

Surgical Masks vs N95 Respirators for Preventing Influenza

To the Editor: The randomized trial by Dr Loeb and colleagues¹ compared surgical masks with N95 respirators for preventing influenza in health care workers. It demonstrated that the lower-cost surgical masks may be as effective as the N95 respirators.

The need for N95 respirator fit testing adds considerable cost to the higher cost of the device itself. However, the article did not state whether the users received training in how often to change either the surgical masks or the N95 respirators. If they did receive such training, it would be helpful to know if the trained auditors collected information regarding whether the nurses changed their masks or respirators at appropriate intervals.

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1. 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(17):1865-1871.

To the Editor: The study by Dr Loeb and colleagues¹ concluded, "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." However, the study methods did not describe the filtering efficiency of the surgical masks that were used in this study.

A study by Oberg and Brosseau² noted that "surgical masks vary widely in style and intended application" and stated that the Food and Drug Administration recommends that surgical masks be rated using the criteria of particulate filtration efficiency and bacterial filtration efficiency. Masks labeled as surgical masks have a wide range of efficiencies and a range of leakage around the periphery of the mask, depending on its fit on the face. The filtering efficiencies of the masks that were used in the study by Loeb et al are relevant to the study results since surgical masks available in other institutions may not have the same efficiencies for particulates and bacteria, or the same fit.

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1. 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(17):1865-1871.
2. Oberg T, Brosseau L. Surgical mask filter and fit performance. *Am J Infect Control*. 2008;36(4):276-282.

To the Editor: I believe that the study by Dr Loeb and colleagues¹ was not sufficiently powered to support their hypothesis that the surgical mask offers protection similar to the N95 respirator among health care workers exposed to influenza. The authors stated that the 20% event rate required to adequately power the study was achieved. However, this would only be accurate had the nurses worn the assigned masks for the entire study period (not solely when caring for isolated patients). Data from the Centers for Disease Control and Prevention (CDC)² and serologic studies, including one cited by the authors,³ suggest that more than 50% of the events (influenza transmissions) likely occurred when nurses were wearing no mask. These events are not usable when deciding to refute or accept the authors' hypothesis. The issue is not whether these "no-mask" transmissions (presumably exposures to nonisolated patients, sick health care workers, or community and household contacts) were evenly distributed between the 2 experimental groups. Instead, these no-mask events cannot be used to power the study because the experimental conditions were not in place.

Imagine a study designed to compare 2 experimental seat belts. Drivers are randomized and their cars equipped with one belt or the other. Driver fatality rate is the primary end point. The experimental belts may be used only when driving to work; at all other times, no belts are used. The majority of events (fatalities that occur when no seat belts are used) need to be ignored. They are nonevents in terms of assessing the comparative efficacy of the 2 seat belts. Only the events (fatalities) when the driver is wearing a seat belt should be included to power the study. Similarly, in the study by Loeb et al, only the events (transmissions) when the nurses

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were wearing the masks should have been included, but it is not possible to know which ones these were.

Given this, I believe that the only conclusion the study is powered to make is that a nurse who wears an N95 respirator rather than a surgical mask when caring for isolated patients during influenza season is unlikely to reduce the combined risk of being infected with influenza at home, in the community, and at work. The study was not powered to conclude that the surgical mask and the N95 respirator are equivalent and does not answer what a nurse should do to reduce risk from a single encounter with an individual influenza patient.

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To the Editor: Dr Loeb and colleagues¹ reported that use of surgical masks compared with N95 respirators among nurses resulted in noninferior rates of laboratory-confirmed influenza. However, their conclusion that the 2 devices offer similar respiratory protection may be inaccurate. The reported influenza rates reflect much more than efficacy of the devices evaluated. Hence, altering clinical practice based on the study's conclusions may expose health care workers and patients to unnecessary risks.

There is no proof that the participating nurses contracted influenza due to failure of the assigned respiratory barrier. It is likely that a significant proportion contracted influenza outside of their clinical duties, which likely represent less than 25% of total weekly hours. Although household exposures were reported, uncontrolled exposures undoubtedly occurred as part of daily activities. Such exposures are especially relevant in the context of the current pandemic. Therefore, attributing infection as solely due to barrier failure is inappropriate in the context of nonusage outside of work. These nonclinical exposures were likely similar between groups and may have contributed to the finding of noninferiority.

Additionally, 2009 influenza A(H1N1) virus can spread via the airborne route,² and up to 90% of aerosol particles may penetrate surgical masks.³ In contrast, N95 respirators filter 95% to 99% of aerosol particles. Therefore, the high infection rate within the N95 group (23%) in the study by Loeb et al suggests that other factors played a role. Because only about 30% of workers may practice consistent

and proper use of respiratory devices throughout a single shift,⁴ the measured effectiveness of these devices will be less than their true efficacy. Thus, the assessment of compliance at only 18 encounters was likely insufficient. The use of eye shields, as recommended by the CDC, may not have been routinely practiced, placing both groups at increased risk of disease. Given that noncompliance increases the likelihood of concluding noninferiority, better compliance assessment and an as-treated analysis should have been conducted.

We believe that these limitations, as well as others described in the accompanying Editorial,⁵ may have led to an inaccurate estimation of the true technical failure rates of the barrier devices evaluated.

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In Reply: Drs Palen and Felix ask about the frequency and auditing of changing respiratory devices. Surgical masks and N95 respirators were used once for each encounter with a febrile respiratory patient; the auditor did not collect data on frequency of device changing. Dr Bitar raises the issue of differing filtering capabilities among surgical masks. Because of the variety of surgical masks used at the various institutions and the lack of epidemiological evidence showing differences in influenza event rates by type of surgical mask, we did not take this into consideration when conducting the trial. Each institution used the surgical mask it had in place, including classic surgical masks (Kimberly-Clark model 48201; Neenah, Wisconsin), duckbill masks (Kimberly-Clark 48220), procedure masks (Kimberly-Clark 47117), and fog-free masks (Kimberly-Clark 49214), each with particle filtration efficiency (PFE) at or above 97% and bacterial filtration efficiency (BFE) at or above 96%; fluid shield masks (Kimberly-Clark 48247, 47107, and 47137), each with PFE at or above 99% and BFE at or above 99%; and cone-style masks (Kimberly-Clark 00152), with PFE not available and BFE at or above 95%.¹ Event rates among institutions were comparable.

Dr Clynes contends that our study was not powered to address the question of noninferiority between the surgical mask and N95 respirator on the basis that some outcome events were not usable. Although Clynes suggests that this is because the majority of infections occurred outside the hospital, the data he cites attribute 50% of infections to hospital exposure, which likely is an underestimate given the passive nature of the data collection.² Because it is not possible to accurately ascertain the origin of influenza infection in health care workers, all outcome events needed to be taken into consideration.

Measuring all outcome events is a key component of clinical trials³ and would apply to Clynes' seat-belt example. The inference derived from our study is based on what we considered the most relevant clinical comparison, not the implausible situation of nurses wearing masks at all times for the entire study period. The randomization process reduces imbalances in exposure outside of the hospital setting, although as Dr Finkelstein and colleagues point out, the fact that we did not measure other daily exposures is a study limitation.

Finkelstein et al are concerned about the high rate of infection in nurses wearing the N95 respirator and suggest noncompliance may have played a role. We agree that the extent of auditing is a study limitation, but the auditing conducted suggested high compliance. Finkelstein et al imply that because N95 respirators filter most aerosol particles and surgical masks do not, similar rates of influenza infection in our study must implicate factors other than the devices tested. This line of reasoning is tenuous because it assumes routine inhalational transmission of influenza with small droplet nuclei. The extent to which such transmission occurs in the field is unknown.⁴ They are also concerned that failure to routinely use eye shields may have increased risk; although this deserves further research, to our knowledge the conjunctivae have not been implicated as a point of entry for influenza.

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Mechanical Ventilation in Critically Ill Patients With 2009 Influenza A(H1N1)

To the Editor: The study by Dr Kumar and colleagues¹ described critically ill patients with 2009 influenza A(H1N1) in Canada, and Dr Domínguez-Cherit and colleagues² described similar patients in Mexico. The 2 articles indicated that patients with influenzalike illness may present with acute lung injury with a remarkably high mortality rate, especially in young adults.

Mechanical ventilation is frequently mandatory and life-saving in acute lung injury. However, mechanical ventilation may also cause harm, predominantly related to using tidal volumes that are too large. Ventilator-induced or ventilator-associated lung injury adds to the mortality of patients experiencing acute lung injury.³ Patients at risk for acute lung injury at onset of mechanical ventilation may benefit from lung-protective mechanical ventilation using lower tidal volumes.⁴

In the studies by Kumar et al and Domínguez-Cherit et al, patients with influenzalike illness were mechanically ventilated with mean (SD) tidal volumes for ideal body weight of 9.2 (2.4) mL/kg (survivors) or 8.6 (2.7) mL/kg (nonsurvivors)¹ and 9.0 (3.2) mL/kg (survivors) or 7.8 (1.8) mL/kg (nonsurvivors).² It appears that tidal volumes per ideal body weight increased in the first 3 days of mechanical ventilation, despite normocapnia.² Such tidal volumes are larger than currently recommended for patients with acute lung injury.⁵

It would therefore be helpful if the authors could clarify why larger than recommended tidal volumes were used. If possible, it would also be informative to analyze the data to determine whether tidal volume settings were independently associated with adverse outcomes in the patients with acute lung injury in influenzalike illness.

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