Respiratory Protection for Health Care Workers
Simplify Procedures and Improve Health

Mark Shirley, MS, Sutter Health; Linda Hawes Clever, MD, California Pacific Medical Center; David J. Prezant, MD, Albert Einstein College of Medicine, Montefiore Medical Center; Kerri Rupe, ARNP, DNP, University of Iowa [1]
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Health care professionals, including emergency response personnel, face unique occupational health and safety challenges, one of which is exposure to uncontrolled airborne infectious particles. To protect themselves, these professionals rely heavily on N95 filtering facepiece respirators (FFRs) which, when used appropriately, provide a known level of respiratory protection.

The National Institute for Occupational Safety and Health (NIOSH) is mandated to certify respirators used in the United States through a set of tests that includes filtration performance assessment (42 CFR Part 84). The Food and Drug Administration (FDA) designates a subset of NIOSH-certified respirators as “surgical N95 respirators” through a clearance process that requires manufacturers to demonstrate that the respirators meet certain standards for fluid resistance, flammability, and biocompatibility (FDA, 2004). Currently, efforts are under way by the two agencies to streamline the regulatory oversight and approval processes, and this commentary offers support for those efforts. A recent National Academies workshop examined the scientific issues critical to these efforts (NASEM, 2017).

While health care organizations are not required to use surgical N95s, there is a common misperception that surgical N95s provide health care workers with an increased level of protection over standard N95s. This misperception places workers, patients, the health care system, and national security at substantial risk. First, surgical N95s do not provide protection from fluids and thermal exposures; therefore, these additional tests for fluid resistance and flammability add cost without benefit and provide a false sense of security. Second, the overregulation involved with N95s has caused supply chain systems to become unnecessarily expensive, overly complicated, and vulnerable to shortages during pandemics. This impairs budgets, ordering processes, education, and national defense.

Filtration Performance: The test used by NIOSH to validate filtration performance uses near “worst case” conditions for all types of airborne particles, including biologicals, to assess respirators (Shaffer and Rengasamy, 2009; Rengasamy et al., 2017). The test is a critical part of the NIOSH certification process. The FDA guidance (FDA, 2004) accepts the NIOSH filtration test.

Fluid Resistance: Most manufacturers use the ASTM F1862 test methodology noted in the FDA guidance document (FDA, 2004) to evaluate fluid resistance. This test is intended to simulate a stream of blood hitting a worker’s FFR in a surgical setting. A visual inspection, a swab of the inside of the FFR, or both, are used to verify fluid resistance. However, these methods are not thought to detect or accurately represent the potential real-world hazards. The false sense of security that health care workers may derive from this performance characteristic is of great concern. In situations in which blood or body fluid streams, sprays, or splashes pose a risk, the only appropriate means to prevent direct contact with a health care worker’s mucous membranes is a face shield.

Flammability: Surgical fires, although rare, do occur, with an estimated 200 cases per year in the United States (ECRI Institute, 2016). However, a review of actual surgical fire events, including those reported by the Pennsylvania Patient Safety Advisory, indicated little to no direct risk to the upper torso and face of surgical staff (Clarke and Bruley, 2012). Thus the need for...
flammability testing as a criterion for respirator approval needs to be reconsidered.

**Biocompatibility:** The purpose of this evaluation is to ensure that the FFR’s materials and ingredients do not result in any undue harm or irritation to the user. Ensuring biocompatibility is inherently in the best interest of the manufacturer and is already evaluated as part of the product development process for all FFRs. Additionally, any concerns related to this issue are adequately captured through NIOSH’s post-market surveillance process.

**Supply Chain:** Informal surveys of health care systems throughout the United States, including the national stockpile, indicate that often both types of N95s are stocked or that sometimes, because of misunderstanding, only the more expensive surgical N95 respirators are stocked. This leads to unnecessarily expensive and overly complicated supply chain systems with an inherent vulnerability to shortages during pandemics. Additionally, because respirator fit-testing must be repeated whenever a substitute manufacturer or model is supplied, such shortages will lead to health care workers being required to have time-consuming repeat fit-testing before re-entering the health care arena or, even worse, not to receive repeat fit-testing at all.

We urge that:

- FDA discontinue the surgical N95 designation and its oversight of FFRs, and
- NIOSH have the sole responsibility to certify all FFRs using science-based methods as is consistent with its mission for respirators used in the United States.

These actions will work to:

- Simplify the respirator selection process,
- Decrease the cost of FFRs used in health care by eliminating unnecessary regulatory burden,
- Increase the variety of makes and models of respirators available to health care providers, and
- Reduce supply chain vulnerability during a global pandemic.

This Perspective is written out of concern for the health and safety of health care workers. We find that currently the overlap of FDA and NIOSH processes for assuring the respiratory health of these critically important yet vulnerable workers can increase rather than reduce respiratory health risks. Enhancing and ensuring respiratory protection for health care workers is vital.

**Notes**

The authors are members of the standing committee on personal protective equipment for workplace safety and health of the National Academies of Sciences, Engineering, and Medicine.

**References**


**Suggested Citation**

Author Information

Mark Shirley, MS, is Environmental Risk Consultant, Sutter Health. Linda Hawes Clever, MD, is President, RENEW; Clinical Professor of Medicine, University of California, San Francisco; Associate Dean for Alumni Affairs, Stanford University School of Medicine; and is founding Chair of the Department of Occupational Health, California Pacific Medical Center. David J. Prezant, MD, is Professor, Albert Einstein College of Medicine and is Chief Medical Officer at the Office of Medical Affairs for the Fire Department of the City of New York (FDNY). Kerri Rupe, ARNP, DNP, is Professor, University of Iowa School of Nursing.

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