Canadian Agency for Drugs and Technologies in Health

RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

TITLE: **Wear Compliance and Donning/Doffing of Respiratory Protection for Bioaerosols or Infectious Agents: A Review of the Effectiveness, Safety, and Guidelines**

DATE: 19 August 2014

CONTEXT AND POLICY ISSUES

Particulate contamination in a health care facility is an ongoing concern for health care workers.[1-4] Under certain conditions, such as pandemics like SARS or avian flu, there will be an increased risk of bioaerosol infection to these workers. Particles capable of becoming aerosolized and causing infection represent a diverse range of sizes, and as a result have a varying degree of microbial contamination and penetrance through barriers which will determine what type of respiratory protection is required.[2] In a health care setting the routes of transmission for these particles can be broadly grouped into three categories; splashes, droplets and bioaerosols.[2] Splashes are defined as larger particles that are >100 µm in size and fall out of airborne suspension within several seconds. Droplets are smaller, 5-100 µm in diameter, and when they are >20 µm they will fall out of the air within a few seconds.[2] Those that are <20 µm can be held in the air for many minutes and therefore pose a greater risk of airborne respiratory infection with penetrance above the alveolar level.[2]

The final category is aerosols and these particles are <5 µm in size and are therefore neutrally buoyant, will remain suspended for long periods of time and are capable of travelling long distances in shifting wind currents.[1,2,5] Upon inhalation they will penetrate down into the alveolar level of the lungs. Infected individuals may produce these aerosols when coughing or sneezing, though the production from these sources is limited.[2] More often these aerosols are produced from medical processes such as intubation, bronchoscopy, non-invasive ventilation, high-frequency oscillating ventilation, induction of sputum and surgical procedures involving high speed devices.[2,4,5]

As a result of these processes the health care environment provides challenging and problematic issues when attempting to protect workers from transmission infection.[1,2] With the outbreak of severe acute respiratory syndrome (SARS) in 2003, 42% of the cases that occurred in Canada were found in health care workers (HCWs) who had suffered from transmission from their patients.[6,7] Other countries had similar effects, for example of the total SARS cases in the

USA 20% occurred in HCWs, 57% in HCW in Vietnam and 41% in HCWs in Singapore.[7] This was followed by the H1N1 outbreak in 2009 where it is estimated that 43 to 89 million people contracted the disease world-wide.[8] Of these infected people 8870 to 18300 died.[8] In 2009, the Centers for Disease Control and Prevention conducted a survey of HCW in the United States and determined that of the 48 HCW suffering from the infection, 27% were a result of transmission from patients at work.[9] These wide spread pandemics result in vastly increased numbers of people visiting emergency rooms and this in turn dramatically increases the risk of transfer to HCWs. Hospitals now have strict respiratory protection programs in place but many studies have shown that compliance of HCWs to the guidelines is lacking especially for use of personal protective equipment (PPE) and proper donning/doffing protocols.[1,10] In addition it has been postulated that in future pandemic situations the supply of respiratory PPE will be lacking, potentially requiring HCW to reuse items such as respirators which may put them at risk of transmission from used equipment if proper protocols are not followed.[11,12]

There are several common issues that factor in to a HCW not being compliant with policies for respirator wear.[8-11,13,14] The most common of these problems is that respirators have tight fitting straps which can cause discomfort.[10] Discomfort is produced by facial pressure, heat, labored movement of facial muscles, and itchiness. Other common complaints are more subjective in nature such as claustrophobia and perceived shortness of breath.[10] In addition the most common problems encountered when respirators are worn is that the straps are not placed in the correct manner, a seal check in not completed after donning, and removal is not done by touching the straps only.[1,3,4]

There are three types of respirators used by health care facilities; particulate-filtering face-piece respirators, elastomeric respirators, and powered air-purifying respirators.[8] The most commonly used group in health care settings are the particulate-filtering face-piece respirators, specifically those certified by the National Institute for Occupational Safety and Health (NIOSH) called N95 respirators.[10,15] The Centers for Disease Control and Prevention (CDC) has estimated that there are approximately 1.7 million health care associated infections yearly which account for 99,000 deaths.[7] Proper use of respiratory protection is a critical part of the process of protecting HCWs from contracting these diseases.

The purpose of this report is to review the effectiveness, safety and guidelines for different levels of wear compliance of HCW along with donning and doffing behavior for respirator use in health care settings.

RESEARCH QUESTIONS

1. What is the comparative clinical evidence on the safety of different levels of wear compliance for respiratory protection for healthcare workers at risk of exposure to bioaerosols or infectious agents?

2. What is the clinical evidence on the safety of repeated donning and doffing of respiratory protection for healthcare workers at risk of exposure to bioaerosols or infectious agents?

3. What are the evidence based guidelines regarding wear compliance, donning and doffing, and reuse of respiratory protection for healthcare workers at risk of exposure to bioaerosols or infectious agents?

KEY FINDINGS

No studies were identified in this review for the safety of different levels of wear compliance. One study was analyzed for the repeated donning and doffing of respiratory protection for healthcare workers. Authors found that multiple donning and doffing processes have a significant impact on protective capability and a maximum of five repeated processes should be instituted as the maximum acceptable. No systematic reviews or health technology assessments were identified for either of these questions. The guidelines that were identified were of excellent quality and contained well represented pictorial depiction for proper donning/doffing techniques though they did suffer from a lack of defined study inclusion criteria.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 7), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused internet search. No filters were applied to limit the retrieval by study type. The search was also limited to English language documents published between January 1, 2003 and July 21, 2014.

Rapid Response reports are organized so that the evidence for each research question is presented separately

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults working in healthcare environments in which they are at risk of exposure to bioaerosols or infectious agents
Intervention	Q1,3: Wear compliance (i.e. percent wear time) Q2,3: donning and doffing of respiratory protection
Comparator	Q1,3: different levels of wear compliance Q2,3: continuous wear
Outcomes	Reduced protection/effectiveness (e.g. infection, contamination, colonization, or other adverse response) Guidelines
Study Designs	HTA/ Systematic review/Meta-analysis, Non-randomized studies, Randomized controlled trials, Guidelines

Exclusion Criteria

Articles were excluded from this report if they did not meet the criteria detailed in Table 1, were included in a selected systemic review, or were published prior to January 1, 2003.

Critical Appraisal of Individual Studies

Non-randomized trials were assessed using the Downs and Black checklist for the adequacy of allocation concealment, blinding of patients, healthcare providers, clinicians, data collectors and outcome assessors, randomization, losses to follow-up, description of intention-to-treat, and early stopping of trial.[16] Guidelines were assessed using the Appraisal of Guidelines for Research and Evaluation II checklist.[17] A numerical score was not calculated for each study. Instead, the strengths and limitations are described narratively.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search identified 239 citations for review. After examination of titles and abstracts, 210 did not meet the inclusion criteria and 29 were retrieved for full text screening. Two additional studies were identified in the grey literature. Of these, 27 did not meet the inclusion criteria and were excluded. In total, four publications were selected for inclusion. These publications included one non-randomized study and three guidelines. No health technology assessments or systematic reviews were identified for inclusion. The study selection process is outlined in a PRISMA flow chart in Appendix 1.

Summary of Study Characteristics

Details for each of the individual investigations discussed in this section may be found in Appendix 2 for clinical studies and Appendix 3 for guidelines.

Clinical evidence on the safety of different levels of wear compliance for respiratory protection

No evidence was found for this question.

Clinical evidence on the safety of repeated donning and doffing of respiratory protection

There was one study found that examined the clinical evidence of the safety of repeated donning and doffing of respiratory protection for health care workers. This investigation was conducted in the United States of America and was completed in 2012 and included 17 participants in a laboratory setting. Six models of the most commonly used N95 respirators were used. Subjects were fit tested for these respirators and were educated in correct donning and doffing techniques. Each model was donned and the subject was allowed to acclimatize to it after which it was fit tested. This process was carried out 20 times with a seal check performed each time. Fit testing was completed using an adapted PORTACOUNT protocol where six testing exercises were conducted. An 8020A PORTACOUNT Plus Fit Tester was used along with a 8095 N95 Companion accessory for measurement. A Fit Factor (FF) of ≥100 indicated a pass and <100 indicated a fail, with three consecutive scores of <100 resulting in the end of testing. In addition the breakage of a head strap also indicated the end of testing.

Evidence based guidelines regarding wear compliance, donning and doffing, and reuse of respiratory protection

There was one evidence based guideline found in the literature search for wear compliance, donning and doffing, and reuse of respiratory protection.[2] In addition, two more guidelines were

found in a search of the grey literature.[3,4] All of these guidelines have been prepared for use by health care providers in either day-to-day functions [2,4] or from a management/supervisory standpoint.[3] The guideline produced by Coia et al.[2] was created in the United Kingdom and is the product of a working group of the Scientific Development Committee of the Healthcare Infection Society. Members for this working group were selected from a wide array of health care societies and associations across Britain and Scotland, though the total number of delegates and their specific expertise were not stated. The first guideline identified from the grey literature[3] was produced in 2014 in the United States of America by the CDC along with NIOSH. No information was given for the author(s) or any contributing expert panel or working group. The final guideline[4] was written in 2012 in Canada and was composed for the Ontario Agency for Health Protection and Promotion. It was produced by the Provincial Infectious Diseases Advisory Committee which is a group made up of 19 experts that routinely advise health care managers in Ontario about infectious disease control measures.

Summary of Critical Appraisal

Details of the critical appraisal of individual studies may be found in Appendix 4.

Clinical evidence on the safety of different levels of wear compliance for respiratory protection

No evidence was found for this question.

Clinical evidence on the safety of repeated donning and doffing of respiratory protection

The study found for this question[12] utilized a wide variety of the most common N95 respirators found in health care settings. In addition the statistical calculations included were appropriate and accurate for the processes being investigated. Unfortunately this study was completed in a laboratory setting and therefore the results should be interpreted cautiously when compared to real world situations. In addition the investigators modified a commonly used protocol in order to save time and effort. Unfortunately this modification removed a large portion of the bending and movement sections of the trials which may have provided critical data for real world health care settings. Finally during the 20 replicate fit testing processes, the wire/metal nose piece on the respirator, if present, was bent back into its original straightened position after each donning /doffing process. This does not represent a real world situation and may have resulted in failures due to nosepiece weakening or breakage that may not occur in a workplace setting where nosepieces are not adjusted as frequently.

Evidence based guidelines regarding wear compliance, donning and doffing, and reuse of respiratory protection

The guidelines found for this investigation are of good quality. Two of them contain excellent use of pictorial representations of proper donning.[2,4] The document produced by the Ontario Agency for Health Protection and Promotion[4] contained the most detailed review of current literature though no discussion of the consequences of not following the guidelines was given. In addition the authors made the assumption that any organization following these guidelines would have a complete understanding of proper hand hygiene, facility cleaning, sterilization/disinfection and ongoing education; therefore these practices were not discussed. None of the publications found for this question included a discussion of how the literature was reviewed for inclusion or exclusion and one of them[2] also did not discuss the backgrounds of the contributing authors, so it is unclear whether all relevant expertise was consulted during the

guideline process. Explicit links between evidence and recommendations were lacking. One of the guidelines[2] indicated that a member of their team was employed by a company that manufacturers respirators which must be noted as a potential conflict of interest. The other two studies[3,4] do not include any conflict of interest statements. Funding for two of these guidelines came from provincial public health[4] or charitable societies[2] while the final report gave no indication of funding sources.[3]

Summary of Findings

Details of the findings for each of the individual investigations discussed in this section may be found in Appendix 5.

Clinical evidence on the safety of different levels of wear compliance for respiratory protection

No evidence was found for this question.

Clinical evidence on the safety of repeated donning and doffing of respiratory protection

The study[12] analyzing the effects of multiple donning/doffing procedures was conducted in a laboratory setting using 17 people who were experienced in the use of respirators. Six models of N95 respirators were chosen which were: Moldex 2200, 3M 8000, 3M 8210, PFR95-270, 3M 1860 and 3M 1870. Ten subjects were used for 20 consecutive donning and doffing procedures for each respirator model and fit testing was conducted for each process to determine if failure had occurred. Head strap breaks occurred in only two models (3M 8210 and 3M 1860) with each model having four breaks in total. Nose piece breakage occurred 3 times in only the PFR95-270 and coincided directly with FF scores <100 indicating failure of respirator function. FF ≥100 for all 20 donning/doffing protocols tested was found in 55% of the tests for Moldex 2200, 3M 8000 and PFR95-270 and was 65% for 3M 1860 and 3M 1870. Regression analysis with an FF≥100 for all six models combined for 1-5, 1-10, 1-15, and 1-20 donning tests have R^2 values of 0.04, 0.23, 0.30 and 0.48 respectively which indicates that more variation occurred with increased donning/doffing cycles. Fit test mean percentage for FF≥100 also showed a reduction with more donning as t-tests comparing donning 1-5 with later stages found statistically significant differences at donning 11-15 for Moldex 2200, 3M 8000 and 3M 8210. For all respirators tested donning 16-20 had significantly lower FF results. Authors also found that there is a cumulative failure rate of 3.3% for donning 1 which was used as the fit test error rate. The evidence demonstrates that after 5 consecutive donning and doffing occurrences the fit factor will drop consistently below 100 and respirator function will be impaired.

Evidence based guidelines regarding wear compliance, donning and doffing, and reuse of respiratory protection

There were three evidence based guidelines found that describe techniques to be used in order to correctly don and doff respirators in health care settings. One guideline stated that if workers in a hospital environment are using respirators in their day-to-day work routinely then a respiratory protection plan must be in place.[4] Two of these guidelines described the process for correct donning.[2,4] The following list is a summary of the correct donning techniques for PPE with a focus on respirators in a step-by-step method:

- perform hand hygiene
- put on gown

- put on mask/respirator:
    - hold respirator in one hand and use the other hand to separate the edges so it is fully open (bend any wire nosepiece so it is in a gentle curve
    - turn the respirator upside down to untangle the head straps (hold the straps with finger)
    - place mask over nose and under chin
    - place upper head strap onto the crown of head above the ears (Not over them), place lower strap at back of head just below ears
- make sure the respirator is flat against cheeks
- tighten metal piece to nose bridge with firm pressure (if this step cannot be completed choose a different respirator)
- perform a seal check on respirator
- don protective eyewear
- put on gloves

The Ontario Agency for Health Protection and Promotion has also described the process for correct removal of PPE, including respirators:

- remove gloves
- remove gown
- perform hand hygiene
- remove eye protection
- remove mask/respirator:
    - all straps/loops/ties are considered clean and therefore touching is acceptable
    - the front part (filter) is contaminated and therefore should not be touched at any time
    - untie/grasp bottom straps followed by top ones
    - pull forward off head while bending forward to ensure that equipment falls away from face
    - discard immediately into appropriate disposal container
- perform hand hygiene

It has been postulated that during a pandemic the supplies of respirators will be limited and hospitals will have to institute reuse practices.[3,8,11] The guideline written by the CDC and NIOSH have examined both reuse and extended use of respirators and produced the following recommendations.

Extended use:

- discard any N95 respirator following use during an aerosol generating procedure
- discard all respirators if contaminated by any sort of bodily fluid
- utilize face shields or surgical masks overtop of respirator in situations where surface contamination is highly likely
- before and after a respirator has been touched hand washing or use of alcohol based gel is essential
- discard any device that has become hard to breathe through or is damaged

The authors stated that the practice of extended use is preferable to reuse as it involves less chance of contact with contaminated filters. The typical life of a respirator is 8 hours and it is essential that the fit and form be maintained throughout its use. If extended practices are put into place, a policy of not touching the respirator must be stressed. It is recommended that a hospital post signage in common locations to help ensure that these policies are followed.

Reuse: (all of the points listed for extended use apply for reuse with the following additions)

- have a designated, open air, breathable storage location to leave respirators when not in use, store so that used respirators are not in contact with each other and have clear signs designating what respirator belongs to whom
- do not touch the inside of the respirator, if contact occurs preform hand hygiene immediately
- when donning a used respirator wear gloves and ensure the seal is functioning correctly, dispose of gloves after all adjustments are made

It was further stated that strict adherence to the manufacturer's guidelines for maximum donning and doffing must be adhered to if it is provided. If no data for this exists then two studies reviewed in the guidelines recommend a maximum of 5 times be used to stay within error margins.

In pandemic situations where respirator supplies are limited it is recommended that the number of health care workers coming into contact with infected patients be kept as low as possible.[3] In addition it was recommended that appropriate alternatives to N95 respirators should be used, and only the workers at highest risk should be issued N95 respirators. The decision to implement either reuse or extended use practices should be made by the team leaders of the hospital respiratory protection program. This decision must take into account advice from various groups such as occupational health and safety, infection control department and any local or regional government public health agencies. It is also stressed that there is never a situation where a patient should be issued a N95 respirator.[4] These patients should be restricted to rooms where appropriate engineering controls are in place, such as negative pressure ventilation, and issued a mask.

In all situations a respirator must be donned correctly following the manufacturer's recommendations. It must also be fit tested and after donned the seal must be checked to ensure it is working properly. If the respirator becomes moist or wet at any time it must be removed and replaced. Disposal of respirators should be done in accordance with institutional protocols and hand hygiene must be performed immediately after removal. At no time should a respirator be pulled down to hang underneath the chin and contact with the filtering materials should be avoided at all times.[2-4]

LIMITATIONS

No publications that discussed the clinical evidence on the safety of different levels of wear compliance for respiratory protection were found for this investigation. One study was identified that examined the safety of repeated donning and doffing of respiratory protection. This study was completed in a laboratory setting and not done through clinical investigation therefore caution must be taken when applying the results to real world situations.

The evidence-based guidelines regarding wear compliance, donning and doffing, and reuse of respiratory protection were well written and contained extensive literature searches. They also used pictorial representation for the correct donning and doffing techniques where it was appropriate. Unfortunately they did not discuss the literature search criteria or the details for study exclusion. In addition one of the guidelines[2] did not discuss the members of the committee or panel that authored the report. One of the guidelines neglected to give any mention of the potential consequences of not following the protocols. Finally one of the guidelines made the assumption that the institution following the protocols already had an understanding of proper hygiene techniques therefore no specifics were given.

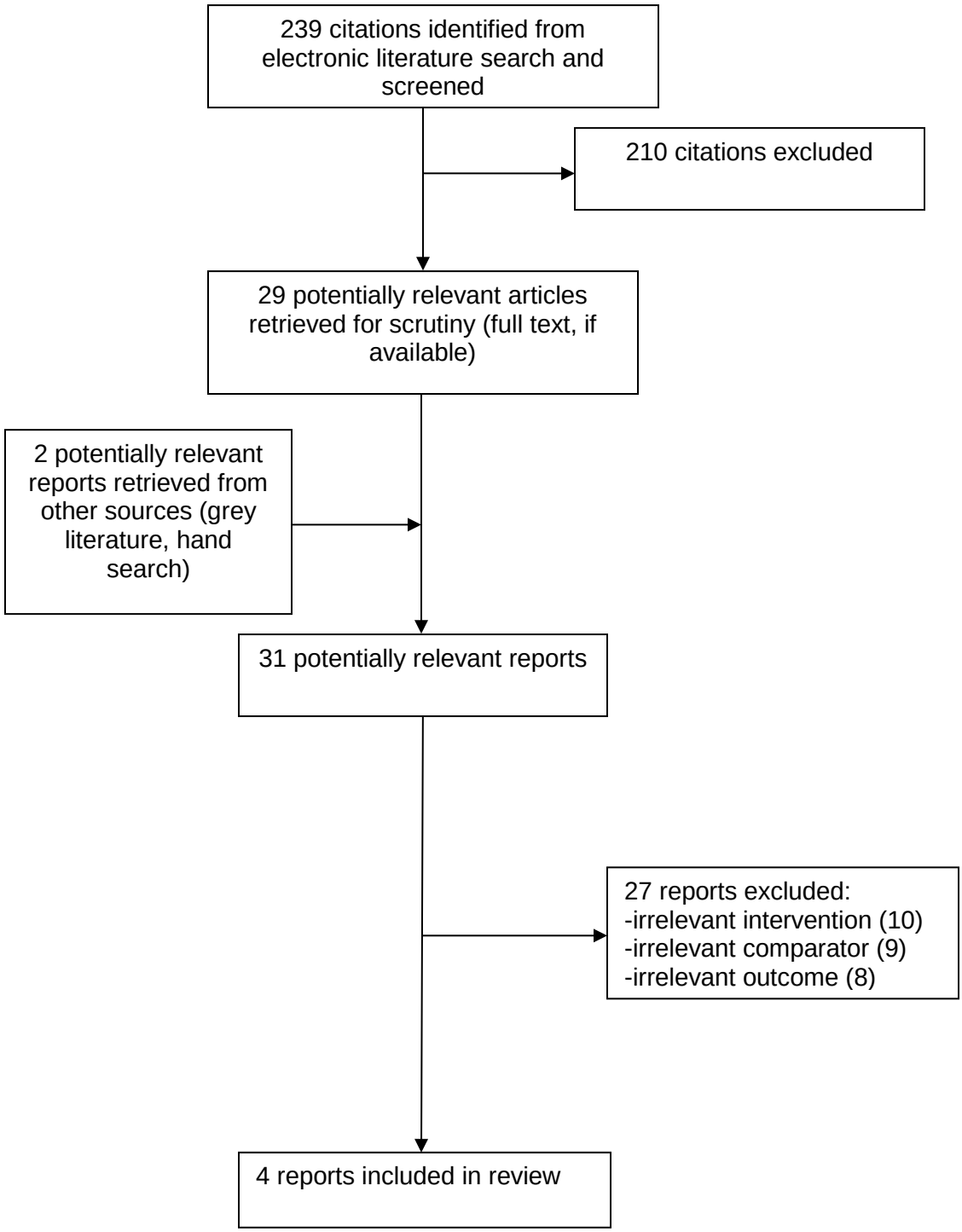
Guidelines on which respirator to use in specific situations were only found in one of the publications that was found in this literature review, but the evidence base for respirator selection was unclear.[2] One of the remaining studies[4] gave very detailed protocols for respirators use but did not give any detail on what should be selected in response to patient infections that are encountered. The final guideline[3] is at a high level and does not give specific end point recommendations but instead gives suggestions appropriate for hospital managers or leaders of respiratory protection programs.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

The question of the clinical evidence on the safety of different levels of wear compliance for respiratory protection remains unclear as no published studies or guidelines could be found. This is likely a result of the fact that in order to properly investigate this problem in a clinical situation there would be a need to recruit human volunteers who would then be at risk of severe illness. Alternatively investigation could use a retrospective analysis of HCW infections correlated to compliance for respirator use though no investigation of this type was identified for this review. The clinical evidence on the safety of repeated donning and doffing of respiratory protection is also limited. One study was found that investigated this problem and it was completed in a laboratory setting not in a working health care environment. This means that the results will have to be interpreted with caution when applied to real world settings. While the relevance of these results to actual healthcare environments is unclear, the authors demonstrated that extended donning and doffing practice resulted in an inability of the respirators to maintain full protective capability and that a maximum of 5 consecutive donning and doffing uses should be adhered to.

The evidence based guidelines that were found regarding wear compliance, donning and doffing, and reuse of respiratory protection were well written and contained step-by-step protocols. In addition they used pictorial representations for proper wear and methods for donning when it was appropriate. Along with this they provide recommendations on when it is appropriate to institute reuse or extended use practices and how these policies should be governed.

APPENDIX 1: Selection of Included Studies



APPENDIX 2: Summary of Study Characteristics

Non-randomized studies

First Author, Publication Year, Country	Study Design, Basic Methodology	Population Characteristics, Sample Size (n)	Goal
Bergman et al., 2012, United States of America[12]	• Examine 6 commonly used N95 respirators for ability to protect after multiple donning and doffing procedures. Fit testing utilized model 802A PORTACOUNT Plus Fit Tester and 8095 N95 Companion accessory with FitPlus software • To examine if the assumption that filtering face piece respirators would lose capability to form seals and filter out airborne pathogens after multiple donning and doffing • Models examined were: 3 N95 respirators (Molders 2200, 3M 8000 and 3M 8210), and 3 N95 surgical respirators (Kimberley Clark PFR95-270, 3M 1860, and 3M 1870)	Completed in laboratory setting using 17 participants who had passed fit testing protocols previously.	To investigate the impact of multiple donning practices on the face piece fit of 6 types of N95 filtering face piece respirator models using a group of 10 experienced test subjects.

APPENDIX 3: Study Characteristics – Guidelines for Respirator Use

First Author, Publication Year, Country	Target Audience and Scope	Included Study Designs
Centers for Disease Control and Prevention and the National Institute for Occupational Health and Safety, 2014, United States of America[3]	• Intended for use by health care professionals who manage respiratory protection programs to ensure their staff remain safe during exposure to infectious bioaerosols	Not given
Ontario Agency for Health Protection and Promotion, 2012, Canada[4]	• Is intended to be used as a guideline on best practices only • Was written to aid in the prevention of transmission of microorganisms in health care settings by describing: o routes of transmission o understanding routine practice o understanding barriers that affect routine practice o knowing when to use additional precautions o achieving correct donning and doffing practices	Not given
Coia et al., 2013, United Kingdom[2]	• Provides best practice guidelines for health care workers in both hospital and community settings to select and wear appropriate respiratory and facial protection to reduce the risk of disease transmission in the workplace	Not discussed in the study though reference is given to an additional document that contains the literature review results. The review panel is only discussed as stating it is a “short-life work group” formed by the Scientific Development Committee of the Healthcare Infection Society, no other detail is given.

APPENDIX 4: Critical Appraisal of Included Literature

First Author, Publication Year	Strengths	Limitations
Non-randomized Studies		
Bergman et al., 2012, United States of America[12]	• The most commonly utilized N95 respirators were chosen for examination • Appropriate statistical calculations were used for result interpretation • Authors caution the interpretation of their results in real world situations	• Conducted in a laboratory setting using bench scale testing as opposed to actual workplace observations • Study used a modified protocol for fit testing from that approved by OSHA (total test time only 5 minutes as opposed to 12 minutes in typical protocol) • During fit testing process the nose piece of the respirators was straightened after each use which is not the same as working conditions where respirators are reused
Guidelines		
Centers for Disease Control and Prevention and the National Institute for Occupational Health and Safety, 2014, United States of America[3]	• Clear and detailed statements on how respirators should be used from a management standpoint • Detailed recommendations of when it is appropriate to institute extended use or reuse policies are given • Clear statements about who should govern policies for respiratory protection programs and institution of respirator extended use or reuse are provided	• No discussion of paper/study inclusion criteria provided • Is written in a high order style and does not include any direct day-to-day recommendations • No guideline for respirator selection is given • Funding sources are not described and no statement about potential conflicts of interest is provided
Ontario Agency for Health Protection and Promotion, 2012, Canada[4]	• Contained the most detailed analysis found • Well described protocols that are backed up using pictorial displays where appropriate • Logical breakdown of all processes of PPE use • Most current review of current literature found	• No detailed discussion of the consequences of not following the protocols in provided is simply an implication of infection • Authors have made assumption made that organizations following these guidelines have an understanding of proper hand hygiene, facility cleaning, sterilization/disinfection and ongoing education are established and monitored • Is no discussion/description of how the literature was included or reviewed though the participating advisory/research panel is described in

First Author, Publication Year	Strengths	Limitations
		detail
Coia et al., 2013, United Kingdom[2]	• Goal of the paper and all aims are well described and the lacking information and future goals are clearly stated • Excellent use of flowcharts and pictographs for donning procedures are provided • Details are provided on what respirator should be used in specific situations	• No discussion of included paper criteria, study designs or exclusion criteria has been given though the review may be found in another document which may or may not give the search criteria used • The review panel/contributing authors/participants backgrounds are not provided • One of the contributing authors has a potential conflict of interest as the individual was employed by a manufacturer of PPE to provide advice on the production of new respirator models

OSHA – Occupational Safety and Health Administration; PPE – personal protective equipment

Appendix 5: Summary of Findings

First Author, Publication Year	Main Study Findings	Author Conclusions
Non-randomized Studies		
Bergman et al., 2012[12]	• Head strap breaks occurred 4 times in two models (3M 8210 and 3M 1860) • Nose piece breaks occurred on only one model (PFR95-270) 3 times which coincided with three failures • Regression analysis with an FF ≥ 100 for all 6 respirators used combined for donning 1-5, 1-10, 1-15 and 1-20 have R^2 values of 0.04, 0.23, 0.30 and 0.48 respectively indicating more variation in fit with increased donning times resulting in less protection • An FF[1] of ≥ 100 for all 20 donning processes was found in: - 55% of tests for models Moldex 2200, 3M 8000 and PFR95-270 - 65% of tests for models 3M 1860, 3M 1870 • Fit test mean percentage for FF ≥ 100 also show reduced protection with more donning (50% for 16-20 donnings) • T-testing comparing donning 1-5 to later stages found statistically significant differences at 11-15 for Moldex 2200, 3M 8000 and 3M 8210 • for all respirators tested donning 16-20 FF values were significantly less • There is a cumulative failure rate of 3.3% for donning 1 which is considered a fit test error rate	• Multiple donning had a significant impact on all respirators tested and this is model dependent • While this impact is found 55-65% of respirators were able to maintain FF ≥ 100 at donning 20 • By calculating the terminal failure rate from 3 consecutive fit test FF < 100 and subtracting the 3.3% error rate the data show that 5 consecutive donning can be achieved before FF < 100 occurs • These results must be taken with caution as the failure rate varied for all 6 models examined therefore generalizing this result to all models in all situations is not recommended

FF - Fit Factor

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