easy to breathe through respirators for all use and I would hope that the committee would take that into consideration and work with their partners at NIOSH to move in that direction as well.

Greta Fox, MS
Nurse Practitioner
Founding Member, WHN

I am Greta Fox. I am a Nurse Practitioner with a degree in Family and Community Health and a Founding Member of the WHN. My concern is that this committee is making a grave error in lumping masks, gowns, and gloves together. Masks and respirators are respiratory protection against airborne pathogens. In combination with gowns and gloves, they are barrier protections against body fluid contact. This is basic. According to the World Health Organization (WHO), COVID is still a threat. It is a preventable airborne infection and leading cause of death, which is killing a person every 4 minutes worldwide. According to Fauci, there is no herd immunity with the continually mutating virus. The arsenal of effective treatments is shrinking as is access to vaccines, tests, and treatments. Any infection poses a risk of disabling long COVID and it goes up with repeated infections. I am speaking out for patients. Any individual anywhere in a facility could be immune-compromised or live with someone who is or simply prefer not to become infected with a Biosafety Level- 3 (BSL-3) pathogen, which is proven to damage the immune and vascular systems and other organs and systems as well. One-way masking is insufficient protection and is impossible for patients who are disabled or unconscious or babies or children to choose to protect themselves. Limiting protection to specific areas of the hospital fails to protect people in waiting rooms, elevators, restrooms, et cetera. We've been advocating for N95s for healthcare workers for reasons already presented. Now we have to beg healthcare workers to at least wear anything with no guarantee that this request for accommodation will be granted. Patients are putting off necessary healthcare because they are afraid of being harmed. We do not consent to risking forced infection, disability, and death in order to access healthcare, nor should we have to. Thank you very much for the opportunity to comment.

Liaison / *Ex-Officio* Reports

***Ex-Officio* Reports**

Agency for Healthcare Research and Quality

Leyi Lin, MD, FACP

**Medical Officer
Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality**

Dr. Lin provided an update on 4 ongoing projects. First, the AHRQ's Safety Program for Improving Antibody Use was led by John Hopkins University and NORC at the University of Chicago. Significant reductions in antibiotic use were seen in over 400 acute care hospitals, over 400 long-term care facilities, and over 350 healthcare practices. The final toolkit is now available on the AHRQ website. Second, the Safety Program for Improving Surgical Care and Recovery (ISCR) project was conducted by Johns Hopkins with partners at the ACS and UCSF. The Comprehensive Unit-Based Safety Program (CUSP) was adapted to improve perioperative practices and was implemented in 342 hospitals nationwide. A toolkit will be publicly available on the AHRQ website. Third, the AHRQ Safety Program for MRSA Prevention implements evidence-based prevention strategies in conjunction with behavioral improvement measures based on the CUSP model. This project is led by the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality and NORC at the University of Chicago. It focuses on the unique circumstances of Intensive Care Unit (ICU), non-ICU, high-risk surgical services, and long-term care cohorts to reduce MRSA and HAIs. An educational toolkit will be available at the end of the project. Fourth, the AHRQ Safety Program for Telemedicine project is being conducted by NORC at the University of Chicago, the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality, and Baylor College of Medicine and is taking place in outpatient, telemedicine, or hybrid care settings. One cohort aims to improve cancer diagnosis, while another cohort focuses on antibiotic stewardship.

US Food and Drug Administration

**LCDR Scott Steffen, PhD
Senior Program Management Officer
Center for Devices and Radiological Health
US Food and Drug Administration**

LCDR Steffen reported that as of May 12, 2023, the FDA COVID Incident Management Group (IMG) was demobilized. Points of contact were identified for anything related to COVID that arises in the future. The FDA webpages have been revised to reflect this determination. In addition, the FDA continues its efforts to address concerns about the use of ethylene oxide (EO) to sterilize medical devices. A new Radiation Sterilization Master File Pilot Program was recently announced. The goal of this program is to help companies advance alternative and innovative ways to sterilize approved medical devices, including changing radiation sources and a less burdensome regulatory approach. The pilot program is voluntary and intends to allow companies to sterilize single use premarket approval application (PMA)-approved medical devices using gamma radiation or EO to submit Master Files when making certain changes to their devices. In March 2023, the FDA updated its PPE webpage that describes N95 respirators, surgical masks, facemasks, and barrier face coverings; compares surgical masks to surgical respirators; discusses general N95 precautions; and discusses the use of N95s in various settings.

National Institutes of Health

**David Henderson, MD
Senior Consultant to the CEO at the Clinical Care**

Associate Director for Hospital Epidemiology and Quality Improvement National Institutes of Health

Dr. Henderson mentioned a couple of highlights from NIH's written report submitted to HICPAC. First, NIH is beginning to relax its strategies that were designed to mitigate the risk of transmission of COVID-19. NIH is continuing to screen inpatients and took advantage of the surge of RSV and influenza A activity in the community to screen its admissions for COVID-19, influenza A, and RSV. An abstract has been submitted to IDWeek to describe those results. There is ongoing surveillance of carbapenemase-producing organisms (CPOs) because of the catastrophic event in 2013. That has been enhanced to conduct surveillance for extended-spectrum beta-lactamases (ESBLs) because there has been a remarkable rise in NIH's clinical isolates of ESBLs, so there is a desire to know more about the epidemiology of those organisms. The NIH has been screening for *Candida auris* (*C. auris*) for the past 2 years. Mitigation efforts designed to address the problem identified of indolent epidemic of *Pseudomonas koreensis* infections continue. However, the precipitous drop in census during the pandemic has made those mitigation efforts much more difficult because not all of the rooms are being used and the water lies stagnant. There was an unusual case of disseminated Acanthamoeba infection on which NIH received considerable assistance from the CDC, particularly from Dr. Matt Arduino and his team, in determining where that organism might be found. The Clinical Center has recruited a new Hospital Epidemiologist, Dr. Alison Han, who likely will replace Dr. Henderson as the NIH HICPAC *Ex Officio*.

Centers for Medicare & Medicaid Services

Jasmine Dhindsa, MD
Technology, Coding, and Pricing Group
Centers for Medicare & Medicaid Services

Dr. Dhindsa indicated that CMS determines the conditions of participation and conditions of coverage, which are the health and safety requirements aimed at protecting all patients; healthcare providers; suppliers; and hospitals, critical access hospitals, and LTCFs that wish to participate in the Medicare and Medicaid programs. In October 2016, with CDC's support, CMS published a Final Rule titled, "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities" (81 FR 68688), which required in a phased-in manner that these facilities provide a robust infection prevention and control program along with new requirements for these facilities to have active Antibody Stewardship Programs (ASPs). In September 2019, after close collaboration with CDC, CMS published the Final Rule revising a number of Quality Assurance Program Improvement (QAPI) requirements for all Medicare- and Medicaid-participating hospitals and critical access hospitals. In 2022, the interim guidelines to agency directors regarding this rule required that hospital infection prevention and control problems identified in these programs must be addressed in collaboration with the Hospital-Wide QAPI program. CMS will continue to collaborate with CDC in areas of healthcare and infection control.

Liaison Reports

The Joint Commission

Tiffany Wiksten, BSN, APN, DNP
Associate Director, Standards Interpretation Group
The Joint Commission

Dr. Wiksten, the new HICPAC Liaison from The Joint Commission (TJC), reported that the Joint Commission proposed revisions to the Infection Prevention and Control Chapter for the Critical Access Hospital and Hospital Programs Field Review is open and available for comment. The proposed revisions can be accessed through the Joint Commission website by clicking on the link found on the Standards Fields Reviews webpage. The Field Review opened on May 25, 2023 and will continue until July 25, 2023. Additionally, members of the Joint Commission have been working with partners at SHEA, APIC, AHA, and IDSA on the updated Hospital Compendium and have been pleased with it being finalized. A link to the compendium in its entirety will be added to the Joint Commission website. In addition, the Joint Commission is working with several Congressional offices that are interested in antibiotic stewardship concerns.

Patient Safety Action Network

Lisa McGiffert
Patient Safety Activist
Patient Safety Action Network

Ms. McGiffert recommended that HICPAC review and listen to public comment before voting in the future. She reported that the Patient Safety Action Network (PSAN) is participating in the Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial-Resistant Pathogens (CORHA) Outbreak Policy WG that developed a framework for notification when outbreaks occur, which can be accessed through the CORHA website. She attended the in-person CORHA Outbreak Policy WG meeting the previous evening. A PSAN member on the Washington committee brought this framework to their attention and they are discussing using it as a model. PSAN would like more state health departments to seriously consider working with local hospitals to implement these frameworks.

American Association of Kidney Patients

Paul Conway
Chair, Policy and Global Affairs
American Association of Kidney Patients

Mr. Conway reported that the American Association of Kidney Patients (AAKP) held a National Patient Consumer Roundtable on May 9, 2023 that included a session focused on COVID-19 concerns for immunocompromised kidney transplant patients. This session featured Jeffery Silberzweig, MD, FASN who is the Co-Chair of the American Society of Nephrology (ASN) COVID-19 Response Team. The report from that roundtable was disseminated to 22,000 high-compromised kidney patients. In April 2023, the AAKP issued a joint statement with the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) on joint principles in regard to increasing organ transplantation and making certain that inequities in the system for minority and high-risk populations were taken into account. The AAKP issued a statement on May 10, 2023 regarding the public health emergency entitled, "Don't Forget Kidney Patients—Their Vulnerabilities Remain." That statement cited the ongoing need for the HHS Office for Civil Rights (OCR) to monitor hospitals and healthcare settings to make certain that high-risk kidney patients, including dialysis patients, are not put at risk again as they were during the pandemic when they were denied access to lifesaving services. This statement was shared with the US Congressional Kidney Caucus, the White House, and HHS Secretary Becerra. The AAKP has ongoing safety concerns for kidney patients and their families in a hospital or any other healthcare setting. The AAKP looks forward to working with the CDC

on several activities, including disseminating the announcement of kidney disease surveillance systems at the CDC will be bringing forward and ongoing work in keeping dialysis safe. In conclusion, Mr. Conway said he thought the process should be re-examined by the CDC to ensure that public comment precedes the vote. As an immunosuppressed kidney patient and for the AAKP members who were listening to this meeting, 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 has occurred over the last 3 years. There is an ongoing and serious concern about the lack of clear communications that are coming out of federal agencies, including the CDC. While he had a role during this meeting as a liaison to HICPAC, he emphasized that the representative voice of patients and caregivers needs to be incorporated throughout the process—not on the day of the meeting. He will ensure that his written comments for the record will reflect the reports that he referenced during this update.

Association of periOperative Registered Nurses

Karen DeKay, MSN, RN, CNOR, CIC
Perioperative Practice Specialist
Association of periOperative Registered Nurses

Ms. DeKay reported that AORN participated in a 17-person committee to develop performance standards for UVC room decontamination systems specific to the operating room (OR) and patient rooms. That draft is completed, and she offered to provide the link to Ms. Byrd to view the draft and comment. AORN recently was named as 1 of 50 professional organizations to *Newsweek* magazine's America's Top Online Learning Providers 2023. AORN was busy in 2022 updating 8 guidelines for its 2023 Print Book, one of which was the hot topic of flexible endoscopes. AORN intends to update 8 additional guidelines in 2023. This includes high-level disinfection, which is currently on the AORN website for public comment. Later in 2023, sterile technique and surgical attire guidelines will be posted for public comment.

Public Health Agency of Canada

Maureen Carew, MD MSc FRCPC
Director, Infection Surveillance and Prevention Division
Centre for Communicable Disease and Infection Control
Public Health Agency of Canada

Dr. Carew reported that the PHAC has been busy making some guideline updates through its National Advisory Committee on Immunization (NACI) on infection prevention and control. By the end of December 2022, they had updated their *C. auris* interim guidelines statement, which was posted on the PHAC website; acute care guidelines and pre-hospital transport guidelines for Ebola Virus Disease (EVD) in response to the Sudan Virus Disease (SVD) outbreak; and Mpox guidelines that were incorporated into the Public Health Measures (PHM) in response to the Mpox outbreak.

American Society of Nephrology & Nephrologists Transforming Dialysis Safety

Kristina Bryant, MD
Professor of Pediatrics
Division of Pediatric Infectious Diseases

University of Louisville School of Medicine

Dr. Bryant noted that the ASN is the world's largest professional society devoted to the study of kidney disease, with over 20,000 members. In addition to reporting on behalf of ASN, she also serves as the Chair of Nephrologists Transforming Dialysis Safety (NTDS). The NTDS is a collaborative effort between ASN and the CDC that is aimed at engaging frontline nephrologists to serve as team leaders in infection prevention. She reported on some of the ASN projects that are focused on infection prevention. ASN recently developed and disseminated 4 project videos specific to infection prevention and a web-based module called, "Let's Reset." The intended audience is people who receive care in dialysis facilities and people who work there. The goal is to empower patients to speak up for dialysis safety. ASN recently collaborated with the American Society of Pediatric Nephrology (ASPN) aimed at promoting vaccine confidence in patients with chronic kidney disease (CKD) and their families. Regarding the environment in which people work impacting the way they do their work, NTDS has an ongoing collaboration with human factors engineers at Virginia Tech and colleagues at CDC to study how work happens in dialysis care. A series of observations have been completed in dialysis centers, with a manuscript expected to be published soon. Recently, the team has moved into observations of home dialysis. In terms of exciting new efforts, ASN is collaborating with CDC to identify essential interventions for the prevention of peritonitis in patients with peritoneal dialysis catheters. While CDC has identified core interventions for the prevention of bloodstream infections (BSI) in patients with hemodialysis catheters, analogous interventions have not been identified for peritoneal dialysis. ASN planned to participate in the Multidisciplinary Summit in Atlanta and the Making Dialysis Safer meeting later in June 2023.

Society for Healthcare Epidemiology of America

Hilary Babcock, MD, MPH

Medical Director of Occupational Health (Infectious Diseases)

Barnes-Jewish and St. Louis Children's Hospitals

Professor of Medicine, Infectious Disease Division

Dr. Babcock reported that SHEA is in the process of applying for joint accreditation so that it can provide educational credits for its educational offerings. There is an upcoming Advancing Health Equity Through Antimicrobial Stewardship Workshop in Atlanta in September 2023 made possible by a grant from the CDC. SHEA's Compendium for *C. Diff* and *SSI* sections were published in April and May 2023 and the MRSA and Implementation sections have been submitted, accepted, and will be published soon. Collaborating organizations have been invited to provide endorsement or support for the overall compendium. There will be a series of webinars throughout the year to review the recommendations and discuss some of the issues thereof. Work is underway on infection prevention in nursing home guidance, with a SHEA panel in collaboration with CDC. SHEA also is working on a sterilization and high-level disinfection guidance document that is in draft form, which is being developed in collaboration with numerous organizations. SHEA published "The Principles of Diagnostic Stewardship," which is the first paper published as part of a series of papers on diagnostic stewardship to be published throughout the year. SHEA has a call for papers to address topics of diversity, equity, and inclusion (DEI) in healthcare epidemiology, infection prevention, and antimicrobial stewardship. SHEA has several awards that are accepting nominations. Links for all of this information are provided in SHEA's written report to be submitted to HICPAC.

Closing Remarks

Michael Bell, MD
HICPAC Designated Federal Officer

Dr. Bell observed that it had been a productive day and expressed gratitude to everyone for their effort and patience. With no additional business or discussion posed, HICPAC stood in recess at 5:06 PM ET.

Friday: June 9, 2023

Call to Order / Roll Call / Announcements

Michael Bell, MD
HICPAC Designated Federal Officer

Dr. Bell called the second day of the HICPAC meeting to order at 9:05 am on Wednesday, June 9, 2023. A roll call by Dr. Bell of HICPAC members, *Ex Officio* members, and Liaison Representatives established that there were no new COIs and that a quorum was present. Quorum was maintained throughout the day.

National Healthcare Safety Network Update

Beth Golshir, MPH
Public Health Advisor, Surveillance Branch
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

Ms. Golshir provided a National Healthcare Safety Network (NHSN) update that focused on an NHSN overview, the end of COVID-19 Public Health Emergency (PHE), modernization of quality measurement, and promoting interoperability and antibiotic use and resistance (AUR). NHSN's work is rooted in advancing DHQP's mission to protect patients; protect HCP; and promote safety, quality, and value in both national and international healthcare delivery systems. Since 2005, NHSN has served as a national surveillance program for healthcare-associated infectious diseases, antibiotic use and resistance, patient safety events, and healthcare preparedness. It is the most comprehensive tracking system for emerging and enduring threats to healthcare. NHSN collects and analyzes healthcare data from across the healthcare continuum. Healthcare facilities utilize NHSN to integrate data into prevention efforts. NHSN is also used to support CMS's pay-for-performance and value-based purchasing programs. The components of NHSN include: Patient Safety, Long-term Care Facilities (LTCF), Outpatient Dialysis, HCP Safety, Biovigilance, Outpatient Procedures, Neonatal, and Medication Safety.

NHSN has grown significantly since its inception, most notably in the last few years during the COVID-19 pandemic, to now have over 38,000 facilities that report to NHSN and over 150,000 active users. NHSN's Help Desk is very busy, typically receiving about 300 to 1000 tickets a day. Annually, they close more than 85,000 Help Desk tickets. NHSN reaches across the healthcare continuum with a variety of facility types that report to NHSN, including 16,757 skilled nursing facilities (SNF), 7266 outpatient dialysis centers, 5625 ambulatory surgical centers, 4136 acute care hospitals, 1368 critical access hospitals, 954 other long-term care facilities, 826

inpatient psychiatric care facilities, 563 home dialysis groups, 445 long-term acute care facilities, and 445 inpatient rehabilitation facilities.

In terms of the status of COVID-19 data reporting post-PHE, NHSN continues to collect COVID-19 data from hospitals and nursing homes and is actively engaging facilities to disseminate information on changes to the post-PHE data reporting requirements that take effect June 11, 2023. The data elements have been reduced for hospitals and nursing homes. Hospitals will provide weekly submission of daily values through April 2024 and fewer data elements. Nursing homes will report weekly until December 2024. These data remain important for national surveillance and monitoring and are used to update CDC's coveted Data Tracker weekly. NHSN continues to collect data on COVID-19 vaccination of HCP. The first submission of the quarterly measure of up-to-date vaccination for CMS Quality Reporting Programs (QRPs) was due May 15, 2023. This reporting requirement resulted in over 14,000 NHSN Help Desk tickets and the highest number ever of user logins recorded, with over 16,000 users logging in daily to NHSN leading up to that May deadline. This coincided with other CMS reporting deadlines, so it was a very busy month overall in terms of monitoring the impact of COVID-19. The effectiveness of prevention and control strategies continues to be a public health priority during the transition from the emergency phase to routine public health practice for NHSN and CDC.

Ms. Golshir moved on to address data modernization and quality measurement. As demonstrated during the COVID-19 Pandemic, the NHSN system is agile and permits timely modification of data collection to meet emerging public health priorities. Modernizing data collection is a public health priority for CDC. The agency is making investments to modernize its data systems, including NHSN. CDC is committed to continuing and improving work in healthcare-associated infections (HAIs) and antibiotic use and resistance, as well as developing new resources that promote patient safety. Expanding electronic data exchange and the integration of information between public health and healthcare is essential for timely, accurate, and accessible disease surveillance. One goal CDC is working toward is developing NHSN Digital Quality Measures (dQMs). These are fully-automated quality measures that are based on standards, measurement science, and clinical science that are used to drive patient-level safety and quality improvement with rigorous benchmarking and appropriate risk-adjustment.

NHSN's Modernization Roadmap Pipeline summarizes its high priority projects and work in this space to modernize NHSN's quality measures for *C. difficile*, hospital-onset bacteremia, and hypoglycemia. We are expanding surveillance activities to include respiratory pathogens, hospital bed capacity reporting, and all-hazard preparedness. The hospital bed capacity reporting will be CDC-led, as the US National Biodefense Strategy names CDC as the leader and convener of these data, but is truly a cross-agency collaboration. CDC is actively working with colleagues across CDC, Administration for Strategic Preparedness and Response (ASPR), CMS, the Office of the National Coordinator for Health Information Technology (ONC), and others to develop data elements and engage stakeholders. We envision vendor-neutral hospital bed capacity reporting, with standardized national definitions. For the bed capacity work, CDC has currently funded Oregon, Massachusetts, and Hawaii through the Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement to establish a near real-time, automated data feed of state hospital bed capacity data to NHSN. The expected outcomes of that work include aligning capacity definitions, reducing manual reporting, and improving timely response and resource allocation. The all-hazards work is focused on data collection of a standardized set of essential elements of information for emergencies. CDC is working closely with ASPR, CMS, and ONC colleagues to plan listening sessions with internal and external stakeholders to better understand the all-hazards needs, gaps, and landscape.

Turning to NHSN's quality measures work beginning with Healthcare facility-onset, antibiotic-Treated *C. difficile* Infection (HT-CDI), there was a 29% reduction in *C. difficile* cases from 2015 to 2018. However, *C. difficile* still caused 76,000 facility-acquired infections in 2018. While progress has been made, there is still work to do, and there are challenges with the current *C. difficile* infection (CDI) measure. NHSN is working to launch a new measure that is anticipated to address some of the shortcomings of the current measure, such as unintended consequences. The goals of the new HT-CDI metric include increasing face validity and clinical validity, decreasing the reporting burden, and, most importantly, promoting improvement in patient care and safety through better infection prevention practices, diagnostic stewardship, and antimicrobial stewardship while reducing unintended consequences. The HT-CDI metric and complementary metrics will be used as balancing measures and measures of unintended consequence. These measures all use patient-level data, which is expected to lead to more robust risk adjustment.

The NHSN team is also in the process of working on a Hospital-Onset Bacteremia & Fungemia (HOB) measure. The purpose of this new measure is surveillance for broader reduction of bloodstream infections (BSIs), regardless of organism or association with a device. The reason for the new HOB measure is that NHSN and colleagues have conducted an observational case match study of HOB and central line-associated bloodstream infection (CLABSI),¹¹ which found that bacteremia is not associated with CLABSI, but CLABSIs are still associated with longer stays, higher costs, and higher mortality. HOB events have a similar impact. The same study found that there are more than four times as many HOB cases as CLABSI. Of the 403 NHSN-reported CLABSIs, 70 met the HOB definition and were picked up by the new HOB measure. These measures have been submitted to the Measures Under Consideration (MUC) List and measure endorsement process. In April 2023, NHSN did a soft launch in the NHSN application for pilot sites to begin testing these measures and the use of the measures. The pilot sites are NHSN CoLabs - academic and healthcare partners - which will work to test and implement these new measures to understand how they will work before moving them forward. The measures are anticipated to launch in the NHSN application for all acute care hospitals to voluntarily report in 2024.

NHSN also is developing a measure for hypoglycemia, with a goal to automate measurement of inpatient medication-related hypoglycemia data using Fast Healthcare Interoperability Resources (FHIR)-based standards and to facilitate benchmarking of hypoglycemia rates for US hospitals. The soft launch for hypoglycemia for the pilot sites was in February 2023, and a FHIR bundle has been received successfully from one of the CoLabs sites, which is very exciting. Similar to our other measures, a 2024 launch is expected in the NHSN application for all acute care hospitals to report voluntarily.

NHSN's Respiratory Pathogen Surveillance (RPS) module will measure facility- and unit-specific incidence and prevalence of COVID-19, influenza, and Respiratory Syncytial Virus (RSV) disease among patients admitted to the hospital. This is another example of ways NHSN is expanding surveillance to improve the ability to prepare and respond to public health threats. There will be fully-automated electronic data capture of these data elements. The soft launch of the RPS module is expected in August of 2023 and is expected to go live in the NHSN application in 2024 at some point for all acute care hospitals.

All of these fully-automated projects are being piloted through the NHSN CoLab sites. This is an example of NHSN collaborating with its healthcare partners to test, pilot, implement, and

¹¹ Yu, K et al. Characteristics, costs, and outcomes associated with central line-associated bloodstream infection and hospital-onset bacteremia and fungemia in US hospitals. ICHE, in press

validate new measure concepts and approaches to data exchange. This work is aligned with the CDC's Data Modernization Initiative (DMI), and it will inform approaches to healthcare event data collection and surveillance concepts that support patient safety, quality reporting, national benchmarking, and public health preparedness and response. There are currently 8 CoLab sites with formal agreements in place, and NHSN is talking to others. The NHSN website has a page specific to CoLabs, which will be updated as this work develops and changes.

In terms of promoting interoperability and AUR surveillance, NHSN is fully-automated. Currently, thousands of hospitals report AUR data voluntarily. This is set to change in 2024, when hospitals will be required to report these data under the CMS Promoting Interoperability Program. NHSN estimates that this year, about 4500 facilities are eligible for the Promoting Interoperability Program. As of May 1, 2023, the cumulative number of facilities that have reported at least one month of AUR data was around 2800. Those reporting AR data was close to 1400. More than half of the facilities that are eligible are already reporting AUR data. AR is somewhat behind, but significant progress has been made. To date, 435 facilities can attest to being in "active engagement" with NHSN using Option 1: Pre-production & validation or Option 2: Production submission.

Discussion Points

Dr. Bell pointed out that they were seeing the active evolution of measures into increasingly more electronic seamless transfer of data. There are a couple of things driving this. It takes a lot of time and effort for people to go around with a clipboard, collect data, and enter it when really, the people who do that are better positioned to implement prevention practices. The goal is to take that administrative burden away as much as possible. It has been a hard slog because technology has not necessarily been ready for it until now. In addition, this is taking away the subjective measures.

PIDS noted the hypoglycemia measure mentioned adults, but the other measures also included pediatric sites and that the hypoglycemia measure would be rolled out only in adult acute care hospitals.

Dr. Bell said he was confident that children's hospitals and healthcare facilities with pediatric centers within them are all represented across NHSN. He did not know how much of the early uptick represented pediatrics versus adult.

Dr. Dantes indicated that he would have to get back to the group about the eligible populations for hypoglycemia (Update: eligible population is 18 years and older). For *C. difficile*, there is a minimum age of 1 year. Hospital bacteremia would include all age groups.

HICPAC inquired as to how the HT-CDI metric would deal with facilities that are using CDI prophylaxis in terms of how that impacts the metrics since it looks for new starts of CDI medication.

Dr. Dantes responded that they are very sensitive to the growing use of *C. difficile* prophylaxis and have been obtaining informal input to understand how this treatment is being done. They will be collecting granular information on the timing of *C. difficile* tests relative to the initiation of treatment and, hopefully, the variations in dosing as well. The hope is that they will be able to tell the difference between prophylactic treatment and therapeutic treatment of *C. difficile* when creating this measure.

SHEA asked how the hypoglycemia measure related to the existing electronic clinical quality measure (eCQM) from CMS and TJC hypoglycemia measure.

Dr. Bell indicated that they are ultimately intended to be unified, so there will not be 2 different measures. While he did not want to over-speak on behalf of another agency, his understanding at the moment was that there is interest in replacing that with the updated electronic measure.

It appeared to SHEA that the hospital-onset bacteremia definition said, “any pathogenic bacteria or fungi in a blood culture in a patient who has been in the hospital for more than 4 days.” There continues to be a struggle even with the CLABSI definition around some of the pathogens that are included on the list of pathogens that make it a CLABSI, some of which are clearly not preventable by the hospital. It was not clear how that would play into an even broader population who would be even more likely to pick up some of these things. The assumption is that the goal is to focus on things that are potentially preventable. The measure should explicitly and clearly state that the goal is not to benchmark one facility against another. But it is not going to be zero because some people may have presented with something they already have that is not related to their medical care.

Dental Unit Waterlines Guideline Update

Michele Neuburger, DDS, MPH
Division of Oral Health
Centers for Disease Control and Prevention

Dr. Neuburger provided a brief status update on the Dental Unit Waterlines Guideline WG. She reminded everyone that the Division of Oral Health presented during the November 2022 HICPAC meeting regarding the concern of multiple outbreaks of non-tuberculous *Mycobacterium* in children following dental procedures. These outbreaks emphasize the importance of disinfecting dental unit waterlines and testing the water regularly to ensure that it meets safety standards. During that meeting, the Division of Oral Health requested HICPAC’s assistance in updating the guidelines on dental unit waterlines, which were last updated in 2003. HICPAC has progressed with the formation of a WG, which will be tasked with providing updated guidelines on infection control in dental healthcare settings, specifically starting with updates to dental unit waterline-related issues. The goal of the WG is to create a new guideline document for dental unit waterlines, biofilm, and water quality in dental settings. The expected timeline to complete this is 18 to 24 months. Some of the preliminary research topics/questions of interest include the following:

- How effective are the germicides that we have today, and how effective are they at removing dental biofilm?
- How frequently should dental unit water be monitored?
- Should the water that comes from a dental unit be used in endodontic procedures, especially pulpotomies in primary teeth?

The Evidence Review Team has been drafting these primary topics of interest into preliminary key questions to guide the preliminary literature search. This preliminary information will be presented to the new WG when they convene for the first introductory meeting in July 2023, and updates will be provided to HICPAC as they progress.

Federal Entity Comment

No federal entity comments were provided on June 9, 2023.

Public Comment

Mary E. Miller, NP
Retired Occupational Health Nurse Practitioner

My name is Mary Miller. I'm a retired Occupational Health Nurse Practitioner. I'm representing the Occupational Health and Safety Section of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities. We are providing these comments in hopes that we can improve infection control guidance for healthcare settings, last updated in 2007. Our comments concur with the feedback from National Nurses United and other occupational health and safety professionals. CDC and HICPAC must fully recognize aerosol transmission of SARS-CoV-2 and other respiratory pathogens while updating this guidance. It's essential that these recommendations align with the current scientific evidence regarding transmission mechanisms and best practices for protective control measures. CDC and HICPAC must maintain and strengthen respiratory protection of health care workers. We are caring for patients with suspected or confirmed respiratory infections. Include the requirement for N95 respirators and incorporating elastomeric respirators and PAPRS into updated guidance. The lack of appropriate guidance and resources for respiratory protection in healthcare settings during the COVID-19 pandemic led to uncounted illnesses among patients and workers. The California Occupational Safety and Health Administration (Cal/OSHA) Aerosol Transmissible Disease (ATD) Standard (8 CCR 5199) is a good example of how to implement the use of PAPRs effectively. I have more to say, but it's notable that OSHA and NIOSH are not included on this committee, nor are unions and other worker groups that represent nurses and other workers. They should be included in future committee meetings. CDC and HICPAC must use an approach that's consistent for all employers to follow—not just a crisis response standard. There must be an approach that is clear and explicit on the precautions that are needed in situations where infectious pathogens are suspected to be present in healthcare settings. There must be a standard approach that does not leave it up to individual employers to make their own decisions with little or no accountability. We need to engage with other stakeholders more effectively, including those who are direct care health workers, patients, community members, and other public health professionals, including occupational health and safety—not just infection control professionals. Thank you very much for this opportunity. Let me know if you have any questions or concerns.

Lisa Brosseau, ScD, CIH
Center for Infectious Disease, Research, and Policy
University of Minnesota

I commend the committee for reconsidering the outmoded paradigm of droplets in airborne for infectious particle exposure, but I encourage you to think carefully about the air mode of transmission. While it is true that particle concentrations can be higher near an infected source, with time the concentration of smaller human-generated infectious particles produced by breathing and speaking will increase throughout a space. Breathing in small particles near an infected person is risky, but sharing or entering a space with an infectious person can also be risky at any distance. Yesterday's presentation recommended well-fitting masks. While it is important to focus on fit, filter efficiency and breathing resistance must come before fit. No

amount of fit will improve on a low-efficiency filter and no one will wear something with high breathing resistance tightly against their face. It is the combination of these three things and in that order from filter efficiency, to breathing resistance, to fit that matter most. Respirators are designed to have good filters, low breathing resistance, and good fit. Facemasks are not. I caution the committee to review the studies comparing surgical masks and respirators from the perspective of exposure to infectious particles, which is a function of exposure time and particle concentration. It only takes one unprotected exposure to be infected. If continuous wear was not required, then a study is incapable of evaluating the effectiveness of anything worn on the face. Finally, I strongly discourage any reference to a reliance on the ASTM Barrier Face Covering Standard. NIOSH proposed workplace performance barrier face coverings, but that was only for workers with lower risks not working in healthcare settings and only during the pandemic. Those types of barrier face coverings are not appropriate for any worker in a healthcare setting. Thank you for the opportunity to speak today.

Dheerendra Kommala, MD
Chief Medical Officer
Emergency Care Research Institute

My name is Dheerendra Kommala. I'm the Chief Medical Officer for Emergency Care Research Institute (ECRI). For the record, I have over 20 years of experience as an academic clinician, researcher, and Chief Medical Officer. ECRI is headquartered in Plymouth Meeting, Pennsylvania. ECRI is a 55-year-old independent not-for-profit organization committed to improving safety, quality, and cost-effectiveness of healthcare. ECRI has built its reputation on disciplined rigor with an unwavering commitment to independence according to our Founder's principles, Dr. Joel Nobel. ECRI is the only organization holding dual federal designations as an Evidence-Based Practice Center (EPC) and a Patient Safety Office by the US Agency of Healthcare Research and Quality (AHRQ). In January 2020, ECRI affiliated with the Institute of Safe Medication Practices (ISMP), a global leader in medication, to form one of the largest patient safety organizations in the country. To date, we have evaluated 5 million critical patient safety events and near-miss reports. Furthermore, our team of clinical engineers conduct independent medical device evaluations with laboratories in the US and Malaysia. We strongly advocate for evidence-based infection prevention and control practices. We agree as a team of infection preventionists, epidemiologists, human factors engineers, biomedical engineers, research librarians, and physicians that provide a comprehensive approach to infectious disease-related issues. Our Infection Prevention Control (IPC) Team is led by Ericka Kalp, our certified subject matter experts on infection issues facing healthcare today. The IPC team has provided hundreds of proactive infection prevention control assessments and outbreak response mitigation efforts within a variety of US healthcare facilities from dental practices, to ambulatory surgery centers, to acute care. In consideration of our expertise and impact in the world of patient safety, infection prevention, and safe medication practices, I request the CDC/HICPAC consider including ECRI as an active participant in this vital committee as a new liaison organization. Our presence will advance our mutual mission to promote the use of clinical evidence to guide practice decisions, along with the integration of human factors engineering to improve patient outcomes. ECRI will serve as an invaluable partner and we stand ready to work collaboratively. Thank you for your time and consideration of my request for liaison organization status.

Kerri Wizner, MPH, CPH
Occupational Epidemiologist

I'm Kerri Wizner. I'm an occupational epidemiologist. I'm representing the Occupational Health and Safety Section of the American Public Health Association. I echo a lot of the things that Mary Miller said that we need to maintain and strengthen respiratory practices for healthcare workers. When left up to employers, respiratory protection programs are weak either due to a lack of resources or lack of understanding. If we could promote EHFRs and PAPRs into regular usage, we wouldn't need to adopt the crisis standard approach in this updated guidance. Like Paul Conway said, people need very specific guidance. Assuming the guideline is the best-case scenario, it is likely implementation will not be followed. Precisely, I'm concerned that the direction of HICPAC is headed sets the bar too low and will mean more health care workers and patient infections. Actively engaging direct health care workers and their unions, and patients, and community members in the process to update infection control guidance is essential to crafting strong and protective infection control measures. I hope that you guys will modify the guidelines based on the feedback that you receive from these communities. Thank you.

Kevin Kavanagh, MD, MS
Health Watch USASM

I'm Kevin Kavanagh from Health Watch USASM. I would like to comment today on enhanced barrier precautions. I would like to echo the concern of the panel regarding these precautions. Enhanced barrier precautions are not taken for what is so-called low-risk activities and residents are allowed to roam around the facility. Back in November 2019, I voiced concern in a CDC public comment regarding enhanced barrier precaution effectiveness. The predicate data of these precautions does not fully support their safety. For example, low-risk activities such as passing meds had an 8% chance of contaminating gowns with MRSA, and that was with each activity. These activities are performed so commonly, transmission will occur. This data was based on an article by Mary-Claire Roghmann et al on May 26, 2015 in *Infection Control in Hospital Epidemiology*. EBP is advocated for use to mitigate the spread of CRE and *C. auris*. These are highly dangerous organisms. A controlled clinical trial is certainly indicated before planning adoption, especially in non-research settings. I would be doing online training for these precautions with extreme caution. A better approach would be to screen and identify the microbiome of residents, decolonize these residents, and if not successful, implement cohorting strategies. Admission and periodic surveillance is key to stopping MRSA in hospitals in mitigating the spread of SARS-CoV-2 and in keeping nursing home residents and working staff safe. It is concerning that the CDC appears to be moving forward with enhanced barrier precautions where there is little supporting evidence of their effectiveness with dangerous pathogens and is also at the same time considering abandoning strong recommendations for N95 masking when there are decades of occupational research supporting their use. Thank you very much.

Summary, Work Plan, & Adjournment

Michael Bell, MD
Outgoing HICPAC Designated Federal Officer

Alexander J. Kallen, MD, MPH
Incoming HICPAC Designated Federal Officer

Dr. Bell summarized that on Day 1, HICPAC reviewed the Isolation Guideline Update draft. There was discussion about the VHF segment of the Isolation Guideline in terms of how that might be made more consistent across several pathogens. The HCP Guideline update focused on CMV, Parvovirus B19, and Conjunctivitis. The Protective Environment was highlighted as an

area that needs clarification of permissive language in terms of allowing source control. They heard from the public. On Day 2, HICPAC heard an extensive overview of NHSN including future plans and evolving metrics. In addition, they heard from the Oral Health colleagues about the dental waterline work that is anticipated, and there was follow-up discussion about enhanced barriers precautions. Lastly, they heard again from the public.

In terms of the work plan, there are numerous WGs that are ongoing. The NHSN WG continues to meet and work through the needs for the MUC list. The Isolation Guideline WG is continuing to work on the draft and will present language during the remote meeting in August 2023. The HCP Guideline Update WG continues to work through their tabular approach to organisms of relevance to occupational infectious diseases. The Dental Waterline-Related WG is filling out their roster and beginning to launch their work. Finally, HICPAC has a new Sub-Mini WG that will engage in further work on the Nipah and Andes updates.

Dr. Bell thanked all of HICPAC members, *ex officios*, and liaisons for their participation. The next meeting in August 2023 will be remote. All of the details for that meeting are available online.

Dr. Kallen, incoming DFO, offered everyone's thanks to Dr. Bell for all of his work as HICPAC DFO and Executive Secretary since 2017. This was his second stint in the role, which he has done probably for most of the last 20 or so years. He has been involved in a huge number of important products that have been created over the last 7 or so years. Those who have had the pleasure of working closely with Dr. Bell have been grateful for his expertise, his strategic thinking, his calm and collected demeanor, and his vision and are thankful for his leadership in the production of high-quality guidance and are glad he can concentrate now on his other more substantial and huge number of items in his portfolio.

With no additional business raised or comments/questions posed, HICPAC stood adjourned at 11:30 AM ET on June 9, 2023.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the June 8-9, 2023 meeting of the Healthcare Infection Control Practices Advisory Committee (HICPAC), CDC are accurate and complete.

Date

Chair, HICPAC / CDC

Attachment #1: Acronyms Used in this Document

Acronym	Expansion
AAirDS	Addenbrooke's Air Disinfection Study
AAKP	American Association of Kidney Patients
ACGIH	American Conference of Governmental Industrial Hygienists
ACOEM	American College of Occupational and Environmental Medicine
ACS	American College of Surgeons
AEs	Adverse Events
AFSCME	American Federation of State, County & Municipal Employees
AGP	Aerosol-Generating Procedure
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AIIR	Airborne Infection Isolation Room
ANA	American Nurses Association
AORN	Association of periOperative Registered Nurses
APHA	American Public Health Association
APIC	Association of Professionals of Infection Control and Epidemiology
ARDS	Acute Respiratory Distress Syndrome
ASPs	Antibody Stewardship Programs
ASN	American Society of Nephrology
ASPEN	American Society of Pediatric Nephrology
ASPR	Administration for Strategic Preparedness and Response
AST	American Society of Transplantation
ASTS	American Society of Transplant Surgeons
ASTM	American Society for Testing and Materials
ATD	Aerosol Transmissible Disease
AUR	Antibiotic Use and Resistance
BSI	Bloodstream Infection
BSL-3	Biosafety Level-3
CAPPEM	Canadian Association of PPE Manufacturers
CBO	Community-Based Organization
CCHF	Crimean Congo Hemorrhagic Fever
CCTI	Cambridge Communications & Training Institute
CDC	Centers for Disease Control and Prevention
CDI	<i>C. difficile</i> Infection
CDPH	California Department of Public Health
CDRH	Center for Devices and Radiological Health
CKD	Chronic Kidney Disease
CLABSI	Central Line-associated Bloodstream Infection
CMS	Centers for Medicare and Medicaid Services
CMV	Cytomegalovirus
COI	Conflicts of Interest
COVID	Coronavirus Disease
CSEA	Civil Service Employees Association
CT	Computerized Tomography
DEI	Diversity, Equity, and Inclusion
DFO	Designated Federal Official
DHA	Defense Health Agency

Acronym	Expansion
DHQP	Division of Healthcare Quality Promotion
DMI	Data Modernization Initiative
dQMs	Digital Quality Measures
ECRI	Emergency Care Research Institute
eCQM	Electronic Clinical Quality Measure
ED	Emergency Department
EHR	Electronic Health Record
ELC	Epidemiology and Laboratory Capacity
EPC	Evidence-Based Practice Center
ET	Eastern Time
EVD	Ebola Virus Disease
FDA	(United States) Food and Drug Administration
FFR	Filtering Facepiece Respirator
FHIR	Fast Healthcare Interoperability Resources
FQHC	Federally Qualified Healthcare Center
FXB	François-Xavier Bagnoud
GI	Gastroenteritis
GRADE	Grades of Recommendation, Assessment, Development, and Evaluation
HAI	Healthcare-Associated Infection
HCP	Healthcare Personnel
HCW	Healthcare Workers
HF	Hemorrhagic Fever
HFE	Human Factors Engineering
HHS	(United States Department of) Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	Human Immunodeficiency Virus
HOB	Hospital-Onset Bacteremia & Fungemia
HT-CDI	Healthcare facility-onset, antibiotic-Treated <i>C. difficile</i> Infection
IDSA	Infectious Disease Society of America
IHS	Indian Health Service
ILI	Influenza-Like Illness
IPC	Infection Prevention Control
ISMP	Institute of Safe Medication Practices
LTCF	Long-Term Care Facilities
MCHE	Massachusetts Coalition for Health Equity
MDRO	Multidrug-resistant Organism
MERS	Middle East Respiratory Syndrome
MInD-Healthcare	Modeling Infectious Diseases in Healthcare Network
ML	Machine Learning
Mpox	Monkeypox
MRSA	Methicillin-Resistant <i>Staphylococcus Aureus</i>
MUC	Measures Under Consideration
NACCHO	National Association of County and City Health Officials
NACI	National Advisory Committee on Immunization
National COSH	National Council for Occupational Safety and Health
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NECSI	New England Complex Systems Institute
NFFE	National Federation of Federal Employees

Acronym	Expansion
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NiV	Nipah Virus
NNU	National Nurses United
NPPTL	National Personal Protective Technology Laboratory
NRHA	National Rural Health Association
NTDS	Nephrologists Transforming Dialysis Safety
OCR	HHS Office for Civil Rights
OGER	Office of Guidelines and Evidence Review
OHB	Occupational Health Branch
OHS	Occupational Health and Safety
ONC	Office of the National Coordinator for Health Information Technology
OSAP	Organization for Safety, Asepsis and Prevention
OSHA	Occupational Safety and Health Administration
PAPR	Powered Air-Purifying Respirator
PBMC	Peripheral Blood Mononuclear Cell
pCO ₂	Partial Pressure Of Carbon Dioxide
PCR	Polymerase Chain Reaction
PHE	Public Health Emergency
PHAC	Public Health Agency of Canada
PHSA	Public Health Service Act
PIDS	Pediatric Infectious Disease Society
PPE	Personal Protective Equipment
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
PSAN	Patient Safety Action Network
PUI	People Under Investigation
RA	Retired Annuitant
RCT	Randomized Control Trial
RGNB	Resistant Gram-Negative Bacteria
RN	Registered Nurse
RNA	Ribonucleic Acid
RPS	Respiratory Pathogen Surveillance
RSV	Respiratory Syncytial Virus
SAHF	South American Hemorrhagic Fevers
SARS	Severe Acute Respiratory Syndrome
SCCM	Society for Critical Care Medicine
SHEA	Society for Healthcare Epidemiology of America
SHM	Society of Hospital Medicine
SNF	Skilled Nursing Facility
SIS	Surgical Site Infection Society
SMEs	Subject Matter Experts
SpO ₂	Saturation of Peripheral Oxygen
TB	Tuberculosis
TCPG	Technology, Coding, and Pricing Group
TJC	The Joint Commission
UAW	United Automobile, Aerospace and Agricultural Implement Workers of America

Acronym	Expansion
UFCW	United Food and Commercial Workers
US	United States
USRDS	United States Renal Data System
VHF	Viral Hemorrhagic Fevers
VRI	Viral Respiratory Infection
WG	Workgroup
WHN	World Health Network
WHO	World Health Organization

Attachment #2: Public Comment Submitted in Writing

Health Watch USAsm

Member of the National Quality Forum and a designated "Community Leader" for Value-Driven Healthcare by the U.S. Dept. of Health and Human Services

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RE: CDC: Healthcare Infection Control Practices Advisory Committee (HICPAC), June 8-9, 2023

We would like to compliment the CDC on addressing aerosol spread of respiratory pathogens. However, we have some concerns regarding the proposed recommendations.

Aerosolized particles have a continuum of sizes and can be both solids and liquids. Smaller particles arise deeper in the respiratory tract and are more likely to contain culturable viral particles.(1) The National Academies of Sciences have found that aerosolization can occur with particle sizes up to 100 microns.(2)

The recent Cochrane Review(3) on masking focused attention on the quality of the randomized controlled trials regarding mask effectiveness. Trials comparing the effectiveness of masks were plagued with poor compliance and intermittent usage. Masking trials cannot ethically be optimally designed and should not be used to undermine decades of occupational research.

We have a number of concerns with the interim guidance for healthcare personnel safety during the COVID-19 pandemic.(4)

1. "Cloth masks" and "surgical masks" should not be advocated for the prevention of spread of respiratory pathogens. These are suboptimal for healthcare personnel and for use in the community.
2. Current recommendations regarding limiting the number of persons in waiting rooms are vague and not specific.
3. Visitors of patients with COVID-19 should not be allowed into other areas of the facility and need to wear full PPE plus N95 masks.

4. COVID-19 patients MUST have, NOT “Ideally” have a dedicated bathroom. They should also have a separately ventilated room which utilizes portable HEPA filters plus upper room UV-C lighting.
5. COVID-19 Nursing Home patients must be placed in single rooms or cohorted. They should not remain in “current location” if this exposes other residents.
6. Healthcare-associated SARS-CoV-2 is an unreliable metric to determine when to use respirators, since the definition of hospital onset is flawed and will rarely be met.
7. Facilities cannot use the levels of community transmission for guidance, since the data is no longer collected. We recommend expanding surveillance and leveraging EMR to identify cases.

Facility wide masking should be universally used in all hospitals and healthcare settings at all times. COVID-19 is endemic at an unacceptable level plus immunocompromised individuals frequent these settings. Even exposure of one susceptible individual is unacceptable.

N95 masks or comparable masks must be used by all. ASHRAE is proposing equivalent air exchanges of 60 liters per second per person in healthcare waiting areas and 90 in healthcare patient rooms.(5) The CDC needs to provide clear and specific recommendations for indoor ventilation, filtration and UV-C utilization.

Thank you for this consideration,

Kevin Kavanagh, MD,
MS Health Watch
USA(sm)

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Written comment to CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) for the meeting on June 8-9, 2023

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Comment:

Aerosol transmission occurs - along with various other forms of transmission - for respiratory viruses. Part of the problem is how these are defined/described/classified.

Traditional 'droplet' transmission actually includes what we now refer to as short-range aerosol transmission, i.e. the direct inhalation of smaller droplets that remain suspended in the air rather than falling to the ground for the larger droplets. This is still essentially aerosol/airborne or 'inhalation' transmission.

The traditional definition of 'airborne' or 'aerosol' transmission as only applying to that which occurs over a long distance (>2 m) is just an artificial construct - and is clearly wrong. Particles of different sizes can travel over different distances carried by local airflow patterns, depending on their strength and direction.

The main issue for CDC and other health institutions is this - instigating airborne/aerosol precautions seems like overkill for seasonal respiratory viruses with low morbidity/mortality - and is costly.

Of course, we get this - especially when influenza (and now RSV) have vaccines that can offer some protection against these seasonal viruses.

However, where a novel infectious pathogen (including more lethal mutant variants of familiar pathogens, like influenza, SARS-COV-2) causes noticeably higher morbidity/mortality, healthcare workers (HCWs) should be able to switch up their level of PPE immediately, to airborne precautions, as a precautionary move pending further characterisation of that new pathogen - without any institutional argument/obstruction.

This means that adequate stocks of that higher level PPE will need to be acquired and maintained, effectively indefinitely - though parts of this can be used in normal routine care and be replaced to maintain that stockpile.

What we got wrong during the early COVID-19 pandemic is that there was a reluctance to switch up the level of PPE despite rapidly accumulating evidence that the virus was aerosol-transmitted.

Time was wasted and evidence was challenged by traditionalists, whilst HCWs and other people got infected and died. This UK Royal College of Nursing report highlights how evidence for aerosol transmission was downplayed, disregarded and ignored there, during the pandemic:

<https://www.rcn.org.uk/news-and-events/press-releases/uk-governments-covid19-infection-controlguidelines-fundamentally-flawed>

If aerosol transmission (both short-range and long-range, as part of a continuum of exposure) was generally accepted and higher level PPE and its use was simply made available as and when needed to all HCWs (just like with hand-washing) - then we would not have lost so many HCWs to COVID-19, either due to sickness or death.

Yes, of course, hand-washing is cheaper than providing N95 masks and PAPR, but allowing HCWs to get infected and die due to inadequate PPE, through a lack of recognition that aerosol transmission is a risk - will prove even more costly, in terms of mental distress and worry, immediate workforce shortages, and potentially, related lawsuits.

The fact that enhancing PPE provision and stockpiles to cover aerosol transmission is costly in terms of materials, should not be the main focus of these guidelines. Rather, this focus should be on the reassurance to HCWs **of rapid access to adequate aerosol/airborne levels of PPE, as and when required**, to allow them to perform their roles better with less anxiety - and less risk of infection.

If HCWs are not adequately protected and are continually concerned for their safety and that of their families, to whom they return home each day - how can they possibly care for their communities to the best of their ability?

Dr. Raymond Tellier adds:

Regarding the cost of aerosol precautions, that the cost of the Covid 19 pandemic in the USA will have reached 14 trillion dollars by the end of 2023

(<https://fortune.com/well/2023/05/16/how-much-did-covid-19-pandemic-coronavirus-costeconomy-14-trillion/>).

It is likely that we will face relatively soon other pandemics with airborne viruses, such as a new emerging coronavirus, a new influenza A (AH2) anyone) , and I don't even want to contemplate influenza A(H5)...

Healthcare Infection Control Practices Advisory Committee (HICPAC)
Public Comment Transcript for June 8, 2023 (with sources)

Thank you. My name is Jester Jersey. I want to mention that I have no pharmaceutical conflicts to disclose. Good afternoon to HICPAC. Thank you for allowing me to address the Committee.

I'm a vaccine advocate and I've worked with the fraternal service organization Kiwanis International as well as UNICEF on the Eliminate Project, a tetanus vaccine campaign that significantly reduced the global incidence of tetanus from 2010-2020¹. I currently volunteer with Vaccinate Your Family² & Voices for Vaccines³, two great organizations that promote vaccine safety, support vaccine policy & the well-being of all Americans from vaccine-preventable diseases. Today, I wanted to speak about my advocacy efforts.

Immunizations are important. Last month, I addressed the FDA to support the new Pfizer vaccine, ABRYSVO, and suggested strategies to limit the spread of RSV & other vaccine-preventable diseases⁴. However, just as important are preventative measures for health personnel like those being discussed today, like gloves, masking & other strategies.

As we continue recovering from the COVID pandemic, more investment is needed towards prevention. You never know when an event arises that requires preventative measures to be taken. An example of this are the Canadian wildfires affecting air quality in many U.S. cities, like New York City⁵. Masking has now returned to the national radar. However, unlike smoke from fires, contagious pathogens circulate silently & invisibly, we don't always have the luxury of national news coverage to inform a prompt, preventative response.

At this time, we have an opportunity to lessen the burden of RSV on the health field. However, recent low vaccination rates for the flu & COVID boosters are concerning as we prepare for this year's colder season⁶. I think there is room for improvement for all of us engaged in preventative work.

Therefore, I have two suggestions to make to the Healthcare Infection Control Practices Advisory Committee to pass on to your colleagues at the CDC, HHS & other health leaders of President Joe Biden's Administration:

First, public prevention implementation is hard. Efforts can be made easier by working with trusted messengers, such as community-based organizations that have vaccine advocacy experience, as Surgeon General Vivek Murthy has suggested early on for COVID⁷.

Second, continue to insure accessibility of vaccines, like Section 317 of the Public Health Service Act does⁸. This insures vaccines are available for providers to give to those who need them & to help Americans catch up on missed routine vaccinations. Together, these two suggestions can prevent strains on the national health system, including health personnel & save lives in the process.

Thank you for your time and consideration, & for the work you do to protect healthcare personnel who in turn are helping protect all Americans.

Sources

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2. Info on Vaccinate Your Family

<https://vaccinateyourfamily.org/about-us/our-mission-history/>

3. Info on Voices For Vaccines

voicesforvaccines.org/about-us/

4. FDA’s 181st VRBPAC meeting May 18, 2023 - (My public comment)

<https://youtu.be/NXVMILYvocM?t=17812>

5. “New York City has the worst air quality in the world as smoke from Canadian wildfires rolls in”

<https://www.nbcnews.com/news/us-news/live-blog/unhealthy-air-quality-canada-wildfires-live-updates-rcna88092>

6. “*It's not too late to get a COVID booster — especially for older adults*”

<https://www.npr.org/sections/health-shots/2022/12/28/1145339626/its-not-too-late-to-get-a-covid-booster-especially-for-older-adults>

7. “*Local 'Trusted Messengers' Key To Boosting COVID Vaccinations, Surgeon General Says*”

<https://www.npr.org/sections/coronavirus-live-updates/2021/05/05/993754369/administration-plan-will-make-it-easier-to-get-access-to-vaccines>

8. “Questions Answered on Vaccines Purchased with 317 Funds”

<https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html>

**Preliminary Comments Concerning HICPAC-CDC
Infection Control Precautions
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May 26,2023**

My understanding is that under consideration by HICPAC and/or the CDC is a respirator selection logic whereby: (i) medical/surgical masks would be worn by healthcare workers (HCWs) who attended patients with seasonal coronavirus and seasonal influenza infections, and (ii) N95 filtering facepiece respirators (FFRs) would be worn by HCWs who attended patients with respiratory tract (RT) infections due to pandemic-phase or novel respiratory tract virus (such as SARS-CoV-2), measles virus, and *M. tuberculosis*. I recommend that, *at a minimum*, a successfully fit-tested NIOSH-approved N95 FFR be worn by HCWs when attending patients with all the RT infections specified above. For agents that can be transmitted person-to-person by aerosol inhalation and that cause severe morbidity and substantial risk of death, a higher level of respiratory infection beyond an N95 FFR is more appropriate.

Two items deserve further comment. First, I have the impression (hopefully a misimpression) that some parties still doubt SARS-CoV-2 is transmissible via aerosol inhalation. However, air sampling studies, experimental animal models, and infection incidence studies all support a primary role for inhalation transmission of SARS-CoV-2. For HCWs who attend patients with a RT infection due to SARS-CoV-2, in general, a successfully fit-tested NIOSH-approved N95 FFR is the minimum level of respiratory protection.

Second, I have the impression that the types of respiratory protection being considered by HICPAC-CDC are based on epidemiology studies of the comparative efficacy of N95 FFRs versus medical/surgical mask in reducing infection incidence among wearers. I offer a comment about interpreting a finding of no difference. Arguments about disease causation based on epidemiology studies usually invoke the Bradford Hill criteria for causation, one of which is *biological plausibility*, i.e., it is biologically plausible that the agent causes the observed disease. The analogous criterion when comparing the efficacy of two types of respiratory protection in preventing RT infections by a pathogen is *physical plausibility*. That is: (i) if RT infections by a pathogen like SARS-CoV-2 can be transmitted person-to-person via aerosol inhalation (and I believe they can), and (ii) given it is established via laboratory testing that a successfully fit-tested NIOSH-approved N95 FFR permits less total inward leakage of aerosol than does a non-fit-tested and non-NIOSH-approved medical/surgical mask, why would one credit a study that claimed there was no difference in protection between the two types of devices when the finding is physically implausible? I do not think such study results can be credited, but I see three possible reasons for the results.

First, the assumption that infection by the pathogen (say, SARS-CoV-2) can be transmitted via aerosol inhalation is incorrect. I do not think the assumption is incorrect, but if it were, that would argue for transmission only by droplet spray and direct contact (touch). In that case, a face shield should be recommended as opposed to a medical/surgical mask, because a face shield protects

against contact with the eyes and the mucous membranes of the nose and mouth; a medical/surgical mask does not protect the eyes.

Second, the study itself was faulty. For example, the exposure assessment was poor such that actual exposure differences between the N95 FFR and medical/surgical mask wearer groups were not discerned. These differences might involve the total time of attending patients, the procedures performed on the patient when attending, and the relative infectiousness of the patients. Or perhaps differences in study subject compliance with wearing the two device types were not accurately assessed. Given that a N95 FFR tends to fit more snugly on the face than does a medical/surgical mask, the greater discomfort might lead to less compliance with wearing the N95 FFR. If study subject exposure and compliance were assessed by self-administered questionnaires, with no attempt at verification by direct observation, I do not think one can have much faith in reported findings about comparative efficacy.

Third, in actual field usage, the N95 FFR physically performs worse than it does in the laboratory, whereas the medical/surgical mask physically performs just as well as it does in the laboratory. I suppose anything is possible, but I see no reason a priori why such a difference in physical performance would occur.

In closing, I urge HICPAC and the CDC to recognize the firm scientific evidence on RT infection transmission by aerosol inhalation. I recommend that HCWs be provided with N95 FFRs *at a minimum*, and where appropriate more protective respirators such as halfmask elastomeric and powered air-purifying respirators, when attending patients with RT infections due to seasonal coronavirus, seasonal influenza, pandemic-phase or novel respiratory tract virus (and specifically SARS-CoV-2), measles virus, and *M. tuberculosis*.

May 26, 2023

Healthcare Infection Control Practices Advisory Committee

HICPAC Committee Management

Centers for Disease Control and Prevention, MS – H16-3

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(Via email: hicpac@cdc.gov)

Re: HICPAC Revision of Guideline for Isolation Precautions

Cal/OSHA, California's state OSHA plan, is pleased to see that HICPAC is actively updating its 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. While we understand that HICPAC/CDC is not authorized to adopt occupational safety and health standards, our experience with a variety of infectious diseases – from tuberculosis to COVID-19 – is that HICPAC/CDC guidance is used by health care and other employers in providing safety protections for workers. We therefore hope that the new HICPAC/CDC guidelines will include clear recommendations that will protect workers.

According to the minutes of the November 2022 meeting, HICPAC has discussed modifying the current approach to infectious aerosols, by removing the droplet and airborne categories, and creating a new category, "air". This category would be further bifurcated into short range and long-range aerosols. Although we have not yet seen how HICPAC proposes to distinguish between the two types of aerosols, we are concerned that infectious aerosols often can travel beyond what has been considered "short range" (sometimes specified as 3 feet or six feet). Large COVID outbreaks in prisons and long-term care health care facilities have demonstrated that the behavior of infectious aerosols is not easily classified, and these aerosols are not easily confined. The lack of effective procedures to prevent transmission of infectious aerosols containing SARS-CoV-2 contributed to illness and death to workers and their families, as well as to patients and incarcerated people¹. HICPAC guidelines should provide appropriate isolation procedures for diseases transmitted by aerosols. It is important that engineering controls, such as airborne infection isolation rooms, be included in CDC recommendations for controlling exposures to infectious aerosols.

The November minutes include a draft determination by the "Evidence Review Team" (ERT) that there is only a "moderate" threat to validity for a determination that there is no difference between the use of respirators certified by the National Institute for Occupational Safety and Health (NIOSH) and surgical masks for preventing the spread of respiratory infections. This draft determination was based on a total of 10 reviewed studies, none of which are identified in the minutes. The minutes further state that in regards to laboratory-confirmed influenza, based on 4 studies, the threat to validity of the same conclusion is low. And yet, the ERT also concluded based on 5 observational studies, that N95 respirators provide greater protection than surgical masks from COVID-19, also with a level of "moderate" threat to the conclusion.

None of these studies are identified, and issues such as study design and what is meant by “respirator use” is not addressed in the mention of this finding by the ERT.

The issue of the use of respirators to protect against infectious aerosols has been the subject of substantial scientific research, debate, and controversy. The ERT’s statement regarding equivalence of surgical masks as compared to respirators should be thoroughly reviewed by occupational health experts. If adopted as is, it will result in under protection of health care workers and other workers in higher risk environments. HICPAC must present the basis for this conclusion and be open for scientific discussion and scrutiny long before any guideline is published.

The minutes also mention a potential recommendation that surgical masks or masks meeting the criteria for “workplace performance” be considered as an alternative to NIOSH certified respirators. As an OSHA state plan, Cal/OSHA enforces a Respiratory Protection Standard that is equivalent to the OSHA Standard 29 CFR 1910.134. These standards require the use of respirators that are certified by NIOSH. NIOSH conducts a comprehensive program for the testing and certification of respirators, which is used throughout the United States and in many other countries. Although NIOSH has recognized a level of “barrier protection” as defined by ASTM, in the “workplace performance” and “workplace performance plus” categories, NIOSH has clearly stated that these devices are not certified as respirators. We would strongly encourage HICPAC/CDC to use NIOSH’s expertise to develop and review any recommendations regarding respiratory protection.

Strong public health recommendations are essential for public health planning. At all levels, government and private organizations were unprepared for a pathogen that was as transmissible and virulent as SARS-CoV-2. If HICPAC/CDC does not clearly recommend respiratory protection, then neither government nor private industry will stockpile them. The results of this failure for COVID-19 was serious destabilization of health care systems, and under-protection of health care workers, some of whom contracted COVID-19 and some of whom died.

Currently, California has the only occupational safety and health regulation to protect employees against aerosol transmissible disease in most health care environments. Although not adopted as an OSHA standard, health care employers in California and the rest of the U.S. rely on HICPAC/CDC guidance for decisions regarding protection of their employees. For that reason, we encourage HICPAC and CDC to have a robust and inclusive process for the development of these guidelines. Specifically, the process should include representation from OSHA and OSHA state plans, and specific NIOSH participation. It also should include robust participation by health care workers and their unions and professional organizations, as well as occupational health specialists.

My name is Yaneer Bar-Yam, I am professor and president of the New England Complex Systems Institute and a co-founder of the World Health Network.

I have six statements to make:

1. The evidence review of N95s respirators compared with surgical masks cited today is incorrect because it is based upon incorrect mathematical assumptions. Even though the studies admit limitations, the mathematical expressions used to evaluate uncertainty intervals is incorrect, both in their means — the results are biased toward null results, and in their range, resulting in smaller ranges than is consistent with the study data. Again, while the limitations of the RCTs are often acknowledged, the mathematics of those studies and of the meta analyses is not corrected to account for those limitations, and thus the study conclusions are based upon the wrong analysis. The evidence review also chose studies that are subject to these errors, omitting many scientific studies whose results indicate that N95s are much better than surgical masks. We have previously published one relevant study on mask study assumptions with a title starting:

Unmasking the mask studies [See <https://academic.oup.com/jtm/article/28/7/taab144/6365138>, or <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8499874/>]

And will submit a second study shortly which we can provide the panel.

2. While invalid, the dismissal of the increased effectiveness of N95s by those studies does not apply to elastomeric masks or PAPRs. Just as for many other measures, scientifically validated causal transmission mechanisms demonstrate their effectiveness. Thus, higher levels of protection from transmission are available and can and should be used in practice and adopted in policies.
3. Where are the studies measuring impact of provider N95 respirators on patients? Absent. Also the adverse effects. Current UK reports say over 1/4 of infected patients were infected in the healthcare setting. Their death rates are also much higher.
4. The Isolation Precautions Guideline Workgroup materials do not directly mention asymptomatic transmission and should.
5. It should be a given that protecting individuals who are vulnerable to consequences of COVID infection should be a top priority in healthcare settings whose responsibility is making people well, not sick.
6. Everyone is vulnerable to organ damage from COVID, this includes but is not limited to Long COVID symptoms. This should be mentioned, indeed it should emphasized in your statements and referred to in your policy recommendations.