Major article

Selecting models for a respiratory protection program: What can we learn from the scientific literature?

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Background: An unbiased source of comparable respirator performance data would be helpful in setting up a hospital respiratory protection program.
Methods: The scientific literature was examined to assess the extent to which performance data (respirator fit, comfort and usability) from N95 filtering facepiece respirator (FFR) models are available to assist with FFR model selection and procurement decisions.
Results: Ten studies were identified that met the search criteria for fit, whereas 5 studies met the criteria for comfort and usability.
Conclusion: Analysis of these studies indicated that it is difficult to directly use the scientific literature to inform the FFR selection process because of differences in study populations, methodologies, and other factors. Although there does not appear to be a single best fitting FFR, studies demonstrate that fit testing programs can be designed to successfully fit nearly all workers with existing products. Comfort and usability are difficult to quantify. Among the studies found, no significant differences were noted.

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Implementing an effective respiratory protection program is important. According to U.S. federal regulations enforced by the Occupational Safety and Health Administration (OSHA), the respirator program must be overseen by a qualified administrator and include written procedures governing respirator use at that site.[1] In addition to implementing respiratory protection programs to reduce health care worker (HCW) exposure to routine infectious diseases (eg, tuberculosis), hospitals are purchasing and stockpiling respirators (typically filtering facepiece respirators [FFRs]) in preparation for future possible public health emergencies (eg, respiratory pathogen outbreak, pandemic).[2] Health care compliance with the OSHA's respiratory protection program requirements is mixed.[3] For example, a recent study evaluating a hospital respiratory protection program in California during the 2009-10 H1N1 influenza pandemic found that only 1 of 16 programs would be considered complete.[4]

One of the key components of a respiratory protection program is that all workers that need to wear a tight-fitting respirator must be qualified via a fit test to wear ≥ 1 specific models.[1] Lee et al described a process to minimize the number of FFR models necessary to successfully qualify a large HCW population.[5] Using fewer models can simplify inventory management, training, and fit testing programs and minimize worker confusion as to which FFR to wear. The suggested procedure involves a team composed of both respiratory protection program management and potential FFR users. This bilateral approach is critical for 2 important reasons. First, employee participation and acceptance have been recognized as important to the success of any safety and health program for many years.[6] Second, it is clear that even well-fitting FFR can protect users only if they are worn for the entire exposure period.[7] HCWs have finite tolerance for the subjective discomfort and job interference FFRs can cause.[8,9] Therefore, FFR comfort assessment by potential users increases the likelihood of success.

However, this best practice process still requires selecting specific respirator models from 1 or more vendors (eg, respirator manufacturers, distributors). The general parameters for selection and procurement are typically established by management and

often consider availability from the supplier and ability to fit employees.[3] The OSHA requires that respirators be certified by the National Institute for Occupational Safety and Health (NIOSH). However, there are hundreds of NIOSH-certified respirator models available on the market today. Even for respirators designed for use in surgical settings where clearance by the Food and Drug Administration (FDA) as a medical device is important, there are still over a dozen different FFR manufacturers, with some manufacturers offering multiple models of varying features and styles. Although NIOSH certification is required by the OSHA and FDA clearance in certain situations is needed, these federal agencies only provide general pass or fail information about the performance of the products they regulate.

Although vendors are often willing and highly capable of assisting in the selection process, it would be advantageous to have an unbiased source of comparable respirator performance data. There is no third party clearing house or *Consumer Reports*-type publication that compares respirator performance data among brands and models. The need for this type of information has been discussed.[3,5,10] In its 2010 report, the Institute of Medicine discussed progress made in the area of personal protective equipment for HCWs and identified future research needs.[2] One of the recommendations for future activities was "To improve consumer and purchaser information on fit capabilities, NIOSH should establish a website to disseminate fit test results for specific respirator models on an anthropometric (NIOSH) test panel, where such data exists." In addition to fit on anthropometric panels, respiratory protection program administrators may benefit from test results for specific models from any well-designed study involving human test subjects or actual workers.

This work was undertaken to assess the scientific literature for respirator performance data to assist with FFR model selection and procurement decisions. The review was focused on NIOSH-certified N95 class FFRs because this type is widely used in health care.

METHODS

Assessment of fit test methods

FFRs must fit properly to provide maximum protection. Mandatory procedures for assuring proper fit can be found in the OSHA Respiratory Protection standard 29 CFR 1910.134.[1] The methods applicable to the N95 FFRs include qualitative fit tests using either saccharin or denatonium benzoate (Macfarlan Smith Ltd, Edinburgh, U.K.) aerosols. Adequate fit is indicated if the test subject does not detect the sweet or bitter taste of saccharin or Bitrex, respectively, while performing a series of 7 specified test exercises. Alternatively, the OSHA permits a quantitative fit test using ambient aerosols to numerically estimate how well the FFR fits the user by measuring the aerosol particle ratio outside (C_o) and inside (C_i) the device. The only instrument currently sold to make these measurements with N95 FFR is the PortaCount Pro+ Fit Tester 8038 (TSI, St Paul, MN) or its predecessor, the PortaCount 8020 and N95-Companion (TSI, St Paul, MN). Both instruments are hereafter referred to as the N95-Companion. The harmonic mean of C_o:C_i ratios measured during individual test exercises is known as a quantitative fit factor. The OSHA defines a fit factor of $\geq$100 as acceptable for FFRs. It is also important to recognize that the 2 qualitative fit tests were developed to screen for a minimum fit factor of 100.[11,12]

Validation of these fit test methods has been done using a generated aerosol quantitative fit test.[11-13] They are therefore considered equivalent to one another for fit testing FFRs. Interestingly, they do not always produce identical pass or fail results.[14-16] Nonetheless, workplace protection factor studies demonstrate that workers fit tested with each method receive expected levels of protection.[17-21]

Therefore, only Bitrex, saccharin, and the N95-Companion fit test passing rates were considered in the analysis. Laboratory results gathered to compare the efficacy of various fit test methods or in the development of new fit test methods were not considered because these methods have not been validated. Studies that prescreened test subjects to eliminate those that could not pass a fit test were excluded because they potentially skew the true pass and fail rate.

Assessment of comfort and usability test methods

The OSHA does not have a comfort or usability requirement. Furthermore, the NIOSH and FDA do not assess these parameters as part of their certification and clearance processes. One promising respirator evaluation tool considers comfort, aesthetics, and somatic impact.[22] Some objective physiologic data (eg, heart rates, air and skin temperatures, humidity levels) exist to compare FFR models,[23-27] but studies to correlate these data with comfort and tolerability are just emerging. Unlike fit or human physiologic data, assessment of comfort and usability is almost entirely subjective. Test subjects are typically asked to rate comfort using a visual or numerical scale. The ends of the scale are identified with terms such as very comfortable and very uncomfortable. No standardized criteria exist by which subjects are to rate comfort, and with current methodology, an FFR that one subject finds comfortable may be uncomfortable to another. However, trends across respirator types (eg, FFRs vs elastomeric half-mask air purifying respirators) appear consistent across studies. Evaluating FFR usability presents similar challenges. No performance standards exist, and acceptable usability of an FFR is largely defined by the user and work environment.

Despite these challenges, our analysis considered articles in which multiple NIOSH-certified N95 FFR models were assessed or compared against each other using some type of standardized questionnaire administered to human test subjects either during or immediately following respirator use. This criterion excludes studies in which only a single N95 FFR model was identified. Because there is no standard way of testing for these parameters or generally agreed on acceptable or unacceptable levels, it is not possible to compare findings across these types of studies.

Search criteria

The internet search engine Google Scholar was used to identify articles published in the peer-reviewed literature that identified individual NIOSH-certified N95-class FFR models by name and included possible comparable performance data using the fit and comfort and usability tests previously described. Published technical reports from government or end-user organizations were also given consideration. Numerous search terms were used, including N95, FFR, filtering facepiece respirator, and facemask, as were the names of common respirator models used in health care. We also searched the Web sites of journals likely to publish articles describing implementation of a respiratory protection program in health care, including *Infection Control and Hospital Epidemiology*, *American Journal of Infection Control*, *Journal of Hospital Infection*, *Annals of Occupational Hygiene*, *Journal of Occupational and Environmental Hygiene*, and *Journal of the International Society for Respiratory Protection*. Citation lists from articles meeting eligibility requirements were also reviewed as a possible source of material. Because manufacturers sometimes update their products without changing model numbers, to increase the relevancy of the data, we limited the search to the years 2003-2013. When assessing articles