

Why N95 Should Be the Standard for All COVID-19 Inpatient Care

Nhu Quyen Dau, PharmD, BCCP; Harry Peled, MD; Helen Lau, RN, MHROD, BSN; Julie Lyou, MD; and Claudia Skinner, DNP

Personal protective equipment (PPE) is currently an emotional topic for frontline health care workers (HCWs) who care for patients with coronavirus disease 2019 (COVID-19). Medical masks are surgical or procedural masks that are regulated as medical devices on the basis of a set of standard test methods. The terms “medical mask” and “surgical mask” are often used interchangeably in the literature to indicate face masks that meet national or international standards and protect against droplet transmission but are not certified as respirators. Filtering facepiece respirators, also commonly called “respirators,” are high-performance filtering masks. N95 respirators approved by the National Institute for Occupational Safety and Health filter at least 95% of NaCl particles. Unlike medical masks, N95 respirators provide a close facial fit, are regulated on filtration, and prevent aerosol transmission to the wearer. All guidelines recommend their use in aerosol-generating procedures (AGPs). However, there is differing guidance for HCWs, particularly regarding N95 respirators versus medical masks for frontline HCWs working with patients with COVID-19 (Table). We believe that a thoughtful evaluation of past and existing data in the setting of the COVID-19 pandemic strongly supports the use of N95 respirators for all inpatient care of patients with COVID-19, not only during AGPs.

Previous randomized controlled trials have demonstrated that N95 respirators are more effective than medical masks in protecting HCWs against clinical respiratory illness (1). However, a study at 8 tertiary care hospitals in Ontario (2) found no difference in the rate of laboratory-confirmed influenza with N95 versus medical masks, although there was a trend toward less influenza-like illness, defined as the presence of cough and fever, with N95 respirators ($P = 0.06$). Furthermore, HCWs in this trial used N95 respirators only when seeing infected patients—that is, targeted use (2). Of note, this study was terminated early because the Ontario Ministry of Health recommended N95 respirators for all HCWs taking care of patients with febrile respiratory illness. A 2016 meta-analysis evaluating the effectiveness of N95 respirators versus surgical masks in a health care setting found an odds ratio of 0.51 (95% CI, 0.19 to 1.41) for influenza-like illness (3). This odds ratio shows the effectiveness of N95 respirators for reducing influenza-like illness and a compelling magnitude of protection against respiratory disease transmission with N95 respirators. The benefit is even greater when the randomized trial with targeted N95 use is excluded. Nevertheless, all of these studies excluded severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Recent COVID-19 guidelines referenced several of these randomized controlled studies and a recent meta-analysis to support their PPE recommendations

for COVID-19. All guidelines currently support use of N95 respirators for AGPs. However, no studies show that N95 respirators reduce risk for clinical infection during AGPs. Furthermore, Tran and colleagues' systematic review (4) of AGPs and SARS transmission showed no statistically significant increase in risk for infection transmission to HCWs during bronchoscopy, nebulizer treatment, high-flow oxygen therapy, or use of a bilevel positive airway pressure mask. Nonetheless, various guidelines consider these procedures to be AGPs; thus, they require N95 respirators. A frequently cited meta-analysis by Long and colleagues (5) evaluated the effectiveness of N95 versus surgical masks against influenza and found no overall difference. However, this meta-analysis defined an outpatient study by Radonovich and colleagues (6) as inpatient and included a household contact study. Of note, Long and colleagues also stated that “the sensitivity analysis after excluding the trial by Loeb et al . . . showed a significant effect of N95 respirators on preventing respiratory viral infections” (5). Another meta-analysis by Bartoszko and colleagues (7) evaluated medical masks versus N95 respirators in HCWs; it also included the outpatient study by Radonovich and colleagues. Ultimately, these recent meta-analyses mixed outpatient and inpatient data and underestimated the true benefit of N95 masks in the inpatient setting. It is apparent that the risk for HCW infection is related to duration and magnitude of exposure. A COVID-19 inpatient unit with multiple patients coughing and breathing will have far higher exposure to droplets, resuspended droplets, and aerosols than an outpatient setting. The data the guidelines referenced do not support the conclusion that medical masks are equivalent to N95 respirators in reducing risk for infection.

Rather than making definitive statements based on theoretical or premature assumptions, we need more focused studies that evaluate SARS-CoV-2 transmission in the inpatient setting. The guideline recommendations stating equivalency of N95 and medical masks for COVID-19 inpatient care are based on inappropriate extrapolation of studies and may not account for the growing body of evidence surrounding aerosol transmission of SARS-CoV-2 (1, 8). Loeb and colleagues are currently conducting a randomized controlled trial evaluating medical masks versus N95 respirators for COVID-19 (NCT04296643). We know that SARS-CoV-2 is more infectious and lethal than seasonal influenza. The reproductive number (R_0) for SARS-CoV-2 is 2.3, compared with 1.8 for the 1918 influenza pandemic and 1.28 for seasonal influenza (9). Therefore, guideline recommendations in the COVID-19 era should take a more precautionary approach for the inpatient setting, especially when no vaccine or effective pharmaco-

Table. Society PPE Recommendations for Non-AGPs

| Organization | Recommendations |
|--|--|
| World Health Organization | "[I]n the absence of AGPs, [the World Health Organization] recommends that health workers providing direct care to COVID-19 patients, should wear a medical mask (in addition to other PPE that are part of droplet and contact precautions)." [*] |
| U.S. Centers for Disease Control and Prevention | "[Health care personnel] who enter the room of a patient with suspected or confirmed SARS-CoV-2 infection should adhere to Standard Precautions and use a . . . respirator (or facemask if a respirator is not available), gown, gloves, and eye protection." [†] |
| Surviving Sepsis Campaign | "For healthcare workers providing usual care for non-ventilated COVID-19 patients, we suggest using surgical/medical masks, as opposed to respirator masks, in addition to other [PPE] (i.e., gloves, gown, and eye protection, such as a face shield or safety goggles) (weak recommendation, low-quality evidence). . . . When scarcity is not an issue, use of a fitted respirator mask is a reasonable option." [‡] |
| National Institutes of Health | "For health care workers who are providing usual care for non-ventilated COVID-19 patients, the Panel recommends using surgical masks or fit-tested respirators (N95 respirators), in addition to other PPE (i.e., gloves, gown, and eye protection, such as a face shield or safety goggles). . . . For health care workers who are performing non-[AGPs] on patients with COVID-19 who are on closed-circuit mechanical ventilation, the Panel recommends using surgical masks or fit-tested respirators (N95 respirators), in addition to other PPE (i.e., gloves, gown, and eye protection, such as a face shield or safety goggles." [§] |
| Australian and New Zealand Intensive Care Society | "Contact and airborne PPE precautions must be used to care for all COVID-19 patients in intensive care. An open cohorted COVID-19 intensive care is an aerosol-generating risk area and we would recommend airborne PPE precautions. We also recommend airborne PPE precautions in any non-ICU room or area where [AGPs] are performed." |
| European Centre for Disease Prevention and Control | "Healthcare workers in contact with a suspected or confirmed COVID-19 case should wear a surgical mask or, if available an FFP2 respirator tested for fitting, eye protection (i.e. visor or goggles), a long-sleeved gown or apron, and gloves." [¶] |
| Public Health England | "Long-sleeved disposable fluid repellent gowns or disposable fluid repellent coveralls, FFP3 respirators, eye protection, and gloves must be worn in higher risk areas containing possible or confirmed cases, or as indicated by local risk assessment. . . . A higher risk acute inpatient care area is defined as a clinical environment where AGPs are regularly performed. . . . A fluid resistant (Type IIR) surgical facemask . . . should be worn whenever a health and social care worker enters or is present inpatient area (for example, ward) containing possible or confirmed COVID-19 cases, whether or not involved in direct patient care. For undertaking any direct patient care, disposable gloves, aprons and eye protection should be worn." ^{**} |

AGP = aerosol-generating procedure; COVID-19 = coronavirus disease 2019; ICU = intensive care unit; PPE = personal protective equipment; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

^{*} From [www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](http://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak). Accessed 17 June 2020.

[†] From www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html. Accessed 17 June 2020.

[‡] From www.ncbi.nlm.nih.gov/pmc/articles/PMC7176264. Accessed 17 June 2020.

[§] From <https://covid19treatmentguidelines.nih.gov/critical-care/infection-control>. Accessed 17 June 2020.

^{||} From www.anzics.com.au/wp-content/uploads/2020/04/ANZI_3367_Guidelines_V2.pdf. Accessed 17 June 2020.

[¶] From www.ecdc.europa.eu/sites/default/files/documents/Infection-prevention-control-for-the-care-of-patients-with-2019-nCoV-healthcare-settings_third-update.pdf. Accessed 17 June 2020.

^{**} From https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/886668/COVID-19_Infection_prevention_and_control_guidance_complete.pdf. Accessed 17 June 2020.

logic treatment exists. Recognizing that medical masks are substandard will empower our society to allocate resources to ensure availability of N95 respirators.

The dilemma of administrators who are responsible for managing supply chains and ensuring adequate supplies for HCWs must be acknowledged. Because various organizations have claimed that medical masks are acceptable, health system administrators may believe that they have a valid reason to deny N95 respirators to HCWs on COVID-19 units and reserve them for AGPs even when other guidelines do recommend their use. Of course, other issues need to be addressed and considered in public policy. These should include evaluating the benefit of placing masks on patients with COVID-19 to reduce transmission; PPE compliance; and basic infection control, such as handwashing.

Instead of allowing our HCWs to work in substandard protection, countries should focus on allocating resources to increase production of medical masks and N95 respirators. N95 respirators are more cost-effective over a wide range of reasonable assumptions (10). Society is rationing optimal PPE because of improper resource allocation. Use of N95 respirators to protect

HCWs should not merely be a preference or a recommendation based on availability. The data indicate that it should be the standard for all inpatient COVID-19 management.

It poses a danger to HCWs for inpatient COVID-19 guidelines to rely on meta-analysis of randomized controlled trials that mix different methods, settings, and outcomes. On the basis of recent data, aerosol transmission is possible. N95 respirators achieve better filtration of airborne particles than medical masks if used properly and continuously. Guideline recommendations that do not support N95 use for all inpatient COVID-19 management should consider reevaluating the existing data or at least acknowledge the issues raised.

From Marshall B. Ketchum University College of Pharmacy, Fullerton, California (N.Q.D.); Providence-St. Jude Medical Center, Fullerton, California (H.P., J.L., C.S.); and Los Angeles, California (H.L.).

Disclaimer: The opinions expressed in this article are the authors' own and do not necessarily reflect the views of the affiliated institutions or organizations.

Disclosures: Authors have disclosed no conflicts of interest. Forms can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M20-2623.

Corresponding Author: Harry Peled, MD, St. Jude Medical Center, 101 Valencia Mesa Drive, Fullerton, CA 92835; e-mail, Harry.Peled@stjoe.org.

Current author addresses and author contributions are available at Annals.org.

Ann Intern Med. doi:10.7326/M20-2623

References

1. MacIntyre CR, Chughtai AA. A rapid systematic review of the efficacy of face masks and respirators against coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick patients. *Int J Nurs Stud.* 2020;108:103629. [PMID: 32512240] doi:10.1016/j.ijnurstu.2020.103629
2. Loeb M, Dafoe N, Mahony J, et al. Surgical mask vs N95 respirator for preventing influenza among health care workers: a randomized trial. *JAMA.* 2009;302:1865-71. [PMID: 19797474] doi:10.1001/jama.2009.1466
3. Smith JD, MacDougall CC, Johnstone J, et al. Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis. *CMAJ.* 2016;188:567-574. [PMID: 26952529] doi:10.1503/cmaj.150835
4. Tran K, Cimon K, Severn M, et al. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. *PLoS One.* 2012;7:e35797. [PMID: 22563403] doi:10.1371/journal.pone.0035797
5. Long Y, Hu T, Liu L, et al. Effectiveness of N95 respirators versus surgical masks against influenza: a systematic review and meta-analysis. *J Evid Based Med.* 2020;13:93-101. [PMID: 32167245] doi:10.1111/jebm.12381
6. Radonovich LJ Jr, Simberkoff MS, Bessesen MT, et al; ResPECT investigators. N95 respirators vs medical masks for preventing influenza among health care personnel: a randomized clinical trial. *JAMA.* 2019;322:824-833. [PMID: 31479137] doi:10.1001/jama.2019.11645
7. Bartoszko JJ, Farooqi MAM, Alhazzani W, et al. Medical masks vs N95 respirators for preventing COVID-19 in healthcare workers: a systematic review and meta-analysis of randomized trials. *Influenza Other Respir Viruses.* 2020;14:365-373. [PMID: 32246890] doi:10.1111/irv.12745
8. Chu DK, Akl EA, Duda S, et al; COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *Lancet.* 2020. [PMID: 32497510] doi:10.1016/S0140-6736(20)31142-9
9. Alhazzani W, Møller MH, Arabi YM, et al. Surviving Sepsis Campaign: guidelines on the management of critically ill adults with coronavirus disease 2019 (COVID-19). *Intensive Care Med.* 2020;46:854-887. [PMID: 32222812] doi:10.1007/s00134-020-06022-5
10. Mukerji S, MacIntyre CR, Seale H, et al. Cost-effectiveness analysis of N95 respirators and medical masks to protect healthcare workers in China from respiratory infections. *BMC Infect Dis.* 2017;17:464. [PMID: 28673259] doi:10.1186/s12879-017-2564-9

Current Author Addresses: Dr. Dau: Marshall B. Ketchum University College of Pharmacy, 2575 Yorba Linda Boulevard, HPB #248, Fullerton, CA 92831.

Dr. Peled and Ms. Skinner: St. Jude Medical Center, 101 Valencia Mesa Drive, Fullerton, CA 92835.

Dr. Lyou: St. Jude Medical Center, 2141 North Harbor Boulevard, Suite 25000, Fullerton, CA 92835.

Author Contributions: Critical revision of the article for important intellectual content: N.Q. Dau, H. Peled, H. Lau, J. Lyou, C. Skinner.

Final approval of the article: N.Q. Dau, H. Peled, H. Lau, J. Lyou, C. Skinner.