Unmasking the Surgical Mask: Does It Really Work?

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For a century, the surgical mask has been the symbol of a safe and sanitary medical environment. The problem: researchers don't really know if that's true.

With the H1N1 influenza pandemic spreading every day, experts are still debating what type of mask to wear and how much protection that mask truly provides, particularly for those at the front lines of transmission -- healthcare workers.

Major health agencies, including the World Health Organization, the CDC, and others, have offered confusing and sometimes contradictory guidelines.

Moreover, those guidelines differ for healthcare workers and ordinary citizens worried about the spread of H1N1. Even among healthcare professionals, there are different guidelines for medical wards and operating rooms.

Still, most healthcare professionals have concluded that, at the very worst, a mask can't hurt, even if it may provide a false sense of safety.

The notion of covering the nose and mouth for infection control actually dates back more than a century to the period when German physician Carl Flügge discovered that exhaled droplets could transmit tuberculosis.

The modern surgical mask, successor to the crude gauze strips those early doctors and nurses employed, is still primarily designed to prevent the passage of relatively large particles, such as sputum droplets and hair.

A high tech version -- the so-called N95 respirator -- seals tightly around mouth and nose and is made of material certified to block 95% of particles 0.3 µm or larger in diameter, roughly the size of a single virus. There's something resembling agreement that, worn properly, these do their job.

Conflicting Guidelines

CDC recommends surgical masks as part of the overall arsenal deployed against seasonal flu, but along with the Institute of Medicine, CDC has recommended only N95 respirators for protection against H1N1 -- in part, because animal studies suggest airborne transmission of the virus via small particles.

Not so for the World Health Organization or the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, the Association for Professionals in Infection Control and Epidemiology, and the American College of Occupational and Environmental Medicine.

They collectively recommended regular surgical masks except in high risk circumstances, such as during open suctioning of airway secretions and other procedures that could "aerosolize" the H1N1 virus.

There's a good reason for this lack of consensus: a dearth of quality evidence in a scientific arena dominated by anecdote and laboratory experiment.

"Some of these practices that have been in place for decades haven't been subjected to the same strenuous investigation that, for instance, a new medicine might be subjected to," Mark Rupp, MD, president of the Society for Healthcare Epidemiology of America, told *MedPage Today*.

Masks, he noted, "are fairly innocuous, relatively cheap, and so people are not really very interested in going through the extensive investigation that would be required."

Conflicting Evidence

In the past two weeks, researchers have released results from the first two randomized clinical trials investigating efficacy of masks and respirators in protecting healthcare workers from respiratory infection.

Did they settle the issue?

Hardly. In fact, their conflicting results simply added fuel to the debate, according to CDC's Arjun Srinivasan, MD.

The first reports came in August, during IOM deliberations over standards for healthcare workers' personal protective equipment, when C. Raina MacIntyre, MBBS, PhD, of the University of New South Wales in Sydney, Australia, presented preliminary results of her randomized clinical trial.

That study involved nearly 2,000 emergency and respiratory ward nurses and physicians in Beijing who were cluster-randomized to wear surgical masks, fit-tested N95 respirators, or non-fit tested N95 respirators during all work hours for four consecutive weeks during the cold and flu season.

Having been through the SARS scare in 2003, the Chinese are regarded as very serious about mask use in the hospital and outside.

At the Interscience Conference on Antimicrobial Agents and Chemotherapy in September, MacIntyre presented the dramatic results: Consistent use of N95 respirators prevented 75% of respiratory infections, while consistent surgical mask use was no better than low use for prevention of clinical respiratory illness (6.7% versus 9.2%, *P*=0.159) or of influenza-like illness (0.6% versus 1.3%, *P*=0.336).

The case against old-fashioned surgical masks seemed clear.

"To me it would not seem justifiable to ask healthcare workers to wear surgical masks," MacIntyre said in an interview.

Then another shocker. A second head-to-head study appeared, this time in the *Journal of the American Medical Association*. It's conclusion: surgical masks *were* just as good as N95 respirators.

The 478 emergency department, medical unit, and pediatric nurses in this Canadian study who were randomized to use a surgical mask when providing care to patients with febrile respiratory illness during the flu season caught seasonal flu at about the same rate as those who wore fit-tested, N95 respirators (23.6% versus 22.9%, *P*=0.86).

For H1N1 influenza, surgical masks again met noninferiority criteria versus the N95 respirator (8.0% versus 11.9%, *P*=0.18).

Design may have accounted for the discrepancy between the trials, at least in part, suggested Srinivasan, who co-authored an editorial accompanying the *JAMA* study with an IOM committee member colleague.

"These types of studies are very difficult to do," he told *MedPage Today*.

The driving factor in effectiveness is how frequently and intensely the wearer is exposed to infection, he said. So one possibility is that masks may have been enough for Canadian nurses in generally lower risk settings, but not for the high-risk Chinese healthcare workers.

In Surgery: Masks Unmasked

Lack of evidence has also plagued surgical masks in their traditional setting, and where their use is still nearly universal: the operating room.

But not for lack of study.

In fact, three large, randomized controlled trials were conducted in the 1980s to determine once and for all if surgical masks actually did prevent surgical wound infection.

Here, where bacteria were the major concern in wound infection, the enemy targets were larger and might not require the fine filtration necessary to keep a respiratory virus away, researchers theorized.

But the trials "showed absolutely no efficacy" for that original purpose, MacIntyre noted.

"Really, the surgeon might as well wear nothing on their face," she said.

Still, the CDC recommends a mask in the operating room, citing long-standing tradition and the benefits of protecting nose and mouth from splashes of blood and other bodily fluids.

MacIntyre noted that a face shield is a better option against splashes because surgeons have to wear eye protection with a mask anyway.

But mask wearing "is so inculcated into the practice of medicine that it's going to be very hard to change," said John G. Bartlett, MD, former chief of infectious diseases at Johns Hopkins.

Tradition and aesthetics play a role in the issue. Patients would not accept a surgeon who doesn't wear a mask because they are so ingrained as a symbol of a safe surgical environment, Bartlett said.

And since the masks are fairly inexpensive and easy to wear, it hasn't been worth challenging the status quo, he declared.

Nor are there likely to be more studies to decide the issue one way or the other, added Rupp. "Those studies are difficult to do because the percentage of patients who develop a surgical site infection is very, very low. So the impact of wearing a surgical mask is difficult to demonstrate," he said.

Masks for the Masses

Unlike the operating room, where it would be impossible to stop people from wearing masks, there are few places outside the hospital where it hasn't been hard to persuade people to put them on.

One of the exceptions is Asia, which has developed has a strong culture of mask use, both in medical settings and in public venues, largely as a result of the SARS epidemic in 2003, Bartlett said.

"Those people did whatever they could to try to prevent SARS," he recalled. "If it turned out that the H1N1 virus became more virulent and started to be a really serious disease, then people would be much more fastidious about how they used the disease prevention tools."

The CDC recommends that people who are ill with suspected or confirmed H1N1 flu wear face masks when at home around family members, in healthcare settings, at school until they can be taken home, and when it's necessary for them to be out and about.

However, the only high-level evidence for efficacy of masks in the community was a trial from Hong Kong -- published online last month in the *Annals of Internal Medicine* -- involving flu patients who were randomized to hand hygiene alone or in combination with surgical masks.

Compared with controls, employing hand hygiene alone or with face masks tended to reduce transmission of the flu to those living in the same house, but not significantly so.

However, when these interventions were initiated within 36 hours of symptom onset, face masks plus hand hygiene reduced risk of transmission by a very significant 67%.

Although the entire benefit can't be attributed to face masks, the results suggest masks may make a difference, MacIntyre said.

Because exposure to pathogens is typically much lower for the general public than for healthcare workers, "surgical masks may be enough in the community," she said.

Rupp agreed, saying he takes a "better safe than sorry" approach. His medical center asks patients with potentially droplet-mediated infections to put on a surgical mask.

"There probably isn't a whole lot of extensive study on the use of this in clinical situation," Rupp said. "We do think it's a pretty obvious way somebody can go about containing their secretions."

N95 masks would likely provide even more protection, MacIntyre said, but there's is fairly clear consensus that they would be intolerable for someone with a respiratory illness.

"They are relatively difficult to breath through; they can be associated also with feelings of claustrophobia and kind of a suffocating sensation," Rupp added. "It's difficult enough to get them to wear a loose fitting and relatively comfortable surgical mask."

Practical Masking

Practical issues such as compliance and supply have been part of the argument for use of surgical masks rather than N95 respirators in most clinical settings.

In a *New England Journal of Medicine* perspective piece last week, several IOM committee members acknowledged that N95 respirators are currently in short supply.

They suggested that healthcare institutions place priority on N95 respirators in the highest-risk areas, "such as enclosed spaces in the respiratory care unit, patients' rooms, and ambulances."

While the IOM was instructed to not take these issues into consideration in its guidelines, a CDC spokesperson said that agency is making them a large factor in revision of its interim guidelines for healthcare worker respiratory protection.

In the end, however, infectious disease specialists always come back to the bigger picture.

Debate over the role of respiratory protection in preventing influenza transmission doesn't "excuse anyone from failing to implement other measures that are known to protect patients and healthcare professionals from influenza," Srinivasan's *JAMA* editorial concluded.

"Masks and respirators should be considered the 'last line of defense' in a hierarchy of infection control measures."

Handwashing, good etiquette when sneezing and coughing, and staying home when sick are still the keys to preventing spread of infectious disease, it said.

Disclosures

Rupp reported being president of the Society for Healthcare Epidemiology of America but no other conflicts of interest.

MacIntyre reported receiving funding for unrelated, investigator-driven studies from GlaxoSmithKline, CSL Biotherapies, and Wyeth and having been an investigator on a Merck clinical trial.

Bartlett and Srinivasan reported no conflicts of interest.