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B95: A new respirator for health care personnel

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Key Words:

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Personal protective equipment**Background:** Respiratory protection relies heavily on user compliance to be effective, but compliance among health care personnel is less than ideal.**Methods:** In 2008, the Department of Veterans Affairs formed the Project Better Respiratory Equipment using Advanced Technologies for Healthcare Employees (BREATHE) Working Group, composed of a variety of federal stakeholders, to discuss strategies for improving respirator compliance, including the need for more comfortable respirators.**Results:** The Working Group developed 28 desirable performance characteristics that can be grouped into 4 key themes: (1) respirators should perform their intended function safely and effectively; (2) respirators should support, not interfere, with occupational activities; (3) respirators should be comfortable and tolerable for the duration of wear; and (4) respiratory protective programs should comply with federal/state standards and guidelines and local policies. As a necessary next step, the Working Group identified the need for a new class of respirators, to be called "B95," which would better address the unique needs of health care personnel.**Conclusion:** This article summarizes the outputs of the Project BREATHE Working Group and provides a national strategy to develop clinically validated respirator test methods, to promulgate B95 respirator standards, and to invent novel design features, which together will lead to commercialized B95 respirators.

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Preventing health care-acquired infections (HAI) has become a major infection control platform, leading to increased efforts and resources in the reduction and elimination of such events. Although there has been significant positive change in the culture of patient safety in hospitals,¹ extension of the same protective measures to those who provide the care lags behind. Health care personnel (HCP) not only face a risk of acquiring respiratory infection in the community but also in the hospital environment, where the likelihood of coming in close contact with an infectious patient is high.^{2,3} To reduce worker exposure to a myriad of hazards, including respiratory hazards, a hierarchy of controls has been

developed. This systematic approach has been used to implement the most effective and practical means of protecting workers.⁴ In health care, the patient is often the source of the exposure but requires medical care. In this case, elimination, substitution, and administrative controls (eg, shorter work times) are often not possible to implement. Engineering controls (eg, isolation rooms, upper room ultraviolet germicidal irradiation) can be an effective option but are typically only utilized after infection is suspected, are expensive, and often need to be factored in during the hospital design phase. Personal protective equipment (PPE) is the least desirable choice because it relies heavily on user compliance but can be implemented widely, quickly (eg, during a pandemic), and seamlessly in a health care setting compared with the other techniques for reducing worker exposure.

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HISTORY OF RESPIRATORY PROTECTION IN HEALTH CARE

Respirators have been used to protect workers from inhaling dangerous substances for over 2,000 years, with these hazards

including dusts, fumes, and vapors.⁵ Not surprisingly, the use of respiratory protection in industry and manufacturing is more common than in health care. According to a 2001 survey, respirator use as a percentage of private sector establishments was less in health care (3.2%) than in manufacturing (12.8%), mining (11.7%), construction (9.6%), or agriculture (9.4%).^{6,7}

Although HCP face a variety of potential respiratory hazards (eg, ethylene oxide and formaldehyde), respiratory protection in health care did not receive much attention until the late 1980s.⁸ A change did not occur until the number of *Mycobacterium tuberculosis* (TB) cases in the United States was observed to be steadily increasing, including outbreaks of multidrug-resistant TB.⁹ After the deaths of 8 HCP who acquired TB in the workplace, the Centers for Disease Control and Prevention (CDC) began recommending the use of respiratory protection among all HCP who cared for patients with known or suspected TB infection.¹⁰ Surgical masks had been commonly used for respiratory protection in TB isolation rooms until this time¹¹; this policy change was the first major guidance document specifically recommending the use of respirators for HCP exposed to an infectious aerosol. In 1997, the Occupational Safety and Health Administration (OSHA) published a proposed rule for occupational exposure to TB, which included respiratory protection. This proposed rule, which was later rescinded, demonstrated an expansion of the use of respirators into new types of workplaces, which were not always familiar with all of the requirements for the proper use of respirators, including fit testing. In 1998 and 2006, OSHA published updates to its respiratory protection standard (29 CFR Part 1910.134), consolidating a number of substance-specific regulations. Through this standard, OSHA enforces the proper use of respiratory protection in workplaces where respirators are needed to reduce worker exposures to acceptable levels, including health care settings.

While CDC and OSHA were expanding the role of respiratory protection into health care settings, the National Institute for Occupational Safety and Health (NIOSH) was revising the federal regulations governing how respirators are certified and labeled in the United States. In 1995, NIOSH published a new regulation, 42 CFR Part 84, replacing 30 CFR Part 11, which gave NIOSH primary authority over certification of respiratory protective devices. These new regulations also created new tests and terminology for particulate respirators, which enabled users to select from a broader range of devices to meet performance criteria recommended by the CDC for protection against TB exposure. By the late 1990s, the N95 class of disposable (single use) filtering face piece respirators (also known informally as an "N95," "N95 respirator," or "N95 Mask") became the standard of practice for HCP providing care to patients with known or suspected TB. In 2002, the Food and Drug Administration (FDA) and NIOSH began issuing approvals for "Surgical N95 respirators," which are NIOSH-approved N95 filtering face piece respirators that also meet the FDA requirements to be labeled as a surgical mask. These devices are often recommended in cases in which a respirator that provides fluid protection and maintaining a sterile surgical field are important.¹²⁻¹⁴

More recently, N95 respirators have been recommended by many public health organizations as a means of reducing exposure to a variety of airborne infectious diseases, such as TB, measles, and varicella (chickenpox).^{15,16} N95 respirators also serve as the foundation for preparations for emerging infectious disease threats where aerosol transmission is considered possible. When severe acute respiratory syndrome (SARS) emerged in 2003, N95 respirators became widely used to protect against this pathogen because little was known about modes of transmission during the early outbreak phase.¹⁷ The emergence of H5N1 influenza in 2005, and the novel H1N1 influenza pandemic of 2009, led to a resurgence of appropriate usage-related questions regarding respirators. For

example, during the initial stages of the 2009 novel H1N1 pandemic, the CDC issued guidance calling for the use of N95 respirators, instead of surgical masks, for HCP protection.¹⁸ This decision differed from recommendations by the World Health Organization¹⁸ and was considered controversial by some,¹⁹ thus leading the Institute of Medicine (IOM) to review the science behind this recommendation and develop a better understanding of PPE necessary for a novel influenza pandemic. The IOM committee concluded that properly used N95 respirators should be better at reducing exposures and protecting against 2009 pandemic influenza than surgical masks.¹⁸ Currently, N95 respirators remain the recommended level of PPE for highly aerosol-generating procedures with seasonal influenza patients.

CURRENT STATE OF RESPIRATORY PROTECTION IN HEALTH CARE

Although it is understood that HCP assume some level of personal occupational risk when caring for contagious patients,²⁰ and numerous policies and regulations call for respiratory protection in the health care environment,^{5,15,16} noncompliance is unfortunately quite common.²¹ As noted above, one of the limitations of PPE as a tool for exposure reduction is its reliance on the wearer to use the device correctly at all times during the entire period of exposure. Figure 1 graphically illustrates the impact of compliance on exposure reduction using a model described previously by the American Industrial Hygiene Association respiratory protection committee.²² In Figure 1, the different lines represent different types of respirators with different levels of potential exposure reduction. A disposable N95 respirator, such as those used in health care, has an assigned protection factor rating of 10.²³ This indicates that the wearer of an N95 respirator, when properly fitted and used correctly, could expect to inhale no more than one-tenth of an airborne contaminant(s) present. Accordingly, wear time needs to be > ~75% to begin seeing a significant difference in exposure reduction, even for better performing respirators with higher assigned protection factor ratings. Ensuring that HCP wear respiratory protection in compliance with guidelines is vital to the effectiveness of the respirator; if the device is not worn during exposure, it is not providing appropriate protection.

Figure 2 graphically illustrates some of the reasons for poor compliance, as identified in the peer-reviewed literature,²⁴ as well as some possible solutions to increase compliance. The solutions listed are only possible solutions; much work has been done to identify the issue, and there is still more to be done to remedy these issues. Some HCP do not believe that the risks of exposure to airborne diseases warrant donning a respirator,^{21,25} perhaps because they do not believe in the necessity and/or effectiveness of these devices²¹ or because they are uncomfortable²⁶⁻²⁸ and tend to interfere with occupational activities.²⁶ Among the many causes of poor compliance, several of them are unique, or of heightened importance, in health care settings. These issues (discomfort, communication, interference, time constraints) are summarized below:

- Discomfort experienced by HCP who wear respirators is often associated with the tight-fitting N95 respirator models.²⁷ Discomfort was routinely raised as a key factor limiting the practicality of the CDC and OSHA recommendations during the 2009 novel H1N1 influenza pandemic. HCP routinely use surgical masks to protect their face from splashes and sprays and, depending on the hazards, may switch several times throughout the course of their work shift between a surgical mask and a respirator. In general, surgical masks are viewed as more comfortable than respirators. Most HCP are more

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