Isolation Precautions Guideline Workgroup

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HICPAC November 14, 2024

Disclaimer

- The findings and conclusions herein are **draft** and have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy.

Declarations of Interest

- None of the Workgroup members reported financial or intellectual interests related to the topics in this guideline update except for the following:
  - Consultant to companies that produce respirators
  - Research support received in the form of contributed products from OpGen and Sage Products (now part of Stryker Corporation)
  - Infection Prevention consultant and lecturer
  - Liaisons to the HICPAC committee for:
    - The Society of Healthcare Epidemiology of America (SHEA), but on this Workgroup, serves as a subject matter expert and does not represent the views of SHEA
    - The American College of Occupational and Environmental Medicine (ACOEM), but on this Workgroup, serves as a subject matter expert and does not represent the views of ACOEM

Overview

- In Nov 2023, HICPAC approved the Part 1 draft update to the 2007 Isolation Precautions Guideline to send to CDC in preparation for public comment period.
- In Jan 2024, HICPAC received 4 questions from CDC related to the Transmission by Air section of the 2023 draft guideline.
  - Portions of this two-day meeting will be dedicated to a detailed discussion of the questions and Workgroup discussion.
  - HICPAC will select final responses to the questions, particularly where differing opinions were put forward by the Workgroup.
  - Following the discussion, the response letter from HICPAC to CDC will be drafted and voted on during Day 2.
- Answers to the 4 CDC questions will provide a framework for the Workgroup to make updates to the 2023 draft, if needed, for presentation at a future meeting.

Roadmap for Today's Discussions

- Background: Workgroup goals, prior work, and membership (10 mins)
- Introduction to the CDC's 4 Questions (5 mins)
  - Context and scope
  - Roles and responsibilities
- Summary of Workgroup thoughts on the CDC's 4 Questions with HICPAC discussion
  - Question 3 (35 mins)
  - Question 4 (35 mins)
  - Question 2
  - Question 1

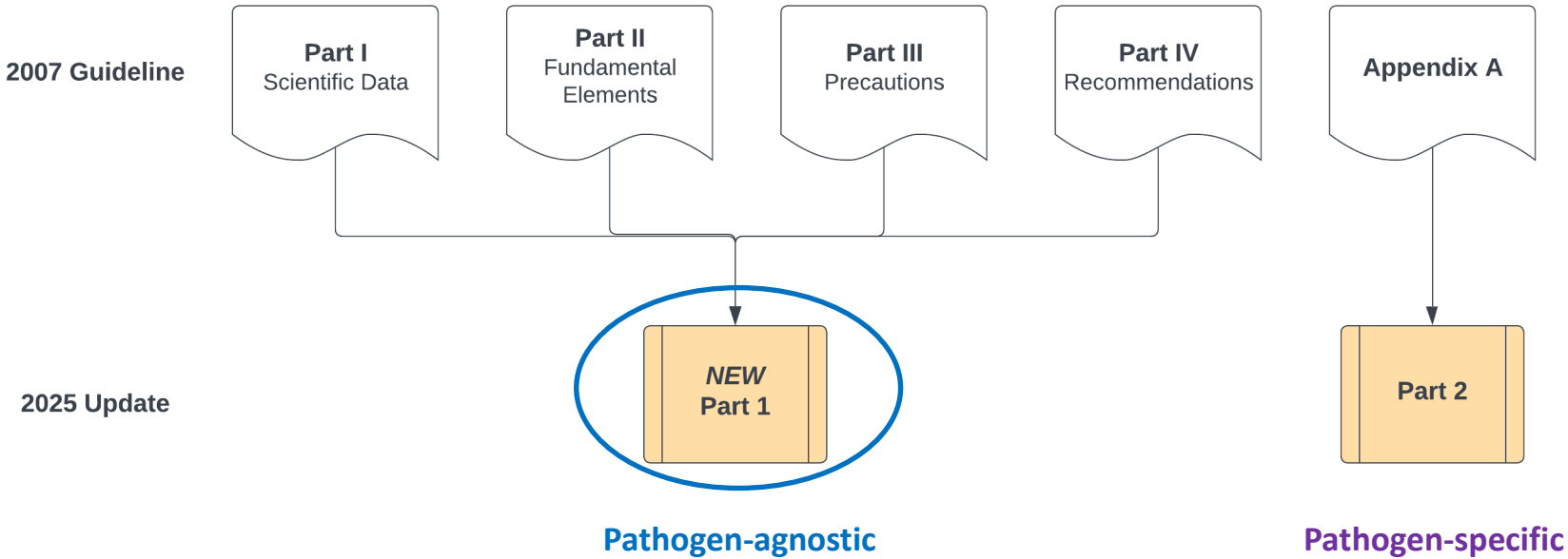
  } (70 mins)
  Will be discussed together

Background

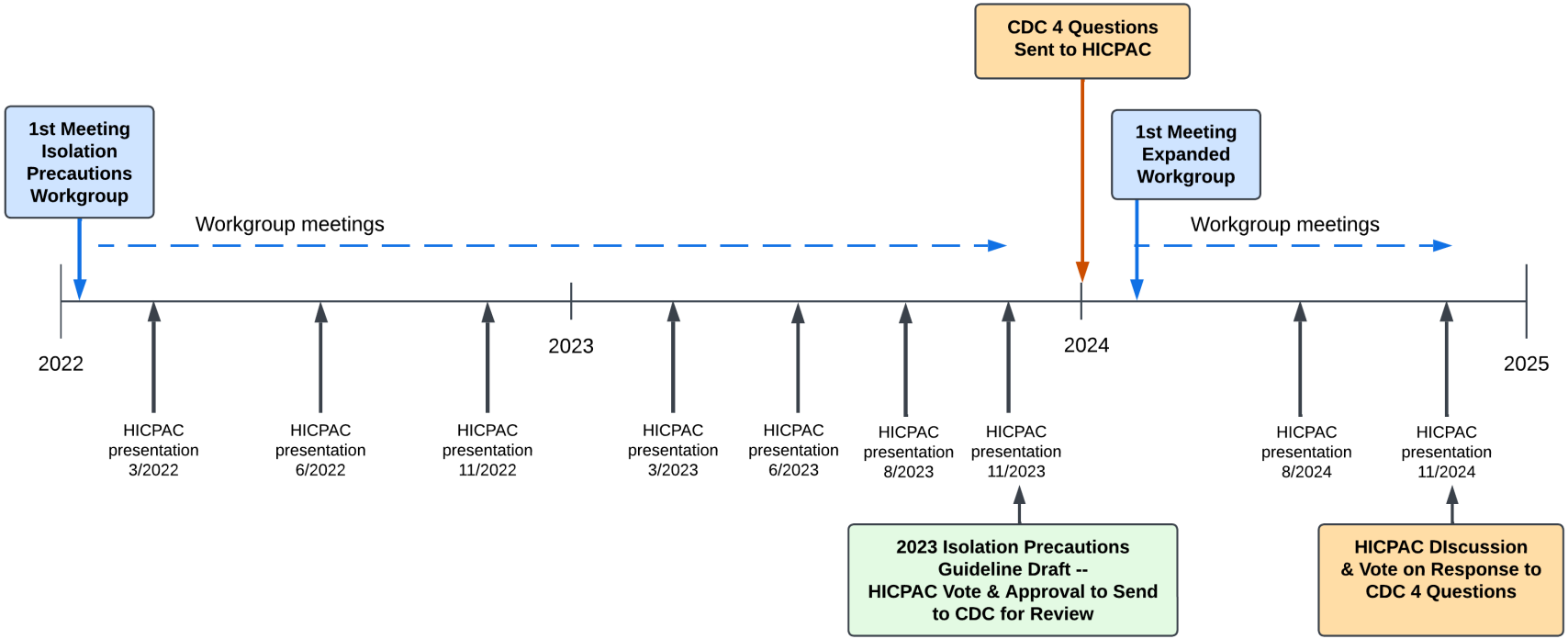
Workgroup Goal Is Creation of Update to 2007 Isolation Precautions Guideline

- Draft guideline is intended to replace corresponding content in the 2007 Guideline
- Clearer and more concise language and formatting
- Recommendations largely address infection prevention strategies that frontline healthcare personnel (HCP) may implement at the point of care
- Intended to be applicable to all healthcare settings

Update to 2007 Isolation Precautions Guideline:
Outline Structure



Timeline of Isolation Precautions Workgroup Progress on Updates to 2007 Guideline



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Workgroup Membership Updates

- Since the November 2023 HICPAC meeting, 7 new Workgroup members have been added.
  - Workgroup areas of expertise include: Infection Prevention, Healthcare Epidemiology, Employee Occupational Health, Aerosol Science, Industrial Hygiene, Long-Term Care/Post-Acute Care.
  - Total of 17 members
- There have been 20 meetings since February 29, 2024.
- External experts from OSHA and NIOSH have been invited to specific meetings to help answer questions that arose during group discussions.

Isolation Precautions Workgroup Participants

Isolation Precautions Guideline Workgroup Members: Michael Lin (Co-Chair), Sharon Wright (Co-Chair), Hilary Babcock, William Bennett, Lisa Brosseau, Elaine Dekker, Judith Guzman-Cottrill, Robert Harrison, Morgan Katz, Anurag Malani, Melissa McDiarmid, Mark Russi, Erica Shenoy, Connie Steed, Jane Thomason, Julie Trivedi, Deborah Yokoe

CDC Support

Workgroup DFO: Mike Bell; **CDC/DHQP/NIOSH Technical Staff**: Marie de Perio, Alex Kallen, David Kuhar, Kenneth Mead, Devon Okasako-Schmucker, Melissa Schaefer, Christine So, Erin Stone, David Weissman, plus pathogen-specific subject matter experts; **CDC/DHQP Support Staff:** Sydnee Byrd (Contractor), Laura Wells (Contractor)

Other Participants

Experts from OSHA, NIOSH and external organizations

Four Questions from CDC

CDC Blog Shared Context for the Four Questions Provided to HICPAC

Based on the significant interest in the draft recommendations, CDC is taking a proactive step of communicating back to HICPAC some initial questions and comments on which we would like additional consideration before submitting the guideline into the Federal Register for public comment. In addition, CDC is working to expand the scope of technical backgrounds of participants on the HICPAC Isolation Guideline Workgroup and eventually among the committee members through established processes in accordance with the Federal Advisory Committee Act (FACA) regulations and guidance. The expanded workgroup and the HICPAC with the newly appointed members will review and discuss these additional considerations and guideline at the next HICPAC meeting, which is open to the public.

Excerpt from the CDC Safe Healthcare Blog, 1/23/24
"A CDC Update on Part One Draft update to the *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*"
Daniel Jernigan, MD, MPH, Director, NCEZID, and
John Howard MD, MPH, JD, LLM, MBA, Director, NIOSH

Roles and Responsibilities Related to Answering Additional Questions from CDC

Isolation Precautions Workgroup	HICPAC
Create a forum for in-depth discussion of experts on these topics.	Evaluate possible responses to CDC questions informed by Workgroup discussions.
Workgroups are responsible for collecting, analyzing, and preparing information for presentation, discussion, deliberation, and vote by the HICPAC parent committee in an open public forum.	Provide clarifications on details of Transmission by Air recommendations to CDC leadership via vote on a response letter to the 4 questions.
Workgroups are non-voting entities and do not directly advise the agency (CDC).	Responses to 4 questions will guide the Workgroup in any needed edits to the 2023 Isolation Precautions Guideline draft.

Questions from CDC to HICPAC

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

Workgroup Created a List of Shared Interests to Guide Its Work in Answering the CDC Questions

- Final list of shared interests to consider, include those that:
  - Protect patients and healthcare personnel from infection that is transmitted via infectious particles in the air
  - Are evidence-based, incorporating science and adapting as science evolves. In the absence of evidence-based research, utilizes expert opinion and evidence from best practices
  - Incorporate risk stratification by pathogen
  - Are feasible and sustainable
  - Balance benefits and harms in relation to both patients and healthcare personnel
- Interests that would not be considered:
  - Costs (e.g., interventions, PPE)
  - Environmental impact

Question 3: Voluntary Use

Question 3

- Is the current guideline language sufficient to allow for voluntary use of a NIOSH-approved® N95 (or higher-level) respirator?
- **Should the document include a recommendation about healthcare organizations allowing voluntary use?**

Voluntary Use

2023 Draft, Air Narrative

Additional Considerations:

- While not required for Routine Air Precautions, HCP may choose to voluntarily wear a NIOSH-approved N95® (or higher level) respirator. Federal regulations specify employers' responsibilities when voluntary use of respirators is allowed in workplaces.

Existing Regulation Related to Voluntary Use of Respirators: *OSHA Respiratory Standard, 1910.134(c)*

- **1910.134(c)(2)**
  Where respirator use is not required:

- **1910.134(c)(2)(i)**
  An employer may provide respirators at the request of employees or permit employees to use their own respirators, if the employer determines that such respirator use will not in itself create a hazard. If the employer determines that any voluntary respirator use is permissible, the employer shall provide the respirator users with the information contained in appendix D to this section ("Information for Employees Using Respirators When Not Required Under the Standard"); and

- **1910.134(c)(2)(ii)**
  In addition, the employer must establish and implement those elements of a written respiratory protection program necessary to ensure that any employee using a respirator voluntarily is medically able to use that respirator, and that the respirator is cleaned, stored and maintained so that its use does not present a health hazard to the user. Exception: Employers are not required to include in a written respiratory protection program those employees whole only use of respirators involves the voluntary use of filtering facepieces (dust masks).

- **1910.134(c)(3)**
  The employer shall designate a program administrator who is qualified by appropriate training or experience that is commensurate with the complexity of the program to administer or oversee the respiratory protection program and conduct the required evaluations of program effectiveness.

https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

Key Discussion Points with Industry Expert

- The Isolation Precautions Workgroup heard an opinion from an OSHA leadership representative on voluntary use of respirators, including a discussion of the standard.
  - As originally developed, the OSHA Respiratory Standard 1910.134(c):
    - Was intended for nuisance dust.
    - Was not intended to address workplace exposures with a significant risk of transmission of infectious diseases.
    - Leaves voluntary use at the discretion of the employer and not the worker.

Workgroup Discussed Reasons to Consider a Formal Recommendation on Voluntary Use

Advantages	Disadvantages
OSHA's Respiratory Protection Program Standard (29 CFR 1910.134) does not guarantee employee voluntary use of a respirator, as it is an employer determination. A recommendation would outline requirements around voluntary use.	Adding a recommendation for voluntary use of respirators would be confusing to staff about what is necessary to prevent transmission of infection.
Permits HCP some autonomy beyond guideline recommendations in making decisions about respirators versus masks, incorporating individual risk assessment and risk tolerance.	OSHA originated the concept of 'voluntary use' through 1910.134 and thus should remain the primary source for an expanded standard regarding voluntary use in the context of infection prevention.

Question 3: Voluntary Use

Should the document include a recommendation about healthcare organizations allowing voluntary use?

Option A

- Yes, the guideline should include a recommendation about healthcare organizations allowing voluntary use. The current guideline language may not be sufficient to allow for voluntary use of a NIOSH-approved® N95 (or higher level) respirator.

Option B

- No, a specific recommendation is not needed. The current guideline language is sufficient to allow voluntary use of a NIOSH-approved® N95 (or higher level) respirator.

Example of Draft Recommendation Language, if HICPAC Selects Option A as Response to Question 3

Recommendation (*Example*):

Employers should develop a program for safe voluntary use of NIOSH-approved® N95 (or higher level) respirators by HCP, when respirator use is not otherwise required.

Discussion: Question 3

Question 4: Source Control

Question 4

- 4a: Should there be a recommendation for use of source control in healthcare settings that is broader than current draft recommendations?
- 4b: Should source control be recommended at all times in healthcare facilities?

CDC Definition of Source Control

- Source control refers to use of respirators or well-fitting facemasks to cover a person's mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing. Masks and respirators also offer varying levels of protection to the wearer.

https://www.cdc.gov/infection-control/hcp/viral-respiratory-prevention/index.html

Definition of the Term “Mask” in Today’s Discussions

- The mask definition used in the 2023 Guideline Draft will be used throughout today’s presentation.
  - Masks include surgical masks, face masks (sometimes referred to as procedure masks), and enhanced barrier face coverings* that are approved for use in healthcare.

*https://www.cdc.gov/niosh/topics/publicppe/barrier-face-coverings.html

Approaches to Source Control in 2023 Draft Represent Expansion to Include Asymptomatic Individuals

- Historically, use of masks for source control focused on **symptomatic individuals** (e.g., respiratory hygiene, cough etiquette).
  - Use of masks for individuals with symptoms suggestive of respiratory infection to reduce the risk of transmission are addressed elsewhere (e.g., in CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, Section, 5e), as are control measures other than masking (e.g., hierarchy of controls).
    https://www.cdc.gov/infection-control/hcp/core-practices/index.html
- In the 2023 guideline draft, source control additionally refers to the use of a mask for **asymptomatic individuals** whose respiratory infection status is unknown.

Approaches to Source Control in Healthcare Settings

2023 Draft, Section C, Transmission by Air

Recommendations:

1. During periods of higher levels of community respiratory virus transmission, facilities should consider implementing one of the following approaches to source control:
    a. HCP use source control when interacting with patients (e.g., on entry to the patient's room or bedspace). (Expert Opinion)
    b. All individuals (e.g., patients, visitors, and HCP) use source control upon entry to the facility or a clinical area. (Standard Practice)
        i. In most circumstances, it is not necessary for a patient to use source control when in their room; it could be considered when care is being provided. (Expert Opinion)
2. At any level of community respiratory virus transmission, consider implementing source control measures targeted toward higher risk areas (e.g., emergency departments, urgent care) or units (e.g., bone marrow transplant units) based on a facility risk assessment. (Standard Practice)

Narrative:

Individuals breathing, speaking, coughing, or sneezing generate aerosols of respiratory secretions that can contain infectious organisms. The use of a mask or respirator by an infectious individual can reduce the amount of secretions released into the environment (source control) and thus reduce exposure of people in a shared space to respiratory pathogens.

Source control, included as part of respiratory hygiene and cough etiquette in CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html), historically focused on use of masks by symptomatic patients (e.g., in waiting areas). Source control is now recognized to be applicable to asymptomatic individuals as well, since a portion of such individuals may be asymptomatically or pre-symptomatically infected with pathogens such as respiratory viruses.

While in their own room, patients would not be expected to use source control unless interacting with HCP.

Questions 4a & 4b: Key Points from Workgroup Discussions on Applications of Source Control

Supports 2023 Draft	Supports Broader Application
Source control use should be recommended based on risk assessment. This could include factors such as local epidemiology and risk of pathogen transmission.	Use of source control in all situations and/or at all times may compensate for inconsistent use of other interventions, such as screening of patients (e.g., for symptoms, exposures).
During periods of lower transmission risk, it is unclear whether source control benefits outweigh downsides (e.g., fatigue, impairment of communication).	Source control protects staff and patients from individuals with presymptomatic or asymptomatic respiratory illnesses, which can happen at any time of year.
Requiring all individuals (patients, visitors, staff) entering a healthcare facility wear source control year-round is not sustainable or practical.	The term “should consider” is not strong enough when describing the situations. Would use “should,” implying that facilities must choose one option.

Question 4a: Source Control

Should there be a recommendation for use of source control in healthcare settings that is broader than current draft recommendations?

Option A

- No, a recommendation for the use of source control in healthcare settings that is broader than the current draft recommendations is not necessary.

Option B

- Yes, a recommendation for the use of source control in healthcare settings should be broader than the current draft recommendations.

Recommendations *(Excerpt):*

1. During periods of higher levels of community respiratory virus transmission, facilities should consider implementing one of the following approaches to source control:
    a. HCP use source control when interacting with patients (e.g., on entry to the patient's room or bedspace). (Expert Opinion)
    b. All individuals (e.g., patients, visitors, and HCP) use source control upon entry to the facility or a clinical area. (Standard Practice)
2. At any level of community respiratory virus transmission, consider implementing source control measures targeted toward higher risk areas (e.g., emergency departments, urgent care) or units (e.g., bone marrow transplant units) based on a facility risk assessment. (Standard Practice)

Question 4b: Source Control

Should source control be recommended at all times in healthcare facilities?

Option A

- No, HICPAC recommends that source control decisions be determined by local risk of pathogen transmission and epidemiology, rather than at all times.

Option B

- Yes, source control should be recommended at all times in healthcare facilities.

Discussion: Question 4

Question 2 (Transmission by Air Categories) and Question 1 (Mask Use)

Question 2 and Question 1

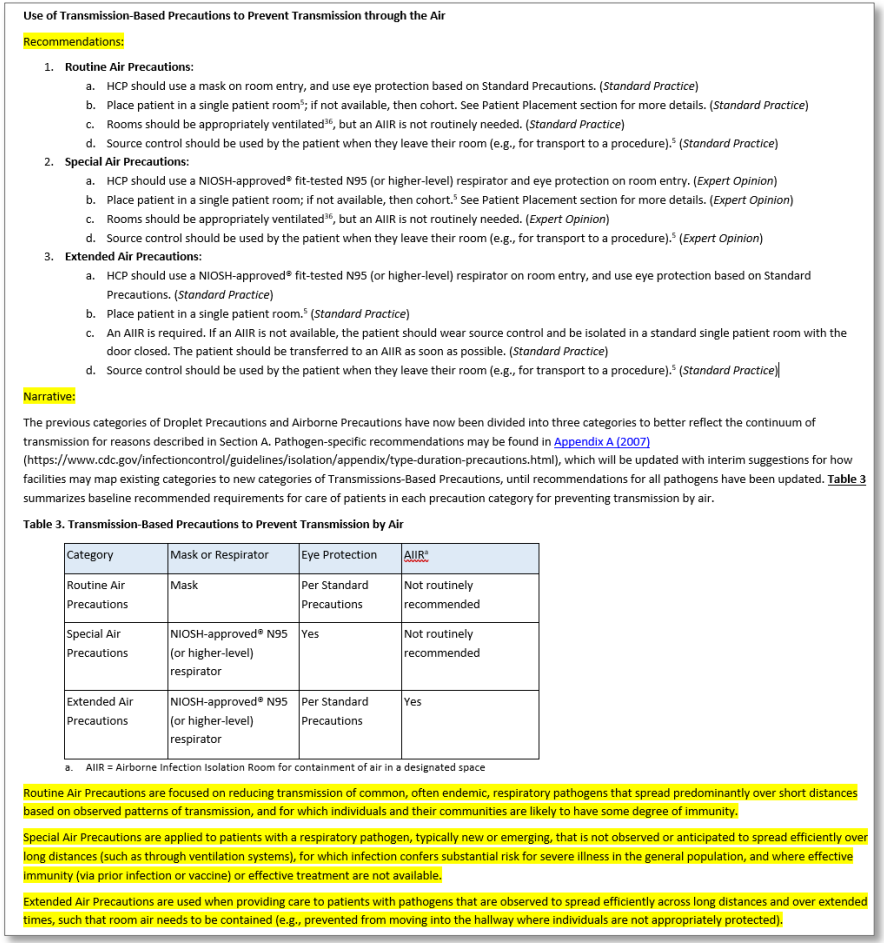
Q2	a.	**Can the WG clarify the criteria that would be used to determine which Transmission by Air category applies for a pathogen?**
	b.	For the category of Special Air Precautions, can you clarify if this category includes only new or emerging pathogens or if this category might also include other pathogens that are more established?
	c.	Can you also clarify what constitutes a severe illness?
Q1	a.	Should there be a category of Transmission-Based Precautions that includes masks (instead of NIOSH-Approved® N95 [or higher-level] respirators) for pathogens that spread by the air?
	b.	Should N95 respirators be recommended for all pathogens that spread by the air?

Roadmap for Question 2 and Question 1 Presentation

- Background (Draft Guideline presented in November 2023)
- Two options for clarification of Transmission-Based Precautions Categories to Prevent Transmission through the Air, with rationales
  - Alternate Narrative A
  - Alternate Narrative B
- Clinical effectiveness studies
- Discussion

Context of Narrative (Original 2023 Draft)

- ‘Use of Transmission-Based Precautions to Prevent Transmission through the Air’ (in Section C) contains a **recommendation section**, followed by a **narrative section** containing a Table and **three paragraphs** providing explanations of the categories of Precautions.



Use of Transmission-Based Precautions to Prevent Transmission through the Air

Recommendations:

1. **Routine Air Precautions:**
   a. HCP should use a mask on room entry, and use eye protection based on Standard Precautions. (*Standard Practice*)
   b. Place patient in a single patient room[5]; if not available, then cohort. See Patient Placement section for more details. (*Standard Practice*)
   c. Rooms should be appropriately ventilated[36], but an AIIR is not routinely needed. (*Standard Practice*)
   d. Source control should be used by the patient when they leave their room (e.g., for transport to a procedure).[5] (*Standard Practice*)
2. **Special Air Precautions:**
   a. HCP should use a NIOSH-approved® fit-tested N95 (or higher-level) respirator and eye protection on room entry. (*Expert Opinion*)
   b. Place patient in a single patient room; if not available, then cohort.[5] See Patient Placement section for more details. (*Expert Opinion*)
   c. Rooms should be appropriately ventilated[36], but an AIIR is not routinely needed. (*Expert Opinion*)
   d. Source control should be used by the patient when they leave their room (e.g., for transport to a procedure).[5] (*Expert Opinion*)
3. **Extended Air Precautions:**
   a. HCP should use a NIOSH-approved® fit-tested N95 (or higher-level) respirator on room entry, and use eye protection based on Standard Precautions. (*Standard Practice*)
   b. Place patient in a single patient room.[5] (*Standard Practice*)
   c. An AIIR is required. If an AIIR is not available, the patient should wear source control and be isolated in a standard single patient room with the door closed. The patient should be transferred to an AIIR as soon as possible. (*Standard Practice*)
   d. Source control should be used by the patient when they leave their room (e.g., for transport to a procedure).[5] (*Standard Practice*)

Narrative:

The previous categories of Droplet Precautions and Airborne Precautions have now been divided into three categories to better reflect the continuum of transmission for reasons described in Section A. Pathogen-specific recommendations may be found in Appendix A (2007) (https://www.cdc.gov/infectioncontrol/guidelines/isolation/appendix/type-duration-precautions.html), which will be updated with interim suggestions for how facilities may map existing categories to new categories of Transmissions-Based Precautions, until recommendations for all pathogens have been updated. **Table 3** summarizes baseline recommended requirements for care of patients in each precaution category for preventing transmission by air.

Table 3. Transmission-Based Precautions to Prevent Transmission by Air

Category	Mask or Respirator	Eye Protection	AIIR[a]
Routine Air Precautions	Mask	Per Standard Precautions	Not routinely recommended
Special Air Precautions	NIOSH-approved® N95 (or higher-level) respirator	Yes	Not routinely recommended
Extended Air Precautions	NIOSH-approved® N95 (or higher-level) respirator	Per Standard Precautions	Yes

a. AIIR = Airborne Infection Isolation Room for containment of air in a designated space

Routine Air Precautions are 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.

Special Air Precautions are applied to patients with a respiratory pathogen, typically new or emerging, that is not observed or anticipated to spread efficiently over long distances (such as through ventilation systems), for which infection confers substantial risk for severe illness in the general population, and where effective immunity (via prior infection or vaccine) or effective treatment are not available.

Extended Air Precautions are used when providing care to patients with pathogens that are observed to spread efficiently across long distances and over extended times, such that room air needs to be contained (e.g., prevented from moving into the hallway where individuals are not appropriately protected).

Original 2023 Draft, Air Narrative, Table 3: Transmission-Based Precautions to Prevent Transmission through the Air

Category	Mask or Respiratory Protection	Eye Protection	AIIR[a]
Routine Air Precautions	Mask	Per Standard Precautions	Not routinely recommended
Special Air Precautions	NIOSH-approved® N95 (or higher-level) respirator	Yes	Not routinely recommended[b]
Extended Air Precautions	NIOSH-approved® N95 (or higher-level) respirator	Per Standard Precautions	Yes

a. AIIR = Airborne Infection Isolation Room for Containment of Air in a Designated Space
b. Although an AIIR is not routinely recommended, an AIIR may be suggested for certain pathogens listed in Appendix A (2007), and for pathogens with uncertain transmission characteristics

Use of Transmission-Based Precautions to Prevent Transmission through the Air: *Narrative (Original 2023 Draft, Section C)*

- **Routine Air Precautions** are 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.

- **Special Air Precautions** are applied to patients with a respiratory pathogen, typically new or emerging, that is not observed or anticipated to spread efficiently over long distances (such as through ventilation systems), for which infection confers substantial risk for severe illness in the general population, and where effective immunity (via prior infection or vaccine) or effective treatment are not available.

- **Extended Air Precautions** are used when providing care to patients with pathogens that are observed to spread efficiently across long distances and over extended times, such that room air needs to be contained (e.g., prevented from moving into the hallway where individuals are not appropriately protected).

Major Pathogens from 2007 Guideline, Appendix A Anticipated to Require Transmission-Based Precautions to Prevent Transmission through the Air

Droplet + Standard (6 bacteria, 7 viruses)	Airborne + Standard (1 bacteria, 3 viruses)
1. Adenovirus (pneumonia only) (+Contact Prec.)	1. Measles
2. *Corynebacterium diphtheriae* (pharyngitis)	2. *Mycobacterium tuberculosis*
3. *Haemophilus influenzae* (meningitis, epiglottitis, pneumonia [children])	3. SARS-CoV-1
4. Influenza virus	4. Varicella-Zoster Virus (chickenpox; disseminated zoster)
5. Mumps (infectious parotitis)	
6. *Mycoplasma pneumoniae* (pneumonia)	
7. *Neisseria meningitidis* (meningitis; sepsis; pneumonia)	
8. Parvovirus B19 (erythema infectiosum)	
9. Pertussis (whooping cough)	
10. Rhinovirus	
11. Rubella (German measles)	
12. *Streptococcus pyogenes* (pneumonia; scarlet fever; major [but not minor] skin/wound/burn)	
13. *Yersinia pestis* (pneumonic)	

Note: This pathogen list is not comprehensive, and other pathogens such as SARS-CoV-2 are anticipated to be included in the updated draft guideline (Part 2). Some pathogens may require additional Precautions such as Contact Precautions.

https://www.cdc.gov/infectioncontrol/guidelines/isolation/appendix/type-duration-precautions.html

Question 2a: *Can the WG clarify the criteria that would be used to determine which transmission by air category applies for a pathogen?*

- There were two major viewpoints that emerged from workgroup discussion, which are captured in **two alternate narratives, A and B.**
  - Significant differences exist between the narratives, including but not limited to the application of masks and respirators, and the approach to determining Transmission by Air categories.

Alternate Narrative A

- Pathogen-specific recommendations for categories of Transmission-Based Precautions to prevent transmission through the air are applied based on an assessment of risk of infection and associated adverse outcomes. Important considerations include:

  (1) **Transmissibility** (i.e., ease of spread as determined by factors related to pathogen, contact patterns, and environmental conditions).

  (2) **Burden of morbidity and mortality associated with infection among patients, healthcare personnel, visitors, and others**. Morbidity and mortality are affected by factors such as level of protective immunity in the population from vaccination or previous infection, the availability of effective treatment, and prevalence of risk factors that increase the risk of infection.

  (3) **Whether a pathogen transmitted via air is observed to spread efficiently over long distances**, such as through ventilation systems.

Alternate Narrative A (cont.)

- **Routine Air Precautions** are focused on reducing transmission of common, often endemic, respiratory pathogens for which individuals and their communities are likely to have some degree of immunity, and for which masks have been observed to be effective at reducing risk of transmission of infection.
- **Special Air Precautions** are focused on reducing transmission of respiratory pathogens for which infection confers substantial risk for severe morbidity or mortality in the general population, and where effective immunity (via prior infection or vaccine) or effective treatment are not available. Pathogens to which Special Air Precautions may be applied are typically, though not exclusively, new and emerging.
- **Extended Air Precautions** are focused on reducing transmission of respiratory pathogens that are observed to spread efficiently across long distances and over extended times, such that additional engineering controls are needed (e.g., special air handling and ventilation).

How Alternate Narrative A Differs from 2023 Draft Narrative

- **No substantive change to original narrative.** However, adds clarifications as follows:
  - New initial paragraph lists important considerations (transmissibility; burden of morbidity and mortality; efficiency of spread over distance).
  - Mask recommendations are based on observed effectiveness in reducing risk of transmission of infection.
  - “Severe illness” has been clarified as ‘morbidity and mortality’ to more clearly encompass a variety of pathogen-related adverse outcomes that are not limited to hospitalization and death.
  - For the category of Special Air Precautions, this category might also include other pathogens that are more established.

Key Points from Workgroup Members Supporting Alternate Narrative A

- Masks should be an option for PPE based on observed clinical effectiveness for reducing risk of transmission for many pathogens.
- Multiple Transmission by Air precaution categories allow recommendations to be matched to pathogen considerations.
- Two proposed categories (Routine Air Precautions; Extended Air Precautions) incorporate approaches considered standard practice, and one proposed category (Special Air Precautions) is expected to increase overall use of NIOSH-approved® N95 (or higher level) respirators for certain pathogens and situations.

Alternate Narrative B

- Pathogen-specific recommendations for categories of Transmission-Based Precautions to prevent transmission through the air are applied based on an assessment of exposure and risk of infection and associated adverse outcomes. Important considerations include:

  (1) **Transmissibility** (i.e., ease of spread as determined by factors related to pathogen, contact patterns, and environmental conditions).

  (2) **Adverse outcomes associated with infection among patients, healthcare personnel, visitors, and others.** Morbidity and mortality are affected by factors such as level of protective immunity or immunocompromise in the population, the availability of effective treatment, and prevalence of risk factors that increase the risk of infection. Adverse outcomes also include lost workdays due to infection and onward transmission to other patients, workers, and others outside the health care facility.

Alternate Narrative B (cont.)

- **Standard of Practice Air Precautions** are applied to patients with any pathogen capable of being transmitted via air* and require the use of a NIOSH-approved® N95 filtering facepiece respirator (FFR).
- **Limited Air Precautions** are applied based on an exposure and risk assessment to pathogens and situations in which there is no risk of aerosol generation. It may be possible to use masks instead of respirators, following consultation with employees. Must allow voluntary use of respirators.
- **Engineering Air Precautions** are used when providing care to patients with pathogens that, based on an exposure and risk assessment, require additional measures to prevent transmission, such as AIIRs and higher-level respirators (powered air purifying respirators [PAPRs] and/or elastomeric respirators). All novel and emerging pathogens must start in this category and may be moved to other categories based on an exposure and risk assessment.

Capable of transmitting through the air means that there is evidence that:

1. Aerosols containing the pathogen can be generated by or from an infectious person
2. The pathogen remains viable in the environment for some period of time
3. The target tissues in which the pathogen initiates infection (or colonization) are accessible to the aerosol

* Includes all pathogens previously identified as “droplet” or “airborne” and other pathogens that meet criteria for biological plausibility of air transmission (Jones and Brosseau, Journal of Occupational and Environmental Medicine, 2015; 57[5])

Key Points from Workgroup Members Supporting Alternate Narrative B

- Start with Standard of Practice Air Precautions (NIOSH-approved® N95 respirator) for all pathogens that are capable of being transmitted through the air. This is based on scientific evidence that indicates:
  - There is no ballistic droplet transmission without inhalation: whenever a person is close enough to an infected individual to receive a sneeze or cough directly into an open mouth/nose/eyes, there are also many large and small aerosols being inhaled at the same time.
  - Masks are not designed to provide filtration and fit to protect the wearer from inhaling aerosols.
  - N95 FFRs are the minimum level of respiratory protection that are designed to protect the wearer from inhaling aerosols. NIOSH-approved® N95 respirators are required to meet performance standards to ensure they provide filtration, breathing resistance, and other metrics necessary to provide reliable respiratory protection.
  - Distance is not an accurate surrogate for an exposure and risk assessment.
  - Disease among healthcare personnel, especially if unrecognized (i.e., mild symptoms or asymptomatic) can result in transmission to patients and other healthcare personnel. It is not just severe disease and mortality that matter in the context of outcomes for prioritizing interventions.

Key Points from Workgroup Members Supporting Alternate Narrative B (cont.)

- Then conduct an exposure and risk assessment to determine whether the pathogen and/or clinical situation should be moved to a higher or lower risk category.
  - Exposure and risk assessments should address the clinical situation and whether infectious aerosols are being generated (e.g., whether the pathogen infects/is present in the respiratory tract and infectious aerosols can be generated by breathing, speaking, coughing, sneezing, etc.; whether infectious aerosols can be generated by other symptoms such as vomiting and diarrhea; whether aerosols can be generated by medical procedures or interventions such as intubation, wound debriding, bed linen changes, etc.) as well as the risk of adverse outcomes (e.g., morbidity, mortality, lost time from work, onward transmission to other patients/workers/community).
  - If there are no infectious aerosols being generated, then may use **Limited Air Precautions**.
  - Exposure and risk assessments may determine that additional measures are necessary to prevent exposure and transmission to patients, visitors, and health care workers (**Engineering Air Precautions**). Factors that may elevate a pathogen and/or clinical situation to Engineering Air Precautions include: pathogen is able to survive in air/environment for long periods of time (e.g., >1 hour), risk of mortality or severe disease with infection, and/or high risk of adverse outcome.

Framework for Alternate Narrative B

Standard of Practice Air Precautions
(NIOSH-approved® N95 respirator)

All pathogens that are capable of being transmitted through the air start here.

Perform exposure and risk assessments to determine whether pathogen and/or clinical situation should be moved to a higher or lower risk category.

Limited Air Precautions
(Mask)

If no infectious aerosols generated and pathogen does not result in significant adverse outcomes.

Engineering Air Precautions
(Respirator plus other controls such as AIIRs and other isolation and air cleaning measures)

Factors that may elevate a pathogen and/or clinical situation to this category include: Pathogen is able to survive in air/environment for long periods of time (e.g., >1 hr.), significant exposure (long duration, close proximity, high aerosol generation), high risk of adverse outcome and/or risk of mortality or severe disease with infection.

Additional Points from Workgroup Members Supporting Alternate Narrative B (cont.)

- Masks are not designed to prevent the wearer from inhaling hazardous aerosols.
  - Respirators, such as N95 filtering facepiece respirators, powered air-purifying respirators, and elastomeric respirators, are designed to provide the tight face seal and filtration levels required to protect the wearer from inhaling hazardous aerosols.
- Thus, masks should not be used for pathogens that spread through the air.

Additional Points from Workgroup Members Supporting Alternate Narrative B (cont.)

- N95 filtering facepiece respirators should be recommended for use with all pathogens that are capable of spreading through the air. This recommendation is based on extensive scientific research into the use of respiratory protection to protect workers from inhaling hazardous aerosols in a variety of industries other than health care.

- Capable of transmitting through the air means that there is evidence that:
  1) Aerosols containing the pathogen can be generated by or from an infectious person,
  2) The pathogen remains viable in the environment for some period of time, and
  3) The target tissues in which the pathogen initiates infection (or colonization) are accessible to the aerosol.

Jones and Brosseau, Journal of Occupational and Environmental Medicine, 2015; 57[5])

Bridging Alternate Narrative B Concepts to Original 2023 Draft Guideline

Key Concepts Discussed for Narrative B	2023 Draft Guideline
Particle inhalation is the predominant mode of transmission by air both near and far from a source.	In draft (Section A) “Pathogens suspended in the air cause infection via inhalation and deposition along the respiratory tract, anywhere from the nasal or oral passages to the lungs.”
Risk is a function of particle concentration in the air and exposure time.	Pathogen load and shedding rate are cited as factors; time concept is also in draft.
Pathogen survival in air for several hours is not confined to just a few organisms.	This will be addressed in Part 2, pathogen-specific portion of draft guideline.
Infection control guidelines should be focused on source and pathway controls that reduce particle concentration and minimize exposure time.	Source control and use of a hierarchy of controls (including PPE) to reduce particle concentration and minimize exposure time are addressed in guideline.
Respirators are effective at limiting inhalation. Surgical masks are not.	Existing draft guideline describes greater expected filtration efficacy for fit-tested respirators (Section B). The draft guideline emphasizes that recommendations are based on evaluation of clinical effectiveness between masks and respirators in healthcare settings. *Merits further HICPAC discussion.*

Rationale of Discussing Clinical Studies

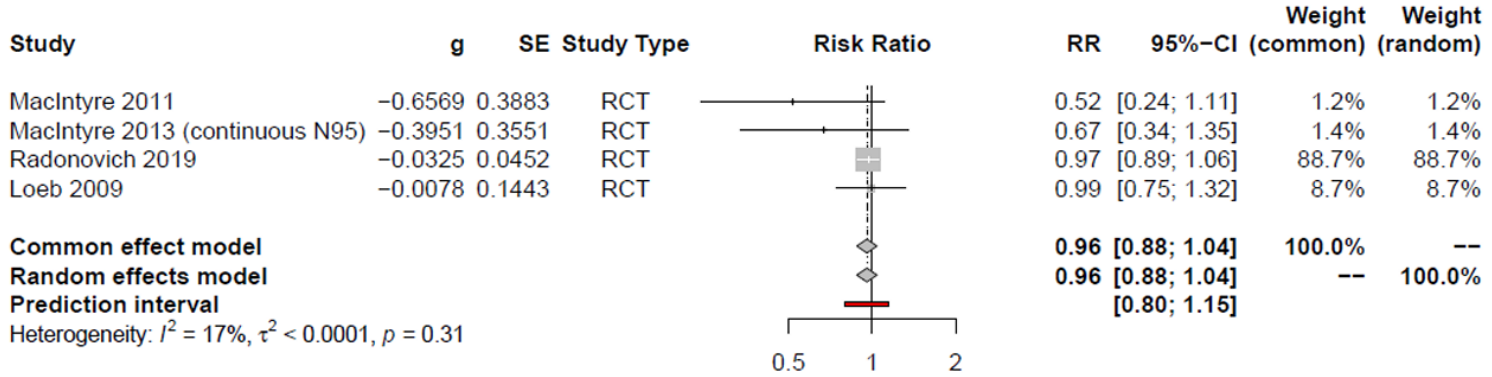
- Clinical studies are critical in informing guideline recommendations for the clinical setting.
  - Such studies compare prevention strategies in the context of feasibility, user adherence, and implementation within a hierarchy of controls (e.g., engineering, administrative, and personal protective equipment controls) available in the healthcare setting to reduce risk of infection.

- Overarching question originally posed to CDC for systematic review: “For healthcare personnel caring for patients with respiratory infections, what is the effectiveness of medical/surgical masks compared with N95 respirators in preventing infection?”

Context for Four Studies Comparing Masks versus Respirators

- Four randomized-controlled studies provide evidence concerning the outcome of seasonal laboratory-confirmed viral respiratory infections

Figure 3. Seasonal Laboratory-confirmed Viral Respiratory Infections



CDC Evidence Review presented at HICPAC meeting November 2023 (Draft Healthcare Personnel Use of N95 Respirators or Medical/ Surgical Masks for Protection Against Respiratory Infections: A Systematic Review and Meta-Analysis)

Loeb, Mark, et al. "Surgical mask vs N95 respirator for preventing influenza among health care workers: a randomized trial." *JAMA* 302.17 (2009): 1865-1871.

Loeb *et al.* JAMA 2009

- **Objective** To compare surgical mask with N95 respirator in protecting workers against influenza.
- **Design, Setting, Participants** Noninferiority randomized clinical trial of 446 nurses in emergency departments, medical units, pediatric units in 89 tertiary care Ontario, Canada hospitals.
- **Intervention** Assignment (subject level randomization) to either fit-tested N95 respirator or surgical mask when providing care to patients with febrile respiratory illness during the 2008-2009 influenza season.
- **Outcome measures** Primary: lab-confirmed influenza (positive PCR or a 4-fold rise in hemagglutinin titers). Secondary: detection of noninfluenza viruses by PCR.
- **Finding** No difference in lab-confirmed influenza (mask 23.5% versus N95 22.9%, $P = .86$).
- **Author Conclusion** "Among nurses in Ontario tertiary care hospitals, use of a surgical mask compared with an N95 respirator resulted in noninferior rates of laboratory-confirmed influenza."

MacIntyre, Chandini Raina, et al. "A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers." *Influenza and other Respiratory Viruses* 5.3 (2011): 170-179.

MacIntyre *et al.* 2011

- **Objective** To determine the efficacy of medical masks compared to fit-tested and non-fit-tested N95 respirators in HCPs in the prevention of disease because of influenza and other respiratory viruses.
- **Design, Setting, Participants** Cluster randomized clinical trial of 1441 HCPs in 15 Beijing, China hospitals during 2008/2009 winter for 4 weeks. A convenience sample no-mask/respirator group of 481 health workers from 9 hospitals was compared.
- **Intervention** Participants wore masks or respirators during the entire work shift for 4 weeks (clustered by hospital group assignment).
- **Outcome measures** Primary endpoints (1) Clinical respiratory illness [CRI] 2+ respiratory OR 1 respiratory + 1 systemic symptom; (2) ILI (fever ≥38°C + one respiratory symptom; (3) lab-confirmed viral respiratory infection; (4) lab-confirmed influenza A or B.
- **Findings:** Non-fit-tested N95 respirators were more protective than medical masks against CRI (OR .48, *P* = .045); no other comparisons significantly different.
- **Author Conclusion** "A benefit of respirators is suggested but would need to be confirmed by a larger trial, as this study may have been underpowered."

MacIntyre *et al.* 2013

MacIntyre, C. Raina, et al. "A randomized clinical trial of three options for N95 respirators and medical masks in health workers." *American Journal of Respiratory and Critical Care Medicine* 187.9 (2013): 960-966.

- **Objective** Comparison of three policy options for the use of medical masks and N95 respirators in healthcare workers.
- **Design, Setting, Participants** Cluster randomized clinical trial of 1,669 hospital-based HCPs in Beijing, China in the winter of 2009-2010.
- **Intervention** Participants were randomized to (1) medical masks for entire shift, (2) N95 respirators for entire shift, (3) N95 respirators while caring for a patient with known respiratory illness or when conducting AGPs, over a 4 week period.
- **Outcome measures** Primary endpoints (1) Clinical respiratory illness [CRI] 2+ respiratory OR 1 respiratory + 1 systemic symptom; (2) ILI (fever ≥38°C + one respiratory symptom; (3) lab-confirmed viral respiratory infection by PCR; (4) lab-confirmed influenza A or B by PCR; (5) lab-confirmed bacterial colonization in symptomatic subjects (*S. pneumoniae*, legionella, *B. pertussis*, chlamydia, *M. pneumoniae*, *H. influenzae* by PCR).
- **Findings** CRI highest in medical mask arm (17.1%) followed by targeted N95 (11.8%) and continuous N95 arm (7.2%), $P = .02$. Bacterial respiratory tract colonization in subjects with CRI was highest in the medical mask arm (14.7%) followed by targeted N95 arm (10.1%) and continuous N95 arm (6.2%), $P = .02$. After adjustment for confounding, only continuous use N95 remained significant against CRI and bacterial colonization.
- **Author Conclusion** “Continuous use of N95 respirators was more efficacious against CRI than intermittent use of N95 or medical masks.” “Continuous use of N95s resulted in significantly lower rates of bacterial colonization…”

Radonovich, Lewis J., et al. "N95 respirators vs medical masks for preventing influenza among health care personnel: a randomized clinical trial." *JAMA* 322.9 (2019): 824-833.

Radonovich *et al.* 2019

- **Objective** To compare the effect of N95 respirators vs medical masks for prevention of influenza and other viral respiratory infections among HCP.
- **Design, Setting, Participants** Cluster randomized pragmatic effectiveness study conducted at 137 outpatient study sites at 7 US medical centers between Sept 2011 and May 2015.
- **Intervention** Each year for 4 years, during 12-week period of peak viral respiratory illness, pairs of outpatient sites (clusters) within each center were matched and randomly assigned to N95 respirator or medical mask groups. HCP instructed to use N95 or mask when in close contact (defined in protocol supplement page 22: within 6 feet or sharing a small enclosed airspace, such as a typical patient treatment room).
- **Outcome measures** Primary: Incidence of laboratory-confirmed influenza, defined as detection of flu A/B by PCR within 7 days of symptom onset OR detection of influenza (PCR) from a randomly obtained swab for asymptomatic participant OR 4-fold rise in hemagglutination Ab to flu A/B deemed not attributable to vaccination. Secondary outcomes: (1) incidence of acute respiratory illness, (2) lab-detected respiratory infections, (3) laboratory-confirmed respiratory illness, and (4) influenza-like illness.

Radonovich *et al.* 2019, Table 1 (adapted)

Radonovich, Lewis J., et al. *JAMA* 322.9 (2019): 824-833.

- Characteristics of occupation, occupation risk, patient risk, and clinic type were balanced between the two comparator groups.

Table 1. Health Care Personnel (HCP) Demographic Characteristics, Risk Factors, and Site Enrollment in a Study of the Effect of N95 Respirators vs Medical Masks for Preventing Laboratory-Confirmed Influenza

Characteristic	No. (%) N95 Respirator (n = 2512 HCP-Seasons)[a]	No. (%) Medical Mask (n = 2668 HCP-Seasons)[a]
Occupation		
Nurse/nursing trainee	1049 (41.8)	1085 (40.7)
Clinical care support staff[b]	574 (22.9)	627 (23.5)
Administrative/clerical	332 (13.2)	337 (12.6)
Other occupation	213 (8.5)	224 (8.4)
Physician/advanced practitioner/ physician trainee	207 (8.2)	240 (9.0)
Registration/clerical reception	94 (3.7)	106 (4.0)
Social worker/pastoral care	35 (1.4)	29 (1.1)
Environmental services/ housekeeping	8 (0.3)	19 (0.7)
Occupational risk[c]		
High	1492 (59.4)	1594 (59.7)
Medium	295 (11.7)	318 (11.9)
Low	724 (28.8)	755 (28.3)
Patient population		
Adult	1409 (56.1)	1486 (55.7)
Pediatric	573 (22.8)	557 (20.9)
Adult and pediatric	530 (21.1)	625 (23.4)
Clinic type		
Primary care	1734 (69.0)	1881 (70.5)
Emergent/urgent care	665 (26.5)	700 (26.2)
Emergency transport	42 (1.7)	33 (1.2)
Specialty care	40 (1.6)	29 (1.1)
Dental/dialysis	31 (1.2)	25 (0.9)

(Blue annotations added for clarity)

Radonovich *et al.* 2019, Table 2

- Primary and secondary outcomes over 4 respiratory virus seasons are shown.
- Serology (Hemagglutination inhibition assay) contributed substantially to influenza infection detection.

Table 2. Primary and Secondary Outcomes in a Study of the Effect of N95 Respirators vs Medical Masks for Preventing Laboratory-Confirmed Influenza Among Health Care Personnel

Primary and Secondary Outcome Events	No. 2011-2012 N95 Respirator	2011-2012 Medical Mask	2012-2013 N95 Respirator	2012-2013 Medical Mask	2013-2014 N95 Respirator	2013-2014 Medical Mask	2014-2015 N95 Respirator	2014-2015 Medical Mask	Totals N95 Respirator	Totals Medical Mask
Influenza (primary outcome)									N = 2512 Seasons	N = 2668 Seasons
Polymerase chain reaction–detected										
Influenza A	2	3	19	19	8	12	37	28	66	62
Influenza B	0	3	8	11	2	1	1	4	11	19
Hemagglutination inhibition assay–detected										
Influenza A	5	9	30	23	38	38	55	47	128	117
Influenza B	0	2	10	11	12	13	14	10	36	36
All events[a]										
Influenza A	6	10	43	37	46	42	85	65	180	154
Influenza B	0	5	15	18	12	14	15	13	42	50
All influenza	6	15	58	55	58	56	100	78	222	204
Laboratory-confirmed influenza	6	13	52	52	55	51	94	77	207	193
Secondary Outcomes										
Acute respiratory illness	235	234	354	446	398	519	569	512	1556	1711
Laboratory-detected respiratory infection[b]	47	71	165	201	217	260	250	213	679	745
Laboratory-confirmed respiratory illness[b]	26	31	91	116	111	150	143	120	371	417
Influenzalike illness	13	10	30	45	22	50	63	61	128	166

[a] Influenza events were defined as the number of influenza infections attributed to the combination of polymerase chain reaction detection and hemagglutination inhibition assay serologies. Instances in which polymerase chain reaction and hemagglutination inhibition assay were both positive counted as 1 event.

[b] All respiratory viruses assayed, including influenza.

Disclaimer: The findings and conclusions herein are draft and have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy.

Radonovich, Lewis J., et al. *JAMA* 322.9 (2019): 824-833.

Radonovich *et al.* 2019, Figure 2a

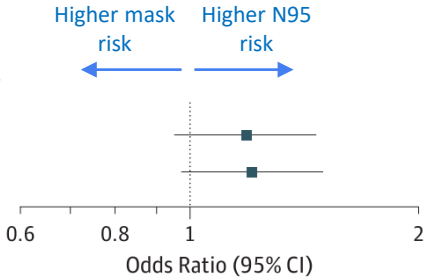
- For **primary outcome** of laboratory-confirmed influenza (detected PCR or serology), no significant difference in risk between comparator groups.

Figure 2. Primary and Secondary Outcomes of Influenza and Respiratory Illnesses and Adjusted Risk Estimates Among Health Care Personnel in the N95 Respirator Group vs the Medical Mask Group

A Primary outcome

	N95 Respirator Events/Seasons	Medical Mask Events/Seasons	Incidence Rate Ratio (95% CI)
Laboratory-confirmed influenza			
ITT cohort	207/2512	193/2668	1.18 (0.95-1.45)
PP cohort	204/2243	190/2446	1.20 (0.97-1.48)

(Blue annotations added for clarity)



The adjusted relative risks for the N95 respirator and medical mask groups for both the intention-to-treat (ITT) and per-protocol (PP) groups for the primary outcome and the other predetermined secondary outcomes. Values above 1 indicate higher relative odds or risk in the N95 respirator group compared with the medical mask group.

Radonovich, Lewis J., et al. *JAMA* 322.9 (2019): 824-833.

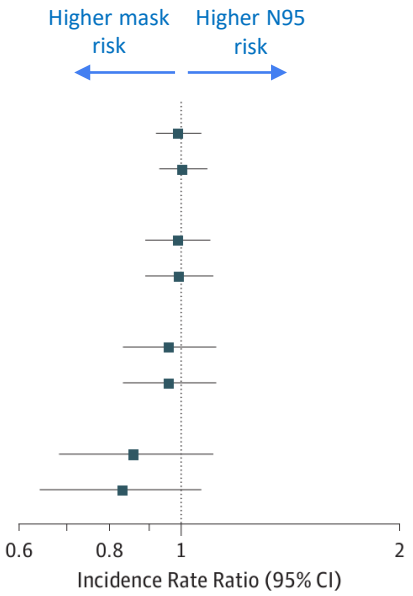
Radonovich *et al.* 2019, Figure 2b

- For **secondary outcomes**, including laboratory-detected and laboratory-confirmed respiratory illness, no significant difference in risk between comparator groups.

B All secondary outcomes

	N95 Respirator Events/Seasons	Medical Mask Events/Seasons	Incidence Rate Ratio (95% CI)
Acute respiratory illness			
ITT cohort	1556/2512	1711/2668	0.99 (0.92-1.06)
PP cohort	1512/2243	1656/2446	1.00 (0.93-1.08)
Laboratory-detected respiratory infection			
ITT cohort	679/2512	745/2668	0.99 (0.89-1.09)
PP cohort	664/2243	733/2446	0.99 (0.89-1.10)
Laboratory-confirmed respiratory illness			
ITT cohort	371/2512	417/2668	0.96 (0.83-1.11)
PP cohort	361/2243	406/2446	0.96 (0.83-1.11)
Influenzalike illness			
ITT cohort	128/2512	166/2668	0.86 (0.68-1.10)
PP cohort	121/2243	161/2446	0.83 (0.64-1.06)

(Blue annotations added for clarity)



The adjusted relative risks for the N95 respirator and medical mask groups for both the intention-to-treat (ITT) and per-protocol (PP) groups for the primary outcome and the other predetermined secondary outcomes. Values above 1 indicate higher relative odds or risk in the N95 respirator group compared with the medical mask group.

Radonovich, Lewis J., et al. *JAMA* 322.9 (2019): 824-833.

Radonovich *et al.* 2019, Strengths and Limitations; Author Conclusion

- **Strengths** (1) Comprehensive lab-confirmed outcome using PCR and serology, to include asymptomatic and pauci-symptom infection for influenza. (2) Representative outpatient adult and pediatric settings including ED were studied over 4 respiratory virus seasons.
- **Limitations** (1) Not possible to determine whether participants acquired respiratory infection due to hospital or community exposure. (2) Incomplete adherence in this pragmatic trial could bias the study to finding no difference.
- **Author Conclusion** "Among outpatient health care personnel, N95 respirators versus medical masks as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza."

Radonovich, Lewis J., et al. *JAMA* 322.9 (2019): 824-833.

Additional Perspectives on Radonovich *et al.* 2019

Methodological Concerns Raised by Some Workgroup Members	Relevant Workgroup Discussion Points
There was a lack of a 'no mask' control group or lack of active covariate adjustment, which could otherwise account for: • Exposure from un-identified infectious patients • Exposure to other potentially infectious staff or household exposures • Differences in exposure (higher versus lower intensity, in different patient care settings) • Potential differences in hand hygiene • Potential differences in other clinic-level infection control practices (e.g., ventilation or patient screening)	A major feature of large randomized clinical trials is that their design allows for balancing of both measured confounders (e.g., adherence to intervention, vaccination rates) and unmeasured confounders (e.g., exposures from sources other than patients with suspected or confirmed respiratory illness). A 'no mask' control group would not be feasible due to ethical concerns.
Intervention used only with 6 feet of patients	The study intervention was used in two situations: within 6 feet of patients, or within a small enclosed airspace (such as a typical clinic room), per manuscript supplement.
Clinics were re-randomized each respiratory season, potentially crossing over from one intervention arm to the other and introducing potential non-adherence to assigned intervention	Each intervention period lasted 12 weeks (respiratory virus season) followed by a 9-month wash-out period. Adherence was measured and was balanced between groups.

Summary for Question 2 Discussion

- The workgroup has created two narratives (A and B) which provide two approaches for clarifying or modifying the original Transmission-Based Precautions Categories to Prevent Transmission through the Air.

Major Contrasts Between Alternate Narratives A and B

Alternate Narrative A	Alternate Narrative B
Retains category framework of 2023 draft guideline: • Routine Air Precautions (mask) • Special Air Precautions (N95 + eye protection) • Extended Air Precautions (N95 + engineering controls)	Proposes a different framework from the 2023 draft guideline: • Standard of Practice Air Precautions (N95) • Limited Air Precautions (mask) • Engineering Air Precautions (N95 + engineering controls)
Pathogen-specific recommendations are based on assessment of risk of infection and associated outcomes. Important considerations: (1) Transmissibility, (2) burden of morbidity and mortality, and (3) ability of pathogen to spread over long distances (e.g., through ventilation systems).	Pathogen-specific recommendations are based on assessment of risk of infection and associated outcomes. Important considerations: (1) Transmissibility, (2) Adverse outcomes, which includes morbidity/mortality, lost workdays, onward transmission of infection.
Multiple categories (including a category for mask as PPE) are considered for pathogen-specific recommendations.	N95 (or higher level) respirators are used initially for all known pathogens with potential to transmit through the air, with subsequent exposure and risk assessment to determine whether the pathogen and/or clinical situation should warrant a higher (engineering controls) or lower risk (possible mask) category. Engineering Air Precautions are used for new/emerging pathogens.

Discussion

- **Which narrative approach (A or B) would be preferred by HICPAC to help answer Question 2 and Question 1?**

Returning to CDC Question 2 and Question 1

Q2	a.	**Can the WG clarify the criteria that would be used to determine which Transmission by Air category applies for a pathogen?**
	b.	For the category of Special Air Precautions, can you clarify if this category includes only new or emerging pathogens or if this category might also include other pathogens that are more established?
	c.	Can you also clarify what constitutes a severe illness?
Q1	a.	Should there be a category of Transmission-Based Precautions that includes masks (instead of NIOSH-Approved® N95 [or higher-level] respirators) for pathogens that spread by the air?
	b.	Should N95 respirators be recommended for all pathogens that spread by the air?

Question 2a: Transmission by Air Categories

Can the WG clarify the criteria that would be used to determine which transmission by air category applies for a pathogen?

Option A

- Narrative A approach

Option B

- Narrative B approach

Note: Voting will be on key concepts representing Alternate Narrative A or Alternate Narrative B, and not exact narrative wording.

Question 2b: Transmission by Air Categories

For the category of Special Air Precautions, can you clarify if this category includes only new or emerging pathogens or if this category might also include other pathogens that are more established?

Potential Response

- The category of Special Air Precautions might also include other pathogens that are more established.

Note: Both Alternate Narratives A and B support including other pathogens that are more established.

Question 2c: Transmission by Air Categories

Can you also clarify what constitutes a severe illness?

Option A (Narrative A)

- "Severe illness" will be clarified as "morbidity and mortality" to more clearly encompass a variety of pathogen-related adverse outcomes that are not limited to hospitalization and death.

Option B (Narrative B)

- "Severe illness" will be clarified as "adverse outcomes" that encompass morbidity and mortality, as well as other adverse outcomes such as lost workdays due to infection and onward transmission to other susceptible persons.

Question 1a: Mask Use

Should there be a category of Transmission-Based Precautions that includes masks (instead of NIOSH-approved® N95 [or higher-level] respirators) for pathogens that spread by the air?

Option A (Narrative A)

- Yes. Among multiple approaches, there should be a category of Transmission-Based Precautions that includes masks for pathogens that spread by air.

Option B (Narrative B)

- No. Through an exposure and risk assessment, there could be a situation in which a mask may be appropriate. But from the beginning, by default, there should not be a category of a mask for a pathogen that spreads by the air.

Question 1b: Mask Use

Should N95 respirators be recommended for all pathogens that spread by the air?

Option A (Narrative A)

- No. N95 respirators should not be recommended for all pathogens that spread by air.

Option B (Narrative B)

- Yes. N95 respirators should be recommended for all pathogens that spread by air.

Next Steps

- Today, we presented and discussed the 4 Questions that were sent by CDC to HICPAC in January 2024
- Day 2 (Friday, November 15, 2024) will include
  - Time to address remaining discussion points
  - Additional public comment
  - A vote on responses to the 4 Questions to return to CDC

Thank you